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To cite the regulations in this volume use title, part and section number. Thus, 42 CFR 430.0 refers to title 42, part 430, section 0.
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.

LEGAL STATUS

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 Code of Federal Regulations is kept up to date by the individual issues of the Federal Register. These two publications must be used together to determine the latest version of any given rule.

To determine whether a Code volume has been amended since its revision date (in this case, October 1, 1998), consult the “List of CFR Sections Affected (LSA),” which is issued monthly, and the “Cumulative List of Parts Affected,” which appears in the Reader Aids section of the daily Federal Register. These two lists will identify the Federal Register page number of the latest amendment of any given rule.

EFFECTIVE AND EXPIRATION DATES

Each volume of the Code contains amendments published in the Federal Register since the last revision of that volume of the Code. Source citations for the regulations are referred to by volume number and page number of the Federal Register and date of publication. Publication dates and effective dates are usually not the same and care must be exercised by the user in determining the actual effective date. In instances where the effective date is beyond the cutoff date for the Code a note has been inserted to reflect the future effective date. In those instances where a regulation published in the Federal Register states a date certain for expiration, an appropriate note will be inserted following the text.

OMB CONTROL NUMBERS

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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**INCORPORATION BY REFERENCE**

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.

What is a proper incorporation by reference? The Director of the Federal Register will approve an incorporation by reference only when the requirements of 1 CFR part 51 are met. Some of the elements on which approval is based are:

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

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

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

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

What if the material incorporated by reference cannot be found? If you have any problem locating or obtaining a copy of material listed in the Finding Aids of this volume as an approved incorporation by reference, please contact the agency that issued the regulation containing that incorporation. If, after contacting the agency, you find the material is not available, please notify the Director of the Federal Register, National Archives and Records Administration, Washington DC 20408, or call (202) 523-4534.

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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.
A List of CFR Sections Affected (LSA) is published monthly, keyed to the revision dates of the 50 CFR titles.

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For a legal interpretation or explanation of any regulation in this volume, contact the issuing agency. The issuing agency's name appears at the top of odd-numbered pages.

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

October 1, 1998.
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, 1998.

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, Gwendolyn J. Henderson was Chief Editor. The Code of Federal Regulations publication program is under the direction of Frances D. McDonal, assisted by Alomha S. Morris.
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PART 430—GRANTS TO STATES FOR MEDICAL ASSISTANCE PROGRAMS

Subpart A—Introduction; General Provisions

§ 430.0 Program description. Title XIX of the Social Security Act, enacted in 1965, authorizes Federal grants to States for medical assistance to low-income persons who are age 65 or over, blind, disabled, or members of families with dependent children or qualified pregnant women or children. The program is jointly financed by the Federal and State governments and administered by States. Within broad Federal rules, each State decides eligible groups, types and range of services, payment levels for services, and administrative and operating procedures. Payments for services are made directly by the State to the individuals or entities that furnish the services.

§ 430.1 Scope of subchapter C. The regulations in subchapter C set forth State plan requirements, standards, procedures, and conditions for obtaining Federal financial participation (FFP). Each part (or subpart of section) in the subchapter describes the specific statutory basis for the regulation. However, where the basis is the Secretary’s general authority to issue regulations for any program under the Act (section 1102 of the Act), or his general authority to prescribe State plan requirements needed for proper and efficient administration of the plan (section 1902(a)(4)), those statutory provisions are simply cited without further description.

Subpart B—State Plans

§ 430.10 The State plan. § 430.12 Submittal of State plans and plan amendments.

Subpart C—Grants; Reviews and Audits; Withholding for Failure To Comply; Deferral and Disallowance of Claims; Reduction of Federal Medicaid Payments

§ 430.30 Grants procedures. § 430.32 Program reviews. § 430.33 Audits. § 430.35 Withholding of payment for failure to comply with Federal requirements. § 430.38 Judicial review. § 430.40 Deferral of claims for FFP. § 430.42 Disallowance of claims for FFP. § 430.45 Reduction of Federal Medicaid payments. § 430.48 Repayment of Federal funds by installments.

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Subpart E—Exclusion from hearing for misconduct. § 430.90

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Subpart J—Decisions following hearing. § 430.102

Subpart K—Decisions that affect FFP. § 430.104

Subpart L—Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

SOURCE: 53 FR 36571, Sept. 21, 1988, unless otherwise noted.
§ 430.2 Other applicable Federal regulations.

Other regulations applicable to State Medicaid programs include the following:

(a) 5 CFR part 900, subpart F, Administration of the Standards for a Merit System of Personnel Administration.

(b) The following HHS Regulations in 45 CFR subtitle A:

Part 16—Procedures of the Departmental Appeals Board.
Part 24—Administration of Grants.
Part 80—Nondiscrimination Under Programs Receiving Federal Assistance Through the Department of Health and Human Services: Effectuation of Title VI of the Civil Rights Act of 1964.
Part 84—Nondiscrimination on the Basis of Handicap in Programs and Activities Receiving or Benefiting From Federal Financial Assistance.
Part 95—General Administration—grant programs (public assistance and medical assistance).

[53 FR 36571, Sept. 21, 1988, as amended at 56 FR 8845, Mar. 1, 1991]

§ 430.3 Appeals under Medicaid.

Three distinct types of disputes may arise under Medicaid.

(a) Compliance with Federal requirements. Disputes that pertain to whether a State’s plan or proposed plan amendments, or its practice under the plan meet or continue to meet Federal requirements are subject to the hearing provisions of subpart D of this part.

(b) FFP in Medicaid expenditures. Disputes that pertain to disallowances of FFP in Medicaid expenditures (mandatory grants) are heard by the Departmental Appeals Board (the Board) in accordance with procedures set forth in 45 CFR part 16.

(c) Discretionary grants disputes. Disputes pertaining to discretionary grants, such as grants for special demonstration projects under sections 1110 and 1115 of the Act, which may be awarded to a Medicaid agency, are also heard by the Board. 45 CFR part 16, appendix A, lists all the types of disputes that the Board hears.

[53 FR 36571, Sept. 21, 1988, as amended at 56 FR 8845, Mar. 1, 1991]
§ 430.18 Changes in Federal law, regulations, policy interpretations, or court decisions; or
(ii) Material changes in State law, organization, or policy, or in the State's operation of the Medicaid program. For changes related to advance directive requirements, amendments must be submitted as soon as possible, but no later than 60 days from the effective date of the change to State law concerning advance directives.

§ 430.16 Timing and notice of action on State plan material.
(a) Timing. (1) A State plan or plan amendment will be considered approved unless HCFA, within 90 days after receipt of the plan or plan amendment in the regional office, sends the State—
(i) Written notice of disapproval; or
(ii) Written notice of any additional information it needs in order to make a final determination.
(2) If HCFA requests additional information, the 90-day period for HCFA action on the plan or plan amendment begins on the day it receives that information.

(b) Notice of final determination. (1) The Regional Administrator or the Administrator notifies the Medicaid agency of the approval of a State plan or plan amendment.
(2) Only the Administrator gives notice of disapproval of a State plan or plan amendment.

§ 430.18 Administrative review of action on State plan material.
(a) Request for reconsideration. Any State dissatisfied with the Administrator's action on plan material under § 430.15 may, within 60 days after receipt of the notice provided under § 430.16(b), request that the Administrator reconsider the issue of whether the plan or plan amendment conforms to the requirements for approval.
(b) Notice and timing of hearing. (1) Within 30 days after receipt of the request, the Administrator notifies the State of the time and place of the hearing.
(2) The hearing takes place not less than 30 days nor more than 60 days after the date of the notice, unless the State and the Administrator agree in writing on an earlier or later date.
(c) Hearing procedures. The hearing procedures are set forth in subpart D of this part.
(d) Decision. A decision affirming, modifying, or reversing the Administrator's original determination is made in accordance with § 430.102.
(e) Effect of hearing decision. (1) Denial of Federal funds, if required by the Administrator's original determination, will not be delayed pending a hearing decision.
§ 430.20 Effective dates of State plans and plan amendments.

For purposes of FFP, the following rules apply:

(a) New plans. The effective date of a new plan—

(1) May not be earlier than the first day of the quarter in which an approvable plan is submitted to the regional office; and

(2) With respect to expenditures for medical assistance, may not be earlier than the first day on which the plan is in operation on a statewide basis.

(b) Plan amendment. (1) For a plan amendment that provides additional services to individuals eligible under the approved plan, increases the payment amounts for services already included in the plan, or makes additional groups eligible for services provided under the approved plan, the effective date is determined in accordance with paragraph (a) of this section.

(2) For a plan amendment that changes the State's payment method and standards, the rules of § 447.256 of this chapter apply.

(3) For other plan amendments, the effective date may be a date requested by the State if HCFA approves it.

[53 FR 36571, Sept. 21, 1988, as amended at 56 FR 8845, Mar. 1, 1991]

§ 430.25 Waivers of State plan requirements.

(a) Scope of section. This section describes the purpose and effect of waivers, identifies the requirements that may be waived and the other regulations that apply to waivers, and sets forth the procedures that HCFA follows in reviewing and taking action on waiver requests.

(b) Purpose of waivers. Waivers are intended to provide the flexibility needed to enable States to try new or different approaches to the efficient and cost-effective delivery of health care services, or to adapt their programs to the special needs of particular areas or groups of recipients. Waivers allow exceptions to State plan requirements and permit a State to implement innovative programs or activities on a time-limited basis, and subject to specific safeguards for the protection of recipients and the program. Detailed rules for waivers are set forth in subpart B of part 431, subpart A of part 440, and subpart G of part 441 of this chapter.

(c) Effect of waivers. (1) Waivers under section 1915(b) allow a State to take the following actions:

(i) Implement a primary care case-management system or a specialty physician system.

(ii) Designate a locality to act as central broker in assisting Medicaid recipients to choose among competing health care plans.

(iii) Share with recipients (through provision of additional services) cost-savings made possible through the recipients’ use of more cost-effective medical care.

(iv) Limit recipients' choice of providers (except in emergency situations and with respect to family planning services) to providers that fully meet reimbursement, quality, and utilization standards, which are established under the State plan and are consistent with access, quality, and efficient and economical furnishing of care.

(2) A waiver under section 1915(c) of the Act allows a State to include as “medical assistance” under its plan home and community based services furnished to recipients who would otherwise need inpatient care that is furnished in a hospital, SNF, ICF, or ICF/MR, and is reimbursable under the State plan.

(3) A waiver under section 1916(a)(3) or (b)(3) of the Act allows a State to impose a deduction, cost-sharing or similar charge of up to twice the “nominal charge” established under the plan for outpatient services, if—

(i) The outpatient services are received in a hospital emergency room but are not emergency services; and

(ii) The State has shown that Medicaid recipients have actually available and accessible to them alternative services of nonemergency outpatient services.

(d) Requirements that are waived. In order to permit the activities described in paragraph (c) of this section, one or
more of the title XIX requirements must be waived, in whole or in part.

(1) Under section 1915(b) of the Act, and subject to certain limitations, any of the State plan requirements of section 1902 of the Act may be waived to achieve one of the purposes specified in that section.

(2) Under section 1915(c) of the Act, the following requirements may be waived:

(i) Statewideness—section 1902(a)(1).

(ii) Comparability of services—section 1902(a)(10)(B).


(3) Under section 1916 of the Act, paragraphs (a)(3) and (b)(3) require that any cost-sharing imposed on recipients be nominal in amount, and provide an exception for nonemergency services furnished in a hospital emergency room if the conditions of paragraph (c)(3) of this section are met.

(e) Submittal of waiver request. The State Governor, the head of the Medicaid agency, or an authorized designee may submit the waiver request.

(f) Review of waiver requests. (1) This paragraph applies to initial waiver requests and to requests for renewal or amendment of a previously approved waiver.

(2) HCFA regional and central office staff review waiver requests and submit a recommendation to the Administrator, who—

(i) Has the authority to approve or deny waiver requests; and

(ii) Does not deny a request without first consulting the Secretary.

(3) A waiver request is considered approved unless, within 90 days after the request is received by HCFA, the Administrator denies the request, or the Administrator or the Regional Administrator sends the State a written request for additional information necessary to reach a final decision. If additional information is requested, a new 90-day period begins on the day the response to the additional information request is received by the addressee.

(g) Basis for approval—(1) Waivers under section 1915 (b) and (c). The Administrator approves waiver requests if the State's proposed program or activity meets the requirements of the Act and the regulations at §431.55 or subpart G of part 441 of this chapter.

(2) Waivers under section 1916. The Administrator approves a waiver under section 1916 of the Act if the State shows, to HCFA's satisfaction, that the Medicaid recipients have available and accessible to them sources, other than a hospital emergency room, where they can obtain necessary nonemergency outpatient services.

(h) Effective date and duration of waivers—(1) Effective date. Waivers receive a prospective effective date determined, with State input, by the Administrator. The effective date is specified in the letter of approval to the State.

(2) Duration of waivers—(i) Home and community-based services under section 1915(c). The initial waiver is for a period of three years and may be renewed thereafter for periods of five years.

(ii) Waivers under sections 1915(b) and 1916. The initial waiver is for a period of two years and may be renewed for additional periods of up to two years as determined by the Administrator.

(3) Renewal of waivers. (i) A renewal request must be submitted at least 90 days (but not more than 120 days) before a currently approved waiver expires, to provide adequate time for HCFA review.

(ii) If a renewal request for a section 1915(c) waiver proposes a change in services provided, eligible population, service area, or statutory sections waived, the Administrator may consider it a new waiver, and approve it for a period of three years.

[56 FR 8846, Mar. 1, 1991]
(2) The amount of the quarterly grant is determined on the basis of information submitted by the State agency (in quarterly estimate and quarterly expenditure reports) and other pertinent documents.

(b) Quarterly estimates. The Medicaid agency must submit Form HCFA-25 (Medicaid Program Budget Report; Quarterly Distribution of Funding Requirements) to the central office (with a copy to the regional office) 45 days before the beginning of each quarter.

(c) Expenditure reports. (1) The State must submit Form HCFA-64 (Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program) to the central office (with a copy to the regional office) not later than 30 days after the end of each quarter.

(2) This report is the State's accounting of actual recorded expenditures. The disposition of Federal funds may not be reported on the basis of estimates.

(d) Grant award—(1) Computation by HCFA. Regional office staff analyzes the State's estimates and sends a recommendation to the central office. Central office staff considers the State's estimates, the regional office recommendations and any other relevant information, including any adjustments to be made under paragraph (d)(2) of this section, and computes the grant.

(2) Content of award. The grant award computation form shows the estimate of expenditures for the ensuring quarter, and the amounts by which that estimate is increased or decreased because of an underestimate or overestimate for prior quarters, or for any of the following reasons:

(i) Penalty reductions imposed by law.
(ii) Accounting adjustments.
(iii) Deferrals or disallowances.
(iv) Interest assessments.
(v) Mandated adjustments such as those required by section 1914 of the Act.

(3) Effect of award. The grant award authorizes the State to draw Federal funds as needed to pay the Federal share of disbursements.

(4) Drawing procedure. The draw is through a commercial bank and the Federal Reserve system against a continuing letter of credit certified to the Secretary of the Treasury in favor of the State payee. (The letter of credit payment system was established in accordance with Treasury Department regulations—Circular No. 1075.)

(e) General administrative requirements. With the following exceptions, the provisions of 45 CFR part 74, which establish uniform administrative requirements and cost principles, apply to all grants made to States under this subpart:

45 CFR part 74
Subpart G—Matching and Cost Sharing
Subpart I—Financial Report Requirements

§ 430.32 Program reviews.

(a) Review of State and local administration. In order to determine whether the State is complying with the Federal requirements and the provisions of its plan, HCFA reviews State and local administration through analysis of the State's policies and procedures, on-site review of selected aspects of agency operation, and examination of samples of individual case records.

(b) Quality control program. The State itself is required to carry out a continuing quality control program as set forth in part 431, subpart P, of this chapter.

(c) Action on review findings. If Federal or State reviews reveal serious problems with respect to compliance with any Federal requirement, the State must correct its practice accordingly.

§ 430.33 Audits.

(a) Purpose. The Department's Office of Inspector General (OIG) periodically audits State operations in order to determine whether—

(1) The program is being operated in a cost-efficient manner; and

(2) Funds are being properly expended for the purposes for which they were appropriated under Federal and State law and regulations.

(b) Reports. (1) The OIG releases audit reports simultaneously to State officials and the Department's program officials.

(2) The reports set forth OIG opinion and recommendations regarding the practices it reviewed, and the allowability of the costs it audited.
§ 430.38 Action on audit exceptions—(1) Concurrency or clearance. The State agency has the opportunity of concurring in the exceptions or submitting additional facts that support clearance of the exceptions.

(2) Appeal. Any exceptions that are not disposed of under paragraph (c)(1) of this section are included in a disallowance letter that constitutes the Department’s final decision unless the State requests reconsideration by the Appeals Board. (Specific rules are set forth in § 430.42.)

(3) Adjustment. If the decision by the Board requires an adjustment of FFP, either upward or downward, a subsequent grant award promptly reflects the amount of increase or decrease.

§ 430.35 Withholding of payment for failure to comply with Federal requirements.

(a) Basis for withholding. HCFA withholds payments to the State, in whole or in part, only if, after giving the agency reasonable notice and opportunity for a hearing in accordance with subpart D of this part, the Administrator finds—

(1) That the plan no longer complies with the provisions of section 1902 of the Act; or

(2) That in the administration of the plan there is failure to comply substantially with any of those provisions.

(Hearings under subpart D are generally not called until a reasonable effort has been made to resolve the issues through conferences and discussions. These may be continued even if a date and place have been set for the hearing.)

(b) Noncompliance of the plan. A question of noncompliance of a State plan may arise from an unapprovable change in the approved State plan or the failure of the State to change its approved plan to conform to a new Federal requirement for approval of State plans.

(c) Noncompliance in practice. A question of noncompliance in practice may arise from the State’s failure to actually comply with a Federal requirement, regardless of whether the plan itself complies with that requirement.

(d) Notice and implementation of withholding. If the Administrator makes a finding of noncompliance under paragraph (a) of this section, the following rules apply:

(1) The Administrator notifies the State:

(i) That no further payments will be made to the State (or that payments will be made only for those portions or aspects of the program that are not affected by the noncompliance); and

(ii) That the total or partial withholding will continue until the Administrator is satisfied that the State’s plan and practice are, and will continue to be, in compliance with Federal requirements.

(2) HCFA withholds payments, in whole or in part, until the Administrator is satisfied regarding the State’s compliance.

§ 430.38 Judicial review.

(a) Right to judicial review. Any State dissatisfied with the Administrator’s final determination on approvability of plan material (§ 430.18) or compliance with Federal requirements (§ 430.35) has a right to judicial review.

(b) Petition for review. (1) The State must file a petition for review with the U.S. Court of Appeals for the circuit in which the State is located, within 60 days after it is notified of the determination.

(2) The clerk of the court will file a copy of the petition with the Administrator and the Administrator will file in the court the record of the proceedings on which the determination was based.

(c) Court action. (1) The court is bound by the Administrator’s findings of fact if they are supported by substantial evidence.

(2) The court has jurisdiction to affirm the Administrator’s decision, to set it aside in whole or in part, or, for good cause, to remand the case for additional evidence.

(d) Response to remand. (1) If the court remands the case, the Administrator may make new or modified findings of fact and may modify his or her previous determination.
§ 430.40  Deferral of claims for FFP.

(a) Requirements for deferral. Payment of a claim or any portion of a claim for FFP is deferred only if—

1. The Regional Administrator or the Administrator questions its allowability and needs additional information in order to resolve the question; and

2. HCFA takes action to defer the claim (by excluding the claimed amount from the grant award) within 60 days after the receipt of a Quarterly Statement of Expenditures (prepared in accordance with HCFA instructions) that includes that claim.

(b) Notice of deferral and State's responsibility. (1) Within 15 days of the action described in paragraph (a)(2) of this section, the Regional Administrator sends the State a written notice of deferral that—

(i) Identifies the type and amount of the deferred claim and specifies the reason for deferral; and

(ii) Requests the State to make available all the documents and materials the regional office then believes are necessary to determine the allowability of the claim.

(2) It is the responsibility of the State to establish the allowability of a deferred claim.

(c) Handling of documents and materials. (1) Within 60 days (or within 120 days if the State requests an extension) after receipt of the notice of deferral, the State must make available to the regional office, in readily reviewable form, all requested documents and materials except any that it identifies as not being available.

(2) Regional office staff usually initiates review within 30 days after receipt of the documents and materials.

(3) If the Regional Administrator finds that the materials are not in readily reviewable form or that additional information is needed, he or she promptly notifies the State that it has 15 days to submit the readily reviewable or additional materials.

(4) If the State does not provide the necessary materials within 15 days, the Regional Administrator disallows the claim.

(5) The Regional Administrator has 90 days, after all documentation is available in readily reviewable form, to determine the allowability of the claim.

(6) If the Regional Administrator cannot complete review of the material within 90 days, HCFA pays the claim, subject to a later determination of allowability.

(d) Effect of decision to pay a deferred claim. Payment of a deferred claim under paragraph (c)(6) of this section does not preclude a subsequent disallowance based on the results of an audit or financial review. (If there is a subsequent disallowance, the State may request reconsideration as provided in paragraph (e)(2) of this section.)

(e) Notice and effect of decision on allowability. (1) The Regional Administrator or the Administrator gives the State written notice of his or her decision to pay or disallow a deferred claim.

(2) If the decision is to disallow, the notice informs the State of its right to reconsideration in accordance with 45 CFR part 16.

§ 430.42  Disallowance of claims for FFP.

(a) Notice of disallowance and of right to reconsideration. When the Regional Administrator or the Administrator determines that a claim or portion of the State's claim for FFP is not allowable, he or she promptly sends the State a disallowance letter that includes the following, as appropriate:

(1) The date or dates on which the State's claim for FFP was made.

(2) The time period during which the expenditures in question were made or claimed to have been made.

(3) The date and amount of any payment or notice of deferral.

(4) A statement of the amount of FFP claimed, allowed, and disallowed and the manner in which these amounts were computed.
§ 430.48 Repayment of Federal funds by installments.

(a) Basic conditions. When Federal payments have been made for claims that are later found to be unallowable, the State may repay the Federal Funds by installments if the following conditions are met:

(1) The amount to be repaid exceeds 2½ percent of the estimated or actual annual State share for the Medicaid program; and

(2) The State has given the Regional Administrator written notice, before total repayment was due, of its intent to repay by installments.

(b) Annual State share determination. HCFA determines whether the amount to be repaid exceeds 2½ percent of the annual State share as follows:

(1) If the Medicaid program is ongoing, HCFA uses the annual estimated State share of Medicaid expenditures. This is the sum of the estimated State shares for four consecutive quarters, beginning with the quarter in which the first installment is to be paid, as shown on the State's latest HCFA-25 form.

(2) If the Medicaid program has been terminated by Federal law or by the State, HCFA uses the actual State share. The actual State share is that shown on the State's Statement of Expenditures reports for the last four quarters before the program was terminated.

(c) Repayment amounts, schedules, and procedures—(1) Repayment amount. The repayment amount may not include

§ 430.45 Reduction of Federal Medicaid payments.

(a) Methods of reduction. HCFA may reduce Medicaid payments to a State as required under the Act by reducing—
any amount previously approved for installment repayment.

(2) Repayment schedule. The number of quarters allowed for repayment is determined on the basis of the ratio of the repayment amount to the annual State share of Medicaid expenditures. The higher the ratio of the total repayment amount to the annual State share, the greater the number of quarters allowed, as follows:

<table>
<thead>
<tr>
<th>Total repayment amount as percentage of State share of annual expenditures for Medicaid</th>
<th>Number of quarters to make repayment</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.5 pct. or less</td>
<td>1</td>
</tr>
<tr>
<td>Greater than 2.5, but not greater than 5</td>
<td>2</td>
</tr>
<tr>
<td>Greater than 5, but not greater than 7.5</td>
<td>3</td>
</tr>
<tr>
<td>Greater than 7.5, but not greater than 10</td>
<td>4</td>
</tr>
<tr>
<td>Greater than 10, but not greater than 15</td>
<td>5</td>
</tr>
<tr>
<td>Greater than 15, but not greater than 20</td>
<td>6</td>
</tr>
<tr>
<td>Greater than 20, but not greater than 25</td>
<td>7</td>
</tr>
<tr>
<td>Greater than 25, but not greater than 30</td>
<td>8</td>
</tr>
<tr>
<td>Greater than 30, but not greater than 47.5</td>
<td>9</td>
</tr>
<tr>
<td>Greater than 47.5, but not greater than 65</td>
<td>10</td>
</tr>
<tr>
<td>Greater than 65, but not greater than 82.5</td>
<td>11</td>
</tr>
<tr>
<td>Greater than 82.5, but not greater than 100</td>
<td>12</td>
</tr>
</tbody>
</table>

(3) Quarterly repayment amounts. The quarterly repayment amounts for each of the quarters in the repayment schedule may not be less than the following percentages of the estimated State share of annual expenditures for Medicaid:

<table>
<thead>
<tr>
<th>For each of the following quarters</th>
<th>Repayment installment may not be less than these percentages</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 to 4</td>
<td>2.5</td>
</tr>
<tr>
<td>5 to 8</td>
<td>5.0</td>
</tr>
<tr>
<td>9 to 12</td>
<td>17.5</td>
</tr>
</tbody>
</table>

(4) Extended schedule. The repayment schedule may be extended beyond 12 quarterly installments if the total repayment amount exceeds 100% of the estimated State share of annual expenditures. In these circumstances, paragraph (c)(2) of this section is followed for repayment of the amount equal to 100 percent of the annual State share. The remaining amount of the repayment is in quarterly amounts equal to not less than 17.5 percent of the estimated State share of annual expenditures.

(5) Repayment process. Repayment is accomplished through adjustment in the quarterly grants over the period covered by the repayment schedule.

If the State chooses to repay amounts representing higher percentages during the early quarters, any corresponding reduction in required minimum percentages is applied first to the last scheduled payment, then to the next to the last payment, and so forth as necessary.

(6) Offseting of retroactive claims. The amount of a retroactive claim to be paid a State will be offset against any amounts to be, or already being, repaid by the State in installments. Under this provision, the State may choose to:

(i) Suspend payments until the retroactive claim due the State has, in fact, been offset; or

(ii) Continue payments until the reduced amount of its debt (remaining after the offset), has been paid in full.

This second option would result in a shorter payment period.

A retroactive claim for the purpose of this regulation is a claim applicable to any period ending 12 months or more before the beginning of the quarter in which HCFA would pay that claim.

Subpart D—Hearings on Conformity of State Medicaid Plans and Practice to Federal Requirements

§ 430.60 Scope.

(a) This subpart sets forth the rules for hearings to States that appeal a decision to disapprove State plan material (under § 430.18) or to withhold Federal funds (under § 430.35), because the State plan or State practice in the Medicaid program is not in compliance with Federal requirements.

(b) Nothing in this subpart is intended to preclude or limit negotiations between HCFA and the State, whether before, during, or after the hearing to resolve the issues that are, or otherwise would be, considered at the hearing. Such negotiations and resolution of issues are not part of the hearing, and are not governed by the rules in this subpart except as expressly provided.
§ 430.62 Records to be public.

All pleadings, correspondence, exhibits, transcripts of testimony, exceptions, briefs, decisions, and other documents filed in the docket in any proceeding may be inspected and copied in the office of the HCFA Docket Clerk. Inquiries may be made to the Docket Clerk, Hearing Staff, Bureau of Eligibility, Reimbursement and Coverage, 300 East High Rise, 6325 Security Boulevard, Baltimore, Maryland, 21207. Telephone: (301) 594-8261.

§ 430.63 Filing and service of papers.

(a) Filing. All papers in the proceedings are filed with the HCFA Docket Clerk, in an original and two copies. Originals only of exhibits and transcripts of testimony need be filed.

(b) Service. All papers in the proceedings are served on all parties by personal delivery or by mail. Service on the party's designated attorney is considered service upon the party.

§ 430.64 Suspension of rules.

Upon notice to all parties, the Administrator or the presiding officer may modify or waive any rule in this subpart upon determination that no party will be unduly prejudiced and the ends of justice will thereby be served.

§ 430.66 Designation of presiding officer for hearing.

(a) The presiding officer at a hearing is the Administrator or his designee.

(b) The designation of the presiding officer is in writing. A copy of the designation is served on all parties.

§ 430.70 Notice of hearing or opportunity for hearing.

The Administrator mails the State a notice of hearing or opportunity for hearing that—

(a) Specifies the time and place for the hearing;

(b) Specifies the issues that will be considered;

(c) Identifies the presiding officer; and

(d) Is published in the Federal Register.

§ 430.72 Time and place of hearing.

(a) Time. The hearing is scheduled not less than 30 nor more than 60 days after the date of notice to the State. The scheduled date may be changed by written agreement between HCFA and the State.

(b) Place. The hearing is conducted in the city in which the HCFA regional office is located or in another place fixed by the presiding officer in light of the circumstances of the case, with due regard for the convenience and necessity of the parties or their representatives.

§ 430.74 Issues at hearing.

The list of issues specified in the notice of hearing may be augmented or reduced as provided in this section.

(a) Additional issues. (1) Before a hearing under §430.35, the Administrator may send written notice to the State listing additional issues to be considered at the hearing. That notice is published in the Federal Register.

(2) If the notice of additional issues is furnished to the State less than 20 days before the scheduled hearing date, postponement is granted if requested by the State or any other party. The new date may be 20 days after the date of the notice, or a later date agreed to by the presiding officer.

(b) New or modified issues. If, as a result of negotiations between HCFA and the State, the submittal of plan amendment, a change in the State program, or other actions by the State, any issue is resolved in whole or in part, new or modified issues are presented, as specified by the presiding officer, the hearing proceeds on the new or modified issues.

(c) Issues removed from consideration—

(1) Basis for removal. If at any time before, during, or after the hearing, the presiding officer finds that the State has come into compliance with Federal requirements on any issue or part of an issue, he or she removes the appropriate issue or part of an issue from consideration. If all issues are removed, the hearing is terminated.

(2) Notice to parties. Before removing any issue or part of an issue from consideration, the presiding officer provides all parties other than HCFA and the State with—

(i) A statement of the intent to remove and the reasons for removal; and
§ 430.76  *Parties to the hearing.*

(a) HCFA and the State. HCFA and the State are parties to the hearing.

(b) Other individuals—(1) Basis for participation. Other individuals or groups may be recognized as parties if the issues to be considered at the hearing have caused them injury and their interest is within the zone of interests to be protected by the governing Federal statute.

(2) Petition for participation. Any individual or group wishing to participate as a party must, within 15 days after notice of hearing is published in the Federal Register, file with the HCFA Docket Clerk, a petition that concisely states—

(i) Petitioner's interest in the proceeding;
(ii) Who will appear for petitioner;
(iii) The issues on which petitioner wishes to participate; and
(iv) Whether petitioner intends to present witnesses.

The petitioner must also serve a copy of the petition on each party of record at that time.

(3) Comments on petition. Any party may, within 5 days of receipt of the copy of the petition, file comments on it.

(4) Action on petition. (i) The presiding officer promptly determines whether each petitioner has the requisite interest in the proceedings and approves or denies participation accordingly.

(ii) If petitions are made by more than one individual or group with common interests, the presiding officer may—

(A) Request all those petitioners to designate a single representative; or

(B) Recognize one or more of those petitioners to represent all of them.

(iii) The presiding officer gives each petitioner written notice of the decision and, if the decision is to deny, briefly states the grounds for denial.

(c) Amicus curiae (friend of the court)—

(1) Petition for participation. Any person or organization that wishes to participate as amicus curiae must, before the hearing begins, file with the HCFA Docket Clerk, a petition that concisely states—

(i) The petitioners' interest in the hearing;
(ii) Who will represent the petitioner; and
(iii) The issues on which the petitioner intends to present argument.

(2) Action on amicus curiae petition. The presiding officer may grant the petition if he or she finds that the petitioner has a legitimate interest in the proceedings, that such participation will not unduly delay the outcome and may contribute materially to the proper disposition of the issues.

(3) Nature of amicus participation. An amicus curiae is not a party to the hearing but may participate by—

(i) Submitting a written statement of position to the presiding officer before the beginning of the hearing;
(ii) Presenting a brief oral statement at the hearing, at the point in the proceedings specified by the presiding officer; and
(iii) Submitting a brief or written statement when the parties submit briefs.

The amicus curiae must serve copies of any briefs or written statements on all parties.

§ 430.80  *Authority of the presiding officer.*

(a) The presiding officer has the duty to conduct a fair hearing, to avoid delay, maintain order, and make a record of the proceedings. He or she has the authority necessary to accomplish
§ 430.88 Evidence.

(a) Evidentiary purpose. The hearing is directed to receiving factual evidence and expert opinion testimony related

§ 430.83 Rights of parties.

All parties may:

(a) Appear by counsel or other authorized representative, in all hearing proceedings.
(b) Participate in any prehearing conference held by the presiding officer.
(c) Agree to stipulations as to facts which will be made a part of the record.
(d) Make opening statements at the hearing.
(e) Present relevant evidence on the issues at the hearing.
(f) Present witnesses who then must be available for cross-examination by all other parties.
(g) Present oral arguments at the hearing.
(h) Submit written briefs, proposed findings of fact, and proposed conclusions of law, after the hearing.

§ 430.86 Discovery.

HCFA and any party named in the notice issued under §430.70 has the right to conduct discovery (including depositions) against opposing parties. Rules 26–37 of the Federal Rules of Civil Procedure apply to such proceedings; there will be no fixed rule on priority of discovery. Upon written motion, the presiding officer promptly rules upon any objection to discovery action initiated under this section. The presiding officer also has the power to grant a protective order or relief to any party against whom discovery is sought and to restrict or control discovery so as to prevent undue delay in the conduct of the hearing. Upon the failure of any party to make discovery, the presiding officer may issue any order and impose any sanction (other than contempt orders) authorized by Rule 37 of the Federal Rules of Civil Procedure.

§ 430.88 Evidence.

(a) Evidentiary purpose. The hearing is directed to receiving factual evidence and expert opinion testimony related

§ 430.83 Rights of parties.

All parties may:

(a) Appear by counsel or other authorized representative, in all hearing proceedings.
(b) Participate in any prehearing conference held by the presiding officer.
(c) Agree to stipulations as to facts which will be made a part of the record.
(d) Make opening statements at the hearing.
(e) Present relevant evidence on the issues at the hearing.
(f) Present witnesses who then must be available for cross-examination by all other parties.
(g) Present oral arguments at the hearing.
(h) Submit written briefs, proposed findings of fact, and proposed conclusions of law, after the hearing.
§ 430.90 Exclusion from hearing for misconduct.

The presiding officer may immediately exclude from the hearing any person who—
(a) Uses disrespectful, disorderly, or contumacious language or engages in contemptuous behavior;
(b) Refuses to comply with directions; or
(c) Uses dilatory tactics.

§ 430.92 Un-sponsored written material.

Letters expressing views or urging action and other un-sponsored written material regarding matters in issue in a hearing are placed in the correspondence section of the docket of the proceeding. These data are not considered part of the evidence or record in the hearing.

§ 430.94 Official transcript.

(a) Filing. The official transcripts of testimony, together with any stipulations, briefs, or memoranda of law, are filed with HCFA.

(b) Availability of transcripts. HCFA designates an official reporter for each hearing. Transcripts of testimony in hearings may be obtained from the official reporter by the parties and the public at rates not in excess of the maximum rates fixed by the contract between HCFA and the reporter.

(c) Correction of transcript. Upon notice to all parties, the presiding officer may authorize corrections that affect substantive matters in the transcript.

§ 430.96 Record for decision.

The transcript of testimony, exhibits, and all papers and requests filed in the proceedings, except the correspondence section of the docket, including rulings and any recommended or initial decision constitute the exclusive record for decision.

§ 430.100 Posthearing briefs.

The presiding officer fixes the time for filing posthearing briefs, which may contain proposed findings of fact and conclusions of law. The presiding officer may also permit reply briefs.

§ 430.102 Decisions following hearing.

(a) Administrator presides. If the presiding officer is the Administrator, he or she issues the hearing decision within 60 days after expiration of the period for submission of posthearing briefs.

(b) Administrator’s designee presides. If the presiding officer is other than the Administrator, the procedure is as follows:
(1) Upon expiration of the period allowed for submission of posthearing briefs, the presiding officer certifies the entire record, including his or her recommended findings and proposed decision, to the Administrator. The Administrator serves a copy of the recommended findings and proposed decision upon all parties and amici, if any.
(2) Any party may, within 20 days, file with the Administrator exceptions to the recommended findings and proposed decision and a supporting brief or statement.

(3) The Administrator reviews the recommended decision and, within 60 days of its issuance, issues his or her own decision.

(c) Effect of Administrator's decision. The decision of the Administrator under this section is the final decision of the Secretary and constitutes “final agency action” within the meaning of 5 U.S.C. 704 and a “final determination” within the meaning of section 1116(a)(3) of the Act and §430.38. The Administrator’s decision is promptly served on all parties and amici.

§ 430.104 Decisions that affect FFP.

(a) Scope of decisions. If the Administrator concludes that withholding of FFP is necessary because a State is out of compliance with Federal requirements, in accordance with §430.35, the decision also specifies—

(1) Whether no further payments will be made to the State or whether payments will be limited to parts of the program not affected by the noncompliance; and

(2) The effective date of the decision to withhold.

(b) Consultation. The Administrator may ask the parties for recommendations or briefs or may hold conferences of the parties on the question of further payments to the State.

(c) Effective date of decision. The effective date of a decision to withhold Federal funds will not be earlier than the date of the Administrator’s decision and will not be later than the first day of the next calendar quarter. The provisions of this section may not be waived under §430.64.
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FEDERAL FINANCIAL PARTICIPATION

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431.700 Basis and purpose.
§ 431.11 Organization for administration.

(a) Basis and purpose. This section, based on section 1902(a)(4) of the Act, prescribes the general organization and staffing requirements for the Medicaid agency and the State plan.

(b) Medical assistance unit. A State plan must provide for a medical assistance unit within the Medicaid agency, staffed with a program director and other appropriate personnel who participate in the development, analysis, and evaluation of the Medicaid program.

(c) Description of organization. (1) The plan must include—

(i) A description of the organization and functions of the Medicaid agency and an organization chart;

(ii) The Medicaid agency; and

(iii) The single State agency for the financial assistance program under title IV-A (in the 50 States or the District of Columbia), or under title I or XVI (AABD), in Guam, Puerto Rico, or the Virgin Islands.

(2) The plan must specify whether the agency that determines eligibility for the aged, blind, or disabled is—

(i) The Medicaid agency;

(ii) The single State agency for the financial assistance program under title IV-A (in the 50 States or the District of Columbia) or under title I or XVI (AABD), in Guam, Puerto Rico, or the Virgin Islands; or

(iii) The Federal agency administering the supplemental security income program under title XVI (SSI). In this case, the plan must also specify whether the Medicaid agency or the title IV-

A agency determines eligibility for any groups whose eligibility is not determined by the Federal agency.

(d) Agreement with Federal or State agencies. The plan must provide for written agreements between the Medicaid agency and the Federal or other State agencies that determine eligibility for Medicaid, stating the relationships and respective responsibilities of the agencies.

(e) Authority of the single State agency. In order for an agency to qualify as the Medicaid agency—

(1) The agency must not delegate, to other than its own officials, authority to—

(i) Exercise administrative discretion in the administration or supervision of the plan, or

(ii) Issue policies, rules, and regulations on program matters.

(2) The authority of the agency must not be impaired if any of its rules, regulations, or decisions are subject to review, clearance, or similar action by other offices or agencies of the State.

(3) If other State or local agencies or offices perform services for the Medicaid agency, they must not have the authority to change or disapprove any administrative decision of that agency, or otherwise substitute their judgment for that of the Medicaid agency with respect to the application of policies, rules, and regulations issued by the Medicaid agency.

[44 FR 17930, Mar. 23, 1979]
§ 431.12 Medical care advisory committee.

(i) A description of the organization and functions of the medical assistance unit and an organization chart; and
(ii) A description of the kinds and number of professional medical personnel and supporting staff used in the administration of the plan and their responsibilities.

(d) Eligibility determined by other agencies. If eligibility is determined by State agencies other than the Medicaid agency or by local agencies under the supervision of other State agencies, the plan must include a description of the staff designated by those other agencies and the functions they perform in carrying out their responsibility.

§ 431.15 Methods of administration.

A State plan must provide for methods of administration that are found by the Secretary to be necessary for the proper and efficient operation of the plan.

§ 431.16 Reports.

A State plan must provide that the Medicaid agency will—

(a) Submit all reports required by the Secretary;

(b) Follow the Secretary's instructions with regard to the form and content of those reports; and

(c) Comply with any provisions that the Secretary finds necessary to verify and assure the correctness of the reports.

§ 431.17 Maintenance of records.

(a) Basis and purpose. This section, based on section 1902(a)(4) of the Act, prescribes the kinds of records a Medicaid agency must maintain, the retention period, and the conditions under which microfilm copies may be substituted for original records.

(b) Content of records. A State plan must provide that the Medicaid agency will maintain or supervise the maintenance of the records necessary for the proper and efficient operation of the plan. The records must include—
§ 431.18 Availability of agency program manuals.

(a) Basis and purpose. This section, based on section 1902(a)(4) of the Act, prescribes State plan requirements for facilitating access to Medicaid rules and policies by individuals outside the State Medicaid agency.

(b) State plan requirements. A State plan must provide that the Medicaid agency meets the requirements of paragraphs (c) through (g) of this section.

(c) Availability in agency offices. (1) The agency must maintain, in all its offices, copies of its current rules and policies that affect the public, including those that govern eligibility, provision of medical assistance, covered services, and recipient rights and responsibilities.

(2) These documents must be available upon request for review, study, and reproduction by individuals during regular working hours of the agency.

(d) Availability through other entities. The agency must provide copies of its current rules and policies to—

(1) Public and university libraries;

(2) The local or district offices of the Bureau of Indian Affairs;

(3) Welfare and legal services offices; and

(4) Other entities that—

(i) Request the material in order to make it accessible to the public;

(ii) Are centrally located and accessible to a substantial number of the recipient population they serve; and

(iii) Agree to accept responsibility for filing all amendments or changes forwarded by the agency.

(e) Availability in relation to fair hearings. The agency must make available to an applicant or recipient, or his representative, a copy of the specific policy materials necessary—

(1) To determine whether to request a fair hearing; or

(2) To prepare for a fair hearing.

(f) Availability for other purposes. The agency must establish rules for making program policy materials available to individuals who request them for other purposes.

(g) Charges for reproduction. The agency must make copies of its program policy materials available without
§ 431.20 Advance directives.  
(a) Basis and purpose. This section, based on section 1902(a) (57) and (58) of the Act, prescribes State plan requirements for the development and distribution of a written description of State law concerning advance directives.  
(b) A State Plan must provide that the State, acting through a State agency, association, or other private non-profit entity, develop a written description of the State law (whether statutory or as recognized by the courts of the State) concerning advance directives, as defined in §489.100 of this chapter, to be distributed by Medicaid providers and health maintenance organizations (as specified in section 1903(m)(1)(A) of the Act) in accordance with the requirements under part 489, subpart I of this chapter. Revisions to the written descriptions as a result of changes in State law must be incorporated in such descriptions and distributed as soon as possible, but no later than 60 days from the effective date of the change in State law, to Medicaid providers and health maintenance organizations.  
[57 FR 8202, Mar. 6, 1992, as amended at 60 FR 33293, June 27, 1995]  

Subpart B—General Administrative Requirements  

Source: 56 FR 8847, Mar. 1, 1991, unless otherwise noted.  
§ 431.40 Basis and scope.  
(a) This subpart sets forth State plan requirements and exceptions that pertain to the following administrative requirements and provisions of the Act:  
(1) Statewideness—section 1902(a)(1);  
(2) Proper and efficient administration—section 1902(a)(4);  
(3) Comparability of services—section 1902(a)(10) (B)-(E);  
(4) Payment for services furnished outside the State—section 1902(a)(16);  
(5) Free choice of providers—section 1902(a)(23);  
(6) Special waiver provisions applicable to American Samoa and the Northern Mariana Islands—section 1902(j); and  
(7) Exceptions to, and waiver of, State plan requirements—sections 1915 (a)-(c) and 1916 (a)(3) and (b)(3).  
(b) Other applicable regulations include the following:  
(1) Section 430.25 Waivers of State plan requirements.  
(2) Section 440.250 Limits on comparability of services.  
§ 431.50 Statewide operation.  
(a) Statutory basis. Section 1902(a)(1) of the Act requires a State plan to be in effect throughout the State, and section 1915 permits certain exceptions.  
(b) State plan requirements. A State plan must provide that the following requirements are met:  
(1) The plan will be in operation statewide through a system of local offices, under equitable standards for assistance and administration that are mandatory throughout the State.  
(2) If administered by political subdivisions of the State, the plan will be mandatory on those subdivisions.  
(3) The agency will ensure that the plan is continuously in operation in all local offices or agencies through—  
(i) Methods for informing staff of State policies, standards, procedures, and instructions;  
(ii) Systematic planned examination and evaluation of operations in local offices by regularly assigned State staff who make regular visits; and  
(iii) Reports, controls, or other methods.  
(c) Exceptions. (1) “Statewide operation” does not mean, for example, that every source of service must furnish the service State-wide. The requirement does not preclude the agency from contracting with a comprehensive health care organization (such as an HMO or a rural health clinic) that serves a specific area of the State, to furnish services to Medicaid recipients who live in that area and chose to receive services from that HMO or rural health clinic. Recipients who live in other parts of the State may receive their services from other sources.
§ 431.51 Free choice of providers.

(a) Statutory basis. This section is based on sections 1902(a)(23), 1902(e)(2), and 1915 (a) and (b) of the Act.

(1) Section 1902(a)(23) of the Act provides that recipients may obtain services from any qualified Medicaid provider that undertakes to provide the services to them.

(2) Section 1915(a) of the Act provides that a State shall not be found out of compliance with section 1902(a)(23) solely because it imposes certain specified allowable restrictions on freedom of choice.

(3) Section 1915(b) of the Act authorizes waiver of the section 1902(a)(23) freedom of choice of providers requirement in certain specified circumstances, but not with respect to providers of family planning services.

(4) Section 1902(a)(23), as amended by section 4113(c) of OBRA '87, provides that a recipient enrolled in a primary care case-management system, an HMO, or a similar entity, may not be denied freedom of choice of qualified providers of family planning services.

(b) State plan requirements. A State plan, except the plan for Puerto Rico, the Virgin Islands, or Guam, must provide as follows:

(1) Except as provided under paragraph (c) of this section, a recipient may obtain Medicaid services from any institution, agency, pharmacy, person, or organization that is—

(i) Qualified to furnish the services; and

(ii) Willing to furnish them to that particular recipient.

This includes an organization that furnishes, or arranges for the furnishing of, Medicaid services on a prepayment basis.

(2) A recipient enrolled in a primary care case-management system, an HMO, or other similar entity will not be restricted in freedom of choice of providers of family planning services.

(c) Exceptions. Paragraph (b) of this section does not prohibit the agency from—

(1) Establishing the fees it will pay providers for Medicaid services;

(2) Setting reasonable standards relating to the qualifications of providers; or

(3) Subject to paragraph (b)(2) of this section, restricting recipients' free choice of providers in accordance with one or more of the exceptions set forth in § 431.54, or under a waiver as provided in § 431.55.

(d) Certification requirement. (1) Content of certification. If a State implements a project under one of the exceptions allowed under § 431.54 (d), (e) or (f), it must certify to HCFA that the statutory safeguards and requirements for an exception under section 1915(a) of the Act are met.

(2) Timing of certification. (i) For an exception under § 431.54(d), the State may not institute the project until after it has submitted the certification and HCFA has made the findings required under the Act, and so notified the State.

(ii) For exceptions under § 431.54 (e) or (f), the State must submit the certificate by the end of the quarter in which it implements the project.

§ 431.52 Payments for services furnished out of State.

(a) Statutory basis. Section 1902(a)(16) of the Act authorizes the Secretary to prescribe State plan requirements for furnishing Medicaid to State residents who are absent from the State.

(b) Payment for services. A State plan must provide that the State will pay for services furnished in another State to the same extent that it would pay for services furnished within its boundaries if the services are furnished to a recipient who is a resident of the State, and any of the following conditions is met:

(1) Medical services are needed because of a medical emergency;
§ 431.53 Assurance of transportation.
A State plan must—
(a) Specify that the Medicaid agency will ensure necessary transportation for recipients to and from providers; and
(b) Describe the methods that the agency will use to meet this requirement.

(Sec. 1902(a)(4) of the Act)

§ 431.54 Exceptions to certain State plan requirements.
(a) Statutory basis. Section 1915(a) of the Act provides that a State shall not be deemed to be out of compliance with the requirements of sections 1902(a) (1), (10), or (23) of the Act solely because it has elected any of the exceptions set forth in paragraphs (b) and (d) through (f) of this section.

(b) Additional services under a prepayment system. If the Medicaid agency contracts on a prepayment basis with an organization that provides services additional to those offered under the State plan, the agency may restrict the provision of the additional services to recipients who live in the area served by the organization and wish to obtain services from it.

(c) [Reserved]

(d) Special procedures for purchase of medical devices and laboratory and X-ray tests. The Medicaid agency may establish special procedures for the purchase of medical devices or laboratory and X-ray tests (as defined in § 440.30 of this chapter) through a competitive bidding process or otherwise, if the State assures, in the certification required under § 431.51(d), and HCFA finds, as follows:

(1) Adequate services or devices are available to recipients under the special procedures.

(2) Laboratory services are furnished through laboratories that meet the following requirements:

(i) They are independent laboratories, or inpatient or outpatient hospital laboratories that provide services for individuals who are not hospital patients, or physician laboratories that process at least 100 specimens for other physicians during any calendar year.

(ii) They meet the requirements of subpart M of part 405 or part 482 of this chapter.

(iii) Laboratories that require an interstate license under 42 CFR part 74 are licensed by HCFA or receive an exemption from the licensing requirement by the College of American Pathologists. (Hospital and physician laboratories may participate in competitive bidding only with regard to services to non-hospital patients and other physicians' patients, respectively.)

(3) Any laboratory from which a State purchases services under this section has no more than 75 percent of its charges based on services to Medicare beneficiaries and Medicaid recipients.

(e) Lock-in of recipients who over-utilize Medicaid services. If a Medicaid agency finds that a recipient has utilized Medicaid services at a frequency or amount that is not medically necessary, as determined in accordance with utilization guidelines established by the State, the agency may restrict that recipient for a reasonable period of time to obtain Medicaid services from designated providers only. The agency may impose these restrictions only if the following conditions are met:

(1) The agency gives the recipient notice and opportunity for a hearing (in accordance with procedures established by the agency) before imposing the restrictions.

(2) The agency ensures that the recipient has reasonable access (taking into
account geographic location and reasonable travel time) to Medicaid services of adequate quality.

(3) The restrictions do not apply to emergency services furnished to the recipient.

(f) Lock-out of providers. If a Medicaid agency finds that a Medicaid provider has abused the Medicaid program, the agency may restrict the provider, through suspension or otherwise, from participating in the program for a reasonable period of time.

Before imposing any restriction, the agency must meet the following conditions:

(1) Give the provider notice and opportunity for a hearing, in accordance with procedures established by the agency.

(2) Find that in a significant number or proportion of cases, the provider has:

(i) Furnished Medicaid services at a frequency or amount not medically necessary, as determined in accordance with utilization guidelines established by the agency; or

(ii) Furnished Medicaid services of a quality that does not meet professionally recognized standards of health care.

(3) Notify HCFA and the general public of the restriction and its duration.

(4) Ensure that the restrictions do not result in denying recipients reasonable access (taking into account geographic location; and reasonable travel time) to Medicaid services of adequate quality, including emergency services.

§ 431.55 Waiver of other Medicaid requirements.

(a) Statutory basis. Section 1915(b) of the Act authorizes the Secretary to waive most requirements of section 1902 of the Act to the extent he or she finds proposed improvements or specified practices in the provision of services under Medicaid to be cost effective, efficient, and consistent with the objectives of the Medicaid program. Sections 1915 (f) and (h) prescribe how such waivers are to be approved, continued, monitored, and terminated. Section 1902(p)(2) of the Act conditions FFP in payments to an entity under a section 1915(b)(1) waiver on the State's provision for exclusion of certain entities from participation.

(b) General requirements. (1) General requirements for submittal of waiver requests, and the procedures that HCFA follows for review and action on those requests are set forth in §430.25 of this chapter.

(2) In applying for a waiver to implement an approvable project under paragraph (c), (d), (e), or (f) of this section, a Medicaid agency must document in the waiver request and maintain data regarding:

(i) The cost-effectiveness of the project;

(ii) The effect of the project on the accessibility and quality of services;

(iii) The anticipated impact of the project on the State's Medicaid program and;

(iv) Assurances that the restrictions on free choice of providers do not apply to family planning services.

(3) No waiver under this section may be granted for a period longer than 2 years, unless the agency requests a continuation of the waiver.

(4) HCFA monitors the implementation of waivers granted under this section to ensure that requirements for such waivers are being met.

(i) If monitoring demonstrates that the agency is not in compliance with the requirements for a waiver under this section, HCFA gives the agency notice and opportunity for a hearing.

(ii) If, after a hearing, HCFA finds an agency to be out of compliance with the requirements of a waiver, HCFA terminates the waiver and gives the agency a specified date by which it must demonstrate that it meets the applicable requirements of section 1902 of the Act.

(5) The requirements of section 1902(s) of the Act, with regard to adjustments in payments for inpatient hospital services furnished to infants who have not attained age 1 and to children who have not attained age 6 and who receive these services in disproportionate share hospitals, may not be waived under a section 1915(b) waiver.

(c) Case-management system. (1) Waivers of appropriate requirements of section 1902 of the Act may be authorized for a State to implement a primary
care case-management system or specialty physician services system.

(i) Under a primary care case-management system the agency assures that a specific person or persons or agency will be responsible for locating, coordinating, and monitoring all primary care or primary care and other medical care and rehabilitative services on behalf of a recipient.

(ii) A specialty physician services system allows States to restrict recipients of specialty services to designated providers of such services, even in the absence of a primary care case-management system.

(2) A waiver under this paragraph (c) may not be approved unless the State’s request assures that the restrictions—

(i) Do not apply in emergency situations; and

(ii) Do not substantially impair access to medically necessary services of adequate quality.

(d) Locality as central broker. Waivers of appropriate requirements of section 1902 of the Act may be authorized for a State to allow a locality to act as a central broker to assist recipients in selecting among competing health care plans. States must ensure that access to medically necessary services of adequate quality is not substantially impaired.

(1) A locality is any defined jurisdiction, e.g., district, town, city, borough, county, parish, or State.

(2) A locality may use any agency or agent, public or private, profit or nonprofit, to act on its behalf in carrying out its central broker function.

(e) Sharing of cost savings. (1) Waivers of appropriate requirements of section 1902 of the Act may be authorized for a State to share with recipients the cost savings resulting from the recipients’ use of more cost-effective medical care.

(2) Sharing is through the provision of additional services, including—

(i) Services furnished by a plan selected by the recipient; and

(ii) Services expressly offered by the State as an inducement for recipients to participate in a primary care case-management system, a competing health care plan or other system that furnishes health care services in a more cost-effective manner.

(f) Restriction of freedom of choice—(1) Waiver of appropriate requirements of section 1902 of the Act may be authorized for States to restrict recipients to obtaining services from (or through) qualified providers or practitioners that meet, accept, and comply with the State reimbursement, quality and utilization standards specified in the State’s waiver request.

(2) An agency may qualify for a waiver under this paragraph (f) only if its applicable State standards are consistent with access, quality and efficient and economic provision of covered care and services and the restrictions it imposes—

(i) Do not apply to recipients residing at a long-term care facility when a restriction is imposed unless the State arranges for reasonable and adequate recipient transfer.

(ii) Do not discriminate among classes of providers on grounds unrelated to their demonstrated effectiveness and efficiency in providing those services; and

(iii) Do not apply in emergency circumstances.

(3) Demonstrated effectiveness and efficiency refers to reducing costs or slowing the rate of cost increase and maximizing outputs or outcomes per unit of cost.

(4) The agency must make payments to providers furnishing services under a freedom of choice waiver under this paragraph (f) in accordance with the timely claims payment standards specified in §447.45 of this chapter for health care practitioners participating in the Medicaid program.

(h) Waivers approved under section 1915(b)(1) of the Act—(1) Basic rules. (i) An agency must submit, as part of its waiver request, assurance that the entities described in paragraph (h)(2) of this section will be excluded from participation under an approved waiver.

(ii) FFP is available in payments to an entity that furnishes services under a section 1915(b)(1) waiver only if the agency excludes from participation any entity described in paragraph (h)(2) of this section.

(2) Entities that must be excluded. The agency must exclude an entity
that meets any of the following conditions:

(i) Could be excluded under section 1128(b)(8) of the Act as being controlled by a sanctioned individual.

(ii) Has a substantial contractual relationship (direct or indirect) with an individual convicted of certain crimes, as described in section 1128(b)(8)(B) of the Act.

(iii) Employs or contracts directly or indirectly with one of the following:

(A) Any individual or entity that, under section 1128 or section 1128A of the Act, is precluded from furnishing health care, utilization review, medical social services, or administrative services.

(B) Any entity described in paragraph (h)(2)(i) of this section.

(3) Definitions. As used in this section, substantial contractual relationship means any contractual relationship that provides for one or more of the following services:

(i) The administration, management, or provision of medical services.

(ii) The establishment of policies, or the provision of operational support, for the administration, management, or provision of medical services.

§ 431.57 Waiver of cost-sharing requirements.

(a) Sections 1916(a)(3) and 1916(b)(3) of the Act specify the circumstances under which the Secretary is authorized to waive the requirement that cost-sharing amounts be nominal.

(b) For nonemergency services furnished in a hospital emergency room, the Secretary may by waiver permit a State to impose a copayment of up to double the “nominal” copayment amounts determined under §447.54(a)(3) of this subchapter.

(c) Nonemergency services are services that do not meet the definition of emergency services at §447.53(b)(4) of this subchapter.

(d) In order for a waiver to be approved under this section, the State must establish to the satisfaction of HCFA that alternative sources of nonemergency, outpatient services are available and accessible to recipients.

(e) Although, in accordance with §431.55(b)(3) of this part, a waiver will generally be granted for a 2-year duration, HCFA will reevaluate waivers approved under this section if the State increases the nominal copayment amounts in effect when the waiver was approved.

(f) A waiver approved under this section cannot apply to services furnished before the waiver was granted.

Subpart C—Administrative Requirements: Provider Relations

§ 431.105 Consultation to medical facilities.

(a) Basis and purpose. This section implements section 1902(a)(24) of the Act, which requires that the State plan provide for consultative services by State agencies to certain institutions furnishing Medicaid services.

(b) State plan requirements. A State plan must provide that health agencies and other appropriate State agencies furnish consultative services to hospitals, nursing homes, home health
§ 431.107 Required provider agreement.

(a) Basis and purpose. This section sets forth State plan requirements, based on sections 1902(a)(4), 1902(a)(27), 1902(a)(57), and 1902(a)(58) of the Act, that relate to the keeping of records and the furnishing of information by all providers of services (including individual practitioners and groups of practitioners).

(b) Agreements. A State plan must provide for an agreement between the Medicaid agency and each provider or organization furnishing services under the plan in which the provider or organization agrees to:

1. Keep any records necessary to disclose the extent of services the provider furnishes to recipients;

2. On request, furnish to the Medicaid agency, the Secretary, or the State Medicaid fraud control unit (if such a unit has been approved by the Secretary under §455.300 of this chapter), any information maintained under paragraph (b)(1) of this section and any information regarding payments claimed by the provider for furnishing services under the plan;

3. Comply with the disclosure requirements specified in part 455, subpart B of this chapter; and

4. Comply with the advance directives requirements for hospitals, nursing facilities, providers of home health care and personal care services, hospices, and HMOs specified in part 489, subpart I, and §417.436(d) of this chapter.

[44 FR 41644, July 17, 1979, as amended at 57 FR 8202, Mar. 6, 1992]

§ 431.108 Effective date of provider agreements.

(a) Applicability—(1) General rule. Except as provided in paragraph (a)(2) of this section, this section applies to Medicaid provider agreements with entities that, as a basis for participation in Medicaid—

(i) Are subject to survey and certification by HCFA or the State survey agency; or

(ii) Are deemed to meet Federal requirements on the basis of accreditation by an accrediting organization whose program has HCFA approval at the time of accreditation survey and accreditation decision.

(2) Exception. A Medicaid provider agreement with a laboratory is effective only while the laboratory has in effect a valid CLIA certificate issued under part 493 of this chapter, and only for the specialty and subspecialty tests it is authorized to perform.

(b) All requirements are met on the date of survey. The agreement is effective on the date the onsite survey (including the Life Safety Code survey if applicable) is completed, if on that date the provider meets—

1. All applicable Federal requirements as set forth in this chapter; and

2. Any other requirements imposed by the State for participation in the Medicaid program. (If the provider has a time-limited agreement, the new agreement is effective on the day following expiration of the current agreement.)

(c) All requirements are not met on the date of survey. If on the date the survey is completed the provider fails to meet any of the requirements specified in paragraph (b) of this section, the following rules apply:

1. An NF provider agreement is effective on the date on which—

(i) The NF is found to be in substantial compliance as defined in §488.301 of this chapter; and
(ii) HCFA or the State survey agency receives from the NF, if applicable, an approvable waiver request.

(2) For an agreement with any other provider, the effective date is the earlier of the following:

(i) The date on which the provider meets all requirements.

(ii) The date on which a provider is found to meet all conditions of participation but has lower level deficiencies, and HCFA or the State survey agency receives from the provider an acceptable plan of correction for the lower level deficiencies, or an approvable waiver request, or both. (The date of receipt is the effective date of the agreement, regardless of when HCFA approves the plan of correction or waiver request, or both.)

(d) Accredited provider requests participation in the Medicaid program—(1) General rule. If a provider is currently accredited by a national accrediting organization whose program had HCFA approval at the time of accreditation and accreditation decision, and on the basis of accreditation, HCFA has deemed the provider to meet Federal requirements, the effective date depends on whether the provider is subject to requirements in addition to those included in the accrediting organization's approved program.

(i) Provider subject to additional requirements. For a provider that is subject to additional requirements, Federal or State, or both, the effective date is the date on which the provider meets all requirements, including the additional requirements.

(ii) Provider not subject to additional requirements. For a provider that is not subject to additional requirements, the effective date is the date of the provider's initial request for participation if on that date the provider met all Federal requirements.

(2) Special rule: Retroactive effective date. If the provider meets the requirements of paragraphs (d)(1) and (d)(1)(i) or (d)(1)(ii) of this section, the effective date may be retroactive for up to one year, to encompass dates on which the provider furnished, to a Medicaid recipient, covered services for which it has not been paid.


§ 431.110 Participation by Indian Health Service facilities.

(a) Basis. This section is based on section 1902(a)(4) of the Act, proper and efficient administration; 1902(a)(23), free choice of provider; and 1911, reimbursement of Indian Health Service facilities.

(b) State plan requirements. A State plan must provide that an Indian Health Service facility meeting State requirements for Medicaid participation must be accepted as a Medicaid provider on the same basis as any other qualified provider. However, when State licensure is normally required, the facility need not obtain a license but must meet all applicable standards for licensure. In determining whether a facility meets these standards, a Medicaid agency or State licensing authority may not take into account the absence of licensure of any staff member of the facility.

§ 431.115 Disclosure of survey information and provider or contractor evaluation.

(a) Basis and purpose. This section implements—

(1) Section 1902(a)(36) of the Act, which requires a State plan to provide that the State survey agency will make publicly available the findings from surveys of health care facilities, laboratories, agencies, clinics, or organizations; and

(2) Section 1106(d) of the Act, which places certain restrictions on the Medicaid agency's disclosure of contractor and provider evaluations.

(b) Definition of State survey agency. The State survey agency referred to in this section means the agency specified under section 1902(a)(9) of the Act as responsible for establishing and maintaining health standards for private or public institutions in which Medicaid recipients may receive services.

(c) State plan requirements. A State plan must provide that the requirements of this section and §488.325 of this chapter are met.

(d) Disclosure procedure. The Medicaid agency must have a procedure for disclosing pertinent findings obtained from surveys made by the State survey agency to determine if a health care facility, laboratory, agency, clinic or
health care organization meets the requirements for participation in the Medicaid program.

(e) Documents subject to disclosure. Documents subject to disclosure include—
(1) Survey reports, except for Joint Commission on the Accreditation of Hospitals reports prohibited from disclosure under §422.426(b)(2) of this chapter;
(2) Official notifications of findings based on survey reports;
(3) Pertinent parts of written documents furnished by the health care provider to the survey agency that relate to the reports and findings; and
(4) Ownership and contract information as specified in §455.104 of this subchapter.

(f) Availability for inspection and copy of statements listing deficiencies. The disclosure procedure must provide that the State survey agency will—
(1) Make statements of deficiencies based on the survey reports available for inspection and copying in both the public assistance office and the Social Security Administration district office serving the area where the provider is located; and
(2) Submit to the Regional Medicaid Director, through the Medicaid agency, a plan for making those findings available in other public assistance offices in standard metropolitan statistical areas where this information would be helpful to persons likely to use the health care provider’s services.

(g) When documents must be made available. The disclosure procedure must provide that the State survey agency will—
(1) Retain in the survey agency office and make available upon request survey reports and current and accurate ownership information; and
(2) Make available survey reports, findings, and deficiency statements immediately upon determining that a health care provider is eligible to begin or continue participation in the Medicaid program, or within 90 days after completion of the survey, whichever occurs first.

(h) Evaluation reports on providers and contractors. (1) If the Secretary sends the following reports to the Medicaid agency, the agency must meet the requirements of paragraphs (h) (2) and (3) of this section in releasing them:
(i) Individual contractor performance reviews and other formal performance evaluations of carriers, intermediaries, and State agencies, including the reports of followup reviews;
(ii) Comparative performance evaluations of those contractors, including comparisons of either overall performance or of any particular aspect of contractor operations; and
(iii) Program validation survey reports and other formal performance evaluations of providers, including the reports of followup reviews.
(2) The agency must not make the reports public until—
(i) The contractor or provider has had a reasonable opportunity, not to exceed 30 days, to comment on them; and
(ii) Those comments have been incorporated in the report.
(3) The agency must ensure that the reports contain no identification of individual patients, individual health care practitioners or other individuals.

§ 431.120 State requirements with respect to nursing facilities.

(a) State plan requirements. A State plan must—
(1) Provide that the requirements of subpart D of part 483 of this chapter are met; and
(2) Specify the procedures and rules that the State follows in carrying out the specified requirements, including review and approval of State-operated programs.
(3) To an NF or ICF/MR that is dissatisfied with a determination as to the effective date of its provider agreement.

(b) Basis and scope of requirements. The requirements set forth in part 483 of this chapter pertain to the following aspects of nursing facility services and are required by the indicated sections of the Act.

(1) Nurse aide training and competency programs, and evaluation of nurse aide competency (1919(e)(1) of the Act).
Subpart D—Appeals Process for NFs and ICFs/MR

§ 431.151 Scope and applicability.

(a) General rules. This subpart sets forth the appeals procedures that a State must make available as follows:

(1) To a nursing facility (NF) that is dissatisfied with a State's finding of noncompliance that has resulted in one of the following adverse actions:

(i) Denial or termination of its provider agreement.

(ii) Imposition of a civil money penalty or other alternative remedy.

(2) To an intermediate care facility for the mentally retarded (ICF/MR) that is dissatisfied with a State's finding of noncompliance that has resulted in the denial, termination, or nonrenewal of its provider agreement.

(3) To an NF or ICF/MR that is dissatisfied with a determination as to the effective date of its provider agreement.

(b) Special rules. This subpart also sets forth the special rules that apply in particular circumstances, the limitations on the grounds for appeal, and the scope of review during a hearing.

§ 431.152 State plan requirements.

The State plan must provide for appeals procedures that, as a minimum, satisfy the requirements of §§ 431.153 and 431.154.

§ 431.153 Evidentiary hearing.

(a) Right to hearing. Except as provided in paragraph (b) of this section, and subject to the provisions of paragraphs (c) through (j) of this section, the State must give the facility a full evidentiary hearing for any of the actions specified in § 431.151.

(b) Limit on grounds for appeal. The following are not subject to appeal:

(1) The choice of sanction or remedy.

(2) The State monitoring remed y.

(3) The loss of approval for a nurse-aide training program.

(4) The level of noncompliance found by a State except when a favorable final administrative review decision would affect the range of civil money penalty amounts the State could collect.

(5) A State survey agency's decision as to when to conduct an initial survey of a prospective provider.

(c) Notice of deficiencies and impending remedies. The State must give the facility a written notice that includes:

(1) The basis for the decision; and

(2) A statement of the deficiencies on which the decision was based.

(d) Request for hearing. The facility or its legal representative or other authorized official must file written request for hearing within 60 days of receipt of the notice of adverse action.

(e) Special rules: Denial, termination or nonrenewal of provider agreement. (1) Appeal by an ICF/MR. If an ICF/MR requests a hearing on denial, termination, or nonrenewal of its provider agreement—

(i) The evidentiary hearing must be completed either before, or within 120 days after, the effective date of the adverse action; and

(ii) If the hearing is made available only after the effective date of the action, the State must, before that date, offer the ICF/MR an informal reconsideration that meets the requirements of § 431.154.

(2) Appeal by an NF. If an NF requests a hearing on the denial or termination of its provider agreement, the request does not delay the adverse action and the hearing need not be completed before the effective date of the action.

(f) Special rules: Imposition of remedies. If a State imposes a civil money penalty or other remedies on an NF, the following rules apply:

(1) Basic rule. Except as provided in paragraph (f)(2) of this section and notwithstanding any provision of State law, the State must impose all remedies timely on the NF, even if the NF requests a hearing.
§ 431.154

(2) Exception. The State may not collect a civil money penalty until after the 60-day period for request of hearing has elapsed or, if the NF requests a hearing, until issuance of a final administrative decision that supports imposition of the penalty.

(g) Special rules: Dually participating facilities. If an NF is also participating or seeking to participate in Medicare as an SNF, and the basis for the State’s denial or termination of participation in Medicaid is also a basis for denial or termination of participation in Medicare, the State must advise the facility that—

(1) The appeals procedures specified for Medicare facilities in part 498 of this chapter apply; and

(2) A final decision entered under the Medicare appeals procedures is binding for both programs.

(h) Special rules: Adverse action by HCFA. If HCFA finds that an NF is not in substantial compliance and either terminates the NF’s Medicaid provider agreement or imposes alternative remedies on the NF (because HCFA’s findings and proposed remedies prevail over those of the State in accordance with §488.452 of this chapter), the NF is entitled only to the appeals procedures set forth in part 498 of this chapter, instead of the procedures specified in this subpart.

(i) Required elements of hearing. The hearing must include at least the following:

(1) Opportunity for the facility—
   (i) To appear before an impartial decision-maker to refute the finding of noncompliance on which the adverse action was based;
   (ii) To be represented by counsel or other representative; and
   (iii) To be heard directly or through its representative, to call witnesses, and to present documentary evidence.

(2) A written decision by the impartial decision-maker, setting forth the reasons for the decision and the evidence on which the decision is based.

(j) Limits on scope of review: Civil money penalty cases. In civil money penalty cases—

(1) The State’s finding as to a NF’s level of noncompliance must be upheld unless it is clearly erroneous; and

(2) The scope of review is as set forth in §488.438(e) of this chapter.


§ 431.154 Informal reconsideration for ICFs/MR.

The informal reconsideration must, at a minimum, include—

(a) Written notice to the facility of the denial, termination or nonrenewal and the findings upon which it was based;

(b) A reasonable opportunity for the facility to refute those findings in writing, and

(c) A written affirmation or reversal of the denial, termination, or nonrenewal.


Subpart E—Fair Hearings for Applicants and Recipients

Source: 44 FR 17932, Mar. 29, 1979, unless otherwise noted.

General Provisions

§ 431.200 Basis and purpose.

This subpart implements section 1902(a)(3) of the Act, which requires that a State plan provide an opportunity for a fair hearing to any person whose claim for assistance is denied or not acted upon promptly. This subpart also prescribes procedures for an opportunity for hearing if the Medicaid agency takes action to suspend, terminate, or reduce services. This subpart also implements sections 1919(f)(3), 1919(f)(3), and 1919(e)(7)(B) of the Act by providing an appeals process for individuals proposed to be transferred or discharged from skilled nursing facilities and nursing facilities and those adversely affected by the preadmission screening and annual resident review requirements of section 1919(e)(7) of the Act.

[57 FR 56505, Nov. 30, 1992]

§ 431.201 Definitions.

For purposes of this subpart:
PHYSICAL THERAPY

ACTION means a termination, suspension, or reduction of Medicaid eligibility or covered services. It also means determinations by skilled nursing facilities and nursing facilities to transfer or discharge residents and adverse determinations made by a State with regard to the preadmission screening and annual resident review requirements of section 1919(e)(7) of the Act.

Adverse determination means a determination made in accordance with sections 1919(b)(3)(F) or 1919(e)(7)(B) of the Act that the individual does not require the level of services provided by a nursing facility or that the individual does or does not require specialized services.

Date of action means the intended date on which a termination, suspension, reduction, transfer or discharge becomes effective. It also means the date of the determination made by a State with regard to the preadmission screening and annual resident review requirements of section 1919(e)(7) of the Act.

De novo hearing means a hearing that starts over from the beginning.

Evidentiary hearing means a hearing conducted so that evidence may be presented.

Notice means a written statement that meets the requirements of §431.210.

Request for a hearing means a clear expression by the applicant or recipient, or his authorized representative, that he wants the opportunity to present his case to a reviewing authority.

§431.205 Provision of hearing system.

(a) The Medicaid agency must be responsible for maintaining a hearing system that meets the requirements of this subpart.

(b) The State’s hearing system must provide for—

(1) A hearing before the agency; or

(2) An evidentiary hearing at the local level, with a right of appeal to a State agency hearing.

(c) The agency may offer local hearings in some political subdivisions and not in others.

(d) The hearing system must meet the due process standards set forth in Goldberg v. Kelly, 397 U.S. 254 (1970), and any additional standards specified in this subpart.

§431.206 Informing applicants and recipients.

(a) The agency must issue and publicize its hearing procedures.

(b) The agency must, at the time specified in paragraph (c) of this section, inform every applicant or recipient in writing—

(1) Of his right to a hearing;

(2) Of the method by which he may obtain a hearing; and

(3) That he may represent himself or use legal counsel, a relative, a friend, or other spokesman.

(c) The agency must provide the information required in paragraph (b) of this section—

(1) At the time that the individual applies for Medicaid;

(2) At the time of any action affecting his or her claim;

(3) At the time a skilled nursing facility or a nursing facility notifies a resident in accordance with §483.12 of this chapter that he or she is to be transferred or discharged; and

(4) At the time an individual receives an adverse determination by the State with regard to the preadmission screening and annual resident review requirements of section 1919(e)(7) of the Act.

§431.210 Content of notice.

A notice required under §431.206 (c)(2), (c)(3), or (c)(4) of this subpart must contain—

(a) A statement of what action the State, skilled nursing facility, or nursing facility intends to take;

(b) The reasons for the intended action;
§ 431.211 Advance notice.

The State or local agency must mail a notice at least 10 days before the date of action, except as permitted under §§431.213 and 431.214 of this subpart.

§ 431.213 Exceptions from advance notice.

The agency may mail a notice not later than the date of action if—

(a) The agency has factual information confirming the death of a recipient;
(b) The agency receives a clear written statement signed by a recipient that—
   (1) He no longer wishes services; or
   (2) Gives information that requires termination or reduction of services and indicates that he understands that this must be the result of supplying that information;
(c) The recipient has been admitted to an institution where he is ineligible under the plan for further services;
(d) The recipient's whereabouts are unknown and the post office returns agency mail directed to him indicating no forwarding address (See §431.231(d) of this subpart for procedure if the recipient's whereabouts become known);
(e) The agency establishes the fact that the recipient has been accepted for Medicaid services by another local jurisdiction, State, territory, or commonwealth;
(f) A change in the level of medical care is prescribed by the recipient's physician;
(g) The notice involves an adverse determination made with regard to the preadmission screening requirements of section 1919(e)(7) of the Act; or
(h) The date of action will occur in less than 10 days, in accordance with §483.12(a)(5)(ii), which provides exceptions to the 30 days notice requirements of §483.12(a)(5)(i).


§ 431.214 Notice in cases of probable fraud.

The agency may shorten the period of advance notice to 5 days before the date of action if—

(a) The agency has facts indicating that action should be taken because of probable fraud by the recipient; and
(b) The facts have been verified, if possible, through secondary sources.

§ 431.220 When a hearing is required.

(a) The agency must grant an opportunity for a hearing to:
   (1) Any applicant who requests it because his claim for services is denied or is not acted upon with reasonable promptness;
   (2) Any recipient who requests it because he or she believes the agency has taken an action erroneously;
   (3) Any resident who requests it because he or she believes a skilled nursing facility or nursing facility has erroneously determined that he or she must be transferred or discharged; and
   (4) Any individual who requests it because he or she believes the State has made an erroneous determination with regard to the preadmission and annual resident review requirements of section 1919(e)(7) of the Act.
   (b) The agency need not grant a hearing if the sole issue is a Federal or State law requiring an automatic change adversely affecting some or all recipients.

[44 FR 17932, Mar. 29, 1979, as amended at 57 FR 56505, Nov. 30, 1992]

§ 431.221 Request for hearing.

(a) The agency may require that a request for a hearing be in writing.
(b) The agency may not limit or interfere with the applicant’s or recipient’s freedom to make a request for a hearing.
(c) The agency may assist the applicant or recipient in submitting and processing his request.

(d) The agency must allow the applicant or recipient a reasonable time, not to exceed 90 days from the date that notice of action is mailed, to request a hearing.

§ 431.222 Group hearings.

The agency—
(a) May respond to a series of individual requests for hearing by conducting a single group hearing;
(b) May consolidate hearings only in cases in which the sole issue involved is one of Federal or State law or policy;
(c) Must follow the policies of this subpart and its own policies governing hearings in all group hearings; and
(d) Must permit each person to present his own case or be represented by his authorized representative.

§ 431.223 Denial or dismissal of request for a hearing.

The agency may deny or dismiss a request for a hearing if—
(a) The applicant or recipient withdraws the request in writing; or
(b) The applicant or recipient fails to appear at a scheduled hearing without good cause.

PROCEDURES

§ 431.230 Maintaining services.

(a) If the agency mails the 10-day or 5-day notice as required under §431.211 or §431.214 of this subpart, and the recipient requests a hearing before the date of action, the agency may not terminate or reduce services until a decision is rendered after the hearing unless—
(1) It is determined at the hearing that the sole issue is one of Federal or State law or policy; and
(2) The agency promptly informs the recipient in writing that services are to be terminated or reduced pending the hearing decision.

(b) If the agency’s action is sustained by the hearing decision, the agency may institute recovery procedures against the applicant or recipient to recoup the cost of any services furnished the recipient, to the extent they were furnished solely by reason of this section.

[44 FR 17932, Mar. 29, 1979, as amended at 45 FR 24882, Apr. 11, 1980]

§ 431.231 Reinstatement of services.

(a) The agency may reinstate services if a recipient requests a hearing not more than 10 days after the date of action.

(b) The reinstated services must continue until a hearing decision unless, at the hearing, it is determined that the sole issue is one of Federal or State law or policy.

(c) The agency must reinstate and continue services until a decision is rendered after a hearing if—
(1) Action is taken without the advance notice required under §431.211 or §431.214 of this subpart;
(2) The recipient requests a hearing within 10 days of the mailing of the notice of action; and
(3) The agency determines that the action resulted from other than the application of Federal or State law or policy.

(d) If a recipient’s whereabouts are unknown, as indicated by the return of unforwardable agency mail directed to him, any discontinued services must be reinstated if his whereabouts become known during the time he is eligible for services.

§ 431.232 Adverse decision of local evidentiary hearing.

If the decision of a local evidentiary hearing is adverse to the applicant or recipient, the agency must—
(a) Inform the applicant or recipient of the decision;
(b) Inform the applicant or recipient that he has the right to appeal the decision to the State agency, in writing, within 15 days of the mailing of the notice of the adverse decision;
(c) Inform the applicant or recipient of his right to request that his appeal be a de novo hearing; and
(d) Discontinue services after the adverse decision.

§ 431.233 State agency hearing after adverse decision of local evidentiary hearing.

(a) Unless the applicant or recipient specifically requests a de novo hearing,
§ 431.240 Conducting the hearing.

(a) All hearings must be conducted—
   (1) At a reasonable time, date, and place;
   (2) Only after adequate written notice of the hearing; and
   (3) By one or more impartial officials or other individuals who have not been directly involved in the initial determination of the action in question.

(b) If the hearing involves medical issues such as those concerning a diagnosis, an examining physician’s report, or a medical review team’s decision, and if the hearing officer considers it necessary to have a medical assessment other than that of the individual involved in making the original decision, such a medical assessment must be obtained at agency expense and made part of the record.

§ 431.241 Matters to be considered at the hearing.

The hearing must cover—

(a) Agency action or failure to act with reasonable promptness on a claim for services, including both initial and subsequent decisions regarding eligibility;

(b) Agency decisions regarding changes in the type or amount of services;

(c) A decision by a skilled nursing facility or nursing facility to transfer or discharge a resident; and

(d) A State determination with regard to the preadmission screening and annual resident review requirements of section 1919(e)(7) of the Act.

[57 FR 56505, Nov. 30, 1992]

§ 431.242 Procedural rights of the applicant or recipient.

The applicant or recipient, or his representative, must be given an opportunity to—

(a) Examine at a reasonable time before the date of the hearing and during the hearing:
   (1) The content of the applicant’s or recipient’s case file; and
   (2) All documents and records to be used by the State or local agency or the skilled nursing facility or nursing facility at the hearing;

(b) Bring witnesses;

(c) Establish all pertinent facts and circumstances;

(d) Present an argument without undue interference; and

(e) Question or refute any testimony or evidence, including opportunity to confront and cross-examine adverse witnesses.

[44 FR 17932, Mar. 29, 1979, as amended at 57 FR 56506, Nov. 30, 1992]

§ 431.243 Parties in cases involving an eligibility determination.

If the hearing involves an issue of eligibility and the Medicaid agency is not responsible for eligibility determinations, the agency that is responsible for determining eligibility must participate in the hearing.

§ 431.244 Hearing decisions.

(a) Hearing recommendations or decisions must be based exclusively on evidence introduced at the hearing.

(b) The record must consist only of—
   (1) The transcript or recording of testimony and exhibits, or an official report containing the substance of what happened at the hearing;
   (2) All papers and requests filed in the proceeding; and
   (3) The recommendation or decision of the hearing officer.

(c) The applicant or recipient must have access to the record at a convenient place and time.

(d) In any evidentiary hearing, the decision must be a written one that—
   (1) Summarizes the facts; and
   (2) Identifies the regulations supporting the decision.

(e) In a de novo hearing, the decision must—
   (1) Specify the reasons for the decision; and
   (2) Identify the supporting evidence and regulations.

(f) The agency must take final administrative action within 90 days.
§ 431.245 Notifying the applicant or recipient of a State agency decision.
The agency must notify the applicant or recipient in writing of—
(a) The decision; and
(b) His right to request a State agency hearing or seek judicial review, to the extent that either is available to him.

§ 431.246 Corrective action.
The agency must promptly make corrective payments, retroactive to the date an incorrect action was taken, and, if appropriate, provide for admission or readmission of an individual to a facility if—
(a) The hearing decision is favorable to the applicant or recipient; or
(b) The agency decides in the applicant's or recipient's favor before the hearing.

§ 431.300 Basis and purpose.
(a) Section 1902(a)(7) of the Act requires that a State plan must provide safeguards that restrict the use or disclosure of information concerning applicants and recipients to purposes directly connected with the administration of the plan. This subpart specifies State plan requirements, the types of information to be safeguarded, the conditions for release of safeguarded information, and restrictions on the distribution of other information.

(b) Section 1137 of the Act, which requires agencies to exchange information in order to verify the income and eligibility of applicants and recipients (see §435.940ff), requires State agencies to have adequate safeguards to assure that—
(1) Information exchanged by the State agencies is made available only to the extent necessary to assist in the valid administrative needs of the program receiving the information, and information received under section 6103(l) of the Internal Revenue Code of 1954 is exchanged only with agencies authorized to receive that information under that section of the Code; and

(2) Meeting other expenses of the applicant or recipient in connection with the hearing;
§ 431.301  
(2) The information is adequately stored and processed so that it is protected against unauthorized disclosure for other purposes.  
[51 FR 7210, Feb. 28, 1986]

§ 431.301  State plan requirements.  
A State plan must provide, under a State statute that imposes legal sanctions, safeguards meeting the requirements of this subpart that restrict the use or disclosure of information concerning applicants and recipients to purposes directly connected with the administration of the plan.  

§ 431.302  Purposes directly related to State plan administration.  
Purposes directly related to plan administration include—
(a) Establishing eligibility;
(b) Determining the amount of medical assistance;
(c) Providing services for recipients; and
(d) Conducting or assisting an investigation, prosecution, or civil or criminal proceeding related to the administration of the plan.  

§ 431.303  State authority for safeguarding information.  
The Medicaid agency must have authority to implement and enforce the provisions specified in this subpart for safeguarding information about applicants and recipients.  

§ 431.304  Publicizing safeguarding requirements.  
(a) The agency must publicize provisions governing the confidential nature of information about applicants and recipients, including the legal sanctions imposed for improper disclosure and use.
(b) The agency must provide copies of these provisions to applicants and recipients and to other persons and agencies to whom information is disclosed.  

§ 431.305  Types of information to be safeguarded.  
(a) The agency must have criteria that govern the types of information about applicants and recipients that are safeguarded.  
(b) This information must include at least—
(1) Names and addresses;
(2) Medical services provided;
(3) Social and economic conditions or circumstances;
(4) Agency evaluation of personal information;
(5) Medical data, including diagnosis and past history of disease or disability; and
(6) Any information received for verifying income eligibility and amount of medical assistance payments (see §435.940ff). Income information received from SSA or the Internal Revenue Service must be safeguarded according to the requirements of the agency that furnished the data.

(7) Any information received in connection with the identification of legally liable third party resources under §433.138 of this chapter.  

§ 431.306  Release of information.  
(a) The agency must have criteria specifying the conditions for release and use of information about applicants and recipients.
(b) Access to information concerning applicants or recipients must be restricted to persons or agency representatives who are subject to standards of confidentiality that are comparable to those of the agency.
(c) The agency must not publish names of applicants or recipients.
(d) The agency must obtain permission from a family or individual, whenever possible, before responding to a request for information from an outside source, unless the information is to be used to verify income, eligibility and the amount of medical assistance payment under section 1137 of this Act and §§435.940 through 435.965 of this chapter. If, because of an emergency situation, time does not permit obtaining consent before release, the agency must notify the family or individual immediately after supplying the information.
(e) The agency’s policies must apply to all requests for information from outside sources, including governmental bodies, the courts, or law enforcement officials.
(f) If a court issues a subpoena for a case record or for any agency representative to testify concerning an applicant or recipient, the agency must inform the court of the applicable statutory provisions, policies, and regulations restricting disclosure of information.

(g) Before requesting information from, or releasing information to, other agencies to verify income, eligibility and the amount of assistance under §§435.940 through 435.965 of this chapter, the agency must execute data exchange agreements with those agencies, as specified in §435.945(f).

(h) Before requesting information from, or releasing information to, other agencies to identify legally liable third party resources under §433.138(d) of this chapter, the agency must execute data exchange agreements, as specified in §433.138(h)(2) of this chapter.

§ 431.610 Relations with standard-setting and survey agencies.

(a) Basis and purpose. This section implements—

(1) Section 1902(a)(9) of the Act, concerning the designation of State authorities to be responsible for establishing and maintaining health and other standards for institutions participating in Medicaid; and

(2) Section 1902(a)(33) of the Act, concerning the designation of the State licensing agency to be responsible for determining whether institutions and agencies meet requirements for participation in the State’s Medicaid program.

(3) Section 1919(g)(1)(A) of the Act, concerning responsibilities of the State for certifying the compliance of non-State operated NFs with requirements of participation in the State’s Medicaid program.

(b) Designated agency responsible for health standards. A State plan must designate, as the State authority responsible for establishing and maintaining health standards for private or public institutions that provide services to Medicaid recipients, the same State agency that is used by the Secretary to determine qualifications of institutions and suppliers of services to participate in Medicare (see 42 CFR 405.1901). The requirement for establishing and maintaining standards does not apply with respect to Christian Science sanitoria operated, or listed and certified, by the First Church of Christ Scientist, Boston, Mass.

(c) Designated agency responsible for standards other than health standards. The plan must designate the Medicaid examinations, availability of surplus food, and consumer protection information.

(d) Under NVRA, the agency must distribute voter information and registration materials as specified in NVRA.


§ 431.307 Distribution of information materials.

(a) All materials distributed to applicants, recipients, or medical providers must—

(1) Directly relate to the administration of the Medicaid program;

(2) Have no political implications except to the extent required to implement the National Voter Registration Act of 1993 (NVRA); Pub. L. 103-324; for States that are exempt from the requirements of NVRA, voter registration may be a voluntary activity so long as the provisions of section 7(a)(5) of NVRA are observed;

(3) Contain the names only of individuals directly connected with the administration of the plan; and

(4) Identify those individuals only in their official capacity with the State or local agency.

(b) The agency must not distribute materials such as “holiday” greetings, general public announcements, partisan voting information and alien registration notices.

(c) The agency may distribute materials directly related to the health and welfare of applicants and recipients, such as announcements of free medical

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agency or other appropriate State authority or authorities to be responsible for establishing and maintaining standards, other than those relating to health, for private or public institutions that provide services to Medicaid recipients.

(d) Description and retention of standards. (1) The plan must describe the standards established under paragraphs (b) and (c) of this section.

(2) The plan must provide that the Medicaid agency keeps these standards on file and makes them available to the Administrator upon request.

(e) Designation of survey agency. The plan must provide that—

(1) The agency designated in paragraph (b) of this section, or another State agency responsible for licensing health institutions in the State, determines for the Medicaid agency whether institutions and agencies meet the requirements for participation in the Medicaid program; and

(2) The agency staff making the determination under paragraph (e)(1) of this section is the same staff responsible for making similar determinations for institutions or agencies participating under Medicare; and

(3) The agency designated in paragraph (e)(1) of this section makes recommendations regarding the effective dates of provider agreements, as determined under §431.108.

(f) Written agreement required. The plan must provide for a written agreement (or formal written intra-agency arrangement) between the Medicaid agency and the survey agency designated under paragraph (e) of this section, covering the activities of the survey agency in carrying out its responsibilities. The agreement must specify that—

(1) Federal requirements and the forms, methods and procedures that the Administrator designates will be used to determine provider eligibility and certification under Medicaid;

(2) Inspectors surveying the premises of a provider will—

(i) Complete inspection reports;

(ii) Note on completed reports whether or not each requirement for which an inspection is made is satisfied; and

(iii) Document deficiencies in reports;

(3) The survey agency will keep on file all information and reports used in determining whether participating facilities meet Federal requirements; and

(4) The survey agency will make the information and reports required under paragraph (f)(3) of this section readily accessible to HHS and the Medicaid agency as necessary—

(i) For meeting other requirements under the plan; and

(ii) For purposes consistent with the Medicaid agency's effective administration of the program.

(g) Responsibilities of survey agency. The plan must provide that, in certifying NFs and ICFs/MR, the survey agency designated under paragraph (e) of this section will—

(1) Review and evaluate medical and independent professional review team reports obtained under part 456 of this subchapter as they relate to health and safety requirements;

(2) Have qualified personnel perform on-site inspections periodically as appropriate based on the timeframes in the correction plan and—

(i) At least once during each certification period or more frequently if there is a compliance question; and

(ii) For non-State operated NFs, within the timeframes specified in §488.308 of this chapter.

(3) Have qualified personnel perform on-site inspections—

(i) At least once during each certification period or more frequently if there is a compliance question; and

(ii) For intermediate care facilities with deficiencies as described in §§442.112 and 442.113 of this subchapter, within 6 months after initial correction plan approval and every 6 months thereafter as required under those sections.

(h) FFP for survey responsibilities. (1) FFP is available in expenditures that the survey agency makes to carry out its survey and certification responsibilities under the agreement specified in paragraph (f) of this section.

(2) FFP is not available in any expenditures that the survey agency makes that are attributable to the State's overall responsibilities under
§ 431.615 Relations with State health and vocational rehabilitation agencies and title V grantees.

(a) Basis and purpose. This section implements section 1902(a)(11) and (22)(C) of the Act, by setting forth State plan requirements for arrangements and agreements between the Medicaid agency and—

(1) State health agencies;
(2) State vocational rehabilitation agencies; and
(3) Grantees under title V of the Act, Maternal and Child Health and Crippled Children’s Services.

(b) Definitions. For purposes of this section—

Title V grantee’ means the agency, institution, or organization receiving Federal payments for part or all of the cost of any service program or project authorized by title V of the Act, including—

(1) Maternal and child health services;
(2) Crippled children’s services;
(3) Maternal and infant care projects;
(4) Children and youth projects; and
(5) Projects for the dental health of children.

(c) State plan requirements. A state plan must—

(1) Describe cooperative arrangements with the State agencies that administer, or supervise the administration of, health services and vocational rehabilitation services designed to make maximum use of these services;
(2) Provide for arrangements with title V grantees, under which the Medicaid agency will utilize the grantee to furnish services that are included in the State plan;
(3) Provide that all arrangements under this section meet the requirements of paragraph (d) of this section; and
(4) Provide, if requested by the title V grantee in accordance with the arrangements made under this section, that the Medicaid agency reimburse the grantee or the provider for the cost of services furnished recipients by or through the grantee.

(d) Content of arrangements. The arrangements referred to in paragraph (c) must specify, as appropriate—

(1) The mutual objectives and responsibilities of each party to the arrangement;
(2) The services each party offers and in what circumstances;
(3) The cooperative and collaborative relationships at the State level;
(4) The kinds of services to be provided by local agencies; and
(5) Methods for—

(i) Early identification of individuals under 21 in need of medical or remedial services;
(ii) Reciprocal referrals;
(iii) Coordinating plans for health services provided or arranged for recipients;
(iv) Payment or reimbursement;
(v) Exchange of reports of services furnished to recipients;
(vi) Periodic review and joint planning for changes in the agreements;
(vii) Continuous liaison between the parties, including designation of State and local liaison staff; and
(viii) Joint evaluation of policies that affect the cooperative work of the parties.

(e) Federal financial participation. FFP is available in expenditures for Medicaid services provided to recipients through an arrangement under this section.

§ 431.620 Agreement with State mental health authority or mental institutions.

(a) Basis and purpose. This section implements section 1902(a)(20)(A) of the Act, for States offering Medicaid services in institutions for mental diseases for recipients aged 65 or older, by specifying the terms of the agreement those States must have with other State authorities and institutions. (See part 441, subpart C of this chapter for regulations implementing section 1902(a)(20) (B) and (C).)

(b) Definition. For purposes of this section, an “institution for mental diseases” means an institution primarily engaged in providing diagnosis, treatment, or care of persons with mental...
§ 431.621 State requirements with respect to nursing facilities.

(a) Basis and purpose. This section implements sections 1919(b)(3)(F) and 1919(e)(7) of the Act by specifying the terms of the agreement the State must have with the State mental health and mental retardation authorities concerning the operation of the State's Preadmission Screening and Annual Resident Review (PASARR) program.

(b) State plan requirement. The State plan must provide that the Medicaid agency has in effect a written agreement with—

(1) The State authority or authorities concerned with mental diseases; and

(2) Any institution for mental diseases that is under the jurisdiction of those State authorities, and that provides services under Medicaid to recipients aged 65 or older.

(d) Provisions required in an agreement. The agreement must specify the respective responsibilities of the agency and the authority or institution, including arrangements for—

(1) Joint planning between the parties to the agreement;

(2) Development of alternative methods of care;

(3) Immediate readmission to an institution when needed by a recipient who is in alternative care;

(4) Access by the agency to the institution, the recipient, and the recipient's records when necessary to carry out the agency's responsibilities;

(5) Recording, reporting, and exchanging medical and social information about recipients; and

(6) Other procedures needed to carry out the agreement.

44 F.R. 17935, Mar. 23, 1979

§ 431.625 Coordination of Medicaid with Medicare part B.

(a) Basis and purpose. (1) Section 1943(a) of the Act requires the Secretary to have entered into an agreement between any State that requested that agreement before January 1, 1970, and the Secretary of Health, Education, and Welfare (now the Secretary of Health, Education, and Welfare) concerning the State's Preadmission Screening and Annual Resident Review (PASARR) program. This section implements section 1902(a)(10) of the Act (in clause (I) following subparagraph (D)) of the Act, allowing the Secretary of Health, Education, and Welfare to make such agreements with States that have not previously entered into agreements, subject to the conditions in the Act.

(b) State plan requirement. The State plan must provide that the Medicaid agency has in effect a written agreement with the State mental health and mental retardation authorities that meets the requirements specified in paragraph (c) of this section.

(c) Provisions required in an agreement. The agreement must specify the respective responsibilities of the agency and the State mental health and mental retardation authorities, including arrangements for—

(1) Joint planning between the parties to the agreement;

(2) Access by the agency to the State mental health and mental retardation authorities' records when necessary to carry out the agency's responsibilities;

(3) Recording, reporting, and exchanging medical and social information about individuals subject to PASARR;

(4) Ensuring that preadmission screenings and annual resident reviews are performed timely in accordance with §483.112(c) and 483.114(c) of this part;

(5) Ensuring that, if the State mental health and mental retardation authorities delegate their respective responsibilities, these delegations comply with §483.106(e) of this part;

(6) Ensuring that PASARR determinations made by the State mental health and mental retardation authorities are not countermanded by the State Medicaid agency, except through the appeals process, but that the State mental health and mental retardation authorities do not use criteria which are inconsistent with those adopted by the State Medicaid agency under its approved State plan;

(7) Designating the independent person or entity who performs the PASARR evaluations for individuals with MI; and

(8) Ensuring that all requirements of §§483.100 through 483.136 are met.

57 F.R. 56506, Nov. 30, 1992; 58 F.R. 25784, Apr. 28, 1993
charges for recipients enrolled under Medicare Part B without obligating itself to provide the range of Part B benefits to other recipients; and

(3) Section 1903(a)(1) and (b) of the Act authorizes FFP for State payment of Medicare Part B premiums for certain recipients.

(4) This section—

(i) Specifies the exception, relating to Part B coverage, from the requirement to provide comparable services to all recipients; and

(ii) Prescribes FFP rules concerning State payment for Medicare premiums and for services that could have been covered under Medicare.

(5) Section 1902(a)(15) of the Act requires that if a State chooses to pay only a portion of deductibles, cost sharing or other charges for recipients enrolled under Medicare Part B, the portion that is to be paid by a Medicaid recipient must be reasonably related to the recipient's income and resources.

(b) Exception from obligation to provide comparable services; State plan requirement. (1) The State's payment of premiums, deductibles, cost sharing, or similar charges under Part B does not obligate it to provide the full range of Part B services to recipients not covered by Medicare.

(2) The State plan must specify this exception if it applies.

(c) Effect of payment of premiums on State liability for cost sharing. (1) State payment of Part B premiums on behalf of a Medicaid recipient does not obligate it to pay on the recipient’s behalf the Part B deductible and coinsurance amounts for those Medicare Part B services not covered by Medicare.

(2) If a State pays on a recipient’s behalf any portion of the deductible or cost sharing amounts under Medicare Part B, the portion paid by a State must be reasonably related to the recipient’s income and resources.

(d) Federal financial participation: Medicare Part B premiums. (1) Basic rule. Except as provided in paragraph (d)(2) of this section, FFP is not available in State expenditures for Medicare Part B premiums for Medicaid recipients unless the recipients receive money payments under title I, IV-A, X, XIV, XVI (AABD or SSI) of the Act, or State supplements as permitted under section 1616(a) of the Act, or as required by section 212 of Pub. L. 93-66.

(2) Exception. FFP is available in expenditures for Medicare Part B premiums for the following groups:

(i) AFDC families required to be covered under §§435.112 and 436.116 of this subchapter, those eligible for continued Medicaid coverage despite increased income from employment;

(ii) Recipients required to be covered under §§435.114, 435.134, and 436.112 of this subchapter, those eligible for continued Medicaid coverage despite increased income from monthly insurance benefits under title II of the Act;

(iii) Recipients required to be covered under §435.135 of this subchapter, those eligible for continued Medicaid coverage despite increased income from cost-of-living increases under title II of the Act;

(iv) Recipients of foster care maintenance payments or adoption assistance payments who, under Part E of title IV of the Act are considered as receiving AFDC;

(v) Individuals required to be covered under §435.120 of this chapter, that is, blind or disabled individuals who, under section 1619(b) of the Act, are considered to be receiving SSI;

(vi) Individuals who, in accordance with §§435.115 and 436.114 of this chapter are, for purposes of Medicaid eligibility, considered to be receiving AFDC. These are participants in a work supplementation program, or individuals denied AFDC because the payment would be less than $10;

(vii) Certain recipients of Veterans Administration pensions during the limited time they are, under section 310(b) of Pub. L. 96-272, considered as receiving SSI, mandatory State supplements, or AFDC;

(viii) Disabled children living at home to whom the State provides Medicaid under section 1902(e)(3) of the Act;

(ix) Individuals who become ineligible for AFDC because of the collection or increased collection of child or spousal support, but, in accordance with section 406(h) of the Act, remain eligible for Medicaid for four more months; and

(x) Individuals who become ineligible for AFDC because they are no longer
eligible for the disregard of earnings of $30 or of $30 plus one-third of the remainder, but, in accordance with section 402(a)(37) of the Act, are considered as receiving AFDC for a period of 9 to 15 months.

(3) No FFP is available in State Medicaid expenditures that could have been paid for under Medicare Part B but were not because the person was not enrolled in Part B. This limit applies to all recipients eligible for enrollment under Part B, whether individually or through an agreement under section 1843(a) of the Act. However, FFP is available in expenditures required by §§435.914 and 436.901 of this subchapter for retroactive coverage of recipients.

§ 431.630 Coordination of Medicaid with PROs.

(a) The State plan may provide for the review of Medicaid services through a contract with a PRO designated under Part 462 of this chapter. Medicaid requirements for medical and utilization review are deemed to be met for those services or providers subject to review under the contract.

(b) The State plan must provide that the contract with the PRO—

(1) Meets the requirements of §434(a) of this part;

(2) Includes a monitoring and evaluation plan by which the State ensures satisfactory performance by the PRO;

(3) Identifies the services and providers subject to PRO review;

(4) Ensures that the review activities performed by the PRO are not inconsistent with PRO review activities of Medicare services and includes a description of whether and to what extent PRO determinations will be considered conclusive for Medicaid payment purposes.

§ 431.635 Coordination of Medicaid with Special Supplemental Food Program for Women, Infants, and Children (WIC).

(a) Basis. This section implements sections 1902(a)(11)(C) and 1902(a)(53) of the Act, which provide for coordination of Medicaid with the Special Supple-
Health Care Financing Administration, HHS

Subpart N—State Programs for Licensing Nursing Home Administrators

§ 431.700 Basis and purpose.
This subpart implements sections 1903(a)(29) and 1908 of the Act which require that the State plan include a State program for licensing nursing home administrators.

§ 431.701 Definitions.
Unless otherwise indicated, the following definitions apply for purposes of this subpart:
Agency means the State agency responsible for licensing individual practitioners under the State's healing arts licensing act.
Board means an appointed State board established to carry out a State program for licensing administrators of nursing homes, in a State that does not have a healing arts licensing act or an agency as defined in this section.
Licensed means certified by a State agency or board as meeting all of the requirements for a licensed nursing home administrator specified in this subpart.
Nursing home means any institution, facility, or distinct part of a hospital that is licensed or formally recognized as meeting nursing home standards established under State law, or that is determined under § 431.704 to be included under the requirements of this subpart. The term does not include—
(a) A Christian Science sanatorium operated, or listed and certified, by the First Church of Christ, Scientist, Boston, Mass.; or
(b) A distinct part of a hospital, if the hospital meets the definition in § 440.10 or § 440.140 of this subchapter, and the distinct part is not licensed separately or formally approved as a nursing home by the State even though it is designated or certified as a skilled nursing facility.
Nursing home administrator means any person who is in charge of the general administration of a nursing home whether or not the person—
(a) Has an ownership interest in the home; or
(b) Shares his functions and duties with one or more other persons.

§ 431.702 State plan requirement.
A State plan must provide that the State has a program for licensing administrators of nursing homes that meets the requirements of §§ 431.703 through 431.713 of this subpart.

§ 431.703 Licensing requirement.
The State licensing program must provide that only nursing homes supervised by an administrator licensed in accordance with the requirements of this subpart may operate in the State.

§ 431.704 Nursing homes designated by other terms.
If a State licensing law does not use the term “nursing home,” the HCF A Administrator will determine the term or terms equivalent to “nursing home” for purposes of applying the requirements of this subpart. To obtain this determination, the Medicaid agency must submit to the Regional Medicaid Director copies of current State laws that define institutional health care facilities for licensing purposes.

§ 431.705 Licensing authority.
(a) The State licensing program must provide for licensing of nursing home administrators by—
(1) The agency designated under the healing arts act of the State; or
(2) A State licensing board.
(b) The State agency or board must perform the functions and duties specified in §§ 431.707 through 431.713 and the board must meet the membership requirements specified in § 431.706 of this subpart.

§ 431.706 Composition of licensing board.
(a) The board must be composed of persons representing professions and institutions concerned with the care and treatment of chronically ill or infirm elderly patients. However—
(1) A majority of the board members may not be representative of a single profession or category of institution; and
(2) Members not representative of institutions may not have a direct financial interest in any nursing home.
(b) For purposes of this section, nursing home administrators are considered representatives of institutions.
§ 431.707 Standards.

(a) The agency or board must develop, impose, and enforce standards that must be met by individuals in order to be licensed as a nursing home administrator.

(b) The standards must be designed to insure that nursing home administrators are—

1. Of good character;
2. Otherwise suitable; and
3. Qualified to serve because of training or experience in institutional administration.

§ 431.708 Procedures for applying standards.

The agency or board must develop and apply appropriate procedures and techniques, including examinations and investigations, for determining if a person meets the licensing standards.

§ 431.709 Issuance and revocation of license.

Except as provided in § 431.714 of this subpart, the agency or board must—

(a) Issue licenses to persons who meet the agency's or board's standards; and

(b) Revoke or suspend a license if the agency or board determines that the person holding the license substantially fails to meet the standards.

§ 431.710 Provisional licenses.

To fill a position of nursing home administrator that unexpectedly becomes vacant, the agency or board may issue one provisional license, for a single period not to exceed 6 months. The license may be issued to a person who does not meet all of the licensing requirements established under § 431.707 but who—

(a) Is of good character and otherwise suitable; and

(b) Meets any other standards established for provisional licensure by the agency or board.

§ 431.711 Compliance with standards.

The agency or board must establish and carry out procedures to insure that licensed administrators comply with the standards in this subpart when they serve as nursing home administrators.

§ 431.712 Failure to comply with standards.

The agency or board must investigate and act on all complaints it receives of violations of standards.

§ 431.713 Continuing study and investigation.

The agency or board must conduct a continuing study of nursing homes and administrators within the State to improve—

(a) Licensing standards; and

(b) The procedures and methods for enforcing the standards.

§ 431.714 Waivers.

The agency or board may waive any standards developed under § 431.707 of this subpart for any person who has served in the capacity of a nursing home administrator during all of the 3 calendar years immediately preceding the calendar year in which the State first meets the requirements in this subpart.

§ 431.715 Federal financial participation.

No FFP is available in expenditures by the licensing board for establishing and maintaining standards for the licensing of nursing home administrators.

Subpart O—[Reserved]

Subpart P—Quality Control

GENERAL PROVISIONS

SOURCE: Sections 431.800 through 431.808 appear at 55 FR 22166, May 31, 1990, unless otherwise noted.

§ 431.800 Scope of subpart.

This subpart—

(a) Establishes State plan requirements for a Medicaid eligibility quality control (MEQC) program designed to reduce erroneous expenditures by monitoring eligibility determinations and a claims processing assessment system that monitors claims processing operations;

(b) Establishes rules and procedures for disallowing Federal financial participation (FFP) in erroneous Medicaid
§ 431.810 Basis.

This subpart implements the following sections of the Act, which establish requirements for State plans and for payment of Federal financial participation (FFP) to States:

1902(a)(4) Administrative methods for proper and efficient operation of the State plan.
1903(u) Limitation of FFP for erroneous medical assistance expenditures.

§ 431.804 Definitions.

As used in this subpart—

Active case means an individual or family determined to be currently authorized as eligible for Medicaid by the agency.

 Administrative period means the period of time recognized by the MEQC program for State agencies to reflect changes in case circumstances, i.e., a change in a common program area, during which no case error based on the circumstance change would be cited. This period consists of the review month and the month prior to the review month.

Claims processing error means FFP has been claimed for a Medicaid payment that was made—

(1) For a service not authorized under the State plan;
(2) To a provider not certified for participation in the Medicaid program;
(3) For a service already paid for by Medicaid; or
(4) In an amount above the allowable reimbursement level for that service.

Eligibility error means that Medicaid coverage has been authorized or payment has been made for a recipient or family under review who—

(1) Was ineligible when authorized or when he received services; or
(2) Was eligible for Medicaid but was ineligible for certain services he received; or
(3) Had not met recipient liability requirements when authorized eligible for Medicaid; that is, he had not incurred medical expenses equal to the amount of his excess income over the State’s financial eligibility level, or he had incurred medical expenses that exceeded the amount of excess income.

Negative case action means an action that was taken to deny or otherwise dispose of a Medicaid application without a determination of eligibility (for instance, because the application was withdrawn or abandoned) or an action to deny, suspend, or terminate an individual or family.

State agency means either the State Medicaid agency or a State agency that is responsible for determining eligibility for Medicaid.

§ 431.806 State plan requirements.

(a) MEQC program. A State plan must provide for operating a Medicaid eligibility quality control program that meets the requirements of §§ 431.810 through 431.822 of this subpart.

(b) Claims processing assessment system. Except in a State that has an approved Medicaid Management Information System (MMIS) under subpart C of part 433 of this subchapter, a State plan must provide for operating a Medicaid quality control claims processing assessment system that meets the requirements of §§ 431.830 through 431.836 of this subpart.

§ 431.808 Protection of recipient rights.

Any individual performing activities under the MEQC program or the claims processing assessment system specified in this subpart must do so in a manner that is consistent with the provisions of §§ 435.902 and 436.901 of this subchapter concerning the rights of recipients.

MEDICAID ELIGIBILITY QUALITY CONTROL (MEQC) PROGRAM

SOURCE: Sections 431.810 through 431.822 appear at 55 FR 22167, May 31, 1990, unless otherwise noted.

§ 431.810 Basic elements of the Medicaid eligibility quality control (MEQC) program.

(a) General requirements. The agency must operate the MEQC program in accordance with this section and §§ 431.812 through 431.822 and other instructions established by HCFA.
§ 431.812 Review procedures.

(a) Active case reviews. (1) Except as provided in paragraph (a)(2) of this section, the agency must review all active cases selected from the State agency’s lists of cases authorized eligible for the review month, to determine if the cases were eligible for services during all or part of the month under review, and, if appropriate, whether the proper amount of recipient liability was computed.

(2) The agency is not required to conduct reviews of the following cases:

(i) Supplemental Security Income (SSI) recipient cases in States with contracts under section 1634 of the Act for determining Medicaid eligibility;

(ii) Foster care and adoption assistance cases under title IV-E of the Act found eligible for Medicaid; and

(iii) Cases under programs that are 100 percent federally funded.

(b) Negative case reviews. Except as provided in paragraph (c) of this section, the agency must review those negative cases selected from the State agency’s lists of cases that are denied, suspended, or terminated in the review month to determine if the reason for the denial, suspension, or termination was correct and if requirements for timely notice of negative action were met. A State’s negative case sample size is determined on the basis of the number of negative case actions in the universe.

(c) Alternate systems of negative case reviews—(1) Basic provision. A State may be exempt from the negative case review requirements specified in paragraphs (b) and (e)(2) of this section and in §431.814(d) upon HCFA’s approval of a plan for the use of a superior system.

(2) Submittal of plan for alternate system. An agency must submit its plan for the use of a superior system to HCFA for approval at least 60 days before the beginning of the review period in which it is to be implemented. If a plan is unchanged from a previous period, the agency is not required to resubmit it.

The agency must receive approval for a plan before it can be implemented.

(3) Requirement for alternate system. To be approved, the State’s plan must—

(i) Clearly define the purpose of the system and demonstrate how the system is superior to the current negative case review requirements.

(ii) Contain a methodology for identifying significant problem areas that could result in erroneous denials, suspensions, and terminations of applicants and recipients. Problem areas selected for review must contain at least as many applicants and recipients as were included in the negative case sample size previously required for the State.

(iii) Provide a detailed methodology describing how the extent of the problem area will be measured through sampling and review procedures, the findings expected from the review, and planned corrective actions to resolve the problem.

(iv) Include documentation supporting the use of the system methodology. Documentation must include the timeframes under which the system will be operated.

(v) Provide a superior means of monitoring denials, terminations, and suspensions than that required under paragraph (b) of this section.

(vi) Provide a statistically valid error rate that can be projected to the universe that is being studied.

(d) Reviews for erroneous payments. The agency must review all claims for services furnished during the review month and paid within 4 months of the review month to all members of each active case related in the sample to identify erroneous payments resulting from—

(1) Ineligibility for Medicaid;

(2) Ineligibility for certain Medicaid services; and

(3) Recipient understated or overstated liability.

(e) Reviews for verification of eligibility status. The agency must collect and verify all information necessary to determine the eligibility status of each
individual included in an active case selected in the sample as of the review month and whether Medicaid payments were for services which the individual was eligible to receive.

The agency must apply the administrative period described in §431.804 when considering the case circumstances and the active case under review. In order to verify eligibility information, the agency must—

(1) Examine and analyze each case record for all cases under review to establish what information is available for use in determining eligibility in the review month;

(2) Conduct field investigations including in-person recipient interviews for each case in the active case sample, and conduct in-person interviews only when the correctness of the agency action cannot be determined by review of the case record with recipients for cases in the negative case action sample (unless this is otherwise addressed in a superior system provided for in paragraph (c)(1) of this section);

(3) Verify all appropriate elements of eligibility for active cases through at least one primary source of evidence or two secondary sources of evidence as defined by HCFA by documentation or by collateral contacts as required, or both, and fully record the information on the appropriate forms;

(4) Determine the basis on which eligibility was established and the eligibility status of the active case and each case member;

(5) Collect copies of State paid claims or recipient profiles for services delivered during the review month and, if indicated, any months prior to the review month in the agency’s selected spenddown period, for all members of the active case under review;

(6) Associate dollar values with eligibility status for each active case under review; and

(7) Complete the payment, case, and review information for all individuals in the active case under review on the appropriate forms.

§431.814 Sampling plan and procedures.

(a) Plan approval. The agency must submit a basic MEQC sampling plan (or revisions to a current plan) that meets the requirements of this section to the appropriate HCFA regional office for approval at least 60 days before the beginning of the review period in which it is to be implemented. If a plan is unchanged from a previous period, the agency is not required to resubmit the entire plan. Universe estimates and sampling intervals are required 2 weeks before the first monthly sample selection for each review period. The agency must receive approval for a plan before it can be implemented.

(b) Plan requirements. The agency must have an approved sampling plan in effect for the full 6-month sampling period that includes the following:

(1) The population to be sampled;

(2) The list(s) from which the sample is selected and the following characteristics of the list(s):

   (i) Sources;

   (ii) All types of cases in the selection lists;

   (iii) Accuracy and completeness of sample lists in reference to the population(s) of interest;

   (iv) Whether or not the selection list was constructed by combining more than one list;

   (v) The form of the selection list (whether the list or part of the list is automated);

   (vi) Frequency and length of delays in updating the selection lists or their sources;

   (vii) Number of items on the lists and proportion of listed-in-error items:

   (viii) Methods of deleting unwanted items from the selection lists; and

   (ix) Structure of the selection lists.

(3) The sample size, including the minimum number of reviews to be completed and the expected number of cases to be selected. Minimum sample sizes are based on the State’s relative level of Medicaid annual expenditures for services for active cases, and on the total number of negative case actions in the universe for negative cases. When the sample is stratified, there can be no fewer than 75 cases in each stratum, except as provided in paragraph (c) of this section or as provided in an exception documented in an approved sampling plan which contains a statement accepting the precision and reliability of the reduced sample.
§ 431.814

(4) The sample selection procedure. Systematic random sampling is recommended. Alternative procedures must provide a representative sample, conform to principles of probability sampling, and yield estimates with the same or better precision than achieved in systematic random sampling.

(5) Procedures used to identify amounts paid for services received in the review month.

(6) Specification as to whether the agency chooses to—
   (i) Use billed amounts to offset recipient liability toward cost of care (No indication will be interpreted to mean that the agency will use paid claims); and
   (ii) Use denied claims to offset recipient liability toward cost of care in the payment review. (No indication will be interpreted to mean denied claims will not be used.)

(7) Indication of whether the agency opts to drop or complete cases selected more than once in a sample period. (No indication will be interpreted to mean that the agency will complete cases selected more than once.)

(c) Eligibility universe—active cases. The MEQC universe for active cases must be divided into two strata, the Aid to Families with Dependent Children (AFDC) stratum and the Medical Assistance Only (MAO) stratum.

   (1) All States must use the AFDC quality control sample for the AFDC stratum.
   (2) States must include in the MAO stratum all cases certified as eligible for Medicaid that are not in the AFDC stratum, excluding individuals specified in paragraph (c)(4) of this section.
   (3) States that do not have an agreement with the Social Security Administration under section 1634 of the Act and do not have more restrictive eligibility criteria under section 1902(f) of the Act but require a separate Medicaid application for recipients of SSI and determine Medicaid eligibility using SSI criteria must divide the MAO stratum into two substrata: MAO cases and SSI cash cases for the first review period beginning after July 1, 1990 and for review periods thereafter. The SSI substratum sample size must be 75 cases or one-half of the total MAO sample, whichever is smaller. The non-SSI MAO substratum sample will be the remainder of the MAO stratum cases.

   States may be exempt from this requirement when implementing an approved sampling option that does not accommodate this stratification method.

   (4) States must exclude from the MEQC universe SSI beneficiaries whose eligibility determinations were made exclusively by the Social Security Administration under an agreement under section 1634 of the Act, individuals in foster care or receiving adoption assistance whose eligibility is determined under title IV-E of the Act, and individuals receiving Medicaid under programs that are 100 percent federally funded.

(d) Eligibility universe—negative cases. Unless the agency has an approved superior system under §431.812(c) that provides otherwise, the universe for negative Medicaid eligibility cases must consist of all denied applications, suspensions, and terminations occurring during the review month except transfers between counties without any break in eligibility, cases in which eligibility is exclusively determined by SSA under a section 1634 contract, cases determined eligible for foster care and adoption assistance under title IV-E of the Act, and cases under programs that are 100 percent federally funded.

(e) Sampling procedures. The agency must document all sampling procedures used by the State agency, including 98 percent accuracy of program identifier codes used in the sampling frame to separate listed-in-error cases from those in the population of interest, must make them available for review by HCFA, and must be able to demonstrate the integrity of its sampling procedures in accordance with this section.

(f) Sampling periods. The agency must use 6-month sampling periods, from April through September and from October through March.

(g) Statistical samples. The agency must select statistically valid samples of both active and negative case actions.

(h) Sample selection lists. The agency must submit to HCFA monthly a list of
cases selected in the sample to be reviewed, after the State's sample selection and before commencing MEQC reviews on the cases in the sample.

(i) Universe estimates and sampling intervals. The agency must submit detailed universe estimates and sampling intervals to HCFA for approval at least 2 weeks before the first sample selection of the review period if the estimates differ from the previous period. The sampling intervals must be used continuously throughout the sampling period unless otherwise specified in an approved sampling plan. Final universe counts based on the actual sampling universe must be determined and reported to HCFA for each stratum/sub-stratum designated in the sampling plan.

The agency also must submit universe counts for cases eligible for foster care and adoption assistance under title IV-E of the Act, and, for States with an agreement under section 1634 of the Act, for cases found eligible by the Social Security Administration.

(j) Sample size and methodology options. The agency may select a sample size in accordance with the minimum established under paragraph (b)(3) of this section or use one of the methodologies specified in paragraph (j)(1) or (2) of this section.

(1) Increase in size. The agency may, at its option, increase its sample size for a sampling period above the federally prescribed minimum sample size provided for under paragraph (b)(3) of this section, and receive FFP for any increased administrative costs the agency incurs by exercising this option.

(2) Retrospective sampling. The agency may, at its option, implement retrospective sampling in which cases are stratified by dollar value of claims paid. If the agency selects retrospective sampling, it must:

(i) Draw an initial case sample size each month that is no less than 5 times the required sample size. The sample will be selected from the universe of cases that were certified eligible in the fourth month prior to the month of case selection;

(ii) Identify claims paid for services furnished to all individuals during the review month (and, if indicated, any months prior to the review month in the agency's selected spenddown period) for these cases;

(iii) Stratify the cases by dollar value of the claims into three strata;

and

(iv) Select a second statistically valid sample within each group subject to the sample size requirements specified in paragraph (b)(3) or (j)(1) of this section.

§431.816 Case review completion deadlines and submittal of reports.

(a) The agency must complete case reviews and submit reports of findings to HCFA as specified in paragraph (b) of this section in the form and at the time specified by HCFA.

(b) In addition to the reporting requirements specified in §431.814 relating to sampling, the agency must complete case reviews and submit reports of findings to HCFA in accordance with paragraphs (b)(1) through (6) of this section for review periods beginning after July 1, 1990. The agency must not combine or otherwise integrate case findings from the MAO and AFDC strata to meet the case percentage deadlines as specified in paragraphs (b)(1) through (6) of this section.

(1) Active case eligibility reviews—MAO stratum. (i) The agency must complete case eligibility reviews and report the findings electronically through the system prescribed by HCFA for 90 percent of all active MAO cases within 105 days of the end of the review month for which those cases were reviewed, within 125 days for 95 percent of all active MAO cases, and within 150 days for 100 percent of all MAO active cases.

(ii) The agency must submit a report on cases selected for the review month.

(2) Active case eligibility reviews—AFDC stratum. (i) The agency must complete case eligibility reviews for AFDC ineligible and overpaid error cases caused by ineligible individuals and report the findings electronically through the system prescribed by HCFA within 105 days of the end of the review month for which those cases were reviewed, within 125 days for 95 percent of all active MAO cases, and within 150 days for 100 percent of all MAO active cases.

(ii) The agency must submit a report on cases selected for the review month.
§ 431.818 Access to records: MEQC program.

(a) The agency, upon written request, must mail to the HHS staff all records, including complete local agency eligibility case files or legible copies and all other documents pertaining to its MEQC reviews to which the State has access, including information available under part 435, subpart I, of this chapter.

(b) The agency must mail requested records within 10 working days of receipt of a request, unless the State has an alternate method of submitting these records that is approved by HCFA or has received, on an as-needed basis, approval from HCFA to extend this timeframe by 3 additional working days to allow for exceptional circumstances.

§ 431.820 Corrective action under the MEQC program.

The agency must—

(a) Take action to correct any active or negative case action errors found in the sample cases;

(b) Take administrative action to prevent or reduce the incidence of those errors; and

(c) By September 15 each year, submit to HCFA a report on its error rate analysis and a corrective action plan based on that analysis. The agency must submit revisions to the plan within 60 days of identification of additional error-prone areas, other significant changes in the error rate (that is, changes that the State experiences that increase or decrease its error rate and necessitate immediate corrective action or discontinuance of corrective actions that effectively control the cause of the error rate change), or changes in planned corrective action.

§ 431.822 Resolution of differences in State and Federal case eligibility or payment findings.

(a) When a difference exists between State and Federal case eligibility or payment findings, the Regional Office will notify the agency by a difference letter.

§ 431.818 150 days of the end of the review month for which those cases were reviewed for 100 percent of the total reviews.

(ii) The agency must report findings electronically through the system prescribed by HCFA for 100 percent of the State agency-reported eligible individuals within 30 days after the final timeframe required by the AFDC program as specified in program regulations at 45 CFR 205.40(b)(2)(ii).

(3) Negative case eligibility reviews. The agency must submit a monthly progress report on negative case reviews completed during the month unless the agency has an approved superior system in effect. The agency must submit a report on its findings by June 30 of each year for the previous April-September sampling period and by December 31, for the October-March sampling period.

(4) Payment reviews. (i) The agency must submit payment review findings electronically through the system prescribed by HCFA.

(ii) The agency must complete payment review findings for 100 percent of the active case reviews in its sample and report the findings within 60 days after the first day of the month in which the claims collection process begins. The agency must wait 5 months after the end of each review month before associating the amount of claims paid for each case for services furnished during the review month unless retrospective sampling is elected.

(iii) The agency must make any necessary corrections to claims payments during the month the claim is paid and the following month. HCFA will take necessary action to reject any State adjustment adversely affecting the error rate, for example, by not paying claims on error cases.

(5) Summary of reviews and findings. The agency must submit summary reports of the findings for all active cases in the 6-month sample by July 31 of each year for the previous April-September sampling period and by January 31 for the October-March sampling period. These summary reports must include findings changed in the Federal re-review process.

(6) Other data and reports. The agency must report other requested data and reports in a manner prescribed by HCFA.
§ 431.836 Corrective action under the MQC claims processing assessment system.

The agency must—
(a) Take action to correct those errors identified through the claims processing assessment system review and, if cost effective, to recover those funds erroneously spent;
(b) Take administrative action to prevent and reduce the incidence of those errors; and
(c) By August 31 of each year, submit to HCFA a report of its error analysis and a corrective action plan on the reviews conducted since the cut-off-date of the previous corrective action plan.

§ 431.832 Reporting requirements for claims processing assessment systems.

(a) The agency must submit reports and data specified in paragraph (b) of this section to HCFA, in the form and at the time specified by HCFA.
(b) Except when HCFA authorizes less stringent reporting, States must submit:
(1) A monthly report on claims processing reviews sampled and or claims processing reviews completed during the month;
(2) A summary report on findings for all reviews in the 6-month sample to be submitted by the end of the 3rd month following the scheduled completion of reviews for that 6-month period; and
(3) Other data and reports as required by HCFA.

§ 431.834 Access to records: Claims processing assessment systems.

The agency, upon written request, must provide HHS staff with access to all records pertaining to its MQC claims processing assessment system reviews to which the State has access, including information available under part 435, subpart J, of this chapter.

§ 431.830 Basic elements of the Medicaid quality control (MQC) claims processing assessment system.

An agency must—
(a) Operate the MQC claims processing assessment system in accordance with the policies, sampling methodology, review procedures, reporting forms, requirements, and other instructions established by HCFA.
(b) Identify deficiencies in the claims processing operations.
(c) Measure cost of deficiencies;
(d) Provide data to determine appropriate corrective action;
(e) Provide an assessment of the State's claims processing or that of its fiscal agent;
(f) Provide for a claim-by-claim review where justifiable by data; and
(g) Produce an audit trail that can be reviewed by HCFA or an outside auditor.

(a) Purpose and applicability—

(1) Purpose. This section establishes rules and procedures for disallowing Federal financial participation (FFP) in erroneous medical assistance payments due to eligibility and beneficiary liability errors, as detected through the Medicaid eligibility quality control (MEQC) program required under §431.806 in effect on and after July 1, 1990.

(2) Applicability. This section applies to all States except Puerto Rico, Guam, the Virgin Islands, the Northern Marian Islands, and American Samoa beginning July 1, 1990.

(b) Definitions. For purposes of this section—

Administrator means the Administrator, Health Care Financing Administration or his or her designee.

Annual assessment period means the 12-month period October 1 through September 30 and includes two 6-month sample periods (October-March and April-September).

Beneficiary liability means—

(1) The amount of excess income that must be offset with incurred medical expenses to gain eligibility; or

(2) The amount of payment a recipient must make toward the cost of services.

Erroneous payments means the Medicaid payment that was made for an individual or family under review who—

(1) Was ineligible for the review month or, in full month coverage is not provided, at the time services were received;

(2) Was ineligible to receive a service provided during the review month; or

(3) Had not properly met beneficiary liability prior to receiving Medicaid services.

National mean error rate means the payment weighted average of the eligibility payment error rates for all States.

National standard means a 3-percent eligibility payment error rate.
foster care and adoption assistance under title IV-E of the Act.

(4) The amount of erroneous payments is determined as follows:

(i) For ineligible cases resulting from excess resources, the amount of error is the lesser of—

(A) The amount of the payment made on behalf of the family or individual for the review month; or

(B) The difference between the actual amount of countable resources of the family or individual for the review month and the State's applicable resources standard.

(ii) For ineligible cases resulting from other than excess resources, the amount of error is the total amount of medical assistance payments made for the individual or family under review for the review month.

(iii) For erroneous payments resulting from failure to properly meet beneficiary liability, the amount of error is the lesser of—

(A) The amount of payments made on behalf of the family or individual for the review month; or

(B) The difference between the correct amount of beneficiary liability and the amount of beneficiary liability met by the individual or family for the review month.

(iv) The amount of payments made for services provided during the review month for which the individual or family was not eligible.

(5) In determining the amount of erroneous payments, errors caused by technical errors are not included.

(6) If a State fails to cooperate in completing a valid MEQC sample or individual reviews in a timely and appropriate fashion as required, HCFA will establish the State's payment error rate based on either—

(i) A special sample or audit;

(ii) The Federal subsample; or

(iii) Other arrangements as the Administrator may prescribe.

(7) When it is necessary for HCFA to exercise the authority in paragraph (c)(6) of this section, the amount that would otherwise be payable to the State under title XIX of the Act is reduced by the full costs incurred by HCFA in making these determinations.

HCFA may make these determinations either directly or under contractual or other arrangements.

(d) Computation of anticipated error rate. (1) Before the beginning of each quarter, HCFA will project the anticipated medical assistance payment error rate for each State for that quarter. The anticipated error rate is the lower of the weighted average error rate of the two most recent 6-month review periods or the error rate of the most recent 6-month review period. In either case, cases in the review periods must have been completed by the State and HCFA. If a State fails to provide HCFA with information needed to project anticipated excess erroneous expenditures, HCFA will assign the State an error rate as prescribed in paragraph (c)(6) of this section.

(2) If the State believes that the anticipated error rate established in accordance with paragraph (d)(1) of this section is based on erroneous data, the State may request copies of data that HCFA used to compute its anticipated error rate within 7 days of receiving notification of its projected error rate. The State has up to 40 days before the quarter begins to present the evidence.

(3) The evidence is subject to the following conditions:

(i) The State must inform HCFA of its intent to submit evidence at least 70 days prior to the beginning of the quarter.

(ii) The State may request copies of data that HCFA used to compute its anticipated error rate within 7 days of receiving notification of its projected error rate.

(iii) The State has up to 40 days before the quarter begins to present the evidence.

(iv) The evidence is restricted to documentation of suspected HCFA data entry errors, processing errors, and resolutions of Federal subsample difference cases subsequent to calculation of the error rate projection as contained in the original notice to the State.

(v) The State may not submit other evidence, such as that consisting of revisions to State errors as a result of changes to the original State review findings submitted to HCFA.
(vi) The State may not submit evidence challenging the error rate computational methodology.

(3) Based on the anticipated error rate established in paragraph (d)(1) or (d)(2) of this section, HCFA reduces its estimate of the State's requirements for FFP for medical assistance for the quarter by the percentage by which the anticipated payment error rate exceeds the 3-percent national standard. This reduction is applied against HCFA's total estimate of FFP for medical assistance expenditures (less payments to Supplemental Security Income beneficiaries in 1634 contract States and payments to children found eligible for foster care and adoption assistance under title IV-E of the Act) prior to any other required reductions. The reduction is noted on the State's grant award for the quarter and does not constitute a disallowance, and, therefore, is not appealable.

(4) After the end of each quarter, an adjustment to the reduction will be made based on the State's actual expenditures.

(5) After the actual payment error rate has been established for each annual assessment period, HCFA will compute the actual amount of the disallowance and adjust the FFP payable to each State based on the difference between the amounts previously withheld for each of the quarters during the appropriate assessment period and the amount that should have been withheld based on the State's actual final error rate. If HCFA determines that the amount withheld for the period exceeds the amount of the actual disallowance, the excess amount withheld will be returned to the States through the normal grant awards process within 30 days of the date the actual disallowance is calculated.

(6) HCFA will compute the amount to be withheld or disallowed as follows:

(i) Subtract the 3-percent national standard from the State's anticipated or actual payment error rate percentage.

(ii) If the difference is greater than zero, the Federal medical assistance funds for the period, excluding payments for those individuals whose eligibility for Medicaid was determined exclusively by the Social Security Administration under a section 1634 agreement and children found eligible for foster care and adoption assistance under title IV-E of the Act, are multiplied by that percentage. This product is the amount of the disallowance or withholding.

(7) A State's payment error rate for an annual assessment period is the weighted average of the payment error rates in the two 6-month review periods comprising the annual assessment period.

(8) The weights are established as the percent of the total annual payments, excluding payments for those individuals whose eligibility for Medicaid was determined exclusively by the Social Security Administration under a section 1634 agreement and children found eligible for foster care and adoption assistance under title IV-E of the Act, that occur in each of the 6-month periods.

(e) Notice to States and showing of good faith.

(1) When the actual payment error rate data are finalized for each annual assessment period ending after July 1, 1990, HCFA will establish each State's error rate and the amount of any disallowance. States that have error rates above the national standard will be notified by letter of their error rates and the amount of the disallowance.

(i) The State has 65 days from the date of receipt of this notification to show that this disallowance should not be made because it failed to meet the national standard despite a good faith effort to do so.

(ii) If HCFA is satisfied that the State did not meet the national standard despite a good faith effort, HCFA may reduce the funds being disallowed in whole or in part as it finds appropriate under the circumstances shown by the State.

(iii) A finding that a State did not meet the national standard despite a good faith effort was made rests entirely with the State.

(2) Some examples of circumstances under which HCFA may find that a State did not meet the national standard despite a good faith effort are—
Health Care Financing Administration, HHS § 431.865

(i) Disasters such as fire, flood, or civil disorders that—
   (A) Require the diversion of significant personnel normally assigned to Medicaid eligibility administration; or
   (B) Destroyed or delayed access to significant records needed to make or maintain accurate eligibility determinations;

(ii) Strikes of State staff or other government or private personnel necessary to the determination of eligibility or processing of case changes;

(iii) Sudden and unanticipated workload changes that result from changes in Federal law and regulation, or rapid, unpredictable caseload growth in excess of, for example, 15 percent for a 6-month period;

(iv) State actions resulting from incorrect written policy interpretations to the State by a Federal official reasonably assumed to be in a position to provide that interpretation; and

(v) The State has taken the action it believed was needed to meet the national standard, but the national standard was not met. HCFA will consider request for a waiver under this criterion only if a State has achieved an error rate for the sample period that (after reducing the error rate by taking into account the cases determined by HCFA to be in error as a result of conditions listed in paragraphs (e)(2) (i) through (iv) of this section) is less than its error rate for the preceding sample year and does not exceed the national mean error rate for the sample period under review (unless that national mean error rate is at or below the 3-percent national standard). If the agency has met this error reduction requirement or had error rates of 3 percent or below for the prior two review periods, and its error rate for the review period under consideration is less than one-third above the national standard, HCFA will evaluate a request for a good faith waiver based on the following factors:

   (A) The State has fully met the performance standards in the operation of a quality control system in accordance with Federal regulations and HCFA guidelines (e.g., adherence to Federal case completion timeliness requirements and verification standards).

(B) The State has achieved substantial performance in the formulation of error reduction initiatives based on the following processes:

   (1) Performance of an accurate and thorough statistical and program analysis for error reduction which utilized quality control and other data:

   (2) The translation of such analysis into specific and appropriate error reduction practices for major error elements; and

   (3) The use of monitoring systems to verify that the error reduction initiatives were implemented at the local office level.

(C) The State has achieved substantial performance in the operation of the following systems supported by evidence of the timely utilization of their outputs in the determination of case eligibility:

   (1) The operation of the Income and Eligibility Verification System in accordance with the requirements of parts 431 and 435 of this chapter, and

   (2) The operation of systems that interface with Social Security data and, where State laws do not restrict agency access, records from agencies responsible for motor vehicles, vital statistics, and State or local income and property taxes (where these taxes exist).

(D) The State has achieved substantial performance in the use of the following accountability mechanisms to ensure that agency staff adhere to error reduction initiatives. The following are minimum requirements:

   (1) Accuracy of eligibility and liability determinations and timely processing of case actions are used as quantitative measures of employee performance and reflected in performance standards and appraisal forms:

   (2) Selective second-party case reviews are conducted. The second-party review results are periodically reported to higher level management, as well as supervisors and workers and are used in performance standards and appraisal forms; and

   (3) Regular operational reviews of local offices are performed by the State to evaluate the offices’ effectiveness in meeting error reduction goals with
periodic monitoring to ensure that review recommendations have been implemented.

(vi) A State that meets the performance standards specified in paragraphs (e)(2)(v) (A) through (D) of this section will be considered for a full or partial waiver of its disallowance amount. The State must submit only specific documentation that verifies that the necessary actions were accomplished. For example, a State could submit worker performance standards reflecting timeliness and case accuracy as quantitative measures of performance.

(3) The failure of a State to act upon necessary legislative changes or to obtain budget authorization for needed resources is not a basis for finding that a State failed to meet the national standard despite a good faith effort.

(f) Disallowance subject to appeal. (1) If a State does not agree with a disallowance imposed under paragraph (e) of this section, it may appeal to the Departmental Appeals Board within 30 days from the date of the final disallowance notice from HCFA. The regular procedures for an appeal of a disallowance will apply, including review by the Appeals Board under 45 CFR part 16.

(2) This appeal provision, as it applies to MEQC disallowances, is not applicable to the Administrator’s decision on a State’s waiver request provided for under paragraph (e) of this section.


PART 432—STATE PERSONNEL ADMINISTRATION

Subpart A—General Provisions

§ 432.1 Basis and purpose.
This part prescribes regulations to implement section 1902(a)(4) of the Act, which relates to a merit system of State personnel administration and training and use of subprofessional staff and volunteers in State Medicaid programs, and section 1903(a), rates of FFP for Medicaid staffing and training costs. It also prescribes regulations, based on the general administrative authority in section 1902(a)(4), for State training programs for all staff.

§ 432.2 Definitions.
As used in this part—
Community service aides means subprofessional staff, employed in a variety of positions, whose duties are an integral part of the agency’s responsibility for planning, administration, and for delivery of health services.
Directly supporting staff means secretarial, stenographic, and copying personnel and file and records clerks who provide clerical services that directly support the responsibilities of skilled professional medical personnel, who are directly supervised by the skilled professional medical personnel, and who are in an employer-employee relationship with the Medicaid agency.
Fringe benefits means the employer’s share of premiums for workmen’s compensation, employees’ retirement, unemployment compensation, health insurance, and similar expenses.
Full-time training means training that requires employees to be relieved of all responsibility for performance of current agency work to participate in a training program.
Part-time training means training that allows employees to continue full-time in their agency jobs or requires only
partial reduction of work activities to participate in the training activity.

Skilled professional medical personnel means physicians, dentists, nurses, and other specialized personnel who have professional education and training in the field of medical care or appropriate medical practice and who are in an employer-employee relationship with the Medicaid agency. It does not include other nonmedical health professionals such as public administrators, medical analysts, lobbyists, senior managers or administrators of public assistance programs or the Medicaid program.

Staff of other public agencies means skilled professional medical personnel and directly supporting staff who are employed in State or local agencies other than the Medicaid agency who perform duties that directly relate to the administration of the Medicaid program.

Subprofessional staff means persons performing tasks that demand little or no formal education; a high school diploma; or less than 4 years of college.

Supporting staff means secretarial, stenographic, clerical, and other subprofessional staff whose activities are directly necessary to the carrying out of the functions which are the responsibility of skilled professional medical personnel, as defined in this section.

Training program means a program of educational activities based on the agency’s training needs and aimed at insuring that agency staff acquire the knowledge and skills necessary to perform their jobs.

Volunteer means a person who contributes personal service to the community through the agency’s program but is not a replacement or substitute for paid staff.

(a) State plan requirement. A State plan must provide that the requirements of paragraphs (c) through (h) of this section are met.

(b) Terms. In this section, “standards” refer to those specified in paragraph (c) of this section.

(c) Methods of personnel administration. Methods of personnel administration must be established and maintained, in the Medicaid agency and in local agencies administering the program, in conformity with:

(1) [Reserved]

(2) 5 CFR part 900, subpart F, Administration of the Standards for Merit System of Personnel Administration.

(d) Compliance of local jurisdictions. The Medicaid agency must have in effect methods to assure compliance with the standards by local jurisdictions included in the plan.

(e) Review and adequacy of State laws, regulations, and policies. The agency must—

(1) Assure that the U.S. Civil Service Commission has determined the adequacy of current State laws, regulations, and policy statements that effect methods of personnel administration in conformity with the standards, and

(2) Submit any changes in them to the Commission for review.

(f) Statements of acceptance by local agencies. If the Medicaid agency changes from a State-administered to a State-supervised, locally administered program, it must obtain statements of acceptance of the standards from the local agencies.

(g) Affirmative action plan. The Medicaid agency must have in effect an affirmative action plan for equal employment opportunity, that includes specific action steps and timetables to assure that opportunity, and meets all other requirements of 45 CFR 70.4.

(h) Submittal of requested materials. The Medicaid agency must submit to HHS, upon request, copies of the affirmative action plan and of the State and local materials that assure compliance with the standards.

§ 432.10 Standards of personnel administration.

(a) State plan requirement. A State plan must provide that the requirements of paragraphs (c) through (h) of this section are met.

(b) Terms. In this section, “standards” refer to those specified in paragraph (c) of this section.

(c) Methods of personnel administration. Methods of personnel administration must be established and maintained, in the Medicaid agency and in local agencies administering the program, in conformity with:

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(1) Assure that the U.S. Civil Service Commission has determined the adequacy of current State laws, regulations, and policy statements that effect methods of personnel administration in conformity with the standards, and

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(1) Assure that the U.S. Civil Service Commission has determined the adequacy of current State laws, regulations, and policy statements that effect methods of personnel administration in conformity with the standards, and

(2) Submit any changes in them to the Commission for review.

(f) Statements of acceptance by local agencies. If the Medicaid agency changes from a State-administered to a State-supervised, locally administered program, it must obtain statements of acceptance of the standards from the local agencies.

(g) Affirmative action plan. The Medicaid agency must have in effect an affirmative action plan for equal employment opportunity, that includes specific action steps and timetables to assure that opportunity, and meets all other requirements of 45 CFR 70.4.

(h) Submittal of requested materials. The Medicaid agency must submit to HHS, upon request, copies of the affirmative action plan and of the State and local materials that assure compliance with the standards.

§ 432.30 Training programs: General requirements.

(a) A State plan must provide for a program of training for Medicaid agency personnel. (See also §§ 432.31 and 432.32 for training programs for subprofessional staff and for volunteers.)

(b) The program must—

(1) Include initial inservice training for newly appointed staff, and continuing training opportunities to improve the operation of the program;

(2) Be related to job duties performed or to be performed by the persons trained; and

(3) Be consistent with the program objectives of the agency.

§ 432.31 Training and use of subprofessional staff.

(a) State plan requirement. A State plan must provide for the training and effective use of subprofessional staff as community service aides, in accordance with the requirements of this section.

(b) Recruitment and selection. The Medicaid agency must have methods of recruitment and selection that afford opportunity for full-time or part-time employment of persons of low income, including:

(1) Young, middle-aged, and older persons;

(2) Physically and mentally disabled; and

(3) Recipients.

(c) Merit system. Subprofessional positions must be subject to merit system requirements except where special exemption is approved on the basis of a State alternative plan for employment of disadvantaged persons.

(d) Staffing plan. The agency staffing plan must include the kinds of jobs that subprofessional staff can perform.

(e) Career service. The agency must have a career service program that allows persons:

(1) To enter employment at the subprofessional level; and

(2) To progress to positions of increasing responsibility and reward:

(i) In accordance with their abilities; and

(ii) Through work experience and preservice and in-service training.

(f) Training, supervision and supportive services. The agency must have an organized training program, supervision, and supportive services for subprofessional staff.

(g) Progressive expansion. The agency must provide for annual increase in the number of subprofessional staff until:

(1) An appropriate ratio of subprofessional and professional staff has been achieved; and

(2) There is maximum use of subprofessional staff as community aides in the operation of the program.

§ 432.32 Training and use of volunteers.

(a) State plan requirement. A State plan must provide for the training and use of non-paid or partially paid volunteers in accordance with the requirements of this section.

(b) Functions of volunteers. The Medicaid agency must make use of volunteers in:

(1) Providing services to applicants and recipients; and

(2) Assisting any advisory committees established by the agency.

As used in this paragraph, ‘partially paid volunteers’ means volunteers who are reimbursed only for actual expenses incurred in giving service, without regard to the value of the service or the time required to provide it.

(c) Staffing. The agency must designate a position whose incumbent is responsible for:

(1) The development, organization, and administration of the volunteer program; and

(2) Coordination of the program with related functions.

(d) Recruitment, selection, training, and supervision. The agency must have:

(1) Methods of recruitment and selection that assure participation of volunteers of all income levels, in planning capacities and service provision; and

(2) A program of organized training and supervision of volunteers.

(e) Reimbursement of expenses. The agency must—

(1) Reimburse volunteers for actual expenses incurred in providing services; and
(2) Assure that no volunteer is deprived of the opportunity to serve because of the expenses involved.

(f) Progressive expansion. The agency must provide for annual increase in the number of volunteers used until the volunteer program is adequate for the achievement of the agency’s service goals.

Subpart C—Staffing and Training Expenditures

§ 432.45 Applicability of provisions in subpart.

The rates of FFP specified in this subpart do not apply to State personnel who conduct survey activities and certify facilities for participation in Medicaid, as provided for under section 1902(a)(33)(B) of the Act.


§ 432.50 FFP: Staffing and training costs.

(a) Availability of FFP. FFP is available in expenditures for salary or other compensation, fringe benefits, travel, per diem, and training, at rates determined on the basis of the individual’s position, as specified in paragraph (b) of this section.

(b) Rates of FFP. (1) For skilled professional medical personnel and directly supporting staff of the Medicaid agency or of other public agencies (as defined in § 432.2), the rate is 75 percent.

(2) For personnel engaged directly in the operation of mechanized claims processing and information retrieval systems, the rate is 75 percent.

(3) For personnel engaged in the design, development, or installation of mechanized claims processing and information retrieval systems, the rate is 50 percent for training and 90 percent for all other costs specified in paragraph (a) of this section.

(4) [Reserved]

(5) For personnel administering family planning services and supplies, the rate is 90 percent.

(6) For all other staff of the Medicaid agency or other public agencies providing services to the Medicaid agency, and for training and other expenses of volunteers, the rate is 50 percent.

(c) Application of rates. (1) FFP is prorated for staff time that is split among functions reimbursed at different rates.

(2) Rates of FFP in excess of 50 percent apply only to those portions of the individual’s working time that are spent carrying out duties in the specified areas for which the higher rate is authorized.

(3) The allocation of personnel and staff costs must be based on either the actual percentages of time spent carrying out duties in the specified areas, or another methodology approved by HCFA.

(d) Other limitations for FFP rate for skilled professional medical personnel and directly supporting staff—(1) Medicaid agency personnel and staff. The rate of 75 percent FFP is available for skilled professional medical personnel and directly supporting staff of the Medicaid agency if the following criteria, as applicable, are met:

(i) The expenditures are for activities that are directly related to the administration of the Medicaid program, and as such do not include expenditures for medical assistance;

(ii) The skilled professional medical personnel have professional education and training in the field of medical care or appropriate medical practice. “Professional education and training” means the completion of a 2-year or longer program leading to an academic degree or certificate in a medically related profession. This is demonstrated by possession of a medical license, certificate, or other document issued by a recognized National or State medical licensure or certifying organization or a degree in a medical field issued by a college or university certified by a professional medical organization. Experience in the administration, direction, or implementation of the Medicaid program is not considered the equivalent of professional training in a field of medical care.

(iii) The skilled professional medical personnel are in positions that have duties and responsibilities that require those professional medical knowledge and skills.

(iv) A State-documented employer-employee relationship exists between the Medicaid agency and the skilled
§ 432.55 Reporting training and administrative costs.

(a) Scope. This section identifies activities and costs to be reported as training or administrative costs on quarterly estimate and expenditure reports to HCFA.

(b) Activities and costs to be reported on training expenditures. (1) For full-time training (with no assigned agency duties): Salaries, fringe benefits, dependency allowances, travel, tuition, books, and educational supplies.

(2) For part-time training: Travel, per diem, tuition, books and educational supplies.

(3) For State and local Medicaid agency staff development personnel (including supporting staff) assigned full-time training functions: Salaries, fringe benefits, travel, and per diem.

Costs for staff spending less than full time on training for the Medicaid program must be allocated between training and administration in accordance with §433.34 of this subchapter.

(4) For experts engaged to develop or conduct special programs: Salary, fringe benefits, travel, and per diem.

(5) For agency training activities directly related to the program: Use of space, postage, teaching supplies, and purchase or development of teaching materials and equipment, for example, books and audiovisual aids.

(6) For field instruction in Medicaid: Instructors’ salaries and fringe benefits, rental of space, travel, clerical assistance, teaching materials and equipment such as books and audiovisual aids.

(c) Activities and costs not to be reported as training expenditures. The following activities are to be reported as administrative costs:

(1) Salaries of supervisors (day-to-day supervision of staff is not a training activity); and

(2) Cost of employing students on a temporary basis, for instance, during summer vacation.


PART 433—STATE FISCAL ADMINISTRATION

Sec. 433.1 Purpose.

Subpart A—Federal Matching and General Administration Provisions

433.8 [Reserved]

433.10 Rates of FFP for program services.

433.15 Rates of FFP for administration.

433.32 Fiscal policies and accountability.

433.34 Cost allocation.

433.35 Equipment—Federal financial participation.

433.36 Liens and recoveries.

433.37 Reporting provider payments to Internal Revenue Service.

433.38 Interest charge on disallowed claims for FFP.

433.40 Treatment of uncashed or cancelled (voided) Medicaid checks.

Subpart B—General Administrative Requirements State Financial Participation

433.50 Basis, scope, and applicability.
§ 433.1 Purpose.

This part specifies the rates of FFP for services and administration, and prescribes requirements, prohibitions, and FFP conditions relating to State fiscal activities.
§ 433.10 Rates of FFP for program services.

(a) Basis. Sections 1903(a)(1), 1903(g), and 1905(b) provide for payments to States, on the basis of a Federal medical assistance percentage, for part of their expenditures for services under an approved State plan.

(b) Federal medical assistance percentage (FMAP) — Computations. The FMAP is determined by the formula described in section 1905(b) of the Act. Under the formula, if a State’s per capita income is equal to the national average per capita income, the Federal share is 55 percent. If a State’s per capita income exceeds the national average, the Federal share is lower, with a statutory minimum of 50 percent. If a State’s per capita income is lower than the national average, the Federal share is increased, with a statutory maximum of 83 percent. The formula used in determining the State and Federal share is as follows:

State Share = \[ \frac{\text{State per capita income}}{\text{National per capita income}} \] \times 45 \text{ percent}

Federal share = 100 percent minus the State share (with a minimum of 50 percent and a maximum of 83 percent).

The formula provides for squaring both the State and national average per capita incomes; this procedure magnifies any difference between the State’s income and the national average. Consequently, Federal matching to lower income States is increased, and Federal matching to higher income States is decreased, within the statutory 50-83 percent limits. The FMAP for Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa is set by statute at 50 percent and is subject to dollar limitations specified in section 1108 of the Act.

(c) Special provisions. (1) Under section 1903(a)(5) of the Act, the Federal share of State expenditures for family planning services is 90 percent.

(2) Under section 1903(b), the Federal share of State expenditures for services provided through Indian Health Service facilities is 100 percent.

(3) Under section 1903(g), the FMAP is reduced if the State does not have an effective program to control use of institutional services.


§ 433.15 Rates of FFP for administration.

(a) Basis. Section 1903(a) (2) through (5) and (7) of the Act provide for payments to States, on the basis of specified percentages, for part of their expenditures for administration of an approved State plan.

(b) Activities and rates. (1) [Reserved]

(2) Administration of family planning services: 90 percent. (Section 1903(a)(5); 42 CFR 432.50(b)(5).)

(3) Design, development, or installation of mechanized claims processing and information retrieval systems: 90 percent. (Section 1903(a)(3)(A)(i); 42 CFR part 433, subpart C, and §432.50(b)(3).)

(4) Operation of mechanized claims processing and information retrieval systems: 75 percent. (Section 1903(a)(3)(B); 42 CFR part 433, subpart C and §432.50(b)(2).)

(5) Compensation and training of skilled professional medical personnel and staff directly supporting those personnel if the criteria specified in §432.50(c) and (d) are met: 75 percent. (Section 1903(a)(3)(B); 42 CFR part 433, subpart C and §432.50(b)(2).)

(6)(i) Funds expended for the performance of medical and utilization review by a PRO under a contract entered into under section 1902(d) of the Act: 75 percent (section 1903(a)(3)(C) of the Act).

(6)(ii) If a State contracts for medical and utilization review with any individual or organization not designated under Part B of Title XI of the Act, funds expended for such review will be reimbursed as provided in paragraph (b)(7) of this section.

(7) All other activities the Secretary finds necessary for proper and efficient administration of the State plan: 50 percent. (Section 1903(a)(7).) (See also §455.300 of this subchapter for FFP at
90 percent for State Medicaid fraud control units under section 1903(a)(6).

(8) Nurse aide training and competency evaluation programs and competency evaluation programs described in 1919(e)(1) of the Act: for calendar quarters beginning on or after July 1, 1988 and before July 1, 1990: The lesser of 90% or the Federal medical assistance percentage plus 25 percentage points; for calendar quarters beginning on or after October 1, 1990: 50%. (Section 1903(a)(2)(B) of the Act.)

(9) Preadmission screening and annual resident review (PASARR) activities conducted by the State: 75 percent. (Sections 1903(a)(2)(C) and 1919(e)(7); 42 CFR part 483, subparts C and E.)

§ 433.32 Fiscal policies and accountability.

A State plan must provide that the Medicaid agency and, where applicable, local agencies administering the plan will—

(a) Maintain an accounting system and supporting fiscal records to assure that claims for Federal funds are in accord with applicable Federal requirements;

(b) Retain records for 3 years from date of submission of a final expenditure report;

(c) Retain records beyond the 3-year period if audit findings have not been resolved; and

(d) Retain records for nonexpendable property acquired under a Federal grant for 3 years from the date of final disposition of that property.

[44 FR 17995, Mar. 23, 1979]

§ 433.34 Cost allocation.

A State plan under Title XIX of the Social Security Act must provide that the single or appropriate Agency will have an approved cost allocation plan on file with the Department in accordance with the requirements contained in subpart E of 45 CFR part 95. Subpart E also sets forth the effect on FFP if the requirements contained in that subpart are not met.

[47 FR 17490, Apr. 23, 1982]

§ 433.35 Equipment—Federal financial participation.

Claims for Federal financial participation in the cost of equipment under the Medicaid Program are determined in accordance with subpart G of 45 CFR part 95. Requirements concerning the management and disposition of equipment under the Medicaid Program are also prescribed in subpart G of 45 CFR part 95.

[47 FR 41564, Sept. 21, 1982]

§ 433.36 Liens and recoveries.

(a) Basis and purpose. This section implements sections 1902(a)(18) and 1917(a) and (b) of the Act, which describe the conditions under which an agency may impose a lien against a recipient’s property, and when an agency may make an adjustment or recover funds in satisfaction of the claim against the individual’s estate or real property.

(b) Definition of property. For purposes of this section, “property” includes the homestead and all other personal and real property in which the recipient has a legal interest.

(c) State plan requirement. If a State chooses to impose a lien against an individual’s real property (or as provided in paragraph (g)(1) of this section, personal property), the State plan must provide that the provisions of paragraphs (d) through (i) of this section are met.

(d) Procedures. The State plan must specify the process by which the State will determine that an institutionalized individual cannot reasonably be expected to be discharged from the medical institution and return home as provided in paragraph (g)(1) of this section. The description of the process must include the type of notice to be given the individual, the process by which the individual will be given the opportunity for a hearing, the hearing procedures, and by whom and on what basis the determination that the individual cannot reasonably be expected to be discharged from the institution should be made.
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will be made. The notice to the individual must explain what is meant by the term lien, and that imposing a lien does not mean that the individual will lose ownership of the home.

(e) Definitions. The State plan must define the following terms used in this section:

(1) Individual’s home.
(2) Equity interest in home.
(3) Residing in the home for at least 1 (or 2) year(s).
(4) On a continuing basis.
(5) Discharge from the medical institution and return home.
(6) Lawfully residing.

(f) Exception. The State plan must specify the criteria by which a son or daughter can establish to the agency’s satisfaction that he or she has been providing care which permitted the individual to reside at home rather than in an institution, as provided in paragraph (h)(2)(iii)(B) of this section.

(g) Lien provisions—(1) Incorrect payments. The agency may place a lien against an individual’s property, both personal and real, before his or her death because of Medicaid claims paid or to be paid on behalf of that individual following a court judgement which determined that benefits were incorrectly paid for that individual.

(2) Correct payments. Except as provided in paragraph (g)(3) of this section, the agency may place a lien against the real property of an individual at any age before his or her death because of Medicaid claims paid or to be paid for that individual when—

(i) An individual is an inpatient of a medical institution and must, as a condition of receiving services in the institution under the State plan, apply his or her income to the cost of care as provided in §§435.725, 435.832 and 436.832; and

(ii) The agency determines that he or she cannot reasonably be expected to be discharged and return home. The agency must notify the individual of its intention to make that determination and provide an opportunity for a hearing in accordance with State established procedures before the determination is made. The notice to an individual must include an explanation of liens and the effect on an individual’s ownership of property.

(3) Restrictions on placing liens. The agency may not place a lien on an individual’s home under paragraph (g)(2) of this section if any of the following individuals is lawfully residing in the home:

(i) The spouse;
(ii) The individual’s child who is under age 21 or blind or disabled as defined in the State plan; or
(iii) The individual’s sibling (who has an equity interest in the home, and who was residing in the individual’s home for at least one year immediately before the date the individual was admitted to the medical institution).

(4) Termination of lien. Any lien imposed on an individual’s real property under paragraph (g)(2) of this section will dissolve when that individual is discharged from the medical institution and returns home.

(h) Adjustments and recoveries. (1) The agency may make an adjustment or recover funds for Medicaid claims correctly paid for an individual as follows:

(i) From the estate of any individual who was 65 years of age or older when he or she received Medicaid; and
(ii) From the estate or upon sale of the property subject to a lien when the individual is institutionalized as described in paragraph (g)(2) of this section.

(2) The agency may make an adjustment or recovery under paragraph (h)(1) of this section only:

(i) After the death of the individual’s surviving spouse; and
(ii) When the individual has no surviving child under age 21 or blind or disabled as defined in the State plan; and
(iii) In the case of liens placed on an individual’s home under paragraph (g)(2) of this section, when there is no—

(A) Sibling of the individual residing in the home, who has resided there for at least one year immediately before the date of the individual’s admission to the institution, and has resided there on a continuous basis since that time; or
(B) Son or daughter of the individual residing in the home, who has resided there for at least two years immediately before the date of the individual’s admission to the institution, has resided there on a continuous basis
since that time, and can establish to the agency's satisfaction that he or she has been providing care which permitted the individual to reside at home rather than in an institution.

(i) Prohibition of reduction of money payments. No money payment under another program may be reduced as a means of recovering Medicaid claims incorrectly paid.

§ 433.37 Reporting provider payments to Internal Revenue Service.

(a) Basis and purpose. This section, based on section 1902(a)(4) of the Act, prescribes requirements concerning—

(1) Identification of providers; and

(2) Compliance with the information reporting requirements of the Internal Revenue Code.

(b) Identification of providers. A State plan must provide for the identification of providers by—

(1) Social security number if—

(i) The provider is in solo practice; or

(ii) The provider is not in solo practice but billing is by the individual practitioner; or

(2) Employer identification number for all other providers.

(c) Compliance with section 6041 of the Internal Revenue Code. The plan must provide that the Medicaid agency complies with the information reporting requirements of section 6041 of the Internal Revenue Code (26 U.S.C. 6041).

§ 433.38 Interest charge on disallowed claims for FFP.

(a) Basis and scope. This section is based on section 1903(d)(5) of the Act, which requires that the Secretary charge a State interest on the Federal share of claims that have been disallowed but have been retained by the State during the administrative appeals process under section 1116(d) of the Act and the Secretary later recovers after the administrative appeals process has been completed. This section does not apply to—

(1) Claims that have been deferred by the Secretary and disallowed within the time limits of §430.40 of this chapter. Deferral of claims for FFP; or

(2) Claims for expenditures that have never been paid on a grant award; or

(3) Disallowances of any claims for services furnished before October 1, 1980, regardless of the date of the claim submitted to HCFA.

(b) General principles. (1) HCFA will charge a State interest on FFP when—

(i) HCFA has notified the Medicaid agency under 45 CFR 74.304 that a State claim for FFP is not allowable;

(ii) The agency has appealed the disallowance to the Grant Appeals Board under 45 CFR Part 16 and has chosen to retain the FFP during the administrative appeals process in accordance with paragraph (c)(2) of this section; and

(iii)(A) The Board has made a final determination upholding part or all of the disallowance; (B) the agency has reversed its decision to retain the funds without withdrawing its appeal and the Board upholds all or part of the disallowance.

(2) If the courts overturn, in whole or in part, a Board decision that has sustained a disallowance, HCFA will return the principal and the interest collected on the funds that were disallowed, upon the completion of all judicial appeals.

(3) Unless an agency decides to withdraw its appeal on part of the disallowance and therefore returns only that part of the funds on which it has withdrawn its appeal, any decision to retain or return disallowed funds must apply to the entire amount in dispute.

(4) If the agency elects to have HCFA recover the disputed amount, it may not reverse that election.

(c) State procedures. (1) If the Medicaid agency has appealed a disallowance to the Board and wishes to retain the disallowed funds until the Board issues a final determination, the agency must notify the HCFA Regional Administrator in writing of its decision to do so.

(2) The agency must mail its notice to the HCFA Regional Administrator
within 30 days of the date of receipt of the notice of the disallowance, as established by the certified mail receipt accompanying the notices.

(3) If the agency withdraws either its decision to retain the FFP or its appeal on all or part of the FFP or both, the agency must notify HCFA in writing.

(4) If the agency does not notify the HCFA Regional Administrator within the time limit set forth in paragraph (c)(2) of this section, HCFA will recover the amount of the disallowed funds from the next possible Medicaid grant award to the State.

(d) Amount of interest charged. (1) If the agency retains funds that later become subject to an interest charge under paragraph (b) of this section, HCFA will offset from the next Medicaid grant award to the State the amount of the funds subject to the interest charge, plus interest on that amount.

(2) The interest charge is at the rate HCFA determines to be the average of the bond equivalent of the weekly 90-day Treasury bill auction rates during the period for which interest will be charged.

(e) Duration of interest. (1) The interest charge on the amount of disallowed FFP retained by the agency will begin on the date of the disallowance notice and end—

(i) On the date of the final determination by the Board;

(ii) On the date HCFA receives written notice from the State that it is withdrawing its appeal on all of the disallowed funds; or

(iii) If the agency withdraws its appeal on part of the funds, on (A) the date HCFA receives written notice from the agency that it is withdrawing its appeal on a specified part of the disallowed funds for the part on which the agency pursues its appeal; and (B) the date of the final determination by the Board on the part for which the agency pursues its appeal; or

(iv) The date HCFA receives written notice from the agency that it no longer chooses to retain the funds.

(2) HCFA will not charge interest on FFP retained by an agency for more than 12 months for disallowances of FFP made between October 1, 1980 and August 13, 1981.

§ 433.40 Treatment of uncashed or cancelled (voided) Medicaid checks.

(a) Purpose. This section provides the rules to ensure that States refund the Federal portion of uncashed or cancelled (voided) checks under title XIX.

(b) Definitions. As used in this section—

Cancelled (voided) check means a Medicaid check issued by a State or fiscal agent which prior to its being cashed is cancelled (voided) by the State or fiscal agent, thus preventing disbursement of funds.

Check means a check or warrant that a State or local agency uses to make a payment.

Fiscal agent means an entity that processes or pays vendor claims for the Medicaid State agency.

Uncashed check means a Medicaid check issued by a State or fiscal agent which has not been cashed by the payee.

Warrant means an order by which the State agency or local agency without the authority to issue checks recognizes a claim. Presentation of a warrant by the payee to a State officer with authority to issue checks will result in release of funds due.

(c) Refund of Federal financial participation (FFP) for uncashed checks—(1) General provisions. If a check remains uncashed beyond a period of 180 days from the date it was issued; i.e., the date of the check, it will no longer be regarded as an allowable program expenditure. If the State has claimed and received FFP for the uncashed check, it must refund the amount of FFP received.

(2) Report of refund. At the end of each calendar quarter, the State must identify those checks which remain uncashed beyond a period of 180 days after issuance. The State agency must refund all FFP that it received for uncashed checks by adjusting the Quarterly Statement of Expenditures for that quarter. If an uncashed check is cashed after the refund is made, the State may file a claim. The claim will be considered to be an adjustment to the costs for the quarter in which the
check was originally claimed. This claim will be paid if otherwise allowed by the Act and the regulations issued pursuant to the Act.

(3) If the State does not refund the appropriate amount as specified in paragraph (c)(2) of this section, the amount will be disallowed.

(d) Refund of FFP for cancelled (voided) checks—(1) General provision. If the State has claimed and received FFP for the amount of a cancelled (voided) check, it must refund the amount of FFP received.

(2) Report of refund. At the end of each calendar quarter, the State agency must identify those checks which were cancelled (voided). The State must refund all FFP that it received for cancelled (voided) checks by adjusting the Quarterly Statement of Expenditures for that quarter.

(3) If the State does not refund the appropriate amount as specified in paragraph (d)(2) of this section, the amount will be disallowed.

§ 433.52 General definitions.

As used in this subpart—

(a) Entity related to a health care provider means—

(1) An organization, association, corporation, or partnership formed by or on behalf of a health care provider;

(2) An individual with an ownership or control interest in the provider, as defined in section 1124(a)(3) of the Act;

(3) Any other person directly or indirectly participating in the management or control of a provider.

(b) Provider-related donations means contributions of cash or other property provided to a provider or the entity related to a provider by a person other than the provider or the entity related to the provider, including:

(1) Contributions from an entity related to a health care provider that are received by a provider or the entity related to a health care provider;

(2) Contributions from a non-profit entity that is not an organization, association, corporation, partnership, or similar entity related to a health care provider; and

(3) Contributions from a person that is not an organization, association, corporation, partnership, or similar entity related to a health care provider.

(c) Health care-related taxes means taxes on health care-related activities, including:

(1) Taxes levied on providers or the public;

(2) Taxes levied on patients or the public;

(3) Taxes levied on property used for health care-related activities;

(4) Taxes levied on providers to finance the State's share of expenditures for medical assistance; and

(5) Taxes levied on the public to finance the State's share of expenditures for medical assistance.

§ 433.51 Public funds as the State share of financial participation.

(a) Public funds may be considered as the State's share in claiming FFP if they meet the conditions specified in paragraphs (b) and (c) of this section.

(b) The public funds are appropriated directly to the State or local Medicaid agency, or transferred from other public agencies (including Indian tribes) to the State or local agency and under its administrative control, or certified by the contributing public agency as representing expenditures eligible for FFP under this section.

(c) The public funds are not Federal funds, or are Federal funds authorized by Federal law to be used to match other Federal funds.

§ 433.50 Basis, scope, and applicability.

(a) Basis. This subpart interprets and implements—

(1) Section 1902(a)(2) of the Act, which requires States to share in the cost of medical assistance expenditures and permits both State and local governments to participate in the financing of the non-Federal portion of medical assistance expenditures.

(2) Section 1903(a) of the Act, which requires the Secretary to pay each State an amount equal to the Federal medical assistance percentage of the total amount expended as medical assistance under the State's plan.

(3) Section 1903(w) of the Act, which specifies the treatment of revenues from provider-related donations and health care-related taxes in determining a State's medical assistance expenditures for which Federal financial participation (FFP) is available under the Medicaid program.

(b) Scope. This subpart—

(1) Specifies State plan requirements for State financial participation in expenditures for medical assistance.

(2) Defines provider-related donations and health care-related taxes that may be received without a reduction in FFP.

(3) Specifies rules for revenues received from provider-related donations and health care-related taxes during a transition period.

(4) Establishes limitations on FFP when States receive funds from provider-related donations and revenues generated by health care-related taxes.

(c) Applicability. The provisions of this subpart apply to the 50 States and the District of Columbia, but not to any State whose entire Medicaid program is operated under a waiver granted under section 1115 of the Act.

[51 FR 36227, Oct. 9, 1986]

Subpart B—General Administrative Requirements State Financial Participation

SOURCE: 57 FR 55138, Nov. 24, 1992, unless otherwise noted.

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check was originally claimed. This claim will be paid if otherwise allowed by the Act and the regulations issued pursuant to the Act.

(3) If the State does not refund the appropriate amount as specified in paragraph (c)(2) of this section, the amount will be disallowed.

(d) Refund of FFP for cancelled (voided) checks—(1) General provision. If the State has claimed and received FFP for the amount of a cancelled (voided) check, it must refund the amount of FFP received.

(2) Report of refund. At the end of each calendar quarter, the State agency must identify those checks which were cancelled (voided). The State must refund all FFP that it received for cancelled (voided) checks by adjusting the Quarterly Statement of Expenditures for that quarter.

(3) If the State does not refund the appropriate amount as specified in paragraph (d)(2) of this section, the amount will be disallowed.

[51 FR 36227, Oct. 9, 1986]
(3) An employee, spouse, parent, child, or sibling of the provider, or of a person with an ownership or control interest in the provider, as defined in section 1124(a)(3) of the Act; or

(4) A supplier of health care items or services or a supplier to providers of health care items or services.

Health care provider means the individual or entity that receives any payment or payments for health care items or services.

Provider-related donation means a donation or other voluntary payment (in cash or in kind) made directly or indirectly to a State or unit of local government by or on behalf of a health care provider, an entity related to such a health care provider, or an entity providing goods or services to the State for administration of the State's Medicaid plan.

(1) Donations made by a health care provider to an organization, which in turn donates money to the State, may be considered to be a donation made indirectly to the State by a health care provider.

(2) When an organization receives less than 25 percent of its revenues from providers and/or provider-related entities, its donations will not generally be presumed to be provider-related donations. Under these circumstances, a provider-related donation to an organization will not be considered a donation made indirectly to the State. However, if the donations from providers to an organization are subsequently determined to be indirect donations to the State or unit of local government for administration of the State's Medicaid program, then such donations will be considered to be health care related.

(3) When the organization receives more than 25 percent of its revenue from donations from providers or provider-related entities, the organization will be considered as acting on behalf of health care providers if it makes a donation to the State. The amount of the organization's donation to the State, in a State fiscal year, that will be considered health care related, will be based on the percentage of donations the organization received from the providers during that period.

§ 433.53 State plan requirements.

A State plan must provide that—

(a) State (as distinguished from local) funds will be used both for medical assistance and administration;

(b) State funds will be used to pay at least 40 percent of the non-Federal share of total expenditures under the plan; and

(c) State and Federal funds will be apportioned among the political subdivisions of the State on a basis that assures that—

(1) Individuals in similar circumstances will be treated similarly throughout the State; and

(2) If there is local financial participation, lack of funds from local sources will not result in lowering the amount, duration, scope, or quality of services or level of administration under the plan in any part of the State.

§ 433.54 Bona fide donations.

(a) A bona fide donation means a provider-related donation, as defined in §433.52, made to the State or unit of local government, that has no direct or indirect relationship, as described in paragraph (b) of this section, to Medicaid payments made to—

(1) The health care provider;

(2) Any related entity providing health care items and services; or

(3) Other providers furnishing the same class of items or services as the provider or entity.

(b) Provider-related donations will be determined to have no direct or indirect relationship to Medicaid payments if those donations are not returned to the individual provider, the provider class, or related entity under a hold harmless provision or practice, as described in paragraph (c) of this section.

(c) A hold harmless practice exists if any of the following applies:

(1) The amount of the payment received (other than under title XIX of the Act) is positively correlated either to the amount of the donation or to the difference between the amount of the donation and the amount of the payment received under the State plan;

(2) All or any portion of the payment made under Medicaid to the donor, the
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§ 433.55 Health care-related taxes defined.

(a) A health care-related tax is a licensing fee, assessment, or other mandatory payment that is related to—

(1) Health care items or services;
(2) The provision of, or the authority to provide, the health care items or services; or
(3) The payment for the health care items or services.

(b) A tax will be considered to be related to health care items or services under paragraph (a)(1) of this section if at least 85 percent of the burden of the tax revenue falls on health care providers.

(c) A tax is considered to be health care related if the tax is not limited to health care items or services, but the treatment of individuals or entities providing or paying for those health care items or services is different than the tax treatment provided to other individuals or entities.

(d) A health care-related tax does not include payment of a criminal or civil fine or penalty, unless the fine or penalty was imposed instead of a tax.

(e) Health care insurance premiums and health maintenance organization premiums paid by an individual or group to ensure coverage or enrollment are not considered to be payments for health care items and services for purposes of determining whether a health care-related tax exists.

§ 433.56 Classes of health care services and providers defined.

(a) For purposes of this subpart, each of the following will be considered as a separate class of health care items or services:

(1) Inpatient hospital services;
(2) Outpatient hospital services;
(3) Nursing facility services (other than services of intermediate care facilities for the mentally retarded);
(4) Intermediate care facility services for the mentally retarded, and similar services furnished by community-based residences for the mentally retarded, under a waiver under section 1915(c) of the Act, in a State in which, as of December 24, 1992, at least 85 percent of such facilities were classified as ICF/MRs prior to the grant of the waiver;
(5) Physician services;
(6) Home health care services;
(7) Outpatient prescription drugs;
(8) Services of health maintenance organizations and health insuring organizations;
(9) Ambulatory surgical center services, as described for purposes of the Medicare program in section 1832(a)(2)(F)(i) of the Social Security Act. These services are defined to include facility services only and do not include surgical procedures;
(10) Dental services;
(11) Podiatric services;
(12) Chiropractic services;
(13) Optometric/optician services;
(14) Psychological services;
(15) Therapist services, defined to include physical therapy, speech therapy, occupational therapy, respiratory therapy, audiological services, and rehabilitative specialist services;
§ 433.57 General rules regarding revenues from provider-related donations and health care-related taxes.

Effective January 1, 1992, HCFA will deduct from a State's expenditures for medical assistance, before calculating FPP, funds from provider-related donations and revenues generated by health care-related taxes received by a State or unit of local government, in accordance with the requirements, conditions, and limitations of this subpart, if the donations and taxes are not—

(a) Donations and taxes that meet the requirements specified in § 433.58, except for certain revenue received during a specified transition period;

(b) Permissible provider-related donations, as specified in § 433.66(b); or

(c) Health care-related taxes, as specified in § 433.68(b).

§ 433.58 Provider-related donations and health care-related taxes during a State's transition period.

(a) General rule. During the State's transition period specified in paragraph (b) of this section, a State may receive certain provider-related donations and health care-related taxes without a reduction in FPP. These provider-related donations and health care-related taxes must meet the conditions specified in this section and are subject to limitations specified in § 433.60.

(b) Transition periods for States.

(1) Except as provided in paragraph (b)(2) of this section, the provisions of this section apply for the period beginning January 1, 1992 and ending—

(i) September 30, 1992, for States whose State fiscal year begins on or before July 1, 1992; or


(2) The provisions of this section apply for the period beginning January 1, 1992 and ending June 30, 1993 for States that—

(i) Are not scheduled to have a regular legislative session in calendar year 1992;

(ii) Are not scheduled to have a regular legislative session in calendar year 1993; or

(iii) Had enacted a health care-related tax program on November 4, 1991.

(c) Permissible donations. To be permissible donations, the donations must be—

(1) Bona fide donations, as defined in § 433.54;

(2) Donations made by a hospital, clinic, or similar entity (such as a Federally-qualified health center) for the direct costs of State or local agency personnel who are stationed at that facility to determine the eligibility (including eligibility redeterminations) of individuals for Medicaid and/or to provide outreach services to eligible (or
potentially eligible) Medicaid individuals. Direct costs of outstationed eligibility workers refers to the costs of training, salaries and fringe benefits associated with each outstationed worker and similar allocated costs of State or local agency support staff, and a prorated cost of outreach activities applicable to the outstationed workers at these sites. The prorated costs of outreach activities will be calculated taking the percent of State outstationed eligibility workers at a facility to total outstationed eligibility workers in the State, and multiplying the percent by the total cost of outreach activities in the State. Costs for such items as State agency overhead and provider office space are not allowable for this purpose; or

(3) Provider-related donations, even if the donations do not qualify under the provisions of paragraph (d)(1) or (2) of this section, that meet the following conditions:

(i) The donation program was in effect on September 30, 1991, described in State plan amendments or related documents submitted to HCFA by that date, or substantiated by written documentary evidence (as described in paragraph (e) of this section) that was in existence as of that date; and

(ii) The donation program is applicable to the State's fiscal year 1992, as demonstrated by written documentary evidence as described in paragraph (e) of this section.

(e) Written documentary evidence. The State must have written documentation, which was in existence on September 30, 1991, of a donation program described in paragraph (d)(3) of this section that includes the dollar amounts it received in State fiscal year 1992 and the amounts it intended to receive, as evidenced by one or more of the following:

(1) Reference to a donation program in a State plan amendment or related documents, including a satisfactory response, as determined by HCFA, to a HCFA request for additional information;

(2) State budget documents identifying the amounts States expected to be received in donations;

(3) Written agreements with the parties donating the funds; and/or

(4) Other written documents that identify amounts that the States planned to receive in donations from specified organizations during that period.

(f) Application of rules to State fiscal year 1993. For any portion of a State's fiscal year 1993 that occurs during the transition period, the State may receive, without a reduction in FFP, the amount of provider-related donations that it received in the corresponding period in State fiscal year 1992, including the 5 days after the end of that period, subject to the limitations specified in §433.60(a).

(g) Health care-related taxes during the transition period. (1) Subject to the limitations specified in §433.60, States may receive, without a reduction in FFP, health care-related taxes during the State's transition period if:

(i) The health care-related taxes are broad-based and uniformly imposed, and the taxpayer will not be held harmless, as specified in §433.68; or

(ii) The health care-related taxes are imposed under—

(A) A tax program that was in effect as of November 22, 1991; or

(B) Legislation or regulations that were enacted or adopted as of November 22, 1991.

(2) A State may not modify health care-related taxes in existence as of November 22, 1991, without a reduction of FFP, unless the modification only—

(i) Extends a tax program that was scheduled to expire before the end of the State's transition period;

(ii) Makes technical changes that do not alter the rate of the tax or the base of the tax (for example, the providers on which the tax is imposed) and do not otherwise increase the proceeds of the tax;

(iii) Decreases the rate of the tax, without altering the base of the tax; or

(iv) Modifies the tax program to bring it into compliance with §433.68(f).

§ 433.60 Limitations on level of FFP in State expenditures from provider-related donations and health care-related taxes during the transition period.

(a) Maximum amounts. The maximum amount of total provider-related donations, as specified in §433.58(d), and health care-related taxes that a State may receive without a reduction in FFP during a State fiscal year in the State's transition period specified in §433.58(b) is calculated by multiplying—

(1) The State's total medical assistance expenditures for the fiscal year; by
(2) The greater of:
   (i) 25 percent; or
   (ii) The “State base percentage” (as described in paragraph (b) of this section).

(b) State base percentage.

(1) The State's base percentage is calculated by dividing the amount of the provider-related donations and health care-related taxes identified in §433.58 and estimated by HCFA to be received in the State's fiscal year 1992 by the total non-Federal share of medical assistance expenditures (including administrative costs) in that fiscal year based on the best available HCFA data.

(2) In calculating the amount of taxes specified in paragraph (b)(1) of this section, taxes (including the tax rate or base) that were not in effect for the entire State fiscal year, but for which legislation or regulations imposing such taxes were enacted or adopted as of November 22, 1991, will be estimated as if they were in effect for the entire fiscal year.

(c) Reductions before calculating FFP. Before calculating FFP, HCFA will deduct from a State's medical assistance expenditures the total amount of any provider-related donations described in §433.58(d)(3), and health care-related taxes in excess of the limit calculated under paragraph (a) of this section.


§ 433.66 Permissible provider-related donations after the transition period.

(a) General rule. (1) Except as specified in paragraph (a)(2) of this section, subsequent to the end of a State's transition period, as defined in §433.58(b), a State may receive revenues from provider-related donations without a reduction in FFP, only in accordance with the requirements of this section.

(2) The provisions of this section relating to provider-related donations for outstationed eligibility workers are effective on October 1, 1992, whether or not the State's transition period continues beyond that date.

(b) Permissible donations. Subject to the limitations specified in §433.67, a State may receive, without a reduction in FFP, provider-related donations that meet at least one of the following requirements:

(1) The donations must be bona fide donations, as defined in §433.54; or
(2) The donations are made by a hospital, clinic, or similar entity (such as a Federally-qualified health center) for the direct costs of State or local agency personnel who are stationed at the facility to determine the eligibility (including eligibility redeterminations) of individuals for Medicaid or to provide outreach services to eligible (or potentially eligible) Medicaid individuals. Direct costs of outstationed eligibility workers refers to the costs of training, salaries and fringe benefits associated with each outstationed worker and similar allocated costs of State or local agency support staff, and a prorated cost of outreach activities applicable to the outstationed workers at these sites. The prorated costs of outreach activities will be calculated taking the percent of State outstationed eligibility workers at a facility to total outstationed eligibility workers in the State, and multiplying the percent by the total cost of outreach activities in the State. Costs for such items as State agency overhead and provider office space are not allowable for this purpose.


§ 433.67 Limitations on level of FFP for permissible provider-related donations.

(a)(1) Limitations on bona fide donations. There are no limitations on the amount of bona fide provider-related donations that a State may receive
§ 433.68 Permissible health care-related taxes after the transition period.

(a) General rule. Beginning on the day after a State's transition period, as defined in §433.58(b), ends, a State may receive health care-related taxes, without a reduction in FFP, only in accordance with the requirements of this section.

(b) Permissible health care-related taxes. Subject to the limitations specified in §433.70, a State may receive, without a reduction in FFP, health care-related taxes if all of the following are met:

1. The taxes are broad based, as specified in paragraph (c) of this section;
2. The taxes are uniformly imposed throughout a jurisdiction, as specified in paragraph (d) of this section; and
3. The tax program does not violate the hold harmless provisions specified in paragraph (f) of this section.

(c) Broad based health care-related taxes. (1) A health care-related tax will be considered to be broad based if the tax is imposed on at least all health care items or services in the class or providers of such items or services furnished by all non-Federal, non-public providers in the State, and is imposed uniformly, as specified in paragraph (d) of this section.

2. If a health care-related tax is imposed by a unit of local government, the tax must extend to all items or services or providers (or to all providers in a class) in the area over which the unit of government has jurisdiction.

3. A State may request a waiver from HCFA of the requirement that a tax program be broad based, in accordance with the procedures specified in §433.72. Waivers from the uniform and broad-based requirements will automatically be granted in cases of variations in licensing and certification fees for providers if the amount of such fees is not more than $1,000 annually per provider and the total amount raised by the State from the fees is used in the administration of the licensing or certification program.

(d) Uniformly imposed health care-related taxes. A health care-related tax will be considered to be imposed uniformly even if it excludes Medicaid or Medicare payments (in whole or in part), or both; or, in the case of a health care-related tax based on revenues or receipts with respect to a class of items or services (or providers of items or services), if it excludes either Medicaid or Medicare revenues with respect to a class of items or services, or both. The exclusion of Medicaid revenues must be applied uniformly to all providers being taxed.

1. A health care-related tax will be considered to be imposed uniformly if it meets any one of the following criteria:
   i. If the tax is a licensing fee or similar tax imposed on a class of health care services (or providers of those health care items or services), the tax is the same amount for every provider furnishing those items or services within the class.

   ii. If the tax is a licensing fee or similar tax imposed on a class of
health care items or services (or providers of those items or services) on the basis of the number of beds (licensed or otherwise) of the provider, the amount of the tax is the same for each bed of each provider of those items or services in the class.

(iii) If the tax is imposed on provider revenue or receipts with respect to a class of items or services (or providers of those health care items or services), the tax is imposed at a uniform rate for all services (or providers of those items or services) in the class on all the gross revenues or receipts, or on net operating revenues relating to the provision of all items or services in the State, unit, or jurisdiction. Net operating revenue means gross charges of facilities less any deducted amounts for bad debts, charity care, and payer discounts.

(iv) The tax is imposed on items or services on a basis other than those specified in paragraphs (d)(1) (i) through (iii) of this section, e.g., an admission tax, and the State establishes to the satisfaction of the Secretary that the amount of the tax is the same for each provider of such items or services in the class.

(2) A tax imposed with respect to a class of health care items or services will not be considered to be imposed uniformly if it meets either one of the following two criteria:

(i) The tax provides for credits, exclusions, or deductions which have as its purpose, or results in, the return to providers of all, or a portion, of the tax paid, and it results, directly or indirectly, in a tax program in which—

(A) The net impact of the tax and payments is not generally redistributive, as specified in paragraph (e) of this section; and

(B) The tax holds taxpayers harmless for the cost of the tax, as described in paragraph (f) of this section.

(3) If a tax does not meet the criteria specified in paragraphs (d)(1)(i) through (iv) of this section, but the State establishes that the tax is imposed uniformly in accordance with the procedures for a waiver specified in §433.72, the tax will be treated as a uniform tax.

(e) Generally redistributive. A tax will be considered to be generally redistributive if it meets the requirements of this paragraph. If the State desires waiver of only the broad-based tax requirement, it must demonstrate compliance with paragraph (e)(1) of this section. If the State desires waiver of the uniform tax requirement, whether or not the tax is broad-based, it must demonstrate compliance with paragraph (e)(2) of this section.

(1) Waiver of broad-based requirement only. This test is applied on a per class basis to a tax that is imposed on all revenues but excludes certain providers. For example, a tax that is imposed on all revenues (including Medicare and Medicaid) but excludes teaching hospitals would have to meet this test. This test cannot be used when a State excludes any or all Medicaid revenue from its tax in addition to the exclusion of providers, since the test compares the proportion of Medicaid revenue being taxed under the proposed tax with the proportion of Medicaid revenue being taxed under a broad-based tax.

(i) A State seeking waiver of the broad-based tax requirement only must demonstrate that its proposed tax plan meets the requirement that its plan is generally redistributive by:

(A) Calculating the proportion of the tax revenue applicable to Medicaid if the tax were broad based and applied to all providers or activities within the class (called P1);

(B) Calculating the proportion of the tax revenue applicable to Medicaid under the tax program for which the State seeks a waiver (called P2); and

(C) Calculating the value of P1/P2.

(ii) If the State demonstrates to the Secretary's satisfaction that the value of P1/P2 is at least 1, HCFA will automatically approve the waiver request.

(iii) If a tax is enacted and in effect prior to August 13, 1993, and the State demonstrates to the Secretary's satisfaction that the value of P1/P2 is at least 0.90, HCFA will review the waiver request. Such a waiver will be approved only if the following two criteria are met:
(A) The value of $P_1/P_2$ is at least 0.90; and
(B) The tax excludes or provides credits or deductions only to one or more of the following providers of items and services within the class to be taxed:

1. Providers that furnish no services within the class in the State;
2. Providers that do not charge for services within the class;
3. Rural hospitals (defined as any hospital located outside of an urban area as defined in §412.62(f)(1)(ii) of this chapter);
4. Sole community hospitals as defined in §412.92(a) of this chapter;
5. Physicians practicing primarily in medically underserved areas as defined in section 1302(7) of the Public Health Service Act;
6. Financially distressed hospitals if:
   i. A financially distressed hospital is defined by the State law;
   ii. The State law specifies reasonable standards for determining financially distressed hospitals, and these standards are applied uniformly to all hospitals in the State; and
   iii. No more than 10 percent of non-public hospitals in the State are exempt from the tax;
7. Psychiatric hospitals; or
8. Hospitals owned and operated by HMOs.

(iv) If a tax is enacted and in effect after August 13, 1993, and the State demonstrates to the Secretary's satisfaction that the value of $P_1/P_2$ is at least 0.95, HCFA will review the waiver request. Such a waiver request will be approved only if the following two criteria are met:

(A) The value of $P_1/P_2$ is at least 0.95; and
(B) The tax complies with the provisions of §433.68(e)(1)(iii)(B).

(2) Waiver of uniform tax requirement. This test is applied on a per class basis to all taxes that are not uniform. This includes those taxes that are neither broad based (as specified in §433.68(c)) nor uniform (as specified in §433.68(d)).

(i) A State seeking waiver of the uniform tax requirement (whether or not the tax is broad based) must demonstrate that its proposed tax plan meets the requirement that its plan is generally redistributive by:

(A) Calculating, using ordinary least squares, the slope (designated as $B_1$) of two linear regressions, in which the dependent variable is each provider's percentage share of the total tax paid by all taxpayers during a 12-month period, and the independent variable is the taxpayer's "Medicaid Statistic". The term "Medicaid Statistic" means the number of the provider's taxable units applicable to the Medicaid program during a 12-month period. If, for example, the State imposed a tax based on provider charges, the amount of a provider's Medicaid charges paid during a 12-month period would be its "Medicaid Statistic". If the tax were based on provider inpatient days, the number of the provider's Medicaid days during a 12-month period would be its "Medicaid Statistic". For the purpose of this test, it is not relevant that a tax program exempts Medicaid from the tax.

(B) Calculating the slope (designated as $B_2$) of the linear regression, as described in paragraph (e)(2)(i) of this section, for the State's tax program, if it were broad based and uniform.

(C) Calculating the slope (designated as $B_3$) of the linear regression, as described in paragraph (e)(2)(i) of this section, for the State's tax program, as proposed.

(ii) If the State demonstrates to the Secretary's satisfaction that the value of $B_2/B_3$ is at least 1, HCFA will automatically approve the waiver request.

(iii) If the State demonstrates to the Secretary's satisfaction that the value of $B_2/B_3$ is at least 0.95, HCFA will review the waiver request. Such a waiver will be approved only if the following two criteria are met:

(A) The value of $B_2/B_3$ is at least 0.95; and
(B) The tax excludes or provides credits or deductions only to one or more of the following providers of items and services within the class to be taxed:

1. Providers that furnish no services within the class;
2. Providers that do not charge for services within the class;
3. Rural hospitals (defined as any hospital located outside of an urban area as defined in §412.62(f)(1)(ii) of this chapter;
§ 433.70 Limitations on level of FFP for revenues from health care-related taxes after the transition period.

(a) Limitations. (1) Subsequent to the end of a State's transition period (as defined in §433.58(b)), and extending through September 30, 1995, the maximum amount of health care-related taxes specified in §433.68 that a State may receive during a State fiscal year (or portion thereof), without a reduction in FFP, is limited to—

(i) The greater of 25 percent or the State base percentage as described in §433.60(b); multiplied by

(ii) The State's share of total medical assistance expenditures for the State fiscal year, less all health care-related taxes other than those described in

(4) Sole community hospitals as defined in §412.92(a) of this chapter;

(5) Physicians practicing primarily in medically underserved areas as defined in section 1302(7) of the Public Health Service Act;

(6) Financially distressed hospitals if:

(i) A financially distressed hospital is defined by the State law;

(ii) The State law specifies reasonable standards for determining financially distressed hospitals, and these standards are applied uniformly to all hospitals in the State; and

(iii) No more than 10 percent of non-public hospitals in the State are exempt from the tax;

(7) Psychiatric hospitals; or

(8) Providers or payers with tax rates that vary based exclusively on regions, but only if the regional variations are coterminous with preexisting political (and not special purpose) boundaries. Taxes within each regional boundary must meet the broad-based and uniformity requirements as specified in paragraphs (c) and (d) of this section.

(iv) A B1/B2 value of 0.70 will be applied to taxes that vary based exclusively on regions, and enacted and in effect prior to November 24, 1992, to permit such variations.

(f) Hold harmless. A taxpayer will be considered to be held harmless under a tax program if any of the following conditions applies:

(1) The State (or other unit of government) imposing the tax provides directly or indirectly for a non-Medicaid payment to those providers or others paying the tax and the amount of the payment is positively correlated to either the amount of the tax or to the difference between the Medicaid payment and the total tax cost.

(2) All or any portion of the Medicaid payment to the taxpayer varies based only on the amount of the total tax payment.

(3) The State (or other unit of local government) imposing the tax provides, directly or indirectly, for any payment, offset, or waiver that guarantees to hold taxpayers harmless for all or a portion of the tax.

(i) An indirect guarantee will be determined to exist under a two prong "guarantee" test. This specific hold harmless test is effective September 13, 1993. In this instance, if the health care-related tax or taxes on each health care class are applied at a rate that produces revenues less than or equal to 6 percent of the revenues received by the taxpayer, the tax or taxes are permissible under this test.

When the tax or taxes are applied at a rate that produces revenues in excess of 6 percent of the revenue received by the taxpayer, HCFA will consider a hold harmless provision to exist if 75 percent or more of the taxpayers in the class receive 75 percent or more of their total tax costs back in enhanced Medicaid payments or other State payments. The second prong of the hold harmless test is applied in the aggregate to all health care taxes applied to each class. If this standard is violated, the amount of tax revenue to be offset from medical assistance expenditures is the total amount of the taxpayers' revenues received by the State.

(ii) If, as of August 13, 1993, a State has enacted a tax in excess of 6 percent that does not meet the requirements in paragraph (f)(3)(i) of this section, HCFA will not disallow funds received by the State resulting from the tax if the State modifies the tax to comply with this requirement by September 13, 1993. If, by September 13, 1993, the tax is not modified, funds received by States on or after September 13, 1993 will be disallowed.

§ 433.68 that are deducted separately pursuant to paragraph (b) of this section.

(2) Beginning October 1, 1995, there is no limitation on the amount of health care-related taxes that a State may receive without a reduction in FFP, as long as the health care-related taxes meet the requirements specified in § 433.68.

(b) Calculation of FFP. HCFA will deduct from a State’s medical assistance expenditures, before calculating FFP, revenues from health care-related taxes that do not meet the requirements of § 433.68 and any health care-related taxes in excess of the limits specified in paragraph (a)(1) of this section.

§ 433.72 Waiver provisions applicable to health care-related taxes.

(a) Bases for requesting waiver. (1) A State may submit to HCFA a request for a waiver if a health care-related tax does not meet any or all of the following:

(i) The tax does not meet the broad based criteria specified in § 433.68c; and/or

(ii) The tax is not imposed uniformly but meets the criteria specified in § 433.68(d)(2) or (d)(3).

(2) When a tax that meets the criteria specified in paragraph (a)(1) of this section is imposed on more than one class of health care items or services, separate waivers must be obtained for each class of health care items and services subject to the tax.

(b) Waiver conditions. In order for HCFA to approve a waiver request that would permit a State to receive tax revenue (within specified limitations) without a reduction in FFP, the State must demonstrate, to HCFA’s satisfaction, that its tax program meets all of the following requirements:

(1) The net impact of the tax and any payments made to the provider by the State under the Medicaid program is generally redistributive, as described in § 433.68(e);

(2) The amount of the tax is not directly correlated to Medicaid payments; and

(3) The tax program does not fall within the hold harmless provisions specified in § 433.68(f).

(c) Effective date. A waiver will be effective:

(1) The date of enactment of the tax for programs in existence prior to August 13, 1993 or;

(2) For tax programs commencing on or after August 13, 1993, on the first day in the quarter in which the waiver is received by HCFA.

§ 433.74 Reporting requirements.

(a) Beginning with the first quarter of Federal fiscal year 1993 each State must submit to HCFA quarterly summary information on the source and use of all provider-related donations (including all bona fide and presumed-to-be bona fide donations) received by the State or unit of local government, and health care-related taxes collected. Each State must also provide any additional information requested by the Secretary related to any other donations made by, or any taxes imposed on, health care providers. States’ reports must present a complete, accurate, and full disclosure of all of their donation and tax programs and expenditures.

(b) Each State must provide the summary information specified in paragraph (a) of this section on a quarterly basis in accordance with procedures established by HCFA.

(c) Each State must maintain, in readily reviewable form, supporting documentation that provides a detailed description and legal basis for each donation and tax program being reported, as well as the source and use of all donations received and taxes collected. This information must be made available to Federal reviewers upon request.

(d) If a State fails to comply with the reporting requirements contained in this section, future grant awards will be reduced by the amount of FFP HCFA estimates is attributable to the sums raised by tax and donation programs as to which the State has not reported properly, until such time as the State complies with the reporting requirements. Deferrals and/or disallowances of equivalent amounts may also be imposed with respect to quarters for which the State has failed to report properly. Unless otherwise prohibited
§ 433.110 Basis, purpose, and applicability.

(a) This subpart implements the following sections of the Act:
(1) Section 1903(a)(3) of the Act, which provides for FFP in State expenditures for the design, development, or installation of mechanized claims processing and information retrieval systems and for the operation of certain systems. Additional HHS regulations and HCFA procedures for implementing these regulations are in 45 CFR part 74, 45 CFR part 95, subpart F, and part 11, State Medicaid Manual; and
(2) Section 1903(r) of the Act, which—
   (i) Requires reductions in FFP otherwise due a State under section 1903(a) if a State fails to meet certain deadlines for operating a mechanized claims processing and information retrieval system or if the system fails to meet certain conditions of approval or conditions of reapproval;
   (ii) Requires a Federal performance review at least every three years of the mechanized claims processing and information retrieval systems; and
   (iii) Allows waivers of conditions of approval, conditions of reapproval, and FFP reductions under certain circumstances.

(b) The requirements under section 1903(r) of the Act do not apply to Puerto Rico, Guam, the Virgin Islands, American Samoa and the Northern Mariana Islands.

§ 433.111 Definitions.

For purposes of this section:
(a) The following terms are defined at 45 CFR part 95, subpart F §95.605:
   "Advance Planning Document"; "Design" or "System Design"; "Development"; "Enhancement"; "Hardware"; "Installation"; "Operation"; and, "Software".

(b) "Mechanized claims processing and information retrieval system" or "system" means the system of software and hardware used to process Medicaid claims from providers of medical care and services for the medical care and services furnished to recipients under the medical assistance program and to retrieve and produce service utilization and management information required by the Medicaid single State agency and Federal Government for program administration and audit purposes. The system consists of
   (1) Required subsystems specified in the State Medicaid Manual;
   (2) Required changes to the required system or subsystem that are published in accordance with §433.123 of this subpart and specified in the State Medicaid Manual; and
   (3) Approved enhancements to the system. Eligibility determination systems are not part of mechanized claims processing and information retrieval systems or enhancements to those systems.

§ 433.112 FFP for design, development, installation or enhancement of mechanized claims processing and information retrieval systems.

(a) FFP is available at the 90 percent rate in State expenditures for the design, development, installation, or enhancement of a mechanized claims processing and information retrieval system only if the APD is approved by HCFA prior to the State's expenditure of funds for these purposes.

(b) HCFA will approve the system described in the APD if the following conditions are met:
   (1) HCFA determines the system is likely to provide more efficient, economical, and effective administration of the State plan.
   (2) The system meets the system requirements and performance standards in Part 11 of the State Medicaid Manual, as periodically amended.
   (3) The system is compatible with the claims processing and information retrieval systems used in the administration of Medicare for prompt eligibility verification and for processing claims for persons eligible for both programs.
§ 433.114 Procedures for obtaining initial approval; notice of decision.

(a) Except as waived under §433.130 or §433.131, FFP will be reduced as specified in paragraph (b) of this section unless the Medicaid agency must inform HCFA in writing that the system meets the conditions specified in §433.116(c) through (h).

(b) If HCFA disapproves the system, or determines that the system met requirements for initial approval on a date later than the date required under §433.113(a)(3), the notice will include—

1. The findings of fact upon which the determination was made; and
§ 433.116 FFP for operation of mechanized claims processing and information retrieval systems.

(a) Subject to 42 CFR 433.113(c), FFP is available at 75 percent of expenditures for operation of a mechanized claims processing and information retrieval system approved by HCFA, from the first day of the calendar quarter after the date the system met the conditions of initial approval, as established by HCFA (including a retroactive adjustment of FFP if necessary to provide the 75 percent rate beginning on the first day of that calendar quarter). Subject to 45 CFR 95.611(a), the State shall obtain prior written approval from HCFA when it plans to acquire ADP equipment or services, when it anticipates the total acquisition costs will exceed thresholds, and meets other conditions of the subpart.

(b) HCFA will approve the system operation if the conditions specified in paragraphs (c) through (h) of this section are met.

(c) The conditions of § 433.112(b) (1) through (4) and (7) through (9), as periodically modified under § 433.112(b)(2), must be met.

(d) The system must have been operating continuously during the period for which FFP is claimed.

(e) The system must provide individual notices, within 45 days of the payment of claims, to all or a sample group of the persons who received services under the plan.

(f) The notice required by paragraph (e) of this section—

(i) Must specify—

(ii) The service furnished;

(iii) The name of the provider furnishing the service;

(iv) The date on which the service was furnished; and

(v) The amount of the payment made under the plan for the service.

(2) Must not specify confidential services (as defined by the State) and must not be sent if the only service furnished was confidential.

(g) The system must provide both patient and provider profiles for program management and utilization review purposes.

(h) If the State has a Medicaid fraud control unit certified under section 1903(q) of the Act and §455.300 of this chapter, the Medicaid agency must have procedures to assure that information on probable fraud or abuse that is obtained from, or developed by, the system is made available to that unit. (See §455.21 of this chapter for State plan requirements.)

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§ 433.117 Initial approval of replacement systems.

(a) A replacement system must meet all conditions of initial approval of a mechanized claims processing and information retrieval system.

(b) The agency must submit an APD that includes—

(1) The date the replacement system will be in operation; and

(2) A plan for orderly transition from the system being replaced to the replacement system.

(c) FFP is available at—

(1) 90 percent in expenditures for design, development, and installation in accordance with the provisions of §433.116; and

(2) 75 percent in expenditures for the operation of an approved replacement system in accordance with the provisions of §433.116(b) through (h), from the date that the system met the conditions of initial approval, as established by HCFA.

(d) FFP is available at 75 percent in expenditures for the operation of an approved system that is being replaced (or at a reduced rate determined under §433.120 of this subpart for a system that has been disapproved) until the replacement system is in operation and approved.

§ 433.119 Conditions for reapproval; notice of decision.

(a) HCFA will review at least once every three years each system operation initially approved under § 433.114 and reapprove it for FFP at 75 percent of expenditures if the following conditions are met:

1. The system meets the conditions of § 433.112(b) (1), (3), (4), and (7) through (9).
2. The system meets the conditions of § 433.116 (d) through (h).
3. The system meets the performance standards for reapproval and the system requirements in part 11 of the State Medicaid Manual as periodically amended.
4. Automated eligibility determination systems approved or operating on or before November 13, 1989, will not qualify for FFP at 75 percent of expenditures after November 13, 1989.

(b) HCFA may review an entire system operation or focus its review on parts of the operation. However, at a minimum, HCFA will review standards, system requirements and other conditions of reapproval that have demonstrated weakness in a previous review or reviews.

(c) HCFA will issue to each Medicaid agency, by the end of the first quarter after the review period, a written notice informing the agency whether its system is reapproved or disapproved. If the system is disapproved, the notice will also include—

1. HCFA’s decision to reduce FFP for system operations, and the percentage to which it is reduced, beginning with the next calendar quarter;
2. The findings of fact upon which the determination was made; and
3. A statement that State claims in excess of the reduced FFP rate will be disallowed and that any such disallowance will be appealable to the Departmental Appeals Board.

§ 433.120 Procedures for reduction of FFP after reapproval review.

(a) If HCFA determines after the reapproval review that the system no longer meets the conditions of reapproval in § 433.119, HCFA will reduce FFP for system operations for at least four quarters. However, no system will be subject to reduction of FFP for at least the first four quarters after the quarter in which the system is initially approved as eligible for 75 percent FFP.

(b) HCFA will reduce FFP in expenditures for system operations from 75 percent to no more than 70 percent and no less than 50 percent; however, HCFA will not reduce FFP by more than 10 percentage points in any four-quarter period. The percentage to which the FFP is reduced will depend primarily on the following criteria:

1. The number of conditions judged unsatisfactory;
2. The extent to which conditions were not met;
3. The significance of the unsatisfactory conditions in overall mechanized claims processing and information retrieval system operations; and
4. The actual and potential program impact attributable to the unsatisfactory conditions.

§ 433.121 Reconsideration of the decision to reduce FFP after reapproval review.

(a) The agency may appeal to the Departmental Appeals Board under 45 CFR part 16, a disallowance concerning a reduction in FFP claimed for system operation caused by a disapproval of the State's system. If the Board finds such a disallowance to be appropriate, the discretionary determination to reduce FFP by a particular percentage amount (instead of by a lesser percentage) is not subject to review by the Board unless the percentage reduction exceeds the range authorized by section 1903(r)(4)(B) of the Act.

(b) The decisions concerning whether to restore any FFP retroactively and the actual number of quarters for which FFP will be restored under § 433.122 of this subpart are not subject to administrative appeal to the Departmental Appeals Board under 45 CFR part 16.

(c) An agency’s request for a reconsideration before the Board under paragraph (a) of this section does not delay implementation of the reduction in FFP. However, any reduction is subject to retroactive adjustment if required.
§ 433.122 Reapproval of a disapproved system.

When FFP has been reduced under § 433.120(a), and HCFA determines upon subsequent review that the system meets all current performance standards, system requirements and other conditions of reapproval, the following provisions apply:

(a) HCFA will resume FFP in expenditures for system operations at the 75 percent level beginning with the quarter following the review determination that the system again meets conditions of reapproval.

(b) HCFA may retroactively waive a reduction of FFP in expenditures for system operations if HCFA determines that the waiver could improve the administration of the State Medicaid plan. However, HCFA cannot waive this reduction for any quarter before the fourth quarter immediately preceding the quarter in which HCFA issues the determination (as part of the review process) stating that the system is reapproved.

(c) Whenever HCFA modifies performance standards and other conditions for reapproval under § 433.119, HCFA will notify Medicaid agencies at least one calendar quarter before the review period to which the new or modified standards or conditions apply.

§ 433.123 Notification of changes in system requirements, performance standards or other conditions for approval or reapproval.

(a) Whenever HCFA modifies system requirements or other conditions for approval under § 433.112 or § 433.116, HCFA will—

(1) Publish a notice in the Federal Register making available the proposed changes for public comment;

(2) Respond in a subsequent Federal Register notice to comments received; and

(3) Issue the new or modified requirements or conditions in the State Medicaid Manual.

(b) For changes in system requirements or other conditions for approval, HCFA will allow an appropriate period for Medicaid agencies to meet the requirement determining this period on the basis of the requirement’s complexity and other relevant factors.

§ 433.127 Termination of FFP for failure to provide access to claims processing and information retrieval systems.

HCFA will terminate FFP at any time if the Medicaid agency fails to provide State and Federal representatives with full access to the system, including on-site inspection. HCFA may request such access at any time to determine whether the conditions in this subpart are being met.

§ 433.130 Waiver of conditions of initial operation and approval.

(a) HCFA will waive requirements for initial operation and approval of systems under § 433.113 for a State meeting the requirements of paragraph (b) of this section and that had a 1976 population of less than one million and made total Federal and State Medicaid expenditures of less than $100 million in fiscal year 1976. Population figures are those reported by the Bureau of the Census. Expenditures for fiscal year 1976 are those reported by the State for that year.

(b) To be eligible for this waiver, the agency must submit its reasons to HCFA in writing and demonstrate to HCFA’s satisfaction that a system will not significantly improve the efficiency of the administration of the State plan.

(c) If HCFA denies the waiver request, the notice of denial will include—

(1) The findings of fact upon which the denial was made; and

(2) The procedures for appeal of the denial.

(d) If HCFA determines, after granting a waiver, that a system would significantly improve the administration of the State Medicaid program, HCFA...
may withdraw the waiver and require that a State obtain initial approval of a system within two years of the date of waiver withdrawal.


§ 433.131 Waiver for noncompliance with conditions of approval and reapproval.

If a State is unable to comply with the conditions of approval or of reapproval and the noncompliance will cause a percentum reduction in FFP, HCFA will waive the FFP reduction in the following circumstances:

(a) Good cause. If HCFA determines that good cause existed, HCFA will waive the FFP reduction attributable to those items for which the good cause existed. A waiver of FFP consequences of the failure to meet the conditions of approval or reapproval based upon good cause will not extend beyond two consecutive quarters.

(b) Circumstances beyond the control of a State. The State must satisfactorily explain the circumstances that are beyond its control. When HCFA grants the waiver, HCFA will also defer all other system deadlines for the same length of time that the waiver applies.


Subpart D—Third Party Liability

Source: 45 FR 8984, Feb. 11, 1980, unless otherwise noted.

§ 433.135 Basis and purpose.

This subpart implements sections 1902(a)(25), 1902(a)(45), 1903(d)(2), 1903(o), 1903(p), and 1912 of the Act by setting forth State plan requirements concerning—

(a) The legal liability of third parties to pay for services provided under the plan;

(b) Assignment to the State of an individual’s rights to third party payments; and

(c) Cooperative agreements between the Medicaid agency and other entities for obtaining third party payments.

[50 FR 46664, Nov. 12, 1985]

§ 433.136 Definitions.

For purposes of this subpart—

Private insurer means:

(1) Any commercial insurance company offering health or casualty insurance to individuals or groups (including both experience-rated insurance contracts and indemnity contracts);

(2) Any profit or nonprofit prepaid plan offering either medical services or full or partial payment for services included in the State plan; and

(3) Any organization administering health or casualty insurance plans for professional associations, unions, fraternal groups, employer-employee benefit plans, and any similar organization offering these payments or services, including self-insured and self-funded plans.

Third party means any individual, entity or program that is or may be liable to pay all or part of the expenditures for medical assistance furnished under a State plan.

Title IV-D agency means the organizational unit in the State that has the responsibility for administering or supervising the administration of a State plan for child support enforcement under title IV-D of the Act.

§ 433.137 State plan requirements.

(a) A State plan must provide that the requirements of §§ 433.138 and 433.139 are met for identifying third parties liable for payment of services under the plan and for payment of claims involving third parties.

(b) A State plan must provide that—

(1) The requirements of §§ 433.145 through 433.148 are met for assignment of rights to benefits, cooperation with the agency in obtaining medical support or payments, and cooperation in identifying and providing information to assist the State in pursuing any liable third parties; and

(2) The requirements of §§ 433.151 through 433.154 are met for cooperative agreements and incentive payments for third party collections.

(c) The requirements of paragraph (b)(1) of this section relating to assignment of rights to benefits and cooperation in obtaining medical support or
§ 433.138 Identifying liable third parties.

(a) Basic provisions. The agency must take reasonable measures to determine the legal liability of the third parties who are liable to pay for services furnished under the plan. At a minimum, such measures must include the requirements specified in paragraphs (b) through (k) of this section, unless waived under paragraph (l) of this section.

(b) Obtaining health insurance information: Initial application and redetermination processes for Medicaid eligibility.

(1) If the Medicaid agency determines eligibility for Medicaid, it must, during the initial application and each redetermination process, obtain from the applicant or recipient such health insurance information as would be useful in identifying legally liable third party resources so that the Medicaid agency may process claims under the third party liability payment procedures specified in §433.139 (b) through (f). Health insurance information may include, but is not limited to, the name of the policy holder, his or her relationship to the applicant or recipient, the social security number (SSN) of the policy holder, and the name and address of insurance company and policy number.

(2) If Medicaid eligibility is determined by any other agency in accordance with a written agreement, the Medicaid agency must modify the agreement to provide for—

   (i) Collection, from the applicant or recipient during the initial application and each redetermination process, of health insurance information in the form and manner specified by the Secretary; and
   (ii) Transmittal of the information to the Medicaid agency.

(3) If Medicaid eligibility is determined by the Federal agency administering the supplemental security income program under title XVI in accordance with a written agreement, the Medicaid agency must modify the agreement to provide for—

   (i) Collection, from the applicant or recipient during the initial application and each redetermination process, of such health insurance information as would be useful in identifying legally liable third party resources so that the Medicaid agency may process claims under the third party liability payment procedures specified in §433.139 (b) through (f). Health insurance information may include, but is not limited to, those elements described in paragraph (b)(1) of this section; and
   (ii) Transmittal of the information to the Medicaid agency.

(c) Obtaining other information. Except as provided in paragraph (l) of this section, to obtain and use information for the purpose of determining the legal liability of the third parties so that the agency may process claims under the third party liability payment procedures specified in §433.139(b) through (f), the agency must take the following actions:

(1) Except as specified in paragraph (d)(2) of this section, as part of the data exchange requirements under §435.945 of this chapter, from the State wage information collection agency (SWICA) defined in §435.4 of this chapter and from the SSA wage and earnings files data as specified in §435.948(a)(2) of this chapter, the agency must—
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(i) Use the information that identifies Medicaid recipients that are employed and their employer(s); and
(ii) Obtain and use, if their names and SSNs are available to the agency under paragraph (c) of this section, information that identifies employed absent or custodial parents of recipients and their employer(s).

(2) If the agency can demonstrate to HCFA that it has an alternate source of information that furnishes information as timely, complete and useful as the SWICA and SSA wage and earnings files in determining the legal liability of third parties, the requirements of paragraph (d)(1) of this section are deemed to be met.

(3) The agency must request, as required under § 435.948(a)(6)(i), from the State title IV±A agency, information not previously reported that identifies those Medicaid recipients that are employed and their employer(s).

(4) Except as specified in paragraph (d)(5) of this section, the agency must attempt to secure agreements (to the extent permitted by State law) to provide for obtaining—
(i) From State Workers' Compensation or Industrial Accident Commission files, information that identifies Medicaid recipients and, if their names and SSNs were available to the agency under paragraph (c) of this section absent or custodial parents of Medicaid recipients with employment-related injuries or illnesses; and
(ii) From State Motor Vehicle accident report files, information that identifies those Medicaid recipients injured in motor vehicle accidents, whether injured as pedestrians, drivers, passengers, or bicyclists.

(5) If unable to secure agreements as specified in paragraph (d)(4) of this section, the agency must submit documentation to the regional office that demonstrates the agency made a reasonable attempt to secure these agreements. If HCFA determines that a reasonable attempt was made, the requirements of paragraph (d)(4) of this section are deemed to be met.

(e) Diagnosis and trauma code edits. (1) Except as specified under paragraph (e)(2) or (l) of this section, or both, the agency must take action to identify those paid claims for Medicaid recipients that contain diagnosis codes 800 through 999 International Classification of Disease, 9th Revision, Clinical Modification, Volume 1 (ICD-9-CM) inclusive, for the purpose of determining the legal liability of third parties so that the agency may process claims under the third party liability payment procedures specified in § 433.139(b) through (f).

(2) The agency may exclude code 994.6, Motion Sickness, from the edits required under paragraph (e)(1) of this section.

(f) Data exchanges and trauma code edits: Frequency. Except as provided in paragraph (l) of this section, the agency must conduct the data exchanges required in paragraphs (d)(1) and (d)(3) of this section in accordance with the intervals specified in § 435.948 of this chapter, and diagnosis and trauma code edits required in paragraphs (d)(4) and (e) of this section on a routine and timely basis. The State plan must specify the frequency of these activities.

(g) Followup procedures for identifying legally liable third party resources. Except as provided in paragraph (l) of this section, the State must meet the requirements of this paragraph.
(1) SWICA, SSA wage and earnings files, and title IV±A data exchanges. With respect to information obtained under paragraphs (d)(1) through (d)(3) of this section—
(i) Except as specified in § 435.952(d) of this chapter, within 45 days, the agency must followup (if appropriate) on such information in order to identify legally liable third party resources and incorporate such information into the eligibility case file and into its third party data base and third party recovery unit so the agency may process claims under the third party liability payment procedures specified in §433.139(b) through (f); and
(ii) The State plan must describe the methods the agency uses for meeting the requirements of paragraph (g)(1)(i) of this section.

(2) Health insurance information and workers' compensation data exchanges. With respect to information obtained under paragraphs (b) and (d)(4)(i) of this section—
(i) Within 60 days, the agency must followup on such information (if appropriate) in order to identify legally liable third party resources and incorporate such information into the eligibility case file and into its third party data base and third party recovery unit so the agency may process claims under the third party liability payment procedures specified in §433.139 (b) through (f); and

(ii) The State plan must describe the methods the agency uses for meeting the requirements of paragraph (g)(2)(i) of this section.

(3) State motor vehicle accident report file data exchanges. With respect to information obtained under paragraph (d)(4)(ii) of this section—

(i) The State plan must describe the methods the agency uses for following up on such information in order to identify legally liable third party resources so the agency may process claims under the third party liability payment procedures specified in §433.139 (b) through (f);

(ii) After followup, the agency must incorporate all information that identifies legally liable third party resources into the eligibility case file and into its third party data base and third party recovery unit; and

(iii) The State plan must specify timeframes for incorporation of the information.

(4) Diagnosis and trauma code edits. With respect to the paid claims identified under paragraph (e) of this section—

(i) The State plan must describe the methods the agency uses to follow up on such claims in order to identify legally liable third party resources so the agency may process claims under the third party liability payment procedures specified in §433.139 (b) through (f) (Methods must include a procedure for periodically identifying those trauma codes that yield the highest third party collections and giving priority to following up on those codes);

(ii) After followup, the agency must incorporate all information that identifies legally liable third party resources into the eligibility case file and into its third party data base and third party recovery unit; and

(iii) The State plan must specify the timeframes for incorporation of the information.

(h) Obtaining other information and data exchanges: Safeguarding information. (1) The agency must safeguard information obtained from and exchanged under this section with other agencies in accordance with the requirements set forth in part 431, subpart F of this chapter.

(2) Before requesting information from, or releasing information to other agencies to identify legally liable third party resources under paragraph (d) of this section the agency must execute data exchange agreements with those agencies. The agreements, at a minimum, must specify—

(i) The information to be exchanged;

(ii) The titles of all agency officials with the authority to request third party information;

(iii) The methods, including the formats to be used, and the timing for requesting and providing the information;

(iv) The safeguards limiting the use and disclosure of the information as required by Federal or State law or regulations; and

(v) The method the agency will use to reimburse reasonable costs of furnishing the information if payment is requested.

(i) Reimbursement. The agency must, upon request, reimburse an agency for the reasonable costs incurred in furnishing information under this section to the Medicaid agency.

(j) Reports. The agency must provide such reports with respect to the data exchanges and trauma code edits set forth in paragraphs (d)(1) through (d)(4) and paragraph (e) of this section, respectively, as the Secretary prescribes for the purpose of determining compliance under §433.138 and evaluating the effectiveness of the third party liability identification system. However, if the State is not meeting the provisions of paragraph (e) of this section because it has been granted a waiver of those provisions under paragraph (l) of this section, it is not required to provide the reports required in this paragraph.

(k) Integration with the State mechanized claims processing and information
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retrieval system. Basic requirement—Development of an action plan. (1) If a State has a mechanized claims processing and information retrieval system approved by HCFA under subpart C of this part, the agency must have an action plan for pursuing third party liability claims and the action plan must be integrated with the mechanized claims processing and information retrieval system.

(2) The action plan must describe the actions and methodologies the State will follow to—

(i) Identify third parties;

(ii) Determine the liability of third parties;

(iii) Avoid payment of third party claims as required in §433.139;

(iv) Recover reimbursement from third parties after Medicaid claims payment as required in §433.139; and,

(v) Record information and actions relating to the action plan.

(3) The action plan must be consistent with the conditions for reapproval set forth in §433.119. The portion of the plan which is integrated with MMIS is monitored in accordance with those conditions and if the conditions are not met, it is subject to FFP reduction in accordance with procedures set forth in §433.120. The State is not subject to any other penalty as a result of other monitoring, quality control, or auditing requirements for those items in the action plan.

(4) The agency must submit its action plan to the HCFA Regional Office within 120 days from the date HCFA issues implementing instructions for the State Medicaid Manual. If a State does not have an approved MMIS on the date of issuance of the State Medicaid Manual but subsequently implements an MMIS, the State must submit its action plan within 90 days from the date the system is operational. The HCFA Regional Office approves or disapproves the action plan.

I. Waiver of requirements.

(1) Agency may request initial and continuing waiver of the requirements to determine third party liability found in paragraphs (c), (d)(4), (d)(5), (e), (f), (g)(1), (g)(2), (g)(3), and (g)(4) of this section if the State determines the activity to be not cost-effective. An activity would not be cost-effective if the cost of the required activity exceeds the third party liability recoupment and the required activity accomplishes, at the same or at a higher cost, the same objective as another activity that is being performed by the State.

(i) The agency must submit a request for waiver of the requirement in writing to the HCFA Regional Office.

(ii) The request must contain adequate documentation to establish that to meet a requirement specified by the agency is not cost-effective. Examples of documentation are claims recovery data and a State analysis documenting a cost-effective alternative that accomplished the same task.

(iii) The agency must agree, if a waiver is granted, to notify HCFA of any event that occurs that changes the conditions upon which the waiver was approved.

(2) HCFA will review a State's request to have a requirement specified under paragraph (l)(1) of this section waived and will request additional information from the State, if necessary. HCFA will notify the State of its approval or disapproval determination within 30 days of receipt of a properly documented request.

(3) HCFA may rescind a waiver at any time that it determines that the agency no longer meets the criteria for approving the waiver. If the waiver is rescinded, the agency has 6 months from the date of the rescission notice to meet the requirement that had been waived.

§433.139 Payment of claims.

(a) Basic provisions. (1) For claims involving third party liability that are processed on or after May 12, 1986, the agency must use the procedures specified in paragraphs (b) through (f) of this section.

(2) The agency must submit documentation of the methods (e.g., cost avoidance, pay and recover later) it uses for payment of claims involving third party liability to the HCFA Regional Office.
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(42 CFR Ch. IV (10-1-98 Edition))

(b) Probable liability is established at the time claim is filed. Except as provided in paragraph (e) of this section—

(1) If the agency has established the probable existence of third party liability at the time the claim is filed, the agency must reject the claim and return it to the provider for a determination of the amount of liability. The establishment of third party liability takes place when the agency receives confirmation from the provider or a third party resource indicating the extent of third party liability. When the amount of liability is determined, the agency must then pay the claim to the extent that payment allowed under the agency’s payment schedule exceeds the amount of the third party’s payment.

(2) The agency may pay the full amount allowed under the agency’s payment schedule for the claim and then seek reimbursement from any liable third party to the limit of legal liability if the claim is for labor and delivery and postpartum care. (Costs associated with the inpatient hospital stay for labor and delivery and postpartum care must be cost-avoided.)

(3) The agency must pay the full amount allowed under the agency’s payment schedule for the claim and seek reimbursement from any liable third party to the limit of legal liability if the third party liability is derived from an absent parent whose obligation to pay support is being enforced by the State title IV-D agency, consistent with paragraph (f) of this section if—

(i) The claim is prenatal care for pregnant women, or preventive pediatric services (including early and periodic screening, diagnosis and treatment services provided for under part 441, subpart B of this chapter), that is covered under the State plan; or

(ii) The claim is for a service covered under the State plan that is provided to an individual on whose behalf child support enforcement is being carried out by the State title IV-D agency. The agency prior to making any payment under this section must assure that the following requirements are met:

(A) The State plan specifies whether or not providers are required to bill the third party.

(B) The provider certifies that before billing Medicaid, if the provider has billed a third party, the provider has waited 30 days from the date of the service and has not received payment from the third party.

(C) The State plan specifies the method used in determining the provider’s compliance with the billing requirements.

(D) Probable liability is not established or benefits are not available at the time claim is filed. If the probable existence of third party liability cannot be established or third party benefits are not available to pay the recipient’s medical expenses at the time the claim is filed, the agency must pay the full amount allowed under the agency’s payment schedule.

(d) Recovery of reimbursement. (1) If the agency has an approved waiver under paragraph (e) of this section to pay a claim in which the probable existence of third party liability has been established and then seek reimbursement, the agency must seek recovery of reimbursement from the third party to the limit of legal liability within 60 days after the end of the month in which payment is made unless the agency has a waiver of the 60-day requirement under paragraph (e) of this section.

(2) Except as provided in paragraph (e) of this section, if the agency learns of the existence of a liable third party after a claim is paid, or benefits become available from a third party after a claim is paid, the agency must seek recovery of reimbursement within 60 days after the end of the month it learns of the existence of the liable third party or benefits become available.

(3) Reimbursement must be sought unless the agency determines that recovery would not be cost effective in accordance with paragraph (f) of this section.

(e) Waiver of requirements. (1) The agency may request initial and continuing waiver of the requirements in paragraphs (b)(1), (d)(1), and (d)(2) of this section, if it determines that the requirement is not cost-effective. An
activity would not be cost-effective if the cost of the required activity exceeds the third party liability recoupment and the required activity accomplishes, at the same or at a higher cost, the same objective as another activity that is being performed by the State.

(i) The agency must submit a request for waiver of the requirement in writing to the HCFA regional office.

(ii) The request must contain adequate documentation to establish that to meet a requirement specified by the agency is not cost-effective. Examples of documentation are costs associated with billing, claims recovery data, and a State analysis documenting a cost-effective alternative that accomplishes the same task.

(iii) The agency must agree, if a waiver is granted, to notify HCFA of any event that occurs that changes the conditions upon which the waiver was approved.

(2) HCFA will review a State's request to have a requirement specified under paragraph (e)(1) of this section waived and will request additional information from the State, if necessary. HCFA will notify the State of its approval or disapproval determination within 30 days of receipt of a properly documented request.

(3) HCFA may rescind the waiver at any time that it determines that the State no longer meets the criteria for approving the waiver. If the waiver is rescinded, the agency has 6 months from the date of the rescission notice to meet the requirement that had been waived.

(4) An agency requesting a waiver of the requirements specifically concerning either the 60-day limit in paragraph (d)(1) or (d)(2) of this section must submit documentation of written agreement between the agency and the third party, including Medicare fiscal intermediaries and carriers, that extension of the billing requirement is agreeable to all parties.

(f) Suspension or termination of recovery of reimbursement. (1) An agency must seek reimbursement from a liable third party on all claims for which it determines that the amount it reasonably expects to recover will be greater than the cost of recovery. Recovery efforts may be suspended or terminated only if they are not cost-effective.

(2) The State plan must specify the threshold amount or other guideline that the agency uses in determining whether to seek recovery of reimbursement from a liable third party, or describe the process by which the agency determines that seeking recovery of reimbursement would not be cost-effective.

(3) The State plan must also specify the dollar amount or period of time for which it will accumulate billings with respect to a particular liable third party in making the decision whether to seek recovery of reimbursement.

§ 433.140 FFP and repayment of Federal share.

(a) FFP is not available in Medicaid payments if—

(1) The agency failed to fulfill the requirements of §§ 433.138 and 433.139 with regard to establishing liability and seeking reimbursement from a third party;

(2) The agency received reimbursement from a liable third party; or

(3) A private insurer would have been obligated to pay for the service except that its insurance contract limits or excludes payments if the individual is eligible for Medicaid.

(b) FFP is available at the 50 percent rate for the agency's expenditures in carrying out the requirements of this subpart.

(c) If the State receives FFP in Medicaid payments for which it receives third party reimbursement, the State must pay the Federal government a portion of the reimbursement determined in accordance with the FMAP for the State. This payment may be reduced by the total amount needed to meet the incentive payment in § 433.153.

§ 433.145 Assignment of rights to benefits—State plan requirements.

(a) A State plan must provide that, as a condition of eligibility, each legally able applicant or recipient is required to:
§ 433.146 Rights assigned; assignment method.

(a) Except as specified in paragraph (b) of this section, the agency must require the individual to assign to the State—

(1) His own rights to any medical care support available under an order of a court or an administrative agency, and any third party payments for medical care; and

(2) The rights of any other individual eligible under the plan, for whom he can legally make an assignment.

(b) Assignment of rights to benefits may not include assignment of rights to Medicare benefits.

(c) If assignment of rights to benefits is automatic because of State law, the agency may substitute such an assignment for an individual executed assignment, as long as the agency informs the individual of the terms and consequences of the State law.

§ 433.147 Cooperation in establishing paternity and in obtaining medical support and payments and in identifying and providing information to assist in pursuing third parties who may be liable to pay.

(a) Scope of requirement. The agency must require the individual who assigns his or her rights to cooperate in—

(1) Establishing paternity of a child born out of wedlock and obtaining medical support and payments for himself or herself and any other person for whom the individual can legally assign rights, except that individuals described in section 1902(l)(1)(A) of the Act (poverty level pregnant women) are exempt from these requirements involving paternity and obtaining medical support and payments from, or derived from, the father of the child born out of wedlock; and

(2) Identifying and providing information to the Medicaid agency in pursuing third parties who may be liable to pay for care and services under the plan.

(b) Essentials of cooperation. As part of a cooperation, the agency may require an individual to—

(1) Appear at a State or local office designated by the agency to provide information or evidence relevant to the case;

(2) Appear as a witness at a court or other proceeding;

(3) Provide information, or attest to lack of information, under penalty of perjury;

(4) Pay to the agency any support or medical care funds received that are covered by the assignment of rights; and

(5) Take any other reasonable steps to assist in establishing paternity and securing medical support and payments, and in identifying and providing information to assist the State in pursuing any liable third party.

(c) Waiver of cooperation for good cause. The agency must waive the requirements in paragraphs (a) and (b) of
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this section if it determines that the individual has good cause for refusing to cooperate.

(1) With respect to establishing paternity of a child born out of wedlock or obtaining medical care support and payments, or identifying or providing information to assist the State in pursuing any liable third party for a child for whom the individual can legally assign rights, the agency must find the cooperation is against the best interests of the child, in accordance with factors specified for the Child Support Enforcement Program at 45 CFR part 232. If the State title IV–A agency has made a finding that good cause for refusal to cooperate does or does not exist, the Medicaid agency must adopt that finding as its own for this purpose.

(2) With respect to obtaining medical care support and payments for an individual and identifying and providing information to assist in pursuing liable third parties in any case not covered by paragraph (c)(1) of this section, the agency must find that cooperation is against the best interests of the individual or the person to whom Medicaid is being furnished because it is anticipated that cooperation will result in reprisal against, and cause physical or emotional harm to, the individual or other person.

(d) Procedures for waiving cooperation. With respect to establishing paternity, obtaining medical care support and payments, or identifying and providing information to assist the State in pursuing liable third parties in any case not covered by paragraph (c)(1) of this section, the agency must find that cooperation is against the best interests of the individual or the person to whom Medicaid is being furnished because it is anticipated that cooperation will result in reprisal against, and cause physical or emotional harm to, the individual or other person.

§433.148 Denial or termination of eligibility.

In administering the assignment of rights provision, the agency must:

(a) Deny or terminate eligibility for any applicant or recipient who—

(1) Refuses to assign his own rights or those of any other individual for whom he can legally make an assignment; or

(2) Refuses to cooperate as required under §433.147(a) unless cooperation has been waived;

(b) Provide Medicaid to any individual who—

(1) Cannot legally assign his own rights; and

(2) Would otherwise be eligible for Medicaid but for the refusal, by a person legally able to assign his rights, to assign his rights or to cooperate as required by this subpart; and

(c) In denying or terminating eligibility, comply with the notice and hearing requirements of part 431, subpart E of this subchapter.

COOPERATIVE AGREEMENTS AND INCENTIVE PAYMENTS

§433.151 Cooperative agreements and incentive payments—State plan requirements.

For medical assistance furnished on or after October 1, 1984—

(a) A State plan must provide for entering into written cooperative agreements for enforcement of rights to and collection of third party benefits with at least one of the following entities: The State title IV–D agency, any appropriate agency of any State, and appropriate courts and law enforcement officials. The agreements must be in accordance with the provisions of §433.152.

(b) A State plan must provide that the requirements for making incentive payments and for distributing third party collections specified in §§433.153 and 433.154 are met.


§433.152 Requirements for cooperative agreements for third party collections.

(a) Except as specified in paragraph (b) of this section, the State agency
§ 433.153  Incentive payments to States and political subdivisions.

(a) When payments are required. The agency must make an incentive payment to a political subdivision, a legal entity of the subdivision such as a prosecuting or district attorney or a friend of the court, or another State that enforces and collects medical support and payments for the agency.

(b) Amount and source of payment. The incentive payment must equal 15 percent of the amount collected, and must be made from the Federal share of that amount.

(c) Payment to two or more jurisdictions. If more than one State or political subdivision is involved in enforcing and collecting support and payments:

(1) The agency must pay all of the incentive payment to the political subdivision, legal entity of the subdivision, or another State that collected medical support and payments at the request of the agency.

(2) The political subdivision, legal entity or other State that receives the incentive payment must then divide the incentive payment equally with any other political subdivisions, legal entities, or other States that assisted in the collection, unless an alternative allocation is agreed upon by all jurisdictions involved.

§ 433.154  Distribution of collections.

The agency must distribute collections as follows—

(a) To itself, an amount equal to State Medicaid expenditures for the individual on whose right the collection was based.

(b) To the Federal Government, the Federal share of the State Medicaid expenditures, minus any incentive payment made in accordance with § 433.153.

(c) To the recipient, any remaining amount. This amount must be treated as income or resources under part 435 or part 436 of this subchapter, as appropriate.
§ 433.310 Applicability of requirements.

(a) General rule. Except as provided in paragraphs (b) and (c) of this section, the provisions of this subpart apply to—

(1) Overpayments made to providers that are discovered by the State;

(2) Overpayments made to providers that are initially discovered by the provider and made known to the State agency; and

(3) Overpayments that are discovered through Federal reviews.

(b) Third party payments and probate collections. The requirements of this subpart do not apply to—

(1) Cases involving third party liability because, in these situations, recovery is sought for a Medicaid payment that would have been made had another party not been legally responsible for payment; and

(2) Probate collections from the estates of deceased Medicaid recipients, as they represent the recovery of payments properly made from resources later determined to be available to the State.

(c) Unallowable costs paid under rate-setting systems. (1) Unallowable costs for a prior year paid to an institutional provider under a rate-setting system that a State recovers through an adjustment to the per diem rate for a subsequent period do not constitute overpayments that are subject to the requirements of this subpart.

In such cases, the State is not required to refund the Federal share explicitly related to the original overpayment in accordance with the regulations in this subpart. Refund of the Federal share occurs when the State claims future expenditures made to the provider at a reduced rate.

(2) Unallowable costs for a prior year paid to an institutional provider under a rate-setting system that a State seeks to recover in a lump sum, by an installment repayment plan, or through reduction of future payments to which the provider would otherwise be entitled constitute overpayments that are subject to the requirements of this subpart.

(d) Recapture of depreciation upon gain on the sale of assets. Depreciation payments are considered overpayments for...
purposes of this subpart if a State requires their recapture in a discrete amount(s) upon gain on the sale of assets.

§ 433.312 Basic requirements for refunds.

(a) Basic rules. (1) Except as provided in paragraph (b) of this section, the Medicaid agency has 60 days from the date of discovery of an overpayment to a provider to recover or seek to recover the overpayment before the Federal share must be refunded to HCFA.

(2) The agency must refund the Federal share of overpayments at the end of the 60-day period following discovery in accordance with the requirements of this subpart, whether or not the State has recovered the overpayment from the provider.

(b) Exception. The agency is not required to refund the Federal share of an overpayment made to a provider when the State is unable to recover the overpayment amount because the provider has been determined bankrupt or out of business in accordance with § 433.318.

(c) Applicability. (1) The requirements of this subpart apply to overpayments made to Medicaid providers that occur and are discovered in any quarter that begins on or after October 1, 1985.

(2) The date upon which an overpayment occurs is the date upon which a Medicaid agency official or other State official first notifies a provider in writing that a Medicaid provider is required to return the overpayment.

§ 433.316 When discovery of overpayment occurs and its significance.

(a) General rule. The date on which an overpayment is discovered is the beginning date of the 60-calendar day period allowed a State to recover or seek to recover an overpayment before a refund of the Federal share of an overpayment must be made to HCFA.

(b) Requirements for notification. Unless a State official or fiscal agent of the State chooses to initiate a formal recoupment action against a provider without first giving written notification of its intent, a State Medicaid agency official or other State official must notify the provider in writing of any overpayment it discovers in accordance with State agency policies and procedures and must take reasonable actions to attempt to recover the overpayment in accordance with State law and procedures.

(c) Overpayments resulting from situations other than fraud or abuse. An overpayment resulting from a situation other than fraud or abuse is discovered on the earliest of—

(1) The date on which any Medicaid agency official or other State official first notifies a provider in writing of an overpayment and specifies a dollar amount that is subject to recovery;

(2) The date on which a provider initially acknowledges a specific overpaid amount in writing to the Medicaid agency; or

(3) The date on which any State official or fiscal agent of the State initiates a formal action to recoup a specific overpaid amount from a provider without having first notified the provider in writing.

(d) Overpayments resulting from fraud or abuse. An overpayment that results from fraud or abuse is discovered on the date of the final written notice of the State's overpayment determination that a Medicaid agency official or other State official sends to the provider.

(e) Overpayments identified through Federal reviews. If a Federal review at any time indicates that a State has failed to identify an overpayment or a State has identified an overpayment but has failed to either send written notice of the overpayment to the provider without having first notified the provider in writing, HCFA will consider the overpayment as discovered on the date that the Federal official first notifies the State in writing of the overpayment and specifies a dollar amount subject to recovery.

(f) Effect of changes in overpayment amount. Any adjustment in the amount of an overpayment during the 60-day period following discovery (made in accordance with the approved State plan, Federal law and regulations governing Medicaid, and the appeals resolution
process specified in State administrative policies and procedures) has the following effect on the 60-day recovery period:

(1) A downward adjustment in the amount of an overpayment subject to recovery that occurs after discovery does not change the original 60-day recovery period for the outstanding balance.

(2) An upward adjustment in the amount of an overpayment subject to recovery that occurs during the 60-day period following discovery does not change the 60-day recovery period for the original overpayment amount. A new 60-day period begins for the incremental amount only, beginning with the date of the State’s written notification to the provider regarding the upward adjustment.

(g) Effect of partial collection by State. A partial collection of an overpayment amount by the State from a provider during the 60-day period following discovery does not change the 60-day recovery period for the original overpayment amount. A new 60-day period begins for the incremental amount only, beginning with the date of the State’s written notification to the provider regarding the upward adjustment.

(h) Effect of administrative or judicial appeals. Any appeal rights extended to a provider do not extend the date of discovery.

§ 433.318 Overpayments involving providers who are bankrupt or out of business.

(a) Basic rules. (1) The agency is not required to refund the Federal share of an overpayment made to a provider as required by §433.312(a) to the extent that the State is unable to recover the overpayment because the provider has been determined bankrupt or out of business in accordance with the provisions of this section.

(2) The agency must notify the provider that an overpayment exists in any case involving a bankrupt or out-of-business provider and, if the debt has not been determined uncollectable, take reasonable actions to recover the overpayment during the 60-day recovery period in accordance with policies prescribed by applicable State law and administrative procedures.

(b) Overpayment debts that the State need not refund. Overpayments are considered debts that the State is unable to recover within the 60-day period following discovery if the following criteria are met:

(1) The provider has filed for bankruptcy, as specified in paragraph (c) of this section; or

(2) The provider has gone out of business and the State is unable to locate the provider and its assets, as specified in paragraph (d) of this section.

(c) Bankruptcy. The agency is not required to refund to HCFA the Federal share of an overpayment at the end of the 60-day period following discovery if—

(1) The provider has filed for bankruptcy in Federal court at the time of discovery of the overpayment or the provider files a bankruptcy petition in Federal court before the end of the 60-day period following discovery; and

(2) The State is on record with the court as a creditor of the petitioner in the amount of the Medicaid overpayment.

(d) Out of business. (1) The agency is not required to refund to HCFA the Federal share of an overpayment at the end of the 60-day period following discovery if the provider is out of business on the date of discovery of the overpayment or if the provider goes out of business before the end of the 60-day period following discovery.

(2) A provider is considered to be out of business on the effective date of a determination to that effect under State law. The agency must—

(i) Document its efforts to locate the party and its assets. These efforts must be consistent with applicable State policies and procedures; and

(ii) Make available an affidavit or certification from the appropriate State legal authority establishing that the provider is out of business and that the overpayment cannot be collected under State law and procedures and citing the effective date of that determination under State law.

(3) A provider is not out of business when ownership is transferred within the State unless State law and procedures deem a provider that has transferred ownership to be out of business and preclude collection of the overpayment from the provider.
§ 433.320

(e) Circumstances requiring refunds. If the 60-day recovery period has expired before an overpayment is found to be uncollectable under the provisions of this section, if the State recovers an overpayment amount under a court-approved discharge of bankruptcy, or if a bankruptcy petition is denied, the agency must refund the Federal share of the overpayment in accordance with the procedures specified in § 433.320.


§ 433.320 Procedures for refunds to HCFA.

(a) Basic requirements. (1) The agency must refund the Federal share of overpayments that are subject to recovery to HCFA through a credit on its Quarterly Statement of Expenditures (Form HCFA–64).

(2) The Federal share of overpayments subject to recovery must be credited on the Form HCFA–64 report submitted for the quarter in which the 60-day period following discovery, established in accordance with § 433.316, ends.

(3) A credit on the Form HCFA–64 must be made whether or not the overpayment has been recovered by the State from the provider.

(b) Effect of reporting collections and submitting reduced expenditure claims. (1) The State is not required to refund the Federal share of an overpayment when the State reports a collection or submits an expenditure claim reduced by a discrete amount to recover an overpayment prior to the end of the 60-day period following discovery.

(2) The State is not required to report on the Form HCFA–64 any collections made on overpayment amounts for which the Federal share has been refunded previously.

(3) If a State has refunded the Federal share of an overpayment as required under this subpart and the State subsequently makes recovery by reducing future provider payments by a discrete amount, the State need not reflect that reduction in its claim for Federal financial participation.

(c) Reclaiming overpayment amounts previously refunded to HCFA. If the amount of an overpayment is adjusted downward after the agency has credited HCFA with the Federal share, the agency may reclaim the amount of the downward adjustment on the Form HCFA–64. Under this provision—

(1) Downward adjustment to an overpayment amount previously credited to HCFA is allowed only if it is properly based on the approved State plan, Federal law and regulations governing Medicaid, and the appeals resolution processes specified in State administrative policies and procedures.

(2) The 2-year filing limit for retroactive claims for Medicaid expenditures does not apply. A downward adjustment is not considered a retroactive claim but rather a reclaiming of costs previously claimed.

(d) Expiration of 60-day recovery period. If an overpayment has not been determined uncollectable in accordance with the requirements of § 433.318 at the end of the 60-day period following discovery of the overpayment, the agency must refund the Federal share of the overpayment to HCFA in accordance with the procedures specified in paragraph (a) of this section.

(e) Court-approved discharge of bankruptcy. If the State recovers any portion of an overpayment under a court-approved discharge of bankruptcy, the agency must refund to HCFA the Federal share of the overpayment amount collected on the next quarterly expenditure report that is due to HCFA for the period that includes the date on which the collection occurs.

(f) Bankruptcy petition denied. If a provider's petition for bankruptcy is denied in Federal court, the agency must credit HCFA with the Federal share of the overpayment on the later of—

(1) The Form HCFA–64 submission due to HCFA immediately following the date of the decision of the court; or

(2) The Form HCFA–64 submission for the quarter in which the 60-day period following discovery of the overpayment ends.

(g) Reclaim of refunds. (1) If a provider is determined bankrupt or out of business under this section after the 60-day period following discovery of the overpayment and the State has not been able to make complete recovery, the agency may reclaim the amount of the Federal share of any unrecovered

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overpayment amount previously re-funded to HCFA. HCFA allows the re-claim of a refund by the agency if the agency submits to HCFA documentation that it has made reasonable efforts to obtain recovery.

(2) If the agency reclaims a refund of the Federal share of an overpayment—
   (i) In bankruptcy cases, the agency must submit to HCFA a statement of its efforts to recover the overpayment during the period before the petition for bankruptcy was filed; and
   (ii) In out-of-business cases, the agency must submit to HCFA a statement of its efforts to locate the provider and its assets and to recover the overpayment during any period before the provider is found to be out of business in accordance with §433.318.
(h) Supporting reports. The agency must report the following information to support each Quarterly Statement of Expenditures Form HCFA-64:
   (1) Amounts of overpayments not collected during the quarter but refunded because of the expiration of the 60-day period following discovery;
   (2) Upward and downward adjustments to amounts credited in previous quarters;
   (3) Amounts of overpayments collected under court-approved discharges of bankruptcy;
   (4) Amounts of previously reported overpayments to providers certified as bankrupt or out of business during the quarter; and
   (5) Amounts of overpayments previously credited and reclaimed by the State.

§433.322 Maintenance of records.

The Medicaid agency must maintain a separate record of all overpayment activities for each provider in a manner that satisfies the retention and access requirements of 45 CFR part 74, subpart D.

PART 434—CONTRACTS

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§ 434.1 Basis and scope.

(a) Basis. This part is based on sections 1902(a)(4) and 1903(m) of the Act. Section 1902(a)(4) requires that the State plan provide for methods of administration that the Secretary finds necessary for proper and efficient operation of the plan. Section 1903(m)(1)(A) of the Act defines an HMO as an entity that meets the requirements of the Public Health Service (PHS) Act to be a Federally qualified HMO, or meets two specified requirements pertaining to accessibility of services and fiscal solvency. Section 1903(m)(2)(A) limits risk-basis contracts for specified health services to entities that meet the HMO definition of section 1903(m)(1)(A) and sets forth certain enrollment and other requirements that these contracts must meet as a condition for FFP. Section 1903(m)(2)(B) exempts, from the limitations of section 1903(m)(2)(A), certain specified prepayment plans that are not HMOs.

(b) Scope. This part sets forth the requirements for contracts with certain organizations for furnishing Medicaid services or processing or paying Medicaid claims, or enhancing the agency’s capability for effective administration of the program:

- (A) A fiscal agent.
- (B) A health care project grant center.
- (C) A private nonmedical institution.
- (D) A health insuring organization.
- (E) A health maintenance organization.
- (F) A prepaid health plan.
- (G) A clinical laboratory.
- (H) A professional management service or consultant firm.

Enrolled recipient means an individual who is eligible for Medicaid and who enters into an agreement to receive services from a health maintenance organization or prepaid health plan that contracts with the agency under this part.

Federally qualified HMO means an HMO that has been determined by HCFA to be a qualified HMO under section 1310(d) of the PHS Act.

Fiscal agent means an entity that processes or pays vendor claims for the agency.

Health care project grant center means an entity that—

- (a) Is supported in whole or in part by Federal project grant financial assistance; and
- (b) Provides or arranges for medical services to recipients.

Health insuring organization (HIO) means an entity that—

- (a) Covers (through payments or arrangements with providers) services for recipients in exchange for a premium or subscription charge paid; and
- (b) Assumes risk for the costs of services it covers.

Health maintenance organization (HMO) means a public or private organization organized under State law that—

- (a) Is a federally qualified HMO; or
- (b) Meets the State plan’s definition of an HMO.

§ 434.2 Definitions.

As used in this part, unless the context indicates otherwise—

- Capitation fee means the fee the agency pays periodically to a contractor for each recipient enrolled under a contract for the provision of medical services under the State plan, whether or not the recipient receives the services during the period covered by the fee.

- Clinical laboratory means a facility that examines materials derived from the human body, for the purpose of providing information for the diagnosis, prevention or treatment of a disease or the assessment of a medical condition.

Contractor means any of the following entities that contract with the Medicaid agency under a State plan and in return for a payment, to process claims, to pay for or provide medical services, or to enhance the agency’s capability for effective administration of the program:

- (a) A fiscal agent.
- (B) A health care project grant center.
- (C) A private nonmedical institution.
- (D) A health insuring organization.
- (E) A health maintenance organization.
- (F) A prepaid health plan.
- (G) A clinical laboratory.
- (H) A professional management service or consultant firm.

Enrolled recipient means an individual who is eligible for Medicaid and who enters into an agreement to receive services from a health maintenance organization or prepaid health plan that contracts with the agency under this part.

Federally qualified HMO means an HMO that has been determined by HCFA to be a qualified HMO under section 1310(d) of the PHS Act.

Fiscal agent means an entity that processes or pays vendor claims for the agency.

Health care project grant center means an entity that—

- (a) Is supported in whole or in part by Federal project grant financial assistance; and
- (b) Provides or arranges for medical services to recipients.

Health insuring organization (HIO) means an entity that—

- (a) Covers (through payments or arrangements with providers) services for recipients in exchange for a premium or subscription charge paid; and
- (b) Assumes risk for the costs of services it covers.

Health maintenance organization (HMO) means a public or private organization organized under State law that—

- (a) Is a federally qualified HMO; or
- (b) Meets the State plan’s definition of an HMO.
Nonrisk means that the contractor is not at financial risk for changes in the cost or utilization of services provided for in the payment rate agreed upon at the beginning of the contract period. Under a nonrisk contract, the State agency may make retroactive adjustment during and at the end of the contract period so that the contractor is reimbursed for costs actually incurred, subject to the upper limit of payment established in §447.362 of this chapter, or any lower limit specified in the contract.

Prepaid health plan (PHP) means an entity that provides medical services to enrolled recipients, under contract with the Medical agency and on the basis of prepaid capitation fees, but is not subject to requirements in section 1903(m)(2)(A) of the Act.

Private nonmedical institution means an institution (such as a child-care facility or a maternity home) that—
(a) Is not, as a matter of regular business, a health insuring organization or a community health care center;
(b) Provides medical care to its residents through contracts or other arrangements with medical providers; and
(c) Receives capitation payments from the Medicaid agency, under a nonrisk contract, for its residents who are eligible for Medicaid.

Professional management service or consultant firm means a firm that performs management services such as auditing or staff training, or carries out studies or provides consultation aimed at improving State Medicaid operations, for example, with respect to reimbursement formulas or accounting systems.

Provisional status HMO means an HMO that the State agency has determined is a provisional status Federally qualified HMO because more than 90 days have elapsed since the HMO applied to the PHS for Federal qualification and the PHS has not made a final determination. The provisional status continues until the PHS makes the final determination or the contract with the Medicaid agency is terminated, whichever occurs first.

Risk or underwriting risk means the possibility that a contractor may incur a loss because the cost of providing services may exceed the payments made by the agency to the contractor for services covered under the contract.

§ 434.4 State plan requirement. If the State plan provides for contracts of the types covered by this part, the plan must also provide for meeting the applicable requirements of this part.

§ 434.6 General requirements for all contracts and subcontracts.

(a) Contracts. All contracts under this part must—
(1) Include provisions that define a sound and complete procurement contract, as required by 45 CFR part 74, appendix G;
(2) Identify the population covered by the contract;
(3) Specify any procedures for enrollment or reenrollment of the covered population;
(4) Specify the amount, duration, and scope of medical services to be provided or paid for;
(5) Provide that the agency and HHS may evaluate through inspection or other means, the quality, appropriateness and timeliness of services performed under the contract;
(6) Specify procedures and criteria for terminating the contract, including a requirement that the contractor promptly supply all information necessary for the reimbursement of any outstanding Medicaid claims;
(7) Provide that the contractor maintains an appropriate record system for services to enrolled recipients;
(8) Provide that the contractor safeguards information about recipients as required by part 431, subpart F of this chapter;
(9) Specify any activities to be performed by the contractor that are related to third party liability requirements in part 433, subpart D of this chapter;
(10) Specify which functions may be subcontracted; and
(11) Provide that any subcontracts meet the requirements of paragraph (b) of this section.
(b) Subcontracts. All subcontracts must be in writing and fulfill the requirements of this part that are appropriate to the service or activity delegated under the subcontract.

(c) Continued responsibility of contractor. No subcontract terminates the legal responsibility of the contractor to the agency to assure that all activities under the contract are carried out.

Subpart B—Contracts with Fiscal Agents and Private Nonmedical Institutions

§ 434.10 Contracts with fiscal agents.

Contracts with fiscal agents must—

(a) Meet the requirements of §434.6;

(b) Include termination procedures that require the contractors to supply promptly all material necessary for continued operation of payment and related systems. This material includes—

(1) Computer programs;

(2) Data files;

(3) User and operation manuals, and other documentation;

(4) System and program documentation; and

(5) Training programs for Medicaid agency staff, their agents or designated representatives in the operation and maintenance of the system;

(c) Offer to the State one or both of the following options, if the fiscal agent or the fiscal agent’s subcontractor has a proprietary right to material specified in paragraph (b) of this section:

(1) Purchasing the material; or

(2) Purchasing the use of the material through leasing or other means; and

(d) State that payment to providers will be made in accordance with part 447 of this chapter.

§ 434.12 Contracts with private nonmedical institutions.

Contracts with private nonmedical institutions must—

(a) Meet the requirements of §434.6;

(b) Specify a capitation fee based on the cost of the services provided, in accordance with the reimbursement requirements prescribed in part 447 of this chapter; and

(c) Specify when the capitation fee must be paid.

§ 434.14 [Reserved]

Subpart C—Contracts With HMOs and PHPs: Contract Requirements

GENERAL REQUIREMENTS

§ 434.20 Basic rules.

(a) Entities eligible for risk contracts for services specified in §434.21. A Medicaid agency may enter into a risk contract for the scope of services specified in §434.21, only with an entity that—

(1) Is a Federally qualified HMO, including a provisional status Federally qualified HMO;

(2) Meets the State plan’s definition of an HMO, as specified in paragraph (c) of this section;

(3) Is one of several entities identified in section 1903(m)(2)(B) (i), (ii) and (iii) of the Act, and considered as PHPs;

(4) Is one of certain Community, Migrant and Appalachian Health Centers identified in section 1903(m)(2)(G) of the Act. Unless they qualify for a total exemption under section 1903(m)(2)(B), these entities are subject to the regulations governing HMOs under this part, with the exception of the requirements of section 1903(m)(2)(A) (i) and (ii) of the Act; or

(5) Is an HIO that arranges for services and becomes operational before January 1, 1986.

(b) Entities eligible for other kinds of contracts. A Medicaid agency may enter into a nonrisk contract, or a risk contract for a scope of services other than the scope specified in §434.21(b), with any of the entities identified in paragraph (a) of this section, or with any other PHP.

(c) State plan definition of HMO. If the plan provides for risk contracts with entities that are not Federally qualified HMOs, for the services specified in §434.21(b), the plan must include a State definition of an HMO. Under the definition, the HMO must meet at least the following requirements:

(1) Be organized primarily for the purpose of providing health care services.

(2) Make the services it provides to its Medicaid enrollees as accessible to them (in terms of timeliness, amount, duration, and scope) as those services
Health Care Financing Administration, HHS

§ 434.26


§ 434.22 Application of sanctions to risk comprehensive contracts.

A risk comprehensive contract must provide that payments provided for under the contract will be denied for new enrollees when, and for so long as, payment for those enrollees is denied by HCFA under §434.67(e).

§ 434.23 Capitation fees.

The contract must specify—
(a) The actuarial basis for computation of the capitation fees; and
(b) That the capitation fees and any other payments provided for in the contract do not exceed the payment limits set forth in §§447.361 and 447.362 of this chapter.

§ 434.25 Coverage and enrollment.

(a) The contract must provide that—
(1) There will be an open enrollment period during which the HMO or PHP will accept individuals who are eligible to be covered under the contract—
(i) In the order in which they apply;
(ii) Without restriction, unless authorized by the Regional Administrator; and
(iii) Up to the limits set under the contract; and
(2) Enrollment is voluntary.
(b) Risk comprehensive contracts with HMOs must also provide that the HMO will not discriminate, against individuals eligible to be covered under contract, on the basis of health status or need for health services.

§ 434.26 Composition of enrollment.

(a) Basic rule. Except as provided in paragraph (b) of this section, the contract must provide that Medicare beneficiaries and Medicaid recipients constitute less than 75 percent of the total enrollment of the HMO or PHP.
(b) Exceptions—(1) Waiver for new HMOs with risk comprehensive contracts. The requirement of paragraph (a) of

are to nonenrolled Medicaid recipients within the area served by the HMO.

(3) Make provision, satisfactory to the Medicaid agency, against the risk of insolvency, and assure that Medicaid enrollees will not be liable for the HMO’s debts if it does become insolvent.

(d) Services that may be covered. A contract with an HMO or a PHP may cover services to enrolled recipients that are not provided under the plan to nonenrolled recipients as permitted under § 440.250(g) of this chapter.

(e) Requirements for all contracts. For all contracts with HMOs or PHPs—
(1) The contract must meet the requirements of §434.6;
(2) The Medicaid agency must carry out the responsibilities specified in subpart E of this part; and
(3) The contract must provide that any cost-sharing requirements imposed for services furnished to recipients are in accordance with §§447.50 through 447.58 of this chapter.


ADDITIONAL REQUIREMENTS

§ 434.21 Contracts that must meet additional requirements.

(a) Unless otherwise indicated, the additional requirements set forth in §§434.23 through 434.38 must be met in all types of contracts with HMOs and PHPs:
(1) Nonrisk contracts;
(2) Risk comprehensive contracts; and
(3) Other risk contracts.

(b) Risk comprehensive contracts are risk contracts for furnishing or arranging for comprehensive services, that is, inpatient hospital services and any of the following services, or any three or more of the following services or groups of services:
(1) Outpatient hospital services and rural health clinic services.
(2) Other laboratory and X-ray services.
(3) Skilled nursing facility (SNF) services, early and periodic screening, diagnosis and treatment (EPSDT), and family planning services.
(4) Physicians’ services.
(5) Home health services.
(c) Other risk contracts are risk contracts for a scope of services other than those specified in paragraph (b) of this section.

this section may be waived for up to three years from the date the Regional Administrator determines the entity to be an HMO (as provided in §434.71) if the HMO submits annual reports demonstrating to the Regional Administrator’s satisfaction, that it is making continuous efforts and progress toward achieving compliance with paragraph (a) of this section.

(2) Waiver for public HMOs with risk comprehensive contracts. The Regional Administrator may approve waiver or modification of the requirement of paragraph (a) of this section, for an HMO that is owned or operated by a State, county or municipal health department or hospital, if—

(i) There are special circumstances that justify modification or waiver; and

(ii) The HMO has made and continues to make reasonable efforts to enroll individuals who are not eligible for Medicare or Medicaid.

(3) Waiver for certain nonprofit HMOs with risk comprehensive contracts. The Regional Administrator may approve waiver or modification of the requirement of paragraph (a) of this section, for a nonprofit HMO which has a minimum of 25,000 members, is and has been federally qualified for a period of at least 4 years, provides basic health services through members of its staff, is located in an area designated as medically underserved under section 1302(7) of the Public Health Service Act, and has previously received a waiver under section 1115 of the Act of the requirement described in paragraph (a) of this section, if—

(i) There are special circumstances that justify modification or waiver; and

(ii) The HMO has made and continues to make reasonable efforts to enroll individuals who are not eligible for Medicare or Medicaid.

(4) Waiver for PHPs and for HMOs that have contracts other than risk comprehensive. The Medicaid agency may waive the requirement of paragraph (a) of this section if the PHP or HMO requests waiver and shows good cause.

(5) Special exemption. (i) Community, Migrant and Appalachian Health Centers identified in section 1903(m)(2)(G) of the Act are exempt from the basic rule; and

(ii) Health maintenance organizations (as defined in section 1903(m)(1)(A) of the Act) that are primarily owned and controlled by centers specified in paragraph (b)(5)(i) of this section are exempt from the basic rule if they furnish primary care services substantially through such centers.

§434.27 Termination of enrollment.

(a) All HMO and PHP contracts must specify—

(1) The reasons for which the HMO or PHP may terminate a recipient’s enrollment;

(2) That the HMO or PHP will not terminate enrollment because of an adverse change in the recipient’s health; and

(3) The methods by which the HMO or PHP will assure the agency that terminations are consistent with the reasons permitted under the contract and are not due to an adverse change in the recipient’s health.

(b) An HMO risk comprehensive contract must specify either—

(1) That an enrollee of an organization with a risk comprehensive contract may terminate enrollment freely at any time, effective no later than the first day of the second month after the month in which he or she requests termination; or

(2) If an agency chooses to restrict disenrollment rights under paragraph (d) of this section, that an enrollee may terminate enrollment freely during the first month of any period of enrollment up to 6 months, and may terminate enrollment during the remainder of the enrollment period only as provided under paragraph (e) of this section. Termination of enrollment during the first month of period of enrollment is effective no later than the first day of the second month after the month in which he or she requests termination. Termination of enrollment during the remainder of a period of enrollment is in accordance with paragraph (f) of this section.
§ 434.28 Advance directives.

A risk comprehensive contract with an HMO must provide for compliance with the requirements of subpart I of part 489 of this chapter relating to maintaining written policies and procedures respecting advance directives.
§ 434.29

This requirement includes provisions to inform and distribute written information to adult individuals concerning policies on advance directives, including a description of applicable State law. 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.

[60 FR 33293, June 27, 1995]

§ 434.29 Choice of health professional.

The contract must allow each enrolled recipient to choose his health professional in the HMO or the PHP to the extent possible and appropriate.

§ 434.30 Emergency medical service.

If the contract covers emergency medical services, it must—
(a) Provide that all covered emergency services are available 24 hours a day and 7 days a week, either in the contractor's own facilities or through arrangements, approved by the agency, with other providers;
(b) Specify the circumstances under which the emergency services will be covered when furnished by a provider with which the contractor does not have arrangements, including at least the following circumstances:
   (1) The services were needed immediately because of an injury or sudden illness; and
   (2) The time required to reach the contractor's facilities, or the facilities of a provider with which the contractor has arrangements, would have meant risk of permanent damage to the recipient's health; and
(c) Specify whether it is the contractor, or the agency, that will make prompt payment for covered emergency services that are furnished by providers specified in paragraph (b) of this section.

§ 434.32 Grievance procedure.

The contract must provide for an internal grievance procedure that—
(a) Is approved in writing by the agency;
(b) Provides for prompt resolution; and
(c) Assures the participation of individuals with authority to require corrective action.

§ 434.34 Quality assurance system.

The contract must provide for an internal quality assurance system that:
(a) Is consistent with the utilization control requirement of part 456 of this chapter;
(b) Provides for review by appropriate health professionals of the process followed in providing health services;
(c) Provides for systematic data collection of performance and patient results;
(d) Provides for interpretation of this data to the practitioners; and
(e) Provides for making needed changes.

[48 FR 54013, Nov. 30, 1983; 49 FR 9173, Mar. 12, 1984]

§ 434.36 Marketing.

The contract must specify the methods by which the HMO or PHP will assure the agency that marketing plans, procedures, and materials are accurate, and do not mislead, confuse, or defraud either recipients or the agency.

[53 FR 12016, Apr. 12, 1988]

§ 434.38 Inspection and audit of HMO's financial records.

A risk comprehensive contract with an HMO must provide that the agency and the Department may inspect and audit any financial records of the HMO or its subcontractors relating to the HMO's capacity to bear the risk of potential financial losses.

Subpart D—Contracts With Health Insuring Organizations

SOURCE: 55 FR 51295, Dec. 13, 1990, unless otherwise noted.

§ 434.40 Contract requirements.

(a) Contracts with health insuring organizations that are not subject to the requirements in section 1903(m)(2)(A) must:
   (1) Meet the general requirements for all contracts and subcontracts specified in §434.6;
   (2) Specify that the contractor assumes at least part of the underwriting risk and;
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§ 434.50 Proof of HMO or PHP capability.

(i) If the contractor assumes the full underwriting risk, specify that payment of the capitation fees to the contractor during the contract period constitutes full payment by the agency for the cost of medical services provided under the contract;

(ii) If the contractor assumes less than the full underwriting risk, specify how the risk is apportioned between the agency and the contractor;

(3) Specify whether the contractor returns to the agency part of any savings remaining after the allowable costs are deducted from the capitation fees, and if savings are returned, the apportionment between agency and the contractor; and

(4) Specify the extent, if any, to which the contractor may obtain reinsurance of a portion of the underwriting risk.

(b) The contract must—

(1) Specify that the capitation fee will not exceed the limits set forth under part 447 of this chapter.

(2) Specify that, except as permitted under paragraph (b) of this section, the capitation fee paid on behalf of each recipient may not be renegotiated—

(i) During the contract period if the contract period is 1 year or less; or

(ii) More often than annually if the contract period is for more than 1 year.

(3) Specify that the capitation fee will not include any amount for recoupment of any specific losses suffered by the contractor for risks assumed under the same contract or a prior contract with the agency; and

(4) Specify the actuarial basis for computation of the capitation fee.

(c) The capitation fee may be renegotiated more frequently than annually for recipients who are not enrolled at the time of renegotiation or if the renegotiation is required by changes in Federal or State law.

§ 434.44 Special rules for certain health insuring organizations.

(a) A health insuring organization that first enrolls patients on or after January 1, 1986, and arranges with other providers (through subcontract, or through other arrangements) for the delivery of services (as described in §434.21(b)) to Medicaid enrollees on a prepaid capitation risk basis—

(1) Subject to the general requirements set forth in §434.20 concerning services that may be covered; §434.20(e), which sets forth the requirements for all contracts; the additional requirements set forth in §§434.21 through 434.38; and the Medicaid agency responsibilities specified in subpart E of this part; and

(2) To be organized under the appropriate laws, including corporation laws, of the State in which it operates.

There is no Federal requirement that an HIO be organized under a State’s HMO law, if it has one. However, the health insuring organization must meet the State plan definition requirements in §434.20(c) (1), (2) and (3) of this chapter.

(b) Special exemption. Any health insuring organization subject to the requirements in paragraph (a) of this section, that is operating under the authority of a waiver granted to a State under section 1915(b) of the Act prior to January 1, 1986, is exempt from those requirements relating to composition of enrollment and disenrollment without cause in §§434.26 and 434.27(b), during the effective period of the waiver, including extensions and renewals.

Subpart E—Contracts with HMOs and PHPs: Medicaid Agency Responsibilities


§ 434.50 Proof of HMO or PHP capability.

The agency must obtain from each contractor proof of—
§ 434.52 Financial responsibility, including proof of adequate protection against insolvency; and

(b) The contractor's ability to provide the services under the contract efficiently, effectively, and economically.


§ 434.52 Furnishing of required services.

The agency must obtain assurances from each contractor that—

(a) It furnishes the health services required by enrolled recipients as promptly as is appropriate; and

(b) The services meet the agency's quality standards.

§ 434.53 Periodic medical audits.

(a) The agency must establish a system of periodic medical audits to ensure that each contractor furnishes quality and accessible health care to enrolled recipients.

(b) The system of periodic medical audits must—

(1) Provide for audits conducted at least once a year for each contractor;

(2) Identify and collect management data for use by medical audit personnel; and

(3) Provide that the data includes—

(i) Reasons for enrollment and termination; and

(ii) Use of services.

§ 434.57 Limit on payment to other providers.

The agency must ensure that, except as specified in §434.30(b) for emergency services, no payment is made for services furnished by a provider other than the contractor, if the services were available under the contract.

§ 434.59 Continued service to recipients whose enrollment is terminated.

The agency must arrange for Medicaid services without delay for any recipient whose enrollment is terminated, unless it is terminated because of ineligibility for Medicaid.

§ 434.61 Computation of capitation fees.

The agency must determine that the capitation fees and any other payments provided for in the contract are computed on an actuarially sound basis.

§ 434.63 Monitoring procedures.

The agency must have procedures to do the following:

(a) Monitor enrollment and termination practices.

(b) Ensure proper implementation of the contractor's grievance procedures.

(c) Monitor for violations of the requirements specified in §434.67 and the conditions necessary for FFP in contracts with HMOs specified in §434.80.

[59 FR 36084, July 15, 1994]

§ 434.65 Services included in the State plan but not covered by the contract.

If the contract does not cover all services available under the State plan, the agency must arrange for services not included to be available and accessible. This may be done by having the contractor refer enrolled recipients to other providers or by some other means.

§ 434.67 Sanctions against HMOs with risk comprehensive contracts.

(a) Basis for imposition of sanctions. The agency may recommend that the intermediate sanction specified in paragraph (e) of this section be imposed if the agency determines that an HMO with a risk comprehensive contract does one or more of the following:

(1) Fails substantially to provide the medically necessary items and services required under law or under the contract to be provided to an enrolled recipient and the failure has adversely affected (or has substantial likelihood of adversely affecting) the individual.

(2) Imposes on Medicaid enrollees premium amounts in excess of premiums permitted.

(3) Engages in any practice that discriminates among individuals on the basis of their health status or requirements for health care services, including expulsion or refusal to reenroll an individual, or any practice that could...
reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by section 1903(m) of the Act) by eligible individuals whose medical conditions or histories indicate a need for substantial future medical services.

(4) Misrepresents or falsifies information that it furnishes, under section 1903(m) of the Act to HCFA, the State agency, an individual, or any other entity.

(5) Fails to comply with the requirements of §417.479(d) through (g) of this chapter relating to physician incentive plans, or fails to submit to the State Medicaid agency its physician incentive plans as required or requested in §434.70.

(b) Effect of an agency determination.

(1) When the agency determines that an HMO with a risk comprehensive contract has committed one of the violations identified in paragraph (a) of this section, the agency must forward this determination to HCFA. This determination becomes HCFA's determination for purposes of section 1903(m)(5)(A) of the Act, unless HCFA reverses or modifies the determination within 15 days.

(2) When the agency decides to recommend imposition of the sanction specified in paragraph (e) of this section, this recommendation becomes HCFA's decision for purposes of section 1903(m)(5)(B)(i) of the Act, unless HCFA reverses or modifies the recommendation within 15 days.

(2) When the agency determines that an HMO with a risk comprehensive contract has committed one of the violations identified in paragraph (a) of this section, the agency must forward this determination to HCFA. This determination becomes HCFA's determination for purposes of section 1903(m)(5)(A) of the Act, unless HCFA reverses or modifies the determination within 15 days.

(c) Notice of sanction. If a determination to impose a sanction becomes HCFA's determination under paragraph (b)(2) of this section, the agency must send a written notice to the HMO stating the nature and basis of the proposed sanction. A copy of the notice is forwarded to the OIG at the same time it is sent to the HMO. The agency allows the HMO 15 days from the date it receives 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. The agency may allow a 15-day addition to the original 15 days upon receipt of a written request from the organization. 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 the organization received the sanction notice. An extension is not granted if HCFA determines that the organization's conduct poses a threat to an enrollee's health and safety.

(d) Informal reconsideration. (1) If the HMO submits a timely response to the agency's notice of sanction, the agency conducts an informal reconsideration that includes—

(i) Review of the evidence by an agency official who did not participate in the initial recommendation to impose the sanction; and

(ii) A concise written decision setting forth the factual and legal basis for the decision.

(2) The agency decision under paragraph (d)(1)(ii) of this section is forwarded to HCFA and becomes HCFA's decision unless HCFA reverses or modifies the decision within 15 days from the date of HCFA's receipt of the agency determination. In the event HCFA modifies or reverses the agency decision, the agency sends the HMO a copy of HCFA's decision under this paragraph.

(e) Denial of payment. If a HCFA determination that a HMO has committed a violation described in paragraph (a) of this section is affirmed on review under paragraph (d) of this section, or is not timely contested by the HMO under paragraph (c) of this section, HCFA, based upon the recommendation of the agency, may deny payment for new enrollees of the HMO under section 1903(m)(5)(B)(ii) of the Act. Under §§434.22 and 434.42, HCFA's denial of payment for new enrollees automatically results in a denial of agency payments to the HMO for the same enrollees. A new enrollee is an enrollee that applies for enrollment after the effective date in paragraph (f)(1) of this section.

(f) Effective date and duration of sanction.

(1) Except as specified in paragraphs (f)(2) and (f)(3) of this section, a sanction is effective 15 days after the date the HMO is notified of the decision to impose the sanction under paragraph (c) of this section.

(2) If the HMO seeks reconsideration under paragraph (d) of this section, the
sanction is effective on the date specified in HCFA’s reconsideration notice.

(3) If HCFA, in consultation with the agency, determines that the HMO’s conduct poses a serious threat to an enrollee’s health and safety, the sanction may be made effective on a date prior to issuance of the decision under paragraph (d)(1)(ii) of this section.

(g) Civil money penalties. If a determination that an organization has committed a violation under paragraph (a) of this section becomes HCFA’s determination under paragraph (b)(1) of this section, HCFA conveys the determination to the OIG. In accordance with the provisions of 42 CFR part 1003, the OIG may impose civil money penalties on the organization in addition to or in place of the sanctions that may be imposed under this section.

(h) HCFA’s role. HCFA retains the right to independently perform the functions assigned to the agency in paragraphs (a) through (f) of this section.

(i) State Plan requirements. The State Plan must include a plan to monitor for violations specified in paragraph (a) of this section and for implementing the provisions of this section.

§ 434.70 Condition for FFP.

(a) FFP is available in expenditures for payments to contractors only for the periods that—

(1) The contract—

(i) Meets the requirements of this part;

(ii) Meets the appropriate requirements of 45 CFR part 74; and

(iii) Is in effect;

(2) The HMO or HIO complies with the physician incentive plan requirements specified in §§ 417.479(d) through (g) of this chapter and the requirements related to subcontracts set forth at § 417.479(i) of this chapter if the sub-contract is for the provision of services to Medicaid recipients;

(3) The HMO, HIO (or, in accordance with §417.479(i) of this chapter, the subcontracting entity) has supplied the information on its physician incentive plan listed in §417.479(h)(1) of this chapter to the State Medicaid agency. The information must contain detail sufficient to enable the State to determine whether the plan complies with the requirements of §417.479(d) through (g) of this chapter. The HMO or HIO must supply the information required under §417.479(h)(1)(i) through (h)(1)(v) of this chapter to the State Medicaid agency as follows:

(i) Prior to approval of its contract or agreement.

(ii) Upon the contract or agreements anniversary or renewal effective date.

(4) The HMO or HIO has provided the information on physician incentive plans listed in §417.479(h)(3) of this chapter to any Medicaid recipient who requests it.

(b) HCFA may withhold FFP for any period during which—

(1) The State fails to meet the State plan requirements of this part;

(2) Either party to a contract substantially fails to carry out the terms of the contract; or

(3) The State fails to obtain from each HMO or HIO contractor proof that it meets the requirements for physician incentive plans specified in §§417.479(d) through (g) and (i) of this chapter.

§ 434.71 Condition for FFP: Prior approval.

FFP is not available in expenditures under an HMO contract unless the agency secured prior written notice from the Regional Office, indicating that the contractor meets the definition of an HMO.

§ 434.72 Effect of a final determination that a provisional status HMO is not an HMO.

(a) FFP is available in expenditures for payments to a provisional status HMO until the Public Health Service reaches a final determination that it is not a federally qualified HMO.
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§ 434.74 Costs under risk-basis contracts.
Under each contract in which the contractor assumes an underwriting risk, the total amount paid by the agency for carrying out the provisions of the contract is a medical assistance cost.

§ 434.75 Costs under no-risk contracts.
Under each contract in which the contractor assumes no underwriting risk—
(a) The amount paid by the agency for furnishing medical services to eligible recipients is a medical assistance cost; and
(b) The amount paid by the agency for the contractor's performance of other functions is an administrative cost.

§ 434.76 Costs under fiscal agent contracts.
Under each contract with a fiscal agent—
(a) The amount paid to the provider of medical services is a medical assistance cost; and
(b) The amount paid to the contractor for performing the agreed-upon functions is an administrative cost.

§ 434.77 Right to reconsideration of disallowance.
A Medicaid agency dissatisfied with a disallowance of FFP under this subpart may request and will be granted reconsideration in accordance with 45 CFR part 16.

§ 434.78 Condition for FFP in contracts with HMOs.
(a) Basic rule. FFP in payments to an HMO is available only if the agency excludes from participation as such an entity any entity described in paragraph (b) of this section.

(b) Entities that must be excluded. (1) An entity that could be excluded under section 1128(b)(8) of the Act as being controlled by a sanctioned individual.
(2) An entity that has a substantial contractual relationship as defined in §431.55(h)(2), either directly or indirectly, with an individual convicted of certain crimes as described in section 1128(b)(8)(B) of the Act.
(3) An entity that employs or contracts, directly or indirectly, with one of the following:
   (i) Any individual or entity excluded from Medicaid participation under section 1128 or section 1129A of the Act for the furnishing of health care, utilization review, medical social work, or administrative services.
   (ii) Any entity for the provision through an excluded individual or entity of services described in paragraph (b)(3)(i) of this section.

[59 FR 36085, July 15, 1994]
Mandatory Coverage of Pregnant Women, Children under 8, and Newborn Children

435.116 Qualified pregnant women and children who are not qualified family members.

435.117 Newborn children.

Mandatory Coverage of Qualified Family Members

435.119 Qualified family members.

Mandatory Coverage of the Aged, Blind, and Disabled

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435.121 Individuals in States using more restrictive requirements for Medicaid than the SSI requirements.

435.122 Individuals who are ineligible for SSI or optional State supplements because of requirements that do not apply under title XIX of the Act.

435.130 Individuals receiving mandatory State supplements.

435.131 Individuals eligible as essential spouses in December 1973.

435.132 Institutionalized individuals who were eligible in December 1973.


435.134 Individuals who would be eligible except for the increase in OASDI benefits under Pub. L. 92-336 (July 1, 1972).

435.135 Individuals who become ineligible for cash assistance as a result of OASDI cost-of-living increases received after April 1977.

435.136 State agency implementation requirements for one-time notice and annual review system.

435.137 Disabled widows and widowers who would be eligible for SSI except for the increase in disability benefits resulting from elimination of the reduction under Pub. L. 98-31.

435.138 Disabled widows and widowers aged 60 through 64 who would be eligible for SSI benefits except for receipt of early social security benefits.

Mandatory Coverage of Certain Aliens

435.139 Coverage for certain aliens.

Mandatory Coverage of Adoption Assistance and Foster Care Children

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Mandatory Coverage of Special Groups

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435.225 Individuals under age 19 who would be eligible for Medicaid if they were in a medical institution.

435.227 Individuals under age 21 who are under State adoption assistance agreements.

Options for Coverage of the Aged, Blind, and Disabled

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435.310 Medically needy coverage of specified relatives.
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435.324 Medically needy coverage of the disabled in States that cover individuals receiving SSI.
435.326 Individuals who would be ineligible if they were not enrolled in an HMO.
435.330 Medically needy coverage of the aged, blind, and disabled in States using more restrictive eligibility requirements for Medicaid than those used under SSI.
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435.733 Post-eligibility treatment of income of institutionalized individuals in States using more restrictive requirements than SSI: Application of patient income to the cost of care.
435.735 Post-eligibility treatment of income and resources of individuals receiving home and community-based services furnished under a waiver: Application of patient income to the cost of care.

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  MEDICALLY NEEDY INCOME ELIGIBILITY

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Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

Source: 43 FR 45204, Sept. 29, 1978, unless otherwise noted.

Subpart A—General Provisions and Definitions

§ 435.2 Purpose and applicability.

This part sets forth, for the 50 States, the District of Columbia, the Northern Mariana Islands, and American Samoa—

(a) The eligibility provisions that a State plan must contain;
(b) The mandatory and optional groups of individuals to whom Medicaid is provided under a State plan;
(c) The eligibility requirements and procedures that the Medicaid agency must use in determining and redetermining eligibility, and requirements it may not use;
(d) The availability of FFP for providing Medicaid and for administering the eligibility provisions of the plan; and
(e) Other requirements concerning eligibility determinations, such as use of an institutionalized individual's income for the cost of care.


§ 435.3 Basis.

(a) This part implements the following sections of the Act and public laws
that mandate eligibility requirements and standards:

402(a)(22) Eligibility of deemed recipients of AFDC who receive zero payments because of recoupment of overpayments.

402(a)(37) Eligibility of individuals who lose AFDC eligibility due to increased earnings.

414(g) Eligibility of certain individuals participating in work supplementation programs.

473(b) Eligibility of children in foster care and adopted children who are deemed AFDC recipients.

1619(b) Benefits for blind individuals or those with disabling impairments whose income equals or exceeds a specific SSI limit.

1634(b) Preservation of benefit status for Medicaid eligible women.

1634(d) Individuals who lose eligibility for Medicaid because of 1983 changes in actuarial reduction formula.

412(e)(5) of Immigration and Nationality Act—Eligibility of certain refugees.


Pub. L. 99±603, section 9406 Payment for emergency medical services provided to aliens.

Pub. L. 99±603, section 99±603 Aliens granted legal status under section 245A of the Immigration and Nationality Act (8 U.S.C. 1255a) may under certain circumstances be eligible for Medicaid.

Pub. L. 99±603, section 302 Aliens granted legal status under section 210 of the Immigration and Nationality Act—Eligibility of certain recipients of Veterans Administration pensions.

Pub. L. 99±509, section 9406 Payment for emergency medical services provided to aliens.


Pub. L. 99±603, section 210 of the Immigration and Nationality Act—Eligibility of certain recipients of Veterans Administration pensions.

(b) This part implements the following other provisions of the Act or public laws that establish additional State plan requirements:

1618 Requirement for operation of certain State supplementation programs.

Pub. L. 93-66, section 212(a) Required mandatory minimum State supplementation of SSI benefits programs.

§ 435.4 Definitions and use of terms.

As used in this part—

AABD means aid to the aged, blind, and disabled under title XVI of the Act;

AB means aid to the blind under title X of the Act;

AFDC means aid to families with dependent children under title IV-A of the Act;

APTD means aid to the permanently and totally disabled under title XIV of the Act;

Categorically needy refers to families and children, aged, blind, or disabled individuals, and pregnant women, described under subparts B and C of this part who are eligible for Medicaid. Subpart B of this part describes the mandatory eligibility groups of individuals who, generally, are receiving or deemed to be receiving cash assistance under the Act. These mandatory groups are specified in sections 1902(a)(10)(A)(i), 1902(e), 1902(f), and 1902(h) of the Act. Subpart C of this part describes the optional eligibility groups of individuals who, generally, meet the categorical requirements or income or resource requirements that are the same as or less restrictive than those of the cash assistance programs and who are not receiving cash payments. These optional groups are specified in sections 1902(a)(10)(A)(ii), 1902(e), and 1902(h) of the Act.

Families and children refers to eligible members of families with children who are financially eligible under AFDC or medically needy rules and who are deprived of parental support or care as defined under the AFDC program (see 45 CFR 233.90, 233.100). In addition, this group includes individuals under age 21 who are not deprived of parental support or care but are financially eligible under AFDC rules or medically needy rules (see optional coverage group, §435.222). It does not include individuals under age 21 whose eligibility for Medicaid is based on blindness or disability—for these individuals, SSI rules govern;

Mandatory State supplement means a cash payment a State is required to make under section 212. Pub. L. 93-66 (July 9, 1973) to an aged, blind, or disabled individual. Its purpose is to provide an individual with the same amount of cash assistance he was receiving under OAA, AB, APTD, or AABD if his SSI payment is less than that amount;

Medically needy refers to families, children, aged, blind, or disabled individuals, and pregnant women listed under subpart D of this part who are not listed in subparts B and C of this part as categorically needy but who may be eligible for Medicaid under this part because their income and resources are within limits set by the State under its Medicaid plan (including persons whose income and resources fall within these limits after their incurred expenses for medical or remedial care are deducted) (Specific financial requirements for determining eligibility of the medically needy appear in subpart I of this part.);

OAA means old age assistance under title I of the Act;

OASDI means old age, survivors, and disability insurance under title II of the Act;

Optional State supplement means a cash payment made by a State, under section 1616 of the Act, to an aged, blind, or disabled individual;

SSI means supplemental security income under title XVI of the Act;

SWICA means the State Wage Information Collection Agency under section 1137(a) of the Act. It is the State agency administering the State unemployment compensation law; a separate agency administering a quarterly wage reporting system; or a State agency administering an alternative system.
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which has been determined by the Secretary of Labor, in consultation with the Secretary of Agriculture and the Secretary of Health and Human Services, to be as effective and timely in providing employment related income and eligibility data.


§ 435.10 State plan requirements.

A State plan must—

(a) Provide that the requirements of this part are met; and

(b) Specify the groups to whom Medicaid is provided, as specified in subparts B, C, and D of this part, and the conditions of eligibility for individuals in those groups.

Subpart B—Mandatory Coverage of the Categorically Needy

§ 435.100 Scope.

This subpart prescribes requirements for coverage of categorically needy individuals.

Mandatory Coverage of Families and Children

§ 435.110 Individuals receiving aid to families with dependent children.

(a) A Medicaid agency must provide Medicaid to individuals receiving AFDC.

(b) For purposes of this section, an individual is receiving AFDC if his needs are included in determining the amount of the AFDC payment. This includes an individual whose presence in the home is considered essential to the well-being of a recipient (see 45 CFR 233.20(a)(2)(vi)) and who could be a recipient under the State's AFDC plan if that plan were as broad as allowed under the Act for FFP.

§ 435.112 Families terminated from AFDC because of increased earnings or hours of employment.

(a) If a family loses AFDC solely because of increased income from employment or increased hours of employment, the agency must continue to provide Medicaid for 4 months to all members of the family if—

(1) The family received AFDC in any 3 or more months during the 6-month period immediately before the month in which it became ineligible for AFDC; and

(2) At least one member of the family is employed throughout the 4-month period, although this need not be the same member for the whole period.

(b) The 4 calendar month period begins on the date AFDC is terminated. If AFDC benefits are terminated retroactively, the 4 calendar month period also begins retroactively with the first month in which AFDC was erroneously paid.


§ 435.113 Individuals who are ineligible for AFDC because of requirements that do not apply under title XIX of the Act.

The agency must provide Medicaid to:

(a) Individuals denied AFDC solely because of policies requiring the deeming of income and resources of the following individuals who are not included as financially responsible relatives under section 1902(a)(17)(D) of the Act;

(1) Stepparents who are not legally liable for support of stepchildren under a State law of general applicability;

(2) Grandparents;

(3) Legal guardians;

(4) Alien sponsors who are not organizations; and

(5) Siblings.

(b) [Reserved]


§ 435.114 Individuals who would be eligible for AFDC except for increased OASDI income under Pub. L. 92-336 (July 1, 1972).

The agency must provide Medicaid to individuals who meet the following conditions:

(a) In August 1972, the individual was entitled to OASDI and—

(1) He was receiving AFDC; or

(2) He would have been eligible for AFDC if he had applied, and the Medicaid plan covered this optional group; or

(3) He was entitled to SSI; and

(b) His OASDI income was less than the amount at which the OASDI income test for (a) above would be met.

(c) His OASDI income was not received in respect of self-employment.

[59 FR 4026, Jan. 19, 1993]
§ 435.115 Individuals deemed to be receiving AFDC.

(a) The Medicaid agency must provide Medicaid to individuals deemed to be receiving AFDC, as specified in this section.

(b) The State must deem individuals to be receiving AFDC who are denied a cash payment from the title IV-A State agency solely because the amount of the AFDC payment would be less than $10.

(c) The State may deem participants in a work supplementation program to be receiving AFDC under section 414(g) of the Act. This section permits States, for purposes of title XIX, to deem an individual and any child or relative of the individual (or other individual living in the same household) to be receiving AFDC, if the individual—

(1) Participates in a State-operated work supplementation program under section 414 of the Act; and

(2) Would be eligible for an AFDC cash payment if the individual were not participating in the work supplementation program.

(d) The State must deem to be receiving AFDC those individuals who are denied AFDC payments from the title IV-A State agency solely because that agency is recovering an overpayment.

(e) The State must deem to be receiving AFDC individuals described in section 473(a)(1) of the Act—

(1) For whom an adoption assistance agreement is in effect under title IV-E of the Act, whether or not adoption assistance is being provided or an interlocutory or other judicial decree of adoption has been issued; or

(2) For whom foster care maintenance payments are made under title IV-E of the Act.

(f) The State must deem an individual to be receiving AFDC if a new collection or increased collection of child or spousal support under title IV-D of the Social Security Act results in the termination of AFDC eligibility in accordance with section 406(h) of the Social Security Act. States must continue to provide Medicaid for four consecutive calendar months, beginning with the first month of AFDC ineligibility, to each dependent child and each relative with whom such a child is living (including the eligible spouse of such relative as described in section 406(b) of the Social Security Act) who:

(1) Becomes ineligible for AFDC on or after August 16, 1984; and

(2) Has received AFDC for at least three of the six months immediately preceding the month in which the individual becomes ineligible for AFDC; and

(3) Becomes ineligible for AFDC wholly or partly as a result of the initiation of or an increase in the amount of the child or spousal support collection under title IV-D.

(g)(1) Except as provided in paragraph (g)(2) of this section, individuals who are eligible for extended Medicaid lose this coverage if they move to another State during the 4-month period. However, if they move back to and re-establish residence in the State in which they have extended coverage, they are eligible for any of the months remaining in the 4-month period in which they are residents of the State.

(2) If a State has chosen in its State plan to provide Medicaid to non-residents, the State may continue to provide the 4-month extended benefits to individuals who have moved to another State.

(h) For purposes of paragraph (f) of this section:

(1) The new collection or increased collection of child or spousal support results in the termination of AFDC eligibility when it actively causes or contributes to the termination. This occurs when:
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(i) The change in support collection in and of itself is sufficient to cause ineligibility. This rule applies even if the support collection must be added to other, stable income. It also applies even if other independent factors, alone or in combination with each other, might simultaneously cause ineligibility; or

(ii) The change in support contributes to ineligibility but does not by itself cause ineligibility. Ineligibility must result when the change in support is combined with other changes in income or changes in other circumstances and the other changes in income or circumstances cannot alone or in combination result in termination without the change in support.

(2) In cases of increases in the amounts of both support collections and earned income, eligibility under this section does not preclude eligibility under 45 CFR 233.20(a)(14) or section 1925 of the Social Security Act (which was added by section 303(a) of the Family Support Act of 1988 (42 U.S.C. 1396r-6)). Extended periods resulting from both an increase in the amount of the support collection and from an increase in earned income must run concurrently.


MANDATORY COVERAGE OF PREGNANT WOMEN, CHILDREN UNDER 8, AND NEWBORN CHILDREN

§ 435.116 Qualified pregnant women and children under 8, and newborn children

(a) The agency must provide Medicaid to a pregnant woman whose pregnancy has been medically verified and who—

(1) Would be eligible for an AFDC cash payment (or would be eligible for an AFDC cash payment if coverage under the State's AFDC plan included an AFDC-unemployed parents program) if her child had been born and was living with her in the month of payment;

(2) Is a member of a family that would be eligible for an AFDC cash payment if the State's AFDC plan included an AFDC-unemployed parents program; or

(3) Meets the income and resource requirements of the State's approved AFDC plan. In determining whether the woman meets the AFDC income and resource requirements, the unborn child or children are considered members of the household, and the woman's family is treated as though deprivation exists.

(b) The provisions of paragraphs (a) (1) and (2) of this section are effective October 1, 1984. The provisions of paragraph (a)(3) of this section are effective July 1, 1986.

(c) The agency must provide Medicaid to children who meet all of the following criteria:

(1) They are born after September 30, 1983;

(2) Effective October 1, 1988, they are under age 6 (or if designated by the State, any age that exceeds age 6 but does not exceed age 8), and effective October 1, 1989, they are under age 7 (or if designated by the State, any age that exceeds age 7 but does not exceed age 8); and

(3) They meet the income and resource requirements of the State's approved AFDC plan.


§ 435.117 Newborn children.

(a) The agency must provide categorically needy Medicaid eligibility to a child born to a woman who is eligible as categorically needy and is receiving Medicaid on the date of the child's birth. The child is deemed to have applied and been found eligible for Medicaid on the date of birth and remains eligible as categorically needy for one year so long as the woman remains eligible as categorically needy and the child is a member of the woman's household. If the mother's basis of eligibility changes to medically needy, the child is eligible as medically needy under § 435.301(b)(1)(iii).

(b) The requirements under paragraph (a) of this section apply to children born on or after October 1, 1984.

[52 FR 43071, Nov. 9, 1987]
MANDATORY COVERAGE OF QUALIFIED FAMILY MEMBERS

§ 435.119 Qualified family members.

(a) Definition. A qualified family member is any member of a family, including pregnant women and children eligible for Medicaid under § 435.116 of this subpart, who would be receiving AFDC cash benefits on the basis of the unemployment of the principal wage earner under section 407 of the Act had the State not chosen to place time limits on those benefits as permitted under section 407(b)(2)(B)(i) of the Act.

(b) State plan requirement. The State plan must provide that the State makes Medicaid available to any individual who meets the definition of “qualified family member” as specified in paragraph (a) of this section.

(c) Applicability. The provisions in this section are applicable in the 50 States and the District of Columbia from October 1, 1990, through September 30, 1998. The provisions are applicable in American Samoa from October 1, 1992, through September 30, 1998.

[58 FR 48614, Sept. 17, 1993]

MANDATORY COVERAGE OF THE AGED, BLIND, AND DISABLED

§ 435.120 Individuals receiving SSI.

Except as allowed under § 435.121, the agency must provide Medicaid to aged, blind, and disabled individuals who are SSI recipients, the agency must provide Medicaid to aged, blind, and disabled individuals who meet eligibility requirements that are specified in paragraph (a) of this section.

(a) Receiving SSI pending a final determination of blindness or disability;

(b) Receiving SSI under an agreement with the Social Security Administration to dispose of resources that exceed the SSI dollar limits on resources; or

(c) Receiving benefits under section 1619(a) of the Act or in section 1619(b) status (blind individuals or those with disabling impairments whose income equals or exceeds a specific Supplemental Security Income limit). (Regulations at 20 CFR 416.260 through 416.269 contain requirements governing determinations of eligibility under this provision.) For purposes of this paragraph (c), this mandatory categorically needy group of individuals includes those qualified severely impaired individuals defined in section 1905(q) of the Act.

§ 435.121 Individuals in States using more restrictive requirements for Medicaid than the SSI requirements.

(a) Basic eligibility group requirements. (1) If the agency does not provide Medicaid under § 435.120 to aged, blind, and disabled individuals who are SSI recipients, the agency must provide Medicaid to aged, blind, and disabled individuals who meet eligibility requirements that are specified in this section.

(2) Except to the extent provided in paragraph (a)(3) of this section, the agency may elect to apply more restrictive eligibility requirements to the aged, blind, and disabled that are more restrictive than those of the SSI program. The more restrictive requirements may be no more restrictive than those requirements contained in the State's Medicaid plan in effect on January 1, 1972. If any of the State's 1972 Medicaid plan requirements were more liberal than of the SSI program, the State must use the SSI requirement instead of the more liberal requirements, except to the extent the State elects to use more liberal criteria under § 435.601.

(b) Mandatory coverage. If the agency chooses to apply more restrictive requirements under the provisions of paragraph (a)(2) of this section if:

(i) The requirement conflicts with the requirements of section 1924 of the Act, which governs the eligibility and post-eligibility treatment of income and resources of institutionalized individuals with community spouses;

(ii) The requirement conflicts with a more liberal requirement which the agency has elected to use under § 435.601; or

(iii) The more restrictive requirement conflicts with a more liberal requirement the State has elected to use under § 435.234(c) in determining eligibility for State supplementary payments.

(b) Mandatory coverage. If the agency chooses to apply more restrictive requirements than SSI to aged, blind, or disabled individuals, it must provide Medicaid to:
§ 435.121

(1) Individuals who meet the requirements of section 1619(b)(3) of the Act even though they may not continue to meet the requirements of this section; and

(2) Qualified Medicare beneficiaries described in section 1905(p) of the Act and qualified working disabled individuals described in section 1905(s) of the Act without consideration of the more restrictive eligibility requirements specified in this section.

(3) Individuals who:

(i) Qualify for benefits under section 1619(a) or are in eligibility status under section 1619(b)(1) of the Act as determined by SSA; and

(ii) Were eligible for Medicaid under the more restrictive criteria in the State's approved Medicaid plan in the reference month—the month immediately preceding the first month in which they became eligible under section 1619(a) or (b)(1) of the Act. “Were eligible for Medicaid” means that individuals were issued Medicaid cards by the State for the reference month. Under this provision, the reference month for determining Medicaid eligibility for all individuals under section 1619 of the Act is the month immediately preceding the first month of the most recent period of eligibility under section 1619 of the Act.

(c) Group composition. The agency may apply more restrictive requirements only to the aged, to the blind, to the disabled, or to any combination of these groups. For example, the agency may apply more restrictive requirements to the aged and disabled under this provision and provide Medicaid to all blind individuals who are SSI recipients.

(d) Nonfinancial conditions. The agency may apply more restrictive requirements that are nonfinancial conditions of eligibility. For example, the agency may use a more restrictive definition of disability or may limit eligibility of the disabled to individuals age 18 and older, or both. If the agency limits eligibility of disabled individuals to individuals age 18 or older, it must provide Medicaid to individuals under age 18 who receive SSI benefits and who would be eligible to receive AFDC under the State's approved plan if they did not receive SSI. If the agency imposed an age limit for disabled individuals under its 1972 approved State plan but does not use that limit, it must apply the same nonfinancial requirement to individuals under age 18 that it applies to disabled individuals age 18 and older.

(e) Financial conditions.

(1) The agency may apply more restrictive requirements that are financial conditions of eligibility.

(2) Any income eligibility standards that the agency applies must:

(i) Equal the income standard (or Federal Benefit Rate (FBR)) that would be used under SSI based on an individual's living arrangement; or

(ii) Be a more restrictive standard which is no more restrictive than that under the approved State's January 1, 1972 Medicaid plan.

(3) If the categorically needy income standard established under paragraph (e)(2) of this section is less than the optional categorically needy standard established under §435.230, the agency must provide Medicaid to all aged, blind, and disabled individuals who have income equal to or below the higher standard.

(4) In a State that does not have a medically needy program that covers aged, blind, and disabled individuals, the agency must allow individuals to deduct from income incurred medical and remedial expenses (that is, spend down) to become eligible under this section. However, individuals with income above the categorically needy standards may only spend down to the standard selected by the State under paragraph (e)(2) of this section which applies to the individual's living arrangement.

(5) In a State that elects to provide medically needy coverage to aged, blind, and disabled individuals, the agency must allow individuals to deduct from income incurred medical and remedial care expenses (spend down) to become categorically needy when they are SSI recipients (including individuals deemed to be SSI recipients under §§435.135, 435.137, and 435.138), eligible spouses of SSI recipients, State supplement recipients, and individuals who are eligible for a supplement but who do not receive supplementary payments. Such persons may only spend...
§ 435.122 Individuals who are ineligible for SSI or optional State supplements because of requirements that do not apply under title XIX of the Act.

If an agency provides Medicaid to aged, blind, or disabled individuals receiving SSI or optional State supplements, it must provide Medicaid to individuals who would be eligible for SSI or optional State supplements except for an eligibility requirement used in those programs that is specifically prohibited under title XIX.

§ 435.130 Individuals receiving mandatory State supplements.

The agency must provide Medicaid to individuals receiving mandatory State supplements.

§ 435.131 Individuals eligible as essential spouses in December 1973.

(a) The agency must provide Medicaid to any person who was eligible for Medicaid in December 1973 as an essential spouse of an aged, blind, or disabled individual who was receiving cash assistance if the conditions in paragraph (b) of this section are met. An "essential spouse" is defined in section 1905(a) of the Act as one who is living with the individual, whose needs were included in determining the amount of cash payment to the individual under OAA, AB, APTD, or AABD, and who is determined essential to the individual's well-being.

(b) The agency must continue Medicaid if—

(1) The aged, blind, or disabled individual continues to meet the December 1973 eligibility requirements of the applicable State cash assistance plan; and

(2) The essential spouse continues to meet the conditions that were in effect in December 1973 under the applicable cash assistance plan for having his needs included in computing the payment to the aged, blind, or disabled individual.

§ 435.132 Institutionalized individuals who were eligible in December 1973.

The agency must provide Medicaid to individuals who were eligible for Medicaid in December 1973, or any part of that month, as inpatients of medical institutions or residents of intermediate care facilities that were participating in the Medicaid program and who—

(a) For each consecutive month after December 1973—

(1) Continue to meet the requirements for Medicaid eligibility that were in effect under the State's plan in
December 1973 for institutionalized individuals; and
(2) Remain institutionalized; and
(b) Are determined by the State or a professional standards review organization to continue to need institutional care.

§ 435.133 Blind and disabled individuals eligible in December 1973.

The agency must provide Medicaid to individuals who—
(a) Meet all current requirements for Medicaid eligibility except the criteria for blindness or disability;
(b) Were eligible for Medicaid in December 1973 as blind or disabled individuals, whether or not they were receiving cash assistance in December 1973; and
(c) For each consecutive month after December 1973, continue to meet the criteria for blindness or disability and the other conditions of eligibility used under the Medicaid plan in December 1973.

§ 435.134 Individuals who would be eligible except for the increase in OASDI benefits under Pub. L. 92-336 (July 1, 1972).

The agency must provide Medicaid to individuals who meet the following conditions:
(a) In August 1972, the individual was entitled to OASDI and—
(1) He was receiving OAA, AB, APTD, or AABD; or
(2) He would have been eligible for one of those programs except that he had not applied, and the Medicaid plan covered this optional group; or
(3) He would have been eligible for one of those programs if he were not in a medical institution or intermediate care facility, and the Medicaid plan covered this optional group.
(b) The individual would currently be eligible for SSI or a State supplement except that the increase in OASDI under Pub. L. 92-336 raised his income over the limit allowed under SSI. This includes an individual who—
(1) Meets all current SSI requirements except for the requirement to file an application; or
(2) Would meet all current SSI requirements if he were not in a medical institution or intermediate care facility, and the State’s Medicaid plan covers this optional group.

§ 435.135 Individuals who become ineligible for cash assistance as a result of OASDI cost-of-living increases received after April 1977.

(a) If an agency provides Medicaid to aged, blind, or disabled individuals receiving SSI or State supplements, it must provide Medicaid to individuals who—
(1) Are receiving OASDI;
(2) Were eligible for and receiving SSI or State supplements but became ineligible for those payments after April 1977; and
(3) Would still be eligible for SSI or State supplements if the amount of OASDI cost-of-living increases paid under section 215(i) of the Act, after the last month after April 1977 for which those individuals were both eligible for and received SSI or a State supplement and were entitled to OASDI, were deducted from current OASDI benefits.

(b) Cost-of-living increases include the increases received by the individual or his or her financially responsible spouse or other family member (e.g., a parent).
(c) If the agency adopts more restrictive eligibility requirements than those under SSI, it must provide Medicaid to individuals specified in paragraph (a) of this section on the same basis as Medicaid is provided to individuals continuing to receive SSI or State supplements. If the individual incurs enough medical expenses to reduce his or her income to the financial eligibility standard for the categorically needy, the agency must cover that individual as categorically needy. In determining the amount of his or her income, the agency may deduct the cost-of-living increases paid under section 215(i) after the last month after April 1977 for which that individual was both eligible for and received SSI or a State supplement and was entitled to OASDI, up to the amount that made him or her ineligible for SSI.

§ 435.136 Individuals who become eligible for cash assistance as a result of OASDI cost-of-living increases received after April 1977.

(a) If an agency provides Medicaid to aged, blind, or disabled individuals receiving SSI or State supplements, it must provide Medicaid to individuals who—
(1) Are receiving OASDI;
(2) Were eligible for and receiving SSI or State supplements but became ineligible for those payments after April 1977; and
(3) Would still be eligible for SSI or State supplements if the amount of OASDI cost-of-living increases paid under section 215(i) of the Act, after the last month after April 1977 for which those individuals were both eligible for and received SSI or a State supplement and were entitled to OASDI, were deducted from current OASDI benefits.

(b) Cost-of-living increases include the increases received by the individual or his or her financially responsible spouse or other family member (e.g., a parent).
(c) If the agency adopts more restrictive eligibility requirements than those under SSI, it must provide Medicaid to individuals specified in paragraph (a) of this section on the same basis as Medicaid is provided to individuals continuing to receive SSI or State supplements. If the individual incurs enough medical expenses to reduce his or her income to the financial eligibility standard for the categorically needy, the agency must cover that individual as categorically needy. In determining the amount of his or her income, the agency may deduct the cost-of-living increases paid under section 215(i) after the last month after April 1977 for which that individual was both eligible for and received SSI or a State supplement and was entitled to OASDI, up to the amount that made him or her ineligible for SSI.
§ 435.136 State agency implementation requirements for one-time notice and annual review system.

An agency must—
(a) Provide a one-time notice of potential Medicaid eligibility under §435.135 to all individuals who meet the requirements of §435.135(a) or (c) who were not receiving Medicaid as of March 9, 1984; and
(b) Establish an annual review system to identify individuals who meet the requirements of §435.135(a) or (c) who lose categorically needy eligibility for Medicaid because of a loss of SSI. States without medically needy programs must send notices of potential eligibility for Medicaid to these individuals for 3 consecutive years following their identification through the annual review system.

[51 FR 12330, Apr. 10, 1986]

§ 435.137 Disabled widows and widowers who would be eligible for SSI except for the increase in disability benefits resulting from elimination of the reduction factor under Pub. L. 98-21.

(a) If the agency provides Medicaid to aged, blind, or disabled individuals receiving SSI or State supplements, the agency must provide Medicaid to disabled widows and widowers who—
(1) Became ineligible for SSI or a mandatory or optional State supplement as a result of the elimination of the additional reduction factor for disabled widows and widowers under age 60 required by section 134 of Pub. L. 98-21, and for purposes of title XIX, are deemed to be title XVI payment recipients under section 1634(b) of the Social Security Act; and
(2) Meet the conditions of paragraphs (b) and (e) of this section.
(b) The individuals must meet the following conditions:
(1) They were entitled to monthly OASDI benefits under title II of the Act as of December 1983;
(2) They were entitled to and received widow's or widower's disability benefits under section 202(e) or (f) of the Act for January 1984;
(3) They became ineligible for SSI or a mandatory or optional State supplement in the first month in which the increase under Pub. L. 98-21 was paid (and in which a retroactive payment for that increase for prior months was not made);
(4) They have been continuously entitled to widow's or widower's disability benefits under section 202(e) or (f) from the first month that the increase under Pub. L. 98-21 was received; and
(5) They would be eligible for SSI benefits or a mandatory or optional State supplement if the amount of the increase under Pub. L. 98-21 and subsequent cost-of-living adjustments in widow's or widower's benefits under section 215(i) of the Act were deducted from their income.

(c) If the agency adopts more restrictive requirements than those under SSI, it must provide Medicaid to individuals specified in paragraph (a) of this section on the same basis as Medicaid is provided to individuals continuing to receive SSI or a mandatory or optional State supplement. The State must consider the individuals specified in paragraph (a) of this section to have no more income than the SSI Federal benefit rate if the individual was eligible for SSI in the month prior to the first month in which the increase under Public Law 98-21 was paid (and in which retroactive payments for that increase for prior months was not being made), and the individual would be eligible for SSI except for the amount of the increase under Public Law 98-21 and subsequent cost-of-living adjustments in his or her widow's or widower's benefits under section 215(i) of the Act. The State must consider individuals who qualify under paragraph (a) of this section on the basis of loss of a mandatory or optional State supplementary payment, rather than the loss of SSI, to have no more income than the relevant SSP rate. If the State's income eligibility level is lower than the SSP or SSI Federal benefit rates, individuals qualifying under paragraph (a) of this section who are deemed to have income at either the SSP rate or the SSI Federal benefit rate may further reduce their countable income by incurring medical expenses in the amount by which their income exceeds the State's income eligibility standard. When the individual has reduced his or her income by this
§ 435.170 Pregnant women eligible for extended coverage.

(a) The agency must provide categorically needy Medicaid eligibility
§ 435.200 Scope.

This subpart specifies options for coverage of individuals as categorically needy.

§ 435.201 Individuals included in optional groups.

(a) The agency may choose to cover as optional categorically needy any group or groups of the following individuals who are not receiving cash assistance and who meet the appropriate eligibility criteria for groups specified in the separate sections of this subpart:

1. Aged individuals (65 years of age or older);
2. Blind individuals (as defined in § 435.530);
3. Disabled individuals (as defined in § 435.541);
4. Individuals under age 21 (or, at State option, under age 20, 19, or 18) or reasonable classifications of these individuals;
5. Specified relatives under section 406(b)(1) of the Act who have in their care an individual who is determined to be dependent (or would, if needy, be dependent) as specified in § 435.510; and
6. Pregnant women.

(b) If the agency provides Medicaid to any individual in an optional group specified in paragraph (a) of this section, the agency must provide Medicaid to all individuals who apply and are found eligible to be members of that group.

(c) States that elect to use more restrictive eligibility requirements for Medicaid than the SSI requirements for any group or groups of aged, blind, and disabled individuals under § 435.121 must apply the specific requirements of § 435.230 in establishing eligibility of these groups of individuals as optional categorically needy.

[58 FR 4927, Jan. 19, 1993]

§ 435.210 Individuals who meet the income and resource requirements of the cash assistance programs.

The agency may provide Medicaid to any group or groups of individuals specified in § 435.201(a)(1) through (a)(3) and (a)(5) and (a)(6) who are not mandatory categorically needy, who meet the income and resource requirements of the appropriate cash assistance program for their status (that is, the State's approved AFDC plan or SSI, or optional State supplements in States that provide Medicaid to optional State supplement recipients).

§ 435.211 Individuals who would be eligible for cash assistance if they were not in medical institutions.

The agency may provide Medicaid to any group or groups of individuals specified in § 435.201(a) who are in title XIX reimbursable medical institutions and who:

(a) Are ineligible for the cash assistance program appropriate for their status (that is, AFDC or SSI, or optional State supplements in States that provide Medicaid to optional State supplement recipients) because of lower income standards used under the program to determine eligibility for institutionalized individuals; but

(b) Would be eligible for aid or assistance under the State's approved AFDC plan, SSI, or an optional State supplement as specified in § 435.232 and 

[58 FR 4027, Jan. 19, 1993]
§ 435.212 Individuals who would be ineligible if they were not enrolled in an HMO.

The agency may provide that a recipient who is enrolled in a federally qualified HMO (under a risk contract as specified in §434.20(a)(1) of this chapter) and who becomes ineligible for Medicaid is considered to continue to be eligible—

(a) For a period specified by the agency, ending no later than 6 months from the date of enrollment; and
(b) Except for family planning services (which the recipient may obtain from any qualified provider) only for services furnished to him or her as an HMO enrollee.

[56 FR 8849, Mar. 1, 1991]

§ 435.217 Individuals receiving home and community-based services.

The agency may provide Medicaid to any group or groups of individuals in the community who meet the following requirements:

(a) The group would be eligible for Medicaid if institutionalized.
(b) In the absence of home and community-based services under a waiver granted under part 441—
(1) Subpart G of this subchapter, the group would otherwise require the level of care furnished in a hospital, NF, or an ICF/MR; or
(2) Subpart H of this subchapter, the group would otherwise require the level of care furnished in an NF and are age 65 or older.
(c) The group receives the waivered services.

[57 FR 29155, June 30, 1992]

§ 435.220 Individuals who would meet the income and resource requirements of AFDC if child care costs were paid from earnings.

(a) The agency may provide Medicaid to any group or groups of individuals specified under §435.201 (a)(4), (a)(5), and (a)(6) who would meet the income and resource requirements under the State’s approved AFDC plan if their work-related child care costs were paid from their earnings rather than by a State agency as a service expenditure.
(b) The agency may use this option only if the State’s AFDC plan deducts work-related child care costs from income to determine the amount of AFDC.


§ 435.221 [Reserved]

§ 435.222 Individuals under age 21 who meet the income and resource requirements of AFDC.

(a) The agency may provide Medicaid to individuals under age 21 (or, at State option, under age 20, 19, or 18); or reasonable categories of these individuals as specified in paragraph (b) of this section, who are not receiving cash assistance under any program but who meet the income and resource requirements of the State’s approved AFDC plan.
(b) The agency may cover all individuals described in paragraph (a) of this section or reasonable classifications of those individuals. Examples of reasonable classifications are as follows:

(1) Individuals in foster homes or private institutions for whom a public agency is assuming a full or partial financial responsibility. If the agency covers these individuals, it may also provide Medicaid to individuals of the same age placed in foster homes or private institutions by private nonprofit agencies.

(2) Individuals in adoptions subsidized in full or in part by a public agency.

(3) Individuals in nursing facilities when nursing facility services are provided under the plan to individuals within the age group selected under this provision. If the agency covers these individuals, it may also provide Medicaid to individuals in intermediate care facilities for the mentally retarded.

(4) Individuals under age 21 receiving active treatment as inpatients in psychiatric facilities or programs, if
§ 435.223 Individuals who would be eligible for AFDC if coverage under the State's AFDC plan were as broad as allowed under title IV-A.

(a) The agency may provide Medicaid to any group or groups of individuals specified under §435.210 (a)(4), (a)(5), and (a)(6) who:

(1) Would be eligible for AFDC if the State's AFDC plan included individuals whose coverage under title IV-A is optional (for example, Medicaid may be provided to members of families with an unemployed parent even though AFDC is not available to them under the State's AFDC plan); or

(2) Would be eligible for AFDC if the State's AFDC plan did not contain eligibility requirements more restrictive than, or in addition to, those required under title IV-A.

(b) The agency may cover any AFDC optional group without covering all such groups.


§ 435.225 Individuals under age 19 who would be eligible for Medicaid if they were in a medical institution.

(a) The agency may provide Medicaid to children 18 years of age or younger who qualify under section 1614(a) of the Act, who would be eligible for Medicaid if they were in a medical institution, and who are receiving, while living at home, medical care that would be provided in a medical institution.

(b) If the agency elects the option provided by paragraph (a) of this section, it must determine, in each case, that the following conditions are met:

(1) The child requires the level of care provided in a hospital, SNF, or ICF.

(2) It is appropriate to provide that level of care outside such an institution.

(3) The estimated Medicaid cost of care outside an institution is no higher than the estimated Medicaid cost of appropriate institutional care.


§ 435.227 Individuals under age 21 who are under State adoption assistance agreements.

(a) The agency may provide Medicaid to individuals under the age of 21 (or, at State option, age 20, 19, or 18)—

(1) For whom an adoption agreement (other than an agreement under title IV-E) between the State and the adoptive parent(s) is in effect;

(2) Who, the State agency responsible for adoption assistance, has determined cannot be placed with adoptive parents without Medicaid because the child has special needs for medical or rehabilitative care; and

(3) Who meet either of the following:

(i) Were eligible for Medicaid under the State plan before the adoption agreement was entered into; or

(ii) Would have been eligible for Medicaid before the adoption agreement was entered into, if the eligibility standards and methodologies of the title IV-E foster care program were used without employing the threshold title IV-A eligibility determination.

(b) For adoption assistance agreements entered into before April 7, 1986—

(1) The agency must deem the requirements of paragraphs (a)(1) and (2) of this section to be met if the State adoption assistance agency determines that—

(i) At the time of the adoption placement, the child had special needs for medical or rehabilitative care that made the child difficult to place; and

(ii) There is in effect an adoption assistance agreement between the State and the adoptive parent(s).

(2) The agency must deem the requirements of paragraph (a)(3) of this section to be met if the child was found by the State to be eligible for Medicaid before the adoption assistance agreement was entered into.

[55 FR 48608, Nov. 21, 1990]
OPTIONS FOR COVERAGE OF THE AGED, BLIND, AND DISABLED

§ 435.230 Aged, blind, and disabled individuals in States that use more restrictive requirements for Medicaid than SSI requirements: Optional coverage.

(a) Basic optional coverage rule. If the agency elects the option under §435.121 to provide mandatory eligibility for aged, blind, and disabled SSI recipients using more restrictive requirements than those used under SSI, the agency may provide eligibility as optional categorically needy to additional individuals who meet the requirements of this section.

(b) Group composition. Subject to the conditions specified in paragraphs (d) and (e) of this section, the agency may provide Medicaid to individuals who:

(1) Meet the nonfinancial criteria that the State has elected to apply under §435.121;
(2) Meet the resource requirements that the State has elected to apply under §435.121; and
(3) Meet the income eligibility standards specified in paragraph (c) of this section.

(c) Criteria for income standards. The agency may provide Medicaid to the following individuals who meet the requirements of paragraphs (b)(1) and (b)(2) of this section:

(1) Individuals who are financially eligible for but not receiving SSI benefits and who, before deduction of incurred medical and remedial expenses, meet the State’s more restrictive eligibility requirements described in §435.121;
(2) Individuals who meet the income standards specified in paragraph (c) of this section.

§ 435.232 Individuals receiving only optional State supplements.

(a) If the agency provides Medicaid to individuals receiving SSI under §435.120, it may provide Medicaid, in one or more of the following classifications, to individuals who receive only an optional State supplement that meets the conditions specified in paragraph (b) of this section and who would be eligible for SSI except for the level of their income.

(1) All aged individuals.
(2) All blind individuals.
(3) All disabled individuals.
(4) Only aged individuals in domiciliary facilities or other group living arrangements as defined under SSI.
(5) Only blind individuals in domiciliary facilities or other group living arrangements as defined under SSI.
(6) Only disabled individuals in domiciliary facilities or other group living arrangements as defined under SSI.
(7) Individuals receiving a federally administered optional State supplement that meets the conditions specified in this section.
(8) Individuals in additional classifications specified by the Secretary for federally administered supplementary payments under 20 CFR 416.2020(d).
(9) Reasonable groups of individuals, as specified by the State, receiving
§ 435.234 State-administered supplementary payments.

(b) Payments under the optional supplement program must be—

(1) Based on need and paid in cash on a regular basis;

(2) Equal to the difference between the individual’s countable income and the income standard used to determine eligibility for supplement. Countable income is income remaining after deductions required under SSI or, at State option, more liberal deductions are made (see §435.1006 for limitations on FFP in Medicaid expenditures for individuals receiving optional State supplements); and

(3) Available to all individuals in each classification in paragraph (a) of this section and available on a statewide basis. However, the plan may provide for variations in the income standard by political subdivision according to cost-of-living differences.


§ 435.234 Individuals receiving only optional State supplements in States using more restrictive eligibility requirements than SSI and certain States using SSI criteria.

(a) In States using more restrictive eligibility requirements than SSI or in States that use SSI criteria but do not have section 1616 or 1634 agreements with the Social Security Administration for eligibility determinations, the agency may provide Medicaid to individuals specified in paragraph (b) of this section who receive only a State supplement if the State supplement meets the conditions specified in paragraph (c) of this section.

(b) The agency may provide Medicaid to all individuals receiving only State supplements if, except for their income, the individuals meet the more restrictive eligibility requirements under §435.121 or SSI criteria, or to one or more of the following classifications of individuals who meet these criteria: (1) All aged individuals. (2) All blind individuals. (3) All disabled individuals. (4) Only aged individuals in domiciliary facilities or other group living arrangements as defined under SSI. (5) Only blind individuals in domiciliary facilities or other group living arrangements as defined under SSI. (6) Only disabled individuals in domiciliary facilities or other group living arrangements as defined under SSI. (7) Individuals receiving a Federally-administered optional State supplement that meets the conditions specified in this section.

(c) Payments under the optional supplement program must be:

(1) Based on need and paid in cash on a regular basis;

(2) Equal to the difference between the individual’s countable income and the income standard used to determine eligibility for supplements. Countable income is income remaining after deductions are applied. The income deductions may be more restrictive than required under SSI (see §435.1006 for limitations on FFP in Medicaid expenditures for individuals receiving optional State supplements); and

(3) Available to all individuals in each classification in paragraph (b) of this section and available on a statewide basis. However, the plan may provide for variations in the income standard by political subdivision according to cost-of-living differences.

[58 FR 4928, Jan. 19, 1993]

§ 435.236 Individuals in institutions who are eligible under a special income level.

(a) If the agency provides Medicaid under §435.211 to individuals in institutions who would be eligible for AFDC, SSI, or State supplements except for their institutional status, it may also cover aged, blind, and disabled individuals in institutions who—

(1) Because of their income, would not be eligible for SSI or State supplements if they were not institutionalized; but

(2) Have income below a level specified in the plan under §435.722. (See §435.1005 for limitations on FFP in Medicaid expenditures for individuals specified in this section.)
Subpart D—Optional Coverage of the Medically Needy

§ 435.300 Scope.

This subpart specifies the option for coverage of medically needy individuals.

§ 435.301 General rules.

(a) An agency may provide Medicaid to individuals specified in this subpart who:

(1) Either:

(i) Have income that meets the applicable standards in §§ 435.811 and 435.814; or

(ii) If their income is more than allowed under the standard, have incurred medical expenses at least equal to the difference between their income and the applicable income standard; and

(2) Have resources that meet the applicable standards in §§ 435.840 and 435.843.

(b) If the agency chooses this option, the following provisions apply:

(1) The agency must provide Medicaid to the following individuals who meet the requirements of paragraph (a) of this section:

(i) All pregnant women during the course of their pregnancy who, except for income and resources, would be eligible for Medicaid as mandatory or optional categorically needy under subparts B or C of this part;

(ii) All individuals under 18 years of age who, except for income and resources, would be eligible for Medicaid as mandatory categorically needy under § 435.117. The child is eligible as categorically needy under § 435.117. The woman is considered to remain eligible if she meets the spend-down requirements in any consecutive budget period following the birth of the child.

(iv) Women who, while pregnant, applied for, were eligible for, and received Medicaid services as medically needy on the day that their pregnancy ends. The agency must provide medically needy eligibility to these women for an extended period following termination of pregnancy. This period extends from the last day of the pregnancy through the end of the month in which a 60-day period, beginning on the last day of pregnancy, ends. Eligibility must be provided, regardless of changes in the woman’s financial circumstances that may occur within this extended period. These women are eligible for the extended period for all services under the plan that are pregnancy-related (as defined in § 440.210(c)(1) of this subchapter).

(2) The agency may provide Medicaid to any of the following groups of individuals:

(i) Individuals under age 21 (§ 435.308).

(ii) Specified relatives (§ 435.310).

(iii) Aged (§ 435.330). (220)


(3) If the agency provides Medicaid to any individual in a group specified in paragraph (b)(2) of this section, the agency must provide Medicaid to all individuals eligible to be members of that group.

§ 435.308 Medically needy coverage of individuals under age 21.

(a) If the agency provides Medicaid to the medically needy, it may provide Medicaid to individuals under age 21 (or, at State option, under age 20, 19, or 18), as specified in paragraph (b) of this section:

(1) Who would not be covered under the mandatory medically needy group
§ 435.310 Medically needy coverage of specified relatives.

(a) If the agency provides for the medically needy, it may provide Medicaid to specified relatives, as defined in paragraph (b) of this section, who meet the income and resource requirements of subpart I of this part.

(b) Specified relatives means individuals who:

1. Are listed under Section 406(b)(1) of the Act and 45 CFR 233.90(c)(1)(v)(A); and

2. Have in their care an individual who is determined to be (or would, if needy, be) dependent, as specified in §435.510.

[58 FR 4929, Jan. 19, 1993]

§ 435.320 Medically needy coverage of the aged in States that cover individuals receiving SSI.

If the agency provides Medicaid to individuals receiving SSI and elects to cover the medically needy, it may provide Medicaid to individuals who—

(a) Are 65 years of age and older, as specified in §435.520; and

(b) Meet the income and resource requirements of subpart I of this part.

[46 FR 47986, Sept. 30, 1981]

§ 435.322 Medically needy coverage of the blind in States that cover individuals receiving SSI.

If the agency provides Medicaid to individuals receiving SSI and elects to cover the medically needy, it may provide Medicaid to blind individuals who—

(a) The requirements for blindness, as specified in §§435.530 and 435.531; and

(b) The income and resource requirements of subpart I of this part.

[46 FR 47986, Sept. 30, 1981]

§ 435.324 Medically needy coverage of the disabled in States that cover individuals receiving SSI.

If the agency provides Medicaid to individuals receiving SSI and elects to cover the medically needy, it may provide Medicaid to disabled individuals who meet—

(a) The requirements for disability, as specified in §§435.540 and 435.541; and

(b) The income and resource requirements of Subpart I of this part.


§ 435.326 Individuals who would be ineligible if they were not enrolled in an HMO.

If the agency provides Medicaid to the categorically needy under §435.212, it may provide Medicaid to the same rules to medically needy recipients who are enrolled in a federally qualified HMO or in an entity specified in §434.20 (a)(3) and (a)(4), §434.26(b)(3), §434.26(b)(5)(ii) or section 1903(m)(6) of the Act which provides services as described in §434.21(b) of this chapter.

[55 FR 23745, June 12, 1990]
§ 435.330 Medically needy coverage of the aged, blind, and disabled in States using more restrictive eligibility requirements for Medicaid than those used under SSI.

(a) If an agency provides Medicaid as categorically needy only to those aged, blind, or disabled individuals who meet more restrictive requirements than used under SSI and elects to cover the medically needy, it may provide Medicaid as medically needy to those aged, blind, or disabled individuals who:

(1) Do not qualify for Medicaid as categorically needy under § 435.121 or § 435.230; and

(2) If applying as blind or disabled, meet the definition of blindness or disability established under § 435.121.

(b) Except as specified in paragraph (c) of this section, the agency must apply to individuals covered under the option of this section the same financial and nonfinancial requirements that are applied to individuals covered as categorically needy under §§ 435.121 and 435.230.

(c) In determining the financial eligibility of individuals who are considered medically needy under this section, the agency must apply the financial eligibility requirements of subparts G and I of this part.

[58 FR 4929, Jan. 19, 1993]

§ 435.340 Protected medically needy coverage for blind and disabled individuals eligible in December 1973.

If an agency provides Medicaid to the medically needy, it must cover individuals who—

(a) Where eligible as medically needy under the Medicaid plan in December 1973 on the basis of the blindness or disability criteria of the AB, APTD, or AABD plan;

(b) For each consecutive month after December 1973, continue to meet—

(1) Those blindness or disability criteria; and

(2) The eligibility requirements for the medically needy under the December 1973 Medicaid plan; and

(c) Meet the current requirements for eligibility as medically needy under the Medicaid plan except for blindness or disability criteria.

[46 FR 47967, Sept. 30, 1981]
(b) Definition. For purposes of this section—Institution has the same meaning as Institution and Medical institution, as defined in §435.1009 of this chapter. For purposes of State placement, the term also includes foster care homes, licensed as set forth in 45 CFR 1355.20, and providing food, shelter and supportive services to one or more persons unrelated to the proprietor.

(c) Incapability of indicating intent. For purposes of this section, an individual is considered incapable of indicating intent if the individual—

(1) Has an I.Q. of 49 or less or has a mental age of 7 or less, based on tests acceptable to the mental retardation agency in the State:

(2) Is judged legally incompetent; or

(3) Is found incapable of indicating intent based on medical documentation obtained from a physician, psychologist, or other person licensed by the State in the field of mental retardation.

(d) Who is a State resident. A resident of a State is any individual who:

(1) Meets the conditions in paragraphs (e) through (i) of this section; or

(2) Meets the criteria specified in an interstate agreement under paragraph (k) of this section.

(e) Placement by a State in an out-of-State institution—(1) General rule. Any agency of the State, including an entity recognized under State law as being under contract with the State for such purposes, that arranges for an individual to be placed in an institution located in another State, is recognized as acting on behalf of the State in making a placement. The State arranging or actually making the placement is considered as the individual's State of residence.

(2) Any action beyond providing information to the individual and the individual's family would constitute arranging or making a State placement. However, the following actions do not constitute State placement:

(i) Providing basic information to individuals about another State's Medicaid program, and information about the availability of health care services and facilities in another State.

(ii) Assisting an individual in locating an institution in another State, provided the individual is capable of indicating intent and independently decides to move.

(3) When a competent individual leaves the facility in which the individual is placed by a State, that individual's State of residence for Medicaid purposes is the State where the individual is physically located.

(4) Where a placement is initiated by a State because the State lacks a sufficient number of appropriate facilities to provide services to its residents, the State making the placement is the individual's State of residence for Medicaid purposes.

(f) Individuals receiving a State supplemental payment (SSP). For individuals of any age who are receiving an SSP, the State of residence is the State paying the SSP.

(g) Individuals receiving Title IV-E payments. For individuals of any age who are receiving Federal payments for foster care and adoption assistance under Title IV-E of the Social Security Act, the State of residence is the State where the child lives.

(h) Individuals under Age 21. (1) For any individual who is emancipated from his or her parents or who is married and capable of indicating intent, the State of residence is the State where the individual is living with the intention to remain there permanently or for an indefinite period.

(2) For any individual not residing in an institution as defined in paragraph (b) whose Medicaid eligibility is based on blindness or disability, the State of residence is the State in which the individual is living.

(3) For any other non-institutionalized individual not subject to paragraph (h)(1) or (h)(2) of this section, the State of residence is determined in accordance with 45 CFR 233.40, the rules governing residence under the AFDC program.

(4) For any institutionalized individual who is neither married nor emancipated, the State of residence is—

(i) The parent's or legal guardian's State of residence at the time of placement (if a legal guardian has been appointed and parental rights are terminated, the State of residence of the guardian is used instead of the parent's); or
(ii) The current State of residence of the parent or legal guardian who files the application if the individual is institutionalized in that State (if a legal guardian has been appointed and parental rights are terminated, the State or residence of the guardian is used in stead of the parent’s).

(iii) The State of residence of the individual or party who files an application is used if the individual has been abandoned by his or her parent(s), does not have a legal guardian and is institutionalized in that State.

(1) Individuals Age 21 and over.

(a) For any individual not residing in an institution as defined in paragraph (b), the State of residence is the State where the individual is—

(i) Living with the intention to remain there permanently or for an indefinite period (or if incapable of stating intent, where the individual is living); or

(ii) Living and which the individual entered with a job commitment or seeking employment (whether or not currently employed).

(2) For any institutionalized individual who became incapable of indicating intent before age 21, the State of residence is—

(i) That of the parent applying for Medicaid on the individual’s behalf, if the parents reside in separate States (if a legal guardian has been appointed and parental rights are terminated, the State of residence of the guardian is used instead of the parent’s);

(ii) The parent’s or legal guardian’s State of residence at the time of placement (if a legal guardian has been appointed and parental rights are terminated, the State of residence of the guardian is used instead of the parent’s); or

(iii) The current State of residence of the parent or legal guardian who files the application if the individual is institutionalized in that State (if a legal guardian has been appointed and parental rights are terminated, the State of residence of the guardian is used instead of the parent’s).

(iv) The State of residence of the individual or party who files an application is used if the individual has been abandoned by his or her parent(s), does not have a legal guardian and is institutionalized in that State.

(iii) For any institutionalized individual who became incapable of indicating intent at or after age 21, the State of residence is the State in which the individual is physically present, except where another State makes a placement.

(4) For any other institutionalized individual, the State of residence is the State where the individual is living with the intention to remain there permanently or for an indefinite period.

(j) Specific prohibitions.

(1) The agency may not deny Medicaid eligibility because an individual has not resided in the State for a specified period.

(2) The agency may not deny Medicaid eligibility to an individual in an institution, who satisfies the residency rules set forth in this section, on the grounds that the individual did not establish residence in the State before entering the institution.

(3) The agency may not deny or terminate a resident’s Medicaid eligibility because of that person’s temporary absence from the State if the person intends to return when the purpose of the absence has been accomplished, unless another State has determined that the person is a resident there for purposes of Medicaid.

(k) Interstate agreements.

A State may have a written agreement with another State setting forth rules and procedures resolving cases of disputed residency. These agreements may establish criteria other than those specified in paragraphs (c) through (i) of this section. The agreements must contain a procedure for providing Medicaid to individuals pending resolution of the case. States may use interstate agreements for purposes other than cases of disputed residency to facilitate administration of the program, and to facilitate the placement and adoption of title IV-E individuals when the child and his or her adoptive parent(s) move into another State.

(l) Continued Medicaid for institutionalized recipients.

If an agency is providing Medicaid to an institutionalized
§ 435.404

recipient who, as a result of this section, would be considered a resident of a different State—

(1) The agency must continue to provide Medicaid to that recipient from June 24, 1983 until July 5, 1984, unless it makes arrangements with another State of residence to provide Medicaid at an earlier date: and

(2) Those arrangements must not include provisions prohibited by paragraph (h) of this section.

(m) Cases of disputed residency.

Where two or more States cannot resolve which State is the State of residence, the State where the individual is physically located is the State of residence.

[49 FR 13531, Apr. 5, 1984, as amended at 55 FR 48609, Nov. 21, 1990]

§ 435.404 Applicant’s choice of category.

The agency must allow an individual who would be eligible under more than one category to have his eligibility determined for the category he selects.

§ 435.406 Citizenship and alienage.

(a) The agency must provide Medicaid to otherwise eligible residents of the United States who are—

(1) Citizens; or

(2) Aliens lawfully admitted for permanent residence or permanently residing in the United States under color of law as defined in §435.408 of this part;

(3) Aliens granted lawful temporary resident status under sections 245A and 210A of the Immigration and Nationality Act if the individual is aged, blind, or disabled as defined in section 1614(a)(1) of the Act, under 18 years of age, or a Cuban/Haitian entrant as defined in section 501(e)(1) and (2)(A) of Public Law 96-422; or

(4) Aliens granted lawful temporary resident status under section 210 of the Immigration and Nationality Act unless the alien would, but for the 5-year bar to receipt of AFDC contained in such section, be eligible for AFDC.

(b) The agency must only provide emergency services (as defined for purposes of section 1916(a)(2)(D) of the Social Security Act), and services for pregnant women as defined in section 1916(a)(2)(B) of the Social Security Act to otherwise eligible residents of the United States not described in paragraph (a)(3) and (a)(4) of this section who have been granted lawful temporary or lawful permanent resident status under sections 245A, 210 or 210A of the Immigration and Nationality Act for five years from the date lawful temporary resident status was granted.

(c) The agency must provide payment for the services described in §440.255(c) of this chapter to residents of the State who otherwise meet the eligibility requirements of the State plan (except for receipt of AFDC, SSI, or State Supplementary payments and the presentation of a social security number) but who do not meet the requirements of paragraphs (a) and (b) of this section.

(d) The limitations on eligibility set forth in paragraph (b) of this section do not apply after 5 years from the date an alien was granted lawful temporary resident status under sections 245A, 210 and 210A of the INA.


§ 435.408 Categories of aliens who are permanently residing in the United States under color of law.

This section describes aliens that the agency must accept as permanently residing in the United States under color of law and who may be eligible for Medicaid.

(a) An individual may be eligible for Medicaid if the individual is an alien residing in the United States with the knowledge and permission of the Immigration and Naturalization Services (INS) and the INS does not contemplate enforcing the alien’s departure. The INS does not contemplate enforcing an alien’s departure if it is the policy or practice of INS not to enforce the departure of aliens in the same category, or if from all the facts and circumstances in a particular case it appears that INS is otherwise permitting the alien to reside in the United States indefinitely, as determined by verifying the alien’s status with INS.

(b) Aliens who are permanently residing in the United States under color of law are listed below. None of the categories includes applicants for an Immigration and Naturalization Service status other than those applicants listed in paragraph (b)(6) of this section or
those covered under paragraph (b)(16) of this section. None of the categories allows Medicaid eligibility for non-immigrants: for example, students or visitors. Also listed are the most commonly used documents that the INS provides to aliens in these categories.


2. Aliens, including Cuban/Haitian entrants, paroled in the United States pursuant to 8 U.S.C. 1182(d)(5) (section 212(d)(5) of the Immigration and Nationality Act). Ask for a copy of INS Form I–94 with notation that the alien was paroled pursuant to section 212(d)(5) of the Immigration and Nationality Act. For Cuban/Haitian entrants, ask for a copy of INS Form I–94 stamped Cuban/Haitian entrant (Status Pending) reviewable January 15, 1981 (Although the forms bear this notation. Cuban/Haitian entrants are admitted under section 212(d)(5) of the Immigration and Nationality Act);

3. Aliens residing in the United States pursuant to an indefinite stay of deportation. Ask for an Immigration and Naturalization Service letter with this information or INS Form I–94 with such a notation;

4. Aliens residing in the United States pursuant to an indefinite voluntary departure. Ask for an Immigration and Naturalization Service letter or INS Form I–94 showing that voluntary departure has been granted for an indefinite time period;

5. Aliens on whose behalf an immediate relative petition has been approved and their families covered by the petition who are entitled to voluntary departure (under 8 CFR 242.5(a)(2)(vi)) and whose departure the Immigration and Naturalization Service does not contemplate enforcing. Ask for a copy of INS Form I–94 or Form I–210 or a letter showing that status;

6. Aliens who have filed applications for adjustment of status pursuant to section 245 of the Immigration and Nationality Act (8 U.S.C. 1255) that the Immigration and Naturalization Service has accepted as “properly filed” (within the meaning of 8 CFR 245.2(a) (1) or (2)) and whose departure the Immigration and Naturalization service does not contemplate enforcing. Ask for a copy of INS Form I–94 or I–181 or a passport appropriately stamped;

7. Aliens granted stays of deportation by court order, statute or regulation, or by individual determination of the Immigration and Naturalization Service pursuant to section 106 of the Immigration and Nationality Act (8 U.S.C. 1105a) or relevant Immigration and Naturalization Service instructions, whose departure that agency does not contemplate enforcing. Ask for a copy of INS Form I–94 or a letter from the Immigration and Naturalization Service, or a copy of a court order establishing the alien’s status;

8. Aliens granted asylum pursuant to section 208 of the Immigration and Nationality Act (8 U.S.C. 1158). Ask for a copy of INS Form I–94 and a letter establishing this status;

9. Aliens admitted as refugees pursuant to section 207 of the Immigration and Nationality Act (8 U.S.C. 1157) or section 203(a)(7) of the Immigration and Nationality Act (8 U.S.C. 1153(a)(7)). Ask for a copy of INS Form I–94 properly endorsed;

10. Aliens granted voluntary departure pursuant to section 242(b) of the Immigration and Nationality Act (8 U.S.C. 1252(b)) or 8 CFR 242.5 whose departure the Immigration and Naturalization Service does not contemplate enforcing. Ask for a Form I–94 or Form I–210 bearing a departure date;

11. Aliens granted deferred action status pursuant to immigration and Naturalization Service Operations Instruction 103.1(a)(ii) prior to June 15, 1984 or §242.1(a)(22) issued June 15, 1984 and later. Ask for a copy of INS Form I–210 or a letter showing that departure has been deferred;

12. Aliens residing in the United States under orders of supervision pursuant to section 242 of the Immigration and Nationality Act (8 U.S.C. 1252(d)). Ask for a copy of Form I–220 B;

13. Aliens who have entered and continuously resided in the United States since before January 1, 1972 (or any date established by section 245 of the Immigration and Nationality Act, 8
§ 435.500

U.S.C. 1259). Ask for any proof establishing this entry and continuous residence;

(14) Aliens granted suspension of deportation pursuant to section 244 of the Immigration and Naturalization Act (8 U.S.C. 1254) and whose departure the Immigration and Naturalization Service does not contemplate enforcing. Ask for an order from an immigration judge showing that deportation has been withheld;

(15) Aliens whose deportation has been withheld pursuant to section 243(h) of the Immigration and Nationality Act (8 U.S.C. 1253(h)). Ask for an order from an immigration judge showing that deportation has been withheld;

or

(16) Any other aliens living in the United States with the knowledge and permission of the Immigration and Naturalization Service and whose departure that agency does not contemplate enforcing. (Including permanent non-immigrants as established by Public Law 99-239, and persons granted Extended Voluntary Departure due to conditions in the alien’s home country based on a determination by the Secretary of State).


Subpart F—Categorical Requirements for Eligibility

§ 435.500 Scope.

This subpart prescribes categorical requirements for determining the eligibility of both categorically and medically needy individuals specified in subparts B, C, and D of this part.

DEPENDENCY

§ 435.510 Determination of dependency.

For families with dependent children who are not receiving AFDC, the agency must use the definitions and procedures set forth under the State’s AFDC plan to determine whether—

(a) An individual is a dependent child because he is deprived of parental support or care; and

(b) An individual is an eligible member of a family with dependent children.


AGE

§ 435.520 Age requirements for the aged.

The agency must not impose an age requirement of more than 65 years.

[58 FR 4929, Jan. 19, 1993]

§ 435.522 Determination of age.

(a) Except as specified in paragraphs (b) and (c) of this section, in determining age, the agency must use the common-law method (under which an age is reached on the anniversary of birth).

(b) For families and children, the agency must use the popular usage method (under which an age is reached the day before the anniversary of birth), if this method is used under the State’s AFDC plan.

(c) For aged, blind, or disabled individuals, the agency must use the popular usage method, if the plan provides under §435.121, §435.230, or §435.330, for coverage of aged, blind, or disabled individuals who meet more restrictive eligibility requirements than those under SSI.

(d) The agency may use an arbitrary date, such as July 1, for determining an individual’s age if the year, but not the month, of his birth is known.

[58 FR 4929, Jan. 19, 1993]

BLINDNESS

§ 435.530 Definition of blindness.

(a) Definition. The agency must use the same definition of blindness as used under SSI, except that—

(1) In determining the eligibility of individuals whose Medicaid eligibility is protected under §§435.130 through 435.134, the agency must use the definition of blindness that was used under the Medicaid plan in December 1973; and

(2) The agency may use a more restrictive definition to determine eligibility under §435.121, if the definition is no more restrictive than that used
under the Medicaid plan on January 1, 1972.
(b) State plan requirement. The State plan must contain the definition of blindness, expressed in ophthalmic measurements.

§435.531 Determinations of blindness.
(a) Except as specified in paragraph (b) of this section, in determining blindness—
(1) A physician skilled in the diseases of the eye or an optometrist, whichever the individual selects, must examine him, unless both of the applicant’s eyes are missing;
(2) The examiner must submit a report of examination to the Medicaid agency; and
(3) A physician skilled in the diseases of the eye (for example, an ophthalmologist or an eye, ear, nose, and throat specialist) must review the report and determine on behalf of the agency—
(i) Whether the individual meets the definition of blindness; and
(ii) Whether and when re-examinations are necessary for periodic rede terminations of eligibility, as required under §435.916 of this part.
(b) If an agency provides Medicaid to individuals receiving SSI on the basis of blindness, this section does not apply for those individuals.


DISABILITY

§435.540 Definition of disability.
(a) Definition. The agency must use the same definition of disability as used under SSI, except that—
(1) In determining the eligibility of individuals whose Medicaid eligibility is protected under §635.130 through 435.134, the agency must use the definition of disability that was used under the Medicaid plan in December 1973; and
(2) The agency may use a more restrictive definition to determine eligibility under §435.121, if the definition is no more restrictive than that used under the Medicaid plan on January 1, 1972.
(b) State plan requirements. The State plan must contain the definition of disability.

§435.541 Determinations of disability.
(a) Determinations made by SSA. The following rules and those under paragraph (b) of this section apply where an individual has applied for Medicaid on the basis of disability.
(1) If the agency has an agreement with the Social Security Administration (SSA) under section 1634 of the Act, the agency may not make a determination of disability when the only application is filed with SSA.
(2) The agency may not make an independent determination of disability if SSA has made a disability determination within the time limits set forth in §435.911 on the same issues presented in the Medicaid application. A determination of eligibility for SSI payments based on disability that is made by SSA automatically confers Medicaid eligibility, as provided for under §435.909.
(b) Effect of SSA determinations. (1) Except in the circumstances specified in paragraph (c)(3) of this section—
(i) An SSA disability determination is binding on an agency until the determination is changed by SSA.
(ii) If the SSA determination is changed, the new determination is also binding on the agency.
(b) The agency must refer to SSA all applicants who allege new information or evidence affecting previous SSA determinations of ineligibility based upon disability for reconsideration or reopening of the determination, except in cases specified in paragraph (c)(4) of this section.
(c) Determinations made by the Medicaid agency. The agency must make a determination of disability in accordance with the requirements of this section if any of the following circumstances exist:
(1) The individual applies for Medicaid as a non-cash recipient and has not applied to SSA for SSI cash benefits, whether or not a State has a section 1634 agreement with SSA; or an individual applies for Medicaid and has applied to SSA for SSI benefits and is found ineligible for SSI for a reason other than disability.
(2) The individual applies both to SSA for SSI and to the State Medicaid agency for Medicaid, the State agency has a section 1634 agreement with SSA,
and SSA has not made an SSI disability determination within 90 days from the date of the individual’s application for Medicaid.

(3) The individual applies to SSA for SSI and to the State Medicaid agency for Medicaid, the State does not have a section 1634 agreement with SSA, and either the State uses more restrictive criteria than SSI for determining Medicaid eligibility under its section 1902(f) option or, in the case of a State that uses SSI criteria, SSA has not made an SSI disability determination in time for the State to comply with the Medicaid time limit for making a prompt determination on an individual’s application for Medicaid.

(4) The individual applies for Medicaid as a non-cash recipient, whether or not the State has a section 1634 agreement with SSA, and—

(i) Alleges a disabling condition different from, or in addition to, that considered by SSA in making its determination; or

(ii) Alleges more than 12 months after the most recent SSA determination denying disability that his or her condition has changed or deteriorated since that SSA determination and alleges a new period of disability which meets the durational requirements of the Act, and has not applied to SSA for a determination with respect to these allegations.

(iii) Alleges less than 12 months after the most recent SSA determination denying disability that his or her condition has changed or deteriorated since that SSA determination, alleges a new period of disability which meets the durational requirements of the Act, and—

(A) Has applied to SSA for reconsideration or reopening of its disability decision and SSA refused to consider the new allegations; and/or

(B) He or she no longer meets the nondisability requirements for SSI but may meet the State’s nondisability requirements for Medicaid eligibility.

(d) Basis for determinations. The agency must make a determination of disability as provided in paragraph (c) of this section—

(1) On the basis of the evidence required under paragraph (e) of this section; and

(2) In accordance with the requirements for evaluating that evidence under the SSI program specified in 20 CFR 416.901 through 416.998.

(e) Medical and nonmedical evidence. The agency must obtain a medical report and other nonmedical evidence for individuals applying for Medicaid on the basis of disability. The medical report and nonmedical evidence must include diagnosis and other information in accordance with the requirements for evidence applicable to disability determinations under the SSI program specified in 20 CFR part 416, subpart I.

(f) Disability review teams—(1) Function. A review team must review the medical report and other evidence required under paragraph (e) of this section and determine on behalf of the agency whether the individual’s condition meets the definition of disability.

(2) Composition. The review team must be composed of a medical or psychological consultant and another individual who is qualified to interpret and evaluate medical reports and other evidence relating to the individual’s physical or mental impairments and, as necessary, to determine the capacities of the individual to perform substantial gainful activity, as specified in 20 CFR part 416, subpart J.

(3) Periodic reexaminations. The review team must determine whether and when reexaminations will be necessary for periodic redeterminations of eligibility as required under §435.916 of this part, using the principles set forth in 20 CFR 416.989 and 416.990. If a State uses the same definition of disability as SSA, as provided for under §435.540, and a recipient is Medicaid eligible because he or she receives SSI, this paragraph (f)(3) does not apply. The reexamination will be conducted by SSA.

[54 FR 50761, Dec. 11, 1989]

Subpart G—General Financial Eligibility Requirements and Options

§435.600 Scope.

This subpart prescribes:

(a) General financial requirements and options for determining the eligibility of both categorically and medically needy individuals specified in
§ 435.601 Application of financial eligibility methodologies.

(a) Definitions. For purposes of this section, cash assistance financial methodologies refers to the income and resources methodologies of the AFDC, SSI, or State supplement programs, or, for aged, blind, and disabled individuals in States that use more restrictive criteria than SSI, the methodologies established in accordance with the requirements of §§ 435.121 and 435.230.

(b) Basic rule for use of cash assistance methodologies. Except as specified in paragraphs (c) and (d) of this section or in § 435.121 in determining financial eligibility of individuals as categorically and medically needy, the agency must apply the financial methodologies and requirements of the cash assistance program that is most closely categorically related to the individual's status.

(c) Financial responsibility of relatives. The agency must use the requirements for financial responsibility of relatives specified in § 435.602.

(d) Use of less restrictive methodologies than those under cash assistance programs. (1) At State option, and subject to the conditions of paragraphs (d)(2) through (d)(5) of this section, the agency may apply income and resource methodologies that are less restrictive than the cash assistance methodologies in determining eligibility of the following groups:

(i) Qualified pregnant women and children under the mandatory categorically needy group under § 435.116;


(iii) Qualified Medicare beneficiaries specified in sections 1902(a)(10)(E) and 1905(p) of the Act;

(iv) Optional categorically needy individuals under groups established under subpart C of this part and section 1902(a)(10)(A)(ii) of the Act;

(v) Medically needy individuals under groups established under subpart D of this part and section 1902(a)(10)(C)(i)(III) of the Act; and

(vi) Aged, blind, and disabled individuals in States using more restrictive eligibility requirements than SSI under groups established under §§ 435.121 and 435.230.

(2) The income and resource methodologies that an agency elects to apply to groups of individuals described in paragraph (d)(1) of this section may be less restrictive, but no more restrictive (except in States using more restrictive requirements than SSI), than:

(i) For groups of aged, blind, and disabled individuals, the SSI methodologies; or

(ii) For all other groups, the methodologies under the State plan most closely categorically related to the individual's status.

(3) A financial methodology is considered to be no more restrictive if, by using the methodology, additional individuals may be eligible for Medicaid and no individuals who are otherwise eligible are by use of that methodology made ineligible for Medicaid.

(4) The less restrictive methodology applied under this section must be comparable for all persons within each category of assistance (aged, or blind, or disabled, or AFDC related) within an eligibility group. For example, if the agency chooses to apply less restrictive income or resource methodology to an eligibility group of aged individuals, it must apply that methodology to all aged individuals within the selected group.

(5) The application of the less restrictive income and resource methodologies permitted under this section must be consistent with the limitations and conditions on FFP specified in subpart K of this part.

(e) [Reserved]

(f) State plan requirements. (1) The State plan must specify that, except to the extent precluded in § 435.602, in determining financial eligibility of individuals, the agency will apply the cash assistance financial methodologies and requirements, unless the agency chooses to apply less restrictive income and resource methodologies in accordance with paragraph (d) of this section.
§ 435.602 Financial responsibility of relatives and other individuals.

(a) Basic requirements. Subject to the provisions of paragraphs (b) and (c) of this section, in determining financial responsibility of relatives and other persons for individuals under Medicaid, the agency must apply the following requirements and methodologies:

(1) Except for a spouse of an individual or a parent for a child who is under age 21 or blind or disabled, the agency must not consider income and resources of any relative as available to an individual.

(2) In relation to individuals under age 21 (as described in section 1905(a)(i) of the Act), the financial responsibility requirements and methodologies that apply include considering the income and resources of parents or spouses whose income and resources would be considered if the individual under age 21 were dependent under the State's approved AFDC plan, whether or not they are actually contributed, except as specified under paragraphs (c) and (d) of this section. These requirements and methodologies must be applied in accordance with the provisions of the State's approved AFDC plan.

(3) When a couple ceases to live together, the agency must count only the income of the individual spouse in determining his or her eligibility, beginning the first month following the month the couple ceases to live together.

(4) In the case of eligible institutionalized spouses who are aged, blind, and disabled and who have shared the same room in a title XIX Medicaid institution, the agency has the option of considering these couples as eligible couples for purposes of counting income and resources or as eligible individuals, whichever is more advantageous to the couple.

(b) Requirements for States using more restrictive requirements. Subject to the provisions of paragraph (c) of this section, in determining financial eligibility of aged, blind, or disabled individuals in States that apply eligibility requirements more restrictive than those used under SSI, the agency must apply:

(1) The requirements and methodologies for financial responsibility of relatives used under the SSI program; or

(2) More extensive requirements for relative responsibility than specified in §435.602(a) but no more extensive than the requirements under the Medicaid plan in effect on January 1, 1972.

(c) Use of less restrictive methodologies. The agency may apply income and resources methodologies that are less restrictive than those used under the cash assistance programs as specified in the State Medicaid plan in accordance with §435.601(d).

(d) [Reserved]

§ 435.604 Applications for other benefits.

(a) As a condition of eligibility, the agency must require applicants and recipients to take all necessary steps to obtain any annuities, pensions, retirement, and disability benefits to which they are entitled, unless they can show good cause for not doing so.

(b) Annuities, pensions, retirement and disability benefits include, but are not limited to, veterans' compensation and pensions, OASDI benefits, railroad retirement benefits, and unemployment compensation.

§ 435.606 Assignment of rights to benefits.

(a) As a condition of eligibility, the agency must require legally able applicants and recipients to:

(1) Assign rights to the Medicaid agency to medical support and to payment for medical care from any third party;
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(2) Cooperate with the agency in establishing paternity and in obtaining medical support and payments, unless the individual establishes good cause for not cooperating, and except for individuals described in section 1902 (1)(1)(A) of the Act (poverty level pregnant women), who are exempt from cooperating in establishing paternity and obtaining medical support and payments from, or derived from, the father of the child born out of wedlock; and

(3) Cooperate in identifying and providing information to assist the Medicaid agency in pursuing third parties who may be liable to pay for care and services under the plan, unless the individual establishes good cause for not cooperating.

(b) The requirements for assignment of rights must be applied uniformly for all groups covered under the plan.

(c) The requirements of paragraph (a) of this section for the assignment of rights to medical support and other payments and cooperation in obtaining medical support and payments are effective for medical assistance furnished on or after October 1, 1984. The requirements for cooperation in identifying and providing information for pursuing liable third parties is effective for medical assistance furnished on or after July 1, 1988.

§ 435.622 Individuals in institutions who are eligible under a special income level.

(a) If an agency, under §435.231, provides Medicaid to individuals in medical institutions, nursing facilities, and intermediate care facilities for the mentally retarded who would not be eligible for SSI or State supplements if they were not institutionalized, the agency must use income standards based on the greater need for financial assistance that the individuals would have if they were not in the institution. The standards may vary by the level of institutional care needed by the individual (hospital, nursing facility, or intermediate level care for the mentally retarded), or by other factors related to individual needs. (See §435.1005 for FFP limits on income standards established under this section.)

(b) In determining the eligibility of individuals under the income standards established under this section, the agency must not take into account income that would be disregarded in determining eligibility for SSI or for an optional State supplement.

(c) The agency must apply the income standards established under this section effective with the first day of a period of not less than 30 consecutive days of institutionalization.

§ 435.631 General requirements for determining income eligibility in States using more restrictive requirements for Medicaid than SSI.

(a) Income eligibility methods. In determining income eligibility of aged, blind, and disabled individuals in a State using more restrictive eligibility requirements than SSI, the agency must use the methods for treating income elected under §§435.121 and 435.230, under §435.601. The methods used must be comparable for all individuals within each category of individuals under §435.121 and each category of individuals within each optional categorically needy group included under §435.230 and for each category of individuals under the medically needy option described under §435.800.

(b) Categorically needy versus medically needy eligibility. (1) Individuals who have income equal to, or below, the categorically needy income standards described in §§435.121 and 435.230 are categorically needy in States that include the medically needy under their plans.

(2) Categorically needy eligibility in States that do not include the medically needy is determined in accordance with the provisions of §435.121 (e)(4) and (e)(5).

[58 FR 4932, Jan. 19, 1993]
§ 435.640 Protected Medicaid eligibility for individuals eligible in December 1973.

In determining whether individuals continue to meet the income requirements used in December 1973, for purposes of determining eligibility under §§435.131, 435.132, and 435.133, the agency must deduct increased OASDI payments to the same extent that these deductions were in effect in December 1973. These deductions are required by section 306 of the Social Security Amendments of 1972 (Pub. L. 92-603) and section 1007 of Pub. L. 91-172 (enacted Dec. 30, 1969), modified by section 304 of Pub. L. 92-603.


Subpart H—Specific Post-Eligibility Financial Requirements for the Categorically Needy

§ 435.700 Scope.

This subpart prescribes specific financial requirements for determining the post-eligibility treatment of income of categorically needy individuals, including requirements for applying patient income to the cost of care.

[58 FR 4931, Jan. 19, 1993]

§ 435.725 Post-eligibility treatment of income of institutionalized individuals in SSI States: Application of patient income to the cost of care.

(a) Basic rules. (1) The agency must reduce its payment to an institution, for services provided to an individual specified in paragraph (b) of this section, by the amount that remains after deducting the amounts specified in paragraphs (c) and (d) of this section, from the individual’s total income.

(2) The individual’s income must be determined in accordance with paragraph (e) of this section.

(c) Required deductions. In reducing its payment to the institution, the agency must deduct the following amounts, in the following order, from the individual’s total income, as determined under paragraph (e) of this section. Income that was disregarded in determining eligibility must be considered in this process.

(1) Personal needs allowance. A personal needs allowance that is reasonable in amount for clothing and other personal needs of the individual while in the institution. This protected personal needs allowance must be at least—

(i) $30 a month for an aged, blind, or disabled individual, including a child applying for Medicaid on the basis of blindness or disability;

(ii) $60 a month for an institutionalized couple if both spouses are aged, blind, or disabled and their income is considered available to each other in determining eligibility; and

(iii) A reasonable amount set by the agency, based on a reasonable difference in their personal needs from those of the aged, blind, and disabled.

(b) Applicability. This section applies to the following individuals in medical institutions and intermediate care facilities.

(1) Individuals receiving cash assistance under SSI or AFDC who are eligible for Medicaid under §435.110 or §435.120.

(2) Individuals who would be eligible for AFDC, SSI, or an optional State supplement except for their institutional status and who are eligible for Medicaid under §435.211.

(3) Aged, blind, and disabled individuals who are eligible for Medicaid, under §435.231, under a higher income standard than the standard used in determining eligibility for SSI or optional State supplements.

(2) Maintenance needs of spouse. For an individual with only a spouse at home, an additional amount for the maintenance needs of the spouse. This amount must be based on a reasonable assessment of need but must not exceed the highest of—

(i) $30 a month for an aged, blind, or disabled individual, including a child applying for Medicaid on the basis of blindness or disability;

(ii) $60 a month for an institutionalized couple if both spouses are aged, blind, or disabled and their income is considered available to each other in determining eligibility; and

(3) Medical expenses. The agency must determine the amount of medical expenses incurred, and the amount of those expenses necessary to maintain the individual’s health and well-being.

(i) The amount of the income standard used to determine eligibility for SSI for an individual living in his own home, if the agency provides Medicaid only to individuals receiving SSI;

(ii) The amount of the highest income standard, in the appropriate category of age, blindness, or disability,
used to determine eligibility for an optional State supplement for an individual in his own home, if the agency provides Medicaid to optional State supplement recipients under §435.230; or

(iii) The amount of the medically needy income standard for one person established under §435.811, if the agency provides Medicaid under the medically needy coverage option.

(3) Maintenance needs of family. For an individual with a family at home, an additional amount for the maintenance needs of the family. This amount must—

(i) Be based on a reasonable assessment of their financial need;

(ii) Be adjusted for the number of family members living in the home; and

(iii) Not exceed the higher of the need standard for a family of the same size used to determine eligibility under the State’s approved AFDC plan or the medically needy income standard established under §435.811, if the agency provides Medicaid under the medically needy coverage option for a family of the same size.

(4) Expenses not subject to third party payment. Amounts for incurred expenses for medical or remedial care that are not subject to payment by a third party, including—

(i) Medicare and other health insurance premiums, deductibles, or coinsurance charges; and

(ii) Necessary medical or remedial care recognized under State law but not covered under the State's Medicaid plan, subject to reasonable limits the agency may establish on amounts of these expenses.

(5) Continued SSI and SSP benefits. The full amount of SSI and SSP benefits that the individual continues to receive under sections 1611(e)(1) (E) and (G) of the Act.

(d) Optional deduction: Allowance for home maintenance. For single individuals and couples, an amount (in addition to the personal needs allowance) for maintenance of the individual’s or couple’s home if—

(1) The amount is deducted for not more than a 6-month period; and

(2) A physician has certified that either of the individuals is likely to return to the home within that period.

(3) For single individuals and couples, an amount (in addition to the personal needs allowance) for maintenance of the individual’s or couple’s home if—

(i) The amount is deducted for not more than a 6-month period; and

(ii) A physician has certified that either of the individuals is likely to return to the home within that period.

(e) Determination of income—(1) Option. In determining the amount of an individual’s income to be used to reduce the agency’s payment to the institution, the agency may use total income received, or it may project monthly income for a prospective period not to exceed 6 months.

(2) Basis for projection. The agency must base the projection on income received in the preceding period, not to exceed 6 months, and on income expected to be received.

(3) Adjustments. At the end of the prospective period specified in paragraph (e)(1) of this section, or when any significant change occurs, the agency must reconcile estimates with income received.

(f) Determination of medical expenses—(1) Option. In determining the amount of medical expenses to be deducted from an individual’s income, the agency may deduct incurred medical expenses, or it may project medical expenses for a prospective period not to exceed 6 months.

(2) Basis for projection. The agency must base the estimate on medical expenses incurred in the preceding period, not to exceed 6 months, and on medical expenses expected to be incurred.

(3) Adjustments. At the end of the prospective period specified in paragraph (f)(1) of this section, or when any significant change occurs, the agency must reconcile estimates with incurred medical expenses.

§ 435.726 Post-eligibility treatment of income of individuals receiving home and community-based services furnished under a waiver: Application of patient income to the cost of care.

(a) The agency must reduce its payment for home and community-based services provided to an individual specified in paragraph (b) of this section, by the amount that remains after deducting the amounts specified in paragraph (c) of this section from the individual’s income.

(b) This section applies to individuals who are eligible for Medicaid under §435.217 and are receiving home and community-based services furnished under a waiver of Medicaid requirements specified in part 441, subpart G or H of this subchapter.

(c) In reducing its payment for home and community-based services, the agency must deduct the following amounts, in the following order, from the individual’s total income (including amounts disregarded in determining eligibility):

(1) An amount for the maintenance needs of the individual that the State may set at any level, as long as the following conditions are met:
   (i) The deduction amount is based on a reasonable assessment of need.
   (ii) The State establishes a maximum deduction amount that will not be exceeded for any individual under the waiver.

(2) For an individual with only a spouse at home, an additional amount for the maintenance needs of the spouse. This amount must be based on a reasonable assessment of need but must not exceed the highest of:
   (i) The amount of the income standard used to determine eligibility for SSI for an individual living in his own home, if the agency provides Medicaid only to individuals receiving SSI;
   (ii) The amount of the highest income standard, in the appropriate category of age, blindness, or disability, used to determine eligibility for an optional State supplement for an individual in his own home, if the agency provides Medicaid to optional State supplement recipients under §435.230; or
   (iii) The amount of the medically needy income standard for one person established under §§435.811 and 435.814, if the agency provides Medicaid under the medically needy coverage option.

(3) For an individual with a family at home, an additional amount for the maintenance needs of the family. This amount must—
   (i) Be based on a reasonable assessment of their financial need;
   (ii) Be adjusted for the number of family members living in the home; and
   (iii) Not exceed the higher of the need standard for a family of the same size used to determine eligibility under the State’s AFDC plan or the medically needy income standard established under §435.811 for a family of the same size.

(d) Amounts for incurred expenses for medical or remedial care that are not subject to payment by a third party including—
   (i) Medicare and other health insurance premiums, deductibles, or coinsurance charges; and
   (ii) Necessary medical or remedial care recognized under State law but not covered under the State’s Medicaid plan, subject to reasonable limits the agency may establish on amounts of these expenses.

§ 435.733 Post-eligibility treatment of income of institutionalized individuals in States using more restrictive requirements than SSI: Application of patient income to the cost of care.

(a) Basic rules. (1) The agency must reduce its payment to an institution, for services provided to an individual specified in paragraph (b) of this section, by the amount that remains after deducting the amounts specified in paragraphs (c) and (d) of this section, from the individual’s total income.

(2) The individual’s income must be determined in accordance with paragraph (e) of this section.

(3) Medical expenses must be determined in accordance with paragraph (f) of this section.

(b) Applicability. This section applies to the following individuals in medical
institutions and intermediate care facilities:

(1) Individuals receiving cash assistance under AFDC who are eligible for Medicaid under §435.110 and individuals eligible under §435.121.

(2) Individuals who would be eligible for AFDC, SSI, or an optional State supplement except for their institutional status and who are eligible for Medicaid under §435.211.

(3) Aged, blind, and disabled individuals who are eligible for Medicaid, under §435.231, under a higher income standard than the standard used in determining eligibility for SSI or optional State supplements.

(c) Required deductions. The agency must deduct the following amounts, in the following order, from the individual’s total income, as determined under paragraph (e) of this section. Income that was disregarded in determining eligibility must be considered in this process.

(1) Personal needs allowance. A personal needs allowance that is reasonable in amount for clothing and other personal needs of the individual while in the institution. This protected personal needs allowance must be at least—

   (i) $30 a month for an aged, blind, or disabled individual, including a child applying for Medicaid on the basis of blindness or disability;
   (ii) $60 a month for an institutionalized couple if both spouses are aged, blind, or disabled and their income is considered available to each other in determining eligibility; and
   (iii) For other individuals, a reasonable amount set by the agency, based on a reasonable difference in their personal needs from those of the aged, blind, and disabled.

(2) Maintenance needs of spouse. For an individual with only a spouse at home, an additional amount for the maintenance needs of the spouse. This amount must be based on a reasonable assessment of need but must not exceed the higher of—

   (i) The more restrictive income standard established under §435.121; or
   (ii) The amount of the medically needy income standard for one person established under §435.811, if the agency provides Medicaid under the medically needy coverage option.

(3) Maintenance needs of family. For an individual with a family at home, an additional amount for the maintenance needs of the family. This amount must—

   (i) Be based on a reasonable assessment of their financial need;
   (ii) Be adjusted for the number of family members living in the home; and
   (iii) Not exceed the higher of the need standard for a family of the same size used to determine eligibility under the State’s approved AFDC plan or the medically needy income standard established under §435.811, if the agency provides Medicaid under the medically needy coverage option for a family of the same size.

(4) Expenses not subject to third party payment. Amounts for incurred expenses for medical or remedial care that are not subject to payment by a third party, including—

   (i) Medicare and other health insurance premiums, deductibles, or coinsurance charges; and
   (ii) Necessary medical or remedial care recognized under State law but not covered under the State’s Medicaid plan, subject to reasonable limits the agency may establish on amounts of these expenses.

(5) Continued SSI and SSP benefits. The full amount of SSI and SSP benefits that the individual continues to receive under sections 1611(e)(1) (E) and (G) of the Act.

(d) Optional deduction: Allowance for home maintenance. For single individuals and couples, an amount (in addition to the personal needs allowance) for maintenance of the individual’s or couple’s home if—

(1) The amount is deducted for not more than a 6-month period; and

(2) A physician has certified that either of the individuals is likely to return to the home within that period.

(e) Determination of income—(1) Option. In determining the amount of an individual’s income to be used to reduce the agency’s payment to the institution, the agency may use total income received, or it may project total monthly income for a prospective period not to exceed 6 months.
§ 435.735 Post-eligibility treatment of income and resources of individuals receiving home and community-based services furnished under a waiver: Application of patient income to the cost of care.

(a) The agency must reduce its payment for home and community-based services provided to an individual specified in paragraph (b) of this section, by the amount that remains after deducting the amounts specified in paragraphs (c) of this section from the individual's income.

(b) This section applies to individuals who are eligible for Medicaid under §435.217, and are eligible for home and community-based services furnished under a waiver of State plan requirements specified in part 441, subpart G or H of this subchapter.

(c) In reducing its payment for home and community-based services, the agency must deduct the following amounts, in the following order, from the individual's total income (including amounts disregarded in determining eligibility):

1. An amount for the maintenance needs of the individual that the State may set at any level, as long as the following conditions are met:
   (i) The deduction amount is based on a reasonable assessment of need;
   (ii) The State establishes a maximum deduction amount that will not be exceeded for any individual under the waiver.

2. For an individual with only a spouse at home, an additional amount for the maintenance needs of the spouse. This amount must be based on a reasonable assessment of need but must not exceed the higher of—
   (i) The more restrictive income standard established under §435.121; or
   (ii) The medically needy standard for an individual.

3. For an individual with a family at home, an additional amount for the maintenance needs of the family. This amount must—
   (i) Be based on a reasonable assessment of their financial need;
   (ii) Be adjusted for the number of family members living in the home; and
   (iii) Not exceed the higher of the need standard for a family of the same size used to determine eligibility under the State's approved AFDC plan or the medically needy income standard established under §435.811 for a family of the same size.

4. Amounts for incurred expenses for medical or remedial care that are not subject to payment by a third party, including—
   (i) Medicare and other health insurance premiums, deductibles, or coinsurance charges; and
   (ii) Necessary medical or remedial care recognized under State law but not covered under the State's Medicaid plan, subject to reasonable limits the agency may establish on amounts of these expenses.


§ 435.735 Post-eligibility treatment of income and resources of individuals receiving home and community-based services furnished under a waiver: Application of patient income to the cost of care.

1. An amount for the maintenance needs of the individual that the State may set at any level, as long as the following conditions are met:
   (i) The deduction amount is based on a reasonable assessment of need;
   (ii) The State establishes a maximum deduction amount that will not be exceeded for any individual under the waiver.

2. For an individual with only a spouse at home, an additional amount for the maintenance needs of the spouse. This amount must be based on a reasonable assessment of need but must not exceed the higher of—
   (i) The more restrictive income standard established under §435.121; or
   (ii) The medically needy standard for an individual.

3. For an individual with a family at home, an additional amount for the maintenance needs of the family. This amount must—
   (i) Be based on a reasonable assessment of their financial need;
   (ii) Be adjusted for the number of family members living in the home; and
   (iii) Not exceed the higher of the need standard for a family of the same size used to determine eligibility under the State's approved AFDC plan or the medically needy income standard established under §435.811 for a family of the same size.

4. Amounts for incurred expenses for medical or remedial care that are not subject to payment by a third party, including—
   (i) Medicare and other health insurance premiums, deductibles, or coinsurance charges; and
   (ii) Necessary medical or remedial care recognized under State law but not covered under the State's Medicaid plan, subject to reasonable limits the agency may establish on amounts of these expenses.

§ 435.800 Scope.
This subpart prescribes specific financial requirements for determining the eligibility of medically needy individuals under subpart D of this part.

§ 435.811 Medically needy income standard: General requirements.
(a) Except as provided in paragraph (d)(2) of this section, to determine eligibility of medically needy individuals, a Medicaid agency must use a single income standard under this subpart that meets the requirements of this section.
(b) The income standard must take into account the number of persons in the assistance unit. Subject to the limitations specified in paragraph (e) of this section. The standard may not diminish by an increase in the number of persons in the assistance unit. For example, if the income level in the standard for an assistance unit of two is set at $400, the income level in the standard for an assistance unit of three may not be less than $400.
(c) In States that do not use more restrictive requirements than SSI, the income standard must be set at an amount that is no lower than the lowest income standards used under the cash assistance programs that are related to the State’s covered medically needy eligibility group or groups of individuals under §435.301. The amount of the income standard is subject to the limitations specified in paragraph (e) of this section.
(d) In States that use more restrictive requirements for aged, blind, and disabled individuals than SSI:
   (1) For all individuals except aged, blind, and disabled individuals who are SSI:
      (a) The agency may establish a separate single medically needy income standard that is more restrictive than the single income standard set under paragraph (c) of this section. However, the amount of the more restrictive separate standard for aged, blind, or disabled individuals must be no lower than the higher of the lowest categorically needy income standard currently applied under the State’s more restrictive criteria under §435.121 or the medically needy income standard in effect under the State’s Medicaid plan on January 1, 1972. The amount of the income standard is subject to the limitations specified in paragraph (e) of this section.
      (b) The income standards specified in paragraphs (c) and (d) of this section must not exceed the maximum dollar amount of income allowed for purposes of FFP under §435.1007.
      (f) The income standard may vary based on the variations between shelter costs in urban areas and rural areas.

§ 435.814 Medically needy income standard: State plan requirements.
The State plan must specify the income standard for the covered medically needy groups.

§ 435.831 Income eligibility.
The agency must determine income eligibility of medically needy individuals in accordance with this section.
(a) Budget periods. (1) The agency must use budget periods of not more than 6 months to compute income. The agency may use more than one budget period.
   (2) The agency may include in the budget period in which income is computed all or part of the 3-month retroactive period specified in §435.914. The budget period can begin no earlier than the first month in the retroactive period in which the individual received covered services. This provision applies to all medically needy individuals except in groups for whom criteria more restrictive than that used in the SSI program apply.
   (3) If the agency elects to begin the first budget period for the medically

[58 FR 4932, Jan. 19, 1993]
§ 435.831

needy in any month of the 3-month period prior to the date of the application in which the applicant received covered services, this election applies to all medically needy groups.

(b) Determining countable income. The agency must deduct the following amounts from income to determine the individual's countable income.

(1) For individuals under age 21 and caretaker relatives, the agency must deduct amounts that would be deducted in determining eligibility under the State's AFDC plan.

(2) For aged, blind, or disabled individuals in States covering all SSI recipients, the agency must deduct amounts that would be deducted in determining eligibility under SSI. However, the agency must also deduct the highest amounts from income that would be deducted in determining eligibility for optional State supplements if these supplements are paid to all individuals who are receiving SSI or would be eligible for SSI except for their income.

(3) For aged, blind, or disabled individuals in States using income requirements more restrictive than SSI, the agency must deduct amounts that are no more restrictive than those used under the Medicaid plan on January 1, 1972 and no more liberal than those used in determining eligibility under SSI. However, the amounts must be at least the same as those that would be deducted in determining eligibility, under §435.121, of the categorically needy.

(c) Eligibility based on countable income. If countable income determined under paragraph (b) of this section is equal to or less than the applicable income standard under §435.834, the individual or family is eligible for Medicaid.

(d) Deduction of incurred medical expenses. If countable income exceeds the income standard, the agency must deduct from income medical expenses incurred by the individual or family or financially responsible relatives that are not subject to payment by a third party. An expense is incurred on the date liability for the expense arises. The agency must determine deductible incurred expenses in accordance with paragraphs (e), (f), and (g) of this section and deduct those expenses in accordance with paragraph (h) of this section.

(e) Determination of deductible incurred expenses: Required deductions based on kinds of services. Subject to the provisions of paragraph (g), in determining incurred medical expenses to be deducted from income, the agency must include the following:

(1) Expenses for Medicare and other health insurance premiums, and deductibles or coinsurance charges, including enrollment fees, copayments, or deductibles imposed under §447.51 or §447.53 of this subchapter;

(2) Expenses incurred by the individual or family or financially responsible relatives for necessary medical and remedial services that are recognized under State law but not included in the plan;

(3) Expenses incurred by the individual or family or by financially responsible relatives for necessary medical and remedial services that are included in the plan, including those that exceed agency limitations on amount, duration, or scope of services.

(f) Determination of deductible incurred expenses: Required deductions based on the age of bills. Subject to the provisions of paragraph (g), in determining incurred medical expenses to be deducted from income, the agency must include the following:

(1) For the first budget period or periods that include only months before the month of application for medical assistance, expenses incurred during such period or periods, whether paid or unpaid, to the extent that the expenses have not been deducted previously in establishing eligibility;

(2) For the first prospective budget period that also includes any of the 3 months before the month of application, expenses incurred during such budget period, whether paid or unpaid, to the extent that the expenses have not been deducted previously in establishing eligibility;

(3) For the first prospective budget period that includes none of the months preceding the month of application, expenses incurred during such
budget period and any of the 3 preceding
months, whether paid or unpaid, to
the extent that the expenses have not
been deducted previously in establish-
ing eligibility;
(4) For any of the 3 months preceding
the month of application that are not
included under paragraph (f)(2) of
this section, expenses incurred in the 3-
month period that were a current li-
bability of the individual in any such
month for which a spenddown calcula-
tion is made and that had not been pre-
viously deducted from income in estab-
lishing eligibility for medical assist-
ance;
(5) Current payments (that is, pay-
ments made in the current budget pe-
riod) on other expenses incurred before
the current budget period and not pre-
viously deducted from income in any
budget period in establishing eligi-
bility for such period; and
(6) If the individual’s eligibility for
medical assistance was established in
each such preceding period, expenses
incurred before the current budget pe-
riod but not previously deducted from
income in establishing eligibility, to
the extent that such expenses are un-
paid and are:
(i) Described in paragraphs (e)(1)
through (e)(3) of this section; and
(ii) Carried over from the preceding
budget period or periods because the
individual had a spenddown liability in
each such preceding period that was
met without deducting all such in-
curred, unpaid expenses.
(g) Determination of deductible incurred
medical expenses: Optional deductions. In
determining incurred medical expenses
to be deducted from income, the agen-
cy
(1) May include medical institutional
expenses (other than expenses in acute
care facilities) projected to the end of
the budget period at the Medicaid re-
imbursement rate;
(2) May, to the extent determined by
the State and specified in its approved
plan, include expenses incurred earlier
than the third month before the month
of application (except States using
more restrictive eligibility criteria
under the option in section 1902(f) of
the Act must deduct incurred expenses
regardless of when the expenses were
incurred); and
(3) May set reasonable limits on the
amount to be deducted for expenses
specified in paragraphs (e)(1), (e)(2),
and (g)(2) of this section.
(h) Order of deduction. The agency
must deduct incurred medical expenses
that are deductible under paragraphs
(e), (f), and (g) of this section in the
order prescribed under one of the fol-
lowing three options:
(1) Type of service. Under this option,
the agency deducts expenses in the fol-
lowing order based on type of expense
or service:
(i) Cost-sharing expenses as specified
in paragraph (e)(1) of this section.
(ii) Services not included in the State
plan as specified in paragraph (e)(2)
of this section.
(iii) Services included in the State
plan as specified in paragraph (e)(3)
of this section but that exceed limita-
tions on amounts, duration, or scope of
services.
(iv) Services included in the State
plan as specified in paragraph (e)(3)
of this section but that are within agency
limitations on amount, duration, or
scope of services.
(2) Chronological order by service date.
Under this option, the agency deducts
expenses in chronological order by the
date each service is furnished, or in the
case of insurance premiums, coinsur-
ance or deductible charges, the date
such amounts are due. Expenses for
services furnished on the same day
may be deducted in any reasonable
order established by the State.
(3) Chronological order by bill submis-
sion date. Under this option, the agency
deducts expenses in chronological
order by the date each bill is submitted
to the agency by the individual. If
more than one bill is submitted at one
time, the agency must deduct the bills
from income in the order prescribed in
either paragraph (h)(1) or (h)(2) of this
section.
(i) Eligibility based on incurred medical
expenses.
(1) Whether a State elects partial or
full month coverage, an individual who
is expected to contribute a portion of
his or her income toward the costs of
institutional care or home and commu-
nity-based services under §§435.725,
§ 435.832 Post-eligibility treatment of income of institutionalized individuals: Application of patient income to the cost of care.

(a) Basic rules. (1) The agency must reduce its payment to an institution, for services provided to an individual specified in paragraph (b) of this section, by the amount that remains after deducting the amounts specified in paragraphs (c) and (d) of this section, from the individual's total income.

(2) The individual's income must be determined in accordance with paragraph (e) of this section.

(3) Medical expenses must be determined in accordance with paragraph (f) of this section.

(b) Applicability. This section applies to medically needy individuals in medical institutions and intermediate care facilities.

(c) Required deductions. The agency must deduct the following amounts, in the following order, from the individual's total income, as determined under paragraph (e) of this section. Income that was disregarded in determining eligibility must be considered in this process.

(1) Personal needs allowance. A personal needs allowance that is reasonable in amount for clothing and other personal needs of the individual while in the institution. This protected personal needs allowance must be at least—

(i) $30 a month for an aged, blind, or disabled individual, including a child applying for Medicaid on the basis of blindness or disability.

(ii) $60 a month for an institutionalized couple if both spouses are aged, blind, or disabled and their income is considered available to each other in determining eligibility; and

(iii) For other individuals, a reasonable amount set by the agency, based on a reasonable difference in their personal needs from those of the aged, blind, and disabled.

(2) Maintenance needs of spouse. For an individual with only a spouse at home, an additional amount for the maintenance needs of the spouse. This amount must be based on a reasonable assessment of need but must not exceed the highest of—

(i) $30 a month for an aged, blind, or disabled individual, including a child applying for Medicaid on the basis of blindness or disability.

(ii) $60 a month for an institutionalized couple if both spouses are aged, blind, or disabled and their income is considered available to each other in determining eligibility; and

(iii) For other individuals, a reasonable amount set by the agency, based on a reasonable difference in their personal needs from those of the aged, blind, and disabled.

(3) Expenses used to meet spenddown liability are not reimbursable under Medicaid. To the extent necessary to prevent the transfer of an individual's spenddown liability to the Medicaid program, States must reduce the amount of provider charges that would otherwise be reimbursable under Medicaid.

[59 FR 1672, Jan. 12, 1994]
used to determine eligibility for an optional State supplement for an individual in his own home, if the agency provides Medicaid to optional State supplement recipients under §435.230 or

(iii) The amount of the medically needy income standard for one person established under §435.811.

(3) Maintenance needs of family. For an individual with a family at home, an additional amount for the maintenance needs of the family. This amount must—

(i) Be based on a reasonable assessment of their financial need;
(ii) Be adjusted for the number of family members living in the home; and
(iii) Not exceed the highest of the following need standards for a family of the same size:
(A) The standard used to determine eligibility under the State's approved AFDC plan.
(B) The medically needy income standard established under §435.811.

(4) Expenses not subject to third party payment. Amounts for incurred expenses for medical or remedial care that are not subject to payment by a third party, including—

(i) Medicare and other health insurance premiums, deductibles, or coinsurance charges; and
(ii) Necessary medical or remedial care recognized under State law but not covered under the State's Medicaid plan, subject to reasonable limits the agency may establish on amounts of these expenses.

(d) Optional deduction: Allowance for home maintenance. For single individuals and couples, an amount (in addition to the personal needs allowance) for maintenance of the individual’s or couple’s home if—

(1) The amount is deducted for not more than a 6-month period; and

(2) A physician has certified that either of the individuals is likely to return to the home within that period.

(e) Determination of income—(1) Option. In determining the amount of an individual’s income to be used to reduce the agency’s payment to the institution, the agency may use total income received or it may project total monthly income for a prospective period not to exceed 6 months.

(2) Basis for projection. The agency must base the projection on income received in the preceding period, not to exceed 6 months, and on income expected to be received.

(3) Adjustments. At the end of the prospective period specified in paragraph (e)(1) of this section, or when any significant change occurs, the agency must reconcile estimates with income received.

(f) Determination of medical expenses—

(1) Option. In determining the amount of medical expenses to be deducted from an individual’s income, the agency may deduct incurred medical expenses, or it may project medical expenses for a prospective period not to exceed 6 months.

(2) Basis for projection. The agency must base the estimate on medical expenses incurred in the preceding period, not to exceed 6 months, and medical expenses expected to be incurred.

(3) Adjustments. At the end of the prospective period specified in paragraph (f)(1) of this section, or when any significant change occurs, the agency must reconcile estimates with incurred medical expenses.


MEDICALLY NEEDY RESOURCE STANDARD

§435.840 Medically needy resource standard: General requirements.

(a) To determine eligibility of medically needy individuals, a Medicaid agency must use a single resource standard that meets the requirements of this section.

(b) In States that do not use more restrictive criteria than SSI for aged, blind, and disabled individuals, the resource standard must be established at an amount that is no lower than the lowest resource standard used under the cash assistance programs that relate to the State’s covered medically needy eligibility group or groups of individuals under §435.301.

(c) In States using more restrictive requirements than SSI:
§ 435.843 Medically needy resource standard: State plan requirements.

The State plan must specify the resource standard for the covered medically needy groups.

[58 FR 4933, J an. 19, 1993]

§ 435.845 Medically needy resource eligibility.

To determine eligibility on the basis of resources for medically needy individuals, the agency must:

(a) Consider only the individual’s resources and those that are considered available to him under the financial responsibility requirements for relatives in § 435.602.

(b) Deduct the amounts that would be deducted in determining resource eligibility for the medically needy group as provided for in § 435.601 or under the criteria of States using more restrictive criteria than SSI as provided for in § 435.121. In determining the amount of an individual’s resources for Medicaid eligibility, States must count amounts of resources that otherwise would not be counted under the conditional eligibility provisions of the SSI or AFDC programs.

(c) Apply the resource standard specified under § 435.840.

[58 FR 4933, J an. 19, 1993]

§§ 435.850–435.852 [Reserved]
§ 435.904 Establishment of outstation locations to process applications for certain low-income eligibility groups.

(a) State plan requirements. The Medicaid State plan must specify that the requirements of this section are met.

(b) Opportunity to apply. The agency must provide an opportunity for the following groups of low-income pregnant women, infants, and children under age 19 to apply for Medicaid at outstation locations other than AFDC offices:

1. The groups of pregnant women or infants with incomes up to 133 percent of the Federal poverty level as specified under section 1902(a)(10)(A)(i)(IV) of the Act;

2. The group of children age 1 up to age 6 with incomes at 133 percent of the Federal poverty level as specified under section 1902(a)(10)(A)(i)(VI) of the Act;

3. The group of children age 6 up to age 19 born after September 30, 1983, with incomes up to 100 percent of the Federal poverty level as specified under section 1902(a)(10)(A)(i)(VII) of the Act; and

4. The groups of pregnant women or infants, children age 1 up to age 6, and children age 6 up to age 19, who are not eligible as a mandatory group, with incomes up to 185 percent of the Federal poverty level as specified under section 1902(a)(10)(A)(iii)(IX) of the Act.

(c) Outstation locations: general requirements.

1. The agency must establish either—

   (i) Outstation locations at each disproportionate share hospital, as defined in section 1923(a)(1)(A) of the Act, and each Federally-qualified health center, as defined in section 1905(l)(2)(B) of the Act, participating in the Medicaid program and providing services to Medicaid-eligible pregnant women and children; or

   (ii) Other outstation locations, which include at least some, disproportionate share hospitals and federally-qualified health centers, as specified under an alternative State plan that is submitted to and approved by HCFA if the following conditions are met:

   (A) The State must demonstrate that the alternative plan for outstationing is equally effective as, or more effective than, a plan that would meet the requirements of paragraph (c)(1)(i) of this section in enabling the individuals described in paragraph (b) of this section to apply for and receive Medicaid; and

   (B) The State must provide assurances that the level of staffing and funding committed by the State under the alternative plan equals or exceeds the level of staffing and funding under a plan that would meet the requirements of establishing the outstation locations at the sites specified in paragraph (c)(1)(i) of this section.

2. The agency must establish outstation locations at Indian health clinics operated by a tribe or tribal organization as these clinics are specifically included in the definition of Federally-qualified health centers under section 1905(l)(2)(B) of the Act and are also included in the definition of rural health clinics under part 491, subpart A of this chapter.

3. The agency may establish additional outstation locations at any other site where potentially eligible pregnant women or children receive services—for example, at school-linked service centers and family support centers. These additional sites may also include sites other than the main outstation location of those Federally-qualified health centers or disproportionate share hospitals providing services to Medicaid-eligible pregnant women and to children and that operate more than one site.

4. The agency may, at its option, enter into reciprocal agreements with neighboring States to ensure that the groups described in paragraph (b) of this section who customarily receive services in a neighboring State have the opportunity to apply at outstation locations specified in paragraphs (c)(1) and (2) of this section.
(d) Outstation functions. (1) The agency must provide for the receipt and initial processing of Medicaid applications from the designated eligibility groups at each outstation location.

(2) “Initial processing” means taking applications, assisting applicants in completing the application, providing information and referrals, obtaining required documentation to complete processing of the application, assuring that the information contained on the application form is complete, and conducting any necessary interviews. It does not include evaluating the information contained on the application and the supporting documentation or making a determination of eligibility or ineligibility.

(3) The agency may, at its option, allow appropriate State eligibility workers assigned to outstation locations to evaluate the information contained on the application and the supporting documentation and make a determination of eligibility if the workers are authorized to determine eligibility for the agency which determines Medicaid eligibility under §431.10 of this subchapter.

(e) Staffing. (1) Except for outstation locations that are infrequently used by the low-income eligibility groups, the State agency must have staff available at each outstation location during the regular office operating hours of the State Medicaid agency to accept applications and to assist applicants with the application process.

(2) The agency may station staff at one outstation location or rotate staff among several locations as workload and staffing availability dictate.

(3) The agency may use State employees, provider or contractor employees, or volunteers who have been properly trained to staff outstation locations under the following conditions:

(i) State outstation intake staff may perform all eligibility processing functions, including the eligibility determination, if the staff is authorized to do so at the regular Medicaid intake office.

(ii) Provider or contractor employees and volunteers may perform only initial processing functions as defined in paragraph (d)(2) of this section.

(4) Provider and contractor employees and volunteers are subject to the confidentiality of information rules specified in part 431, subpart F, of this subchapter, to the prohibition against reassignment of provider claims specified in §447.10 of this subchapter, and to all other State or Federal laws concerning conflicts of interest.

(5) At locations that are infrequently used by the designated low-income eligibility groups, the State agency may use volunteers, provider or contractor employees, or its own eligibility staff, or telephone assistance.

(i) The agency must display a notice in a prominent place at the outstation location advising potential applicants of when outstation intake workers will be available.

(ii) The notice must include a telephone number that applicants may call for assistance.

(iii) The agency must comply with Federal and State laws and regulations governing the provision of adequate notice to persons who are blind or deaf or who are unable to read or understand the English language.

[59 FR 48809, Sept. 23, 1994]

§435.906 Opportunity to apply.

The agency must afford an individual wishing to do so the opportunity to apply for Medicaid without delay.

[44 FR 17937, Mar. 23, 1979, as amended at 45 FR 24887, Apr. 11, 1980]
§ 435.907 Written application.

(a) The agency must require a written application from the applicant, an authorized representative, or, if the applicant is incompetent or incapacitated, someone acting responsibly for the applicant.

(b) Subject to the conditions specified in paragraph (c) of this section, the application must be on a form prescribed by the agency and signed under a penalty of perjury.

(c) The application form used at outstation locations for low-income pregnant women, infants, and children specified in § 435.904 must not be the application form used to apply for AFDC. The application form (including any computerized application form) for these designated eligibility groups may be—

1. A Medicaid-only form prescribed by the agency specifically for the designated eligibility groups;
2. An existing Medicaid-only application; or
3. A multiple-program application that contains clearly identifiable Medicaid-only sections or parts.

§ 435.908 Assistance with application.

The agency must allow an individual or individuals of the applicant’s choice to accompany, assist, and represent the applicant in the application process or a redetermination of eligibility.

§ 435.909 Automatic entitlement to Medicaid following a determination of eligibility under other programs.

The agency must not require a separate application for Medicaid from an individual, if—

(a) The individual receives AFDC; or
(b) The agency has an agreement with the Social Security Administration (SSA) under section 1634 of the Act for determining Medicaid eligibility; and—

1. The individual receives SSI;
2. The individual receives a mandatory State supplement under either a federally-administered or State-administered program; or
3. The individual receives an optional State supplement and the agency provides Medicaid to recipients of optional supplements under § 435.230.

§ 435.910 Use of social security number.

(a) The agency must require, as a condition of eligibility, that each individual (including children) requesting Medicaid services furnish each of his or her social security numbers (SSNs).

(b) The agency must advise the applicant of—

1. [Reserved]
2. The statute or other authority under which the agency is requesting the applicant’s SSN; and
3. The uses the agency will make of each SSN, including its use for verifying income, eligibility, and amount of medical assistance payments under §§ 435.940 through 435.960.

(c)—(d) [Reserved]

(e) If an applicant cannot recall his SSN or SSNs or has not been issued a SSN the agency must—

1. Assist the applicant in completing an application for an SSN;
2. Obtain evidence required under SSA regulations to establish the age, the citizenship or alien status, and the true identity of the applicant; and
3. Either send the application to SSA or, if there is evidence that the applicant has previously been issued a SSN, request SSA to furnish the number.

(f) The agency must not deny or delay services to an otherwise eligible applicant pending issuance or verification of the individual’s SSN by SSA.

(g) The agency must verify each SSN of each applicant and recipient with SSA, as prescribed by the Commissioner, to insure that each SSN furnished was issued to that individual, and to determine whether any others were issued.


DETERMINATION OF MEDICAID ELIGIBILITY

§ 435.911 Timely determination of eligibility.

(a) The agency must establish time standards for determining eligibility and inform the applicant of what they are. These standards may not exceed—
§ 435.912 Notice of agency's decision concerning eligibility.

The agency must send each applicant a written notice of the agency's decision on his application, and, if eligibility is denied, the reasons for the action, the specific regulation supporting the action, and an explanation of his right to request a hearing. (See subpart E of part 431 of this subchapter for rules on hearings.)


§ 435.913 Case documentation.

(a) The agency must include in each applicant's case record facts to support the agency's decision on his application.

(b) The agency must dispose of each application by a finding of eligibility or ineligibility, unless—

(1) There is an entry in the case record that the applicant voluntarily withdrew the application, and that the agency sent a notice confirming his decision;

(2) There is a notice confirming the case record that the applicant has died; or

(3) There is a supporting entry in the case record that the applicant cannot be located.

§ 435.914 Effective date.

(a) The agency must make eligibility for Medicaid effective no later than the third month before the month of application if the individual—

(1) Received Medicaid services, at any time during that period, of a type covered under the plan; and

(2) Would have been eligible for Medicaid at the time he received the services if he had applied (or someone had applied for him), regardless of whether the individual is alive when application for Medicaid is made.

(b) The agency may make eligibility for Medicaid effective on the first day of a month if an individual was eligible at any time during that month.

(c) The State plan must specify the date on which eligibility will be made effective.

§ 435.916 Periodic redeterminations of Medicaid eligibility.

(a) The agency must redetermine the eligibility of Medicaid recipients, with respect to circumstances that may change, at least every 12 months, however—

(1) The agency may consider blindness as continuing until the review physician under § 435.531 determines that a recipient's vision has improved beyond the definition of blindness contained in the plan; and

(2) The agency may consider disability as continuing until the review team under § 435.541 determines that a recipient's disability no longer meets the definition of disability contained in the plan.

(b) Procedures for reporting changes. The agency must have procedures designed to ensure that recipients make timely and accurate reports of any change in circumstances that may affect their eligibility.
§ 435.919 Timely and adequate notice concerning adverse actions.

(a) The agency must give recipients timely and adequate notice of proposed action to terminate, discontinue, or suspend their eligibility or to reduce or discontinue services they may receive under Medicaid.

(b) The notice must meet the requirements of subpart E of part 431 of this subchapter.

§ 435.920 Verification of SSNs.

(a) In redetermining eligibility, the agency must review case records to determine whether they contain the recipient's SSN or, in the case of families, each family member's SSN.

(b) If the case record does not contain the required SSNs, the agency must require the recipient to furnish them and meet other requirements of §435.910.

(c) For any recipient whose SSN was established as part of the case record without evidence required under the SSA regulations as to age, citizenship, alien status, or true identity, the agency must obtain verification of these factors in accordance with §435.910.

§ 435.940 Basis and scope.

(a) Section 1137 of the Act requires certain Federally-funded, State-administered public assistance programs to establish procedures for obtaining, using and verifying information relevant to determinations as to eligibility and the amount of assistance. Section 1902(a)(4) of the Act allows the Secretary to prescribe methods of administration found necessary for the proper and efficient operation of a State's Medicaid plan.

(b) The agency must maintain information, as enumerated in §435.960, to exchange for the purpose of enabling any agency or program referenced in §435.945(b) to verify income, eligibility of, and the amount of assistance for its applicants and recipients.

§ 435.945 General requirements.

(a) The agency must request and use information timely in accordance with §§435.948, 435.952, and 435.953 of this subpart for verifying Medicaid eligibility and the amount of medical assistance payments.

(b) The agency must furnish timely to other agencies in the State and in other States and to Federal programs income, eligibility and medical assistance payment information for verifying eligibility or benefit amounts for the programs listed in §435.948(a)(6) of this subpart. In addition, the agency must furnish income and eligibility information to—

(1) The child support enforcement program under part D of title IV of the Act; and

(2) SSA for old age, survivors and disability benefits under title II and for SSI benefits under title XVI of the Act.

(c) Make arrangements to assist applicants and recipients to get emergency medical care whenever needed, 24 hours a day and 7 days a week.

§ 435.949 Timely and adequate notice concerning adverse actions.

§ 435.920 Verification of SSNs.

§ 435.930 Furnishing Medicaid.

The agency must—

(a) Furnish Medicaid promptly to recipients without any delay caused by the agency's administrative procedures;

(b) Continue to furnish Medicaid regularly to all eligible individuals until they are found to be ineligible; and

(c) Reimburse another agency listed in

FURNISHING MEDICAID

§ 435.940 Basis and scope.

(a) Section 1137 of the Act requires certain Federally-funded, State-administered public assistance programs to establish procedures for obtaining, using and verifying information relevant to determinations as to eligibility and the amount of assistance.

(b) The agency must maintain information, as enumerated in §435.960, to exchange for the purpose of enabling any agency or program referenced in §435.945(b) to verify income, eligibility of, and the amount of assistance for its applicants and recipients.

§ 435.945 General requirements.

(a) The agency must request and use information timely in accordance with §§435.948, 435.952, and 435.953 of this subpart for verifying Medicaid eligibility and the amount of medical assistance payments.

(b) The agency must furnish timely to other agencies in the State and in other States and to Federal programs income, eligibility and medical assistance payment information for verifying eligibility or benefit amounts for the programs listed in §435.948(a)(6) of this subpart. In addition, the agency must furnish income and eligibility information to—

(1) The child support enforcement program under part D of title IV of the Act; and

(2) SSA for old age, survivors and disability benefits under title II and for SSI benefits under title XVI of the Act.

(c) Make arrangements to assist applicants and recipients to get emergency medical care whenever needed, 24 hours a day and 7 days a week.
§ 435.948 Requesting information.

(a) Except as provided in paragraphs (d), (e), and (f) of this section, the agency must request information from the sources specified in this paragraph for verifying Medicaid eligibility and the correct amount of medical assistance payments for each applicant (unless obviously ineligible on the face of his or her application) and recipient. The agency must request—

(ii) Justification and expected results;
(iii) Records description (including specific identification of the system of records, the number of records, what data elements will be included in the match, and projected starting and completion dates);
(iv) Notice procedures;
(v) Verification procedures;
(vi) Disposition of matched items;
(vii) Security procedures;
(viii) Records usage, duplication and redisclosure restrictions;
(ix) Records accuracy assessments; and
(x) Access by the Comptroller General.

(g) SWICA that does not use the quarterly wages reported by employers as required by Section 1137 of the Act of unemployment insurance benefit calculations must maintain wage information that:

(1) Contains the SSN, full name, wages earned for the period of the report, and an identifier of the employer;
(2) Includes all employers covered by the States' UC law;
(3) Accumulates earnings reported by employers for no longer periods than calendar quarters;
(4) Is reported to the SWICA within 30 days after the end of the quarter;
(5) Is machine readable; and
(6) Is accessible to agencies in other States that have executed agreements as required in §435.945(f) of this chapter and to SSA for use in making eligibility or benefit determinations under Title II or XVI of the Act.

(1) State wage information maintained by the SWICA during the application period and at least on a quarterly basis;

(2) Information about net earnings from self-employment, wage and payment of retirement income, maintained by SSA and available under Section 6103(l)(7)(A) of the Internal Revenue Code of 1954, for applicants during the application period and for recipients for whom the information has not previously been requested;

(3) Information about benefit and other eligibility related information available from SSA under titles II and XVI of the Social Security Act for applicants during the application period and for recipients for whom the information has not previously been requested;

(4) Unearned income information from the Internal Revenue Service available under Section 6103(l)(7)(B) of the Internal Revenue Code of 1954, during the application period and at least yearly;

(5) Unemployment compensation information maintained by the agency administering State unemployment compensation laws (under the provisions of section 3304 of the Internal Revenue Code and section 303 of the Act) as follows:
   (i) For an applicant, during the application period and at least for each of the three subsequent months;
   (ii) For a recipient that reports a loss of employment, at the time the recipient reports that loss and for at least each of the three subsequent months.
   (iii) For an applicant or a recipient who is found to be receiving unemployment compensation benefits, at least for each month until the benefits are reported to be exhausted.

(6) Any additional income, resource, or eligibility information relevant to determinations concerning eligibility or correct amount of medical assistance or payments available from agencies in the State or other States administering the following programs as provided in the agency’s State plan:
   (i) AFDC;
   (ii) Medicaid;
   (iii) State-administered supplementary payment programs under Section 1616(a) of the Act;
   (iv) SWICA;
   (v) Unemployment compensation;
   (vi) Food stamps; and
   (vii) Any State program administered under a plan approved under Title I (assistance to the aged), X (aid to the blind), XIV (aid to the permanently and totally disabled), or XVI (aid to the aged, blind, and disabled in Puerto Rico, Guam, and the Virgin Islands) of the Act.

(b) The agency must request information on applicants from the sources listed in paragraph (a)(1) through (a)(5) of this section at the first opportunity provided by these sources following the receipt of the application. If an applicant cannot provide an SSN at application, the agency must request the information at the next available opportunity after receiving the SSN.

(c) The agency must request the information required in paragraph (a) of this section by SSN, using each SSN furnished by the individual or received through verification.

(d) Exception: In cases where the individual is institutionalized, the agency needs to obtain and use information from SWICA only during the application period and on a yearly basis, and from unemployment compensation agencies only during the application period. An individual is institutionalized for purposes of this section when he or she is required to apply his or her income to the cost of medical care as required by §§435.725, 435.733, and 435.832.

(e) Exception: Alternate sources. (1) The Secretary may, upon application from a State agency, permit an agency to request and use income information from a source or sources alternative to those listed in paragraph (a) of this section. The agency must demonstrate to the Secretary that the alternative source(s) is as timely, complete and useful for verifying eligibility and benefit amounts. The Secretary will consult with the Secretary of Agriculture and the Secretary of Labor before determining whether an agency may use an alternate source.

(2) The agency must continue to meet the requirements of this section unless the Secretary has approved the request.
§ 435.952 Use of information.

(a) Except as provided under §435.953, the agency must review and compare against the case file all information received under §§435.940 through 435.960 to determine whether it affects the applicant’s or recipient’s eligibility or amount of medical assistance payment. The agency also must independently verify the information if required by §435.955 or if determined appropriate by agency experience.

(b) For applicants, if the information is received during the application period, it must be used, to the extent possible, making eligibility determinations. If it is received after the eligibility determination, it must be used as specified for recipients in paragraphs (c) and (d) of this section.

(c) Except as specified in §435.953 of this subpart and paragraph (d) of this section, for recipients, the agency must, within 45 days of receipt of an item of information, request verification (if appropriate), determine whether the information affects eligibility or the amount of medical assistance payment, and either initiate a notice of case action to advise the recipient of any adverse action the agency intends to take or make an entry in the casefile that no further action is necessary.

(d) Subject to paragraph (e) of this section, if the agency does not receive requested third party verification within the 45-day period after receipt of information, the agency may determine whether the information affects eligibility or correct amount of medical assistance payment after the 45-day period. However, the agency must make any delayed determinations permitted under this paragraph—

(1) Promptly, as required by §435.916, if the verification is received before the next redetermination; or

(2) In conjunction with the next redetermination if no verification is received before that redetermination.

(e) The number of determinations delayed beyond 45 days from receipt of an item of information (as permitted by paragraph (d) of this section) must not exceed twenty percent of the number of items of information for which verification was requested.

(f) The agency must use appropriate procedures to monitor the timeliness requirements of this section.

§ 435.953 Identifying items of information to use.

(a) With respect to information received on recipients under §§435.940 through 435.960, the agency may either review and compare against the case file all items of information received or it may identify (target) separately for each data source the information items that are most likely to be most productive in identifying and preventing ineligibility and incorrect payments.

(b) An agency that wishes to exclude categories of information items must submit for the Secretary’s approval a follow-up plan describing the categories that it proposes to exclude. For each category, the agency must provide a reasonable justification that follow-up is not cost-effective; a formal cost/benefit analysis is not required.

(c) If an agency receives an item of unemployment compensation information from the Internal Revenue Service or earnings information from SSA that duplicates an item of information previously received from another source and followed up, the agency may exclude that information item without justification.

(d) An agency may submit a follow-up plan or alter its plan at any time by notifying the Secretary and submitting the necessary justification. The Secretary approves or disapproves categories of items to be excluded under the plan within 60 days of its submission. The categories approved by the
§ 435.955 Additional requirements regarding information released by a Federal agency.

(a) Unless waived under paragraph (d) of this section, based on information received from a computerized data match in which information on an individual is provided to the agency by a Federal agency, the agency may not terminate, deny, suspend, or reduce medical assistance to that individual until it has taken appropriate steps to verify the information independently. The agency must independently verify information relating to—

(1) The amount of the income and resource that generated the income involved;

(2) Whether the applicant or recipient actually has (or had) access to the resource or income (or both) for his or her own use;

(3) The period or periods when the individual actually has (or had) access to the resource or income or both.

(b) The agency must verify the information by either

(1) Requesting the entity from which the information originally came to verify the fact and amount of income or resource; or

(2) Sending the applicant or recipient a letter informing that individual of the information received and asking him or her to respond within a specified period. The letter must clearly explain the information the agency has and its possible relevance to the individual’s past or future eligibility, and be as neutral in tone as possible.

(c)(1) If the original source of the income or resource or the applicant or recipient verifies the information, and the agency intends to reduce, suspend, terminate or deny medical assistance based on the information, the agency must send the applicant or recipient a notice of the action to be taken and include information on the right to appeal and opportunity for a hearing under §§431.200 through 431.246 of this chapter (see also §435.912 and §435.919).

(2) If the applicant or recipient fails to respond after reasonable attempts to contact him or her, the agency must proceed to deny, terminate, reduce or suspend medical assistance based on the applicant’s or recipient’s failure to cooperate.

(3) If the applicant or recipient disputes the information, the agency must obtain evidence (from the source of the data, applicant, recipient, or otherwise) to substantiate any negative case action it may take.

(d) The independent verification requirement concerning a category of data received from a Federal benefit agency may be waived if the Federal agency’s Data Integrity Board approves the waiver. The Federal benefit agency involved in the data exchange will develop the request by petitioning its Data Integrity Board for a waiver of independent verification by a Medicaid State agency. The State agency must furnish the Federal agency with any information it needs to seek the Data Integrity Board’s approval of the waiver.

(e) In accordance with the Federal agency’s procedures, the agency must provide data on the costs and benefits of the matching program to the Federal agency from which it receives information on individuals.

(f) In accordance with the Federal agency’s procedures, the agency must certify to the Federal agency that it will not take adverse action against an individual until the information has been independently verified and until 10 days (or sooner if permitted by §431.213 or §431.214) after the individual has been notified of the findings and given an opportunity to contest.

(g) In accordance with the Federal agency’s procedures for renewals of matching programs, the agency must certify to the Federal agency that the terms of the agreement have been followed.

[59 FR 4255, Jan. 31, 1994]

§ 435.960 Standardized formats for furnishing and obtaining information to verifying income and eligibility.

(a) The agency must maintain for all applicants and recipients within an agency file the SSN, surname and other data elements in a format that at
a minimum allows the agency to furnish and to obtain eligibility and income information from the agencies or programs referenced in §435.945(b) and §435.948(a).

(b) The format to be used will be prescribed by—

(1) HCFA when the agency furnishes information to, or requests information from, any Federal or State agency, except SSA and the Internal Revenue Service as specified in paragraphs (b) (2) and (3), respectively;

(2) The Commissioner of Social Security when the agency requests information from SSA; and

(3) The Commissioner of Internal Revenue when the agency requests information from the Internal Revenue Service.

[52 FR 5977, Feb. 27, 1987]

§ 435.965 Delay of effective date.

(a) If the agency submits, by May 29, 1986, a plan describing a good faith effort to come into compliance with the requirements of section 1137 of the Act and of §§ 435.910 and 435.940 through 435.960 of this subpart, the Secretary may, after consultation with the Secretary of Agriculture and the Secretary of Labor, grant a delay in the effective date of §§ 435.910 and 435.940 through 435.960, but not beyond September 30, 1986.

(b) The Secretary may not grant a delay of the effective date of section 1137(c) of the Act, which is implemented by §435.955 (a) and (c). (The provisions of these statutory and regulation sections require the agency to follow certain procedures before taking any adverse actions based on information from the Internal Revenue Service concerning unearned income.)

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Subpart K—Federal Financial Participation

§ 435.1000 Scope.

This subpart specifies when, and the extent to which, FFP is available in expenditures for determining eligibility and for Medicaid services to individuals determined eligible under this part, and prescribes limitations and conditions on FFP for those expenditures.

§ 435.1000 Scope.

This subpart specifies when, and the extent to which, FFP is available in expenditures for determining eligibility and for Medicaid services to individuals determined eligible under this part, and prescribes limitations and conditions on FFP for those expenditures.
§ 435.1007 Categorically needy, medically needy, and qualified Medicare beneficiaries.

(a) FFP is available in expenditures for covered services provided to categorically needy recipients, medically needy recipients, and qualified Medicare beneficiaries, subject to the restrictions contained in subpart K of this part and as provided in paragraphs (b) and (e) of this section. However, the restrictions listed in paragraphs (b) and (e) of this section do not apply to expenditures for medical assistance made on behalf of qualified Medicare beneficiaries under section 1905(p) of the Act; individuals receiving Medicaid as categorically needy under section 1902(a)(10)(A)(i) (I), (II), (III), (IV), (V), (VI), or (VII) and section 1902(a)(10)(A)(ii) (I), (IX), or (X) of the Act; individuals who are eligible to receive benefits (or would be eligible for those benefits if they were not in a medical institution); and any individuals deemed to be members of the groups identified in this sentence.

(b) Except as provided in paragraphs (c) and (d) of this section, FFP is not available in State expenditures for individuals (including the medically

§ 435.1004 Recipients overcoming certain conditions of eligibility.

(a) FFP is available, as specified in paragraph (b) of this section, in expenditures for services provided to recipients who are overcoming certain eligibility conditions, including blindness, disability, continued absence or incapacity of a parent, or unemployment of a parent.

(b) FFP is available for a period not to exceed—

(1) The period during which a recipient of AFDC, SSI or an optional State supplement continues to receive cash payments while these conditions are being overcome; or

(2) For recipients eligible for Medicaid only and recipients of AFDC, SSI or an optional State supplement who do not continue to receive cash payments, the second month following the month in which the recipient’s Medicaid eligibility would have been terminated.

§ 435.1008

Institutionalized individuals.

(a) FFP is not available in expenditures for services provided to—

(1) Individuals who are inmates of public institutions as defined in § 435.1009; or

(2) Individuals under age 65 who are patients in an institution for mental diseases unless they are under age 22 and are receiving inpatient psychiatric services under § 440.160 of this subchapter.

(b) The exclusion of FFP described in paragraph (a) of this section does not apply during that part of the month in which the individual is not an inmate of a public institution or a patient in an institution for tuberculosis or mental diseases.

(c) An individual on conditional release or convalescent leave from an institution for mental diseases is not considered to be a patient in that institution. However, such an individual who is under age 22 and has been receiving inpatient psychiatric services under § 440.160 of this subchapter is considered to be a patient in the institution until he is unconditionally released or, if earlier, the date he reaches age 22.


§ 435.1009 Definitions relating to institutional status.

For purposes of FFP, the following definitions apply:

Active treatment in intermediate care facilities for the mentally retarded means treatment that meets the requirements specified in the standard concerning active treatment for intermediate care facilities for persons with mental retardation under § 483.440(a) of this subchapter.

Child-care institution means a nonprofit private child-care institution, or a public child-care institution that accommodates no more than twenty-five children, which is licensed by the State...
in which it is situated, or has been approved by the agency of the State responsible for licensing or approval of institutions of this type, as meeting the standards established for licensing.

The term does not include detention facilities, forestry camps, training schools or any other facility operated primarily for the detention of children who are determined to be delinquent.

In an institution refers to an individual who is admitted to live there and receive treatment or services provided there that are appropriate to his requirements.

Inmate of a public institution means a person who is living in a public institution. An individual is not considered an inmate if—
(a) He is in a public educational or vocational training institution for purposes of securing education or vocational training; or
(b) He is in a public institution for a temporary period pending other arrangements appropriate to his needs.

Inpatient means a patient who has been admitted to a medical institution as an inpatient on recommendation of a physician or dentist and who—
(1) Receives room, board and professional services in the institution for a 24 hour period or longer, or
(2) Is expected by the institution to receive room, board and professional services in the institution for a 24 hour period or longer even though it later develops that the patient dies, is discharged or is transferred to another facility and does not actually stay in the institution for 24 hours.

Institution means an establishment that furnishes (in single or multiple facilities) food, shelter, and some treatment or services to four or more persons unrelated to the proprietor.

Institution for mental diseases means a hospital, nursing facility, or other institution of more than 16 beds that is primarily engaged in providing diagnosis, treatment or care of persons with mental diseases, including medical attention, nursing care and related services. Whether an institution is an institution for mental diseases is determined by its overall character as that of a facility established and maintained primarily for the care and treatment of individuals with mental diseases, whether or not it is licensed as such. An institution for the mentally retarded is not an institution for mental diseases.

Institution for the mentally retarded or persons with related conditions means an institution (or distinct part of an institution) that—
(a) Is primarily for the diagnosis, treatment, or rehabilitation of the mentally retarded or persons with related conditions; and
(b) Provides, in a protected residential setting, ongoing evaluation, planning, 24-hour supervision, coordination, and integration of health or rehabilitative services to help each individual function at his greatest ability.

Institution for tuberculosis means an institution that is primarily engaged in providing diagnosis, treatment, or care of persons with tuberculosis, including medical attention, nursing care, and related services. Whether an institution is an institution for tuberculosis is determined by its overall character as that of a facility established and maintained primarily for the care and treatment of tuberculosis, whether or not it is licensed as such.

Medical institution means an institution that—
(a) Is organized to provide medical care, including nursing and convalescent care;
(b) Has the necessary professional personnel, equipment, and facilities to manage the medical, nursing, and other health needs of patients on a continuing basis in accordance with accepted standards;
(c) Is authorized under State law to provide medical care; and
(d) Is staffed by professional personnel who are responsible to the institution for professional medical and nursing services. The services must include adequate and continual medical care and supervision by a physician; registered nurse or licensed practical nurse supervision and services and nurses’ aid services, sufficient to meet nursing care needs; and a physician’s guidance on the professional aspects of operating the institution.

Outpatient means a patient of an organized medical facility or distinct part of that facility who is expected by
the facility to receive, and who does receive, professional services for less than a 24-hour period regardless of the hour of admission, whether or not a bed is used or whether or not the patient remains in the facility past midnight.

Patient means an individual who is receiving needed professional services that are directed by a licensed practitioner of the healing arts toward maintenance, improvement, or protection of health, or lessening of illness, disability, or pain.

Persons with related conditions means individuals who have a severe, chronic disability that meets all of the following conditions:

(a) It is attributable to—
(1) Cerebral palsy or epilepsy; or
(2) Any other condition, other than mental illness, found to be closely related to mental retardation because this condition results in impairment of general intellectual function or adaptive behavior similar to that of mentally retarded persons, and requires treatment or services similar to those required for these persons.
(b) It is manifested before the person reaches age 22.
(c) It is likely to continue indefinitely.
(d) It results in substantial functional limitations in three or more of the following areas of major life activity:
   (1) Self-care.
   (2) Understanding and use of language.
   (3) Learning.
   (4) Mobility.
   (5) Self-direction.
   (6) Capacity for independent living.

Public institution means an institution that is the responsibility of a governmental unit or over which a governmental unit exercises administrative control. The term “public institution” does not include
(a) A medical institution as defined in this section;
(b) An intermediate care facility as defined in §§440.140 and 440.150 of this chapter;
(c) A publicly operated community residence that serves no more than 16 residents, as defined in this section; or
(d) A child-care institution as defined in this section with respect to
   (1) Children for whom foster care maintenance payments are made under title IV-E of the Act; and
   (2) Children receiving AFDC—foster care under title IV-A of the Act.

Publicly operated community residence that serves no more than 16 residents is defined in 20 CFR 416.231(b)(2). A summary of that definition is repeated here for the information of readers.

(a) In general, a publicly operated community residence means—
   (1) It is publicly operated as defined in 20 CFR 416.231(b).
   (2) It is designed or has been changed to serve no more than 16 residents and it is serving no more than 16; and
   (3) It provides some services beyond food and shelter such as social services, help with personal living activities, or training in socialization and life skills. Occasional medical or remedial care may also be provided as defined in 45 CFR 228.1; and
   (b) A publicly operated community residence does not include the following facilities, even though they accommodate 16 or fewer residents:

   (1) Residential facilities located on the grounds of, or immediately adjacent to, any large institution or multiple purpose complex.
   (2) Educational or vocational training institutions that primarily provide an approved, accredited, or recognized program to individuals residing there.
   (3) Correctional or holding facilities for individuals who are prisoners, have been arrested or detained pending disposition of charges, or are held under court order as material witnesses or juveniles.
   (4) Hospitals, nursing facilities, and intermediate care facilities for the mentally retarded.

§435.1009 42 CFR Ch. IV (10-1-98 Edition)
§ 435.1010 Requirement for mandatory State supplements.
(a) Except as specified in paragraph (b) of this section, FFP is not available in Medicaid expenditures in any quarter in which the State does not have in effect an agreement with the Secretary under section 212 of Pub. L. 93-66 (July 9, 1973) for minimum mandatory State supplements of the basic SSI benefit.
(b) This section does not apply to any State that meets the conditions of section 212(f) of Pub. L. 93-66.

§ 435.1011 Requirement for maintenance of optional State supplement expenditures.
(a) This section applies to States that make optional State supplement payments under section 1616(a) of the Act and mandatory supplement payments under section 212(a) of Pub. L. 93-66.
(b) FFP in Medicaid expenditures is not available during any period in which the State does not have in effect an agreement with the Secretary under section 1618 of the Act to maintain its supplementary payments.

§ 436.1 Purpose and applicability.

This part sets forth, for Guam, Puerto Rico, and the Virgin Islands—
(a) The eligibility provisions that a State plan must contain;
(b) The mandatory and optional groups of individuals to whom Medicaid is provided under a State plan;
(c) The eligibility requirements and procedures that a Medicaid agency

42 CFR Ch. IV (10-1-98 Edition)

MEDICALLY NEEDED INCOME ELIGIBILTY AND LIABILITY FOR PAYMENT OF MEDICAL EXPENSES

436.3 Medically needy income eligibility.
436.4 Post-eligibility treatment of income of institutionalized individuals: Application of patient income to the cost of care.

MEDICALLY NEEDED RESOURCE STANDARD

436.35 Medically needy resource standard: General requirements.
436.4 Medically needy resource standard: State plan requirements.

DETERMINING ELIGIBILITY ON THE BASIS OF RESOURCES

436.5 Medically needy resource eligibility.

Subpart J—Eligibility in Guam, Puerto Rico, and the Virgin Islands

436.10 Scope.
436.11 General requirements.
436.12 Automatic entitlement to Medicaid following a determination of eligibility under other programs.

Subpart K—Federal Financial Participation (FFP)

436.10 Scope.
436.11 FFP for administration.
436.12 FFP for services.
436.13 Recipients overcoming certain conditions of eligibility.
436.14 Institutionalized individuals.
436.15 Definitions relating to institutional status.

AUTHORITY: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

SOURCE: 43 FR 45218, Sept. 29, 1978, unless otherwise noted.
must use in determining and redetermining eligibility, and requirements it may not use; and

(d) The availability of FFP for providing Medicaid and for administering the eligibility provisions of the plan.


§ 436.2 Basis.

This part implements the following sections of the Act and public laws that state requirements and standards for eligibility:

402(a)(22) Eligibility of deemed recipients of AFDC who receive zero payments because of recoupment of overpayments.

402(a)(37) Eligibility of individuals who lose AFDC eligibility due to increased earnings.

414(g) Eligibility of certain individuals participating in work supplementation programs.

473(b) Eligibility of children in foster care and adopted children who are deemed AFDC recipients.

1902(a)(8) Opportunity to apply; assistance must be furnished promptly.

1902(a)(10) Required and optional groups.


1902(a)(17) Standards for determining eligibility; flexibility in the application of income eligibility standards.

1902(a)(19) Safeguards for simplicity of administration and best interests of recipients.

1902(a)(34) Three-month retroactive eligibility.

1902(a)(second paragraph after (47)) Eligibility despite increased monthly insurance benefits under title II.

1902(a)(55) Mandatory use of outstation locations other than welfare offices to receive and initially process applications of certain low-income pregnant women, infants, and children under age 19.

1902(b) Prohibited conditions for eligibility: Age requirements of more than 65 years; State residence requirements excluding individuals who reside in the State; and Citizenship requirement excluding United States citizens.

1902(e) Four-month continued eligibility for families ineligible because of increased hours or income from employment.

1902(e)(2) Minimum eligibility period for recipients enrolled in HMO.

1902(e)(3) Optional coverage of certain disabled children at home.

1902(e)(4) Eligibility of newborn children of Medicaid-eligible women.

1902(e)(5) Eligibility of pregnant women for extended coverage for a specified period after pregnancy ends.

1903(v) Payment for emergency services under Medicaid provided to aliens.

1905(a) (i)-(viii) List of eligible individuals.

1905(a) (clause following (2)) Prohibitions against providing Medicaid to certain institutionalized individuals.

1905(a) (second sentence) Definition of essential person.

1905(d)(2) Definition of resident of an intermediate care facility for the mentally retarded.

1905(n) Definition of qualified pregnant woman and child.

1912(a) Conditions of eligibility.

1915(c) Home or community based services.

1915(d) Home and community-based services for individuals age 65 or older.

412(e)(5) of Immigration and Nationality Act—Eligibility of certain refugees.


Pub. L. 93–66, section 231 Deemed eligibility of certain persons in medical institutions.


Pub. L. 99–509, section 9406 Payment for emergency medical services provided to aliens.


§ 436.3 Definitions and use of terms.

As used in this part—

AABD means aid to the aged, blind, and disabled under title XVI of the Act; AB means aid to the blind under title X of the Act; AFDC means aid to families with dependent children under title IV-A of the Act;
§ 436.10  State plan requirements.

A State plan must—
(a) Provide that the requirements of this part are met; and
(b) Specify the groups to whom Medicaid is provided, as specified in subparts B, C, and D of this part, and the conditions of eligibility for individuals in those groups.

Subpart B—Mandatory Coverage of the Categorically Needy

§ 436.100  Scope.

This subpart prescribes requirements for coverage of categorically needy individuals.

§ 436.110  Individuals receiving cash assistance.

(a) A Medicaid agency must provide Medicaid to individuals receiving cash assistance under OAA, AFDC, AB, APTD, or AABD.

(b) For purposes of this section, an individual is receiving cash assistance if his needs are considered in determining the amount of the payment. This includes an individual whose presence in the home is considered essential to the well-being of a recipient under the State's plan for OAA, AFDC, AB, APTD, or AABD if that plan were as broad as allowed under the Act for FFP.

§ 436.111  Individuals who are not eligible for cash assistance because of a requirement not applicable under Medicaid.

(a) The agency must provide Medicaid to individuals who would be eligible for OAA, AB, APTD, or AABD except for an eligibility requirement used in those programs that is specifically prohibited under title XIX of the Act.

(b) The agency also must provide Medicaid to:
§ 436.114 Individuals deemed to be receiving AFDC.

(a) The Medicaid agency must provide Medicaid to individuals deemed to be receiving AFDC, as specified in this section.

(b) The State must deem individuals to be receiving AFDC who are denied a cash payment from the title IV-A State agency solely because the amount of the AFDC payment would be less than $10.

(c) The State may deem participants in a work supplementation program to be receiving AFDC under section 414(g) of the Act. This section permits States, for purposes of title XIX, to deem an individual and any child or relative of the individual (or other individual living in the same household) to be receiving AFDC, if the individual—

(1) Participates in a State-operated work supplementation program under section 414 of the Act; and

(2) Would be eligible for an AFDC cash payment if the individual were not participating in the work supplementation program.

(d) The State must deem to be receiving AFDC those individuals who are denied AFDC payments from the title IV-A State agency solely because that agency is recovering an overpayment.

(e) The State must deem to be receiving AFDC individuals described in section 473(a)(1) of the Act—

(1) For whom an adoption assistance agreement is in effect under title IV-E of the Act, whether or not adoption assistance is being provided or an interlocutory or other judicial decree of adoption has been issued; or

(2) For whom foster care maintenance payments are made under title IV-E of the Act.

(f) The State must deem an individual to be receiving AFDC if a new collection or increased collection of child or spousal support under title IV-D of the Social Security Act results in the termination of AFDC eligibility in accordance with section 406(h) of the Social Security Act. States must continue to provide Medicaid for four consecutive calendar months, beginning with the first month of AFDC ineligibility, to each dependent child and each relative with whom such a child is living (including the eligible spouse of such relative as described in section 406(b) of the Social Security Act) who:

(1) Becomes ineligible for AFDC on or after August 16, 1984; and
§ 436.116 Families terminated from AFDC because of increased earnings or hours of employment.

(a) If a family loses AFDC solely because of increased income from employment or increased hours of employment, the agency must continue to provide Medicaid for 4 months to all members of the family if—

(1) The family received AFDC in any 3 or more months during the 6-month period immediately before the month in which it became ineligible for AFDC; and

(2) At least one member of the family is employed throughout the 4-month period, although this need not be the same member for the whole period.

(b) The 4 calendar month period begins on the date AFDC is terminated. If AFDC benefits are terminated retroactively, the 4 calendar month period also begins retroactively with the first month in which AFDC was erroneously paid.

§ 436.118 Children for whom adoption assistance or foster care maintenance payments are made.

The agency must provide Medicaid to children for whom adoption assistance or foster care maintenance payments are made under title IV-E of the Act.

§ 436.120 Qualified pregnant women and children who are not qualified family members.

(a) The Medicaid agency must provide Medicaid to a pregnant woman whose pregnancy has been medically verified and who—

(1) Would be eligible for an AFDC cash payment (or would be eligible for section 1925 of the Social Security Act (which was added by section 303(a) of the Family Support Act of 1988 (42 U.S.C. 1396r–6)). Extended periods resulting from both an increase in the amount of the support collection and from an increase in earned income must run concurrently.

§ 436.121 Qualified family members.

(a) Definition. A qualified family member is any member of a family, including pregnant women and children eligible for Medicaid under §436.120 of this subpart, who would be receiving AFDC cash benefits on the basis of the unemployment of the principal wage earner under section 407 of the Act had the State not chosen to place time limits on those benefits as permitted under section 407(b)(2)(B)(I) of the Act.

(b) State plan requirement. The State plan must provide that the State makes Medicaid available to any individual who meets the definition of "qualified family member" as specified in paragraph (a) of this section.

(c) Applicability. The provisions in this section are applicable from October 1, 1992, through September 30, 1998.

§ 436.122 Pregnant women eligible for extended coverage.

(a) The Medicaid agency must provide categorically needy Medicaid eligibility for an extended period following termination of pregnancy to women who, while pregnant, applied for, were eligible for, and received Medicaid services on the day that their pregnancy ends. This period extends from the last day of pregnancy through the end of the month in which a 60-day period, beginning on the last day of the pregnancy, ends. Eligibility must be provided, regardless of changes in the woman's financial circumstances that may occur within this extended period. These pregnant women are eligible for the extended period for all services under the plan that are pregnancy-related (as defined in §440.210(c)(1) of this subchapter).

(b) The provisions of paragraph (a) of this section apply to Medicaid furnished on or after April 7, 1986.

§ 436.124 Newborn children.

(a) The Medicaid agency must provide categorically needy Medicaid eligibility to a child born to a woman who is eligible for and receiving Medicaid on the date of the child's birth. The child is deemed to have applied and been found eligible for Medicaid on the date of birth and remains eligible as categorically needy for one year so long as the woman remains eligible and the child is a member of the woman's household. If the mother's basis of eligibility changes to medically needy, the child is eligible as medically needy under §436.301(b)(1)(iii).

(b) The requirements under paragraph (a) of this section apply to children born on or after October 1, 1984.
§ 436.128 Coverage for certain qualified aliens.

The agency must provide the services necessary for the treatment of an emergency medical condition as defined in § 440.255(c) of this chapter to those aliens described in § 436.406(c) of this subpart.

[55 FR 36820, Sept. 7, 1990]

Subpart C—Options for Coverage as Categorically Needy

§ 436.200 Scope.

This subpart specifies options for coverage of individuals as categorically needy.

§ 436.201 Individuals included in optional groups.

(a) The agency may choose to cover as optional categorically needy any group or groups of the following individuals who are not receiving cash assistance and who meet the appropriate eligibility criteria for groups specified in the separate sections of this subpart:

(1) Aged individuals (65 years of age or older);
(2) Blind individuals (as defined in § 436.530);
(3) Disabled individuals (as defined in § 436.541);
(4) Individuals under age 21 (or, at State option), under age 20, 19, or 18) or reasonable classifications of these individuals;
(5) Specified relatives under section 406(b)(1) of the Act who have in their care an individual who is determined to be dependent) as specified in § 436.510;
(6) Pregnant women; and
(7) Essential spouses specified under § 436.230.

(b) If the agency provides Medicaid to any individual in an optional group specified in paragraph (a) of this section, the agency must provide Medicaid to all individuals who apply and are found eligible to be members of that group.

[58 FR 4935, Jan. 19, 1993]

§ 436.210 Individuals who meet the income and resource requirements of the cash assistance programs.

The agency may provide Medicaid to any group or groups of individuals specified under § 436.201(a)(1), (a)(2), (a)(3), (a)(5), and (a)(6) who are not mandatory categorically needy and who meet the income and resource requirements of the appropriate cash assistance program for their status (that is, OAA, AFDC, AB, APTD, or AABD).

[58 FR 4935, Jan. 19, 1993]

§ 436.211 Individuals who would be eligible for cash assistance if they were not in medical institutions.

The agency may provide Medicaid to any group or groups of individuals specified in § 436.201(a) who are in title XIX reimbursable medical institutions and who:

(a) Are ineligible for the cash assistance program appropriate for their status (that is, OAA, AFDC, AB, APTD, or AABD) because of lower income standards used under the program to determine eligibility for institutionalized individuals; but
(b) Would be eligible for aid or assistance under the State’s approved plan under OAA, AFDC, AB, APTD, or AABD if they were not institutionalized.

[58 FR 4935, Jan. 19, 1993]

§ 436.212 Individuals who would be eligible for cash assistance if the State plan for OAA, AFDC, AB, APTD, or AABD were as broad as allowed under the Act.

(a) The agency may provide Medicaid to any group or groups of individuals specified under § 436.201(a) who:

(1) Would be eligible for OAA, AFDC, AB, APTD, or AABD if the State’s plan under those programs included individuals whose coverage under title I, IV-A, X, XIV, or XVI of the Act is optional (for example, the agency may provide Medicaid to individuals who are 18
§ 436.222 Individuals under age 21 who meet the income and resource requirements of AFDC.

(a) The agency may provide Medicaid to individuals under age 21 (or at State option, under age 20, 19, or 18) or reasonable categories of these individuals as specified in paragraph (b) of this section, who are not receiving cash assistance but who meet the income and resource requirements of the State’s approved AFDC plan.

(b) The agency may cover all individuals described in paragraph (a) of this section or reasonable classifications of those individuals. Examples of reasonable classifications are as follows:

1. Individuals in foster homes or private institutions for whom a public agency is assuming full or partial financial responsibility. If the agency covers these individuals, it may also provide Medicaid to individuals of the same age in foster homes or private institutions by private nonprofit agencies.

2. Individuals in adoptions subsidized in full or in part by a public agency.

3. Individuals in nursing facilities when nursing facility services are provided under the plan to individuals within the age group selected under this provision. If the agency covers these individuals, it may also provide Medicaid to individuals in intermediate care facilities for the mentally retarded.

4. Individuals receiving active treatment as inpatients in psychiatric facilities or programs, if inpatient psychiatric services for individuals under 21 are provided under the plan.


§ 436.220 Individuals who would meet the income and resource requirements under AFDC if child care costs were paid from earnings.

(a) The agency may provide Medicaid to any group or groups of individuals specified under § 436.201(a)(4), (a)(5), and (a)(6) who would meet the income and resource requirements under the State’s AFDC plan if their work-related child care costs were paid from their earnings rather than by a State agency as a service expenditure.

(b) The agency may use this option only if the State’s AFDC plan deducts work-related child care costs from income to determine the amount of AFDC.


§ 436.217 Individuals receiving home and community-based services.

The agency may provide Medicaid to any group or groups of individuals in the community who meet the following requirements:

(a) The group would be eligible for Medicaid if institutionalized.

(b) In the absence of home and community-based services under a waiver granted under part 441—

1. Subpart G of this subchapter, the group would otherwise require the level of care furnished in a hospital, NF, or an ICF/MR; or

2. Subpart H of this subchapter, the group would otherwise require the level of care furnished in an NF and are age 65 or older.

(c) The group receives the waivered services.

[57 FR 29155, June 30, 1992]

§ 436.222 Individuals under age 21 who meet the income and resource requirements of AFDC.

(a) The agency may provide Medicaid to individuals under age 21 (or at State option, under age 20, 19, or 18) or reasonable categories of these individuals as specified in paragraph (b) of this section, who are not receiving cash assistance but who meet the income and resource requirements of the State’s approved AFDC plan.

(b) The agency may cover all individuals described in paragraph (a) of this section or reasonable classifications of those individuals. Examples of reasonable classifications are as follows:

1. Individuals in foster homes or private institutions for whom a public agency is assuming full or partial financial responsibility. If the agency covers these individuals, it may also provide Medicaid to individuals of the same age in foster homes or private institutions by private nonprofit agencies.

2. Individuals in adoptions subsidized in full or in part by a public agency.

3. Individuals in nursing facilities when nursing facility services are provided under the plan to individuals within the age group selected under this provision. If the agency covers these individuals, it may also provide Medicaid to individuals in intermediate care facilities for the mentally retarded.

4. Individuals receiving active treatment as inpatients in psychiatric facilities or programs, if inpatient psychiatric services for individuals under 21 are provided under the plan.

§ 436.224 Individuals under age 21 who are under State adoption assistance agreements.

(a) The agency may provide Medicaid to individuals under the age of 21 (or, at State option, age 20, 19, or 18)—
   (1) For whom an adoption agreement (other than an agreement under title IV-E) between the State and adoptive parent(s) is in effect;
   (2) Who, the State agency responsible for adoption assistance has determined, cannot be placed with adoptive parents without Medicaid because the child has special needs for medical or rehabilitative care; and
   (3) Who meet either of the following:
      (i) Were eligible for Medicaid under the State plan before the adoption agreement was entered into; or
      (ii) Would have been eligible for Medicaid before the adoption agreement was entered into, if the eligibility standards and methodologies of the foster care program were used without employing the threshold title IV-A eligibility determination.

(b) For adoption assistance agreements entered into before April 7, 1986—
   (1) The agency must deem the requirements of paragraph (a)(1) and (2) of this section to be met if the State adoption assistance agency determines that—
      (i) At the time of the adoption placement, the child had special needs for medical or rehabilitative care that made the child difficult to place; and
      (ii) There is in effect an adoption assistance agreement between the State and the adoptive parent(s).
   (2) The agency must deem the requirements of paragraph (a)(3) of this section to be met if the child was found by the State to be eligible for Medicaid before the adoption assistance agreement was entered into.

[55 FR 48610, Nov. 21, 1990]

§ 436.230 Essential spouses of aged, blind, or disabled individuals receiving cash assistance.

The agency may provide Medicaid to the spouse of an individual receiving OAA, AB, APTD, or AABD, if—
   (a) The spouse is living with the individual receiving cash assistance;
   (b) The cash assistance agency has determined that the spouse is essential to the well-being of the individual and has considered the spouse's needs in determining the amount of cash assistance provided to the individual.

Subpart D—Optional Coverage of the Medically Needy

§ 436.300 Scope.

This subpart specifies the option for coverage of medically needy individuals.

§ 436.301 General rules.

(a) A Medicaid agency may provide Medicaid to individuals specified in this subpart who:
   (1) Either:
      (i) Have income that meets the standard in §436.811; or
      (ii) If their income is more than allowed under the standard, have incurred medical expenses at least equal to the difference between their income and the applicable income standards; and
   (2) Have resources that meet the standard in §§436.840 and 436.843.

(b) If the agency chooses this option, the following provisions apply:
   (1) The agency must provide Medicaid to the following individuals who meet the requirements of paragraph (a) of this section:
      (i) All pregnant women during the course of their pregnancy who, except for income and resources, would be eligible for Medicaid as mandatory or optional categorically needy under subparts B and C of this part;
      (ii) All individuals under 18 years of age who, except for income and resources, would be eligible for Medicaid as mandatory categorically needy under subpart B of this part;
      (iii) All newborn children born on or after October 1, 1984, to a woman who is eligible as medically needy and receiving Medicaid on the date of the child's birth. The child is deemed to have applied and been found eligible for Medicaid on the date of birth and remains eligible as medically needy for one year so long as the woman remains eligible.
and the child is a member of the woman’s household. If the woman’s basis of eligibility changes to categorically needy, the child is eligible as categorically needy under §436.124. The woman is considered to remain eligible if she meets the spend-down requirements in any consecutive budget period following the birth of the child.

(iv) Women who, while pregnant, applied for, were eligible for, and received Medicaid services as medically needed on the day that their pregnancy ends. The agency must provide medically needy eligibility to these women for an extended period following termination of pregnancy. This period begins on the last day of the pregnancy and extends through the end of the month in which a 60-day period following termination of pregnancy ends. Eligibility must be provided, regardless of changes in the women’s financial circumstances that may occur within this extended period. These women are eligible for the extended period for all services under the plan that are pregnancy-related (as defined in §440.210(c)(1) of this subchapter).

(2) The agency may provide Medicaid to any or all of the following groups of individuals:

(i) Individuals under age 21 (§436.308).
(ii) Specified relatives (§436.310).
(iii) Aged (§436.320).
(iv) Blind (§436.321).
(v) Disabled (§436.322).

(3) If the agency provides Medicaid to any individual in a group specified in paragraph (b)(2) of this section, the agency must provide Medicaid to all individuals eligible to be members of that group.

§436.310 Medically needy coverage of specified relatives.

(a) If the agency provides Medicaid to the medically needy, it may provide Medicaid to specified relatives, defined in paragraph (b)(2) of this section, who meet the income and resource requirements of subparagraph I of this part.

(b) Specified relatives means individuals who:

(1) Are listed under section 406(b)(1) of the Act and in 45 CFR 233.90(c)(1)(ii)(A); and

(2) Have in their care an individual who is determined to be (or would, if needy, be) dependent, as specified in §436.510.
§ 436.320 Medically needy coverage of the aged.

If the agency provides Medicaid to the medically needy, it may provide Medicaid to individuals who—
(a) Are 65 years of age and older, as provided for in §436.520; and
(b) Meet the income and resource requirements of subpart I of this part.

[46 FR 47991, Sept. 30, 1981]

§ 436.321 Medically needy coverage of the blind.

If the agency provides Medicaid to the medically needy, it may provide Medicaid to blind individuals who—
(a) The requirements for blindness, as specified in §§436.530 and 436.531; and
(b) The income and resource requirements of subpart I of this part.

[46 FR 47991, Sept. 30, 1981]

§ 436.322 Medically needy coverage of the disabled.

If the agency provides Medicaid to the medically needy, it may provide Medicaid to disabled individuals who meet—
(a) The requirements for disability, as specified in §§436.540 and 436.541; and
(b) The income and resource requirements of subpart I of this part.

[46 FR 47991, Sept. 30, 1981]

§ 436.330 Coverage for certain aliens.

If an agency provides Medicaid to the medically needy, it must provide the services necessary for the treatment of an emergency medical condition, as defined in §440.255(c) of this chapter to those aliens described in §436.406(c) of this subpart.

[55 FR 36820, Sept. 7, 1990]

Subpart E—General Eligibility Requirements

§ 436.400 Scope.

This subpart prescribes general requirements for determining the eligibility of both categorically needy and medically needy individuals specified in subparts B, C, and D of the part.

§ 436.401 General rules.

(a) The agency may not impose any eligibility requirement that is prohibited under title XIX.
(b) The agency must base any optional group covered under subparts B and C of this part on reasonable classifications that do not result in arbitrary or inequitable treatment of individuals and groups and are consistent with the objectives of title XIX.
(c) The agency must not use requirements for determining eligibility for optional coverage groups that are more restrictive than those used under the State plans for OAA, AFDC, AB, APTD, or AABD.

§ 436.402 [Reserved]

§ 436.403 State residence.

(a) Requirement. The agency must provide Medicaid to eligible residents of the State, including residents who are absent from the State. The conditions under which payment for service is provided to out-of-State residents are set forth in §431.52 of this chapter.
(b) Definition. For purposes of this section—Institution has the same meaning as Institution and Medical institution, as defined in §435.1009 of this chapter. For purposes of State placement, the term also includes “foster care homes”, licensed as set forth in 45 CFR 1355.20, and providing food, shelter and supportive services to one or more persons unrelated to the proprietor.
(c) Incapability of indicating intent. For purposes of this section, an individual is considered incapable of indicating intent if the individual—
(1) Has an I.Q. of 49 or less or has a mental age of 7 or less, based on tests acceptable to the mental retardation agency in the State;
(2) Is judged legally incompetent; or
(3) Is found incapable of indicating intent based on medical documentation obtained from a physician, psychologist, or other person licensed by the State in the field of mental retardation.
(d) Who is a State resident. A resident of a State is any individual who:
(1) Meets the conditions in paragraphs (e) through (h) of this section; or
(2) Meets the criteria specified in an interstate agreement under paragraph (j) of this section.

(e) Placement by a State in an out-of-state institution—(1) General rule. Any agency of the State, including an entity recognized under State law as being under contract with the State for such purposes, that arranges for an individual to be placed in an institution located in another State, is recognized as acting on behalf of the State in making a placement. The State arranging or actually making the placement is considered as the individual’s State of residence.

(2) Any action beyond providing information to the individual and the individual’s family would constitute arranging or making a State placement. However, the following actions do not constitute State placement:

(i) Providing basic information to individuals about another State’s Medicaid program, and information about the availability of health care services and facilities in another State.

(ii) Assisting an individual in locating an institution in another State provided the individual is capable of indicating intent and independently decides to move.

(3) When a competent individual leaves the facility in which the individual is placed by a State, that individual’s State of residency for Medicaid purposes is the State where the individual is physically located.

(4) Where placement is initiated by a State because the State lacks a sufficient number of appropriate facilities to provide services to its residents, the State making the placement is the individual’s State of residence for Medicaid purposes.

(f) Individuals receiving title IV-E payments. For individuals of any age who are receiving Federal payment for foster care and adoption assistance under title IV-E of the Social Security Act, the State of residence is the State where the child lives.

(g) Individuals under age 21. (1) For any individual who is emancipated from his or her parents or who is married and capable of indicating intent, the State of residence is the State where the individual is living with the intention to remain there permanently or for an indefinite period.

(2) For any individual not residing in an institution as defined in paragraph (b) whose Medicaid eligibility is based on blindness or disability, the State of residence is the State in which the individual is living.

(3) For any other non-institutionalized individual not subject to paragraph (h)(1) or (h)(2) of this section, the State of residence is determined in accordance with 45 CFR 233.40, the rules governing residence under the AFDC program.

(4) For any institutionalized individual who is neither married nor emancipated, the State of residence is—

(i) The parents’ or legal guardian’s current State of residence at the time of placement; or

(ii) The current State of residence of the parent or legal guardian who files the application, if the individual is institutionalized in that State. If a legal guardian has been appointed and the parental rights are terminated, the State of residence of the guardian is used instead of the parent’s.

(iii) The State of residence of the individual or party who files an application is used if the individual has been abandoned by his or her parent(s), does not have a legal guardian and is institutionalized in that State.

(h) Individuals age 21 and over. (1) For any individual not residing in an institution as defined in paragraph (b), the State of residence is the State where the individual is—

(i) Living with the intention to remain there permanently or for an indefinite period (or if incapable of stating intent, where the individual is living); or

(ii) Living and which the individual entered with a job commitment or seeking employment (whether or not currently employed).

(2) For any institutionalized individual who became incapable of indicating intent before age 21, the State of residence is—

(i) That of the parents applying for Medicaid on the individual’s behalf, if the parents reside in separate States;

(ii) The parent’s or legal guardian’s State of residence at the time of placement; or
§ 436.404 Applicant’s choice of category.

The agency must allow an individual who would be eligible under more than one category to have his eligibility determined for the category he selects.

§ 436.406 Citizenship and alienage.

(a) The agency must provide Medicaid to otherwise eligible residents of the United States who are—

(1) Citizens; or

(2) Aliens lawfully admitted for permanent residence or permanently residing in the United States under color of law, as defined in § 436.408 of this part;

(3) Aliens granted lawful temporary resident status under sections 245A and 210A of the Immigration and Nationality Act if the individual is aged, blind, or disabled as defined in section 1614(a)(1) of the Act, under 18 years of age, or a Cuban/Haitian entrant as defined in section 501 (e)(1) and (2)(A) of Pub. L. 96-422; or

(iii) The current State of residence of the parent or legal guardian who files the application, if the individual is institutionalized in that State. If a legal guardian has been appointed and parental rights are terminated, the State of residence of the guardian is used instead of the legal parent’s.

(iv) The State of residence of the individual or party who files an application is used if the individual has been abandoned by his or her parent(s), does not have a legal guardian and is institutionalized in that State.

(3) For any institutionalized individual who became incapable of indicating intent at or after age 21, the State of residence is the State in which the individual is physically present, except where another State makes a placement.

(4) For any other institutionalized individual, the State of residence is the State where the individual is living with the intention to remain there permanently or for an indefinite period.

(i) Specific prohibitions. (1) The agency may not deny Medicaid eligibility because an individual has not resided in the State for a specified period.

(2) The agency may not deny Medicaid eligibility to an individual in an institution, who satisfies the residency rules set forth in this section, on the grounds that the individual did not establish residence in the State before entering the institution.

(3) The agency may not deny or terminate a resident’s Medicaid eligibility because of that person’s temporary absence from the State if the person intends to return when the purpose of the absence has been accomplished, unless another State has determined that the person is a resident there for purposes of Medicaid.

(j) Interstate agreements. A State may have a written agreement with another State setting forth rules and procedures resolving cases of disputed residency. These agreements may establish criteria other than those specified in paragraphs (c) through (h) of this section, but must not include criteria that result in loss of residency in both States or that are prohibited by paragraph (i) of this section. The agreements must contain a procedure for providing Medicaid to individuals pending resolution of the case.

States may use interstate agreements for purposes other than cases of disputed residency to facilitate administration of the program, and to facilitate the placement and adoption of title IV-E individuals when the child and his or her adoptive parent(s) move into another State.

(k) Continued Medicaid for institutionalized recipients. An agency is providing Medicaid to an institutionalized recipient who, as a result of this section, would be considered a resident of a different State—

(1) The agency must continue to provide Medicaid to that recipient from June 24, 1983 until July 5, 1984 unless it makes arrangements with another State of residence to provide Medicaid at an earlier date; and

(2) Those arrangements must not include provisions prohibited by paragraph (g) of this section.

(1) Cases of disputed residency. Where two or more States cannot resolve which State is the State of residence, the State where the individual is physically located is the State of residence.

Health Care Financing Administration, HHS  § 436.408

§ 436.408 Categories of aliens who are permanently residing in the United States under color of law.

This section describes aliens that the agency must accept as permanently residing in the United States under color of law and who may be eligible for Medicaid.

(a) An individual may be eligible for Medicaid if the individual is an alien residing in the United States with the knowledge and permission of the Immigration and Naturalization Service (INS) and the INS does not contemplate enforcing the alien's departure. The INS does not contemplate enforcing the alien's departure if it is the policy or practice of INS not to enforce the departure of aliens in the same category, or if from all the facts and circumstances in the case it appears that INS is otherwise permitting the alien to reside in the United States indefinitely, as determined by verifying the alien's status with INS.

(b) Aliens who are permanently residing in the United States under color of law are listed below. None of the categories includes applicants for an Immigration and Naturalization Service status other than those applicants listed in paragraph (b)(6) of this section, or those covered under paragraph (b)(3) of this section. None of the categories allows Medicaid eligibility for non-immigrants: for example, students or visitors. Also listed are the most common documents that the INS provides to aliens in these categories.


(2) Aliens, including Cuban/Haitian entrants, paroled in the United States pursuant to 8 U.S.C. 1182(d)(5) section 212(d)(5) of the Immigration and Nationality Act. For Cuban/Haitian entrants ask for a copy of INS Form I-94 stamped Cuban/Haitian entrant (Status Pending) reviewable January 15, 1981. (Although the forms bear this notation, Cuban/Haitian entrants are admitted under section 212(d)(5) of the Immigration and Nationality Act.);

(3) Aliens residing in the United States pursuant to an indefinite stay of deportation. Ask for an Immigration and Naturalization Service letter with this information or INS Form I-94 with such a notation;

(4) Aliens residing in the United States pursuant to an indefinite voluntary departure. Ask for an Immigration and Naturalization Service letter or INS Form I-94 showing that a voluntary departure has been granted for an indefinite time period;

(5) Aliens on whose behalf an immediate relative petition has been approved and their families covered by the petition who are entitled to voluntary departure (under 8 CFR 242.5(a)(2)(vi)) and whose departure the
Immigration and Naturalization Service does not contemplate enforcing. Ask for a copy of INS Form I-94 or INS Form I-210 or a letter showing this status;

(6) Aliens who have filed applications for adjustment of status pursuant to section 245 of the Immigration and Nationality Act (8 U.S.C. 1255) that the Immigration and Naturalization Service has accepted as “properly filed” (within the meaning of 8 CFR 245.2(a)(1) or (2)) and whose departure the Immigration and Naturalization Service does not contemplate enforcing. Ask for a copy of INS Form I-94 or I-181 or a passport properly endorsed;

(7) Aliens granted stays of deportation by court order, statute or regulation, or by individual determination of the Immigration and Naturalization Service pursuant to section 106 of the Immigration and Nationality Act (8 U.S.C. 1105a) or relevant Immigration and Naturalization Service instructions, whose departure that agency does not contemplate enforcing. Ask for a copy of INS Form I-94 or a letter from the Immigration and Naturalization Service, or a copy of a court order establishing the alien's status;

(8) Aliens granted asylum pursuant to section 208 of the Immigration and Nationality Act (8 U.S.C. 1158). Ask for a copy of INS Form I-94 and a letter establishing this status;

(9) Aliens admitted as refugees pursuant to section 207 of the Immigration and Nationality Act (8 U.S.C. 1157) or section 203(a)(7) of the Immigration and Nationality Act (8 U.S.C. 1153(a)(7)). Ask for a copy of INS Form I-94 properly endorsed;

(10) Aliens granted voluntary departure pursuant to section 242(b) of the Immigration and Nationality Act (8 U.S.C. 1252(b)) or 8 CFR 242.5 whose departure the Immigration and Naturalization Service does not contemplate enforcing. Ask for a copy of INS Form I-94 or I-210 bearing a departure date;

(11) Aliens granted deferred action status pursuant to Immigration and Naturalization Service Operations Instruction 103.1(a)(ii) prior to June 15, 1994 or §242.1(a)(22) issued June 15, 1994 and later. Ask for a copy of INS Form I-210 or a letter showing that departure has been deferred;

(12) Aliens residing in the United States under orders of supervision pursuant to section 242 of the Immigration and Nationality Act (8 U.S.C. 1152(d)). Ask for a copy of Form I-220 B;

(13) Aliens who have entered and continuously resided in the United States since before January 1, 1972 (or any date established by section 249 of the Immigration and Nationality Act, 8 U.S.C. 1259). Ask for any proof establishing this entry and continuous residence;

(14) Aliens granted suspension of deportation pursuant to section 244 of the Immigration and Nationality Act (8 U.S.C. 1254) and whose departure the Immigration and Naturalization Service does not contemplate enforcing. Ask for an order from the immigration judge;

(15) Aliens whose deportation has been withheld pursuant to section 243(h) of the Immigration and Nationality Act (8 U.S.C. 1253(h)). Ask for an order from an immigration judge showing that deportation has been withheld; or

(16) Any other aliens living in the United States with the knowledge and permission of the Immigration and Naturalization Service and whose departure that agency does not contemplate enforcing, including permanent non-immigrants as established by Public Law 99-239, and persons granted Extended Voluntary Departure due to conditions in the alien's home country based on a determination by the Secretary of State.


Subpart F—Categorical Requirements for Medicaid Eligibility

§ 436.500 Scope.

This subpart prescribes categorical requirements for determining the eligibility of both categorically needy and medically needy individuals specified in subparts B, C, and D of this part.
Health Care Financing Administration, HHS

§ 436.510 Determination of dependency.
For families with dependent children who are not receiving AFDC, the agency must use the definitions and procedures used under the State’s AFDC plan to determine whether—
(a) An individual is a dependent child because he is deprived of parental support or care; and
(b) An individual is an eligible member of a family with dependent children.

§ 436.520 Age requirements for the aged.
The agency must not impose an age requirement of more than 65 years.
[58 FR 4936, Jan. 19, 1993]

§ 436.522 Determination of age.
(a) In determining age, the agency must use the common law method (under which an age is reached the day before the anniversary of birth) or the popular usage method (under which a specific age is reached on the anniversary of birth), whichever is used under the corresponding State plan for OAA, AFDC, AB, APTD, or AABD.
(b) The agency may use an arbitrary date, such as July 1, for determining an individual’s age if the year, but not the month, of his birth is known.
[58 FR 4936, Jan. 19, 1993]

§ 436.530 Definition of blindness.
(a) Definition. The agency must use the definition of blindness that is used in the State plan for AB or AABD.
(b) State plan requirement. The State plan must contain the definition of blindness, expressed in ophthalmic measurements.

§ 436.531 Determination of blindness.
In determining blindness—
(a) A physician skilled in the diseases of the eye or an optometrist, whichever the individual selects, must examine him, unless both of the applicant’s eyes are missing;
(b) The examiner must submit a report of examination to the Medicaid agency; and
(c) A physician skilled in the diseases of the eye (for example, an ophthalmologist or an eye, ear, nose, and throat specialist) must review the report and determine on behalf of the agency—
(1) Whether the individual meets the definition of blindness; and
(2) Whether and when reexaminations are necessary for periodic redeterminations of eligibility, as required under §435.916 of this subchapter. Blindness is considered to continue until the reviewing physician determines that the recipient’s vision no longer meets the definition.

§ 436.540 Definition of disability.
(a) Definition. The agency must use the definition of permanent and total disability that is used in the State plan for APTD or AABD. (See 45 CFR 233.80(a)(1) for the Federal recommended definition of permanent and total disability.)
(b) State plan requirement. The State plan must contain the definition of permanent and total disability.

§ 436.541 Determination of disability.
(a) Basic requirements. (1) At a minimum, the agency must use the review team, information, and evidence requirements specified in paragraph (b) through (d) of this section in making a determination of disability.
(2) If the requirements or determining disability under the State’s APTD or AABD program are more restrictive than the minimum requirements specified in this section, the agency must use the requirements applied under the APTD or AABD program.
(b) The agency must obtain a medical report and a social history for individuals applying for Medicaid on the basis of disability. The medical report must include a diagnosis based on medical evidence. The social history must contain enough information to enable the agency to determine disability.
§ 436.600 Scope.
This subpart prescribes:
(a) General financial requirements and options for determining the eligibility of both categorically needy and medically needy individuals specified in subparts B, C, and D of this part. Subparts H and I of this part prescribe additional financial requirements.
(b) [Reserved]

Subpart G—General Financial Eligibility Requirements and Options
§ 436.601 Application of financial eligibility methodologies.
(a) Definitions. For purposes of this section, cash assistance financial methodologies refers to the income and resource methodologies of the OAA, AFDC, AB, APTD, and AABD programs.
(b) Basic rule for use of cash assistance methodologies. Except as specified in paragraphs (c) and (d) of this section, in determining financial eligibility of individuals as categorically and medically needy, the agency must apply the cash assistance financial methodologies and requirements of the cash assistance program that is most closely categorically related to the individual's status.
(c) Financial responsibility of relatives. The agency must use the requirements for financial responsibility of relatives specified in §436.602.
(d) Use of less restrictive methodologies than under cash assistance program. (1) At State option, and subject to the conditions of paragraphs (d)(2) through (d)(5) of this section, the agency may apply income and resource methodologies that are less restrictive than the cash assistance methodologies in determining financial eligibility of the following groups:
   (i) Qualified pregnant women and children under the mandatory categorically needy group under §436.120;
   (ii) Low-income pregnant women, infants, and children specified in section 1902(a)(10)(i) (IV), (VI), and (VII) of the Act;
   (iii) Qualified Medicare beneficiaries specified in sections 1902(a)(10)(E) and 1905(p) of the Act;
   (iv) Optional categorically needy individuals under groups established under subpart C of this part and section 1902(a)(10)(A)(ii) of the Act; and
   (v) Medically needy individuals under groups established under subpart D of this part and section 1902(a)(10)(C)(i)(III) of the Act.
(2) The income and resource methodologies that an agency elects to apply to groups of individuals under paragraph (c)(1) of this section may be less restrictive, but no more restrictive, than:
   (i) For groups of aged, blind, and disabled individuals, the SSI methodologies; or
   (ii) For all other groups, the methodologies under the State plan most closely categorically related to the individual's status.
(3) A financial methodology is considered to be no more restrictive if, by using the methodology, additional individuals may be eligible for Medicaid and no individuals who are otherwise eligible are by use of that methodology made ineligible for Medicaid.
(4) The less restrictive methodology applied under this section must be comparable for all persons within each category of assistance (aged, or blind, or disabled, or AFDC-related) within each eligibility group. For example, if
the agency chooses to apply a less restrictive income or resource methodology to aged individuals, it must apply that methodology to an eligibility group of all aged individuals within the selected group.

(5) The application of the less restrictive income and resource methodologies permitted under this section must be consistent with the limitations and conditions on FFP specified in subpart K of this part.

(e) [Reserved]

(f) State plan requirements. (1) The State plan must specify that, except to the extent precluded by §436.602 in determining financial eligibility of individuals, the agency will apply the cash assistance financial methodologies and requirements, unless the agency chooses to apply less restrictive income and resource methodologies, in accordance with paragraph (d) of this section. (2) If the agency chooses to apply less restrictive income and resource methodologies, the State plan must specify:

(i) The less restrictive methodologies that will be applied; and

(ii) The eligibility groups or groups to which the less restrictive methodologies will be applied.

§436.602 Financial responsibility of relatives and other individuals.

(a) Subject to the provisions of paragraphs (b) and (c) of this section, in determining financial responsibility of relatives and other persons for individuals under Medicaid, the agency must use the following financial responsibility requirements and methodologies.

(1) Except for a spouse of an individual or a parent for a child who is under age 21 or blind or disabled, the agency must not consider income and resources of any relative as available to an individual.

(2) In relation to individuals under 21 (as described in section 1905(a)(1) of the Act), the financial responsibility requirements and methodologies include considering the income and resources of parents or spouses whose income and resources would be considered if the individual under age 21 were dependent under the State’s approved AFDC plan, whether or not they are actually contributed. These requirements and methodologies must be applied in accordance with provisions of the State’s approved AFDC plan.

(3) When a couple ceases to live together, the agency must count only the income and resources of the individual in determining his or her eligibility, beginning the first month following the month the couple ceases to live together.

(b) The agency may apply income and resource methodologies that are less restrictive than the cash assistance methodologies as specified in the State plan in accordance with §436.601(d).

(c) [Reserved]

§436.604 [Reserved]

§436.606 [Reserved]

§436.608 Applications for other benefits.

(a) As a condition of eligibility, the agency must require applicants and recipients to take all necessary steps to obtain any annuities, pensions, and retirement and disability benefits to which they are entitled, unless they can show good cause for not doing so.

(b) Annuities, pensions, and retirement and disability benefits include, but are not limited to, veterans’ compensation and pensions, OASDI benefits, railroad retirement benefits, and unemployment compensation.

§436.610 Assignment of rights to benefits.

(a) As a condition of eligibility, the agency must require legally able applicants and recipients to:

(1) Assign rights to the Medicaid agency to medical support and to payment for medical care from any third party;

(2) Cooperate with the agency in establishing paternity and in obtaining medical support and payments, unless the individual establishes good cause for not cooperating, and except for individuals described in section 1902(l)(1)(A) of the Act (poverty level pregnant women), who are exempt from
§ 436.800 Scope.

This subpart prescribes financial requirements for determining the eligibility of medically needy individuals under subpart D of this part.

MEDICALLY NEEDY INCOME STANDARD

§ 436.811 Medically needy income standard: General requirements.

(a) To determine eligibility of medically needy individuals, the agency must use a single income standard for all covered medically needy groups that meets the requirements of this section.

(b) The income standard must take into account the number of persons in the assistance unit. The standard may not diminish by the number of persons in the unit (for example, if the income level in the standard for an assistance unit of two is set at $400, the income level in the standard for an assistance unit of three may not be less than $400).

(c) The income standard must be set at an amount that is no lower than the lowest income standard used on or after January 1, 1966, to determine eligibility under the cash assistance programs that are related to the State's covered medically needy group or groups of individuals under §436.301.

(d) The income standard may vary based on the variations between shelter costs in urban areas and rural areas.

[58 FR 4938, Jan. 19, 1993]
Health Care Financing Administration, HHS § 436.831

(c) Eligibility based on countable income. If countable income determined under paragraph (b) of this section is equal to or less than the applicable income standard under §436.814, the individual is eligible for Medicaid.

(d) Deduction of incurred medical expenses. If countable income exceeds the income standard, the agency must deduct from income medical expenses incurred by the individual or family or financially responsible relatives that are not subject to payment by a third party. An expense is incurred on the date liability for the expense arises. The agency must determine deductible incurred expenses in accordance with paragraphs (e), (f) and (g) of this section and deduct those expenses in accordance with paragraph (h) of this section.

(e) Determination of deductible incurred expenses: Required deductions based on kinds of services. Subject to the provisions of paragraph (g) of this section, in determining incurred medical expenses to be deducted from income, the agency must include the following:

(1) Expenses for Medicare and other health insurance premiums, and deductibles or coinsurance charges, including enrollment fees, copayments, or deductibles imposed under §447.51 or §447.53 of this chapter;

(2) Expenses incurred by the individual or family or financially responsible relatives for necessary medical and remedial services that are recognized under State law but not included in the plan;

(3) Expenses incurred by the individual or family or by financially responsible relatives for necessary medical and remedial services that are included in the plan, including those that exceed agency limitations on amount, duration or scope of services;

(f) Determination of deductible incurred expenses: Required deductions based on the age of bills. Subject to the provisions of paragraph (g) of this section, in determining incurred medical expenses to be deducted from income, the agency must include the following:

(1) For the first budget period or periods that include only months before the month of application for medical assistance, expenses incurred during such budget period, whether paid or unpaid, to the extent that the expenses have not been deducted previously in establishing eligibility;

(2) For the first prospective budget period that also includes any of the 3 months before the month of application for medical assistance, expenses incurred during such budget period, whether paid or unpaid, to the extent that the expenses have not been deducted previously in establishing eligibility;

(3) For the first prospective budget period that includes none of the months preceding the month of application, expenses incurred during such budget period and any of the 3 preceding months, whether paid or unpaid, to the extent that the expenses have not been deducted previously in establishing eligibility;

(4) For any of the 3 months preceding the month of application that are not includable under paragraph (f)(2) of this section, expenses incurred in the 3-month period that were a current liability of the individual in any such month for which a spenddown calculation is made and that had not been previously deducted from income in establishing eligibility for medical assistance;

(5) Current payments (that is, payments made in the current budget period) on other expenses incurred before the current budget period and not previously deducted from income in any budget period in establishing eligibility for such period; and

(6) If the individual's eligibility for medical assistance was established in each such preceding period, expenses incurred before the current budget period but not previously deducted from income, to the extent that such expenses are unpaid and are:

(i) Described in paragraphs (e)(1) through (e)(3) of this section; and

(ii) Are carried over from the preceding budget period or periods because the individual had a spenddown liability in each such preceding period that was met without deducting all such incurred, unpaid expenses.

(g) Determination of deductible incurred medical expenses: Optional deductions. In determining incurred medical expenses to be deducted from income, the agency—
§ 436.831

(1) May include medical institutional expenses (other than expenses in acute care facilities) projected to the end of the budget period at the Medicaid reimbursement rate;

(2) May, to the extent determined by the agency and specified in its approved plan, include expenses incurred earlier than the third month before the month of application; and

(3) May set reasonable limits on the amount to be deducted for expenses specified in paragraphs (e)(1), (e)(2), and (g)(2) of this section.

(h) Order of deduction. The agency must deduct incurred medical expenses that are deductible under paragraphs (e), (f), and (g) of this section, in the order prescribed under one of the following three options:

(1) Type of service. Under this option, the agency deducts expenses in the following order based on type of service:

(i) Cost-sharing expenses as specified in paragraph (e)(1) of this section.

(ii) Services not included in the State plan as specified in paragraph (e)(2) of this section.

(iii) Services included in the State plan as specified in paragraph (e)(3) of this section but that exceed agency limitations on amount, duration, or scope of services.

(iv) Services included in the State plan as specified in paragraph (e)(3) of this section but that are within agency limitations on amount, duration, or scope of services.

(2) Chronological order by service date. Under this option, the agency deducts expenses in chronological order by the date each service is furnished, or in the case of insurance premiums, coinsurance, or deductibles charges the date such amounts are due. Expenses for services furnished on the same day may be deducted in any reasonable order established by the State.

(3) Chronological order by bill submission date. Under this option, the agency deducts expenses in chronological order by the date each bill is submitted to the agency by the individual. If more than one bill is submitted at one time, the agency must deduct the bills from income in the order prescribed in either paragraph (h)(1) or (h)(2) of this section.

(i) Eligibility based on incurred medical expenses. (1) Whether a State elects partial or full month coverage, an individual who is expected to contribute a portion of his or her income toward the costs of institutional care or home and community-based services under §436.832 is eligible on the first day of the applicable budget (spenddown) period—

(i) If his or her spenddown liability is met after the first day of the budget period; and

(ii) If beginning eligibility after the first day of the budget period makes the individual's share of health care expenses under §436.832 greater than the individual's contributable income determined under this section.

(2) At the end of the prospective period specified in paragraph (f)(2) or (f)(3) of this section and any subsequent prospective period or, if earlier, when any significant change occurs, the agency must reconcile the projected amounts with the actual amounts incurred, or with changes in circumstances, to determine if the adjusted deduction of incurred expenses reduces income to the income standard.

(3) Except as provided in paragraph (i)(1) of this section, if agencies elect partial month coverage, an individual is eligible for Medicaid on the day that the deduction of incurred health care expenses (and of projected institutional expenses if the agency elects the option under paragraph (g)(1) of this section) reduces income to the income standard.

(4) Except as provided in paragraph (i)(1) of this section, if agencies elect full month coverage, an individual is eligible on the first day of the month in which spenddown liability is met.

(5) Expenses used to meet spenddown liability are not reimbursable under Medicaid. Therefore, to the extent necessary to prevent the transfer of an individual's spenddown liability to the Medicaid program, States must reduce the amount of provider charges that would otherwise be reimbursable under Medicaid.

[59 FR 1674, Jan. 12, 1994]
§ 436.832 Post-eligibility treatment of income of institutionalized individuals: Application of patient income to the cost of care.

(a) Basic rules. (1) The agency must reduce its payment to an institution, for services provided to an individual specified in paragraph (b) of this section, by the amount that remains after deducting the amounts specified in paragraphs (c) and (d) of this section from the individual’s total income.

(2) The individual’s income must be determined in accordance with paragraph (e) of this section.

(3) Medical expenses must be determined in accordance with paragraph (f) of this section.

(b) Applicability. This section applies to medically needy individuals in medical institutions and intermediate care facilities.

(c) Required deductions. The agency must deduct the following amounts, in the following order, from the individual’s total income as determined under paragraph (e) of this section. Income that was disregarded in determining eligibility must be considered in this process.

(1) Personal needs allowance. A personal needs allowance that is reasonable in amount for clothing and other personal needs of the individual while in the institution. This protected personal needs allowance must be at least—

(i) $30 a month for an aged, blind, or disabled individual, including a child applying for Medicaid on the basis of blindness or disability;

(ii) $60 a month for an institutionalized couple if both spouses are aged, blind, or disabled and their income is considered available to each other in determining eligibility; and

(iii) For other individuals, a reasonable amount set by the agency, based on a reasonable difference in their personal needs from those of the aged, blind, or disabled.

(2) Maintenance needs of spouse. For an individual with only a spouse at home, an additional amount for the maintenance needs of the spouse. This amount must be based on a reasonable assessment of need but must not exceed the higher of—

(i) The amount of the highest need standard for an individual without income and resources under the State’s approved plan for OAA, AFDC, AB, APTD, or AABD; or

(ii) The amount of the highest medically needy income standard for one person established under §436.811.

(3) Maintenance needs of family. For an individual with a family at home, an additional amount for the maintenance needs of the family. This amount must—

(i) Be based on a reasonable assessment of their financial need;

(ii) Be adjusted for the number of family members living in the home; and

(iii) Not exceed the highest of the following need standards for a family of the same size:

(A) The standard used to determine eligibility under the State’s Medicaid plan, as provided for in §436.811.

(B) The standard used to determine eligibility under the State’s approved AFDC plan.

(4) Expenses not subject to third party payment. Amounts for incurred expenses for medical or remedial care that are not subject to payment by a third party, including—

(i) Medicare and other health insurance premiums, deductibles, or coinsurance charges; and

(ii) Necessary medical or remedial care recognized under State law but not covered under the State’s Medicaid plan, subject to reasonable limits the agency may establish on amounts of these expenses.

(d) Optional deduction: Allowance for home maintenance. For single individuals and couples, an amount (in addition to the personal needs allowance) for maintenance of the individual’s or couple’s home if—

(1) The amount is deducted for not more than a 6-month period; and

(2) A physician has certified that either of the individuals is likely to return to the home within that period.

(e) Determination of income—(1) Option. In determining the amount of an individual’s income to be used to reduce the agency’s payment to the institution, the agency may use total income received or it may project total

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monthly income for a prospective period not to exceed 6 months.

(2) Basis for projection. The agency must base the projection on income received in the preceding period, not to exceed 6 months, and on income expected to be received.

(3) Adjustments. At the end of the prospective period specified in paragraph (e)(1) of this section, or when any significant change occurs, the agency must reconcile estimates with income received.

(f) Determination of medical expenses—

(1) Option. In determining the amount of medical expenses to be deducted from an individual's income, the agency may deduct incurred medical expenses, or it may project medical expenses for a prospective period not to exceed 6 months.

(2) Basis for projection. The agency must base the estimate on medical expenses incurred in the preceding period, not to exceed 6 months, and medical expenses expected to be incurred.

(3) Adjustments. At the end of the prospective period specified in paragraph (f)(1) of this section, or when any significant change occurs, the agency must reconcile estimates with incurred medical expenses.

§ 436.840 Medically needy resource standard: General requirements.

(a) To determine eligibility of medically needy individuals, the Medicaid agency must use a single resource standard that is set at an amount that is no lower than the lowest resource standard used on or after January 1, 1966, to determine eligibility under the cash assistance programs that are related to the State's covered medically needy group or groups of individuals under §436.301.

(b) The resource standard established under paragraph (a) of this section may not diminish by an increase in the number of persons in the assistance unit. For example, the resource level in the standard for an assistance unit of three may not be less than that set for an assistance unit of two.

§ 436.843 Medically needy resource standard: State plan requirements.

The State plan must specify the resource standard for the covered medically needy groups.

§ 436.845 Medically needy resource eligibility.

To determine eligibility on the basis of resources for medically needy individuals, the agency must—

(a) Consider only the individual's resources and those that are considered available to him under the financial responsibility requirements for relatives under §436.602;

(b) Consider only resources available during the period for which income is computed under §436.831(a);

(c) Deduct the value of resources that would be deducted in determining eligibility under the State's plan for OAA, AFDC, AB, APTD, or AABD or under the State's less restrictive financial methodology specified in the State Medicaid plan in accordance with §436.601. In determining the amount of an individual's resources for Medicaid eligibility, States must count amounts of resources that otherwise would not be counted under the conditional eligibility provisions of the AFDC program.

(d) Apply the resource standards established under §436.840.

§ 436.900 Scope.

This subpart sets forth requirements for processing applications, determining eligibility, and furnishing Medicaid.
§ 436.901 General requirements.
The Medicaid agency must comply with all the requirements of part 435, subpart J, of this subchapter, except those specified in §435.909.

§ 436.909 Automatic entitlement to Medicaid following a determination of eligibility under other programs.
The agency may not require a separate application for Medicaid from an individual if the individual receives cash assistance under a State plan for OAA, AFDC, AB, APTD, or AABD.

Subpart K—Federal Financial Participation (FFP)

§ 436.1000 Scope.
This subpart specifies when, and the extent to which, FFP is available in expenditures for determining eligibility and for Medicaid services to individuals determined eligible under this part, and prescribes limitations and conditions on FFP for those expenditures.

FFP FOR EXPENDITURES FOR DETERMINING ELIGIBILITY AND PROVIDING SERVICES

§ 436.1001 FFP for administration.
(a) FFP is available in the necessary administrative costs the State incurs in determining and redetermining Medicaid eligibility and in providing Medicaid to eligible individuals.
(b) Administrative costs include any costs incident to an eye examination or medical examination to determine whether an individual is blind or disabled.

§ 436.1002 FFP for services.
(a) FFP is available in expenditures for Medicaid services for all recipients whose coverage is required or allowed under this part.
(b) FFP is available in expenditures for services provided to recipients who were eligible for Medicaid in the month in which the medical care or services were provided, except that, for recipients who establish eligibility for Medicaid by deducting incurred medical expenses from income, FFP is not available for expenses that are the recipient’s liability.

§ 436.1003 Recipients overcoming certain conditions of eligibility.
FFP is available for a temporary period specified in the State plan in expenditures for services provided to recipients who are overcoming certain eligibility conditions, including blindness, disability, continued absence or incapacity of a parent, or unemployment of a parent.

§ 436.1004 Institutionalized individuals.
(a) FFP is not available in expenditures for services provided to—
(1) Individuals who are inmates of public institutions as defined in §435.1009; or
(2) Individuals under age 65 who are patients in an institution for mental diseases unless they are under age 22 and are receiving inpatient psychiatric services under §440.160 of this subchapter.
(b) The exclusion of FFP described in paragraph (a) of this section does not apply during that part of the month in which the individual is not an inmate of a public institution or a patient in an institution for mental diseases.
(c) An individual on conditional release or convalescent leave from an institution for mental diseases is not considered to be a patient in that institution. However, such an individual who is under age 22 and has been receiving inpatient psychiatric services under §440.160 of this subchapter is considered to be a patient in the institution until he is unconditionally released or, if earlier, the date he reaches age 22.

§ 436.1005 Definitions relating to institutional status.
For purposes of FFP, the definitions in §435.1009 of this subchapter apply to this part.
PART 440—SERVICES: GENERAL PROVISIONS

Subpart A—Definitions

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440.130 Diagnostic, screening, preventive, and rehabilitative services.
440.140 Inpatient hospital services, nursing facility services, and intermediate care facility services for individuals age 65 or older in institutions for mental diseases.
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Subpart B—Requirements and Limits Applicable to All Services

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Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

Source: 43 FR 45224, Sept. 29, 1978, unless otherwise noted.

§ 440.1 Basis and purpose.

This subpart interprets and implements the following sections of the Act:

1905(a) Services included in the term "medical assistance."
1905 (c), (d), (f) through (i), (l), and (m) Definitions of institutions and services that are included in the term "medical assistance."
1913 "Swing-bed" services. (See §§ 447.280 and 482.66 of this chapter for related provisions on "swing-bed" services.)
1915(c) Home and community-based services listed as "medical assistance" and furnished under waivers under that section to individuals who would otherwise require the level of care furnished in a hospital, NF, or ICF/MR.
1915 (d) Home and community-based services listed as "medical assistance" and furnished under waivers under that section to individuals age 65 or older who would otherwise require the level of care furnished in a NF.

[57 FR 29155, June 30, 1992, as amended at 61 FR 38398, July 24, 1996]

§ 440.2 Specific definitions; definitions of services for FFP purposes.

(a) Specific definitions.

Inpatient means a patient who has been admitted to a medical institution as an inpatient on recommendation of a physician or dentist and who—

(1) Receives room, board and professional services in the institution for a 24 hour period or longer, or
(2) Is expected by the institution to receive room, board and professional services in the institution for a 24 hour period or longer even though it later
§ 440.20 Outpatient hospital services and rural health clinic services.

(a) Outpatient hospital services means preventive, diagnostic, therapeutic, rehabilitative, or palliative services that—

(1) Are furnished to outpatients;

(2) Are furnished by or under the direction of a physician or dentist; and

(3) Are furnished by an institution that—

(i) Is licensed or formally approved as a hospital by an officially designated authority for State standard-setting; and

(ii) Meets the requirements for participation in Medicare as a hospital; and

(4) May be limited by a Medicaid agency in the following manner: A Medicaid agency may exclude from the definition of “outpatient hospital services” those types of items and services that are not generally furnished by most hospitals in the State.

(b) Rural health clinic services. If nurse practitioners or physician assistants (as defined in §481.2401 of this chapter) are not prohibited by State law from furnishing primary health care, “rural health clinic services” means the following services when furnished by a rural health clinic that has been certified in accordance with part 491 of this chapter:

(1) Services furnished by a physician within the scope of practice of his profession under State law, if the physician performs the services in the clinic or the services are furnished away from the clinic and the physician has an agreement with the clinic providing that he will be paid by it for such services.

(2) Services furnished by a physician assistant, nurse practitioner, nurse midwife or other specialized nurse practitioner (as defined in §§405.2401 and 491.2 of this chapter) if the services are furnished in accordance with the...
requirements specified in §405.2414(a) of this chapter.

(3) Services and supplies that are furnished as an incident to professional services furnished by a physician, physician assistant, nurse practitioner, nurse midwife, or specialized nurse practitioner. (See §§405.2413 and 405.2415 of this chapter for the criteria for determining whether services and supplies are included under this paragraph.)

(4) Part-time or intermittent visiting nurse care and related medical supplies (other than drugs and biologicals) if:

(i) The clinic is located in an area in which the Secretary has determined that there is a shortage of home health agencies (see §405.2417 of this chapter);

(ii) The services are furnished by a registered nurse or licensed practical nurse or a licensed vocational nurse employed by, or otherwise compensated for the services by, the clinic;

(iii) The services are furnished under a written plan of treatment that is established and reviewed at least every 60 days by a supervising physician of the clinic or that is established by a physician, physician assistant, nurse practitioner, nurse midwife, or specialized nurse practitioner and reviewed and approved at least every 60 days by a supervising physician of the clinic; and

(iv) The services are furnished to a homebound recipient. For purposes of visiting nurse care, a "homebound" recipient means one who is permanently or temporarily confined to his place of residence because of a medical or health condition. He may be considered homebound if he leaves the place of residence infrequently. For this purpose, "place of residence" does not include a hospital or a skilled nursing facility.

(c) Other ambulatory services furnished by a rural health clinic. If the State plan covers rural health clinic services, other ambulatory services means ambulatory services other than rural health clinic services, as defined in paragraph (b) of this section, that are otherwise included in the plan and meet specific State plan requirements for furnishing those services. Other ambulatory services furnished by a rural health clinic are not subject to the physician supervision requirements specified in §491.8(b) of this chapter, unless required by State law or the State plan.


§440.30 Other laboratory and X-ray services.

Other laboratory and X-ray services means professional and technical laboratory and radiological services—

(a) Ordered and provided by or under the direction of a physician or other licensed practitioner of the healing arts within the scope of his practice as defined by State law or ordered by a physician but provided by referral laboratory;

(b) Provided in an office or similar facility other than a hospital outpatient department or clinic; and

(c) Furnished by a laboratory that meets the requirements of part 493 of this chapter.


§440.40 Nursing facility services for individuals age 21 or older (other than services in an institution for mental disease), EPSDT, and family planning services and supplies.

(a) Nursing facility services. (1) "Nursing facility services for individuals age 21 or older, other than services in an institution for mental disease", means services that are—

(i) Needed on a daily basis and required to be provided on an inpatient basis under §§409.31 through 409.35 of this chapter.

(ii) Provided by—

(A) A facility or distinct part of a facility that is certified to meet the requirements for participation under subpart C of part 442 of this chapter, as evidenced by a valid agreement between the Medicaid agency and the facility for providing nursing facility services and making payments for services under the plan; or

(B) If specified in the State plan, a swing-bed hospital that has an approval from HCFA to furnish skilled nursing facility services in the Medicare program; and

(iii) Ordered by and provided under the direction of a physician.
(2) Nursing facility services include services provided by any facility located on an Indian reservation and certified by the Secretary as meeting the requirements of subpart B of part 483 of this chapter.

(b) EPSDT. “Early and periodic screening and diagnosis and treatment” means—

(1) Screening and diagnostic services to determine physical or mental defects in recipients under age 21; and

(2) Health care, treatment, and other measures to correct or ameliorate any defects and chronic conditions discovered. (See subpart B of part 441 of this chapter.)

(c) Family planning services and supplies for individuals of child-bearing age. [Reserved]

§ 440.50 Physicians’ services and medical and surgical services of a dentist.

(a) “Physicians’ services,” whether furnished in the office, the recipient’s home, a hospital, a skilled nursing facility, or elsewhere, means services furnished by a physician—

(1) Within the scope of practice of medicine or osteopathy as defined by State law; and

(2) By or under the personal supervision of an individual licensed under State law to practice medicine or osteopathy.

(b) “Medical and surgical services of a dentist” means medical and surgical services furnished, on or after January 1, 1988, by a doctor of dental medicine or dental surgery if the services are those that—

(1) If furnished by a physician, would be considered physician’s services.

(2) Under the law of the State where they are furnished, may be furnished either by a physician or by a doctor of dental medicine or dental surgery; and

(3) Are furnished by a doctor of dental medicine or dental surgery who is authorized to furnish those services in the State in which he or she furnished the services.

§ 440.60 Medical or other remedial care provided by licensed practitioners.

(a) “Medical care or any other type remedial care provided by licensed practitioners” means any medical or remedial care or services, other than physicians’ services, provided by licensed practitioners within the scope of practice as defined under State law.

(b) Chiropractors’ services include only services that—

(1) Are provided by a chiropractor who is licensed by the State and meets standards issued by the Secretary under §405.232(b) of this chapter; and

(2) Consists of treatment by means of manual manipulation of the spine that the chiropractor is legally authorized by the State to perform.

§ 440.70 Home health services.

(a) “Home health services” means the services in paragraph (b) of this section that are provided to a recipient—

(1) At his place of residence, as specified in paragraph (c) of this section; and

(2) On his or her physician’s orders as part of a written plan of care that the physician reviews every 60 days, except as specified in paragraph (b)(3) of this section.

(b) Home health services include the following services and items. Those listed in paragraphs (b) (1), (2) and (3) of this section are required services; those in paragraph (b)(4) of this section are optional.

(1) Nursing service, as defined in the State Nurse Practice Act, that is provided on a part-time or intermittent basis by a home health agency, or if there is no agency in the area, a registered nurse who—

(i) Is currently licensed to practice in the State;

(ii) Receives written orders from the patient’s physician;

(iii) Documents the care and services provided; and

(iv) Has had orientation to acceptable clinical and administrative recordkeeping from a health department nurse.

(2) Home health aide service provided by a home health agency,
§ 440.80 Private duty nursing services.

Private duty nursing services means nursing services for recipients who require more individual and continuous care than is available from a visiting nurse or routinely provided by the nursing staff of the hospital or skilled nursing facility. These services are provided—

(a) By a registered nurse or a licensed practical nurse;

(b) Under the direction of the recipient’s physician; and

(c) To a recipient in one or more of the following locations at the option of the State—

(1) His or her own home;

(2) A hospital; or

(3) A skilled nursing facility.

§ 440.90 Clinic services.

Clinic services means preventive, diagnostic, therapeutic, rehabilitative, or palliative services that are furnished by a facility that is not part of a hospital but is organized and operated to provide medical care to outpatients. The term includes the following services furnished to outpatients:

(a) Services furnished at the clinic by or under the direction of a physician or dentist.

(b) Services furnished outside the clinic, by clinic personnel under the direction of a physician, to an eligible individual who does not reside in a permanent dwelling or does not have a fixed home or mailing address.

§ 440.100 Dental services.

(a) “Dental services” means diagnostic, preventive, or corrective procedures provided by or under the supervision of a dentist in the practice of his profession, including treatment of—

(1) The teeth and associated structures of the oral cavity; and
(2) Disease, injury, or impairment that may affect the oral or general health of the recipient.

(b) “Dentist” means an individual licensed to practice dentistry or dental surgery.

§ 440.110 Physical therapy, occupational therapy, and services for individuals with speech, hearing, and language disorders.

(a) Physical therapy. (1) Physical therapy means services prescribed by a physician or other licensed practitioner of the healing arts within the scope of his or her practice under State law and provided to a recipient by or under the direction of a qualified physical therapist. It includes any necessary supplies and equipment.

(2) A “qualified physical therapist” is an individual who is—

(i) A graduate of a program of physical therapy approved by both the Committee on Allied Health Education and Accreditation of the American Medical Association and the American Physical Therapy Association or its equivalent; and

(ii) Where applicable, licensed by the State.

(b) Occupational therapy. (1) Occupational therapy means services prescribed by a physician or other licensed practitioner of the healing arts within the scope of his or her practice under State law and provided to a recipient by or under the direction of a qualified occupational therapist. It includes any necessary supplies and equipment.

(2) A “qualified occupational therapist” is an individual who is—

(i) Registered by the American Occupational Therapy Association; or

(ii) A graduate of a program in occupational therapy approved by the Committee on Allied Health Education and Accreditation of the American Medical Association and engaged in the supplemental clinical experience required before registration by the American Occupational Therapy Association.

(c) Services for individuals with speech, hearing, and language disorders. (1) Services for individuals with speech, hearing, and language disorders means diagnostic, screening, preventive, or corrective services provided by or under the direction of a speech pathologist or audiologist, for which a patient is referred by a physician or other licensed practitioner of the healing arts within the scope of his or her practice under State law. It includes any necessary supplies and equipment.

(2) A “speech pathologist or audiologist” is an individual who—

(i) Has a certificate of clinical competence from the American Speech and Hearing Association;

(ii) Has completed the equivalent educational requirements and work experience necessary for the certificate; or

(iii) Has completed the academic program and is acquiring supervised work experience to qualify for the certificate.

§ 440.120 Prescribed drugs, dentures, prosthetic devices, and eyeglasses.

(a) “Prescribed drugs” means simple or compound substances or mixtures of substances prescribed for the cure, mitigation, or prevention of disease, or for health maintenance that are—

(i) Prescribed by a physician or other licensed practitioner of the healing arts within the scope of this professional practice as defined and limited by Federal and State law;

(ii) Dispensed by licensed pharmacists and licensed authorized practitioners in accordance with the State Medical Practice Act; and

(iii) Dispensed by the licensed pharmacist or practitioner on a written prescription that is recorded and maintained in the pharmacist’s or practitioner’s records.

(b) “Dentures” are artificial structures made by or under the direction of a dentist to replace a full or partial set of teeth.

(c) “Prosthetic devices” means replacement, corrective, or supportive devices prescribed by a physician or other licensed practitioner of the healing arts within the scope of his practice as defined by State law to—

(i) Artificially replace a missing portion of the body;
§ 440.130 Diagnostic, screening, preventive, and rehabilitative services.

(a) "Diagnostic services," except as otherwise provided under this subpart, includes any medical procedures or supplies recommended by a physician or other licensed practitioner of the healing arts, within the scope of his practice under State law, to enable him to identify the existence, nature, or extent of illness, injury, or other health deviation in a recipient.

(b) "Screening services" means the use of standardized tests given under medical direction in the mass examination of a designated population to detect the existence of one or more particular diseases or health deviations or to identify for more definitive studies individuals suspected of having certain diseases.

(c) "Preventive services" means services provided by a physician or other licensed practitioner of the healing arts within the scope of his practice under State law to—

(1) Prevent disease, disability, and other health conditions or their progression;
(2) Prolong life; and
(3) Promote physical and mental health and efficiency.

(d) "Rehabilitative services," except as otherwise provided under this subpart, includes any medical or remedial services recommended by a physician or other licensed practitioner of the healing arts, within the scope of his practice under State law, for maximum reduction of physical or mental disability and restoration of a recipient to his best possible functional level.

§ 440.140 Inpatient hospital services, nursing facility services, and intermediate care facility services for individuals age 65 or older in institutions for mental diseases.

(a) Inpatient hospital services. "Inpatient hospital services for individuals age 65 or older in institutions for mental diseases" means services provided under the direction of a physician for the care and treatment of recipients in an institution for mental diseases that meets the requirements specified in §482.60(b), (c), and (e) of this chapter and—

(1) Meets the requirements for utilization review in §482.30(a), (b), (d), and (e) of this chapter; or
(2) Has been granted a waiver of those utilization review requirements under section 1903(i)(4) of the Act and subpart H of part 456 of this chapter.

(b) Nursing facility services. "Nursing facility services for individuals age 65 or older in institutions for mental diseases" means nursing facility services as defined in §440.40 and in subpart B of part 483 of this chapter that are provided in institutions for mental diseases, as defined in §435.1009 of this chapter.

[59 FR 56234, Nov. 10, 1994]

§ 440.150 Intermediate care facility (ICF/MR) services.

(a) "ICF/MR services" means those items and services furnished in an intermediate care facility for the mentally retarded if the following conditions are met:

(1) The facility fully meets the requirements for a State license to provide services that are above the level of room and board;
(2) The primary purpose of the ICF/MR is to furnish health or rehabilitative services to persons with mental retardation or persons with related conditions;
(3) The ICF/MR meets the standards specified in subpart C of part 483 of this chapter.

(b) ICF/MR services may be furnished in a distinct part of a facility other than an ICF/MR if the distinct part—
§ 440.165 Nurse-midwife service.

(a) "Nurse-midwife services" means services that—
(1) Are furnished by a nurse-midwife within the scope of practice authorized by State law or regulation and, in the case of inpatient or outpatient hospital services or clinic services, are furnished by or under the direction of a nurse-midwife to the extent permitted by the facility; and
(2) Unless required by State law or regulations or a facility, are reimbursed without regard to whether the nurse-midwife is under the supervision of, or associated with, a physician or other health care provider. (See §441.21

§ 440.160 Inpatient psychiatric services for individuals under age 21.

"Inpatient psychiatric services for individuals under age 21" means services that—
(a) Are provided under the direction of a physician;
(b) Are provided in a facility or program accredited by the Joint Commission on Accreditation of Hospitals; and
(c) Meet the requirements in subpart D of part 441.

§ 440.155 Nursing facility services, other than in institutions for mental diseases.

(a) "Nursing facility services, other than in an institution for mental diseases" means services provided in a facility that—
(1) Fully meets the requirements for a State license to provide, on a regular basis, health-related services to individuals who do not require hospital care, but whose mental or physical condition requires services that—
(i) Are above the level of room and board; and
(ii) Can be made available only through institutional facilities;
(2) Has been certified to meet the requirements of subpart C of part 442 of this chapter as evidenced by a valid agreement between the Medicaid agency and the facility for providing nursing facility services and making payments for services under the plan; and
(b) "Nursing facility services" include services—
(1) Considered appropriate by the State and provided by a Christian Science sanatorium operated, or listed and certified, by the First Church of Christ, Scientist, Boston, Mass.; or
(2) Provided by a facility located on an Indian reservation that—
(i) Furnishes, on a regular basis, health-related services; and
(ii) Is certified by the Secretary to meet the standards in subpart E of part 442 of this chapter.

(c) "Nursing facility services" may include services provided in a distinct part of a facility other than a nursing facility if the distinct part—
(1) Meets all requirements for a nursing facility;
(2) Is a identifiable unit, such as an entire ward or contiguous ward, a wing, floor, or building;
(3) Consists of all beds and related facilities in the unit;
(4) Houses all recipients for whom payment is being made for nursing facility services, except as provided in paragraph (d) of this section;
(5) Is clearly identified; and
(6) Is approved in writing by the survey agency.

(d) If a State includes as nursing facility services those services provided by a distinct part of a facility other than a nursing facility, it may not require transfer of a recipient within or between facilities if, in the opinion of the attending physician, it might be harmful to the physical or mental health of the recipient.

(e) Nursing facility services may include services provided in a swing-bed hospital that has an approval to furnish nursing facility services.

§ 440.165 Nurse-midwife service.

(a) "Nurse-midwife services" means services that—
(1) Are furnished by a nurse-midwife within the scope of practice authorized by State law or regulation and, in the case of inpatient or outpatient hospital services or clinic services, are furnished by or under the direction of a nurse-midwife to the extent permitted by the facility; and
(2) Unless required by State law or regulations or a facility, are reimbursed without regard to whether the nurse-midwife is under the supervision of, or associated with, a physician or other health care provider. (See §441.21

§ 440.160 Inpatient psychiatric services for individuals under age 21.

"Inpatient psychiatric services for individuals under age 21" means services that—
(a) Are provided under the direction of a physician;
(b) Are provided in a facility or program accredited by the Joint Commission on Accreditation of Hospitals; and
(c) Meet the requirements in subpart D of part 441.

§ 440.155 Nursing facility services, other than in institutions for mental diseases.

(a) "Nursing facility services, other than in an institution for mental diseases" means services provided in a facility that—
(1) Fully meets the requirements for a State license to provide, on a regular basis, health-related services to individuals who do not require hospital care, but whose mental or physical condition requires services that—
(i) Are above the level of room and board; and
(ii) Can be made available only through institutional facilities;
(2) Has been certified to meet the requirements of subpart C of part 442 of this chapter as evidenced by a valid agreement between the Medicaid agency and the facility for providing nursing facility services and making payments for services under the plan; and
(b) "Nursing facility services" include services—
(1) Considered appropriate by the State and provided by a Christian Science sanatorium operated, or listed and certified, by the First Church of Christ, Scientist, Boston, Mass.; or
(2) Provided by a facility located on an Indian reservation that—
(i) Furnishes, on a regular basis, health-related services; and
(ii) Is certified by the Secretary to meet the standards in subpart E of part 442 of this chapter.

(c) "Nursing facility services" may include services provided in a distinct part of a facility other than a nursing facility if the distinct part—
(1) Meets all requirements for a nursing facility;
(2) Is an identifiable unit, such as an entire ward or contiguous ward, a wing, floor, or building;
(3) Consists of all beds and related facilities in the unit;
(4) Houses all recipients for whom payment is being made for nursing facility services, except as provided in paragraph (d) of this section;
(5) Is clearly identified; and
(6) Is approved in writing by the survey agency.

(d) If a State includes as nursing facility services those services provided by a distinct part of a facility other than a nursing facility, it may not require transfer of a recipient within or between facilities if, in the opinion of the attending physician, it might be harmful to the physical or mental health of the recipient.

(e) Nursing facility services may include services provided in a swing-bed hospital that has an approval to furnish nursing facility services.
§ 440.166 Nurse practitioner services.

(a) Definition of nurse practitioner services. Nurse practitioner services means services that are furnished by a registered professional nurse who meets a State's advanced educational and clinical practice requirements, if any, beyond the 2 to 4 years of basic nursing education required of all registered nurses.

(b) Requirements for certified pediatric nurse practitioner. The practitioner must be a registered professional nurse who meets the requirements specified in either paragraphs (b)(1) or (b)(2) of this section.

(1) If the State specifies qualifications for pediatric nurse practitioners, the practitioner must—

(i) Be currently licensed to practice in the State as a registered professional nurse; and

(ii) Meet the State requirements for qualification of pediatric nurse practitioners in the State in which he or she furnishes the services.

(2) If the State does not specify, by specialty, qualifications for pediatric nurse practitioners, but the State does define qualifications for nurses in advanced practice or general nurse practitioners, the practitioner must—

(i) Meet qualifications for nurses in advanced practice or general nurse practitioners as defined by the State; and

(ii) Have a pediatric nurse practice limited to providing primary health care to persons less than 21 years of age.

(c) Requirements for certified family nurse practitioner. The practitioner must be a registered professional nurse who meets the requirements specified in either paragraph (c)(1) or (c)(2) of this section.

(1) If the State specifies qualifications for family nurse practitioners, the practitioner must—

(i) Be currently licensed to practice in the State as a registered professional nurse; and

(ii) Meet the State requirements for qualification of family nurse practitioners in the State in which he or she furnishes the services.

(2) If the State does not specify, by specialty, qualifications for family nurse practitioners, but the State does define qualifications for nurses in advanced practice or general nurse practitioners, the practitioner must—

(i) Meet qualifications for nurses in advanced practice or general nurse practitioners as defined by the State; and

(ii) Have a family nurse practice limited to providing primary health care to individuals and families.
§ 440.170 Any other medical care or remedial care recognized under State law and specified by the Secretary.

(a) Transportation. (1) "Transportation" includes expenses for transportation and other related travel expenses determined to be necessary by the agency to secure medical examinations and treatment for a recipient.

(2) Transportation, as defined in this section, is furnished only by a provider to whom a direct vendor payment can appropriately be made by the agency. If other arrangements are made to assure transportation under §431.53 of this subchapter, FFP is available as an administrative cost.

(3) "Travel expenses" include—

(i) The cost of transportation for the recipient by ambulance, taxicab, common carrier, or other appropriate means;

(ii) The cost of meals and lodging en route to and from medical care, and while receiving medical care; and

(iii) The cost of an attendant to accompany the recipient, if necessary, and the cost of the attendant's transportation, meals, lodging, and, if the attendant is not a member of the recipient's family, salary.

(b) Services of Christian Science nurses. "Services of Christian Science nurses" mean services provided by nurses who are listed and certified by the First Church of Christ, Scientist, Boston, Mass., if—

(1) The services have been requested by the recipient; and

(2) The services are provided—

(i) By or under the supervision of a Christian Science visiting nurse organization listed and certified by the First Church of Christ, Scientist, Boston, Mass.; or

(ii) As private duty services to a recipient in his own home or in a Christian Science sanatorium operated, or listed and certified, by the First Church of Christ, Scientist, Boston, Mass., if the recipient requires individual and continuous care beyond that available from a visiting nurse or that routinely provided by the nursing staff of the sanatorium.

(c) Services in Christian Science sanatoriums. "Services in Christian Science sanatoriums" means services provided in Christian Science sanatoriums that are operated by, or listed and certified by, the First Church of Christ, Scientist, Boston, Mass.

(d) Skilled nursing facility services for individuals under age 21. "Skilled nursing facility services for individuals under 21" means those services provided in §440.40 that are provided to recipients under 21 years of age.

(e) Emergency hospital services. "Emergency hospital services" means services that—

(1) Are necessary to prevent the death or serious impairment of the health of a recipient; and

(2) Because of the threat to the life or health of the recipient necessitate the use of the most accessible hospital available that is equipped to furnish the services, even if the hospital does not currently meet—
§ 440.180 Home or community-based services.

(a) Description and requirements for services. “Home or community-based services” means services, not otherwise furnished under the State’s Medicaid plan, that are furnished under a waiver granted under the provisions of part 441, subpart G of this chapter.

(1) These services may consist of any or all of the services listed in paragraph (b) of this section, as those services are defined by the agency and approved by HCFA.

(2) The services must meet the standards specified in §441.302(a) of this chapter concerning health and welfare assurances.

(3) The services are subject to the limits on FFP described in §441.310 of this chapter.

(b) Included services. Home or community-based services may include the following services, as they are defined by the agency and approved by HCFA:

(1) Case management services.
(2) Homemaker services.
(3) Home health aide services.
(4) Personal care services.
(5) Adult day health services.
(6) Habilitation services.
(7) Respite care services.
(8) Day treatment or other partial hospitalization services, psychosocial rehabilitation services and clinic services (whether or not furnished in a facility) for individuals with chronic mental illness, subject to the conditions specified in paragraph (d) of this section.

(9) Other services requested by the agency and approved by HCFA as cost effective and necessary to avoid institutionalization.

(c) Expanded habilitation services, effective April 7, 1986—(1) General rule. Expanded habilitation services are those services specified in paragraph (c)(2) of this section, that are provided to recipients who have been discharged from a Medicaid-certified NF or ICF/MR, regardless of when the discharge occurred.

(2) Services included. The agency may include as expanded habilitation services the following services:

(i) Prevocational services, which means services that prepare an individual for paid or unpaid employment and that are not job-task oriented but are, instead, aimed at a generalized result. These services may include, for example, teaching an individual such concepts as compliance, attendance, task completion, problem solving and safety. Prevocational services are distinguishable from noncovered vocational services by the following criteria:

(A) The services are provided to persons who are not expected to be able to join the general work force or participate in a transitional sheltered workshop within one year (excluding supported employment programs).
(B) If the recipients are compensated, they are compensated at less than 50 percent of the minimum wage;
(C) The services include activities which are not primarily directed at teaching specific job skills but at underlying habilitative goals (for example, attention span, motor skills); and
(D) The services are reflected in a plan of care directed to habilitative rather than explicit employment objectives.

(ii) Educational services, which means special education and related services (as defined in sections 602(16) and (17) of the Education of the Handicapped Act) (20 U.S.C. 1401 (16 and 17)) to the extent they are not prohibited under paragraph (c)(3)(i) of this section.
§ 440.185 Respiratory care for ventilator-dependent individuals.

(a) "Respiratory care for ventilator-dependent individuals" means services that are not otherwise available under...
§ 440.200 Basis, purpose, and scope.

(a) This subpart implements the following statutory requirements—

(1) Section 1902(a)(10), regarding comparability of services for groups of recipients, and the amount, duration, and scope of services described in section 1905(a) of the Act that the State plan must provide for recipients;

(2) Section 1902(a)(22)(D), which provides for standards and methods to assure quality of services;

(3) Section 1903(v)(1), which provides that payment may be made to a State under this section for medical assistance furnished to an alien who is not lawfully admitted for permanent residence or otherwise permanently residing in the United States under color of law;

(4) Section 1903(v)(2) which provides that FFP will be available for services necessary to treat an emergency medical condition of an alien not described in paragraph (a)(3) of this section if that alien otherwise meets the eligibility requirements of the State plan;

(5) Section 1907 on observance of religious beliefs;

(6) Section 1915 on exceptions to section 1902(a)(10) and waivers of other requirements of section 1902 of the Act; and

(7) Sections 245A(h), 210 and 210A of the Immigration and Nationality Act which provide that certain aliens who are legalized may be eligible for Medicaid.

(b) The requirements and limits of this subpart apply for all services defined in subpart A of this part.

[55 FR 36822, Sept. 7, 1990]
§ 440.240 Comparability of services for groups.

Except as limited in § 440.250—
§ 440.250  
(a) The plan must provide that the services available to any categorically needy recipient under the plan are not less in amount, duration, and scope than those services available to a medically needy recipient; and
(b) The plan must provide that the services available to any individual in the following groups are equal in amount, duration, and scope for all recipients within the group:

(1) The categorically needy.

(2) A covered medically needy group.

[46 FR 47993, Sept. 30, 1981]

§ 440.250 Limits on comparability of services.

(a) Skilled nursing facility services (§ 440.40(a)) may be limited to recipients age 21 or older.
(b) Early and periodic screening, diagnosis, and treatment (§ 440.40(b)) must be limited to recipients under age 21.
(c) Family planning services and supplies must be limited to recipients of childbearing age, including minors who can be considered sexually active and who desire the services and supplies.
(d) If covered under the plan, services to recipients in institutions for mental diseases (§ 440.140) must be limited to those age 65 or older.
(e) If covered under the plan, inpatient psychiatric services (§ 440.160) must be limited to recipients under age 22 as specified in § 441.151(c) of this subchapter.
(f) If Medicare benefits under Part B of title XVIII are made available to recipients through a buy-in agreement or payment of premiums, or part or all of the deductibles, cost sharing or similar charges, they may be limited to recipients who are covered by the agreement or payment.
(g) If services in addition to those offered under the plan are made available under a contract between the agency or political subdivision and an organization providing comprehensive health services, those additional services may be limited to recipients who reside in the geographic area served by the contracting organization and who elect to receive services from it.
(h) Ambulatory services for the medically needy (§ 440.220(a)(2)) may be limited to:

(1) Individuals under age 18; and
(2) Groups of individuals entitled to institutional services.
(i) Services provided under an exception to requirements allowed under § 431.54 may be limited as provided under that exception.
(j) If HCFA has approved a waiver of Medicaid requirements under § 431.55, services may be limited as provided by the waiver.
(k) If the agency has been granted a waiver of the requirements of § 440.240 (Comparability of services) in order to provide for home or community-based services under §§ 440.180 or 441.181, the services provided under the waiver need not be comparable for all individuals within a group.
(l) If the agency imposes cost sharing on recipients in accordance with 447.53, the imposition of cost sharing on an individual who is not exempted by one of the conditions in section 447.53(b) shall not require the State to impose copayments on an individual who is eligible for such exemption.
(m) Eligible legalized aliens who are not in the exempt groups described in §§ 435.406(a) and 436.406(a), and considered categorically needy or medically needy must be furnished only emergency services (as defined in § 440.255), and services for pregnant women as defined in section 1916(a)(2)(B) of the Social Security Act for 5 years from the date the alien is granted lawful temporary resident status.
(n) Aliens who are not lawful permanent residents, permanently residing in the United States under color of law, or granted lawful status under section 245A, 210 or 210A of the Immigration and Nationality Act, who, otherwise meet the eligibility requirements of the State plan (except for receipt of AFDC, SSI or a State Supplementary payment) must be furnished only those services necessary to treat an emergency medical condition of the alien as defined in § 440.255(c).
(o) If the agency makes respiratory care services available under § 440.185, the services need not be made available in equal amount, duration, and scope to any individual not eligible for coverage under that section. However, the services must be made available in equal amount, duration, and scope to
§ 440.270 Religious objections.

(a) Except as specified in paragraph (b) of this section, the agency may not require any individual to undergo any medical service, diagnosis, or treatment or to accept any other health service provided under the plan if the individual objects, or in the case of a child, a parent or guardian objects, on religious grounds.

(b) If a physical examination is necessary to establish eligibility based on disability or blindness, the agency may not find an individual eligible for Medicaid unless he undergoes the examination.

§ 440.260 Methods and standards to assure quality of services.

The plan must include a description of methods and standards used to assure that services are of high quality.

§ 440.255 Limited services available to certain aliens.

(a) FFP for services. FFP is available for services provided to aliens described in this section which are necessary to treat an emergency medical condition as defined in paragraphs (b)(1) and (c) or services for pregnant women described in paragraph (b)(2).

(b) Legalized aliens eligible only for emergency services and services for pregnant women. Aliens granted lawful temporary resident status, or lawful permanent resident status under sections 245A, 210 or 210A of the Immigration and Nationality Act, who are not in one of the exempt groups described in §§435.406(a)(3) and 436.406(a)(3) and who meet all other requirements for Medicaid will be eligible for the following services—

(1) Emergency services required 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:

(i) Placing the patient’s health in serious jeopardy;

(ii) Serious impairment to bodily functions; or

(iii) Serious dysfunction of any bodily organ or part.

(2) Services for pregnant women which are included in the approved State plan. These services include routine prenatal care, labor and delivery, and routine post-partum care. States, at their option, may provide additional plan services for the treatment of conditions which may complicate the pregnancy or delivery.

(c) Effective January 1, 1987, aliens who are not lawfully admitted for permanent residence in the United States or permanently residing in the United States under the color of law must receive the services necessary to treat the condition defined in paragraph (1) of this section if—

(1) The alien has, after sudden onset, a medical condition (including emergency labor and delivery) 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:

(i) Placing the patient’s health in serious jeopardy;

(ii) Serious impairment to bodily functions; or

(iii) Serious dysfunction of any bodily organ or part, and

(2) The alien otherwise meets the requirements in §§435.406(c) and 436.406(c) of this subpart.

§ 440.270 Religious objections.

(a) Except as specified in paragraph (b) of this section, the agency may not require any individual to undergo any medical service, diagnosis, or treatment or to accept any other health service provided under the plan if the individual objects, or in the case of a child, a parent or guardian objects, on religious grounds.

(b) If a physical examination is necessary to establish eligibility based on disability or blindness, the agency may not find an individual eligible for Medicaid unless he undergoes the examination.
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§ 441.11 Continuation of FFP for institutional services.

(a) Basic conditions for continuation of FFP. FFP may be continued for up to 30 days after the effective date of termination or expiration of a provider agreement, if the following conditions are met:

1. The Medicaid payments are for recipients admitted to the facility before the effective date of termination or expiration.
2. The State agency is making reasonable efforts to transfer those recipients to other facilities or to alternate care.

(b) When the 30-day period begins. The 30-day period begins on one of the following:

1. The effective date of termination of the facility's provider agreement by HCFA.
2. The effective date of termination of the facility's Medicaid provider agreement by the Medicaid agency on its own volition; or
3. The date of issuance of an administrative hearing decision that upholds the agency's termination or nonrenewal action.

(c) Services for which FFP may be continued. FFP may be continued for any of the following services, as defined in subpart A of part 440 of this chapter:

1. Inpatient hospital services.

 attending physician or other licensed practitioner (§ 441.12).

(h) Section 1903(i)(18) for the requirement that each home health agency provide the Medicaid agency with a surety bond (§ 441.16).

(i) Section 1905(a)(4)(C) for family planning (§ 441.20).

(j) Sections 1905(a)(12) and (e) for optometric services (§ 441.30).

(k) Section 1905(a)(17) for nurse-midwife services (§ 441.21).

(l) Section 1905(a) (following (a)(24)) for prohibition of FFP in expenditures for certain services (§ 441.13).

[60 FR 19862, Apr. 21, 1995, as amended at 63 FR 310, Jan. 5, 1998]
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(2) Inpatient hospital services for individuals age 65 or older in an institution for mental diseases.

(3) Nursing facility services for individuals age 21 or older.

(4) Nursing facility services for individuals age 65 or older in an institution for mental diseases.

(5) Inpatient psychiatric services for individuals under age 21.

(6) Nursing facility services for individuals under 21.

(7) Intermediate care facility services for the mentally retarded.

[59 FR 56234, Nov. 10, 1994]

§ 441.12 Inpatient hospital tests.

Except in an emergency situation (see § 440.170(e)(1) of this chapter for definition), FFP is not available in expenditures for inpatient hospital tests unless the tests are specifically ordered by the attending physician or other licensed practitioner, acting within the scope of practice as defined under State law, who is responsible for the diagnosis or treatment of a particular patient’s condition.


§ 441.13 Prohibitions on FFP: Institutionalized individuals.

(a) FFP is not available in expenditures for services for—

(1) Any individual who is in a public institution, as defined in § 435.1009 of this subchapter; or

(2) Any individual who is under age 65 and is in an institution for mental diseases, except an individual who is under age 22 and receiving inpatient psychiatric services under subpart D of this part.

(b) With the exception of active treatment services (as defined in § 483.440(a) of this chapter for residents of ICFs/MR and in § 441.154 for individuals under age 21 receiving inpatient psychiatric services), payments to institutions for the mentally retarded or persons with related conditions and to psychiatric facilities or programs providing inpatient psychiatric services to individuals under age 21 may not include reimbursement for formal educational services or for vocational services. Formal educational services relate to training in traditional academic subjects. Subject matter rather than setting, time of day, or class size determines whether a service is educational. Traditional academic subjects include, but are not limited to, science, history, literature, foreign languages, and mathematics. Vocational services relate to organized programs that are directly related to the preparation of individuals for paid or unpaid employment. An example of vocational services is time-limited vocational training provided as a part of a regularly scheduled class available to the general public.

(c) FFP is not available in expenditures for services furnished by an organ procurement organization on or after April 1, 1988, that does not meet the requirements of part 485, subpart D of this chapter.


§ 441.15 Home health services.

With respect to the services defined in § 440.70 of this subchapter, a State plan must provide that—

(a) Home health services include, as a minimum—

(1) Nursing services;

(2) Home health aide services; and

(3) Medical supplies, equipment, and appliances.

(b) The agency provides home health services to—

(1) Categorically needy recipients age 21 or over;

(2) Categorically needy recipients under age 21, if the plan provides skilled nursing facility services for them; individuals; and

(3) Medically needy recipients to whom skilled nursing facility services are provided under the plan.

(c) The eligibility of a recipient to receive home health services does not depend on his need for or discharge from institutional care.

(d) The agency providing home health services meets the capitalization requirements included in § 489.28 of this chapter.

§ 441.16 Home health agency requirements for surety bonds; Prohibition on FFP.

(a) Definitions. As used in this section, unless the context indicates otherwise—

Assets includes but is not limited to any listing that identifies Medicaid recipients to whom home health services were furnished by a participating or formerly participating HHA.

Participating home health agency means a "home health agency" (HHA) as that term is defined at §440.70(d) of this subchapter.

Surety bond means one or more bonds issued by one or more surety companies under 31 U.S.C. 9304 to 9308 and 31 CFR parts 223, 224, and 225, provided the bond otherwise meets the requirements of this section.

Uncollected overpayment means an "overpayment," as that term is defined under §433.304 of this subchapter, plus accrued interest, for which the HHA is responsible, that has not been recouped by the Medicaid agency within a time period determined by the Medicaid agency.

(b) Prohibition. FFP is not available in expenditures for home health services under §440.70 of this subchapter unless the home health agency furnishing these services meets the surety bond requirements of paragraphs (c) through (l) of this section.

(c) Basic requirement. Except as provided in paragraph (d) of this section, each HHA that is a Medicaid participating HHA or that seeks to become a Medicaid participating HHA must—

(1) Obtain a surety bond that meets the requirements of this section and instructions issued by the Medicaid agency; and

(2) Furnish a copy of the surety bond to the Medicaid agency.

(d) Requirement waived for Government-operated HHAs. An HHA operated by a Federal, State, local, or tribal government agency is deemed to have provided the Medicaid agency with a comparable surety bond under State law, and is therefore exempt from the requirements of this section if, during the preceding 5 years, the HHA has not had any uncollected overpayments.

(e) Parties to the bond. The surety bond must name the HHA as Principal, the Medicaid agency as Obligee, and the surety company (and its heirs, executors, administrators, successors and assignees, jointly and severally) as Surety.

(f) Authorized Surety and exclusion of surety companies. An HHA may obtain a surety bond required under this section only from an authorized Surety.

(1) An authorized Surety is a surety company that—

(i) Has been issued a Certificate of Authority by the U.S. Department of the Treasury in accordance with 31 U.S.C. 9304 to 9308 and 31 CFR parts 223, 224, and 225 as an acceptable surety on Federal bonds and the Certificate has neither expired nor been revoked;

(ii) Has not been determined by the Medicaid agency to be an unauthorized Surety for the purpose of an HHA obtaining a surety bond under this section; and

(iii) Meets other conditions, as specified by the Medicaid agency.

(2) The Medicaid agency may determine that a surety company is an unauthorized Surety under this section—

(i) If, upon request by the Medicaid agency, the surety company fails to furnish timely confirmation of the issuance of, and the validity and accuracy of information appearing on, a surety bond that an HHA presents to the Medicaid agency that shows the surety company as Surety on the bond;

(ii) If, upon presentation by the Medicaid agency to the surety company of a request for payment on a surety bond and of sufficient evidence to establish the surety company's liability on the bond, the surety company fails to timely pay the Medicaid agency in full the amount requested up to the face amount of the bond; or

(iii) For other good cause.

(3) The Medicaid agency must specify the manner by which public notification of a determination under paragraph (f)(2) of this section is given and the effective date of the determination.

(4) A determination by the Medicaid agency that a surety company is an unauthorized Surety under paragraph (f)(2) of this section—

(i) Has effect only within the State; and

(ii) Is subject to judicial review.
(ii) Is not a debarment, suspension, or exclusion for the purposes of Executive Order No. 12549 (3 CFR 1986 Comp., p. 189).

(g) Amount of the bond.

(1) Basic rule. The amount of the surety bond must be $50,000 or 15 percent of the annual Medicaid payments made to the HHA by the Medicaid agency for home health services furnished under this subchapter for which FFP is available, whichever is greater.

(2) Computation of the 15 percent: Participating HHA. The 15 percent is computed by the Medicaid agency on the basis of Medicaid payments made to the HHA for the most recent annual period for which information is available as specified by the Medicaid agency.

(3) Computation of 15 percent: An HHA that seeks to become a participating HHA by obtaining assets or ownership interest. For an HHA that seeks to become a participating HHA by purchasing the assets or the ownership interest of a participating or formerly participating HHA, the 15 percent is computed on the basis of Medicaid payments made by the Medicaid agency to the participating or formerly participating HHA for the most recent annual period as specified by the Medicaid agency.

(4) Computation of 15 percent: Change of ownership. For an HHA that undergoes a change of ownership (as “change of ownership” is defined by the State Medicaid agency) the 15 percent is computed on the basis of Medicaid payments made by the Medicaid agency to the HHA for the most recent annual period as specified by the Medicaid agency.

(5) An HHA that seeks to become a participating HHA without obtaining assets or ownership interest. For an HHA that seeks to become a participating HHA without purchasing the assets or the ownership interest of a participating or formerly participating HHA, the 15 percent computation does not apply.

(6) Exception to the basic rule. If an HHA’s overpayment in the most recent annual period exceeds 15 percent, the State Medicaid agency may require the HHA to secure a bond in an amount up to or equal to the amount of the overpayment, provided the amount of the bond is not less than $50,000.

(7) Expiration of the 15 percent provision. For an annual surety bond, or for a rider on a continuous surety bond, that is required to be submitted on or after June 1, 2005, notwithstanding any reference in this section to 15 percent as a basis for determining the amount of the bond, the amount of the bond or rider, as applicable, must be $50,000 or such amount as the Medicaid agency specifies in accordance with paragraph (g)(6) of this section, whichever amount is greater.

(h) Additional requirements of the surety bond. The surety bond that an HHA obtains under this section must meet the following additional requirements:

(1) The bond must guarantee that, upon written demand by the Medicaid agency to the Surety for payment under the bond and the Medicaid agency furnishing to the Surety sufficient evidence to establish the Surety’s liability under the bond, the Surety will timely pay the Medicaid agency the amount so demanded, up to the stated amount of the bond.

(2) The bond must provide that the Surety is liable for uncollected overpayments, as defined in paragraph (a), provided such uncollected overpayments are determined during the term of the bond and regardless of when the overpayments took place. Further, the bond must provide that the Surety remains liable if the HHA fails to furnish a subsequent annual bond that meets the requirements of this subpart or fails to furnish a rider for a year for which a rider is required to be submitted, or if the HHA’s provider agreement terminates and that the Surety’s liability shall be based on the last bond or rider in effect for the HHA, which shall then remain in effect for an additional 2-year period.

(3) The bond must provide that the Surety’s liability to the Medicaid agency is not extinguished by any of the following:

(i) Any action by the HHA or the Surety to terminate or limit the scope or term of the bond. The Surety’s liability may be extinguished, however, when—

(A) The Surety furnishes the Medicaid agency with notice of such action not later than 10 days after receiving notice from the HHA of action by the HHA to terminate or limit the scope of
the bond, or not later than 60 days before the effective date of such action by the Surety; or
(B) The HHA furnishes the Medicaid agency with a new bond that meets the requirements of both this section and the Medicaid agency.

(ii) The Surety’s failure to continue to meet the requirements of paragraph (f)(1) of this section or the Medicaid agency’s determination that the surety company is an unauthorized surety under paragraph (f)(2) of this section.

(iii) Termination of the HHA’s provider agreement described under §431.107 of this subchapter.

(iv) Any action by the Medicaid agency to suspend, offset, or otherwise recover payments to the HHA.

(v) Any action by the HHA to—
(A) Cease operation;
(B) Sell or transfer any assets or ownership interest;
(C) File for bankruptcy; or
(D) Fail to pay the Surety.

(vi) Any fraud, misrepresentation, or negligence by the HHA in obtaining the surety bond or by the Surety (or by the Surety’s agent, if any) in issuing the surety bond, except that any fraud, misrepresentation, or negligence by the HHA in identifying to the Surety (or to the Surety’s agent) the amount of Medicaid payments upon which the amount of the surety bond is determined shall not cause the Surety’s liability to the Medicaid agency to exceed the amount of the bond.

(vii) The HHA’s failure to exercise available appeal rights under Medicaid or to assign such rights to the Surety (provided the Medicaid agency permits such rights to be assigned).

(4) The bond must provide that actions under the bond may be brought by the Medicaid agency or by an agent that the Medicaid agency designates.

(i) Term and type of bond. (1) Initial term: Each participating HHA that is not exempted by paragraph (d) of this section must submit to the State Medicaid agency a surety bond for a term beginning January 1, 1998. If an annual bond is submitted for the initial term it must be effective for an annual period specified by the State Medicaid agency.

(2) Type of bond. The type of bond required to be submitted by an HHA, under this section, may be either—

(i) An annual bond (that is, a bond that specifies an effective annual period that corresponds to an annual period specified by the Medicaid agency); or

(ii) A continuous bond (that is, a bond that remains in full force and effect from term to term unless it is terminated or canceled as provided for in the bond or as otherwise provided by law) that is updated by the Surety for a particular period, via the issuance of a “rider,” when the bond amount changes. For the purposes of this section, “Rider” means a notice issued by a Surety that a change to a bond has occurred or will occur. If the HHA has submitted a continuous bond and there is no increase or decrease in the bond amount, no action is necessary by the HHA to submit a rider as long as the continuous bond remains in full force and effect.

(3) HHA that seeks to become a participating HHA.

(i) An HHA that seeks to become a participating HHA must submit a surety bond before a provider agreement described under §431.107 of this subchapter can be entered into.

(ii) An HHA that seeks to become a participating HHA through the purchase or transfer of assets or ownership interest of a participating or formerly participating HHA must also ensure that the surety bond is effective from the date of such purchase or transfer.

(4) Change of ownership. An HHA that undergoes a change of ownership (as “change of ownership” is defined by the State Medicaid agency) must submit the surety bond to the State Medicaid agency by such time and for such term as is specified in the instructions of the State Medicaid agency.

(5) Government-operated HHA that loses its waiver. A government-operated HHA that, as of January 1, 1998, meets the criteria for waiver of the requirements of this section but thereafter is determined by the Medicaid agency to not meet such criteria, must submit a surety bond to the Medicaid agency within 30 days after it receives notice from the Medicaid agency that it does not meet the criteria for waiver.
(6) Change of Surety. An HHA that obtains a replacement surety bond from a different Surety to cover the remaining term of a previously obtained bond must submit the new surety bond to the Medicaid agency within 60 days (or such earlier date as the Medicaid agency may specify) of obtaining the bond from the new Surety for a term specified by the Medicaid agency.

(j) Effect of failure to obtain, maintain, and timely file a surety bond.

(1) The Medicaid agency must terminate the HHA’s provider agreement if the HHA fails to obtain, file timely, and maintain a surety bond in accordance with this section and the Medicaid agency’s instructions.

(2) The Medicaid agency must refuse to enter into a provider agreement with an HHA if an HHA seeking to become a participating HHA fails to obtain and file timely a surety bond in accordance with this section and instructions issued by the State Medicaid agency.

(k) Evidence of compliance.

(1) The Medicaid agency may at any time require an HHA to make a specific showing of being in compliance with the requirements of this section and may require the HHA to submit such additional evidence as the Medicaid agency considers sufficient to demonstrate the HHA’s compliance.

(2) The Medicaid agency may terminate the HHA’s provider agreement or refuse to enter into a provider agreement if an HHA fails to timely furnish sufficient evidence at the Medicaid agency’s request to demonstrate compliance with the requirements of this section.

(l) Surety’s standing to appeal Medicaid determinations. The Medicaid agency must establish procedures for granting appeal rights to Sureties.

(m) Effect of conditions of payment. If a Surety has paid the Medicaid agency an amount on the basis of liability incurred under a bond obtained by an HHA under this section, and the Medicaid agency subsequently collects from the HHA, in whole or in part, on such overpayment that was the basis for the Surety’s liability, the Medicaid agency must reimburse the Surety such amount as the Medicaid agency collected from the HHA, up to the amount paid by the Surety to the Medicaid agency, provided the Surety has no other liability under the bond.

§ 441.17 Laboratory services.

(a) The plan must provide for payment of laboratory services as defined in §440.30 of this subchapter if provided by—

(1) An independent laboratory that meets the requirements for participation in the Medicare program found in §405.1316 of this chapter;

(2) A hospital-based laboratory that meets the requirements for participation in the Medicare program found in §482.27 of this chapter;

(3) A rural health clinic, as defined in §491.9 of this chapter; or

(4) A skilled nursing facility—based clinical laboratory, as defined in §405.1128(a) of this chapter.

(b) Except as provided under paragraph (c), if a laboratory or other entity is requesting payment under Medicaid for testing for the presence of the human immunodeficiency virus (HIV) antibody or for the isolation and identification of the HIV causative agent as described in §405.1316(f) (2) and (3) of this chapter, the laboratory records must contain the name and other identification of the person from whom the specimen was taken.

(c) An agency may choose to approve the use of alternative identifiers, in place of the requirement for patient’s name, in paragraph (b) of this section for HIV antibody or causative agent testing of Medicaid recipients.

§ 441.20 Family planning services.

For recipients eligible under the plan for family planning services, the plan must provide that each recipient is free from coercion or mental pressure and free to choose the method of family planning to be used.

§ 441.21 Nurse-midwife services.

If a State plan, under §440.210 or 440.220 of this subchapter, provides for nurse-midwife services, as defined in
§ 440.165, the plan must provide that the nurse-midwife may enter into an independent provider agreement, without regard to whether the nurse-midwife is under the supervision of, or associated with, a physician or other health care provider.

[47 FR 21051, May 17, 1982]

§ 441.22 Nurse practitioner services.

With respect to nurse practitioner services that meet the definition of § 440.166(a) and the requirements of either § 440.166(b) or § 440.166(c), the State plan must meet the following requirements:

(a) Provide that nurse practitioner services are furnished to the categorically needy.

(b) Specify whether those services are furnished to the medically needy.

(c) Provide that services furnished by a nurse practitioner, regardless of whether the nurse practitioner is under the supervision of, or associated with, a physician or other health care provider, may—

1. Be reimbursed by the State Medicaid agency through an independent provider agreement between the State and the nurse practitioner; or

2. Be paid through the employing provider.

[60 FR 19862, Apr. 21, 1995]

§ 441.25 Prohibition on FFP for certain prescribed drugs.

(a) FFP is not available in expenditures for the purchase or administration of 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 (see 21 CFR 310.6 for an explanation of this program), that there is a compelling justification of the drug product's medical need.

(b) FFP is not available in expenditures for the purchase or administration of 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 (a) of this section.


§ 441.30 Optometric services.

The plan must provide for payment of optometric services as physician services, whether furnished by an optometrist or a physician, if—

(a) The plan does not provide for payment for services provided by an optometrist, except for eligibility determinations under § 435.531 and 436.531 of this subchapter, but did provide for those services at an earlier period; and

(b) The plan specifically provides that physicians' services include services an optometrist is legally authorized to perform.

[56 FR 8851, Mar. 1, 1991]

§ 441.35 Organ transplants.

(a) FFP is available in expenditures for services furnished in connection with organ transplant procedures only if the State plan includes written standards for the coverage of those procedures, and those standards provide that—

1. Similarly situated individuals are treated alike; and

2. Any restriction on the practitioners or facilities that may provide organ transplant procedures is consistent with the accessibility of high quality care to individuals eligible for the procedures under the plan.

(b) Nothing in paragraph (a) permits a State to provide, under its plan, services that are not reasonable in amount, duration, and scope to achieve their purpose.

[56 FR 8851, Mar. 1, 1991]

§ 441.40 End-stage renal disease.

FFP in expenditures for services described in subpart A of part 440 is available for facility treatment of end-stage renal disease only if the facility has
§ 441.50 Basis and purpose.

This subpart implements sections 1902(a)(43) and 1905(a)(4)(B) of the Social Security Act, by prescribing State plan requirements for providing early and periodic screening and diagnosis of eligible Medicaid recipients under age 21 to ascertain physical and mental defects, and providing treatment to correct or ameliorate defects and chronic conditions found.

§ 441.55 State plan requirements.

A State plan must provide that the Medicaid agency meets the requirements of §§441.56-441.62, with respect to EPSDT services, as defined in §440.40(b) of this subchapter.

§ 441.56 Required activities.

(a) Informing. The agency must—

(1) Provide for a combination of written and oral methods designed to inform effectively all EPSDT eligible individuals (or their families) about the EPSDT program.

(2) Using clear and nontechnical language, provide information about the following—

(i) The benefits of preventive health care;

(ii) The services available under the EPSDT program and where and how to obtain those services;

(iii) That the services provided under the EPSDT program are without cost to eligible individuals under 18 years of age, and if the agency chooses, to those 18 or older, up to age 21, except for any enrollment fee, premium, or similar charge that may be imposed on medically needy recipients; and

(iv) That necessary transportation and scheduling assistance described in §441.62 of this subpart is available to the EPSDT eligible individual upon request.

(3) Effectively inform those individuals who are blind or deaf, or who cannot read or understand the English language.

(4) Provide assurance to HCFA that processes are in place to effectively inform individuals as required under this paragraph, generally, within 60 days of the individual's initial Medicaid eligibility determination and in the case of families which have not utilized EPSDT services, annually thereafter.

(b) Screening. (1) The agency must provide to eligible EPSDT recipients who request it, screening (periodic comprehensive child health assessments); that is, regularly scheduled examinations and evaluations of the general physical and mental health, growth, development, and nutritional status of infants, children, and youth. (See paragraph (c)(3) of this section for requirements relating to provision of immunization at the time of screening.) As a minimum, these screenings must include, but are not limited to:

(i) Comprehensive health and developmental history.

(ii) Comprehensive unclothed physical examination.

(iii) Appropriate vision testing.

(iv) Appropriate hearing testing.

(v) Appropriate laboratory tests.

(vi) Dental screening services furnished by direct referral to a dentist for children beginning at 3 years of age. An agency may request from HCFA an exception from this age requirement (within an outer limit of age 9) for a two year period and may request additional two year exceptions. If an agency requests an exception, it must demonstrate to HCFA's satisfaction that there is a shortage of dentists that prevents the agency from meeting the age 3 requirement.

(2) Screening services in paragraph (b)(1) of this section must be provided...
in accordance with reasonable standards of medical and dental practice determined by the agency after consultation with recognized medical and dental organizations involved in child health care.

(c) Diagnosis and treatment. In addition to any diagnostic and treatment services included in the plan, the agency must provide to eligible EPSDT recipients, the following services, the need for which is indicated by screening, even if the services are not included in the plan—
   (1) Diagnosis of and treatment for defects in vision and hearing, including eyeglasses and hearing aids;
   (2) Dental care, at as early an age as necessary, needed for relief of pain and infections, restoration of teeth and maintenance of dental health; and
   (3) Appropriate immunizations. (If it is determined at the time of screening that immunization is needed and appropriate to provide at the time of screening, then immunization treatment must be provided at that time.)

(d) Accountability. The agency must maintain as required by §§431.17 and 431.18—
   (1) Records and program manuals;
   (2) A description of its screening package under paragraph (b) of this section; and
   (3) Copies of rules and policies describing the methods used to assure that the informing requirement of paragraph (a)(1) of this section is met.

(e) Timeliness. With the exception of the informing requirements specified in paragraph (a) of this section, the agency must set standards for the timely provision of EPSDT services which meet reasonable standards of medical and dental practice, as determined by the agency after consultation with recognized medical and dental organizations involved in child health care, and must employ processes to ensure timely initiation of treatment, if required, generally within an outer limit of 6 months after the request for screening services.

[49 FR 43666, Oct. 31, 1984; 49 FR 45431, Nov. 16, 1984]

§ 441.57 Discretionary services.

Under the EPSDT program, the agency may provide for any other medical or remedial care specified in part 440 of this subchapter, even if the agency does not otherwise provide for these services to other recipients or provides for them in a lesser amount, duration, or scope.

§ 441.58 Periodicity schedule.

The agency must implement a periodicity schedule for screening services that—
   (a) Meets reasonable standards of medical and dental practice determined by the agency after consultation with recognized medical and dental organizations involved in child health care;
   (b) Specifies screening services applicable at each stage of the recipient’s life, beginning with a neonatal examination, up to the age at which an individual is no longer eligible for EPSDT services; and
   (c) At the agency’s option, provides for needed screening services as determined by the agency, in addition to the otherwise applicable screening services specified under paragraph (b) of this section.

§ 441.59 Treatment of requests for EPSDT screening services.

(a) The agency must provide the screening services described in §441.56(b) upon the request of an eligible recipient.

(b) To avoid duplicate screening services, the agency need not provide requested screening services to an EPSDT eligible if written verification exists that the most recent age-appropriate screening services, due under the agency’s periodicity schedule, have already been provided to the eligible.

§ 441.60 Continuing care.

(a) Continuing care provider. For purposes of this subpart, a continuing care provider means a provider who has an agreement with the Medicaid agency to provide reports as required under paragraph (b) of this section and to provide at least the following services to eligible EPSDT recipients formally enrolled with the provider:
   (1) With the exception of dental services required under §441.56, screening, diagnosis, treatment, and referral for
§ 441.61 Utilization of providers and
coordination with related programs.

(a) The agency must provide referral assistance for treatment not covered by the plan, but found to be needed as a result of conditions disclosed during screening and diagnosis. This referral assistance must include giving the family or recipient the names, addresses, and telephone numbers of providers who have expressed a willingness to furnish uncovered services at little or no expense to the family.

(b) The agency must make available a variety of individual and group providers qualified and willing to provide EPSDT services.

(c) The agency must make appropriate use of State health agencies, State vocational rehabilitation agencies, and Title V grantees (Maternal and Child Health/Crippled Children's Services). Further, the agency should make use of other public health, mental health, and education programs and related programs, such as Head Start, Title XX (Social Services) programs, and the Special Supplemental Food Program for Women, Infants and Children (WIC), to ensure an effective child health program.

§ 441.62 Transportation and scheduling assistance.

The agency must offer to the family or recipient, and provide if the recipient requests—

(a) Necessary assistance with transportation as required under §431.53 of this chapter; and

(b) Necessary assistance with scheduling appointments for services.
§ 441.100 Basis and purpose.

This subpart implements section 1905(a)(14) of the Act, which authorizes State plans to provide for inpatient hospital services, skilled nursing services, and intermediate care facility services for individuals age 65 or older in an institution for mental diseases, and sections 1902(a)(20)(B) and (C) and 1902(a)(21), which prescribe the conditions a State must meet to offer these services. (See §431.620 of this subchapter for regulations implementing section 1902(a)(20)(A), which prescribe interagency requirements related to these services.)

§ 441.101 State plan requirements.

A State plan that includes Medicaid for individuals age 65 or older in institutions for mental diseases must provide that the requirements of this subpart are met.

§ 441.102 Plan of care for institutionalized recipients.

(a) The Medicaid agency must provide for a recorded individual plan of treatment and care to ensure that institutional care maintains the recipient at, or restores him to, the greatest possible degree of health and independent functioning.

(b) The plan must include—

(1) An initial review of the recipient’s medical, psychiatric, and social needs—

(i) Within 90 days after approval of the State plan provision for services in institutions for mental disease; and

(ii) After that period, within 30 days after the date payments are initiated for services provided a recipient.

(2) Periodic review of the recipient’s medical, psychiatric, and social needs;

(3) A determination, at least quarterly, of the recipient’s need for continued institutional care and for alternative care arrangements;

(4) Appropriate medical treatment in the institution; and

(5) Appropriate social services.

§ 441.103 Alternate plans of care.

(a) The agency must develop alternate plans of care for each recipient age 65 or older who would otherwise need care in an institution for mental diseases.

(b) These alternate plans of care must—

(1) Make maximum use of available resources to meet the recipient’s medical, social, and financial needs; and

(2) In Guam, Puerto Rico, and the Virgin Islands, make available appropriate social services authorized under sections 3(a)(4) (i) and (ii) or 1603(a)(4)(A) (i) and (ii) of the Act.

§ 441.105 Methods of administration.

The agency must have methods of administration to ensure that its responsibilities under this subpart are met.

§ 441.106 Comprehensive mental health program.

(a) If the plan includes services in public institutions for mental diseases, the agency must show that the State is making satisfactory progress in developing and implementing a comprehensive mental health program.

(b) The program must—

(1) Cover all ages;

(2) Use mental health and public welfare resources; including—

(i) Community mental health centers;

(ii) Nursing homes; and

(iii) Other alternatives to public institutional care; and

(3) Include joint planning with State authorities.

(c) The agency must submit annual progress reports within 3 months after the end of each fiscal year in which Medicaid is provided under this subpart.

Subpart D—Inpatient Psychiatric Services for Individuals Under Age 21 in Psychiatric Facilities or Programs

§ 441.150 Basis and purpose.

This subpart specifies requirements applicable if a State provides inpatient psychiatric services to individuals...
§ 441.151 General requirements.

Inpatient psychiatric services for recipients under age 21 must be provided—
(a) Under the direction of a physician;
(b) By a psychiatric facility or an inpatient program in a psychiatric facility, either of which is accredited by the Joint Commission on Accreditation of Hospitals; and
(c) Before the recipient reaches age 21 or, if the recipient was receiving the services immediately before he reached age 21, before the earlier of the following—
(1) The date he no longer requires the services; or
(2) The date he reaches age 22.

§ 441.152 Certification of need for services.

(a) A team specified in §441.154 must certify that—
(1) Ambulatory care resources available in the community do not meet the treatment needs of the recipient;
(2) Proper treatment of the recipient’s psychiatric condition requires services on an inpatient basis under the direction of a physician; and
(3) The services can reasonably be expected to improve the recipient’s condition or prevent further regression so that the services will no longer be needed.

(b) The certification specified in this section and in §441.153 satisfies the utilization control requirement for physician certification in §§456.60, 456.160, and 456.360 of this subchapter.


§ 441.153 Team certifying need for services.

Certification under §441.152 must be made by terms specified as follows:
(a) For an individual who is a recipient when admitted to a facility or program, certification must be made by an independent team that—
(1) Includes a physician;
(2) Has competence in diagnosis and treatment of mental illness, preferably in child psychiatry; and
(3) Has knowledge of the individual’s situation.
(b) For an individual who applies for Medicaid while in the facility of program, the certification must be—
(1) Made by the team responsible for the plan of care as specified in §441.156; and
(2) Cover any period before application for which claims are made.
(c) For emergency admissions, the certification must be made by the team responsible for the plan of care (§441.156) within 14 days after admission.

§ 441.154 Active treatment.

Inpatient psychiatric services must involve “active treatment”, which means implementation of a professionally developed and supervised individual plan of care, described in §441.155 that is—
(a) Developed and implemented no later than 14 days after admission; and
(b) Designed to achieve the recipient’s discharge from inpatient status at the earliest possible time.

§ 441.155 Individual plan of care.

(a) “Individual plan of care” means a written plan developed for each recipient in accordance with §§456.180 and 456.181 of this chapter, to improve his condition to the extent that inpatient care is no longer necessary.
(b) The plan of care must—
(1) Be based on a diagnostic evaluation that includes examination of the medical, psychological, social, behavioral and developmental aspects of the recipient’s situation and reflects the need for inpatient psychiatric care;
(2) Be developed by a team of professionals specified under §441.156 in consultation with the recipient; and his parents, legal guardians, or others in whose care he will be released after discharge;
(3) State treatment objectives;
(4) Prescribe an integrated program of therapies, activities, and experiences designed to meet the objectives; and
(5) Include, at an appropriate time, post-discharge plans and coordination
of inpatient services with partial discharge plans and related community services to ensure continuity of care with the recipient’s family, school, and community upon discharge.

(c) The plan must be reviewed every 30 days by the team specified in §441.156 to—
   (1) Determine that services being provided are or were required on an inpatient basis, and
   (2) Recommend changes in the plan as indicated by the recipient’s overall adjustment as an inpatient.

(d) The development and review of the plan of care as specified in this section satisfies the utilization control requirements for—
   (1) Recertification under §§456.60(b), 456.160(b), and 456.360(b) of this subchapter; and
   (2) Establishment and periodic review of the plan of care under §§456.80, 456.180, and 456.380 of this subchapter.

§441.156 Team developing individual plan of care.

(a) The individual plan of care under §441.155 must be developed by an interdisciplinary team of physicians and other personnel who are employed by, or provide services to patients in, the facility.

(b) Based on education and experience, preferably including competence in child psychiatry, the team must be capable of—
   (1) Assessing the recipient’s immediate and long-range therapeutic needs, developmental priorities, and personal strengths and liabilities;
   (2) Assessing the potential resources of the recipient’s family;
   (3) Setting treatment objectives; and
   (4) Prescribing therapeutic modalities to achieve the plan’s objectives.

(c) The team must include, as a minimum, either—
   (1) A Board-eligible or Board-certified psychiatrist;
   (2) A clinical psychologist who has a doctoral degree and a physician licensed to practice medicine or osteopathy; or
   (3) A physician licensed to practice medicine or osteopathy with specialized training and experience in the diagnosis and treatment of mental diseases, and a psychologist who has a master’s degree in clinical psychology or who has been certified by the State or by the State psychological association.

(d) The team must also include one of the following:
   (1) A psychiatric social worker.
   (2) A registered nurse with specialized training or one year’s experience in treating mentally ill individuals.
   (3) An occupational therapist who is licensed, if required by the State, and who has specialized training or one year of experience in treating mentally ill individuals.
   (4) A psychologist who has a master’s degree in clinical psychology or who has been certified by the State or by the State psychological association.

§441.180 Maintenance of effort: General rule.

FFP is available only if the State maintains fiscal effort as prescribed under this subpart.

§441.181 Maintenance of effort: Explanation of terms and requirements.

(a) For purposes of §441.182:
   (1) The base year is the 4-quarter period ending December 31, 1971.
   (2) Quarterly per capita non-Federal expenditures are expenditures for inpatient psychiatric services determined by reimbursement principles under Medicare. (See part 405, subpart D.)
   (3) The number of individuals receiving inpatient psychiatric services in the current quarter means—
      (i) The number of individuals receiving services for the full quarter; plus
      (ii) The full quarter composite number of individuals receiving services for less than a full quarter.
   (4) In determining the per capita expenditures for the base year, the Medicaid agency must compute the number of individuals receiving services in a manner similar to that in paragraph (a)(3) of this section.
   (5) Non-Federal expenditures means the total amount of funds expended by the State and its political subdivisions, excluding Federal funds received directly or indirectly from any source.
§ 441.182 Maintenance of effort: Computation.

(a) For expenditures for inpatient psychiatric services for individuals under age 21 in any calendar quarter, FFP is available only to the extent that the total State Medicaid expenditures in the current quarter for inpatient psychiatric services and outpatient psychiatric treatment for individuals under age 21 exceed the sum of the following:

1. The total number of individuals receiving inpatient psychiatric services in the current quarter times the average quarterly per capita non-Federal expenditures for the base year; and
2. The average non-Federal quarterly expenditures for the base year for outpatient psychiatric services for individuals under age 21.

(b) FFP is available for 100 percent of the increase in expenditures over the base year period, but may not exceed the Federal medical assistance percentage times the expenditures under this subpart for inpatient psychiatric services for individuals under age 21.

§ 441.200 Basis and purpose.

This subpart implements section 402 of Pub. L. 97-12, and subsequent laws that appropriate funds for the Medicaid program, including section 204 of Pub. L. 98-619. All of these laws prohibit the use of Federal funds to pay for abortions except when continuation of the pregnancy would endanger the mother’s life.

§ 441.201 Definition.

As used in this subpart, “physician” means a doctor of medicine or osteopathy who is licensed to practice in the State.

§ 441.203 Life of the mother would be endangered.

FFP is available in expenditures for an abortion when a physician has found, and certified in writing to the Medicaid agency, that on the basis of his professional judgment, the life of the mother would be endangered if the fetus were carried to term. The certification must contain the name and address of the patient.

§ 441.206 Documentation needed by the Medicaid agency.

FFP is not available in any expenditures for abortions or other medical procedures otherwise provided for under § 441.203 if the Medicaid agency has paid without first having received the certifications and documentation specified in that section.
§ 441.207 Drugs and devices and termination of ectopic pregnancies.

FFP is available in expenditures for drugs or devices to prevent implantation of the fertilized ovum and for medical procedures necessary for the termination of an ectopic pregnancy.

§ 441.208 Recordkeeping requirements.

Medicaid agencies must maintain copies of the certifications and documentation specified in § 441.203 for 3 years under the recordkeeping requirements at 45 CFR 74.20.

[52 FR 47935, Dec. 17, 1987]

Subpart F—Sterilizations

SOURCE: 43 FR 52171, Nov. 8, 1978, unless otherwise noted.

§ 441.250 Applicability.

This subpart applies to sterilizations and hysterectomies reimbursed under Medicaid.

§ 441.251 Definitions.

As used in this subpart:

Hysterectomy means a medical procedure or operation for the purpose of removing the uterus.

Institutionalized individual means an individual who is (a) involuntarily confined or detained, under a civil or criminal statute, in a correctional or rehabilitative facility, including a mental hospital or other facility for the care and treatment of mental illness; or (b) confined, under a voluntary commitment, in a mental hospital or other facility for the care and treatment of mental illness.

Mentally incompetent individual means an individual who has been declared mentally incompetent by a Federal, State, or local court of competent jurisdiction for any purpose, unless the individual has been declared competent for purposes which include the ability to consent to sterilization.

Sterilization means any medical procedure, treatment, or operation for the purpose of rendering an individual permanently incapable of reproducing.

§ 441.252 State plan requirements.

A State plan must provide that the Medicaid agency will make payment under the plan for sterilization procedures and hysterectomies only if all the requirements of this subpart were met.

§ 441.253 Sterilization of a mentally competent individual aged 21 or older.

FFP is available in expenditures for the sterilization of an individual only if—

(a) The individual is at least 21 years old at the time consent is obtained;

(b) The individual is not a mentally incompetent individual;

(c) The individual has voluntarily given informed consent in accordance with all the requirements prescribed in §§ 441.257 and 441.258;

(d) At least 30 days, but not more than 180 days, have passed between the date of informed consent and the date of the sterilization, except in the case of premature delivery or emergency abdominal surgery. An individual may consent to be sterilized at the time of a premature delivery or emergency abdominal surgery, if at least 72 hours have passed since he or she gave informed consent for the sterilization. In the case of premature delivery, the informed consent must have been given at least 30 days before the expected date of delivery.

§ 441.254 Mentally incompetent or institutionalized individuals.

FFP is not available for the sterilization of a mentally incompetent or institutionalized individual.

§ 441.255 Sterilization by hysterectomy.

(a) FFP is not available in expenditures for a hysterectomy if—

(1) It was performed solely for the purpose of rendering an individual permanently incapable of reproducing; or

(2) If there was more than one purpose to the procedure, it would not have been performed but for the purpose of rendering the individual permanently incapable of reproducing.

(b) FFP is available in expenditures for a hysterectomy not covered by paragraph (a) of this section only under the conditions specified in paragraph (c), (d), or (e) of this section.

(c) FFP is available if—
(1) The person who secured authorization to perform the hysterectomy has informed the individual and her representative, if any, orally and in writing, that the hysterectomy will make the individual permanently incapable of reproducing; and

(2) The individual or her representative, if any, has signed a written acknowledgment of receipt of that information.

(d) Effective on March 8, 1979 or any date thereafter through the date of publication of these regulations at the option of the State, FFP is available if—

(1) The individual—
   (i) Was already sterile before the hysterectomy; or
   (ii) Requires a hysterectomy because of a life-threatening emergency situation in which the physician determines that prior acknowledgment is not possible; and

(2) The physician who performs the hysterectomy—
   (i) Certifies in writing that the individual was already sterile at the time of the hysterectomy, and states the cause of the sterility; or
   (ii) Certifies in writing that the hysterectomy was performed under a life-threatening emergency situation in which he or she determined prior acknowledgment was not possible. He or she must also include a description of the nature of the emergency.

(e) Effective March 8, 1979, or any date thereafter through the date of publication of these regulations at the option of the State, FFP is available for hysterectomies performed during a period of an individual’s retroactive Medicaid eligibility if the physician who performed the hysterectomy certifies in writing that—

(1) The individual was informed before the operation that the hysterectomy would make her permanently incapable of reproducing; or

(2) One of the conditions in paragraph (d)(1) of this section was met. The physician must supply the information specified in paragraph (d)(2) of this section.

[47 FR 33702, Aug. 4, 1982]

§ 441.256 Additional condition for Federal financial participation (FFP).

(a) FFP is not available in expenditures for any sterilization or hysterectomy unless the Medicaid agency, before making payment, obtained documentation showing that the requirements of this subpart were met. This documentation must include a consent from, an acknowledgment of receipt of hysterectomy information or a physician’s certification under §441.255(d)(2), as applicable.

(b) With regard to the requirements of §441.255(d) for hysterectomies performed from March 8, 1979 through November 2, 1992, FFP is available in expenditures for those services if the documentation showing that the requirements of that paragraph were met is obtained by the Medicaid agency before submitting a claim for FFP for that procedure.

[47 FR 33702, Aug. 4, 1982]

§ 441.257 Informed consent.

(a) Informing the individual. For purposes of this subpart, an individual has given informed consent only if—

(1) The person who obtained consent for the sterilization procedure offered to answer any questions the individual to be sterilized may have concerning the procedure, provided a copy of the consent form and provided orally all of the following information or advice to the individual to be sterilized:
   (i) Advice that the individual is free to withhold or withdraw consent to the procedure at any time before the sterilization without affecting the right to future care or treatment and without loss or withdrawal of any federally funded program benefits to which the individual might be otherwise entitled.
   (ii) A description of available alternative methods of family planning and birth control.
   (iii) Advice that the sterilization procedure is considered to be irreversible.
   (iv) A thorough explanation of the specific sterilization procedure to be performed.
   (v) A full description of the discomforts and risks that may accompany or follow the performing of the procedure, including an explanation of the type
and possible effects of any anesthetic to be used.

(vi) A full description of the benefits or advantages that may be expected as a result of the sterilization.

(vii) Advice that the sterilization will not be performed for at least 30 days, except under the circumstances specified in §441.253(c).

(2) Suitable arrangements were made to insure that the information specified in paragraph (a)(1) of this section was effectively communicated to any individual who is blind, deaf, or otherwise handicapped;

(3) An interpreter was provided if the individual to be sterilized did not understand the language used on the consent form or the language used by the person obtaining consent;

(4) The individual to be sterilized was permitted to have a witness of his or her choice present when consent was obtained;

(5) The consent form requirements of §441.258 were met; and

(6) Any additional requirement of State or local law for obtaining consent, except a requirement for spousal consent, was followed.

(b) When informed consent may not be obtained. Informed consent may not be obtained. Informed consent may not be obtained while the individual to be sterilized is—

(1) In labor or childbirth;
(2) Seeking to obtain or obtaining an abortion; or
(3) Under the influence of alcohol or other substances that affect the individual’s state of awareness.

§ 441.258 Consent form requirements.

(a) Content of consent form. The consent form must be a copy of the form appended to this subpart or another form approved by the Secretary.

(b) Required signatures. The consent form must be signed and dated by—

(1) The individual to be sterilized;
(2) The interpreter, if one was provided;
(3) The person who obtained the consent; and
(4) The physician who performed the sterilization procedure.

(c) Required certifications. (1) The person securing the consent must certify, by signing the consent form, that

(i) Before the individual to be sterilized signed the consent form, he or she advised the individual to be sterilized that no Federal benefits may be withdrawn because of the decision not to be sterilized;
(ii) He or she explained orally the requirements for informed consent as set forth on the consent form; and
(iii) To the best of his or her knowledge and belief, the individual to be sterilized appeared mentally competent and knowingly and voluntarily consented to be sterilized.

(2) The physician performing the sterilization must certify, by signing the consent form, that:

(i) Shortly before the performance of sterilization, he or she advised the individual to be sterilized that no Federal benefits may be withdrawn because of the decision not to be sterilized;
(ii) He or she explained orally the requirements for informed consent as set forth on the consent form; and
(iii) To the best of his or her knowledge and belief, the individual appeared mentally competent and knowingly and voluntarily consented to be sterilized.

Except in the case of premature delivery or emergency abdominal surgery, the physician must further certify that at least 30 days have passed between the date of the individual’s signature on the consent form and the date upon which the sterilization was performed.

(3) In the case of premature delivery or emergency abdominal surgery performed within 30 days of consent, the physician must certify that the sterilization was performed less than 30 days, but not less than 72 hours after informed consent was obtained because of premature delivery or emergency abdominal surgery and—

(i) In the case of premature delivery, must state the expected date of delivery;
(ii) In the case of abdominal surgery, must describe the emergency.

(4) If an interpreter is provided, the interpreter must certify that he or she translated the information and advice presented orally and read the consent form and explained its contents to the individual to be sterilized and that, to the best of the interpreter’s knowledge
§ 441.259  Review of regulations.

The Secretary will request public comment on the operation of this subpart not later than 3 years after its effective date.

APPENDIX TO SUBPART F—REQUIRED CONSENT FORM

CONSENT TO STERILIZATION

I have asked for and received information about sterilization from (doctor or clinic). When I first asked for the information, I was told that the decision to be sterilized is completely up to me. I was told that I could decide not to be sterilized. If I decide not to be sterilized, my decision will not affect my right to future care or treatment. I will not lose any help or benefits from programs receiving Federal funds, such as A.F.D.C. or Medicaid that I am now getting or for which I may become eligible.

I understand that the sterilization must be considered permanent and not reversible. I have decided that I do not want to become pregnant, bear children or father children.

I was told about those temporary methods of birth control that are available and could be provided to me which will allow me to bear or father a child in the future. I have rejected these alternatives and chosen to be sterilized.

I understand that I will be sterilized by an operation known as . The discomforts, risks and benefits associated with the operation have been explained to me. All my questions have been answered to my satisfaction.

I understand that the operation will not be done until at least 30 days after I sign this form. I understand that I can change my mind at any time and that my decision at any time not to be sterilized will not result in the withholding of any benefits or medical services provided by Federally funded programs.

I am at least 21 years of age and was born on (Day) (Month) (Year).

, hereby consent of my own free will to be sterilized by . My consent expires 180 days from the date of my signature below.

I also consent to the release of this form and other medical records about the operation to:

Representatives of the Department of Health and Human Services or Employees of programs or projects funded by that Department but only for determining if Federal laws were observed.

I have received a copy of this form. (Signature) (Date) (Month) (Day) (Year).

You are requested to supply the following information, but it is not required: (Race and ethnicity designation (please check)) Black (not of Hispanic origin); Hispanic; Asian or Pacific Islander; American Indian or Alaskan native; or White (not of Hispanic origin).

INTERPRETER'S STATEMENT

If an interpreter is provided to assist the individual to be sterilized:

I have translated the information and advice presented orally to the individual to be sterilized by the person obtaining this consent. I have also read him/her the consent form in language and explained its contents to him/her. To the best of my knowledge and belief he/she understood this explanation. (Interpreter) (Date).

STATEMENT OF PERSON OBTAINING CONSENT

Before (name of individual) signed the consent form, I explained to him/her the nature of the sterilization operation , the fact that it is intended to be a final and irreversible procedure and the discomforts, risks and benefits associated with it.

I counseled the individual to be sterilized that alternative methods of birth control are available which are temporary. I explained that sterilization is different because it is permanent.

I informed the individual to be sterilized that his/her consent can be withdrawn at any time and that he/she will not lose any health services or any benefits provided by Federal funds.

To the best of my knowledge and belief the individual to be sterilized is at least 21 years old and appears mentally competent. He/She knowingly and voluntarily requested to be sterilized and appears to understand the nature and consequence of the procedure. (Signature of person obtaining consent) (Date) (Facility) (Address).

PHYSICIAN'S STATEMENT

Shortly before I performed a sterilization operation upon (Name of individual to be sterilized) on (Date of sterilization) (operation), I explained to him/her the nature of the sterilization operation (specify type of operation), the fact that it is intended to be a final and irreversible procedure and the discomforts, risks and benefits associated with it.

I counseled the individual to be sterilized that alternative methods of birth control are available which are temporary. I explained
that sterilization is different because it is permanent.

I informed the individual to be sterilized that his/her consent can be withdrawn at any time and that he/she will not lose any health services or benefits provided by Federal funds.

To the best of my knowledge and belief the individual to be sterilized is at least 21 years old and appears mentally competent. He/She knowingly and voluntarily requested to be sterilized and appeared to understand the nature and consequences of the procedure.

(Instructions for use of alternative final paragraphs: Use the first paragraph below except in the case of premature delivery or emergency abdominal surgery where the sterilization is performed less than 30 days after the date of the individual’s signature on the consent form. In those cases, the second paragraph below must be used. Cross out the paragraph which is not used.)

(1) At least 30 days have passed between the date of the individual’s signature on this consent form and the date the sterilization was performed.

(2) This sterilization was performed less than 30 days but more than 72 hours after the date of the individual’s signature on this consent form because of the following circumstances (check applicable box and fill in information requested): Premature delivery.

Subpart G—Home and Community-Based Services: Waiver Requirements

SOURCE: 46 FR 48541, Oct. 1, 1981, unless otherwise noted.

§ 441.300 Basis and purpose.

Section 1915(c) of the Act permits States to offer, under a waiver of statutory requirements, an array of home and community-based services that an individual needs to avoid institutionalization. Those services are defined in § 440.180 of this subchapter. This subpart describes what the Medicaid agency must do to obtain a waiver.

§ 441.301 Contents of request for a waiver.

(a) A request for a waiver under this section must consist of the following:

(1) The assurances required by § 441.302 and the supporting documentation required by § 441.303.

(2) When applicable, requests for waivers of the requirements of section 1902(a)(1), section 1902(a)(10)(B), or section 1902(a)(10)(C)(i)(III) of the Act, which concern respectively, statewide application of Medicaid, comparability of services, and income and resource rules applicable to individuals with spouses living in the community.

(3) A statement explaining whether the agency will refuse to offer home or community-based services to any recipient if the agency can reasonably expect that the cost of the services would exceed the cost of an equivalent level of care provided in—

(i) A hospital (as defined in § 440.10 of this chapter);

(ii) A NF (as defined in section 1919(a) of the Act); or

(iii) An ICF/MR (as defined in § 440.150 of this chapter), if applicable.

(b) If the agency furnishes home and community-based services, as defined in § 440.180 of this subchapter, under a waiver granted under this subpart, the waiver request must—

(1) Provide that the services are furnished—

(i) Under a written plan of care subject to approval by the Medicaid agency;

(ii) Only to recipients who are not inpatients of a hospital, NF, or ICF/MR; and

(iii) Only to recipients who the agency determines would, in the absence of these services, require the Medicaid covered level of care provided in—

(A) A hospital (as defined in § 440.10 of this chapter);

(B) A NF (as defined in section 1919(a) of the Act); or

(C) An ICF/MR (as defined in § 440.150 of this chapter);

(2) Describe the qualifications of the individual or individuals who will be responsible for developing the individual plan of care;

(3) Describe the group or groups of individuals to whom the services will be offered;

(4) Describe the services to be furnished so that each service is separately defined. Multiple services that are generally considered to be separate services may not be consolidated under a single definition. Commonly accepted terms must be used to describe the

Emergency abdominal surgery: (describe circumstances):______________ (Physician) (Date).
§ 441.302

Service and definitions may not be open ended in scope. HCFA will, however, allow combined service definitions (bundling) when this will permit more efficient delivery of services and not compromise either a recipient's access to or free choice of providers.

(5) Provide that the documentation requirements regarding individual evaluation, specified in § 441.303(c), will be met; and

(6) Be limited to one of the following target groups or any subgroup thereof that the State may define:

(i) Aged or disabled, or both.

(ii) Mentally retarded or developmentally disabled, or both.

(iii) Mentally ill.


EFFECTIVE DATE NOTE: At 59 FR 37717, July 25, 1994, in §441.301, paragraph (a), (b) introductory text, (b)(1)(ii) and (b)(4) were revised, and (b)(1)(iii) was added. This amendment contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget. A notice will be published in the FEDERAL REGISTER once approval has been obtained.

§ 441.302 State assurances.

Unless the Medicaid agency provides the following satisfactory assurances to HCFA, HCFA will not grant a waiver under this subpart and may terminate a waiver already granted:

(a) Health and Welfare—Assurance that necessary safeguards have been taken to protect the health and welfare of the recipients of the services. Those safeguards must include—

(1) Adequate standards for all types of providers that provide services under the waiver;

(2) Assurance that the standards of any State licensure or certification requirements are met for services or for individuals furnishing services that are provided under the waiver; and

(3) Assurance that all facilities covered by section 1616(e) of the Act, in which home and community-based services will be provided, are in compliance with applicable State standards that meet the requirements of 45 CFR Part 1397 for board and care facilities.

(b) Financial accountability—The agency will assure financial accountability for funds expended for home and community-based services, provide for an independent audit of its waiver program (except as HCFA may otherwise specify for particular waivers), and it will maintain and make available to HHS, the Comptroller General, other designees, appropriate financial records documenting the cost of services provided under the waiver, including reports of any independent audits conducted.

(c) Evaluation of need. Assurance that the agency will provide for the following:

(1) Initial evaluation. An evaluation of the need for the level of care provided in a hospital, a NF, or an ICF/MR when there is a reasonable indication that a recipient might need the services in the near future (that is, a month or less) unless he or she receives home or community-based services. For purposes of this section, “evaluation” means a review of an individual recipient’s condition to determine—

(i) If the recipient requires the level of care provided in a hospital as defined in §440.40 of this subchapter, a NF as defined in section 1919(a) of the Act, or an ICF/MR as defined by §440.150 of this subchapter; and

(ii) That the recipient, but for the provision of waiver services, would otherwise be institutionalized in such a facility.

(2) Periodic reevaluations. Reevaluations, at least annually, of each recipient receiving home or community-based services to determine if the recipient continues to need the level of care provided and would, but for the provision of waiver services, otherwise be institutionalized in one of the following institutions:

(i) A hospital;

(ii) A NF; or

(iii) An ICF/MR.

(d) Alternatives—Assurance that when a recipient is determined to be likely to require the level of care provided in an SNF, ICF, or ICF/MR, the recipient or his or her legal representative will be—

(1) Informed of any feasible alternatives available under the waiver; and

(2) Given the choice of either institutional or home and community-based services.
(e) Average per capita expenditures. Assurance that the average per capita fiscal year expenditures under the waiver will not exceed 100 percent of the average per capita expenditures that would have been made in the fiscal year for the level of care provided in a hospital, NF, or ICF/MR under the State plan had the waiver not been granted.

(1) These expenditures must be reasonably estimated and documented by the agency.

(2) The estimate must be on an annual basis and must cover each year of the waiver period.

(f) Actual total expenditures. Assurance that the agency's actual total expenditures for home and community-based and other Medicaid services under the waiver and its claim for FFP in expenditures for the services provided to recipients under the waiver will not, in any year of the waiver period, exceed 100 percent of the amount that would be incurred by the State's Medicaid program for these individuals, absent the waiver, in—

(1) A hospital;
(2) A NF; or
(3) An ICF/MR.

(g) Institutionalization absent waiver. Assurance that, absent the waiver, recipients in the waiver would receive the appropriate type of Medicaid-funded institutional care (hospital, NF, or ICF/MR) that they require.

(h) Reporting. Assurance that annually, the agency will provide HCFA with information on the waiver's impact. The information must be consistent with a data collection plan designed by HCFA and must address the waiver's impact on—

(1) The type, amount, and cost of services provided under the State plan; and
(2) The health and welfare of recipients.

(i) Habilitation services. Assurance that prevocational, educational, or supported employment services, or a combination of these services, if provided as habilitation services under the waiver, are—

(1) Not otherwise available to the individual through a local educational agency under section 602 (16) and (17) of the Education of the Handicapped Act (20 U.S.C. 1401 (16 and 17)) or as services under section 110 of the Rehabilitation Act of 1973 (29 U.S.C. 730); and
(2) Furnished only to individuals who have been deinstitutionalized, regardless of discharge date from a Medicaid-certified NF or ICF/MR.

(3) Furnished as part of expanded habilitation services on or after April 7, 1986, if the State has requested and received HCFA's approval under a waiver or an amendment to a waiver.

(j) Day treatment or partial hospitalization, psychosocial rehabilitation services, and clinic services for individuals with chronic mental illness. Assurance that FFP will not be claimed in expenditures for waiver services including, but not limited to, day treatment or partial hospitalization, psychosocial habilitation services, and clinic services provided as home and community-based services to individuals with chronic mental illnesses if these individuals, in the absence of a waiver, would be placed in an IMD and are—

(1) Age 22 to 64;
(2) Age 65 and older and the State has not included the optional Medicaid benefits cited in §440.140; or
(3) Age 21 and under and the State has not included the optional Medicaid benefit cited in §440.160.


§ 441.303 Supporting documentation required.

The agency must furnish HCFA with sufficient information to support the assurances required by §441.302. Except as HCFA may otherwise specify for particular waivers, the information must consist of the following:

(a) A description of the safeguards necessary to protect the health and welfare of recipients. This information must include a copy of the standards established by the State for facilities
§ 441.303  

that are covered by section 1616(e) of the Act.

(b) A description of the records and information that will be maintained to support financial accountability.

(c) A description of the agency’s plan for the evaluation and reevaluation of recipients, including—

(1) A description of who will make these evaluations and how they will be made;

(2) A copy of the evaluation form to be used; and if it differs from the form used to placing recipients in hospitals, NFs, or ICFs/MR, a description of how and why it differs and an assurance that the outcome of the new evaluation form is reliable, valid, and fully comparable to the form used for hospital, NF, or ICF/MR placement;

(3) The agency’s procedure to ensure the maintenance of written documentation on all evaluations and reevaluations; and

(4) The agency’s procedure to ensure reevaluations of need at regular intervals.

(d) A description of the agency’s plan for informing eligible recipients of the feasible alternatives available under the waiver and allowing recipients to choose either institutional services or home and community-based services.

(e) An explanation of how the agency will apply the applicable provisions regarding the post-eligibility treatment of income and resources of those individuals receiving home and community-based services.

(f) An explanation with supporting documentation satisfactory to HCFA of how the agency estimated the average per capita expenditures for services.

(1) The annual average per capita expenditure estimate of the cost of home and community-based services under the waiver must not exceed the estimated annual average per capita expenditures of the cost of services in the absence of a waiver. The estimates are to be based on the following equation:

\[ D + D' \leq G + G' \]

The symbol “\( \leq \)” means that the result of the left side of the equation must be less than or equal to the result of the right side of the equation.

D = the estimated annual average per capita Medicaid cost for home and community-based services for individuals in the waiver program.

D’ = the estimated annual average per capita Medicaid cost for all other services provided to individuals in the waiver program.

G = the estimated annual average per capita Medicaid cost for hospital, NF, or ICF/MR care that would be incurred for individuals served in the waiver, were the waiver not granted.

G’ = the estimated annual average per capita Medicaid costs for all services other than those included in factor G for individuals served in the waiver, were the waiver not granted.

(2) For purposes of the equation, the prime factors include the average per capita cost for all State plan services and expanded EPSDT services provided that are not accounted for in other formula values.

(3) In making estimates of average per capita expenditures for a waiver that applies only to individuals with a particular illness (for example, acquired immune deficiency syndrome) or condition (for example, chronic mental illness) who are inpatients in or who would require the level of care provided in hospitals as defined by §440.10, NFs as defined in section 1919(a) of the Act, or ICFs/MR, the agency may determine the average per capita expenditures for these individuals absent the waiver without including expenditures for other individuals in the affected hospitals, NFs, or ICFs/MR.

(4) In making estimates of average per capita expenditures for a separate waiver program that applies only to individuals identified through the preadmission screening annual resident review (PASARR) process who are developmentally disabled, inpatients of a NF, and require the level of care provided in an ICF/MR as determined by the State on the basis of an evaluation under §441.303(c), the agency may determine the average per capita expenditures that would have been made in a fiscal year for those individuals based on the average per capita expenditures for inpatients in an ICF/MR. When submitting estimates of institutional costs without the waiver, the agency may use the average per capita costs of
ICF/MR care even though the deinstitutionalized developmentally disabled were inpatients of NFs.

(5) For persons diverted rather than deinstitutionalized, the State’s evaluation process required by §441.303(c) must provide for a more detailed description of their evaluation and screening procedures for recipients to ensure that waiver services will be limited to persons who would otherwise receive the level of care provided in a hospital, NF, or ICF/MR, as applicable.

(6) The State must indicate the number of unduplicated beneficiaries to which it intends to provide waiver services in each year of its program. This number will constitute a limit on the size of the waiver program unless the State requests and the Secretary approves a greater number of waiver participants in a waiver amendment.

(7) In determining the average per capita expenditures that would have been made in a waiver year, for waiver estimates that apply to persons with mental retardation or related conditions, the agency may include costs of Medicaid residents in ICFs/MR that have been terminated on or after November 5, 1990.

(8) In submitting estimates for waivers that include personal caregivers as a waiver service, the agency may include a portion of the rent and food attributed to the unrelated personal caregiver who resides in the home or residence of the recipient covered under the waiver. The agency must submit to HCFA for review and approval the method it uses to apportion the costs of rent and food. The method must be explained fully to HCFA. A personal caregiver provides a waiver service to meet the recipient’s physical, social, or emotional needs (as opposed to services not directly related to the care of the recipient; that is, housekeeping or chore services). FFP for live-in caregivers is not available if the recipient lives in the caregiver’s home or in a residence that is owned or leased by the caregiver.

(9) In submitting estimates for waivers that apply to individuals with mental retardation or a related condition, the agency may adjust its estimate of average per capita expenditures to include increases in expenditures for ICF/MR care resulting from implementation of a PASARR program for making determinations for individuals with mental retardation or related conditions on or after January 1, 1989.

(10) For a State that has HCFA approval to bundle waiver services, the State must continue to compute separately the costs and utilization of the component services that make up the bundled service to support the final cost and utilization of the bundled service that will be used in the cost-neutrality formula.

(g) The State, at its option, may provide for an independent assessment of its waiver that evaluates the quality of care provided, access to care, and cost-neutrality. The results of the assessment should be submitted to HCFA at least 90 days prior to the expiration date of the approved waiver-period and cover the first 24 or 48 months of the waiver. If a State chooses to provide for an independent assessment, FFP is available for the costs attributable to the independent assessment.

(h) For States offering habilitation services that include prevocational, educational, or supported employment services, or a combination of these services, consistent with the provisions of §440.180(c) of this chapter, an explanation of why these services are not available as special education and related services under sections 602 (16) and (17) of the Education of the Handicapped Act (20 U.S.C. 1411 (16 and 17)) or as services under section 110 of the Rehabilitation Act of 1973 (29 U.S.C. section 730);

(i) For States offering home and community-based services for individuals diagnosed as chronically mentally ill, an explanation of why these individuals would not be placed in an institution for mental diseases (IMD) absent the waiver, and the age group of these individuals.

§441.304 Duration of a waiver.

(a) The effective date for a new waiver of Medicaid requirements to provide home and community-based services approved under this subpart is established by HCFA prospectively on or
§ 441.305 Replacement of recipients in approved waiver programs.

(a) Regular waivers. A State's estimate of the number of individuals who may receive home and community-based services must include those who will replace recipients who leave the program for any reason. A State may replace recipients who leave the program for any reason. A State may replace recipients who leave the program due to death or loss of eligibility under the State plan without regard to any federally-imposed limit on utilization, but must maintain a record of recipients replaced on this basis.

(b) Model waivers. (1) The number of individuals who may receive home and community-based services under a model waiver may not exceed 200 recipients at any one time.

(2) The agency may replace any individuals who die or become ineligible for State plan services to maintain a count up to the number specified by the State and approved by HCFA within the 200-maximum limit.

§ 441.306 Cooperative arrangements with the Maternal and Child Health program.

Whenever appropriate, the State agency administering the plan under Medicaid may enter into cooperative arrangements with the State agency responsible for administering a program for children with special health care needs under the Maternal and Child Health program (Title V of the...
§ 441.307 Notification of a waiver termination.

(a) If a State chooses to terminate its waiver before the three-year period is up, it must notify HCFA in writing 30 days before terminating services to recipients.

(b) If HCFA or the State terminates the waiver, the State must notify recipients of services under the waiver in accordance with §431.210 of this subchapter and notify them 30 days before terminating services.

§ 441.308 Hearings procedures for waiver terminations.

The procedures specified in subpart D of part 430 of this chapter are applicable to State requests for hearings on terminations.

§ 441.310 Limits on Federal financial participation (FFP).

(a) FFP for home and community-based services listed in §440.180 of this chapter is not available in expenditures for the following:

1. Services provided in a facility subject to the health and welfare requirements described in §441.302(a) during any period in which the facility is found not to be in compliance with the applicable State standards described in that section.

2. The cost of room and board except when provided as—

(i) Part of respite care services in a facility approved by the State that is not a private residence; or

(ii) For waivers that allow personal caregivers as providers of approved waiver services, a portion of the rent and food that may be reasonably attributed to the unrelated caregiver who resides in the same household with the waiver recipient. FFP for a live-in caregiver is not available if the recipient lives in the caregiver’s home or in a residence that is owned or leased by the provider of Medicaid services (the caregiver). For purposes of this provision, “board” means 3 meals a day or any other full nutritional regimen and does not include meals provided as part of a program of adult day health services as long as the meals provided do not constitute a “full” nutritional regimen.

3. Prevocational, educational, or supported employment services, or any combination of these services, as part of habilitation services that are—

(i) Provided prior to April 7, 1986;

(ii) Provided in approved waivers that include a definition of “habilitation services” but which have not included prevocational, educational and supported employment services in that definition;

(iii) Provided to recipients who were never institutionalized in a Medicaid certified NF, or ICF/MR; or

(iv) Otherwise available to the recipient under either special education and related services as defined in section 602(16) and (17) of the Education of the Handicapped Act (20 U.S.C. 1401 (16) and (17)) or vocational rehabilitation services available to the individual through a program funded under section 110 of the Rehabilitation Act of 1973 (29 U.S.C. 730).

(b) FFP is available for expenditures for expanded habilitation services, as described in §440.180, if the services are included under a waiver or waiver amendment approved by HCFA on or after October 21, 1986.

[59 FR 37720, July 25, 1994]
§ 441.350 Basis and purpose.

Section 1915(d) of the Act permits States to offer, under a waiver of statutory requirements, home and community-based services not otherwise available under Medicaid to individuals age 65 or older, in exchange for accepting an aggregate limit on the amount of expenditures for which they claim FFP for certain services furnished to these individuals. The home and community-based services that may be furnished are listed in §440.181 of this subchapter. This subpart describes the procedures the Medicaid agency must follow to request a waiver.

§ 441.351 Contents of a request for a waiver.

A request for a waiver under this section must meet the following requirements:

(a) Required signatures. The request must be signed by the Governor, the Director of the Medicaid agency or the Director of the larger State agency of which the Medicaid agency is a component or any official of the Medicaid agency to whom this authority has been delegated. A request from any other agency of State government will not be accepted.

(b) Assurances and supporting documentation. The request must provide the assurances required by §441.352 of this part and the supporting documentation required by §441.353.

(c) Statement for sections of the Act. The request must provide a statement as to whether waiver of section 1902(a)(1), 1902(a)(10)(B), or 1902(a)(10)(C)(i)(I) of the Act is requested. If the State requests a waiver of section 1902(a)(1) of the Act, the waiver must clearly specify the geographic areas or political subdivisions in which the services will be offered. The State must indicate whether it is requesting a waiver of one or all of these sections. The State may request a waiver of any one of the sections cited above.

(d) Identification of services. The request must identify all services available under the approved State plan, which are also included in the APEL and which are identified under §440.181, and any limitations that the State has imposed on the provision of any service. The request must also identify and describe each service specified in §440.181 of this subchapter to be furnished under the waiver, and any additional services to be furnished under the authority of §440.181(b)(7). Descriptions of additional services must explain how each additional service included under §440.181(b)(7) will contribute to the health and well-being of the recipients and to their ability to reside in a community-based setting.

(e) Recipients served. The request must provide that the home and community-based services described in §440.181 of this subchapter, are furnished only to individuals who—

1. Are age 65 or older;
2. Are not inpatients of a hospital, NF, or ICF/MR; and
3. The agency determines would be likely to require the care furnished in a NF under Medicaid.

(f) Plan of care. The request must provide that the home and community-based services described in §440.181 of this subchapter, are furnished under a written plan of care based on an assessment of the individual’s health and welfare needs and developed by qualified individuals for each recipient under the waiver. The qualifications of the individual or individuals who will be responsible for developing the individual plan of care must be described. Each plan of care must contain, at a minimum, the medical and other services to be provided, their frequency, and the type of provider to furnish them. Plans of care must be subject to the approval of the Medicaid agency.

(g) Medicaid agency review. The request must assure that the State agency maintain and exercise its authority to review (at a minimum) a valid statistical sample of each month’s plans of care. When the services in a plan do not comport with the stated disabilities and needs of the recipient, the agency must implement immediate
§ 441.352 State assurances.

Unless the Medicaid agency provides the following satisfactory assurances to HCFA, HCFA will not grant a waiver under this subpart and may terminate a waiver already granted.

(a) Health and welfare. The agency must assure that necessary safeguards have been taken to protect the health and welfare of the recipients of services by assuring that the following conditions are met:

(1) Adequate standards for all types of providers that furnish services under the waiver are met. (These standards must be reasonably related to the requirements of the waiver service to be furnished.)

(2) The standards of any State licensure or certification requirements are met for services or for individuals furnishing services under the waiver.

(3) All facilities covered by section 1619(e) of the Act, in which home and community-based services are furnished, are in compliance with applicable State standards that meet the requirements of 45 CFR part 1397 for board and care facilities.

(4) Physician reviews of prescribed psychotropic drugs (when prescribed for purposes of behavior control of waiver recipients) occur at least every 30 days.

(b) Financial accountability. The agency must assure financial accountability for funds expended for home and community-based services. The State must provide for an independent audit of its waiver program. The performance of a single financial audit, in accordance with the Single Audit Act of 1984 (Pub. L. 98-502, enacted on October 19, 1984), is deemed to satisfy the requirement for an independent audit. The agency must maintain and make available to HHS, the Comptroller General, or other designees, appropriate financial records documenting the cost of services furnished to individuals age 65 or older under the waiver and the State plan, including reports of any independent audits conducted.

(c) Evaluation of need. The agency must provide for an initial evaluation (and periodic reevaluations) of the need for the level of care furnished in a NF when there is a reasonable indication that individuals age 65 or older might need those services in the near future, but for the availability of home and community-based services. The procedures used to assess level of care for a potential waiver recipient must be at least as stringent as any existing State procedures applicable to individuals entering a NF. The qualifications of individuals performing the waiver assessment must be as high as those of individuals assessing the need for NF care, and the assessment instrument itself must be the same as any assessment instrument used to establish level of care of prospective inpatients in NFs. A periodic reevaluation of the level of care must be performed. The period of reevaluation of level of care cannot extend beyond 1 year.

(d) Expenditures. The agency must assure that the total amount expended by the State for medical assistance with respect to NF, home health, private duty nursing, personal care, and home and community-based services described in §§440.180 and 440.181 of this subchapter and furnished as an alternative to NF care will not exceed the aggregate projected expenditure limit (APEL) defined in §441.354.

(e) Reporting. The agency must assure that it will provide HCFA annually
§ 441.353 Supporting documentation required.

The agency must furnish HCFA with sufficient information to support the assurances required under §441.352, in order to meet the requirement that the assurances are satisfactory. At a minimum, this information must consist of the following:

(a) Safeguards. A description of the safeguards necessary to protect the health and welfare of recipients.

(b) Records. A description of the records and information that are maintained by the agency and by providers of services to support financial accountability, information regarding how the State assures that there is an audit trail for State and Federal funds expended for section 1915(d) home and community-based waiver services. If the State has an approved Medicaid Management Information System (MMIS), this system must be used to process individual claims data and account for funds expended for services furnished under the waiver.

(c) Evaluation and reevaluation of recipients. A description of the agency's plan for the evaluation and reevaluation of recipients' level of care, including the following:

(1) A description of who makes these evaluations and how they are made.

(2) A copy of the evaluation instrument.

(3) The agency's procedure to assure the maintenance of written documentation on all evaluations and reevaluations and copies of the forms. In accordance with regulations at 45 CFR part 74, written documentation of all evaluations and reevaluations must be maintained for a minimum period of 3 years.

(4) The agency's procedure to assure reevaluations of need at regular intervals.

(5) The intervals at which reevaluations occur, which may be no less frequent than for institutionalized individuals at comparable levels of care.

(6) The procedures and criteria used for evaluation and reevaluation of waiver recipients must be the same or more stringent than those used for individuals served in NFs.

(d) Alternatives available. A description of the agency's plan for informing eligible recipients of the feasible alternatives available under the waiver and allowing recipients to choose either institutional or home and community-based services must be submitted to HCFA. A copy of the forms or documentation used by the agency to verify that this choice has been offered and that recipients of waiver services, or their legal representatives, have been given the free choice of the providers of both waiver and State plan services must also be available for HCFA review. The Medicaid agency must provide an opportunity for a fair hearing, under 42 CFR part 431, subpart E, to recipients who are not given the choice of home or community-based services as an alternative to institutional care in a NF or who are denied the service(s) or the providers of their choice.

(e) Post-eligibility of income. An explanation of how the agency applies the applicable provisions regarding the post-eligibility treatment of income and resources of those individuals receiving home and community-based services who are eligible under a special income level (included in §435.217 of this subchapter).
§ 441.354 Aggregate projected expenditure limit (APEL).

(a) Definitions. For purposes of this section, the term base year means—

(1) Federal fiscal year (FFY) 1987 (that is, October 1, 1986 through September 30, 1987); or

(2) In the case of a State which did not report expenditures on the basis of age categories during FFY 1987, the base year means FFY 1989 (that is, October 1, 1988 through September 30, 1989).

(b) General. (1) The total amount expended by the State for medical assistance with respect to NF, home and community-based services under the waiver, home health services, personal care services, private duty nursing services, and services furnished under a waiver under subpart G of this part to individuals age 65 or older furnished as an alternative to care in an SNF or ICF (NF effective October 1, 1990), may not exceed the APEL calculated in accordance with paragraph (c) of this section.

(2) In applying for a waiver under this subpart, the agency must clearly identify the base year it intends to use.

(3) The State may make a preliminary calculation of the expenditure limit at the time of the waiver approval; however, HCFA makes final calculations of the aggregate limit after base data have been verified and accepted.

(4) All base year and waiver year data are subject to final cost settlement within 2 years from the end of the base or waiver year involved.

(c) Formula for calculating APEL. Except as provided in paragraph (d) of this section, the formula for calculating the APEL follows:

\[ \text{APEL} = P \times (1+Y) + V \times (1+Z), \]

where

- \( P \) = The aggregate amount of the State’s medical assistance under title XIX for NF and ICF (NF effective October 1, 1990) services furnished to individuals who have reached age 65, defined as the total medical assistance payments and HI and SMI in that State reported on form HCFA 64 (as adjusted)
- \( V \) = The aggregate amount of the State’s medical assistance payments (Federal and State) reported on line 6 of form HCFA 2082, for the base year.
- \( Y \) = The greater of:
  - \((U \times 0.07)\), or \((Q/R) \times 1+(S/T) \times 1+(U \times 0.02)\)
  - \((U \times 0.07)\), or \((W/X) \times 1+(S/T) \times 1+(U \times 0.02)\)

(d) Amendment of the APEL. The State may request amendment of its APEL to reflect an increase in the aggregate amount of medical assistance for NF services and for services included in
the calculation of the APEL as required by paragraph (c) of this section when the increase is directly attributable to legislation enacted on or after December 22, 1987, which amends title XIX of the Act. Costs attributable to laws enacted before December 22, 1987 will not be considered. Because the APEL for each year of the waiver is computed separately from the APEL for any other waiver year, a separate amendment must be submitted for each year in which the State chooses to raise its APEL. Documentation specific to the waiver year involved must be submitted to HCFA.

§ 441.355 Duration, extension, and amendment of a waiver.

(a) Effective dates and extension periods. (1) The effective date for a waiver of Medicaid requirements to furnish home and community-based services to individuals age 65 or older under this subpart is established by HCFA prospectively on the first day of the FFY following the date on which the waiver is approved.

(2) The initial waiver is approved for a 3-year period from the effective date. Subsequent renewals are approved for 5-year periods.

(3) If the agency requests it, the waiver may be extended for an additional 5-year period if HCFA prospectively on the first day of the FFY following the date on which the waiver is approved.

(4) The agency may request that waiver modifications be made effective retroactive to the first day of the waiver year in which the amendment is submitted, unless the amendment involves substantive change. Substantive changes may include, but are not limited to, addition of services under the waiver, a change in the qualifications of service providers, or a change in the eligible population.

(5) A request for an amendment that involves a substantive change is given a prospective effective date, but this date need not coincide with the start of the next FFY.

(b) Extension or new waiver request. HCFA determines whether a request for extension of an existing waiver is actually an extension request, or a request for a new waiver. Generally, if a State's extension request proposes a substantive change in services furnished, eligible population, service area, statutory sections waived, or qualifications of service providers, HCFA considers it a new waiver request.

(c) Reconsideration of denial. A determination of HCFA to deny a request for a waiver (or for extension of a waiver) under this subpart may be reconsidered in accordance with §441.357.

(d) Existing waiver effectiveness after denial. If HCFA denies a request for an extension of an existing waiver under this subpart:

(1) The existing waiver remains in effect for a period of not less than 90 days after the date on which HCFA denies the request, or, if the State seeks reconsideration in accordance with §441.357, the date on which a final determination is made with respect to that review.

(2) HCFA calculates an APEL for the period for which the waiver remains in effect, and this calculation is used to pro-rate the limit according to the number of days to which it applies.

§ 441.356 Waiver termination.

(a) Termination by the State. If a State chooses to terminate its waiver before an approved program is due to expire, the following conditions apply:

(1) The State must notify HCFA in writing at least 30 days before terminating services to recipients.

(2) The State must notify recipients of services under the waiver at least 30 days before terminating services in accordance with §431.210 of this chapter.

(3) HCFA continues to apply the APEL described in §441.354 through the end of the waiver year, but this limit is not applied in subsequent years.

(4) The State may not decrease the services available under the approved State plan to individuals age 65 or older by an amount that violates the comparability of service requirements set forth in §440.240 of this chapter.

(b) Termination by HCFA. (1) If HCFA finds, during an approved waiver period, that an agency is not meeting one or more of the requirements for a waiver contained in this subpart, HCFA notifies the agency in writing of its findings and grants an opportunity for a hearing in accordance with §441.357. If
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§ 441.365 Periodic evaluation, assessment, and review.

(a) Purpose. This section prescribes requirements for periodic evaluation, assessment, and review of the care and services furnished to individuals receiving home and community-based waiver services under this subpart.

(b) Evaluation and assessment review team. (1) A review team, as described in paragraphs (b)(2) and (c) of this section, must periodically evaluate and assess the care and services furnished to recipients under this subpart. The review team must be created by the State agency directly, or (through interagency agreement) by other departments of State government (such as the Department of Health or the Agency on Aging).

(2) Each review team must consist of at least one physician or registered nurse, and at least one other individual with health and social service credentials who the State believes is qualified to properly evaluate and assess the care and services provided under the waiver. If there is no physician on the review team, the Medicaid agency must ensure that a physician is available to provide consultation to the review team.

(3) For waiver services furnished to individuals who have been found to be likely to require the level of care furnished in a NF that is also an IMD, each review team must have a psychiatrist or physician and other appropriate mental health or social service personnel who are knowledgeable about geriatric mental illness.

(c) Financial interests and employment of review team members. (1) No member of a review team may have a financial

(d) Services that are not included in the approved State plan and not approved as waiver services by HCFA.

(e) Services furnished to recipients who are ineligible under the terms of the approved waiver.

(f) Services furnished by a provider when either the services or the provider do not meet the standards that are set by the State and included in the approved waiver.

(g) Services furnished to a recipient by his or her spouse.

§ 441.360 Limits on Federal financial participation (FFP).

FFP for home and community-based services listed in § 440.181 of this subchapter is not available for expenditures for the following:

(a) Services furnished in a facility subject to the health and welfare requirements described in § 441.352(a) during any period in which the facility is found not to be in compliance with the applicable State requirements described in that section.

(b) The cost of room and board except when furnished as part of respite care services in a facility, approved by the State, that is not a private residence. For purposes of this subpart, “board” means three meals a day or any other full nutritional regimen. “Board” does not include meals, which do not comprise a full nutritional regimen, furnished as part of adult day health services.

(c) The portion of the cost of room and board attributed to unrelated, live-in personal caregivers when the waiver recipient lives in the caregiver’s home or a residence owned or leased by the provider of the Medicaid services (the caregiver).

(d) Services that are not included in the approved State plan and not approved as waiver services by HCFA.

(e) Services furnished to recipients who are ineligible under the terms of the approved waiver.

(f) Services furnished by a provider when either the services or the provider do not meet the standards that are set by the State and included in the approved waiver.

(g) Services furnished to a recipient by his or her spouse.

§ 441.357 Hearing procedures for waiver denials.

The procedures specified in § 430.18 of this subchapter apply to State requests for hearings on denials, renewals, or amendments of waivers for home and community-based services for individuals age 65 or older.
§ 441.365 42 CFR Ch. IV (10-1-98 Edition)

interest in or be employed by any entity that furnishes care and services under the waiver to a recipient whose care is under review.

(2) No physician member of a review team may evaluate or assess the care of a recipient for whom he or she is the attending physician.

(3) No individual who serves as case manager, caseworker, benefit authorizer, or any similar position, may serve as member of a review team that evaluates and assesses care furnished to a recipient with whom he or she has had a professional relationship.

(d) Number and location of review teams. A sufficient number of teams must be located within the State so that onsite inspections can be made at appropriate intervals at sites where waiver recipients receive care and services.

(e) Frequency of periodic evaluations and assessments. Periodic evaluations and assessments must be conducted at least annually for each recipient under the waiver. The review team and the agency have the option to determine the frequency of further periodic evaluations and assessments, based on the quality of services and access to care being furnished under the waiver and the condition of patients receiving care and services.

(f) Notification before inspection. No provider of care and services under the waiver may be notified in advance of a periodic evaluation, assessment, and review. However, when a recipient receives services in his own home or the home of a relative, notification must be provided to the residents of the household at least 48 hours in advance. The recipient must have an opportunity to decline access to the home. If the recipient declines access to his or her own home, or the home of a relative, the review is limited solely to the review of the provider’s records. If the recipient is incompetent, the head of the household has the authority to decline access to the home.

(g) Personal contact with and observation of recipients and review of records.

(1) For recipients of care and services under a waiver, the review team’s evaluation and assessment must include—

(i) A review of each recipient’s medical record, the evaluation and reevaluation required by §441.353(c), and the plan of care under which the waiver and other services are furnished; and

(ii) If the records described in paragraph (g)(1)(i) of this section are inadequate or incomplete, personal contact and observation of each recipient.

(2) The review team may personally contact and observe any recipient whose care the team evaluates and assesses.

(3) The review team may consult with both formal and informal caregivers when the recipient’s records are inadequate or incomplete and when any apparent discrepancy exists between services required by the recipient and services furnished under the waiver.

(h) Determinations by the review team. The review team must determine in its evaluation and assessment whether—

(1) The services included in the plan of care are adequate to meet the health and welfare needs of each recipient;

(2) The services included in the plan of care have been furnished to the recipient as planned;

(3) It is necessary and in the interest of the recipient to continue receiving services through the waiver program; and

(4) It is feasible to meet the recipient’s health and welfare needs through the waiver program.

(i) Other information considered by review team. When making determinations, under paragraph (h) of this section, for each recipient, the review team must consider the following information and may consider other information as it deems necessary:

(1) Whether the medical record, the determination of level of care, and the plan of care are consistent, and whether all ordered services have been furnished and properly recorded;

(2) Whether physician review of prescribed psychotropic medications (when required for behavior control) has occurred at least every 30 days.

(3) Whether tests or observations of each recipient indicated by his or her medical record are made at appropriate times and properly recorded.

(4) Whether progress notes entered in the record by formal and informal
§ 441.404

Subpart I—Community Supported Living Arrangements Services

SOURCE: 56 FR 48114, Sept. 24, 1991, unless otherwise noted.

§ 441.400 Basis and purpose.

This subpart implements section 1905(a)(24) of the Act, which adds community supported living arrangements services to the list of services that States may provide as medical assistance under title XIX (to the extent and as defined in section 1930 of the Act), and section 1930(h)(1)(B) of the Act, which specifies minimum protection requirements that a State which provides community supported living arrangements services as an optional Medicaid service to developmentally disabled individuals must meet to ensure the health, safety and welfare of those individuals.

§ 441.402 State plan requirements.

If a State that is eligible to provide community supported living arrangements services as an optional Medicaid service to developmentally disabled individuals provides such services, the State plan must specify that it complies with the minimum protection requirements in §441.404.

§ 441.404 Minimum protection requirements.

To be eligible to provide community supported living arrangements services to developmentally disabled individuals, a State must assure, through methods other than reliance on State licensure processes or the State quality assurance programs described under section 1930(d) of the Act, that:

(a) Individuals receiving community supported living arrangements services are protected from neglect, physical and sexual abuse, and financial exploitation;

(b) Providers of community supported living arrangements services—

(1) Do not use individuals who have been convicted of child or client abuse, neglect, or mistreatment, or of a felony involving physical harm to an individual; and
(2) Take all reasonable steps to determine whether applicants for employment by the provider have histories indicating involvement in child or client abuse, neglect, or mistreatment, or a criminal record involving physical harm to an individual; and

c) Providers of community supported living arrangements services are not unjustly enriched as a result of abusive financial arrangements (such as owner lease-backs) with developmentally disabled clients; and

d) Providers of community supported living arrangements services, or the relatives of such providers, are not named beneficiaries of life insurance policies purchased by or on behalf of developmentally disabled clients.

PART 442—STANDARDS FOR PAYMENT TO NURSING FACILITIES AND INTERMEDIATE CARE FACILITIES FOR THE MENTALLY RETARDED

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Subparts D-F—[Reserved]

AUTHORITY: Sec. 1102 of the Social Security Act (42 U.S.C. 1302), unless otherwise noted.

SOURCE: 43 FR 45233, Sept. 29, 1978, unless otherwise noted.

Subpart A—General Provisions

§ 442.1 Basis and purpose.

(a) This part states requirements for provider agreements for facility certification relating to the provision of services furnished by nursing facilities and intermediate care facilities for the mentally retarded. This part is based on the following sections of the Act:

Section 1902(a)(4), administrative methods for proper and efficient operation of the State plan;

Section 1902(a)(27), provider agreements;

Section 1902(a)(28), nursing facility standards;

Section 1902(a)(33)(B), State survey agency functions; Section 1902(i), circumstances and procedures for denial of payment and termination of provider agreements in certain cases;

Section 1905(c), definition of nursing facility;

Section 1905(d), definition of intermediate care facility for the mentally retarded;

Section 1905 (f), definition of nursing facility services;

Section 1910, certification and approval of ICFs/MR and of RHCs;

Section 1913, hospital providers of nursing facility services;

Section 1919 (g) and (h), survey, certification and enforcement of nursing facilities; and

Section 1922, correction and reduction plans for intermediate care facilities for the mentally retarded.

(b) Section 431.610 of this subchapter contains requirements for designating the State licensing agency to survey these facilities and for certain survey agency responsibilities.


§ 442.2 Terms.

In this part—

Facility refers to a nursing facility, and an intermediate care facility for
the mentally retarded or persons with related conditions (ICF/MR).

Facility, and any specific type of facility referred to, may include a distinct part of a facility as specified in §440.40 or §440.150 of this subchapter.

Immediate jeopardy means a situation in which immediate corrective action is necessary because the provider's noncompliance with one or more requirements of participation or conditions of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to an individual receiving care in a facility.

New admission means the admission of a Medicaid recipient who has never been in the facility or, if previously admitted, had been discharged or had voluntarily left the facility. The term does not include the following:

(a) Individuals who were in the facility before the effective date of denial of payment for new admissions, even if they become eligible for Medicaid after that date.

(b) If the approved State plan includes payments for reserved beds, individuals who, after a temporary absence from the facility, are readmitted to beds reserved for them in accordance with §447.40(a) of this chapter.

(c) Conformance with certification condition. An agreement must be in accordance with the certification provisions set by the Secretary or the survey agency under subpart C of this part for ICFs/MR or subpart E of part 488 of this chapter for NFs.

(d) Denial for good cause. (1) If the Medicaid agency has adequate documentation showing good cause, it may refuse to execute an agreement, or may cancel an agreement, with a certified facility.

(2) A provider agreement is not a valid agreement for purposes of this part even though certified by the State survey agency, if the facility fails to meet the civil rights requirements set forth in 45 CFR parts 80, 84, and 90.

§442.13 Effective date of provider agreement.

The effective date of a provider agreement with an NF or ICF/MR is determined in accordance with the rules set forth in §431.108.

§442.14 Effect of change of ownership.

(a) Assignment of agreement. When there is a change of ownership, the Medicaid agency must automatically assign the agreement to the new owner.

(b) 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) Any existing plan of correction.

(2) Any expiration date for ICFs/MR.

(3) Compliance with applicable health and safety requirements.

(4) Compliance with the ownership and financial interest disclosure requirements of §§455.104 and 455.105 of this chapter.
§ 442.15 Duration of agreement for ICFs/MR.

(a) Except as specified under §442.16, the duration of an agreement may not exceed 12 months.

(b) The agreement must be for the same duration as the certification period set by the survey agency. However, if the Medicaid agency has adequate documentation showing good cause, it may make an agreement for less than this period.

(c) FFP is available for services provided by a facility for up to 30 days after its agreement expires or terminates under the conditions specified in §441.11 of this subchapter.

§ 442.16 Extension of agreement for ICFs/MR.

A Medicaid agency may extend a provider agreement for a single period of up to 2 months beyond the original expiration date specified in the agreement if it receives written notice from the survey agency, before the expiration date of the agreement, that extension will not jeopardize the patients' health and safety, and—

(a) Is needed to prevent irreparable harm to the facility or hardship to the recipients in the facility; or

(b) Is needed because it is impracticable to determine, before the expiration date, whether the facility meets certification requirements.

§ 442.30 Agreement as evidence of certification.

(a) Under §§440.40(a) and 440.150 of this chapter, FFP is available in expenditures for NF and ICF/MR services only if the facility has been certified as meeting the requirements for Medicaid participation, as evidenced by a provider agreement executed under this part. An agreement is not valid evidence that a facility has met those requirements if HCFA determines that—

(1) The survey agency failed to apply the applicable requirements under subpart B of part 483 of this chapter for NFs or subpart I of part 483 of this chapter, which set forth the conditions of participation for ICFs/MR.

(2) The survey agency failed to follow the rules and procedures for certification set forth in subpart C of this part, subpart E of part 488, and §431.610 of this subchapter;

(3) The survey agency failed to perform any of the functions specified in §431.610(g) of this subchapter relating to evaluating and acting on information about the facility and inspecting the facility;

(4) The agency failed to use the Federal standards, and the forms, methods and procedures prescribed by HCFA as required under §431.610(f)(1) or §488.318(b) of this chapter, for determining the qualifications of providers; or

(5) The survey agency failed to adhere to the following principles in determining compliance:

(i) The survey process is the means to assess compliance with Federal health, safety and quality standards;

(ii) The survey process uses resident outcomes as the primary means to establish the compliance status of facilities. Specifically, surveyors will directly observe the actual provision of care and services to residents, and the effects of that care, to assess whether the care provided meets the needs of individual residents;

(iii) Surveyors are professionals who use their judgment, in concert with Federal forms and procedures, to determine compliance;

(iv) Federal procedures are used by all surveyors to ensure uniform and consistent application and interpretation of Federal requirements;

(v) Federal forms are used by all surveyors to ensure proper recording of findings and to document the basis for the findings.
(6) The survey agency failed to assess in a systematic manner a facility’s actual provision of care and services to residents and effects of that care on residents.

(7) Required elements of the NF survey process fail to include all of the following:
   (i) An entrance conference;
   (ii) A resident-centered tour of facility;
   (iii) An in-depth review of a sample of residents including observation, interview and record review;
   (iv) Observation of the preparation and administration of drugs for a sample of residents;
   (v) Evaluation of a facility’s meals, dining areas and eating assistance procedures;
   (vi) Formulation of a deficiency statement based on the incorporation of all appropriate findings onto the survey report form;
   (vii) An exit conference; and
   (viii) Follow-up surveys as appropriate.

(8) The agreement’s terms and conditions do not meet the requirements of this subpart.

(b) The Administrator will make the determination under paragraph (a) of this section through onsite surveys, other Federal reviews, State certification records, or reports he may require from the Medicaid or survey agency.

(c) If the Administrator disallows a State’s claim for FFP because of a determination under paragraph (a) of this section, the State is entitled upon request to reconsideration of the disallowance under 45 CFR part 16.

§ 442.40 Availability of FFP during appeals for ICFs/MR.

(a) Definitions. As used in this section—
   Effective date of expiration means the date of expiration originally specified in the provider agreement, or the later date specified if the agreement is extended under § 442.16; and
   Effective date of termination means a date earlier than the expiration date, set by the Medicaid agency when continuing participation until the expiration date is not justified, because the facility no longer meets the requirements for participation.

(2) The Administrator will make the determination under paragraph (a) of this section through onsite surveys, other Federal reviews, State certification records, or reports he may require from the Medicaid or survey agency.

(3) When the State acts under instructions from HCFA, FFP ends on the date specified by HCFA (HCFA instructs the State to terminate the Medicaid provider agreement when HCFA in validating a State survey agency certification, determines that an ICF/MR does not meet the requirements for participation.)

(4) Effective date. This section and § 442.42 apply only when the Medicaid agency, of its own volition, terminates or does not renew and provider agreement, and only when the survey agency certifies that there is no jeopardy to recipient health and safety. When the survey agency certifies that there is jeopardy to recipient health and safety, or when it fails to certify that there is no jeopardy, FFP ends on the effective date of termination or expiration.

(5) When the State acts under instructions from HCFA, FFP ends on the date specified by HCFA (HCFA instructs the State to terminate the Medicaid provider agreement when HCFA in validating a State survey agency certification, determines that an ICF/MR does not meet the requirements for participation.)

(6) Basic rules. (1) Except as provided in paragraphs (d) and (e) of this section, FFP in payments to an ICF/MR ends on the effective date of termination of the facility’s provider agreement, or if the agreement is not terminated, on the effective date of expiration.

(2) If State law, or a Federal or State court order or injunction, requires the agency to extend the provider agreement or continue payments to a facility after the dates specified in paragraph (d) of this section, FFP is not available in those payments.

(d) Exception: Continuation of FFP after termination or expiration of provider agreement.
§ 442.42 FFP under a retroactive provider agreement following appeal.

(a) Basic rule. Except as specified in paragraph (b) of this section, if an NF or ICF/MR prevails on appeal from termination or, in the case of an ICF/MR, nonrenewal of a provider agreement, and the State issues a retroactive agreement, FFP is available beginning with the retroactive effective date, which must be determined in accordance with §442.13.

(b) Exception. This rule does not apply if HCFA determines, under §442.30, that the agreement is not valid evidence that the facility meets the requirements for participation. This exclusion applies even if the State issues the new agreement as the result of an administrative hearing decision favorable to the facility or under a Federal or State court order.


Subpart C—Certification of ICFs/ MR

§ 442.100 State plan requirements.

A State plan must provide that the requirements of this subpart and part 483 are met.

[53 FR 20495, June 3, 1988]

§ 442.101 Obtaining certification.

(a) This section states the requirements for obtaining notice of an ICF/MR’s certification before a Medicaid agency executes a provider agreement under §442.12.

(b) The agency must obtain notice of certification from the Secretary for an ICF/MR located on an Indian reservation.

(c) The agency must obtain notice of certification from the survey agency for all other ICFs/MR.

(d) The notice must indicate that one of the following provisions pertains to the ICF/MR:

(1) An ICF/MR meets the conditions of participation set forth in subpart I of part 483 of this chapter.

(2) The ICF/MR has been granted a waiver or variance by HCFA or the survey agency under subpart I of part 483 of this chapter.

(3) An ICF/MR has been certified with standard-level deficiencies and

(i) All conditions of participation are found met; and

(ii) The facility submits an acceptable plan of correction covering the remaining deficiencies, subject to other limitations specified in §442.105.

(e) The failure to meet one or more of the applicable conditions of participation is cause for termination or non-renewal of the ICF/MR provider agreement.

§ 442.105 Certification of ICFs/MR with deficiencies: General provisions.

If a survey agency finds a facility deficient in meeting the standards for ICFs/MR, as specified under subpart I of part 483 of this chapter, the agency may certify the facility for Medicaid purposes under the following conditions:

(a) The agency finds that the facility’s deficiencies, individually or in combination, do not jeopardize the patient’s health and safety, nor seriously limit the facility’s capacity to give adequate care.

(b) The agency finds acceptable the facility’s written plan for correcting the deficiencies.

(c) If a facility was previously certified with a deficiency and has a different deficiency at the time of the next survey, the agency documents that the facility—

(1) Was unable to stay in compliance with the standard for ICFs/MR for reasons beyond its control, or despite intensive efforts to comply; and

(2) Is making the best use of its resources to furnish adequate care.

(d) If a facility has the same deficiency it had under the prior certification, the agency documents that the facility—

(1) Did achieve compliance with the standard for ICFs/MR at some time during the prior certification period;

(2) Made a good faith effort, as judged by the survey agency, to stay in compliance; and

(3) Again became out of compliance for reasons beyond its control.


§ 442.109 Certification period for ICFs/MR: General provisions.

(a) A survey agency may certify a facility that fully meets applicable requirements for up to 12 months.

(b) The survey agency may notify the Medicaid agency that the term of a provider agreement may be extended up to 2 months after the expiration date of the agreement under the conditions specified in § 442.16.


§ 442.110 Certification period for ICFs/MR with standard-level deficiencies.

(a) Facilities with deficiencies may be certified under § 442.105 for the period specified in either paragraph (b) or (c) of this section.

(b) The survey agency may certify a facility for a period that ends no later than 60 days after the last day specified in the plan for correcting deficiencies. The certification period must not exceed 12 months, including the period allowed for corrections.

(c) The survey agency may certify a facility for up to 12 months with a condition that the certification will be automatically canceled on a specified date within the certification period unless:

(1) The survey agency finds that all deficiencies have been satisfactorily corrected; or

(2) The survey agency finds and notifies the Medicaid agency that the facility has made substantial progress in correcting the deficiencies and has a new plan for correction that is acceptable.

The automatic cancellation date must be no later than 60 days after the last day specified in the plan for correction of deficiencies under § 442.105.


§ 442.117 Termination of certification for ICFs/MR whose deficiencies pose immediate jeopardy.

(a) A survey agency must terminate a facility’s certification if it determines that—

(1) The facility no longer meets conditions of participation for ICFs/MR as specified in subpart I of part 483 of this chapter.

(2) The facility’s deficiencies pose immediate jeopardy to residents’ health and safety.

(b) Subsequent to a certification of a facility’s noncompliance, the Medicaid agency must, in terminating the provider agreement, follow the appeals process specified in part 431, subpart D of this chapter.

§ 442.118 Denial of payments for new admissions to an ICF/MR.

(a) Basis for denial of payments. The Medicaid agency may deny payment for new admissions to an ICF/MR that no longer meets the applicable conditions of participation specified under subpart I of part 483 of this chapter.

(b) Agency procedures. Before denying payments for new admissions, the Medicaid agency must comply with the following requirements:

1. Provide the facility up to 60 days to correct the cited deficiencies and comply with conditions of participation for ICFs/MR.

2. If at the end of the specified period the facility has not achieved compliance, give the facility notice of intent to deny payment for new admissions, and opportunity for an informal hearing.

3. If the facility requests a hearing, provide an informal hearing that includes—

   (i) The opportunity for the facility to present, before a State Medicaid official who was not involved in making the initial determination, evidence or documentation, in writing or in person, to refute the decision that the facility is out of compliance with the conditions of participation for ICFs/MR.

   (ii) A written decision setting forth the factual and legal bases pertinent to a resolution of the dispute.

4. If the decision of the informal hearing is to deny payments for new admissions, provide the facility and the public, at least 15 days before the effective date of the denial, with a notice that includes the effective date and the reasons for the denial of payments.


§ 442.119 Duration of denial of payments and subsequent termination of an ICF/MR.

(a) Period of denial. The denial of payments for new admissions will continue for 11 months after the month it was imposed unless, before the end of that period, the Medicaid agency finds that—

1. The facility has corrected the deficiencies or is making a good faith effort to achieve compliance with the conditions of participation for ICFs/MR; or

2. The deficiencies are such that it is necessary to terminate the facility's provider agreement.

(b) Subsequent termination. The Medicaid agency must terminate a facility's provider agreement—

1. Upon the agency's finding that the facility has been unable to achieve compliance with the conditions of participation for ICFs/MR during the period that payments for new admissions have been denied;

2. Effective the day following the last day of the denial of payments period; and

3. In accordance with the procedures for appeal of terminations set forth in subpart D of part 431 of this chapter.


Subparts D-F—[Reserved]

PART 447—PAYMENTS FOR SERVICES

Subpart A—Payments: General Provisions

Sec.

447.1 Purpose.

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COST SHARING

447.50 Cost sharing: Basis and purpose.

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447.52 Minimum and maximum income-related charges.
§ 447.10 Prohibition against reassignment of provider claims.

(a) Basis and purpose. This section implements section 1902(a)(32) of the

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§ 447.15 Acceptance of State payment as payment in full.

A State plan must provide that the Medicaid agency must limit participation in the Medicaid program to providers who accept, as payment in full, the amounts paid by the agency plus any deductible, coinsurance or copayment required by the plan to be paid by the individual. However, the provider may not deny services to any eligible individual on account of the individual’s inability to pay the cost sharing amount imposed by the plan in accordance with §431.55(g) or §447.53. The previous sentence does not apply to an individual who is able to pay. An individual’s inability to pay does not eliminate his or her liability for the cost sharing charge.

§ 447.20 Provider restrictions: State plan requirements.

A State plan must provide for the following:

(a) In the case of an individual who is eligible for medical assistance under the plan for service(s) for which a third party or parties is liable for payment, if the total amount of the established liability of the third party or parties for the service is—
§ 447.30 Withholding the Federal share of payments to Medicaid providers to recover Medicare overpayments.

(a) Basis and purpose. This section implements section 1914 of the Act, which provides for withholding the Federal share of Medicaid payments to a provider if the provider has not arranged to repay Medicare overpayments or has failed to provide information to determine the amount of the overpayments. The intent of the statute and regulations is to facilitate the recovery of Medicare overpayments.

(b) The reduction may be equal to up to three times the amount that the provider sought to collect in violation of § 447.20(a).

[55 FR 1433, Jan. 16, 1990]
The provision enables recovery of overpayments when institutions have reduced participation in Medicare or when physicians and suppliers have submitted few or no claims under Medicare, thus not receiving enough in Medicare reimbursement to permit offset of the overpayment.

(b) When withholding occurs. The Federal share of Medicaid payments may be withheld from any provider specified in paragraph (c) of this section to recover Medicare overpayments that HCFA has been unable to collect if the provider participates in Medicaid and—

1. The provider has not made arrangements satisfactory to HCFA to repay the Medicare overpayment; or
2. HCFA has been unable to collect information from the provider to determine the existence or amount of Medicare overpayment.

(c) The Federal share of Medicaid payments may be withheld with respect to the following providers:

1. An institutional provider that has or previously had in effect a Medicare provider agreement under section 1866 of the Act; and
2. A Medicaid provider who has previously accepted Medicare payment on the basis of an assignment under section 1842(b)(3)(B)(ii) of the Act; and during the 12 month period preceding the quarter in which the Federal share is to be withheld for a Medicare overpayment, submitted no claims under Medicare or submitted claims which total less than the amount of overpayment.

(d) Order to reduce State payment.

1. HCFA may, at its discretion, issue an order to the Medicaid agency of any State that is using the provider's services, to reduce its payment to the provider by the amount specified in paragraph (f) of this section.
2. The order to reduce payment to the provider will remain in effect until—

(i) The Medicaid agency determines that the overpayment has been completely recovered; or
(ii) HCFA terminates the order.
3. HCFA may withhold FFP from any State that does not comply with the order specified in paragraph (d)(1) of this section to reduce payment to the provider and claims FFP for the expenditure on its quarterly expenditure report.

(e) Notice of withholding. (1) Before the Federal share of payments may be withheld under this section, HCFA will notify the provider and the Medicaid agency of each State that HCFA believes may use the overpaid provider's services under Medicaid.

2. The notice will include the instruction to reduce State payments, as provided under paragraph (d) of this section.

3. HCFA will send the notice referred to in paragraph (e)(1) by certified mail, return receipt requested.

4. Each Medicaid agency must identify the amount of payment due the provider under Medicaid and give that information to HCFA in the next quarterly expenditure report.

5. The Medicaid agency may appeal any disallowance of FFP resulting from the withholding decision to the Grant Appeals Board, in accordance with 45 CFR part 16.

(f) Amount to be withheld. HCFA may require the Medicaid agency to reduce the Federal share of its payment to the provider by the lesser of the following amounts.

1. The Federal matching share of payments to the provider, or
2. The total Medicare overpayment to the provider.

(g) Effective date of withholding. Withholding of payment will become effective no less than 60 days after the day on which the agency receives notice of withholding.

(h) Duration of withholding. No Federal funds are available in expenditures for services that are furnished by a provider specified in paragraph (c) of this section from the date on which the withholding becomes effective until the termination of withholding under paragraph (i) of this section.

(i) Termination of withholding.

1. HCFA will terminate the order to reduce State payment if it determines that any of the following has occurred:

(i) The Medicare overpayment is completely recovered:
(ii) The institution or person makes an agreement satisfactory to HCFA to repay the overpayment; or
(iii) HCFA determines that there is no overpayment based on newly acquired evidence or a subsequent audit.

(2) HCFA will notify each State that previously received a notice ordering the withholding that the withholding has been terminated.

(j) Procedures for restoring excess withholding. If an amount ultimately determined to be in excess of the Medicare overpayment is withheld, HCFA will restore any excess funds withheld.

(k) Recovery of funds from Medicaid agency. A provider is not entitled to recover from the Medicaid agency the amount of payment withheld by the agency in accordance with a HCFA order issued under paragraph (d) of this section.

[50 FR 19688, May 10, 1985; 50 FR 23307, June 3, 1985]

§ 447.31 Withholding Medicare payments to recover Medicaid overpayments.

(a) Basis and purpose. Section 1885 of the Act provides authority for HCFA to withhold Medicare payments to a Medicaid provider in order to recover Medicaid overpayments to the provider. Section 405.377 of this chapter sets forth the Medicare rules implementing section 1885, and specifies under what circumstances withholding will occur and the providers that are subject to withholding. This section establishes the procedures that the Medicaid agency must follow when requesting that HCFA withhold Medicare payments.

(b) Agency notice to providers. (1) Before the agency requests recovery of a Medicaid overpayment through Medicare, the agency must send either or both of the following notices, in addition to that required under paragraph (b)(2) of this section, to the provider.

(i) Notice that—
(A) There has been an overpayment;
(B) Repayment is required; and
(C) The overpayment determination is subject to agency appeal procedures, but we may withhold Medicare payments while an appeal is in progress.

(ii) Notice that—
(A) Information is needed to determine the amount of overpayment if any; and
(B) The provider has at least 30 days in which to supply the information to the agency.

(2) Notice that, 30 days or later from the date of the notice, the agency intends to refer the case to HCFA for withholding of Medicare payments.

(3) The agency must send all notices to providers by certified mail, return receipt requested.

(c) Documentation to be submitted to HCFA. The agency must submit the following information or documentation to HCFA (unless otherwise specified) with the request for withholding of Medicare payments.

(1) A statement of the reason that withholding is requested.

(2) The amount of overpayment, type of overpayment, date the overpayment was determined, and the closing date of the pertinent cost reporting period (if applicable).

(3) The quarter in which the overpayment was reported on the quarterly expenditure report (Form HCFA 64).

(4) As needed, and upon request from HCFA, the names and addresses of the provider’s officers and owners for each period that there is an outstanding overpayment.

(5) A statement of assurance that the State agency has met the notice requirements under paragraph (b) of this section.

(6) As needed, and upon request for HCFA, copies of notices (under paragraph (b) of this section), and reports of contact or attempted contact with the provider concerning the overpayment, including any reduction or suspension of Medicaid payments made with respect to that overpayment.

(7) A copy of the provider’s agreement with the agency under §431.107 of this chapter.

(d) Notification to terminate withholding. (1) If an agency has requested withholding under this section, it must notify HCFA if any of the following occurs:

(i) The Medicaid provider makes an agreement satisfactory to the agency to repay the overpayment;

(ii) The Medicaid overpayment is completely recovered; or

(iii) The agency determines that there is no overpayment, based on
§ 447.40 Payments for reserving beds in institutions.

(a) The Medicaid agency may make payments to reserve a bed during a recipient's temporary absence from an inpatient facility, if—

(1) The State plan provides for such payments and specifies any limitations on the policy; and

(2) Absences for purposes other than required hospitalization (which cannot be anticipated and planned) are included in the patient’s plan of care.

(b) An agency that pays for reserved beds in an inpatient facility may pay less for a reserved bed than an occupied bed if there is a cost differential between the two beds. (Section 1102 of the Act.)


§ 447.45 Timely claims payment.

(a) Basis and purpose. This section implements section 1902(a)(37) of the Act by specifying—

(1) State plan requirements for—

(i) Timely processing of claims for payment;

(ii) Prepayment and postpayment claims reviews; and

(2) Conditions under which the Administrator may grant waivers of the time requirements.

(b) Definitions. Claim means (1) a bill for services, (2) a line item of service, or (3) all services for one recipient within a bill.

Clean claim means one that can be processed without obtaining additional information from the provider of the service or from a third party. It includes a claim with errors originating in a State's claims system. It does not include a claim from a provider who is under investigation for fraud or abuse, or a claim under review for medical necessity.

A shared health facility means any arrangement in which—

(1) Two or more health care practitioners practice their professions at a common physical location;

(2) The practitioners share common waiting areas, examining rooms, treatment rooms, or other space, the services of supporting staff, or equipment;

(3) The practitioners have a person (who may himself be a practitioner)—

(i) Who is in charge of, controls, manages, or supervises substantial aspects of the arrangement or operation for the delivery of health or medical services at the common physical location other than the direct furnishing of professional health care services by the practitioners to their patients; or

(ii) Who makes available to the practitioners the services of supporting staff who are not employees of the practitioners; and

(iii) Who is compensated in whole or in part, for the use of the common physical location or related support services, on a basis related to amounts charged or collected for the services rendered or ordered at the location or on any basis clearly unrelated to the value of the services provided by the person; and

(4) At least one of the practitioners received payments on a fee-for-service basis under titles V, XVIII, and XIX in an amount exceeding $40,000 during the preceding 12 months. The term does not include a provider of services (as specified in §489.2(b) of this chapter), a health maintenance organization (as defined in section 1301(a) of the Public Health Service Act), a hospital cooperative shared services organization meeting the requirements of section 501(e) of the Internal Revenue Code of 1954, or any public entity.
Third party is defined in §433.135 of this chapter.

(c) State plan requirements. A State plan must (1) provide that the requirements of paragraphs (d), (e)(2), (f) and (g) of this section are met; and

(2) Specify the definition of a claim, as provided in paragraph (b) of this section, to be used in meeting the requirements for timely claims payment. The definition may vary by type of service (e.g., physician service, hospital service).

(d) Timely processing of claims. (1) The Medicaid agency must require providers to submit all claims no later than 12 months from the date of service.

(2) The agency must pay 90 percent of all clean claims from practitioners, who are in individual or group practice or who practice in shared health facilities, within 30 days of the date of receipt.

(3) The agency must pay 99 percent of all clean claims from practitioners, who are in individual or group practice or who practice in shared health facilities, within 90 days of the date of receipt.

(4) The agency must pay all other claims within 12 months of the date of receipt, except in the following circumstances:

(i) This time limitation does not apply to retroactive adjustments paid to providers who are reimbursed under a retrospective payment system, as defined in §447.272 of this part.

(ii) If a claim for payment under Medicare has been filed in a timely manner, the agency may pay a Medicaid claim relating to the same services within 6 months after the agency or the provider receives notice of the disposition of the Medicare claim.

(iii) The time limitation does not apply to claims from providers under investigation for fraud or abuse.

(iv) The agency may make payments at any time in accordance with a court order, to carry out hearing decisions or agency corrective actions taken to resolve a dispute, or to extend the benefits of a hearing decision, corrective action, or court order to others in the same situation as those directly affected by it.

(5) The date of receipt is the date the agency receives the claim, as indicated by its date stamp on the claim.

(6) The date of payment is the date of the check or other form of payment.

(e) Waivers. (1) The Administrator may waive the requirements of paragraphs (d) (2) and (3) of this section upon request by an agency if he finds that the agency has shown good faith in trying to meet them. In deciding whether the agency has shown good faith, the Administrator will consider whether the agency has received an unusually high volume of claims which are not clean claims, and whether the agency is making diligent efforts to implement an automated claims processing and information retrieval system.

(2) The agency’s request for a waiver must contain a written plan of correction specifying all steps it will take to meet the requirements of this section.

(3) The Administrator will review each case and if he approves a waiver, will specify its expiration date, based on the State’s capability and efforts to meet the requirements of this section.

(f) Prepayment and postpayment claims review. (1) For all claims, the agency must conduct prepayment claims review consisting of—

(i) Verification that the recipient was included in the eligibility file and that the provider was authorized to furnish the service at the time the service was furnished;

(ii) Checks that the number of visits and services delivered are logically consistent with the recipient’s characteristics and circumstances, such as type of illness, age, sex, service location;

(iii) Verification that the claim does not duplicate or conflict with one reviewed previously or currently being reviewed;

(iv) Verification that a payment does not exceed any reimbursement rates or limits in the State plan; and

(v) Checks for third party liability within the requirements of §433.137 of this chapter.

(2) The agency must conduct postpayment claims review that meets the requirements of parts 455 and 456 of this chapter, dealing with fraud and utilization control.
§ 447.50 Cost sharing: Basis and purpose.

(a) Section 1902(a)(14) of the Act permits States to require certain recipients to share some of the costs of Medicaid by imposing upon them such payments as enrollment fees, premiums, deductibles, coinsurance, co-payments, or similar cost sharing charges. For States that impose cost sharing payments, §§ 447.51 through 447.59 prescribe State plan requirements and options for cost sharing, specify the standards and conditions under which States may impose cost sharing, set forth minimum amounts and the methods for determining maximum amounts, and prescribe conditions for FFP that relate to cost sharing requirements.

ENROLLMENT FEE, PREMIUM OR SIMILAR COST SHARING CHARGE

§ 447.51 Requirements and options.

(a) The plan must provide that the Medicaid agency does not impose any enrollment fee, premium, or similar charge upon categorically needy individuals, as defined in §§ 435.4 and 436.3 of this subchapter, for any services available under the plan.

(b) The plan may impose an enrollment fee, premium, or similar charge on medically needy individuals, as defined in §§ 435.4 and 436.3 of this subchapter, for any services available under the plan.

(c) For each charge imposed under paragraph (b) of this section, the plan must specify—

(1) The amount of the charge;
(2) The period of liability for the charge; and
(3) The consequences for an individual who does not pay.

(d) The plan must provide that any charge imposed under paragraph (b) of this section is related to total gross family income as set forth under §§ 447.52.

§ 447.52 Minimum and maximum income-related charges.

For the purpose of relating the amount of an enrollment fee, premium, or similar charge to total gross family income, as required under § 447.51(d), the following rules apply:

(a) Minimum charge. A charge of at least $1.00 per month is imposed on each—

(1) One- or two-person family with monthly gross income of $150 or less;
(2) Three- or four-person family with monthly gross income of $300 or less; and
(3) Five- or more-person family with monthly gross income of $350 or less.

(b) Maximum charge. Any charge related to gross family income that is above the minimum listed in paragraph (a) of this section may not exceed the standards shown in the following table:

MAXIMUM MONTHLY CHARGE

<table>
<thead>
<tr>
<th>Gross family income (per month)</th>
<th>Family size</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>1 or 2</td>
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<tr>
<td>$150 or less</td>
<td>$1</td>
</tr>
<tr>
<td>$151 or $200</td>
<td>2</td>
</tr>
<tr>
<td>$201 to $250</td>
<td>3</td>
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<tr>
<td>$251 to $300</td>
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<td>$501 to $550</td>
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<tr>
<td>$901 to $950</td>
<td>17</td>
</tr>
<tr>
<td>$951 to $1,000</td>
<td>18</td>
</tr>
<tr>
<td>More than $1,000</td>
<td>19</td>
</tr>
</tbody>
</table>

(c) Income-related charges. The agency must impose an appropriately higher charge for each higher level of family income, within the maximum amounts specified in paragraph (b) of this section.

§ 447.53 Applicability; specification; multiple charges.

(a) Basic requirements. Except as specified in paragraph (b) of this section, the plan may impose a nominal deductible, coinsurance, copayment, or similar charge upon categorically and medically needy individuals for any service under the plan.

(b) Exclusions from cost sharing. The plan may not provide for impositions of a deductible, coinsurance, copayment, or similar charge upon categorically or medically needy individuals (except as specified in paragraph (b)(6) of this section) for the following:

(1) Children. Services furnished to individuals under 18 years of age (and, at the option of the State, individuals under 21, 20, or 19 years of age, or any reasonable category of individuals 18 years of age or over but under 21) are excluded from cost sharing.

(2) Pregnant women. Services furnished to pregnant women if such services related to the pregnancy, or to any other medical condition which may complicate the pregnancy are excluded from cost sharing obligations. These services include routine prenatal care, labor and delivery, routine postpartum care, family planning services, complications of pregnancy or delivery likely to affect the pregnancy, such as hypertension, diabetes, urinary tract infection, and services furnished during the postpartum period for conditions or complications related to the pregnancy. The postpartum period is the immediate postpartum period which begins on the last day of pregnancy and extends through the end of the month in which the 60-day period following termination of pregnancy ends. States may further exclude from cost sharing all services furnished to pregnant women if they desire.

(c) Prohibition against multiple charges. For any service, the plan may not impose more than one type of charge referred to in paragraph (a) of this section.

(d) State plan specifications. For each charge imposed under this section, the plan must specify—

(1) The service for which the charge is made;

(2) The amount of the charge;

(3) The basis for determining the charge;

(4) The basis for determining whether an individual is unable to pay the charge and the means by which such an individual will be identified to providers; and

(5) The procedures for implementing and enforcing the exclusions from cost sharing found in paragraph (b) of this section.

§ 447.53 Applicability; specification; multiple charges.

(a) Basic requirements. Except as specified in paragraph (b) of this section, the plan may impose a nominal deductible, coinsurance, copayment, or similar charge upon categorically and medically needy individuals for any service under the plan.

(b) Exclusions from cost sharing. The plan may not provide for impositions of a deductible, coinsurance, copayment, or similar charge upon categorically or medically needy individuals (except as specified in paragraph (b)(6) of this section) for the following:

(1) Children. Services furnished to individuals under 18 years of age (and, at the option of the State, individuals under 21, 20, or 19 years of age, or any reasonable category of individuals 18 years of age or over but under 21) are excluded from cost sharing.

(2) Pregnant women. Services furnished to pregnant women if such services related to the pregnancy, or to any other medical condition which may complicate the pregnancy are excluded from cost sharing obligations. These services include routine prenatal care, labor and delivery, routine postpartum care, family planning services, complications of pregnancy or delivery likely to affect the pregnancy, such as hypertension, diabetes, urinary tract infection, and services furnished during the postpartum period for conditions or complications related to the pregnancy. The postpartum period is the immediate postpartum period which begins on the last day of pregnancy and extends through the end of the month in which the 60-day period following termination of pregnancy ends. States may further exclude from cost sharing all services furnished to pregnant women if they desire.

(c) Prohibition against multiple charges. For any service, the plan may not impose more than one type of charge referred to in paragraph (a) of this section.

(d) State plan specifications. For each charge imposed under this section, the plan must specify—

(1) The service for which the charge is made;

(2) The amount of the charge;

(3) The basis for determining the charge;

(4) The basis for determining whether an individual is unable to pay the charge and the means by which such an individual will be identified to providers; and

(5) The procedures for implementing and enforcing the exclusions from cost sharing found in paragraph (b) of this section.

§ 447.54 Maximum allowable charges.

(a) Non-institutional services. Except as specified in paragraph (b), for non-institutional services, the plan must provide that—

1. Any deductible it imposes does not exceed $2.00 per month per family for each period of Medicaid eligibility. For example, if Medicaid eligibility is certified for a 3-month period, the maximum deductible which may be imposed on a family for that period of eligibility is $6.00;

2. Any coinsurance rate it imposes does not exceed 5 percent of the payment the agency makes for the services; and

3. Any co-payments it imposes do not exceed the amounts shown in the following table:

<table>
<thead>
<tr>
<th>States payment for the service</th>
<th>Maximum copayment chargeable to recipient</th>
</tr>
</thead>
<tbody>
<tr>
<td>$10 or less</td>
<td>$0.50</td>
</tr>
<tr>
<td>$10.01 to $25</td>
<td>1.00</td>
</tr>
<tr>
<td>$25.01 to $50</td>
<td>2.00</td>
</tr>
<tr>
<td>$50.01 or more</td>
<td>3.00</td>
</tr>
</tbody>
</table>

(b) Waiver of the requirement that cost sharing amounts be nominal. Upon approval from HCFA, the requirement that cost sharing charges must be nominal may be waived, in accordance with section 431.55(g) for nonemergency services furnished in a hospital emergency room.

(c) Institutional services. For institutional services, the plan must provide that the maximum deductible, coinsurance or co-payment charges that it imposes on any family during a specified period of time.

§ 447.55 Standard co-payment.

(a) The plan may provide for a standard, or fixed, co-payment amount for any service.

(b) This standard copayment amount for any service may be determined by applying the maximum co-payment amounts specified in §447.54 (a) and (b) to the agency's average or typical payment for that service. For example, if the agency's typical payment for prescribed drugs is $4 to $5 per prescription, the agency might set a standard copayment of $0.50 per prescription.

§ 447.56 Income-related charges.

Subject to the maximum allowable charges specified in §447.54 (a) and (b), the plan may provide for income-related deductible, coinsurance or co-payment charges. For example, an agency may impose a higher charge on medically needy recipients than it imposes upon categorically needy recipients.

§ 447.57 Restrictions on payments to providers.

(a) The plan must provide that the agency does not increase the payment it makes to any provider to offset uncollected amounts for deductibles, coinsurance, copayments or similar charges that the provider has waived or are uncollectable, except as permitted under paragraph (b) of this section.

(b) For those providers that the agency reimburses under Medicare reasonable cost reimbursement principles, in accordance with subpart B of this part, an agency may increase its payment to offset uncollected deductible, coinsurance, copayment, or similar charges that are bad debts of providers.

§ 447.58 Payments to prepaid capitation organizations.

Except for HMO services subject to the co-payment exclusion in §447.53(b)(6), if the agency contracts with a prepaid capitation organization that does not impose the agency's deductibles, coinsurance, co-payments or similar charges on its recipient members, the plan must provide that the agency calculates its payments to the organization as if those cost sharing charges were collected.

§ 447.59 FFP: Conditions relating to cost sharing.

No FFP in the State's expenditures for services is available for—
(a) Any cost sharing amounts that recipients should have paid as enrollment fees, premiums, deductibles, coinsurance, copayments, or similar charges under §§447.50 through 447.58 (except for amounts that the agency pays as bad debts of providers under §447.57); and
(b) Any amounts paid by the agency on behalf of ineligible individuals, whether or not the individual had paid any required premium or enrollment fee.

Subpart B—Payment Methods: General Provisions

§447.200 Basis and purpose.
This subpart prescribes State plan requirements for setting payment rates to implement, in part, section 1902(a)(30) of the Act, which requires that payments for services be consistent with efficiency, economy, and quality of care.


§447.201 State plan requirements.
(a) A State plan must provide that the requirements in this subpart are met.
(b) The plan must describe the policy and the methods to be used in setting payment rates for each type of service included in the State's Medicaid program.

§447.202 Audits.
The Medicaid agency must assure appropriate audit of records if payment is based on costs of services or on a fee plus cost of materials.

§447.203 Documentation of payment rates.
(a) The agency must maintain documentation of payment rates and make it available to HHS upon request.
(b) The agency must record, in State manuals or other official files, the following information for increases in payment rates for individual practitioner services:
(1) An estimate of the percentile of the range of customary charges to which the revised payment structure equates and a description of the methods used to make the estimate.
(2) An estimate of the composite average percentage increase of the revised payment rates over the preceding rates.

§447.204 Encouragement of provider participation.
The agency's payments must be sufficient to enlist enough providers so that services under the plan are available to recipients at least to the extent that those services are available to the general population.

§447.205 Public notice of changes in statewide methods and standards for setting payment rates.
(a) When notice is required. Except as specified in paragraph (b) of this section, the agency must provide public notice of any significant proposed change in its methods and standards for setting payment rates for services.
(b) When notice is not required. Notice is not required if—
(1) The change is being made to conform to Medicare methods or levels of reimbursement;
(2) The change is required by court order; or
(3) The change is based on changes in wholesalers' or manufacturers' prices of drugs or materials, if the agency's reimbursement system is based on material cost plus a professional fee.
(c) Content of notice. The notice must—
(1) Describe the proposed change in methods and standards;
(2) Give an estimate of any expected increase or decrease in annual aggregate expenditures;
(3) Explain why the agency is changing its methods and standards;
(4) Identify a local agency in each county (such as the social services agency or health department) where copies of the proposed changes may be sent and reviewed by the public; and
(5) Give an address where written comments may be sent and reviewed by the public; and
(6) If there are public hearings, give the location, date and time for hearings or tell how this information may be obtained.
(d) Publication of notice. The notice must—
§ 447.250  Basis and purpose.

(a) This subpart implements section 1902(a)(13)(A) of the Act, which requires that the State plan provide for payment for hospital and long-term care facility services through the use of rates that the State finds, and makes assurances satisfactory to the Secretary, are reasonable and adequate to meet the costs that must be incurred by efficiently and economically operated facilities to provide services in conformity with State and Federal laws, regulations, and quality and safety standards.

(b) Section 447.253(a)(2) implements section 1902(a)(30) of the Act, which requires payments be consistent with efficiency, economy, and quality of care;

(c) Sections 447.253(c) and (d) implement sections 1902(a)(13)(B) and 1902(a)(13)(C) of the Act, which require a State Medicaid agency to make certain assurances to the Secretary regarding increases in payments resulting solely from changes in ownerships of hospitals, NF’s, and ICFs/MR.

(d) Section 447.271 implements section 1903(i)(3) of the Act, which requires that payments for inpatient hospital services not exceed the hospital’s customary charges.

(e) Section 447.280 implements section 1913(b) of the Act, which concerns reimbursement for long-term care services furnished by swing-bed hospitals.

42 CFR Ch. IV (10-1-98 Edition)

§ 447.251  Definitions.

For the purposes of this subpart—

Long-term care facility services means intermediate care facility services for the mentally retarded (ICF/MR) and nursing facility (NF) services.

Provider means an institution that furnishes inpatient hospital services or an institution that furnishes long-term care facility services.

§ 447.252  State plan requirements.

(a) The plan must provide that the requirements of this subpart are met.

(b) The plan must specify comprehensively the methods and standards used by the agency to set payment rates in a manner consistent with §430.10 of this chapter.

(c) If the agency chooses to apply the cost limits established under Medicare (see §413.30 of this chapter) on an individual provider basis, the plan must specify this requirement.

§ 447.253  Other requirements.

(a) State assurances. In order to receive HCFA approval of a State plan change in payment methods and standards, the Medicaid agency must make assurances satisfactory to HCFA that the requirements set forth in paragraphs (b) through (i) of this section are being met, must submit the related information required by §447.255 of this subpart, and must comply with all other requirements of this subpart.

(b) Findings. Whenever the Medicaid agency makes a change in its methods and standards, but not less often than annually, the agency must make the following findings:
(1) Payment rates. (i) The Medicaid agency pays for inpatient hospital services and long-term care facility services through the use of rates that are reasonable and adequate to meet the costs that must be incurred by efficiently and economically operated providers to provide services in conformity with applicable State and Federal laws, regulations, and quality and safety standards.

(ii) With respect to inpatient hospital services—

(A) The methods and standards used to determine payment rates take into account the situation of hospitals which serve a disproportionate number of low income patients with special needs;

(B) If a State elects in its State plan to cover inappropriate level of care services (that is, services furnished to hospital inpatients who require a lower covered level of care such as skilled nursing or intermediate care services) under conditions similar to those described in section 1861(v)(1)(G) of the Act, the methods and standards used to determine payment rates must specify that the payments for this type of care must be made at rates lower than those for inpatient hospital level of care services, reflecting the level of care actually received, in a manner consistent with section 1861(v)(1)(G) of the Act; and

(C) The payment rates are adequate to assure that recipients have reasonable access, taking into account geographic location and reasonable travel time, to inpatient hospital services of adequate quality.

(iii) With respect to nursing facility services—

(A) Except for preadmission screening for individuals with mental illness and mental retardation under § 483.20(f) of this chapter, the methods and standards used to determine payment rates take into account the costs of complying with the requirements of part 483 subpart B of this chapter;

(B) The methods and standards used to determine payment rates provide for an appropriate reduction to take into account the lower costs (if any) of the facility for nursing care under a waiver of the requirement in § 483.30(c) of this chapter to provide licensed nurses on a 24-hour basis;

(C) The State establishes procedures under which the data and methodology used in establishing payment rates are made available to the public.

(2) Upper payment limits. The agency's proposed payment rate will not exceed the upper payment limits as specified in § 447.272.

(c) Changes in ownership of hospitals. In determining payment when there has been a sale or transfer of the assets of a hospital, the State's methods and standards must provide that payment rates can reasonably be expected not to increase in the aggregate solely as a result of changes of ownership, more than the payments would increase under Medicare under §§ 413.130, 413.134, 413.153, and 413.157 of this chapter, insofar as these sections affect payments for depreciation, interest on capital indebtedness, return on equity capital (if applicable), acquisition costs for which payments were previously made to prior owners, and the recapture of depreciation.

(d) Changes in ownership of NFs and ICFs/MR. In determining payment when there has been a sale or transfer of assets of an NF or ICF/MR, the State's methods and standards must provide the following depending upon the date of the transfer.

(1) For transfers on or after July 18, 1984 but before October 1, 1985, the State's methods and standards must provide that payment rates can reasonably be expected not to increase in the aggregate, solely as the result of a change in ownership, more than payments would increase under Medicare under §§ 413.130, 413.134, 413.153, and 413.157 of this chapter, insofar as these sections affect payment for depreciation, interest on capital indebtedness, return on equity capital (if applicable), acquisition costs for which payments were previously made to prior owners, and the recapture of depreciation.

(2) For transfers on or after October 1, 1985, the State's methods and standards must provide that the valuation of capital assets for purposes of determining payment rates for NFs and ICFs/MR is not to increase (as measured from the date of acquisition by the
seller to the date of the change of ownership solely as a result of a change of ownership, by more than the lesser of—

(i) One-half of the percentage increase (as measured from the date of acquisition by the seller to the date of the change of ownership, or, if necessary, as extrapolated retrospectively by the Secretary) in the Dodge construction index applied in the aggregate with respect to those facilities that have undergone a change of ownership during the fiscal year; or

(ii) One-half of the percentage increase (as measured from the date of acquisition by the seller to the date of the change of ownership) in the Consumer Price Index for All Urban Consumers (CPI-U) (United States city average) applied in the aggregate with respect to those facilities that have undergone a change of ownership during the fiscal year.

(e) Provider appeals. The Medicaid agency must provide an appeals or exception procedure that allows individual providers an opportunity to submit additional evidence and receive prompt administrative review, with respect to such issues as the agency determines appropriate, of payment rates.

(f) Uniform cost reporting. The Medicaid agency must provide for the filing of uniform cost reports by each participating provider.

(g) Audit requirements. The Medicaid agency must provide for periodic audits of the financial and statistical records of participating providers.

(h) Public notice. The Medicaid agency must provide that it has complied with the public notice requirements in §447.205 of this chapter when it is proposing significant changes to its methods or standards for setting payment rates for inpatient hospital or LTC facility services.

(i) Rates paid. The Medicaid agency must pay for inpatient hospital and long-term care services using rates determined in accordance with methods and standards specified in an approved State plan.

§ 447.255 Related information.

The Medicaid agency must submit, with the assurances described in §447.253(a), the following information:

(a) The amount of the estimated average proposed payment rate for each type of provider (hospital, ICF/MR, or nursing facility), and the amount by which that estimated average rate increased or decreased relative to the average payment rate in effect for each type of provider during the immediately preceding rate period;

(b) An estimate of the short-term and, to the extent feasible, long-term effect the change in the estimated average rate will have on—

(1) The availability of services on a Statewide and geographic area basis;

(2) The type of care furnished;

(3) The extent of provider participation; and

(4) The degree to which costs are covered in hospitals that serve a disproportionate number of low-income patients with special needs.

§ 447.256 Procedures for HCFA action on assurances and State plan amendments.

(a) Criteria for approval. (1) HCFA approval action on State plans and State plan amendments, is taken in accordance with subpart B of part 430 of this chapter and sections 1116, 1902(b) and 1915(f) of the Act.

(2) In the case of State plan and plan amendment changes in payment methods and standards, HCFA bases its approval on the acceptability of the Medicaid agency's assurances that the requirements of §447.253 have been met, and the State's compliance with the other requirements of this subpart.

(b) Time limit. HCFA will send a notice to the agency of its determination as to whether the assurances regarding a State plan amendment are acceptable within 90 days of the date HCFA receives the assurances described in
§ 447.253, and the related information described in §447.255 of this subpart. If HCFA does not send a notice to the agency of its determination within this time limit and the provisions in paragraph (a) of this section are met, the assurances and/or the State plan amendment will be deemed accepted and approved.

(c) Effective date. A State plan amendment that is approved will become effective not earlier than the first day of the calendar quarter in which an approvable amendment is submitted in accordance with §430.20 of this chapter and 447.253.


FEDERAL FINANCIAL PARTICIPATION

§ 447.257 FFP: Conditions relating to institutional reimbursement.

FFP is not available for a State's expenditures for hospital inpatient or long-term care facility services that are in excess of the amounts allowable under this subpart.

[52 FR 28147, July 28, 1987]

UPPER LIMITS

§ 447.271 Upper limits based on customary charges.

(a) Except as provided in paragraph (b) of this section, the agency may not pay a provider more for inpatient hospital services under Medicaid than the provider's customary charges to the general public for the services.

(b) The agency may pay a public provider that provides services free or at a nominal charge at the same rate that would be used if the provider's charges were equal to or greater than its costs.

§ 447.272 Application of upper payment limits.

(a) General rule. Except as provided in paragraph (c) of this section, aggregate payments by an agency to each group of health care facilities (that is, hospitals, nursing facilities and ICFs/MR), may not exceed the amount that can reasonably be estimated would have been paid under Medicare payment principles.

(b) State operated facilities. In addition to meeting the requirement of paragraph (a) of this section, aggregate payments to each group of State-operated facilities (that is, hospitals, nursing facilities and ICFs/MR) may not exceed the amount that can reasonably be estimated would have been paid under Medicare payment principles.

(c) Disproportionate share. The upper payment limitation established under paragraphs (a) and (b) of this section does not apply to payment adjustments made under a State plan to hospitals found to serve a disproportionate number of low-income patients with special needs as provided in §447.253(b)(1)(i)(A). The payment limitations for aggregate State disproportionate share hospital payments are specified in §§447.296 through 447.299. States must submit a separate upper payment limit assurance that its aggregate disproportionate share hospital payments do not exceed the disproportionate share hospital payment limits.


SWING-BED HOSPITALS

§ 447.280 Hospital providers of NF services (swing-bed hospitals).

(a) General rule. If the State plan provides for NF services furnished by a swing-bed hospital, as specified in §§440.40(a) and 440.150(f) of this chapter, the methods and standards used to determine payment rates for routine NF services must—

(1) Provide for payment at the average rate per patient day paid to NFs, as applicable, for routine services furnished during the previous calendar year; or

(2) Meet the State plan and payment requirements described in this subpart, as applicable.

(b) Application of the rule. The payment methodology used by a State to set payment rates for routine NF services must apply to all swing-bed hospitals in the State.

[59 FR 56237, Nov. 10, 1994]
Subpart E—Payment Adjustments for Hospitals That Serve a Disproportionate Number of Low-Income Patients

Source: 57 FR 55143, Nov. 24, 1992, unless otherwise noted.


(a) The provisions of this section apply to the 50 States and the District of Columbia, but not to any State whose entire Medicaid program is operated under a waiver granted under section 1115 of the Act.

(b) For the period January 1, 1992 through September 30, 1992, FFP is available for aggregate payments to hospitals that serve a disproportionate number of low-income patients with special needs only if the payments are made in accordance with sections 1902(a)(13)(A) and 1923 of the Act, and with one of the following:

3. A State plan amendment, or modification thereof, submitted to HCFA between October 1, 1991 and November 26, 1991, if the amendment, or modification thereof, was intended to limit the State’s definition of disproportionate share hospitals to those hospitals with Medicaid inpatient utilization rates or low-income utilization rates (as defined in section 1923(b) of the Act) at or above the statewide arithmetic mean.
4. A methodology for disproportionate share hospital payments that was established and in effect as of September 30, 1991, or in accordance with a State law enacted or State regulation adopted as of September 30, 1991.
5. A State plan amendment submitted to HCFA by September 30, 1992 that increases aggregate disproportionate share hospitals payments in order to meet the minimum payment adjustments required by section 1923(c)(1) of the Act. The minimum payment adjustment is the amount required by the Medicare methodology described in section 1923(c)(1) of the Act for those hospitals that satisfy the minimum Federal definition of a disproportionate share hospital in section 1923(b) of the Act.

6. A State plan amendment submitted to HCFA by September 30, 1992 that provides for a redistribution of disproportionate share hospital payments within the State without raising total payments compared to the previously approved State plan. HCFA will approve the amendment only if the State submits written documentation that demonstrates to HCFA that the aggregate payments that will be made after the redistribution are no greater than those payments made before the redistribution.

7. A State plan amendment submitted to HCFA by September 30, 1992 that provides for a reduction in disproportionate share hospital payments.

§ 447.297 Limitations on aggregate payments for disproportionate share hospitals beginning October 1, 1992.

(a) Applicability. The provisions of this section apply to the 50 States and the District of Columbia, but not to any State whose entire Medicaid program is operated under a waiver granted under section 1115 of the Act.

(b) National payment target. The national payment target for disproportionate share hospital (DSH) payments for any Federal fiscal year is equal to 12 percent of the total medical assistance expenditures that will be made during the Federal fiscal year under State plans, excluding administrative costs. A preliminary national expenditure target will be published by HCFA prior to October 1 of each year. This preliminary national expenditure target will be superseded by a final national expenditure target published by April 1 of each Federal fiscal year, as specified in paragraph (d) of this section.

(c) State disproportionate share hospital allotments. Prior to October 1 of each Federal fiscal year, HCFA will publish in the Federal Register preliminary State DSH allotments for each State.
These preliminary State DSH allotments will be determined using the most current applicable actual and estimated State expenditure information as reported to HCFA and adjusted by HCFA as may be necessary using the methodology described in §447.298. HCFA will publish final State DSH allotments by April 1 of each Federal fiscal year, as described in paragraph (d) of this section.

(d) Final national disproportionate share hospitals expenditure target and State disproportionate share hospitals allotments.

(1) HCFA will revise the preliminary national expenditure target and the preliminary State DSH allotments by April 1 of each Federal fiscal year. The final national DSH expenditure target and State DSH allotments will be based on the most current applicable actual and estimated expenditure information reported to HCFA and adjusted by HCFA as may be necessary immediately prior to the April 1 publication date. The final national expenditure target and State DSH allotments will not be recalculated for that Federal fiscal year based upon any subsequent actual or estimated expenditure information reported to HCFA.

(2) If HCFA determines that at any time a State has exceeded its final DSH allotment for a Federal fiscal year, FFP attributable to the excess DSH expenditures will be disallowed.

(3) If a State's actual DSH expenditures applicable to a Federal fiscal year are less than its final State DSH allotment for that Federal fiscal year, the State is permitted, to the extent allowed by its approved State plan, to make additional DSH expenditures applicable to that Federal fiscal year up to the amount of its final DSH allotment for that Federal fiscal year.

(e) Publication of limits.

(1) Before the beginning of each Federal fiscal year, HCFA will publish in the Federal Register—

(i) A preliminary national DSH expenditure target for the Federal fiscal year; and

(ii) A preliminary DSH allotment for each State for the Federal fiscal year.

(2) The final national DSH expenditure target and State DSH allotments will be published in the Federal Register by April 1 of each Federal fiscal year.

§447.298 State disproportionate share hospital allotments.

(a) Calculation of State's base allotment for Federal fiscal year 1993.

(1) For Federal fiscal year 1993, HCFA will calculate for each State a DSH allotment, using the State's "base allotment." The State's base allotment is the greater of:

(i) The total amount of the State's projected DSH payments for Federal fiscal year 1992 under the State plan applicable to Federal fiscal year 1992, calculated in accordance with paragraph (a)(2) of this section; or

(ii) $1,000,000.

(2) In calculating the State's DSH payments applicable to Federal fiscal year 1992, HCFA will derive amounts from payments applicable to the period of October 1, 1991, through September 30, 1992, under State plans or plan amendments that meet the requirements specified in §447.296(b). The calculation will not include—

(i) DSH payment adjustments made by the State applicable to the period October 1, 1991 through December 31, 1991 under State plans or plan amendments that do not meet the criteria described in §447.296; and

(ii) Retroactive DSH payments made in 1992 that are not applicable to Federal fiscal year 1992.

(3) HCFA will calculate a percentage for each State by dividing the DSH base allotment by the total unadjusted medical assistance expenditures, excluding administrative costs, made under the State plan applicable to Federal fiscal year 1992. On the basis of this percentage, HCFA will classify each State as a "high-DSH" or "low-DSH" State.

(i) If the State's base allotment exceeded 12 percent of its total unadjusted medical assistance expenditures made under the State plan in Federal fiscal year 1992, HCFA will classify the State as a "high-DSH" State.

(ii) If the State's base allotment was 12 percent or less of its total unadjusted medical assistance expenditures made under the State plan in Federal fiscal year 1992, HCFA will classify the State as a "low-DSH" State.
Federal fiscal year 1992, HCFA will classify the State as a “low-DSH” State.

(b) State disproportionate share hospital allotments for Federal fiscal year 1993. (1) For Federal fiscal year 1993, HCFA will calculate a DSH allotment for each low-DSH State that equals the State’s base allotment described under paragraph (a) of this section, increased by State growth, as specified in paragraph (d) of this section.

(2) For high-DSH States, the dollar amount of DSH payments in Federal fiscal year 1993 may not exceed the dollar amount of DSH payments applicable to Federal fiscal year 1992 (that is, the State base allotment).

(c) State disproportionate share hospital allotment for Federal fiscal years 1994 and after. For Federal fiscal years 1994 and after—

(1) For low-DSH States, HCFA will calculate the DSH allotment for each Federal fiscal year by increasing the prior year’s State DSHs allotment by—

(i) State growth, as specified in paragraph (d) of this section; and

(ii) A supplemental amount, if applicable, as described in paragraph (e) of this section.

(2) For high-DSH States, the dollar amount of DSH payments applicable to any Federal fiscal year may not exceed the dollar amount of payments applicable to Federal fiscal year 1992 (that is, the State base allotment). This payment limitation will apply until the Federal fiscal year in which the State’s DSH payments applicable to that Federal fiscal year, expressed as a percentage of the State’s total unadjusted medical assistance expenditures in that Federal fiscal year, equals 12 percent or less. When a high-DSH State’s percentage equals 12 percent or less, the State will be reclassified as a low-DSH State.

(d) State growth. (1) The State growth for a State in a Federal fiscal year is equal to the product of—

(i) The growth factor that is HCFA’s projected percentage increase in the State’s total unadjusted medical assistance expenditures (including administrative costs) relative to the corresponding amount in the previous year; and

(ii) The State’s prior year DSH allotment.

(2) If the growth factor is zero or is negative, the State growth is zero.

(3) If a low-DSH State experiences a level of negative growth to the extent that its previous Federal fiscal year’s DSH allotment would be more than 12 percent of its current Federal fiscal year’s total unadjusted medical assistance expenditures (excluding administrative costs), the low-DSH State’s previous year’s DSH allotment will be reduced to the extent necessary to maintain the individual low-DSH State’s 12-percent limit and that amount will become the low-DSH State’s DSH allotment for the current Federal fiscal year. In no Federal fiscal year will a low-DSH State’s DSH allotment be allowed to exceed its individual State 12-percent limit.

(e) Supplemental amount available for low-DSH States.

(1) A supplemental amount is the State’s share of a pool of money (referred to as a redistribution pool).

(2) HCFA will calculate the redistribution pool for the appropriate Federal fiscal year by subtracting from the projected national DSH expenditure target the following:

(i) The total of the State DSH base allotments for all high-DSH States;

(ii) The total of the previous year’s State DSH allotments for all low-DSH States;

(iii) The State growth amount for all low-DSH States;

(iv) The total amount of additional DSH payment adjustments made in order to meet the minimum payment adjustments required under section 1923(c)(1) of the Act, which are made in accordance with §447.296(b)(5).

(3) HCFA will determine the percent of the redistribution pool for each low-DSH State on the basis of each State’s relative share of the total unadjusted medical assistance expenditures for the Federal fiscal year compared to the total unadjusted medical assistance expenditures for the Federal fiscal year projected to be made by all low-DSH States. The percent of the redistribution pool that each State will receive is equal to the State’s total unadjusted medical assistance expenditures divided by the total unadjusted medical assistance expenditures for all low-DSH States.
§ 447.301 Definitions.

(a) In this section—

(1) Brand name means any registered trade name commonly used to identify a drug.

(2) Estimated acquisition cost means the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers.

(4) HCFA will not provide any low-DSH State a supplemental amount that would result in the State's total DSH allotment exceeding 12 percent of its projected total unadjusted medical assistance expenditures. HCFA will reallocate any supplemental amounts not allocated to States because of this 12-percent limitation to other low-DSH States in accordance with the percentage determined in paragraph (e)(3) of this section.

(5) HCFA will not reallocate to low-DSH States the difference between any State's actual DSH expenditures allocable to a Federal fiscal year and its State DSH allotment allocable to that Federal fiscal year. Thus, any unspent DSH allotment may not be reallocated.

(f) Special provision. Any increases in a State's aggregate disproportionate payments, that are made to meet the minimum payment requirements specified in §447.299(b)(5), may exceed the State base allotment to the extent such increases are made to satisfy the minimum payment requirement. In such cases, HCFA will adjust the State's base allotment in the subsequent Federal fiscal year to include the increased minimum payments.


§ 447.299 Reporting requirements.

(a) Beginning with the first quarter of Federal fiscal year 1993, each State must submit to HCFA the quarterly aggregate amount of its disproportionate payments made to each individual public and private provider, or facility. States' reports must present a complete, accurate, and full disclosure of all of their DSH programs and expenditures.

(b) Each State must report the aggregate information specified under paragraph (a) of this section on a quarterly basis in accordance with procedures established by HCFA.

(c) Each State must maintain, in readily reviewable form, supporting documentation that provides a detailed description of each DSH program, the legal basis of each DSH program, and the amount of DSH payments made to each individual public and private provider or facility each quarter. This information must be made available to Federal reviewers upon request.

(d) If a State fails to comply with the reporting requirements contained in this section, future grant awards will be reduced by the amount of FFP HCFA estimates is attributable to the expenditures made to the disproportionate share hospitals as to which the State has not reported properly, until such time as the State complies with the reporting requirements. Deferrals and/or disallowances of equivalent amounts may also be imposed with respect to quarters for which the State has failed to report properly. Unless otherwise prohibited by law, FFP for those expenditures will be released when the State complies with all reporting requirements.

Subpart F—Payment Methods for Other Institutional and Non-Institutional Services


§ 447.300 Basis and purpose.

In this subpart, §§ 447.302 through 447.334 and 447.361 implement section 1902(a)(30) of the Act, which requires that payments be consistent with efficiency, economy and quality of care. Section 447.371 implements section 1902(a)(13)(F) of the Act, which requires that the State plan provide for payment for rural health clinic services in accordance with regulations prescribed by the Secretary.


§ 447.301 Definitions.

For the purposes of this subpart—

(a) Brand name means any registered trade name commonly used to identify a drug.

(b) Estimated acquisition cost means the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers.
§ 447.302 Multiple source drug means a drug marketed or sold by two or more manufacturers or labelers or a drug marketed or sold by the same manufacturer or labeler under two or more different proprietary names or both under a proprietary name and without such a name.

[52 FR 28657, July 31, 1987]

§ 447.303 State plan requirements.
A State plan must provide that the requirements of this subpart are met.

[46 FR 48560, Oct. 1, 1981]

§ 447.304 Adherence to upper limits; FFP.
(a) The Medicaid agency must not pay more than the upper limits described in this subpart.
(b) In the case of payments made under the plan for deductibles and co-insurance payable on an assigned Medicare claim for noninstitutional services, those payments may be made only up to the reasonable charge under Medicare.
(c) FFP is available in expenditures for payments for services that do not exceed the upper limits.

NOTE: The Secretary may waive any limitation on reimbursement imposed by Subpart D of this part for experiments conducted under section 402 of Pub. L. 90-428, Incentives for Economy Experimentation, as amended by section 222(b) of Pub. L. 92-603, and under section 447.332. If a specific limit has not been established under §447.332, then the rule for “other drugs” set forth in paragraph (b) applies.

(b) Other drugs. The agency payments for brand name drugs certified in accordance with paragraph (c) of this section and drugs other than multiple source drugs for which a specific limit has been established under §447.332 must not exceed in the aggregate, payment levels that the agency has determined by applying the lower of the—
(1) Estimated acquisition costs plus reasonable dispensing fees established by the agency; or
(2) Providers’ usual and customary charges to the general public.
(c) Certification of brand name drugs. The upper limit for payment for multiple source drugs for which a specific limit has been established under §447.332 does not apply if a physician certifies in his or her own handwriting that a specific brand is medically necessary for a particular recipient.
(2) The agency must decide what certification form and procedure are used.
(3) A checkoff box on a form is not acceptable but a notation like “brand necessary” is allowable.

OUTPATIENT HOSPITAL AND CLINIC SERVICES

§ 447.321 Outpatient hospital services and clinic services: Upper limits of payment.
(a) General rule. FFP is not available for any payment that exceeds the amount that would be payable to providers under comparable circumstances under Medicare.
(b) Application of the rule. Payments by an agency for outpatient hospital services may not exceed the total payments received by all providers from beneficiaries and carriers or intermediaries for providing comparable services under comparable circumstances under Medicare.

[52 FR 28148, July 28, 1987]

OTHER INPATIENT AND OUTPATIENT FACILITIES

§ 447.325 Other inpatient and outpatient facility services: Upper limits of payment.

The agency may pay the customary charges of the provider but must not pay more than the prevailing charges in the locality for comparable services under comparable circumstances.

DRUGS

§ 447.331 Drugs: Aggregate upper limits of payment.
(a) Multiple source drugs. Except for brand name drugs that are certified in accordance with paragraph (c) of this section, the agency payment for multiple source drugs must not exceed the amount that would result from the application of the specific limits established in accordance with §447.332. If a specific limit has not been established under §447.332, then the rule for “other drugs” set forth in paragraph (b) applies.
(b) Other drugs. The agency payments for brand name drugs certified in accordance with paragraph (c) of this section and drugs other than multiple source drugs for which a specific limit has been established under §447.332 must not exceed in the aggregate, payment levels that the agency has determined by applying the lower of the—
(1) Estimated acquisition costs plus reasonable dispensing fees established by the agency; or
(2) Providers’ usual and customary charges to the general public.
(c) Certification of brand name drugs. The upper limit for payment for multiple source drugs for which a specific limit has been established under §447.332 does not apply if a physician certifies in his or her own handwriting that a specific brand is medically necessary for a particular recipient.
(2) The agency must decide what certification form and procedure are used.
(3) A checkoff box on a form is not acceptable but a notation like “brand necessary” is allowable.
(4) The agency may allow providers to keep the certification forms if the forms will be available for inspection by the agency or HHS.

§ 447.332 Upper limits for multiple source drugs.

(a) Establishment and issuance of a listing. (1) HCFA will establish listings that identify and set upper limits for multiple source drugs that meet the following requirements:

(i) All of the formulations of the drug approved by the Food and Drug Administration (FDA) have been evaluated as therapeutically equivalent in the most current edition of their publication, Approved Drug Products with Therapeutic Equivalence Evaluations (including supplements or in successor publications) based on all listings contained in current editions (or updates) of published compendia of cost information for drugs available for sale nationally.

(ii) At least three suppliers list the drug (which has been classified by the FDA as category "A" in its publication, Approved Drug Products with Therapeutic Equivalence Evaluations, including supplements or in successor publications) based on all listings contained in current editions (or updates) of published compendia of cost information for drugs available for sale nationally.

(2) HCFA publishes the list of multiple source drugs for which upper limits have been established and any revisions to the list in Medicaid program instructions.

(3) HCFA will identify the sources used in compiling these lists.

(b) Specific upper limits. The agency's payments for multiple source drugs identified and listed in accordance with paragraph (a) of this section must not exceed, in the aggregate, payment levels determined by applying for each drug entity a reasonable dispensing fee established by the agency plus an amount established by HCFA that is equal to 150 percent of the published price for the least costly therapeutic equivalent (using all available national compendia) that can be purchased by pharmacists in quantities of 100 tablets or capsules (or, if the drug is not commonly available in quantities of 100, the package size commonly listed) or, in the case of liquids, the commonly listed size.

§ 447.333 State plan requirements, findings and assurances.

(a) State plan. The State plan must describe comprehensively the agency's payment methodology for prescription drugs.

(b) Findings and assurances. Upon proposing significant State plan changes in payments for prescription drugs, and at least annually for multiple source drugs and triennially for all other drugs, the agency must make the following findings and assurances:

(1) Findings. The agency must make the following separate and distinct findings:

(i) In the aggregate, its Medicaid expenditures for multiple source drugs, identified and listed in accordance with §447.332(a) of this subpart, are in accordance with the upper limits specified in §447.332(b) of this subpart; and

(ii) In the aggregate, its Medicaid expenditures for all other drugs are in accordance with §447.331 of this subpart.

(2) Assurances. The agency must make assurances satisfactory to HCFA that the requirements set forth in §§447.331 and 447.332 concerning upper limits and in paragraph (b)(1) of this section concerning agency findings are met.

(c) Recordkeeping. The agency must maintain and make available to HCFA, upon request, data, mathematical or statistical computations, comparisons, and any other pertinent records to support its findings and assurances.

§ 447.334 Upper limits for drugs furnished as part of services.

The upper limits for payment for prescribed drugs in this subpart also apply to payment for drugs provided as part of skilled nursing facility services and intermediate care facility services and under prepaid capitation arrangements.
§ 447.342 [Reserved]

Prepaid Capitation Plans

§ 447.342 Upper limits of payment: Risk contract.

Under a risk contract, Medicaid payments to the contractor, for a defined scope of services to be furnished to a defined number of recipients, may not exceed the cost to the agency of providing those same services on a fee-for-service basis, to an actuarially equivalent nonenrolled population group.

[48 FR 54025, Nov. 30, 1983]


Under a nonrisk contract, Medicaid payments to the contractor may not exceed—
(a) What Medicaid would have paid, on a fee-for-service basis, for the services actually furnished to recipients: plus
(b) The net savings of administrative costs the Medicaid agency achieves by contracting with the plan instead of purchasing the services on a fee-for-service basis.

[48 FR 54025, Nov. 30, 1983]

Rural Health Clinic Services

§ 447.371 Services furnished by rural health clinics.

The agency must pay for rural health clinic services, as defined in §440.20(b) of this subchapter, and for other ambulatory services furnished by a rural health clinic, as defined in §440.20(c) of this subchapter, as follows:
(a) For provider clinics, the agency must pay the reasonable cost of rural health clinic services and other ambulatory services on the basis of the cost reimbursement principles in part 413 of this chapter. For purposes of this section, a provider clinic is an integral part of a hospital, skilled nursing facility, or home health agency that is participating in Medicare and is licensed, governed, and supervised with other departments of the facility.
(b) For clinics other than provider clinics that do not offer any ambulatory services other than rural health clinic services, the agency must pay for rural health clinic services at the reasonable cost rate per visit determined by a Medicare carrier under §§405.2426 through 405.2429 of this chapter.
(c) For clinics other than provider clinics that do offer ambulatory services other than rural health clinic services, the agency must pay for the other ambulatory services by one of the following methods:
(1) The agency may pay for other ambulatory services and rural health clinic services at a single rate per visit that is based on the cost of all services furnished by the clinic. The rate must be determined by a Medicare carrier under §§405.2426 through 405.2429 of this chapter.
(2) The agency may pay for other ambulatory services at a rate set for each service by the agency. The rate must not exceed the upper limits in this subpart. The agency must pay for rural health clinic services at the Medicare reimbursement rate per visit, as specified in §405.2426 of this chapter.
(3) The agency may pay for dental services at a rate per visit that is based on the cost of dental services furnished by the clinic. The rate must be determined by a Medicare carrier under §§405.2426 through 405.2429 of this chapter.
(d) For purposes of paragraph (c) (1) and (3) of this section, “visit” means a face-to-face encounter between a clinic patient and any health professional whose services are reimbursed under the State plan. 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 the patient, after the first encounter, suffers illness or injury requiring additional diagnosis or treatment.


PART 455—PROGRAM INTEGRITY: MEDICAID

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455.106 Disclosure by providers: Information on persons convicted of crimes.

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

Source: 43 FR 45262, Sept. 29, 1978, unless otherwise noted.

§ 455.2 Definitions.

As used in this part unless the context indicates otherwise—

Abuse means provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to the Medicaid program, or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. It also includes recipient practices that result in unnecessary cost to the Medicaid program.

Conviction or Convicted means that a judgment of conviction has been entered by a Federal, State, or local court, regardless of whether an appeal from that judgment is pending.

Exclusion means that items or services furnished by a specific provider who has defrauded or abused the Medicaid program will not be reimbursed under Medicaid.

Fraud means an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable Federal or State law.

Furnished refers to items and services provided directly by, or under the direct supervision of, or ordered by, a practitioner or other individual (either as an employee or in his or her own capacity), a provider, or other supplier of services. (For purposes of denial of reimbursement within this part, it does not refer to services ordered by one party but billed for and provided by or under the supervision of another.) Practitioner means a physician or other individual licensed under State law to practice his or her profession.

Suspension means that items or services furnished by a specified provider who has been convicted of a program-related offense in a Federal, State, or
§ 455.3 Other applicable regulations.

Part 1002 of this title sets forth the following:
(a) State plan requirements for excluding providers for fraud and abuse, and suspending practitioners convicted of program-related crimes.
(b) The limitations on FFP for services furnished by excluded providers or suspended practitioners.
(c) The requirements and procedures for reinstatement after exclusion or suspension.
(d) Requirements for the establishment and operation of State Medicaid fraud control units and the rates of FFP for their fraud control activities.

§ 455.12 State plan requirement.

A State plan must meet the requirements of §§ 455.13 through 455.23.

§ 455.13 Methods for identification, investigation, and referral.

The Medicaid agency must have—
(a) Methods and criteria for identifying suspected fraud cases;
(b) Methods for investigating these cases that—
(1) Do not infringe on the legal rights of persons involved; and
(2) Afford due process of law; and
(c) Procedures, developed in cooperation with State legal authorities, for referring suspected fraud cases to law enforcement officials.

§ 455.14 Preliminary investigation.

If the agency receives a complaint of Medicaid fraud or abuse from any source or identifies any questionable practices, it must conduct a preliminary investigation to determine whether there is sufficient basis to warrant a full investigation.

§ 455.15 Full investigation.

If the findings of a preliminary investigation give the agency reason to believe that an incident of fraud or abuse has occurred in the Medicaid program, the agency must take the following action, as appropriate:
(a) If a provider is suspected of fraud or abuse, the agency must—
(1) In States with a State Medicaid fraud control unit certified under subpart C of part 1002 of this title, refer the case to the unit under the terms of its agreement with the unit entered into under §1002.309 of this title; or
(2) In States with no certified Medicaid fraud control unit, or in cases where no referral to the State Medicaid fraud control unit is required under paragraph (a)(1) of this section, conduct a full investigation or refer the case to the appropriate law enforcement agency.
(b) If there is reason to believe that a recipient has defrauded the Medicaid program, the agency must refer the case to an appropriate law enforcement agency.
(c) If there is reason to believe that a recipient has abused the Medicaid program, the agency must conduct a full investigation of the abuse.

§ 455.16 Resolution of full investigation.

A full investigation must continue until—
(a) Appropriate legal action is initiated;
(b) The case is closed or dropped because of insufficient evidence to support the allegations of fraud or abuse; or
(c) The matter is resolved between the agency and the provider or recipient. This resolution may include but is not limited to—
(1) Sending a warning letter to the provider or recipient, giving notice that continuation of the activity in question will result in further action;
§ 455.21 Cooperation with State Medicaid fraud control units.

In a State with a Medicaid fraud control unit established and certified under subpart C of this part,
(a) The agency must—
(1) Refer all cases of suspected provider fraud to the unit;
(2) If the unit determines that it may be useful in carrying out the unit's responsibilities, promptly comply with a request from the unit for—
(i) Access to, and free copies of, any records or information kept by the agency or its contractors;
(ii) Computerized data stored by the agency or its contractors. These data must be supplied without charge and in the form requested by the unit; and
(iii) Access to any information kept by providers to which the agency is authorized access by section 1902(a)(27) of the Act and §431.107 of this subchapter.
In using this information, the unit
must protect the privacy rights of recipients; and

(3) On referral from the unit, initiate any available administrative or judicial action to recover improper payments to a provider.

(b) The agency need not comply with specific requirements under this subpart that are the same as the responsibilities placed on the unit under subpart D of this part.

§ 455.23 Withholding of payments in cases of fraud or willful misrepresentation.

(a) Basis for withholding. The State Medicaid agency may withhold Medicaid payments, in whole or in part, to a provider upon receipt of reliable evidence that the circumstances giving rise to the need for a withholding of payments involve fraud or willful misrepresentation under the Medicaid program. The State Medicaid agency may withhold payments without first notifying the provider of its intention to withhold such payments. A provider may request, and must be granted, administrative review where State law so requires.

(b) Notice of withholding. The State agency must send notice of its withholding of program payments within 5 days of taking such action. The notice must set forth the general allegations as to the nature of the withholding action, but need not disclose any specific information concerning its ongoing investigation. The notice must:

(1) State that payments are being withheld in accordance with this provision;

(2) State that the withholding is for a temporary period, as stated in paragraph (c) of this section, and cite the circumstances under which withholding will be terminated; and

(3) Specify, when appropriate, to which type or types of Medicaid claims withholding is effective; and

(4) Inform the provider of the right to submit written evidence for consideration by the agency.

(c) Duration of withholding. All withholding of payment actions under this section will be temporary and will not continue after:

(1) The agency or the prosecuting authorities determine that there is insufficient evidence of fraud or willful misrepresentation by the provider; or

(2) Legal proceedings related to the provider’s alleged fraud or willful misrepresentation are completed.

[52 FR 48817, Dec. 28, 1987]

Subpart B—Disclosure of Information by Providers and Fiscal Agents

SOURCE: 44 FR 41644, July 17, 1979, unless otherwise noted.

§ 455.100 Purpose.

This subpart implements sections 1124, 1126, 1902(a)(38), 1903(i)(2), and 1903(n) of the Social Security Act. It sets forth State plan requirements regarding—

(a) Disclosure by providers and fiscal agents of ownership and control information; and

(b) Disclosure of information on a provider’s owners and other persons convicted of criminal offenses against Medicare, Medicaid, or the title XX services program.

The subpart also specifies conditions under which the Administrator will deny Federal financial participation for services furnished by providers or fiscal agents who fail to comply with the disclosure requirements.

§ 455.101 Definitions.

Agent means any person who has been delegated the authority to obligate or act on behalf of a provider.

Disclosing entity means a Medicaid provider (other than an individual practitioner or group of practitioners), or a fiscal agent.

Other disclosing entity means any other Medicaid disclosing entity and any entity that does not participate in Medicaid, but is required to disclose certain ownership and control information because of participation in any of the programs established under title V, XVIII, or XX of the Act. This includes:

(a) Any hospital, skilled nursing facility, home health agency, independent clinical laboratory, renal disease facility, rural health clinic, or health maintenance organization that participates in Medicare (title XVIII);
(b) Any Medicare intermediary or carrier; and
(c) Any entity (other than an individual practitioner or group of practitioners) that furnishes, or arranges for the furnishing of, health-related services for which it claims payment under any plan or program established under title V or title XX of the Act.

Fiscal agent means a contractor that processes or pays vendor claims on behalf of the Medicaid agency.

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 an ownership interest in an entity that has an ownership interest in the disclosing entity. This 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 an 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—
(a) Has an ownership interest totaling 5 percent or more in a disclosing entity;
(b) Has an indirect ownership interest equal to 5 percent or more in a disclosing entity;
(c) Has a combination of direct and indirect ownership interests equal to 5 percent or more in a disclosing entity;
(d) 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;
(e) Is an officer or director of a disclosing entity that is organized as a corporation; or
(f) Is a partner in a disclosing entity that is organized as a partnership.

Significant business transaction means any business transaction or series of transactions that, during any one fiscal year, exceed the lesser of $25,000 and 5 percent of a provider's total operating expenses.

Subcontractor means—
(a) 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
(b) An individual, agency, or organization with which a fiscal agent 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 Medicaid agreement.

Supplier means an individual, agency, or organization from which a provider purchases goods and services used in carrying out its responsibilities under Medicaid (e.g., a commercial laundry, a manufacturer of hospital beds, or a pharmaceutical firm).

Wholly owned supplier means a supplier whose total ownership interest is held by a provider or by one person, persons, or other entity with an ownership or control interest in a provider.

[44 FR 41644, July 17, 1979, as amended at 51 FR 34788, Sept. 30, 1986]

§ 455.102 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 which owns 80 percent of the stock 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 which 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 percentage of ownership, mortgage, deed of
trust, note, or other obligation, the percentage of interest owned in the 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.

§ 455.103 State plan requirement.
A State plan must provide that the requirements of §§ 455.104 through 455.106 are met.

§ 455.104 Disclosure by providers and fiscal agents: Information on ownership and control.
(a) Information that must be disclosed. The Medicaid agency must require each disclosing entity to disclose the following information in accordance with paragraph (b) of this section:
(1) The name and address of each person with an ownership or control interest in the disclosing entity or in any subcontractor in which the disclosing entity has direct or indirect ownership of 5 percent or more;
(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 a person with an ownership or control interest in the disclosing entity also has an ownership or control interest. This requirement applies to the extent that the disclosing entity has obtained this information by requesting it in writing from the person. The disclosing entity must—
(i) Keep copies of all these requests and the responses to them;
(ii) Make them available to the Secretary or the Medicaid agency upon request; and
(iii) Advise the Medicaid agency when there is no response to a request.
(b) Time and manner of disclosure. (1) Any disclosing entity that is subject to periodic survey and certification of its compliance with Medicaid 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 must promptly furnish the information to the Secretary and the Medicaid agency.
(2) Any disclosing entity that is not subject to periodic survey and certification and has not supplied the information specified in paragraph (a) of this section to the Secretary within the prior 12-month period, must submit the information to the Medicaid agency before entering into a contract or agreement to participate in the program. The Medicaid agency must promptly furnish the information to the Secretary.
(3) Updated information must be furnished to the Secretary or the State survey or Medicaid agency at intervals between recertification or contract renewals, within 35 days of a written request.
(c) Provider agreements and fiscal agent contracts. A Medicaid agency shall not approve a provider agreement or a contract with a fiscal agent, and must terminate an existing agreement or contract, if the provider or fiscal agent fails to disclose ownership or control information as required by this section.
(d) Denial of Federal financial participation (FFP). FFP is not available in payments made to a provider or fiscal agent that fails to disclose ownership or control information as required by this section.

§ 455.105 Disclosure by providers: Information related to business transactions.
(a) Provider agreements. A Medicaid agency must enter into an agreement with each provider under which the provider agrees to furnish to it or to the Secretary on request, information related to business transactions in accordance with paragraph (b) of this section.
(b) Information that must be submitted. A provider must submit, within 35 days of the date on a request by the Secretary or the Medicaid agency, full and complete information about—
(1) The ownership of any subcontractor with whom the provider has had business transactions totaling more
than $25,000 during the 12-month period ending on the date of the request; and
(2) Any significant business transactions between the provider and any wholly owned supplier, or between the provider and any subcontractor, during the 3-year period ending on the date of the request.
(c) Denial of Federal financial participation (FFP). (1) FFP is not available in expenditures for services furnished by providers who fail to comply with a request made by the Secretary or the Medicaid agency under paragraph (b) of this section or under §420.205 of this chapter (Medicare requirements for disclosure).
(2) FFP will be denied in expenditures for services furnished during the period beginning on the day following the date the information was due to the Secretary or the Medicaid agency and ending on the day before the date on which the information was supplied.
§455.106 Disclosure by providers: Information on persons convicted of crimes.
(a) Information that must be disclosed. Before the Medicaid agency enters into or renews a provider agreement, or at any time upon written request by the Medicaid agency, the provider must disclose to the Medicaid agency the identity of any person who:
(1) Has ownership or control interest in the provider, or is an agent or managing employee of the provider; and
(2) Has been convicted of a criminal offense related to that person's involvement in any program under Medicare, Medicaid, or the title XX services program since the inception of those programs.
(b) Notification to Inspector General. (1) The Medicaid agency must notify the Inspector General of the Department of any disclosures made under paragraph (a) of this section within 20 working days from the date it receives the information.
(2) The agency must also promptly notify the Inspector General of the Department of any action it takes on the provider's application for participation in the program.
(c) Denial of termination of provider participation. (1) The Medicaid agency may refuse to enter into or renew an agreement with a provider if any person who has an ownership or control interest in the provider, or who is an agent or managing employee of the provider, has been convicted of a criminal offense related to that person's involvement in any program established under Medicare, Medicaid or the title XX Services Program.
(2) The Medicaid agency may refuse to enter into or may terminate a provider agreement if it determines that the provider did not fully and accurately make any disclosure required under paragraph (a) of this section.
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Subpart A—General Provisions

§ 456.1 Basis and purpose of part.

(a) This part prescribes requirements concerning control of the utilization of Medicaid services including—

(1) A statewide program of control of the utilization of all Medicaid services; and

(2) Specific requirements for the control of the utilization of Medicaid services in institutions.

(b) The requirements in this part are based on the following sections of the Act. Table 1 shows the relationship between these sections of the Act and the requirements in this part.

(1) Methods and procedures to safeguard against unnecessary utilization of care and services. Section 1902(a)(30) requires that the State plan provide methods and procedures to safeguard against unnecessary utilization of care and services.

(2) Penalty for failure to have an effective program to control utilization of institutional services. Section 1903(g)(1) provides for a reduction in the amount of Federal Medicaid funds paid to a State for long-stay inpatient services if the State does not make a showing satisfactory to the Secretary that it has an effective program of control over utilization of those services. This penalty provision applies to inpatient services in hospitals, mental hospitals, and intermediate care facilities (ICF’s). Specific requirements are:

(i) Under section 1903(g)(1)(A), a physician must certify at admission, and a physician (or physician assistant or nurse practitioner under the supervision of a physician) must periodically recertify, the individual’s need for inpatient care.

(ii) Under section 1903(g)(1)(B), services must be furnished under a plan established and periodically evaluated by a physician.

(iii) Under section 1903(g)(1)(C), the State must have in effect a continuous program of review of utilization of care and services under section 1902(a)(30) whereby each admission is reviewed or screened in accordance with criteria established by medical and other professional personnel.

(iv) Under section 1903(g)(1)(D), the State must have an effective program under sections 1902(a) (26) and (31) of review of care in intermediate care facilities and mental hospitals. This must include evaluation at least annually of the professional management of each case.

(3) Medical review in mental hospitals. Section 1902(a)(26)(A) requires that the plan provide for a program of medical review that includes a medical evaluation of each individual’s need for care in a mental hospital, a plan of care, and, where applicable, a plan of rehabilitation.

(4) Independent professional review in intermediate care facilities. Section 1902(a)(31)(A) requires that the plan provide for a program of independent professional review that includes a medical evaluation of each individual’s need for intermediate care and a written plan of service.

(5) Inspection of care and services in institutions. Sections 1902(a)(26) (B) and (C) and 1902(a)(31) (B) and (C) require that the plan provide for periodic inspections and reports, by a team of professional persons, of the care being provided to each recipient in institutions for mental diseases (IMD’s), and ICF’s participating in Medicaid.

(6) Denial of FFP for failure to have specified utilization review procedures. Section 1903(i)(4) provides that FFP is not available in a State’s expenditures for hospital or mental hospital services unless the institution has in effect a utilization review plan that meets Medicare requirements. However, the Secretary may waive this requirement if the Medicaid agency demonstrates to
his satisfaction that it has utilization review procedures superior in effectiveness to the Medicare procedures.

(7) State health agency guidance on quality and appropriateness of care and services. Section 1902(a)(33)(A) requires that the plan provide that the State health or other appropriate medical agency establish a plan for review, by professional health personnel, of the appropriateness and quality of Medicaid services to provide guidance to the Medicaid agency and the State licensing agency in administering the Medicaid program.

(8) Drug use review program. Section 1927(g) of the Act provides that, for payment to be made under section 1903 of the Act for covered outpatient drugs, the State must have in operation, by not later than January 1, 1993, a drug use review (DUR) program. It also requires that each State provide, either directly or through a contract with a private organization, for the establishment of a DUR Board.

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§ 456.2 State plan requirements.

(a) A State plan must provide that the requirements of this part are met.

(b) These requirements may be met by the agency by:

(1) Assuming direct responsibility for assuring that the requirements of this part are met; or

(2) Deeming of medical and utilization review requirements if the agency contracts with a PRO to perform that review, which in the case of inpatient acute care review will also serve as the initial determination for PRO medical necessity and appropriateness review for patients who are dually entitled to benefits under Medicare and Medicaid.

(c) In accordance with §431.15 of this subchapter, FFP will be available for expenses incurred in meeting the requirements of this part.

§ 456.3 Statewide surveillance and utilization control program.

The Medicaid agency must implement a statewide surveillance and utilization control program that—

(a) Safeguards against unnecessary or inappropriate use of Medicaid services and against excess payments;

(b) Assesses the quality of those services;

(c) Provides for the control of the utilization of all services provided under the plan in accordance with subpart B of this part; and
(d) Provides for the control of the utilization of inpatient services in accordance with subparts C through I of this part.

§ 456.4 Responsibility for monitoring the utilization control program.

(a) The agency must—
(1) Monitor the statewide utilization control program;
(2) Take all necessary corrective action to ensure the effectiveness of the program;
(3) Establish methods and procedures to implement this section;
(4) Keep copies of these methods and procedures on file; and
(5) Give copies of these methods and procedures to all staff involved in carrying out the utilization control program.

§ 456.5 Evaluation criteria.

The agency must establish and use written criteria for evaluating the appropriateness and quality of Medicaid services. This section does not apply to services in hospitals and mental hospitals. For these facilities, see the following sections: §§ 456.122 and 456.132 of subpart C; and § 456.232 of subpart D.


§ 456.6 Review by State medical agency of appropriateness and quality of services.

(a) The Medicaid agency must have an agreement with the State health agency or other appropriate State medical agency, under which the health or medical agency is responsible for establishing a plan for the review by professional health personnel of the appropriateness and quality of Medicaid services.

(b) The purpose of this review plan is to provide guidance to the Medicaid agency in the administration of the State plan and, where applicable, to the State licensing agency described in § 431.610.
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(b) Exclude services provided in mental hospitals. Utilization control requirements for mental hospitals appear in subpart D.

Medical care appraisal norms or norms means numerical or statistical measures of usually observed performance.

Medical care criteria or criteria means predetermined elements against which aspects of the quality of a medical service may be compared. These criteria are developed by health professionals relying on their expertise and the professional health care literature.


CERTIFICATION OF NEED FOR CARE

§ 456.60 Certification and recertification of need for inpatient care.

(a) Certification. (1) A physician must certify for each applicant or recipient that inpatient services in a hospital are or were needed.

(2) The certification must be made at the time of admission or, if an individual applies for assistance while in a hospital, before the Medicaid agency authorizes payment.

(b) Recertification. (1) A physician, or physician assistant or nurse practitioner (as defined in §491.2 of this chapter) acting within the scope of practice as defined by State law and under the supervision of a physician, must recertify for each applicant or recipient that inpatient services in a hospital are needed.

(2) Recertifications must be made at least every 60 days after certification.

[46 FR 48561, Oct. 1, 1981]

PLAN OF CARE

§ 456.80 Individual written plan of care.

(a) Before admission to a hospital or before authorization for payment, a physician and other personnel involved in the care of the individual must establish a written plan of care for each applicant or recipient.

(b) The plan of care must include—

1) Diagnoses, symptoms, complaints, and complications indicating the need for admission;

2) A description of the functional level of the individual;

3) Any orders for—

(i) Medications;

(ii) Treatments;

(iii) Restorative and rehabilitative services;

(iv) Activities;

(v) Social services;

(vi) Diet;

4) Plans for continuing care, as appropriate; and

5) Plans for discharge, as appropriate.

(c) Orders and activities must be developed in accordance with physician's instructions.

(d) Orders and activities must be reviewed and revised as appropriate by all personnel involved in the care of an individual.

(e) A physician and other personnel involved in the recipient's case must review each plan of care at least every 60 days.

UTILIZATION REVIEW (UR) PLAN: GENERAL REQUIREMENT

§ 456.100 Scope.

Sections 456.101 through 456.145 of this subpart prescribe requirements for a written utilization review (UR) plan for each hospital providing Medicaid services. Sections 456.105 and 456.106 prescribe administrative requirements: §§456.111 through 456.113 prescribe informational requirements; §§456.121 through 456.129 prescribe requirements for admission review; §§456.131 through 456.137 prescribe requirements for continued stay review; and §§456.141 through 456.145 prescribe requirements for medical care evaluation studies.

§ 456.101 UR plan required for inpatient hospital services.

(a) A State plan must provide that each hospital furnishing inpatient services under the plan has in effect a written UR plan that provides for review of each recipient's need for the services that the hospital furnishes him.

(b) Each written hospital UR plan must meet the requirements under §§456.101 through 456.145.

UR PLAN: ADMINISTRATIVE REQUIREMENTS

§ 456.105 UR committee required.

The UR plan must—

§ 456.106 Organization and composition of UR committee; disqualification from UR committee membership.

(a) For the purpose of this subpart, "UR committee" includes any group organized under paragraphs (b) and (c) of this section.

(b) The UR committee must be composed of two or more physicians, and assisted by other professional personnel.

(c) The UR committee must be constituted as—

(1) A committee of the hospital staff;

(2) A group outside the hospital staff, established by the local medical or osteopathic society and at least some of the hospitals and SNFs in the locality;

(3) A group capable of performing utilization review, established and organized in a manner approved by the Secretary.

(d) The UR committee may not include any individual who—

(1) Is directly responsible for the care of the patient whose care is being reviewed; or

(2) Has a financial interest in any hospital.

§ 456.112 Records and reports.

The UR plan must describe—

(a) The types of records that are kept by the committee; and

(b) The type and frequency of committee reports and arrangements for their distribution to appropriate individuals.

§ 456.113 Confidentiality.

The UR plan must provide that the identities of individual recipients in all UR records and reports are kept confidential.

§ 456.121 Admission review required.

The UR plan must provide for a review of each recipient's admission to the hospital to decide whether it is needed, in accordance with the requirements of §§ 456.122 through 456.129.

§ 456.122 Evaluation criteria for admission review.

The UR plan must provide that—

(a) The committee develops written medical care criteria to assess the need for admission; and

(b) The committee develops more extensive written criteria for cases that its experience shows are—

(1) Associated with high costs.

1 The Department was enjoined in 1975 in the case of American Medical Assn. et al. v. Weinberger, 395 F. Supp. 515 (N.D. Ill., 1975), aff'd, 522 F.2d 921 (7th cir., 1975) from implementing the admission review requirements contained in §§ 456.121-456.127. This case was dismissed on the condition that these requirements be revised. They are presently being revised, and will not be in force until that revision is completed.
§ 456.123 Admission review process.

The UR plan must provide that—

(a) Admission review is conducted by—

(1) The UR committee;

(2) A subgroup of the UR committee; or

(3) A designee of the UR committee;

(b) The committee, subgroup, or designee evaluates the admission against the criteria developed under §456.122 and applies close professional scrutiny to cases selected under §456.129(b);

(c) If the committee, subgroup, or designee finds that the admission is needed, the committee assigns an initial continued stay review date in accordance with §456.128;

(d) If the committee, subgroup, or designee finds that the admission does not meet the criteria, the committee or a subgroup that includes at least one physician reviews the case to decide the need for admission;

(e) If the attending physician does not present additional information or clarification of the need for the admission, the committee or subgroup makes a final decision on the need for the continued stay;

(f) If the attending physician presents additional information or clarification of the need for the admission, the decision of the committee or subgroup is final; and

(g) If the attending physician presents additional information or clarification of the need for the admission, at least two physician members of the committee review the need for the admission. If they find that the admission is not needed, their decision is final.

§ 456.124 Notification of adverse decision.

The UR plan must provide that written notice of any adverse final decision on the need for admission under §456.123(e) through (g) is sent to—

(a) The hospital administrator;

(b) The attending physician;

(c) The Medicaid agency;

(d) The recipient; and

(e) If possible, the next of kin or sponsor.

§ 456.125 Time limits for admission review.

Except as required under §456.127, the UR plan must provide that review of each recipient’s admission to the hospital is conducted—

(a) Within one working day after admission, for an individual who is receiving Medicaid at that time; or

(b) Within one working day after the hospital is notified of the application for Medicaid, for an individual who applies while in the hospital.

§ 456.126 Time limits for final decision and notification of adverse decision.

Except as required under §456.127, the UR plan must provide that the committee makes a final decision on a recipient’s need for admission and gives notice of an adverse final decision—

(a) Within two working days after admission, for an individual who is receiving Medicaid at that time; or

(b) Within two working days after the hospital is notified of the application for Medicaid, for an individual who applies while in the hospital.

§ 456.127 Pre-admission review.

The UR plan must provide for review and final decision prior to admission for certain providers or categories of admissions that the UR committee designates under §456.142(b) (4)(iii) to receive pre-admission review.

§ 456.128 Initial continued stay review date.

The UR plan must provide that—

(a) When a recipient is admitted to the hospital under the admission review requirements of this subpart, the committee assigns a specified date by which the need for his continued stay will be reviewed;

(b) The committee bases its assignment of the initial continued stay review date on—

(1) The methods and criteria required to be described under §456.129;

(2) The individual’s condition; and
§ 456.129 Description of methods and criteria: Initial continued stay review date; close professional scrutiny; length of stay modification.

The UR plan must describe—
(a) The methods and criteria, including norms if used, that the committee uses to assign the initial continued stay review date under §456.128;
(b) The methods that the committee uses to select categories of admission to receive close professional scrutiny under §456.123(b); and
(c) The methods that the committee uses to modify an approved length of stay when the recipient’s condition or treatment schedule changes.

UR PLAN: REVIEW OF NEED FOR CONTINUED STAY

§ 456.131 Continued stay review required.

The UR plan must provide for a review of each recipient’s continued stay in the hospital to decide whether it is needed, in accordance with the requirements of §§456.132 through 456.137.

§ 456.132 Evaluation criteria for continued stay.

The UR plan must provide that—
(a) The committee develops written medical care criteria to assess the need for continued stay;
(b) The committee develops more extensive written criteria for cases that its experience shows are—
(1) Associated with high costs;
(2) Associated with the frequent furnishing of excessive services; or
(3) Attended by physicians whose patterns of care are frequently found to be questionable.

§ 456.133 Subsequent continued stay review dates.

The UR plan must provide that—
(a) The committee assigns subsequent continued stay review dates in accordance with §§456.128 and 456.134(a);
(b) The committee assigns a subsequent review date each time it decides under §456.135 that the continued stay is needed; and
(c) The committee ensures that each continued stay review date it assigns is recorded in the recipient’s record.

§ 456.134 Description of methods and criteria: Subsequent continued stay review dates; length of stay modification.

The UR plan must describe—
(a) The methods and criteria, including norms if used, that the committee uses to assign subsequent continued stay review dates under §456.133; and
(b) The methods that the committee uses to modify an approved length of stay when the recipient’s condition or treatment schedule changes.

§ 456.135 Continued stay review process.

The UR plan must provide that—
(a) Review of continued stay cases is conducted by—
(1) The UR committee;
(2) A subgroup of the UR committee; or
(3) A designee of the UR committee;
(b) The committee, subgroup or designee reviews a recipient’s continued stay on or before the expiration of each assigned continued stay review date;
(c) For each continued stay of a recipient in the hospital, the committee,
subgroup or designee reviews and evaluates the documentation described under §456.111 against the criteria developed under §456.132 and applies close professional scrutiny to cases selected under §456.129(b);
(d) If the committee, subgroup, or designee finds that a recipient’s continued stay in the hospital is needed, the committee assigns a new continued stay review date in accordance with §456.133;
(e) If the committee, subgroup, or designee finds that a continued stay case does not meet the criteria, the committee or a subgroup that includes at least one physician reviews the case to decide the need for continued stay;
(f) If the committee or subgroup making the review under paragraph (e) of this section finds that a continued stay is not needed, it notifies the recipient’s attending physician and gives him an opportunity to present his reviews before it makes a final decision on the need for the continued stay;
(g) If the attending physician does not present additional information or clarification of the need for the continued stay, the decision of the committee or subgroup is final; and
(h) If the attending physician presents additional information or clarification, at least two physician members of the committee review the need for the continued stay. If they find that the recipient no longer needs inpatient hospital services, their decision is final.

§456.136 Notification of adverse decision.
The UR plan must provide that written notice of any adverse final decision on the need for continued stay under §456.135(f) through (h) is sent to—
(a) The hospital administrator;
(b) The attending physician;
(c) The Medicaid agency;
(d) The recipient; and
(e) If possible, the next of kin or sponsor.

§456.137 Time limits for final decision and notification of adverse decision.
The UR plan must provide that—
(a) The committee makes a final decision on a recipient’s need for continued stay and gives notice under §456.136 of an adverse final decision within 2 working days after the assigned continued stay review dates, except as required under paragraph (b) of this section.
(b) If the committee makes an adverse final decision on a recipient’s need for continued stay before the assigned review date, the committee gives notice under §456.136 within 2 working days after the date of the final decision.

UR PLAN: MEDICAL CARE EVALUATION STUDIES

§456.141 Purpose and general description.
(a) The purpose of medical care evaluation studies is to promote the most effective and efficient use of available health facilities and services consistent with patient needs and professionally recognized standards of health care.
(b) Medical care evaluation studies—
(1) Emphasize identification and analysis of patterns of patient care; and
(2) Suggest appropriate changes needed to maintain consistently high quality patient care and effective and efficient use of services.

§456.142 UR plan requirements for medical care evaluation studies.
(a) The UR plan must describe the methods that the committee uses to select and conduct medical care evaluation studies under paragraph (b)(1) of this section.
(b) The UR plan must provide that the UR committee—
(1) Determines the methods to be used in selecting and conducting medical care evaluation studies in the hospital;
(2) Documents for each study—
(i) Its results; and
(ii) How the results have been used to make changes to improve the quality of care and promote more effective and efficient use of facilities and services;
(3) Analyzes its findings for each study; and
(4) Takes action as needed to—
(i) Correct or investigate further any deficiencies or problems in the review
§ 456.143 Process for admissions or continued stay cases;
   (ii) Recommend more effective and efficient hospital care procedures; or
   (iii) Designate certain providers or categories of admissions for review prior to admission.

§ 456.143 Content of medical care evaluation studies.
Each medical care evaluation study must—
   (a) Identify and analyze medical or administrative factors related to the hospital's patient care;
   (b) Include analysis of at least the following:
      (1) Admissions;
      (2) Durations of stay;
      (3) Ancillary services furnished, including drugs and biologicals;
      (4) Professional services performed in the hospital; and
   (c) If indicated, contain recommendations for changes beneficial to patients, staff, the hospital, and the community.

§ 456.144 Data sources for studies.
Data that the committee uses to perform studies must be obtained from one or more of the following sources:
   (a) Medical records or other appropriate hospital data;
   (b) External organizations that compile statistics, design profiles, and produce other comparative data;
   (c) Cooperative endeavors with—
      (1) PROs;  
      (2) Fiscal agents;  
      (3) Other service providers; or
      (4) Other appropriate agencies.

§ 456.145 Number of studies required to be performed.
The hospital must, at least, have one study in progress at any time and complete one study each calendar year.

Subpart D—Utilization Control: Mental Hospitals

§ 456.150 Scope.
This subpart prescribes requirements for control of utilization of inpatient services in mental hospitals, including requirements concerning—
   (a) Certification of need for care;
   (b) Medical evaluation and admission review;
   (c) Plan of care; and
   (d) Utilization review plans.

§ 456.151 Definitions.
As used in this subpart:
Medical care appraisal norms or norms means numerical or statistical measures of usually observed performance.
Medical care criteria or criteria means predetermined elements against which aspects of the quality of a medical service may be compared. These criteria are developed by health professionals relying on their expertise and the professional health care literature.

CERTIFICATION OF NEED FOR CARE

§ 456.160 Certification and recertification of need for inpatient care.
   (a) Certification. (1) A physician must certify for each applicant or recipient that inpatient services in a mental hospital are or were needed.
      (2) The certification must be made at the time of admission or, if an individual applies for assistance while in a mental hospital, before the Medicaid agency authorizes payment.
   (b) Recertification. (1) A physician, or physician assistant or nurse practitioner (as defined in § 491.2 of this chapter) acting within the scope of practice as defined by State law and under the supervision of a physician, must recertify for each applicant or recipient that inpatient services in a mental hospital are needed.
      (2) Recertification must be made at least every 60 days after certification.

MEDICAL, PSYCHIATRIC, AND SOCIAL EVALUATIONS AND ADMISSION REVIEW

§ 456.170 Medical, psychiatric, and social evaluations.
   (a) Before admission to a mental hospital or before authorization for payment, the attending physician or staff physician must make a medical evaluation of each applicant's or recipient's need for care in the hospital; and appropriate professional personnel must make a psychiatric and social evaluation.
(b) Each medical evaluation must include—
(1) Diagnoses;
(2) Summary of present medical findings;
(3) Medical history;
(4) Mental and physical functional capacity;
(5) Prognoses; and
(6) A recommendation by a physician concerning—
   (i) Admission to the mental hospital; or
   (ii) Continued care in the mental hospital for individuals who apply for Medicaid while in the mental hospital.

§ 456.171 Medicaid agency review of need for admission.

Medical and other professional personnel of the Medicaid agency or its designees must evaluate each applicant’s or recipient’s need for admission by reviewing and assessing the evaluations required by § 456.170.

PLAN OF CARE

§ 456.180 Individual written plan of care.

(a) Before admission to a mental hospital or before authorization for payment, the attending physician or staff physician must establish a written plan of care for each applicant or recipient.

(b) The plan of care must include—
(1) Diagnoses, symptoms, complaints, and complications indicating the need for admission;
(2) A description of the functional level of the individual;
(3) Objectives;
(4) Any orders for—
   (i) Medications;
   (ii) Treatments;
   (iii) Restorative and rehabilitative services;
   (iv) Activities;
   (v) Therapies;
   (vi) Social services;
   (vii) Diet; and
   (viii) Special procedures recommended for the health and safety of the patient;
(5) Plans for continuing care, including review and modification to the plan of care; and
(6) Plans for discharge.

(c) The attending or staff physician and other personnel involved in the recipient’s care must review each plan of care at least every 90 days.

§ 456.181 Reports of evaluations and plans of care.

A written report of each evaluation and plan of care must be entered in the applicant’s or recipient’s record—
(a) At the time of admission; or
(b) If the individual is already in the facility, immediately upon completion of the evaluation or plan.

UTILIZATION REVIEW (UR) PLAN:
GENERAL REQUIREMENTS

§ 456.200 Scope.

Sections 456.201 through 456.245 of this subpart prescribe requirements for a written utilization review (UR) plan for each mental hospital providing Medicaid services. Sections 456.205 and 456.206 prescribe administrative requirements; §§ 456.211 through 456.213 prescribe informational requirements; §§ 456.231 through 456.238 prescribe requirements for continued stay review; and §§ 456.241 through 456.245 prescribe requirements for medical care evaluation studies.

§ 456.201 UR plan required for inpatient mental hospital services.

(a) The State plan must provide that each mental hospital furnishing inpatient services under the plan has in effect a written UR plan that provides for review of each recipient’s need for the services that the mental hospital furnishes him.

(b) Each written mental hospital UR plan must meet the requirements under §§ 456.201 through 456.245.

UR PLAN: ADMINISTRATIVE REQUIREMENTS

§ 456.205 UR committee required.

The UR plan must—
(a) Provide for a committee to perform UR required under this subpart;
(b) Describe the organization, composition, and functions of this committee; and
(c) Specify the frequency of meetings of the committee.
§ 456.206 Organization and composition of UR committee; disqualification from UR committee membership.

(a) For the purpose of this subpart, “UR committee” includes any group organized under paragraphs (b) and (c) of this section.

(b) The UR committee must be composed of two or more physicians, one of whom is knowledgeable in the diagnosis and treatment of mental diseases, and assisted by other professional personnel.

(c) The UR committee must be constituted as—

1. A committee of the mental hospital staff;
2. A group outside the mental hospital staff, established by the local medical or osteopathic society and at least some of the hospitals and SNFs in the locality; or
3. A group capable of performing utilization review, established and organized in a manner approved by the Secretary.

(d) The UR committee may not include any individual who—

1. Is directly responsible for the care of patients whose care is being reviewed; or
2. Has a financial interest in any mental hospital.

§ 456.211 Recipient information required for UR.

The UR plan must provide that each recipient’s record includes information needed to perform UR required under this subpart. This information must include, at least, the following:

(a) Identification of the recipient.
(b) The name of the recipient’s physician.
(c) Date of admission, and dates of application for and authorization of Medicaid benefits if application is made after admission.
(d) The plan of care required under § 456.172.
(e) Initial and subsequent continued stay review dates described under §§ 456.233 and 456.234.

(f) Reasons and plan for continued stay, if the attending physician believes continued stay is necessary.

(g) Other supporting material that the committee believes appropriate to be included in the record.

§ 456.212 Records and reports.

The UR plan must describe—

(a) The types of records that are kept by the committee; and
(b) The type and frequency of committee reports and arrangements for their distribution to appropriate individuals.

§ 456.213 Confidentiality.

The UR plan must provide that the identities of individual recipients in all UR records and reports are kept confidential.

UR PLAN: REVIEW OF NEED FOR CONTINUED STAY

§ 456.231 Continued stay review required.

The UR plan must provide for a review of each recipient’s continued stay in the mental hospital to decide whether it is needed, in accordance with the requirements of §§ 456.232 through 456.238.

§ 456.232 Evaluation criteria for continued stay.

The UR plan must provide that—

(a) The committee develops written medical care criteria to assess the need for continued stay.
(b) The committee develops more extensive written criteria for cases that its experience shows are—

1. Associated with high costs;
2. Associated with the frequent furnishing of excessive services; or
3. Attended by physicians whose patterns of care are frequently found to be questionable.

§ 456.233 Initial continued stay review date.

The UR plan must provide that—

(a) When a recipient is admitted to the mental hospital under admission review requirements of this subpart, the committee assigns a specified date by which the need for his continued stay will be reviewed;
§ 456.236 Continued stay review process.

The UR plan must provide that—
(a) Review of continued stay cases is conducted by—
(1) The UR committee;
(2) A subgroup of the UR committee; or
(3) A designee of the UR committee;
(b) The committee, subgroup or designee reviews a recipient’s continued stay on or before the expiration of each assigned continued stay review date;
(c) For each continued stay of a recipient in the mental hospital, the committee, subgroup or designee reviews and evaluates the documentation described under §456.211 against the criteria developed under §456.232 and applies close professional scrutiny to cases described under §456.232(b).
(d) If the committee, subgroup or designee finds that a recipient’s continued stay in the mental hospital is needed, the committee assigns a new continued stay review date in accordance with §456.234;
(e) If the committee, subgroup or designee finds that a continued stay case does not meet the criteria, the committee or a subgroup that includes at least one physician reviews the case to decide the need for continued stay;
(f) If the committee or subgroup making the review under paragraph (e) of this section finds that a continued stay is not needed, it notifies the recipient’s attending or staff physician and gives him an opportunity to present his views before it makes a...
§ 456.237 Notification of adverse decision.

The UR plan must provide that written notice of any adverse final decision on the need for continued stay under § 456.236(f) through (h) is sent to—
(a) The hospital administrator;
(b) The attending or staff physician;
(c) The Medicaid agency;
(d) The recipient; and
(e) If possible, the next of kin or sponsor.

§ 456.238 Time limits for final decision and notification of adverse decision.

The UR plan must provide that—
(a) The committee makes a final decision on a recipient's need for continued stay and gives notice under § 456.237 of an adverse decision within 2 working days after the assigned continued stay review date, except as required under paragraph (b) of this section.
(b) If the committee makes an adverse final decision on a recipient's need for continued stay before the assigned review date, the committee gives notice under § 456.237 within 2 working days after the date of the final decision.

UR PLAN: MEDICAL CARE EVALUATION STUDIES

§ 456.241 Purpose and general description.

(a) The purpose of medical care evaluation studies is to promote the most effective and efficient use of available health facilities and services consistent with patient needs and professionally recognized standards of health care.
(b) Medical care evaluation studies—
(1) Emphasize identification and analysis of patterns of patient care; and
(2) Suggest appropriate changes needed to maintain consistently high quality patient care and effective and efficient use of services.

§ 456.242 UR plan requirements for medical care evaluation studies.

(a) The UR plan must describe the methods that the committee uses to select and conduct medical care evaluation studies under paragraph (b)(1) of this section.
(b) The UR plan must provide that the UR committee—
(1) Determines the methods to be used in selecting and conducting medical care evaluation studies in the mental hospital;
(2) Documents for each study—
(i) Its results; and
(ii) How the results have been used to make changes to improve the quality of care and promote more effective and efficient use of facilities and services;
(3) Analyzes its findings for each study; and
(4) Takes action as needed to—
(i) Correct or investigate further any deficiencies or problems in the review process; or
(ii) Recommend more effective and efficient hospital care procedures.

§ 456.243 Content of medical care evaluation studies.

Each medical care evaluation study must—
(a) Identify and analyze medical or administrative factors related to the mental hospital's patient care;
(b) Include analysis of at least the following:
(1) Admissions.
(2) Durations of stay.
(3) Ancillary services furnished, including drugs and biologicals.
(4) Professional services performed in the hospital; and
(c) If indicated, contain recommendations for change beneficial to patients, staff, the hospital, and the community.
§ 456.244 Data sources for studies.

Data that the committee uses to perform studies must be obtained from one or more of the following sources:

(a) Medical records or other appropriate hospital data.
(b) External organizations that compile statistics, design profiles, and produce other comparative data.
(c) Cooperative endeavors with—
1) PR Os;
2) Fiscal agents;
3) Other service providers; or
4) Other appropriate agencies.


§ 456.245 Number of studies required to be performed.

The mental hospital must, at least, have one study in progress at any time and complete one study each calendar year.

Subpart E—[Reserved]

Subpart F—Utilization Control:

Intermediate Care Facilities

§ 456.350 Scope.

This subpart prescribes requirements for control of utilization of intermediate care facility (ICF) services including requirements concerning—

(a) Certification of need for care;
(b) Medical evaluation and admission review;
(c) Plan of care; and
(d) Utilization review plans.

§ 456.351 Definition.

As used in this subpart:

Intermediate care facility services means those items and services furnished in an intermediate care facility as defined in §§440.140 and 440.150 of this subchapter, but excludes those services if they are provided in Christian Science sanitoria.

CERTIFICATION OF NEED FOR CARE

§ 456.360 Certification and recertification of need for inpatient care.

(a) Certification. (1) A physician must certify for each applicant or recipient that ICF services are or were needed.
(2) The certification must be made at the time of admission or, if an individual applies for assistance while in an ICF, before the Medicaid agency authorizes payment.
(b) Recertification. (1) A physician, or physician assistant or nurse practitioner (as defined in §491.2 of this chapter) acting within the scope of practice as defined by State law and under the supervision of a physician, must recertify for each applicant or recipient that ICF services are needed.
(2) Recertification must be made at least—
(i) Every 12 months after certification in an institution for the mentally retarded or persons with related conditions; and
(ii) Every 60 days after certification in an ICF other than an institution for the mentally retarded or persons with related conditions.


MEDICAL, PSYCHOLOGICAL, AND SOCIAL EVALUATIONS AND ADMISSION REVIEW

§ 456.370 Medical, psychological, and social evaluations.

(a) Before admission to an ICF or before authorization for payment, an interdisciplinary team of health professionals must make a comprehensive medical and social evaluation and, where appropriate, a psychological evaluation of each applicant’s or recipient’s need for care in the ICF.
(b) In an institution for the mentally retarded or persons with related conditions, the team must also make a psychological evaluation of need for care. The psychological evaluation must be made before admission or authorization of payment, but not more than three months before admission.
(c) Each evaluation must include—
(1) Diagnoses;
(2) Summary of present medical, social, and where appropriate, developmental findings;
(3) Medical and social family history;
(4) Mental and physical functional capacity;
(5) Prognoses;
(6) Kinds of services needed;
§ 456.371 Exploration of alternative services.

If the comprehensive evaluation recommends ICF services for an applicant or recipient whose needs could be met by alternative services that are currently unavailable, the facility must enter this fact in the recipient’s record and begin to look for alternative services.

§ 456.372 Medicaid agency review of need for admission.

Medical and other professional personnel of the Medicaid agency or its designees must evaluate each applicant’s or recipient’s need for admission by reviewing and assessing the evaluations required by § 456.370.

§ 456.380 Individual written plan of care.

(a) Before admission to an ICF or before authorization for payment, a physician must establish a written plan of care for each applicant or recipient.

(b) The plan of care must include—

(1) Diagnoses, symptoms, complaints, and complications indicating the need for admission;

(2) A description of the functional level of the individual;

(3) Objectives;

(4) Any orders for—

(i) Medications;

(ii) Treatments;

(iii) Restorative and rehabilitative services;

(iv) Activities;

(v) Therapies;

(vi) Social services;

(vii) Diet; and

(viii) Special procedures designed to meet the objectives of the plan of care;

(5) Plans for continuing care, including review and modification of the plan of care; and

(6) Plans for discharge.

(c) The team must review each plan of care at least every 90 days.

§ 456.381 Reports of evaluations and plans of care.

A written report of each evaluation and plan of care must be entered in the applicant’s or recipient’s record—

(a) At the time of admission; or

(b) If the individual is already in the ICF, immediately upon completion of the evaluation or plan.

§ 456.400 Scope.

Sections 456.401 through 456.438 of this subpart prescribe requirements for a written utilization review (UR) plan for each ICF providing Medicaid services. Sections 456.405 through 456.407 prescribe administrative requirements; §§ 456.411 through 456.413 prescribe informational requirements; and §§ 456.431 through 456.438 prescribe requirements for continued stay review.

§ 456.401 State plan UR requirements and options; UR plan required for intermediate care facility services.

(a) The State plan must provide that—

(1) UR is performed for each ICF that furnishes inpatient services under the plan;

(2) Each ICF has on file a written UR plan that provides for review of each recipient’s need for the services that the ICF furnishes him; and

(3) Each written ICF UR plan meets requirements under §§ 456.401 through 456.438.

(b) The State plan must specify the method used to perform UR, which may be—

(1) Review conducted by the facility;

(2) Direct review in the facility by individuals—

(i) Employed by the medical assistance unit of the Medicaid agency; or

(ii) Under contract to the Medicaid agency; or

(3) Any other method.
§ 456.405 Description of UR review function: How and when.
The UR plan must include a written description of—
(a) How UR is performed in the ICF; and
(b) When UR is performed.

§ 456.406 Description of UR review function: Who performs UR; disqualification from performing UR.
(a) The UR plan must include a written description of who performs UR in the ICF.
(b) UR must be performed using a method specified under § 456.401(b) by a group of professional personnel that includes—
(1) At least one physician;
(2) In an ICF that cares primarily for mental patients, at least one individual knowledgeable in the treatment of mental diseases; and
(3) In an institution for the mentally retarded, at least one individual knowledgeable in the treatment of mental retardation.
(c) The group performing UR may not include any individual who—
(1) Is directly responsible for the care of the recipient whose care is being reviewed;
(2) Is employed by the ICF; or
(3) Has a financial interest in any ICF.

§ 456.407 UR responsibilities of administrative staff.
The UR plan must describe—
(a) The UR support responsibilities of the ICF’s administrative staff; and
(b) Procedures used by the staff for taking needed corrective action.

§ 456.411 Recipient information required for UR.
The UR plan must provide that each recipient’s record include information needed to perform UR required under this subpart. This information must include, at least, the following:
(a) Identification of the recipient.
(b) The name of the recipient’s physician.
(c) The name of the qualified mental retardation professional (as defined under § 442.401 of this subchapter), if applicable.
(d) Date of admission, and dates of application for and authorization of Medicaid benefits if application is made after admission.
(e) The plan of care required under § 456.372.
(f) Initial and subsequent continued stay review dates described under §§ 456.433 and 456.434.
(g) Reasons and plan for continued stay, if the attending physician or qualified mental retardation professional believes continued stay is necessary.
(h) Other supporting material that the UR group believes appropriate to be included in the record.

§ 456.412 Records and reports.
The UR plan must describe—
(a) The types of records that are kept by the group performing UR; and
(b) The type and frequency of reports made by the UR group, and arrangements for distribution of the reports to appropriate individuals.

§ 456.413 Confidentiality.
The UR plan must provide that the identities of individual recipients in all UR records and reports are kept confidential.

§ 456.431 Continued stay review required.
(a) The UR plan must provide for a review of each recipient’s continued stay in the ICF at least every 6 months to decide whether it is needed.
(b) The UR plan requirement for continued stay review may be met by—
(1) Reviews that are performed in accordance with the requirements of §§ 456.432 through 456.437; or
(2) Reviews that meet on-site inspection requirements under subpart I if—
(i) The composition of the independent professional review team under subpart I meets the requirements of § 456.406; and
§ 456.432  Evaluation criteria for continued stay.

The UR plan must provide that—
(a) The group performing UR develops written criteria to assess the need for continued stay;
(b) The group develops more extensive written criteria for cases that its experience shows are—
   (1) Associated with high costs;
   (2) Associated with the frequent furnishing of excessive services; or
   (3) Attended by physicians whose patterns of care are frequently found to be questionable.

§ 456.433  Initial continued stay review date.

The UR plan must provide that—
(a) When a recipient is admitted to the ICF under admission review requirements of this subpart, the group performing UR assigns a specified date by which the need for his continued stay will be reviewed;
(b) The group performing UR bases its assignment of the initial continued stay review date on the methods and criteria required to be described under § 456.435(a);
(c) The initial continued stay review date is—
   (1) Not later than 6 months after admission; or
   (2) Earlier than 6 months after admission, if indicated at the time of admission; and
(d) The group performing UR insures that the initial continued stay review date is recorded in the recipient's record.

§ 456.434  Subsequent continued stay review dates.

The UR plan must provide that—
(a) The group performing UR assigns subsequent continued stay review dates in accordance with § 456.435.
(b) The group assigns a subsequent continued stay review date each time it decides under § 456.436 that the continued stay is needed—
   (1) At least every 6 months; or
   (2) More frequently than every six months if indicated at the time of continued stay review; and
(c) The group insures that each continued stay review date it assigns is recorded in the recipient's record.

§ 456.435  Description of methods and criteria: Continued stay review dates.

The UR plan must describe the methods and criteria that the group performing UR uses to assign initial and subsequent continued stay review dates under §§ 456.433 and 456.434.

§ 456.436  Continued stay review process.

The UR plan must provide that—
(a) Review of continued stay cases is conducted by—
   (1) The group performing UR; or
   (2) A designee of the UR group;
(b) The group or its designee reviews a recipient's continued stay on or before the expiration of each assigned continued stay review date.
(c) For each continued stay of a recipient in the ICF, the group or its designee reviews and evaluates the documentation described under § 456.411 against the criteria developed under § 456.432 and applies close professional scrutiny to cases described under § 456.432(b);
(d) If the group or its designee finds that a recipient's continued stay in the ICF is needed, the group assigns a new continued stay review date in accordance with § 456.434;
(e) If the group or its designee finds that a continued stay case does not meet the criteria, the group or a subgroup that includes at least one physician reviews the case to decide the need for continued stay;
(f) If the group or subgroup making the review under paragraph (e) of this section finds that a continued stay is not needed, it notifies the recipient's attending physician or, in institutions for the mentally retarded, the recipient's qualified mental retardation professional, within 1 working day of its decision, and gives him 2 working days from the notification date to present his views before it makes a final decision on the need for the continued stay.
(g) If the attending physician or qualified mental retardation professional does not present additional information or clarification of the need for the continued stay, the decision of the UR group is final;
(h) If the attending physician or qualified mental retardation professional presents additional information or clarification, the need for continued stay is reviewed by—
(1) The physician member(s) of the UR group, in cases involving a medical determination; or
(2) The UR group, in cases not involving a medical determination; and
(i) If the individuals performing the review under paragraph (h) of this section find that the recipient no longer needs ICF services, their decision is final.

§ 456.437 Notification of adverse decision.
The UR plan must provide that written notice of any adverse final decision on the need for continued stay under § 456.436 (g) through (i) is sent to—
(a) The ICF administrator;
(b) The attending physician;
(c) The qualified mental retardation professional, if applicable;
(d) The Medicaid agency;
(e) The recipient; and
(f) If possible, the next of kin or sponsor.

§ 456.438 Time limits for notification of adverse decision.
The UR plan must provide that the group gives notice under § 456.437 of an adverse decision not later than 2 days after the date of the final decision.

Subpart G—Inpatient Psychiatric Services for Individuals Under Age 21: Admission and Plan of Care Requirements

§ 456.480 Scope.
This subpart concerns admission and plan of care requirements that apply to inpatient psychiatric services for individuals under age 21 in hospitals, mental hospitals, and intermediate care facilities.

§ 456.481 Admission certification and plan of care.
If a facility provides inpatient psychiatric services to a recipient under age 21—
(a) The admission certification by the review team required in § 441.152 satisfies the requirement for physician certification of need for care in §§ 456.60, 456.160, and 456.360; and
(b) The development and review of the plan of care required in § 441.154 satisfies the requirement for physician recertification of need for care in the sections cited in paragraph (a) and the requirement for establishment and periodic review of the plan of care in §§ 456.80, 456.180, and 456.380.
(c) The plan of care must be established by the team described in § 441.156.

§ 456.482 Medical, psychiatric, and social evaluations.
If a facility provides inpatient psychiatric services to a recipient under age 21, the medical, psychiatric, and social evaluations required by §§ 456.170, and 456.370 must be made by the team described in § 441.153.

Subpart H—Utilization Review Plans: FFP, Waivers, and Variances for Hospitals and Mental Hospitals

§ 456.500 Purpose.
For hospitals and mental hospitals, this subpart—
(a) Prescribes conditions for the availability of FFP relating to UR plans;
(b) Prescribes conditions for granting a waiver of UR plan requirements; and
(c) Prescribes conditions for granting a variance in UR plan requirements for remote facilities.
§ 456.501 UR plans as a condition for FFP.

(a) Except when waived under §§ 456.505 through 456.508, FFP is not available in expenditures for Medicaid services furnished by a hospital or mental hospital unless the facility has in effect a UR plan that meets the utilization review requirements for Medicare under section 1861(k) of the Act.

(b) A facility that participates in Medicare and Medicaid must use the same UR standards and procedures and review committee for Medicaid as it uses for Medicare.

(c) A facility that does not participate in Medicare must meet the UR plan requirements in subpart C or D of this part, which are equivalent to the Medicare UR plan requirements in §§ 405.1137, 482.30, and 482.60 of this chapter.

§ 456.505 Applicability of waiver.

The Administrator may waive the UR plan requirements of subparts C or D of this part, except for provisions relating to disqualification of UR committee members under § 456.106 of subpart C, and § 456.206 of subpart D, if the Medicaid agency—

(a) Applies for a waiver; and

(b) Demonstrates to the Administrator's satisfaction that it has in operation specific UR procedures that are superior in their effectiveness to the UR plan requirements under subpart C or D of this part.

§ 456.506 Waiver options for Medicaid agency.

(a) The agency may apply for a waiver at any time it has the procedures referred to under § 456.505(b) in operation at least—

(1) On a demonstration basis; or

(2) In any part of the State.

(b) Any hospital or mental hospital participating under the plan that is not covered by a waiver must continue to meet all the UR plan requirements under subpart C or D of this part.

§ 456.507 Review and granting of waiver requests.

(a) When the agency applies for a waiver, the Administrator will assess the agency's UR procedures and grant the waiver if he determines that the procedures meet criteria he establishes.

(b) The Administrator will review and evaluate each waiver between 1 and 2 years after he has granted it and between 1 and 2 years periodically thereafter.

§ 456.508 Withdrawal of waiver.

(a) The Administrator will withdraw a waiver if he determines that State procedures are no longer superior in their effectiveness to the procedures required for UR plans under subpart C or D of this part.

(b) If a waiver is withdrawn by the Administrator, each hospital or mental hospital covered by the waiver must meet all the UR plan requirements under subpart C or D of this part.

§ 456.520 Definitions.

As used in §§ 456.521 through 456.525 of this subpart:

Available physician or other professional personnel means an individual who—

(a) Is professionally qualified;

(b) Is not precluded from participating in UR under § 456.107 of subpart C; or § 456.207 of subpart D; and

(c) Is not precluded from effective participation in UR because he requires travel between the remote facility and his place of work.

Remote facility means a facility located in an area that does not have enough available physicians or other professional personnel to perform UR as required under subparts C or D of this part, and for which the State requests a variance.
Variance means permission granted by the Administrator to the Medicaid agency for a specific remote facility to use time periods different from those specified for the start and completion of reviews of all cases under the following sections: §§ 456.125, 456.126, 456.136, and 456.137 of subpart C; and § 456.238 of subpart D.

§ 456.521 Conditions for granting variance requests.

(a) Except as described under paragraph (b) of this section, the administrator may grant a variance for a specific remote facility if the agency submits concurrently—

(1) A request for the variance that documents to his satisfaction that the facility is unable to meet the time requirements for which the variance is requested; and

(2) A revised UR plan for the facility.

(b) The Administrator will not grant a variance if the remote facility is operating under a UR plan waiver that the Secretary has granted or is considering under §§ 456.505 through 456.508.

§ 456.522 Content of request for variance.

The agency’s request for a variance must include—

(a) The name, location, and type of the remote facility;

(b) The number of total patient admissions and the average daily patient census at the facility in the 6 months preceding the request;

(c) The number of Medicare and Medicaid patient admissions and the average daily Medicare and Medicaid patient census at the facility in the 6 months preceding the request;

(d) The name and location of each hospital, mental hospital, and ICF located within a 50-mile radius of the facility;

(e) The distance and average travel time between the remote facility and each facility listed in paragraph (e) of this section;

(f) Documentation by the facility of its attempts to obtain the services of available physicians or other professional personnel, or both;

(g) The names of all physicians on the active staff, and the names of all other professional personnel on the staff whose availability is relevant to the request;

(h) The practice locations of available physicians and the estimated number of available professional personnel whose availability is relevant to the request;

(i) Documentation by the facility of its inability to perform UR within the time requirements for which the variance is requested and its good faith efforts to comply with the UR plan requirements of subpart C or D of this part;

(j) An assurance by the facility that it will continue its good faith efforts to meet the UR plan requirements of subpart C or D of this part; and

(k) A statement of whether a planning or conditional PSRO exists in the area where the facility is located.

§ 456.523 Revised UR plan.

(a) The revised UR plan for the remote facility must specify the methods and procedures that the facility will use if a variance is granted to insure that it—

(1) Maintains effective and timely control over the utilization of services; and

(2) Conducts reviews in a way that improves the quality of care provided to patients.

(b) The revised UR plan for the remote facility is the basis for validation of UR under sec. 1903(g)(2) of the Act for the period when a variance is in effect.

§ 456.524 Notification of Administrator’s action and duration of variance.

(a) The Administrator—

(1) Will notify the agency of the action he takes on its request for a variance; and

(2) Will specify the period of time, not to exceed 1 year, for which the variance may be granted.

(b) When it receives the Administrator’s notification, the agency must promptly notify the remote facility of his action.
§ 456.525 Request for renewal of variance.

(a) The agency must submit a request for renewal of a variance to the Administrator at least 30 days before the variance expires.

(b) The renewal request must contain the information required under § 456.522.

(c) The renewal request must show, to the Administrator’s satisfaction, that the remote facility continues to meet the requirements of §§ 456.521 through 456.523.

Subpart I—Inspections of Care in Intermediate Care Facilities and Institutions for Mental Diseases

§ 456.600 Purpose.

This subpart prescribes requirements for periodic inspections of care and services intermediate care facilities (ICF’s), and institutions for mental diseases (IMD’s).


§ 456.601 Definitions.

For purposes of this subpart—

Facility means an institution for mental diseases, or an intermediate care facility.

Intermediate care facility includes institutions for the mentally retarded or persons with related conditions but excludes Christian Science sanatoria operated, or listed and certified, by the First Church of Christ Scientist, Boston, Mass.

Institution for mental diseases includes a mental hospital, a psychiatric facility, and a intermediate care facility that primarily cares for mental patients.

Psychiatric facility includes a facility or program that provides inpatient psychiatric services for individuals under 21, as specified in § 441.151 of this chapter, but does not include psychiatric wards in acute care hospitals.


§ 456.602 Inspection team.

(a) A team, as described in this section and § 456.603 must periodically inspect the care and services provided to recipients in each facility.

(b) Each team conducting periodic inspections must have at least one member who is a physician or registered nurse and other appropriate health and social service personnel.

(c) For an IMD other than an ICF, each team must have a psychiatrist or physician knowledgeable about mental institutions and other appropriate mental health and social service personnel.

(d) For an ICF that primarily cares for mental patients, each team must have at least one member who knows the problems and needs of mentally retarded individuals.

(e) For an institution for the mentally retarded or persons with related conditions, each team must have at least one member who knows the problems and needs of mentally retarded individuals.

(f) For ICFs primarily serving individuals 65 years of age or older, each team must have at least one member who knows the problems and needs of those individuals.

(g) If there is no physician on the team, the Medicaid agency must insure that a physician is available to provide consultation to the team.

(h) If a team has one or more physicians, it must be supervised by a physician.

§ 456.603 Financial interests and employment of team members.

(a) Except as provided in paragraph (b) of this section—

(1) [Reserved]

(2) No member of a team that reviews care in an ICF may have a financial interest in or be employed by any ICF.

(b) A member of a team that reviews care in an IMD or an institution for the mentally retarded or persons with related conditions—

(1) May not have a financial interest in any institution of that same type but may have a financial interest in other facilities or institutions; and
§ 456.610  May not review care in an institution where he is employed but may review care in any other facility or institution.

§ 456.604  Physician team member inspecting care of recipients.
No physician member of a team may inspect the care of a recipient for whom he is the attending physician.

§ 456.605  Number and location of teams.
There must be a sufficient number of teams so located within the State that onsite inspections can be made at appropriate intervals in each facility caring for recipients.

§ 456.606  Frequency of inspections.
The team and the agency must determine, based on the quality of care and services being provided in a facility and the condition of recipients in the facility, at what intervals inspections will be made. However, the team must inspect the care and services provided to each recipient in the facility at least annually.

§ 456.607  Notification before inspection.
No facility may be notified of the time of inspection more than 48 hours before the scheduled arrival of the team.

§ 456.608  Personal contact with and review of records.
(a) For recipients under age 21 in psychiatric facilities and recipients in ICFs, other than those described in paragraph (b) of this section, the team’s inspection must include—
(1) Personal contact with and observation of each recipient; and
(2) Review of each recipient’s medical record.
(b) For recipients age 65 or older in IMDs, the team’s inspection must include—
(1) Review of each recipient’s medical record; and
(2) If the record does not contain complete reports of periodic assessments required by § 441.102 of this subchapter or, if such reports are inadequate, personal contact with and observation of each recipient.

§ 456.609  Determinations by team.
The team must determine in its inspection whether—
(a) The services available in the facility are adequate to—
(1) Meet the health needs of each recipient, and the rehabilitative and social needs of each recipient in an ICF; and
(2) Promote his maximum physical, mental, and psychosocial functioning.
(b) It is necessary and desirable for the recipient to remain in the facility; (c) It is feasible to meet the recipient’s health needs and, in an ICF, the recipient’s rehabilitative needs, through alternative institutional or noninstitutional services; and
(d) Each recipient under age 21 in a psychiatric facility and each recipient in an institution for the mentally retarded or persons with related conditions is receiving active treatment as defined in § 441.154 of this subchapter.

§ 456.610  Basis for determinations.
In making the determinations on adequacy of services and related matters under § 456.609 for each recipient, the team may consider such items as whether—
(a) The medical evaluation, any required social and psychological evaluations, and the plan of care are complete and current; the plan of care and, where required, the plan of rehabilitation are followed; and all ordered services, including dietary orders, are provided and properly recorded;
(b) The attending physician reviews prescribed medications—
(1) At least every 30 days in psychiatric facilities, and mental hospitals; and
(2) At least quarterly in ICFs;
(c) Tests or observations of each recipient indicated by his medication regimen are made at appropriate times and properly recorded;
§ 456.611 Reports on inspections.
(a) The team must submit a report promptly to the agency on each inspection.
(b) The report must contain the observations, conclusions, and recommendations of the team concerning—
   (1) The adequacy, appropriateness, and quality of all services provided in the facility or through other arrangements, including physician services to recipients; and
   (2) Specific findings about individual recipients in the facility.
(c) The report must include the dates of the inspection and the names and qualifications of the members of the team.

§ 456.612 Copies of reports.
The agency must send a copy of each inspection report to—
(a) The facility inspected;
(b) The facility’s utilization review committee;
(c) The agency responsible for licensing, certification, or approval of the facility for purposes of Medicare and Medicaid; and
(d) Other State agencies that use the information in the reports to perform their official function, including, if inspection reports concern IMD’s, the appropriate State mental health authorities.

§ 456.613 Action on reports.
The agency must take corrective action as needed based on the report and recommendations of the team submitted under this subpart.

§ 456.614 Inspections by utilization review committee.
A utilization review committee under subparts C through F of this part may conduct the periodic inspections required by this subpart if—
(a) The committee is not based in the facility being reviewed; and
(b) The composition of the committee meets the requirements of this subpart.

Subpart J—Penalty for Failure To Make a Satisfactory Showing of an Effective Institutional Utilization Control Program

Authority: Secs. 1102 and 1903(g) of the Social Security Act (42 U.S.C. 1302 and 1396b(g)).
Source: 44 FR 56338, Oct. 1, 1979, unless otherwise noted.

§ 456.650 Basis, purpose and scope.
(a) Basis. Section 1903(g) of the Act requires that FFP for long-stay inpatient services at a level of care be reduced, by a specified formula, for any quarter in which a State fails to make a satisfactory showing that it has an effective program of utilization control for that level of care.
(b) Purpose. This subpart specifies—
   (1) What States must do to make a satisfactory showing;
   (2) How the Administrator will determine whether reductions will be imposed; and
§ 456.653 Acceptable reasons for not meeting requirements for annual on-site review.

The Administrator will find an agency's showing satisfactory, even if it failed to meet the annual review requirements of § 456.652(a)(4), if—

(a) The agency demonstrates that—

(1) It completed reviews by the end of the quarter in at least 98 percent of all facilities requiring review by the end of the quarter;
§ 456.654 Requirements for content of showings and procedures for submittal.

(a) An agency’s showing for a quarter must—

(1) Include a certification by the agency that the requirements of §456.652(a) (1) through (4) were met during the quarter for each level of care or, if applicable, a certification of the reasons the annual on-site review requirements of §456.652(a)(4) were not met in any facilities;

(2) For all mental hospitals, intermediate care facilities, and facilities providing inpatient psychiatric services for individuals under 21, participating in Medicaid any time during the 12-month period ending on the last day of the quarter, list each facility by level of care, name, address and provider number;

(3) For each facility entering or leaving the program during the 12-month period ending on the last day of the quarter, list the beginning or ending dates of the provider agreement and supply a copy of the provider agreement;

(4) If review has been contracted to a PRO under §431.630 of this chapter, list the date the PRO contracted for review;

(5) List all dates of on-site reviews completed by review teams anytime during the 12-month period ending on the last day of the quarter;

(6) For all facilities in which an on-site review was required but not conducted, list the facility by name, address and provider number;

(7) For each on-site review in a mental hospital, intermediate care facility that primarily cares for mental patients, or inpatient psychiatric facility, list the name and qualifications of one team member who is a physician; and

(8) For each on-site review in an intermediate care facility that does not primarily care for mental patients, list the name and qualifications of one team member who is either a physician or registered nurse.

(b) The quarterly showing must be in the form prescribed by the Administrator.

(c) The quarterly showing must be postmarked or received within 30 days after the close of the quarter for which it is made, unless the agency demonstrates good cause for later submittal and the showing is postmarked or received within 45 days after the close of the quarter. Good cause means unanticipated circumstances beyond the agency’s control.

§ 456.655 Validation of showings.

(a) The Administrator will periodically validate showings submitted under §456.654. Validation procedures will include on-site sample surveys of institutions and surveys at the Medicaid agencies.

(b) The Administrator will not find an agency’s showing satisfactory if the information obtained through his validation procedures demonstrates, that any of the requirements of §456.652(a) (1) through (4) were not met during the quarter for which the showing was made.

§ 456.656 Reductions in FFP.

(a) If the Administrator determines an agency’s showing does not meet each of the requirements of this subpart, he will give the agency 30 days
§ 456.702 Computation of reductions in FFP.

(a) For each level of care specified in a provider agreement, and for each quarter for which a satisfactory showing is not made, the amount of the reduction in FFP is computed as follows:

(1) For each level of care, the number of recipients who received services in facilities that did not meet the requirements of this subpart is divided by the total number of recipients who received services in facilities for which a showing was required under this subpart. If any of the requirements specified in § 456.652(a)(1) through (4) were not met for any recipient in a facility, the reduction will be computed on the total number of recipients in that facility at the level of care in question.

(2) The fraction obtained in paragraph (a)(1) of this section is multiplied by one-third.

(3) The product obtained in paragraph (a)(2) of this section is multiplied by the Federal Medical Assistance Percentage (FMAP).

(4) The product obtained in paragraph (a)(3) of this section is multiplied by the agency payments for longstay services furnished during the quarter at that level of care.

(b) If any of the data required to compute the amount of the reduction in FFP are unavailable, the Administrator will substitute an estimate. If the agency determines the exact data to the satisfaction of the Administrator, the estimate may later be adjusted. If the number of recipients in individual facilities is not available, the fraction specified in paragraph (a)(1) of this section will be estimated, for each level of care, by dividing the total number of facilities in which the requirements were not met by the total number of facilities for which a showing is required under this subpart.

Subpart K—Drug Use Review (DUR) Program and Electronic Claims Management System for Outpatient Drug Claims

SOURCE: 57 FR 49408, Nov. 2, 1992, unless otherwise noted.

§ 456.700 Scope.

This subpart prescribes requirements for—

(a) An outpatient DUR program that includes prospective drug review, retrospective drug use review, and an educational program;

(b) The establishment, composition, and functions of a State DUR Board; and

(c) An optional point-of-sale electronic claims management system for processing claims for covered outpatient drugs.

§ 456.702 Definitions.

For purposes of this subpart—

Abuse is defined as in § 455.2 of this chapter.

Adverse medical result means a clinically significant undesirable effect, experienced by a patient, due to a course of drug therapy.

Appropriate and medically necessary means drug prescribing and dispensing that is in conformity with the predetermined standards established in accordance with § 456.703.

Criteria is defined as in § 466.1 of this chapter.

Fraud is defined as in § 455.2 of this chapter.
§ 456.703 Drug use review program.

(a) General. Except as provided in paragraphs (b) and (c) of this section, in order for FFP to be paid or made available under section 1903 of the Act for covered outpatient drugs, the State must have in operation, by not later than January 1, 1993, a DUR program consisting of prospective drug review, retrospective drug use review, and an educational program that meets the requirements of this subpart. The goal of the State's DUR program must be to ensure appropriate drug therapy, while permitting sufficient professional prerogatives to allow for individualized drug therapy.

(b) Exception for drugs dispensed to certain nursing facility residents. Prospective drug review and retrospective drug use review (including interventions and education) under the DUR program are not required for drugs dispensed to residents of nursing facilities that are in compliance with the drug regimen review procedures set forth in part 483 of this chapter. This does not preclude the State agency from making such drugs subject to prospective DUR or retrospective DUR or both, provided the State agency makes the drugs subject to all the requirements of this subpart applicable to the respective review.

(c) Exemption for certain covered outpatient drugs dispensed by hospitals and health maintenance organizations.

(1) The State plan must provide that covered outpatient drugs dispensed by a hospital using drug formulary systems and billed to the plan at no more than the hospital’s purchasing costs are not subject to the requirements of this subpart. Individual hospitals requesting this exemption must provide assurances to the State agency that they meet the requirements specified in section 1927(j)(2) of the Act.

(2) The State plan must provide that covered outpatient drugs dispensed by health maintenance organizations are not subject to the requirements of this subpart.

(d) Use of predetermined standards. A DUR program must assess drug use information against predetermined standards.

(e) Source of predetermined standards. The predetermined standards must be—

(1) Developed directly by the State or its contractor;

(2) Obtained by the State through contracts with commercial vendors of DUR services;

(3) Obtained by the State from independent organizations, such as the United States Pharmacopeial Convention, or entities receiving funding from the Public Health Service, HCFA, or State agencies; or

(4) Any combination of paragraphs (e)(1) through (e)(3) of this section.

(f) Requirements for predetermined standards. The predetermined standards used in the DUR program must meet the following requirements:

(1) The source materials for their development are consistent with peer-reviewed medical literature (that is, scientific, medical, and pharmaceutical publications in which original manuscripts are published only after having been critically reviewed by unbiased independent experts) and the following compendia:

(i) American Hospital Formulary Service Drug Information;

(ii) United States Pharmacopeia-Drug Information;

(iii) American Medical Association Drug Evaluations.

(2) Differences between source materials were resolved by physicians and pharmacists developing consensus solutions. The consensus process means the reliance, by the criteria developers, on the expertise of physicians and pharmacists to evaluate differences in criteria source materials and to come to agreement on how differences should be resolved.

(3) They are non-proprietary and readily available to providers of services. Systems and algorithms using the predetermined standards may remain proprietary.

(4) They are clinically-based and scientifically valid.

(5) The review based on clinical criteria uses predetermined standards to determine the population at risk of a clinically significant adverse medical result and applies standards, appropriate to this population, across providers and patients to determine the provider outliers whose prescribing, dispensing, or consumption practices may not conform to accepted standards of care. Various statistical measures (including mean, range, or other measures at the discretion of the State) may be applied to these data. Standards may be considered in deciding if an in-depth review is needed to determine whether to intervene once the potential therapeutic problems have been identified through the use of clinical criteria.

(6) They have been tested against claims data prior to adoption in order to validate the level of possibly significant therapeutic problems without undue levels of false positives.

(7) The predetermined standards for prospective and retrospective DUR are compatible.

(8) They are subjected to ongoing evaluation and modification either as a result of actions by their developer or as a result of recommendations by the DUR Board.

(g) Access to predetermined standards. Upon their adoption, predetermined standards must be available to the public. Pharmacists and physicians must be informed of the existence of predetermined standards and of how they can obtain copies of them.

(h) Confidentiality of patient related data. In implementing the DUR program, the agency must establish, in regulations or through other means, policies concerning confidentiality of patient related data that are consistent with applicable Federal confidentiality requirements at part 431, subpart F of this chapter; the State Pharmacy Practice Act; and the guidelines adopted by the State Board of Pharmacy or other relevant licensing bodies.

§ 456.705 Prospective drug review.

(a) General. Except as provided in §§ 456.703 (b) and (c), the State plan must provide for a review of drug therapy before each prescription is filled or delivered to a recipient, and applicable State law (including State Board policy incorporated in the State law by reference) must establish standards for counseling of the recipient or the recipient’s caregiver. The State must provide pharmacies with detailed information as to what they must do to comply with prospective DUR requirements, including guidelines on counseling, profiling, and documentation of prospective DUR activities by the pharmacists. The pharmacies, in turn, must provide this information to their pharmacists. This information is to be based on guidelines provided by this subpart and by other sources that the State may specify.

(b) Point-of-sale or point-of-distribution review. Except as provided in §§ 456.703 (b) and (c), the State plan must provide for point-of-sale or point-of-distribution review of drug therapy using predetermined standards before each prescription is filled or delivered to the recipient or the recipient’s caregiver. The review must include screening to identify potential drug therapy problems of the following types:

(1) Therapeutic duplication, that is, the prescribing and dispensing of two or more drugs from the same therapeutic class such that the combined daily dose puts the recipient at risk of an adverse medical result or incurs additional program costs without additional therapeutic benefit.
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(2) Drug-disease contraindication, that is, the potential for, or the occurrence of—
   (i) An undesirable alteration of the therapeutic effect of a given drug because of the presence, in the patient for whom it is prescribed, of a disease condition; or
   (ii) An adverse effect of the drug on the patient's disease condition.

(3) Adverse drug-drug interaction, that is, the potential for, or occurrence of, a clinically significant adverse medical effect as a result of the recipient using two or more drugs together.

(4) Incorrect drug dosage, that is, the dosage lies outside the daily dosage specified in predetermined standards as necessary to achieve therapeutic benefit. Dosage is the strength multiplied by the quantity dispensed divided by day's supply.

(5) Incorrect duration of drug treatment, that is, the number of days of prescribed therapy exceeds or falls short of the recommendations contained in the predetermined standards.

(6) Drug-allergy interactions, that is, the significant potential for, or the occurrence of, an allergic reaction as a result of drug therapy.

(7) Clinical abuse/misuse, that is, the occurrence of situations referred to in the definitions of abuse, gross overuse, overutilization, and underutilization, as defined in §456.702, and incorrect dosage and incorrect duration, as defined in paragraphs (b)(4) and (b)(5) of this section, respectively.

(c) Drug counseling. (1) As part of the prospective drug review program, standards for counseling by pharmacists of recipients or the recipients' caregivers must be established by State law or other method that is satisfactory to the State agency. A State agency's counseling standards must address special situations where the patient or the patient's representative is not readily available to receive the offer to counsel or the actual counseling, for example, prescriptions delivered offsite or through the mail. The State agency, at a minimum, must also address the following issues in their counseling standards:
   (i) Whether the offer to counsel is required for new prescriptions only, or for both new and refill prescriptions;
   (ii) Whether pharmacists must make the offer to counsel or auxiliary personnel are authorized to make the offer;
   (iii) Whether only a patient's refusal of the offer to counsel must be documented, or whether documentation of all offers is required;
   (iv) Whether documentation of counseling is required; and
   (v) Whether counseling is required in situations where the patient's representative is not readily available to receive a counseling offer or the counseling itself.

(2) The standards must meet the following requirements:
   (i) They must require pharmacists to offer to counsel (in person, whenever practicable, or through access to a telephone service that is toll-free for long-distance calls) each recipient or recipient's caregiver who presents a prescription. A pharmacist whose primary patient population is accessible through a local measured or toll-free exchange need not be required to offer toll-free service. Mail order pharmacies are required to provide toll-free telephone service for long distance calls.
   (ii) They need not require a pharmacist to provide consultation when a Medicaid recipient or the recipient's caregiver refuses that consultation.
   (iii) They must specify what documentation by the pharmacy of refusal of the offer of counseling is required.
   (iv) They must specify that the counseling include those matters listed in paragraphs (c)(3)(i) through (c)(3)(viii) of this section that, in the exercise of his or her professional judgement (consistent with State law regarding the provision of such information), the pharmacist considers significant as well as other matters the pharmacist considers significant.
   (i) The name and description of the medication;
   (ii) The dosage form, dosage, route of administration, and duration of drug therapy;
   (iii) Special directions and precautions for preparation, administration, and use by the patient;
   (iv) Common severe side or adverse effects or interactions and therapeutic
§ 456.711 Educational program.

The State plan must provide for ongoing educational outreach programs that, using DUR Board data on common drug therapy problems, educate practitioners on common drug therapy problems with the aim of improving prescribing and dispensing practices. The program may be established directly by the DUR Board or through contracts with accredited health care educational institutions, State medical societies or State pharmacists associations/societies, or other organizations. The program must include the interventions listed in paragraphs (a) through (d) of this section. The DUR Board determines the content of education regarding common therapy problems and the circumstances in which each of the interventions is to be used.

(a) Dissemination of information to physicians and pharmacists in the State concerning the duties and powers of the DUR Board and the basis for the standards required by § 456.705(c) for use in assessing drug use.

§ 456.709 Retrospective drug use review.

(a) General. The State plan must provide for a retrospective DUR program for ongoing periodic examination (no less frequently than quarterly) of claims data and other records in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and Medicaid recipients, or associated with specific drugs or groups of drugs. This examination must involve pattern analysis, using predetermined standards, of physician prescribing practices, drug use by individual patients and, where appropriate, dispensing practices of pharmacies. This program must be provided through the State’s mechanized drug claims processing and information retrieval systems approved by HCFA (that is, the Medicaid Management Information System (MMIS)) or an electronic drug claims processing system that is integrated with MMIS. States that do not have MMIS systems may use existing systems provided that the results of the examination of drug claims as described in this section are integrated within their existing system.

(b) Use of predetermined standards. Retrospective DUR includes, but is not limited to, using predetermined standards to monitor for the following:

(1) Therapeutic appropriateness, that is, drug prescribing and dispensing that is in conformity with the predetermined standards.

(2) Overutilization and underutilization, as defined in § 456.702.

(3) Appropriate use of generic products, that is, use of such products in conformity with State product selection laws.

(4) Therapeutic duplication as described in § 456.705(b)(1).

(5) Drug-disease contraindication as described in § 456.705(b)(2).

(6) Drug-drug interaction as described in § 456.705(b)(3).

(7) Incorrect drug dosage as described in § 456.705(b)(4).

(8) Incorrect duration of drug treatment as described in § 456.705(b)(5).

(9) Clinical abuse or misuse as described in § 456.705(b)(7).
§ 456.712 Annual report.

(a) DUR Board report. The State must require the DUR Board to prepare and submit an annual DUR report to the Medicaid agency that contains information specified by the State.

(b) Medicaid agency report. The Medicaid agency must prepare and submit, on an annual basis, a report to the Secretary that incorporates the DUR Board's report and includes the following information:

1. A description of the nature and scope of the prospective drug review program.

2. A description of how pharmacies performing prospective DUR without computers are expected to comply with the statutory requirement for written criteria.

3. Detailed information on the specific criteria and standards in use. After the first annual report, information regarding only new or changed criteria must be identified.

4. A description of the steps taken by the State to include in the prospective and retrospective DUR program drugs dispensed to residents of a nursing facility that is not in compliance with the drug regimen review procedures set forth in part 483 of this chapter. After the first annual report, only changes must be reported.

5. A description of the steps taken by the State to ensure compliance with the requirements for predetermined standards at § 456.703(f) and with the access to the predetermined standards requirement at § 456.703(g). After the first annual report, only changes must be reported.

6. A description of the nature and scope of the retrospective DUR program.

7. A summary of the educational interventions used and an assessment of the effect of these educational interventions on the quality of care.

8. A description of the steps taken by the State to monitor compliance by pharmacies with the prospective DUR counseling requirements contained in Federal and State laws and regulations. After the first annual report, only changes must be reported.

9. Clear statements of purpose that delineate the respective goals, objectives, and scopes of responsibility of the DUR and surveillance and utilization (SUR) functions. These statements must clarify the working relationships between DUR and SUR functions and other entities such as the Medicaid Fraud Control Unit and State Board of Pharmacy. The annual report must include a statement delineating how functional separation will be maintained between the fraud and abuse activities and the educational activities. After the first annual report, only changes must be reported.

10. An estimate of the cost savings generated as a result of the DUR program. This report must identify costs of DUR and savings to the Medicaid drug program attributable to prospective and retrospective DUR.

§ 456.714 DUR/surveillance and utilization review relationship.

(a) The retrospective DUR requirements in this subpart parallel a portion of the surveillance and utilization review (SUR) requirements in subpart A of this part and in part 455 of this chapter.

(b) A State agency may direct DUR staffs to limit review activities to those that focus on what constitutes appropriate and medically necessary care to avoid duplication of activities relating to fraud and abuse under the SUR program.
§ 456.716 DUR Board.

(a) State DUR Board requirement and member qualifications. Each State must establish, either directly or through a contract with a private organization, a DUR Board. The DUR Board must include health care professionals who have recognized knowledge and expertise in at least one of the following:

(1) Clinically appropriate prescribing of covered outpatient drugs.
(2) Clinically appropriate dispensing and monitoring of covered outpatient drugs.
(3) Drug use review, evaluation, and intervention.
(4) Medical quality assurance.

(b) Board composition. At least one-third but not more than 51 percent of the DUR Board members must be physicians, and at least one-third of the Board members must be pharmacists. These physicians and pharmacists must be actively practicing and licensed.

(c) Medicaid agency/DUR Board relationship. The Medicaid agency is ultimately responsible for ensuring that the DUR program is operational and conforms with the requirements of this subpart. The agency has the authority to accept or reject the recommendations or decisions of the DUR Board.

(d) DUR Board activities. The State agency must ensure that the operational tasks involved in carrying out the DUR Board activities set forth at section 1927(g)(3)(C) of the Act are assigned, limited only by the requirements of section 1927(g)(3)(C) of the Act, based on consideration of operational requirements and on where the necessary expertise resides. Except as limited by the requirements of section 1927(g)(3)(C) of the Act, the State agency may alter the suggested working relationships set forth in this paragraph.

(1) Application of predetermined standards: Board's activities. The DUR Board should perform the following activities:

(i) Review and make recommendations to the Medicaid agency or the agency's contractor concerning modification or elimination of existing predetermined standards or the addition of new ones.
(ii) Recommend guidelines governing written predetermined standards that pharmacies not using approved software must use in conducting prospective DUR.
(2) Application of predetermined standards: Medicaid agency role. The Medicaid agency or its contractor should perform the following activities:

(i) Submit predetermined standards to the DUR Board for its review and recommendations before the Medicaid agency applies them to drug claims data.
(ii) If prospective DUR is conducted using an electronic claims management (ECM) system, apply software approved by the Board.
(iii) If prospective DUR is not conducted through an ECM system, as part of general compliance monitoring, ensure that Medicaid participating pharmacies conduct prospective drug review that screens for the potential drug therapy problems listed in section 1927(g)(2)(A) of the Act.

(3) Retrospective DUR: Board's activities. The DUR Board should perform the following activities:

(i) Review and make recommendations on predetermined standards submitted to it by the Medicaid agency or the agency's contractor.
(ii) Make recommendations to the Medicaid agency or the agency's contractor concerning modification or elimination of existing predetermined standards or the addition of new ones.
(4) Retrospective DUR: Medicaid agency role. The Medicaid agency or its contractor should apply the predetermined standards to drug claims data in order to generate reports that identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care.

(5) Education program (including interventions): Board's activities. The DUR Board must perform the following activities:

(i) Identify and develop educational topics if education of practitioners on common drug therapy problems is...
§ 456.719
needed to improve prescribing or dispensing practices.

(ii) Make recommendations as to which mix of the interventions set forth in §§456.711(a) through (d) would most effectively lead to improvement in the quality of drug therapy. The DUR board recommendations must be based upon an in-depth review of the results of the application of predetermined standards against claims data reports, must be appropriate based upon program experience, and must match the educational program with the drug therapy problems identified.

(iii) Periodically re-evaluate and, if necessary, modify the interventions.

(6) Education program (including interventions): Medicaid agency's role. The Medicaid agency or its contractor should perform the following activities.

(i) Apply predetermined standards to drug claims data to generate reports that provide the basis for retrospective education and interventions and furnish those reports to the Board.

(ii) Carry out the educational programs and interventions specified by the Board.

(e) Funding for the Board. FFP is available for expenses associated with the operation of the DUR Board in carrying out its responsibilities, and payment is made under procedures established in part 433 of this chapter as follows:

(1) If the requirements for skilled professional medical personnel at §432.50 of this chapter are met, at the rate of 75 percent.

(2) If the requirements for skilled professional medical personnel at §432.50 of this chapter are not met, at the rate specified in §456.719.


§ 456.719 Funding for DUR program.

(a) For funds expended by the State after December 31, 1993, at the rate of 50 percent.

§ 456.722 Electronic claims management system.

(a) Point-of-sale system. Each Medicaid agency, at its option, may establish, as its principal (but not necessarily exclusive) means of processing claims for covered outpatient drugs, a point-of-sale electronic claims management (ECM) system to perform on-line, real-time (that is, immediate) eligibility verifications, claims data capture, adjudication of claims, and to assist pharmacists and other authorized persons (including dispensing physicians) in applying for and receiving payment. The State determines who must participate in an ECM system and who may decline to do so. If the State exercises this option and wishes to receive FFP for its ECM system, the system must meet the functional and additional procurement and system requirements in paragraphs (b) and (c) of this section.

(b) Functional requirements. The ECM system developed by the State must include at least the on-line, real-time capabilities specified in paragraphs (b)(1) through (3) of this section. The real-time requirement for prescriptions filled for nursing facilities and prescriptions filled by mail order dispensers may be waived by the State to permit claims to be processed in the batch mode at the end of the day or other time mutually agreed to by the nursing facility or mail order dispenser and Medicaid agency.

(1) Eligibility verification, including identification of the following:

(i) Third-party payers.

(ii) Recipients in managed care programs.

(iii) Recipients and providers in restricted service programs (for example, lock-in and lock-out).

(iv) Properly enrolled providers.

(2) Claims data capture, including the following:

(i) Transfer of claims information from the pharmacy to the Medicaid agency or the Medicaid agency's contractor.

(ii) Identification of prescriber.
(iii) Minimum data set (as defined in Part 11 of the State Medicaid Manual).

(3) Claims adjudication, including the following:

(i) Performing all edits and audits contained in the State's Medicaid Management Information System (MMIS) applicable to prescription drugs.

(ii) Notifying the pharmacist (or other authorized person, such as the dispensing physician) about the claim status.

(iii) Taking steps up to, but not including, payment of the claim.

(c) Additional requirements. In order to receive FFP for its ECM system, the State must meet the following requirements:

(1) The ECM system must be acquired through applicable competitive procurement process in the State and must be the most cost-effective telecommunications network and automatic data processing services and equipment. The procurement must meet the procurement requirements set forth in 45 CFR part 74, subpart P, and appendix G-O of OMB circular A-102. The request for proposal (RFP) may be substituted for the advance planning and implementation documents otherwise required by part 433 of this chapter, 45 CFR 95.205, and 45 CFR part 307. A cost-benefit analysis must accompany the RFP. If in its advance planning document, a State establishes that a separate procurement is not cost-effective, modification of an existing fiscal agent contract will be acceptable. In this case, procurement of network services and equipment (but not software modifications) must be competitively procured.

(2) States wishing to do prospective DUR as part of their ECM must do the following:

(i) Submit a cost benefit analysis showing the cost-effectiveness of such a system. A State's decisions as to who must participate in the ECM system and who may decline to do so must be included in the cost-benefit analysis.

(ii) Establish a central State-wide electronic repository for capturing, storing, and updating data for all prescriptions dispensed and for providing access to such data by all authorized participants.

(iii) Design the system to assess data for a review of drug therapy before each prescription is filled or delivered to a Medicaid recipient. The type of review conducted must meet the requirements for prospective drug review set forth in §456.705.

(3) ECM is considered a subsystem and must be fully integrated with the remainder of the State's MMIS. In addition, information about ECM claims must be part of the single comprehensive utilization and management reporting system used by the DUR program.

§ 456.725 Funding of ECM system.

(a) For funds expended during calendar quarters in fiscal years 1991 and 1992 and attributable to the design, development, and implementation of an on-line, real-time claims management system (that is, the most cost-effective telecommunications network and automatic data processing services and equipment) that meets the requirements of §456.722, FFP is available at a matching rate of 90 percent. After fiscal year 1992, ECM subsystems are funded at the standard applicable MMIS enhanced rates, subject to the requirements of part 433, subpart A of this chapter.

(b) FFP is available at a matching rate of 75 percent for funds expended for the following:

(1) Telecommunications equipment and other equipment to directly access MMIS files.

(2) Telecommunications equipment (such as modems and point of sale terminals) furnished to providers.

(3) Operational costs including telecommunications network costs, provided that the ECM system includes eligibility verification systems, electronic claims capture, claims adjudication (except for payment), and a claims data process that is integrated into a single comprehensive utilization and information reporting system.
PART 462—PEER REVIEW ORGANIZATIONS

Subpart A—General Provisions

Sec. 462.1 Definitions.

Subpart B—[Reserved]

Subpart C—Utilization and Quality Control Peer Review Organizations

462.100 Scope and applicability.
462.101 Eligibility requirements for PRO contracts.
462.102 Eligibility of physician-sponsored organizations.
462.103 Eligibility of physician-access organizations.
462.104 Requirements for demonstrating ability to perform review.
462.105 Prohibition against contracting with health care facilities.
462.106 Prohibition against contracting with payor organizations.
462.107 PRO contract award.

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

Subpart A—General Provisions

§ 462.1 Definitions.

For purposes of this part:

Five percent or more owner means a person (including, where appropriate, a corporation) who:

(a) Has an ownership interest of 5 percent or more;

(b) Has an indirect ownership interest equal to 5 percent or more;

(c) Has a combination of direct and indirect ownership interests (the possession of equity in the capital, the stock, or the profits of an entity) equal to 5 percent or more; or

(d) Is the owner of an interest of 5 percent or more in any obligation secured by an entity, if the interest equals at least 5 percent of the value of the property or assets of the entity.

Health care facility means an institution that directly provides or supplies health care services for which payment may be made in whole or in part under Title XVIII of the Act. A health care facility may be a hospital, skilled nursing facility, home health agency, free-standing ambulatory surgical center, or outpatient facility or any other entity which provides or supplies direct care to Medicare beneficiaries.

Managing employee means a general manager, business manager, administrator, director or other individual who exercises operational or managerial control over the entity or organization, or who, directly or indirectly, conducts the day-to-day operations of the entity or organization.

Payor organization means any organization, other than a self-insured employer, which makes payments directly or indirectly to health care practitioners or providers whose health care services are reviewed by the organization or would be reviewed by the organization if it entered into a PRO contract.

"Payor organization" also means any organization which is affiliated with any entity which makes payments as described above, by virtue of the organization having two or more governing body members who are also either governing body members, officers, partners, 5 percent or more owners or managing employees in a health maintenance organization or competitive medical plan.

Physician means:

(1) A doctor of medicine or osteopathy licensed under State law to practice medicine, surgery, or osteopathy in the State in which the PRO is located;

(2) An intern, resident, or Federal Government employee authorized under State or Federal law to practice medicine, surgery, or osteopathy in the PRO area; and

(3) An individual licensed to practice medicine in American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands.

§ 462.100 Scope and applicability.

This subpart implements sections 1152 and 1153(b) of the Social Security Act as amended by the Peer Review Improvement Act of 1982 (Pub. L. 97-248). It defines the types of organizations eligible to become PROs and establishes certain limitations and priorities regarding PRO contracting.

§ 462.101 Eligibility requirements for PRO contracts.

In order to be eligible for a PRO contract an organization must—

(a) Be either a physician-sponsored organization as described in § 462.102; or a physician-access organization as described in § 462.103 and

(b) Demonstrate its ability to perform review as set forth in § 462.104.

§ 462.102 Eligibility of physician-sponsored organizations.

(a) In order to be eligible for designation as a physician-sponsored PRO, an organization must meet the following conditions:

(1) Be composed of a substantial number of the licensed doctors of medicine and osteopathy practicing medicine or surgery in the review area and who are representative of the physicians practicing in the area.

(2) Not be a health care facility, health care facility association, or health care facility affiliate, as specified in § 462.105.

(b) In order to meet the requirements of paragraph (a)(1) of this section, an organization must state and have documentation in its files showing that it is composed of at least 20 percent of the licensed doctors of medicine and osteopathy practicing medicine or surgery in the review area; or

(2) If the organization is not composed of at least 20 percent of the licensed doctors of medicine and osteopathy practicing medicine or surgery in the review area, then the organization must demonstrate in its contract proposal, through letters of support from physicians or physician organizations, or through other means, that it is representative of the area physicians.

(d) Organizations that meet the requirements in paragraph (a) of this section will receive, during the contract evaluation process, a set number of bonus points.

§ 462.103 Eligibility of physician-access organizations.

(a) In order to be eligible for designation as a physician-access PRO, an organization must meet the following conditions:

(1) Have available to it, by arrangement or otherwise, the services of a sufficient number of licensed doctors of medicine or osteopathy practicing medicine or surgery in the review area to assure adequate peer review of the services provided by the various medical specialties and subspecialties.

(2) Not be a health care facility, health care facility association, or health care facility affiliate, as specified in § 462.105.

(b) An organization meets the requirements of paragraph (a)(1) of this section if it demonstrates—

(1) That it has available to it at least one physician in every generally recognized specialty; and

(2) The existence of an arrangement or arrangements with physicians under which the physicians would conduct review for the organization.

§ 462.104 Requirements for demonstrating ability to perform review.

(a) A physician-sponsored or physician-access organization will be found capable of conducting review if HCFA
§ 462.105 Prohibition against contracting with health care facilities.

(a) Basic rule. Except as permitted under paragraph (b) of this section, the following are not eligible for PRO contracts:

(1) A health care facility in the PRO area.
(2) An association of health care facilities in the PRO area.
(3) A health care facility affiliate; that is, an organization in which more than 20 percent of the members of the governing body are also either a governing body member, officer, partner, five percent or more owner, or managing employee in a health care facility or association of health care facilities in the PRO area.

(b) Exceptions. Effective November 15, 1984, the prohibition stated in paragraph (a) of this section will not apply to a payor organization if HCFA determines under §462.106 that there is no other eligible organization available.

(c) Subcontracting. A PRO must not subcontract with a facility to conduct any review activities except for the review of the quality of care.

[50 FR 15328, Apr. 17, 1985]

§ 462.106 Prohibition against contracting with payor organizations.

Payor organizations are not eligible to become PROs for the area in which they make payments until November 15, 1984. If no PRO contract for an area is awarded before November 15, 1984, a payor organization will be determined eligible by HCFA, if an eligible organization that is not a payor organization is unavailable at that time. HCFA may determine the unavailability of nonpayor organizations based on the lack of response to an appropriate Request for Proposal.

[50 FR 15328, Apr. 17, 1985]

§ 462.107 PRO contract award.

HCFA, in awarding PRO contracts, will take the following actions—

(a) Identify from among all proposals submitted in response to an RFP for a given PRO area all proposals submitted by organizations that meet the requirements of §§462.102 or 462.103;

(b) Identify from among all proposals identified in paragraph (a) of this section all proposals that set forth minimally acceptable plans in accordance with the requirements of §§462.104 and the RFPs;

(c) Assign bonus points not to exceed 10% of the total points available to all physician-sponsored organizations identified in paragraph (b) of this section, consistent with statute; and

(d) Subject to the limitations established by §§462.105 and 462.106, award the contract for the given PRO area to the selected organization for a period of two years.

Subpart B—[Reserved]

Subpart C—Review Responsibilities of Utilization and Quality Control Peer Review Organizations (PROs)

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

SOURCE: 44 FR 32081, June 4, 1979, unless otherwise noted.

Subpart A—General Provisions

§ 466.1 Definitions.

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

Active staff privileges means: (a) That a physician is authorized on a regular, rather than infrequent or courtesy, basis: (1) to order the admission of patients to a facility; (2) to perform diagnostic services in a facility; or (3) to care for and treat patients in a facility; or (b) that a health care practitioner other than a physician is authorized on a regular, rather than infrequent or courtesy, basis to order the admission of patients to a facility.

Admission review means a review and determination by a PRO of the medical necessity and appropriateness of a patient's admission to a specific facility.

Continued stay review means PRO review that is performed after admission review and during a patient's hospitalization to determine the medical necessity and appropriateness of continuing the patient's stay at a hospital level of care.

Criteria means predetermined elements of health care, developed by health professionals relying on professional expertise, prior experience, and the professional literature, with which aspects of the quality, medical necessity, and appropriateness of a health care service may be compared.

Diagnosis related group (DRG) means a system for classifying inpatient hospital discharges. DRGs are used for purposes of determining payment to hospitals for inpatient hospital services under the Medicare prospective payment system.

DRG validation means a part of the prospective payment system in which a PRO validates that DRG assignments are based on the correct diagnostic and procedural information.

Elective, when applied to admission or to a health care service, means an admission or a service that can be delayed without substantial risk to the health of the individual.

Five percent or more owner means a person (including, where appropriate, a corporation) who:

(a) Has an ownership interest of 5 percent or more;
(b) Has an indirect ownership interest equal to 5 percent or more;
(c) Has a combination of direct and indirect ownership interests (the possession of equity in the capital, the
stock, or the profits of an entity) equal to five percent or more; or
(d) Is the owner of an interest of five percent or more in any obligation secured by an entity, if the interest equals at least five percent of the value of the property or assets of the entity.

Health care facility or facility means an organization involved in the delivery of health care services for which reimbursement may be made in whole or in part under Title XVIII of the Act.

Health care practitioners other than physicians means those health professionals who do not hold a doctor of medicine or doctor of osteopathy degree, who meet all applicable State or Federal requirements for practice of their professions, and who are in active practice.

Hospital means a health care institution or distinct part of a health care institution, as defined in Section 1861(e)-(g) of the Act, other than a Christian Science sanatorium operated, or listed and certified, by the First Church of Christ, Scientist, Boston, Massachusetts.

Initial denial determination means an initial negative decision by a PRO, regarding the medical necessity, quality, or appropriateness of health care services furnished, or proposed to be furnished, to a patient.

Major clinical area means medicine, surgery, pediatrics, obstetrics and gynecology, or psychiatry.

Major procedure means a diagnostic or therapeutic procedure which involves a surgical or anesthetic risk or requires highly trained personnel or special facilities or equipment.

Non-facility organization means a corporate entity that (1) is not a health care facility; (2) is not a 5 percent or more owner of a facility; and (3) is not owned by one or more health care facilities or association of facilities in the PRO area.

Norm means a pattern of performance in the delivery of health care services that is typical for a specified group.

Norms means numerical or statistical measures of average observed performance in the delivery of health care services.

Outliers means those cases that have either an extremely long length of stay or extraordinarily high costs when compared to most discharges classified in the same DRG.

Peer review means review by health care practitioners of services ordered or furnished by other practitioners in the same professional field.

Physician means a doctor of medicine or osteopathy or another individual who is authorized under State or Federal law to practice medicine and surgery, or osteopathy. This includes medical officers in American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands.

Practitioner means an individual credentialed within a recognized health care discipline and involved in providing the services of that discipline to patients.

Preadmission certification means a favorable determination, transmitted to the hospital and the fiscal intermediary, approving the patient's admission for payment purposes.

Preadmission review means review prior to a patient's admission to a hospital to determine, for payment purposes, the reasonableness, medical necessity and appropriateness of placement at an acute level of care.

Preprocedure review means review of a surgical or other invasive procedure prior to the conduct of the procedure.

PRO review means review performed in fulfillment of a contract with HCFA, either by the PRO or its subcontractors.

Profile means aggregated data in formats that display patterns of health care services over a defined period of time.

Profile analysis means review and analysis of profiles to identify and consider patterns of health care services.

Quality review study means an assessment conducted by or for a PRO of a patient care problem for the purpose of improving patient care through peer analysis, intervention, resolution of the problem and follow-up.

Regional norms, criteria, and standards means norms, criteria, and standards that apply to a geographic division which is larger than a PRO area.

Retrospective review means review that is conducted after services are
provided to a patient. The review is focused on determining the appropriateness, necessity, quality, and reasonableness of health care services provided.

Review responsibility means (1) the responsibility of the PRO to perform review functions prescribed under Part B of Title XI of the Act and the Social Security Amendments of 1983 (Pub. L. No. 98-21) and the regulations of this part; (2) the responsibility to fulfill the terms and meet the objectives set forth in the negotiated contract between HCFA and the PRO; and (3) the authority of a PRO to make conclusive initial denial determinations regarding the medical necessity and appropriateness of health care and changes as a result of DRG validations.

Skilled nursing facility (SNF) means a health care institution or distinct part of an institution that (a) is primarily engaged in providing skilled nursing care or rehabilitative services to injured, disabled, or sick persons, and (b) has an agreement to participate in Medicare or Medicaid or both, and (c) is not a Christian Science sanatorium operated or listed and certified by the First Church of Christ Scientist, Boston, Massachusetts.

Standards means professionally developed expressions of the range of acceptable variation from a norm or criterion.

Subcontractor means a facility or a non-facility organization under contract with a PRO to perform PRO review functions.

Working day means any one of at least five days of each week (excluding, at the option of each PRO, legal holidays) on which the necessary personnel are available to perform review.

§ 466.72 Review of the quality of care of risk-basis health maintenance organizations and competitive medical plans.

(a) (1) For purposes of a review under section 1154(a)(4) of the Act, a PRO must determine whether the quality of services (including both inpatient and outpatient services) provided by an HMO or CMP meets professionally recognized standards of health care, including whether appropriate health care services have not been provided or have been provided in inappropriate settings.

(2) Paragraph (a)(1) of this section will not apply with respect to a contract year if another entity has been awarded a contract to perform those reviews under section 1154(a)(4)(C) of the Act.

(b) For purposes of reviews under this section, non-PRO entities selected to perform these reviews under section 1154(a)(4)(C) of the Act are subject to the requirements of paragraph (a)(1) of this section and—

(1) Part 476 of this chapter regarding acquisition, protection, and disclosure of peer review information; and

(2) Part 1004 of Chapter V regarding a PRO’s responsibilities, and sanctions imposed by such agencies.

(c) The PRO must review at least a random sample of hospital discharges each quarter and submit new diagnostic and procedural information to the Medicare fiscal intermediary or carrier if it determines that the information submitted by the hospital was incorrect.

(d) Coordination of sanction activities. The PRO must carry out the responsibilities specified in subpart C of part 1004 of this title regarding imposition of sanctions on providers and practitioners who violate their statutory obligations under section 1156 of the Act.

§ 466.72 Review of the quality of care of risk-basis health maintenance organizations and competitive medical plans.

(a) (1) A malformed body member, or (with respect to pneumococcal vaccine) for prevention of illness or (in the case of hospice care) for the palliation and management of terminal illness;

(2) Whether the quality of the services meets professionally recognized standards of health care;

(3) Whether those services furnished or proposed to be furnished on an inpatient basis could, consistent with the provisions of appropriate medical care, be effectively furnished more economically on an outpatient basis or in an inpatient health care facility of a different type;

(4) Through DRG validation, the validity of diagnostic and procedural information supplied by the hospital;

(5) The completeness, adequacy and quality of hospital care provided;

(6) The medical necessity, reasonableness and appropriateness of hospital admissions and discharges;

(7) 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; and

(8) Whether a hospital has misrepresented admission or discharge information or has taken an action that results in—

(i) The unnecessary admission of an individual entitled to benefits under part A;

(ii) Unnecessary multiple admissions of an individual; or

(iii) Other inappropriate medical or other practices with respect to beneficiaries or billing for services furnished to beneficiaries.

(b) Payment determinations. On the basis of the review specified under paragraphs (a) (1), (3), (6), (7), and (8) of this section, the PRO must determine whether payment may be made for these services. A PRO may grant a period of not more than two days (grace days) for the purpose of arranging post discharge care when the provider did not know or could not reasonably be expected to have known that payment for the service(s) would not be made under the Medicare program as specified in § 405.330(b).

(c) Other duties and functions. (1) The PRO must review at least a random sample of hospital discharges each quarter and submit new diagnostic and procedural information to the Medicare fiscal intermediary or carrier if it determines that the information submitted by the hospital was incorrect.

(2) As directed by HCFA, the PRO must review changes in DRG assignment made by the intermediary under the provisions of § 412.60(d) that result in the assignment of a higher-weighted DRG. The PRO’s review must verify that the diagnostic and procedural information supplied by the hospital is substantiated by the information in the medical record.

(d) Coordination of sanction activities. The PRO must carry out the responsibilities specified in subpart C of part 1004 of this title regarding imposition of sanctions on providers and practitioners who violate their statutory obligations under section 1156 of the Act.

(e) Other duties and functions. (1) The PRO must review at least a random sample of hospital discharges each quarter and submit new diagnostic and procedural information to the Medicare fiscal intermediary or carrier if it determines that the information submitted by the hospital was incorrect.

(2) As directed by HCFA, the PRO must review changes in DRG assignment made by the intermediary under the provisions of § 412.60(d) that result in the assignment of a higher-weighted DRG. The PRO’s review must verify that the diagnostic and procedural information supplied by the hospital is substantiated by the information in the medical record.

(f) Coordination of sanction activities. The PRO must carry out the responsibilities specified in subpart C of part 1004 of this title regarding imposition of sanctions on providers and practitioners who violate their statutory obligations under section 1156 of the Act.

(g) Other duties and functions. (1) The PRO must review at least a random sample of hospital discharges each quarter and submit new diagnostic and procedural information to the Medicare fiscal intermediary or carrier if it determines that the information submitted by the hospital was incorrect.

(2) As directed by HCFA, the PRO must review changes in DRG assignment made by the intermediary under the provisions of § 412.60(d) that result in the assignment of a higher-weighted DRG. The PRO’s review must verify that the diagnostic and procedural information supplied by the hospital is substantiated by the information in the medical record.

(h) Coordination of sanction activities. The PRO must carry out the responsibilities specified in subpart C of part 1004 of this title regarding imposition of sanctions on providers and practitioners who violate their statutory obligations under section 1156 of the Act.

(i) Other duties and functions. (1) The PRO must review at least a random sample of hospital discharges each quarter and submit new diagnostic and procedural information to the Medicare fiscal intermediary or carrier if it determines that the information submitted by the hospital was incorrect.

(2) As directed by HCFA, the PRO must review changes in DRG assignment made by the intermediary under the provisions of § 412.60(d) that result in the assignment of a higher-weighted DRG. The PRO’s review must verify that the diagnostic and procedural information supplied by the hospital is substantiated by the information in the medical record.

(j) Coordination of sanction activities. The PRO must carry out the responsibilities specified in subpart C of part 1004 of this title regarding imposition of sanctions on providers and practitioners who violate their statutory obligations under section 1156 of the Act.

(k) Other duties and functions. (1) The PRO must review at least a random sample of hospital discharges each quarter and submit new diagnostic and procedural information to the Medicare fiscal intermediary or carrier if it determines that the information submitted by the hospital was incorrect.

(2) As directed by HCFA, the PRO must review changes in DRG assignment made by the intermediary under the provisions of § 412.60(d) that result in the assignment of a higher-weighted DRG. The PRO’s review must verify that the diagnostic and procedural information supplied by the hospital is substantiated by the information in the medical record.

(l) Coordination of sanction activities. The PRO must carry out the responsibilities specified in subpart C of part 1004 of this title regarding imposition of sanctions on providers and practitioners who violate their statutory obligations under section 1156 of the Act.

(m) Other duties and functions. (1) The PRO must review at least a random sample of hospital discharges each quarter and submit new diagnostic and procedural information to the Medicare fiscal intermediary or carrier if it determines that the information submitted by the hospital was incorrect.

(2) As directed by HCFA, the PRO must review changes in DRG assignment made by the intermediary under the provisions of § 412.60(d) that result in the assignment of a higher-weighted DRG. The PRO’s review must verify that the diagnostic and procedural information supplied by the hospital is substantiated by the information in the medical record.

(n) Coordination of sanction activities. The PRO must carry out the responsibilities specified in subpart C of part 1004 of this title regarding imposition of sanctions on providers and practitioners who violate their statutory obligations under section 1156 of the Act.

(o) Other duties and functions. (1) The PRO must review at least a random sample of hospital discharges each quarter and submit new diagnostic and procedural information to the Medicare fiscal intermediary or carrier if it determines that the information submitted by the hospital was incorrect.

(2) As directed by HCFA, the PRO must review changes in DRG assignment made by the intermediary under the provisions of § 412.60(d) that result in the assignment of a higher-weighted DRG. The PRO’s review must verify that the diagnostic and procedural information supplied by the hospital is substantiated by the information in the medical record.

(p) Coordination of sanction activities. The PRO must carry out the responsibilities specified in subpart C of part 1004 of this title regarding imposition of sanctions on providers and practitioners who violate their statutory obligations under section 1156 of the Act.
§ 466.73 Notification of PRO designation and implementation of review.

(a) Notice of HCFA’s decision. HCFA sends written notification of a PRO contract award to the State survey agency and Medicare fiscal intermediaries and carriers. The notification includes the effective dates of the PRO contract and specifies the area and types of health care facilities to be reviewed by the PRO. The PRO must make a similar notification when review responsibilities are subcontracted.

(b) Notification to health care facilities and the public. As specified in its contract with HCFA, the PRO must—

(1) Provide, to each health care facility scheduled to come under review, a timely written notice that specifies the date and manner in which the PRO proposes to implement review, and the information to be furnished by the facility to each Medicare beneficiary upon admission as specified in § 466.78(b)(3) of this part.

(2) Publish, in at least one local newspaper of general circulation in the PRO area, a notice that states the date the PRO will assume review responsibilities and lists each area health care facility to be under review. The PRO must indicate that its plan for the review of health care services as approved in its contract with HCFA is available for public inspection in the PRO’s business office and give the address, telephone number and usual hours of business.

§ 466.74 General requirements for the assumption of review.

(a) A PRO must assume review responsibility in accordance with the schedule, functions and negotiated objectives specified in its contract with HCFA.

(b) A PRO must notify the appropriate Medicare fiscal intermediary or carrier of its assumption of review in specific health care facilities no later than five working days after the day that review is assumed in the facility.

(c) A PRO must maintain and make available for public inspection at its principal business office—

(1) A copy of each agreement with Medicare fiscal intermediaries and carriers;

(2) A copy of its currently approved review plan that includes the PRO’s method for implementing review; and

(3) Copies of all subcontracts for the conduct of review.

(d) A PRO must not subcontract with a facility to conduct any review activities except for the review of the quality of care. The PRO may subcontract with a non-facility organization to conduct review in a facility.

(e) If required by HCFA, a PRO is responsible for compiling statistics based on the criteria contained in § 405.332 of this chapter and making limitation of liability determinations on excluded coverage of certain services that are made under section 1879 of the Act. If required by HCFA, PROs must also notify a provider of these determinations. These determinations and further appeals are governed by the reconsideration and appeals procedures in part 405, subpart G of this chapter for Medicare Part A related determinations and part 405, subpart H of this chapter for Medicare Part B related determinations.

(f) A PRO must make its responsibilities under its contract with HCFA, primary to all other interests and activities that the PRO undertakes.

§ 466.76 Cooperation with health care facilities.

Before implementation of review, a PRO must make a good faith effort to discuss the PRO’s administrative and review procedures with each involved health care facility.

§ 466.78 Responsibilities of health care facilities.

(a) Every hospital seeking payment for services furnished to Medicare beneficiaries must maintain a written agreement with a PRO operating in the area in which the hospital is located. These agreements must provide for the PRO review specified in § 466.71.
(b) Cooperation with PROs. Health care facilities that submit Medicare claims must cooperate in the assumption and conduct of PRO review. Facilities must—

(1) Allocate adequate space to the PRO for its conduct of review at the times the PRO is conducting review.

(2) Provide patient care data and other pertinent data to the PRO at the time the PRO is collecting review information that is required for the PRO to make its determinations. The facility must photocopy and deliver to the PRO all required information within 30 days of a request. PROs pay hospitals paid under the prospective payment system for the costs of photocopying records requested by the PRO in accordance with the payment rate determined under the methodology described in paragraph (c) of this section and for first class postage for mailing the records to the PRO. When the PRO does post-admission, preprocedure review, the facility must provide the necessary information before the procedure is performed, unless it must be performed on an emergency basis.

(3) Inform Medicare beneficiaries at the time of admission, in writing, that the care for which Medicare payment is sought will be subject to PRO review and indicate the potential outcomes of that review. Furnishing this information to the patient does not constitute notice, under §405.332(a) of this chapter, that can support a finding that the beneficiary knew the services were not covered.

(4) When the facility has issued a written determination in accordance with §412.42(c)(3) of this chapter that a beneficiary no longer requires inpatient hospital care, it must submit a copy of its determination to the PRO within 3 working days.

(5) Assure, in accordance with the provisions of its agreement with the PRO, that each case subject to preadmission review has been reviewed and approved by the PRO before admission to the hospital or a timely request has been made for PRO review.

(6)(i) Agree to accept financial liability for any admission subject to preadmission review that was not reviewed by the PRO and is subsequently determined to be inappropriate or not medically necessary.

(ii) The provisions of paragraph (b)(6)(i) of this section do not apply if a facility, in accordance with its agreement with a PRO, makes a timely request for preadmission review and the PRO does not review the case timely. Cases of this type are subject to retrospective prepayment review under paragraph (b)(7) of this section.

(7) Agree that, if the hospital admits a case subject to preadmission review without certification, the case must receive retrospective prepayment review, according to the review priority established by the PRO.

(c) Photocopying reimbursement methodology for prospective payment system hospitals. Hospitals subject to the prospective payment system are paid for the photocopying costs that are directly attributable to the hospitals' responsibility to provide photocopies of requested hospital records. The payment is in addition to payment already provided for these costs under other provisions of the Social Security Act and is based on a fixed amount per page as determined by HCFA as follows:

(1) Step one. HCFA adds the annual salary of a photocopy machine operator and the costs of fringe benefits as determined in accordance with the principles set forth in OMB Circular A-76.

(2) Step two. HCFA divides the amount determined in paragraph (c)(1) of this section by the number of pages that can be reasonably expected to be made annually by the photocopy machine operator to establish the labor cost per page.

(3) HCFA adds to the per-page labor cost determined in paragraph (c)(2) of this section the per-page costs of supplies.

(d) Appeals. Reimbursement for the costs of photocopying and mailing records for PRO review is an additional payment to hospitals under the prospective system, as specified in §412.115
§ 466.80 Coordination with Medicare fiscal intermediaries and carriers.

(a) Procedures for agreements. The Medicare fiscal intermediary or carrier must have a written agreement with the PRO. The PRO must take the initiative with the fiscal intermediary or carrier in developing the agreement. The following steps must be taken in developing the agreement.

(1) The PRO and the fiscal intermediary or carrier must negotiate in good faith in an effort to reach written agreement. If they cannot reach agreement, HCFA will assist them in resolving matters in dispute.

(2) The PRO must incorporate its administrative procedures into an agreement with the fiscal intermediary or carrier and obtain approval from HCFA, before it makes conclusive determinations for the Medicare program, unless HCFA finds that the fiscal intermediary or carrier has—

(i) Refused to negotiate in good faith or in a timely manner, or

(ii) Insisted on including in the agreement, provisions that are outside the scope of its authority under the Act.

(b) Content of agreement. The agreement must include procedures for—

(1) Informing the appropriate Medicare fiscal intermediaries and carriers of—

(i) Changes as a result of DRG validations and revisions as a result of the review of these changes; and

(ii) Initial denial determinations and revisions of these determinations as a result of reconsideration, or reopening all approvals and denials with respect to cases subject to preadmission review, and outlier claims in hospitals under a prospective payment system for health care services and items;

(2) Exchanging data or information;

(3) Modifying the procedures when additional review responsibility is authorized by HCFA; and

(4) Any other matters that are necessary for the coordination of functions.

(c) Action by HCFA. (1) Within the time specified in its contract, the PRO must submit to HCFA for approval its agreement with the Medicare fiscal intermediaries and carriers, or if an agreement has not been established, the PRO’s proposed administrative procedures, including any comments by the Medicare fiscal intermediaries and carriers.

(2) If HCFA approves the agreement or the administrative procedures (after a finding by HCFA as specified in paragraph (a)(2) of this section), the PRO may begin to make determinations under its contract with HCFA.

(3) If HCFA disapproves the agreement or procedures, it will—

(i) Notify the PRO and the appropriate fiscal agents in writing, stating the reasons for disapproval; and

(ii) Require the PRO and fiscal intermediary or carrier to revise its agreements or procedures.

(d) Modification of agreements. Agreements or procedures may be modified, with HCFA’s approval—

(1) Through a revised agreement with the fiscal intermediary or carrier, or

(2) In the case of procedures, by the PRO, after providing opportunity for comment by the fiscal intermediary or carrier.

(e) Role of the fiscal intermediary. (1) The fiscal intermediary will not pay any claims for those cases which are subject to preadmission review by the PRO, until it receives notice that the PRO has approved the admission after preadmission or retrospective review.

(2) A PRO’s determination that an admission is medically necessary is not a guarantee of payment by the fiscal intermediary. Medicare coverage requirements must also be applied.

[50 FR 15330, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985]

§ 466.82 Continuation of functions not assumed by PROs.

Any of the duties and functions under Part B of Title XI of the Act for which a PRO has not assumed responsibility under its contract with HCFA must be
performed in the manner and to the extent otherwise provided for under the Act or in regulations.

PRO REVIEW FUNCTIONS

§ 466.83 Initial denial determinations.
A determination by a PRO that the health care services furnished or proposed to be furnished to a patient are not medically necessary, are not reasonable, or are not at the appropriate level of care, is an initial denial determination and is appealable under part 473 of this chapter.

§ 466.84 Changes as a result of DRG validation.
A provider or practitioner may obtain a review by a PRO under part 473 of this chapter for changes in diagnostic and procedural coding that resulted in a change in DRG assignment as a result of PRO validation activities.

§ 466.85 Conclusive effect of PRO initial denial determinations and changes as a result of DRG validations.
A PRO initial denial determination or change as a result of DRG validation is final and binding unless, in accordance with the procedures in part 473—
(a) The initial denial determination is reconsidered and revised; or
(b) The change as a result of DRG validation is reviewed and revised.

§ 466.86 Correlation of Title XI functions with Title XVIII functions.
(a) Payment determinations. (1) PRO initial denial determinations under this part with regard to the reasonableness, medical necessity, and appropriateness of placement at an acute level of patient care as are also conclusive for payment purposes with regard to the following medical issues:
   (i) Whether inpatient care furnished in a psychiatric hospital meets the requirements of § 424.14 of this chapter.
   (ii) Whether payment for inpatient hospital or SNF care beyond 20 consecutive days is excluded under § 489.50 of this chapter because of failure to perform review of long-stay cases.
   (iii) Whether the care furnished was custodial care or care not reasonable and necessary and, as such, excluded under § 405.310(g) or § 405.310(k) of this chapter.
   (iv) Whether the care was appropriately furnished in the inpatient or outpatient setting.
   (2) Reviews with respect to determinations listed in paragraph (a)(1) of this section must not be conducted, for purposes of payment, by Medicare fiscal intermediaries or carriers except as outlined in paragraph (c) of this section.
   (3) PROs make determinations as to the appropriateness of the location in which procedures are performed. A procedure may be medically necessary but denied if the PRO determines that it could, consistent with the provision of appropriate medical care, be effectively provided more economically on an outpatient basis or in an inpatient health care facility of a different type.
   (4) PRO determinations as to whether the provider and the beneficiary knew or could reasonably be expected to have known that the services described in paragraph (a)(1) of this section were excluded are also conclusive for payment purposes.

(b) Utilization review activities. PRO review activities to determine whether inpatient hospital or SNF care services are reasonable and medically necessary and are furnished at the appropriate level of care fulfill the utilization review requirements set forth in §§ 405.1035, 405.1042, and 405.1137 of this chapter.

(c) Coverage. Nothing in paragraphs (a)(1) and (3) of this section will be construed as precluding HCFA or a Medicare fiscal intermediary or carrier, in the proper exercise of its duties and functions, from reviewing claims to determine:
   (1) In the case of items or services not reviewed by a PRO, whether they meet coverage requirements of Title XVIII relating to medical necessity, reasonableness, or appropriateness of placement at an acute level of patient care. However, if a coverage determination pertains to medical necessity, reasonableness, or appropriateness of placement at an acute level of patient care, the fiscal intermediary or carrier...
must use a PRO to make a determination on those issues if a PRO is conducting review in the area and must abide by the PRO's determination.

(2) Whether any claim meets coverage requirements of Title XVIII relating to issues other than medical necessity, reasonableness or appropriateness of placement at an acute level of patient care.

(d) Payment. Medicare fiscal intermediaries and carriers are not precluded from making payment determinations with regard to coverage determinations made under paragraph (c) of this section.

(e) Survey, compliance and assistance activities. PRO review and monitoring activities fulfill the requirements for compliance and assistance activities of State survey agencies under section 1864(a) with respect to sections 1861(e)(6), 1861(j)(8), 1861(j)(12), and 1861(k) of the Act, and activities required of intermediaries and carriers under §§ 421.100(d) and 421.200(f) of this chapter.

(f) Appeals. The requirements and procedures for PRO review of changes as a result of DRG validation and the reconsideration, hearing and judicial review of PRO initial denial determinations are set forth in part 473 of this chapter.

§ 466.88 Examination of the operations and records of health care facilities and practitioners.

(a) Authorization to examine records. A facility claiming Medicare payment must permit a PRO or its subcontractor to examine its operation and records (including information on charges) that are pertinent to health care services furnished to Medicare beneficiaries and are necessary for the PRO or its subcontractor to—

(1) Perform review functions including, but not limited to—

(ii) DRG validation;

(2) Evaluate cases that have been identified as deviating from the PRO norms and criteria, or standards; and

(3) Evaluate the capability of the facility to perform quality review functions under a subcontract with the PRO.

(b) Limitations on access to records. A PRO has access to the records of non-Medicare patients if—

(1) The records relate to review performed under a non-Medicare PRO contract and if authorized by those patients in accordance with State law; or

(2) The PRO needs the records to perform its quality review responsibilities under the Act and receives authorization from the facility or practitioner.

(c) Conditions of examination. When examining a facility's operation or records the PRO must—

(1) Examine only those operations and records (including information on charges) required to fulfill the purposes of paragraph (a) of this section;

(2) Cooperate with agencies responsible for other examination functions under Federal or Federally assisted programs in order to minimize duplication of effort;

(3) Conduct the examinations during reasonable hours; and

(4) Maintain in its principal office written records of the results of the examination of the facility.

§ 466.90 Lack of cooperation by a health care facility or practitioner.

(a) If a health care facility or practitioner refuses to allow a PRO to enter and perform the duties and functions required under its contract with HCFA, the PRO may—

(1) Determine that the health care facility or practitioner has failed to comply with the requirements of §474.30(c) of this chapter and report the matter to the HHS Inspector General; or

(2) Issue initial denial determinations for those claims it is unable to review, make the determination that financial liability will be assigned to the health care facility, and report the matter to the HHS Inspector General.

(b) If a PRO provides a facility with sufficient notice and a reasonable amount of time to respond to a request for information about a claim, and if
§ 466.93 Opportunity to discuss proposed initial denial determination and changes as a result of a DRG validation.

Before a PRO reaches an initial denial determination or makes a change as a result of a DRG validation, it must—

(a) Promptly notify the provider or supplier and the patient's attending physician (or other attending health care practitioner) of the proposed determination or DRG change; and

(b) Afford an opportunity for the provider or supplier and the physician (or other attending health care practitioner) to discuss the matter with the PRO physician advisor and to explain the nature of the patient's need for health care services, including all factors which preclude treatment of the patient as an outpatient or in an alternative level of inpatient care.

§ 466.94 Notice of PRO initial denial determination and changes as a result of a DRG validation.

(a) Notice of initial denial determination—(1) Parties to be notified. A PRO must provide written notice of an initial denial determination to—

(i) The patient, or if the patient is expected to be unable to comprehend the notice, the patient's next of kin, guardian or other representative or sponsor;

(ii) The attending physician, or other attending health care practitioner;

(iii) The facility; and

(iv) The fiscal intermediary or carrier.

(2) Timing of the notice. The notice must be delivered to beneficiaries in the facility or mailed to those no longer in the facility, within the following time periods—

(i) For admission, on the first working day after the initial denial determination;

(ii) For continued stay (e.g., outliers in facilities under a prospective payment system), by the first working day after the initial denial determination if the beneficiary is still in the facility, and within 3 working days if the beneficiary has been discharged;

(iii) For preprocedure review, before the procedure is performed;

(iv) For preadmission review, before admission;

(v) If identification as a Medicare program patient has been delayed, within three working days of identification;

(vi) For retrospective review, (excluding DRG validation and post procedure review), within 3 working days of the initial denial determination; and

(vii) For post-procedure review, within 3 working days of the initial denial determination.

(3) Preadmission review. In the case of preadmission review, the PRO must document that the patient and the facility received notice of the initial denial determination.

(b) Notice of changes as a result of a DRG validation. The PRO must notify the provider and practitioner of changes to procedural and diagnostic information that result in a change of DRG assignment, within 30 days of the PRO's decision.

(c) Content of the notice. The notice must be understandable and written in plain English and must contain—

(1) The reason for the initial denial determination or change as a result of the DRG validation;

(2) For day outliers in hospitals, the date on which the stay or services in the facility will not be approved as being reasonable and medically necessary or appropriate to the patients' health care needs;

(3) A statement informing each party or his or her representative of the right to request in accordance with the provisions of part 473, subpart B of this chapter—

(i) Review of a change resulting from DRG validation; or

(ii) Reconsideration of the initial denial determination;

(4) The locations for filing a request for reconsideration or review and the time period within which a request must be filed;

(5) A statement about who is liable for payment of the denied services under section 1879 of the Act; and

(6) A statement concerning the duties and functions of the PRO under the Act.
(d) Notice to payers. The PRO must provide prompt written notice of an initial denial determination or changes as a result of a DRG validation to the Medicare fiscal intermediary or carrier within the same time periods as the notices to the other parties.

(e) Record of initial denial determination and changes as a result of a DRG validation. (1) The PRO must document and preserve a record of all initial denial determinations and changes as a result of DRG validations for six years from the date the services in question were provided.

(2) The documentary record must include—
   (i) The detailed basis for the initial denial determination or changes as a result of a DRG validation; and
   (ii) A copy of the determination or change in DRG notices sent to all parties and identification of each party and the date on which the notice was mailed or delivered.

§ 466.96 Review period and reopening of initial denial determinations and changes as a result of DRG validations.

(a) General timeframe. A PRO or its subcontractor—
   (1) Within one year of the date of the claim containing the service in question, may review and deny payment; and
   (2) Within one year of the date of its decision, may reopen an initial denial determination or a change as a result of a DRG validation.

(b) Extended timeframes. (1) An initial denial determination or change as a result of a DRG validation may be made after one year but within four years of the date of the claim containing the service in question, if HCFA approves.

(2) A reopening of an initial denial determination or change as a result of a DRG validation may be made after one year but within four years of the PRO's decision if—
   (i) Additional information is received on the patient's condition;
   (ii) Reviewer error occurred in interpretation or application of Medicare coverage policy or review criteria;
   (iii) There is an error apparent on the face of the evidence upon which the initial denial or DRG validation was based; or
   (iv) There is a clerical error in the statement of the initial denial determination or change as a result of a DRG validation.

(c) Fraud and abuse. (1) A PRO or its subcontractor may review and deny payment anytime there is a finding that the claim for service involves fraud or a similar abusive practice that does not support a finding of fraud.

(2) An initial denial determination or change as a result of a DRG validation may be reopened and revised anytime there is a finding that it was obtained through fraud or a similar abusive practice that does not support a finding of fraud.

§ 466.98 Reviewer qualifications and participation.

(a) Peer review by physician. (1) Except as provided in paragraph (a)(2) of this section, each person who makes an initial denial determination about services furnished or proposed to be furnished by a licensed doctor of medicine or osteopathy or by a doctor of dentistry must be respectively another licensed doctor of medicine or osteopathy or of dentistry with active staff privileges in one or more hospitals in the PRO area.

(2) If a PRO determines that peers are not available to make initial denial determinations, a doctor of medicine or osteopathy may make denial determinations for services ordered or performed by a doctor in any of the three specialties.

(b) Peer review by health care practitioners other than physicians. Health care practitioners other than physicians who make determinations on care ordered or furnished by their peers but not on care ordered or furnished by licensed doctors of medicine or osteopathy.

(c) DRG validation review. Decisions about procedural and diagnostic information must be made by physicians.
§ 466.100 Use of norms and criteria.  
(a) Use of norms. As specified in its contract, a PRO must use national, or where appropriate, regional norms in conducting review to achieve PRO contract objectives. However, with regard to determining the number of procedures selected for preadmission review, a PRO must use national admission norms.  
(b) Use of criteria. In assessing the need for and appropriateness of an inpatient health care facility stay, a PRO must apply criteria to determine—  
(1) The necessity for facility admission and continued stay (in cases of day outliers in hospitals under prospective payment);  
(2) The necessity for surgery and other invasive diagnostic and therapeutic procedures; or  
(3) The appropriateness of providing services at a particular health care facility or at a particular level of care. The PRO must determine whether the beneficiary requires the level of care received or whether a lower and less costly level of care would be equally effective.  
(c) Establishment of criteria and standards. For the conduct of review a PRO must—  
(1) Establish written criteria based upon typical patterns of practice in the PRO area, or use national criteria where appropriate; and  
(2) Establish written criteria and standards to be used in conducting quality review studies.  
(d) Variant criteria and standards. A PRO may establish specific criteria and standards to be applied to certain locations and facilities in the PRO area if the PRO determines that—  
(1) The patterns of practice in those locations and facilities are substantially different from patterns in the remainder of the PRO area; and  
(2) There is a reasonable basis for the difference which makes the variation appropriate.

§ 466.102 Involvement of health care practitioners other than physicians.  
(a) Basic requirement. Except as provided in paragraph (b) of this section, a PRO must meet the following requirements:  
(1) Consult with the peers of the practitioners who furnish the services under review if the PRO reviews care and services delivered by health care practitioners other than physicians.  
(2) Assure that in determinations regarding medical necessity of services or the quality of the services they furnish, these practitioners are involved in—  
(i) Developing PRO criteria and standards;  
(ii) Selecting norms to be used; and  
(iii) Developing review mechanisms for care furnished by their peers.  
(3) Ensure that an initial denial determination or a change as a result of DRG validation of services provided by a health care practitioner other than a physician is made by a physician only after consultation with a peer of that practitioner. Initial denial determinations and changes as a result of DRG validations must be made only by a physician or dentist.  
(b) Exception. The requirements of paragraph (a) of this section do not apply if—  
(1) The PRO has been unable to obtain a roster of peer practitioners available to perform review; or  
(2) The practitioners are precluded from performing review because they
Health Care Financing Administration, HHS § 473.12

participated in the treatment of the patient, the patient is a relative, or the practitioners have a financial interest in the health care facility as described in §466.98(d).

(c) Peer involvement in quality review studies. Practitioners must be involved in the design of quality review studies, development of criteria, and actual conduct of studies involving their peers.

(d) Consultation with practitioners other than physicians. To the extent practicable, a PRO must consult with nurses and other professional health care practitioners (other than physicians defined in 1861(r) (1) and (2) of the Act) and with representatives of institutional and noninstitutional providers and suppliers with respect to the PRO's responsibility for review.


§ 466.104 Coordination of activities.

In order to achieve efficient and economical review, a PRO must coordinate its activities (including information exchanges) with the activities of—

(a) Medicare fiscal intermediaries and carriers;
(b) Other PROs; and
(c) Other public or private review organizations as may be appropriate.

PART 473—RECONSIDERATIONS AND APPEALS

Subpart A—[Reserved]

Subpart B—Utilization and Quality Control Peer Review Organization (PRO) Reconsiderations and Appeals

SOURCE: 50 F.R. 15372, Apr. 17, 1985, unless otherwise noted.

§ 473.10 Scope.

This subpart establishes the requirements and procedures for—

(a) Reconsiderations conducted by a Utilization and Quality Control Peer Review Organization (PRO) or its subcontractor of initial denial determinations concerning services furnished or proposed to be furnished under Medicare;
(b) Hearings and judicial review of reconsidered determinations; and
(c) PRO review of a change in diagnostic and procedural coding information.


§ 473.12 Statutory basis.

(a) Under section 1154 of the Act, a PRO may make an initial determination that services furnished or proposed to be furnished are not reasonable, necessary, or delivered in the most appropriate setting.

(b) Under section 1155 of the Act, the following rules apply:
§ 473.14  Applicability.

(a) Basic provision. This subpart applies to reconsiderations and hearings of a PRO initial denial determination involving the following issues:

(1) Reasonableness of services.

(2) Medical necessity of services.

(3) Appropriateness of the inpatient setting in which services were furnished or are proposed to be furnished.

(b) Concurrent appeal. A reconsideration or hearing provided under this subpart fulfills the requirements of any other review, hearing, or appeal under the Act to which a party may be entitled with respect to the same issues.

(c) Nonapplicability of rules to related determinations. (1) A PRO may not reconsider its decision whether to grant grace days.

(2) Limitation of liability determinations on excluded coverage of certain services are made under section 1879 of the Act. Initial determinations under section 1879 and further appeals are governed by the reconsideration and appeal procedures in part 405, subpart G of this chapter for determinations under Medicare Part A, and part 405, subpart H of this chapter for determinations under Medicare Part B. References in those subparts to initial and reconsidered determinations made by an intermediary, carrier or HCFA should be read to mean initial and reconsidered determinations made by a PRO.

[50 FR 15372, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985]

§ 473.15  PRO review of changes resulting from DRG validation.

(a) General rules. (1) A provider or practitioner dissatisfied with a change to the diagnostic or procedural coding information made by a PRO as a result of DRG validation under section 1866(a)(1)(F) of the Act is entitled to a review of that change if—

(i) The change caused an assignment of a different DRG; and

(ii) Resulted in a lower payment.

(2) A beneficiary may obtain a review of a PRO DRG coding change only if that change results in noncoverage of a furnished service.

(3) The individual who reviews changes in DRG procedural or diagnostic information must be a physician, and the individual who reviews changes in DRG coding must be qualified through training and experience with ICD-9-CM coding.

(b) Procedures. Procedures described in §§473.18 through 473.36, and 473.48 (a) and (c) for a PRO reconsideration or reopening also apply to PRO review of a DRG coding change.

(c) Finality of review. No additional review or appeal for matters governed by paragraph (a) of this section is available.

[50 FR 15372, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985]

§ 473.16  Right to reconsideration.

A beneficiary, provider or practitioner who is dissatisfied with a PRO initial denial determination on one of the issues specified in §473.14(a) has a right to a reconsideration of that determination by the PRO that made the initial denial determination.

§ 473.18  Location for submitting requests for reconsideration.

(a) Beneficiaries. Except as provided in paragraph (c) of this section concerning requests for expedited reconsideration, a beneficiary who wishes to
obtain a reconsideration must submit a written request to one of the following:

(1) The PRO or the PRO subcontractor that made the initial determination.
(2) An SSA District Office.
(3) A Railroad Retirement Board Office, if the beneficiary is a railroad retiree.
(b) Others. A provider, physician or other practitioner that wishes to obtain reconsideration must submit a written request to the PRO or PRO subcontractor that made the initial determination.
(c) Expedited reconsideration. A request for an expedited reconsideration of a preadmission denial determination must be submitted directly to the PRO.

§ 473.20 Time limits for requesting reconsideration.
(a) Basic rules. (1) Except for a request for expedited reconsideration as provided in paragraph (c) of this section, or a late request with good cause under § 473.22, a dissatisfied party must file a request for reconsideration within 60 days after receipt of the notice of an initial determination.
(2) The date of receipt of the notice of the initial determination is presumed to be five days after the date on the notice, unless there is a reasonable showing to the contrary.
(3) A request is considered filed on the date it is postmarked.
(b) Late filing of request. A PRO will accept a request filed after 60 days after receipt of the notice of the initial determination if the PRO finds under the criteria set forth in § 473.22 that there was good cause for the party’s failure to file a timely request.
(c) Request for expedited reconsideration. A request for an expedited reconsideration under § 473.18(c) must be submitted within three days after receipt of the notice of the initial denial determination.

§ 473.22 Good cause for late filing of a request for a reconsideration or hearing.
(a) General Rule. In determining whether a party has good cause for not filing a request for reconsideration or hearing timely, the PRO or ALJ, respectively, must consider the following:
(1) What circumstances kept the party from making the request on time.
(2) Whether an action by the PRO misled the party.
(3) Whether the party understood the requirements of the Act as affected by amendments to the Act, other legislation, or court decisions.
(b) Examples. Examples of circumstances in which good cause may exist include, but are not limited to, the following:
(1) A party was seriously ill and was prevented from requesting a reconsideration in person, through another person, or in writing.
(2) There was a death or serious illness in a party’s immediate family.
(3) Important records were accidentally destroyed or damaged by fire or other cause.
(4) A party made a diligent effort but could not find or obtain necessary relevant information within the appropriate time period.
(5) A party requested additional information to further explain the determination within the time limit, and requested reconsideration within 60 days of receiving the explanation (or within 30 days for a Departmental Appeals Board hearing).
(6) The PRO gave the party incorrect or incomplete information about when and how to request a reconsideration or hearing.
(7) A party sent the request to another Government agency in good faith within the time limit, but the request did not reach an office authorized to receive the request until after the time period had expired.
(8) Other unusual or unavoidable circumstances exist that—
(i) Show that a party could not have known of the need to file timely; or
(ii) Prevented a party from filing timely.

§ 473.24 Opportunity for a party to obtain and submit information.
(a) Subject to the rules concerning disclosure of PRO information in section 1160 of the Act, at the request of a
§ 473.26 Provider, practitioner or beneficiary, the PRO must provide an opportunity for examination of the material upon which the initial denial determination was based. The PRO may not furnish a provider, practitioner or beneficiary with—

(1) A record of the PRO deliberation; or

(2) The identity of the PRO review coordinators, physician advisors, or consultants who assisted in the initial denial determination without their consent.

(b) The PRO may require the requester to pay a reasonable fee for the reproduction of the material requested.

(c) The PRO must provide a party with an opportunity to submit new evidence before the reconsidered determination is made.

§ 473.28 Qualifications of a reconsideration reviewer.

A reconsideration reviewer must be someone who is—

(a) Qualified under §466.98 of this chapter to make an initial determination.

(b) Not the individual who made the initial denial determination.

(c) A specialist in the type of services under review, except where meeting this requirement would compromise the effectiveness or efficiency of PRO review.

§ 473.30 Evidence to be considered by the reconsideration reviewer.

A reconsidered determination must be based on—

(a) The information that led to the initial determination;

(b) New information found in the medical records; or

(c) Additional evidence submitted by a party.

§ 473.32 Time limits for issuance of the reconsidered determination.

(a) Beneficiaries. If a beneficiary files a timely request for reconsideration of an initial denial determination, the PRO must complete its reconsidered determination and send written notice to the beneficiary within the following timelines—

(1) Within three working days after the PRO receives the request for reconsideration if—

(i) The beneficiary is still an inpatient in a hospital for the stay in question when the PRO receives the request for reconsideration; or

(ii) The initial determination relates to institutional services for which admission to the institution is sought, the initial determination was made before the patient was admitted to the institution; and a request was submitted timely for an expedited reconsideration.

(2) Within 10 working days after the PRO receives the request for reconsideration if the beneficiary is still an inpatient in a SNF for the stay in question when the PRO receives the request for reconsideration.

(3) Within 30 working days after the PRO receives the request for reconsideration if—

(i) The initial determination concerns ambulatory or noninstitutional services;

(ii) The beneficiary is no longer an inpatient in a hospital or SNF for the stay in question; or

(iii) The beneficiary does not submit a request for expedited reconsideration timely.

(b) Providers or practitioners. If the provider or practitioner files a request for reconsideration of an initial determination, the PRO must complete its reconsidered determination and send written notice to the provider or practitioner within 30 working days.

§ 473.34 Notice of a reconsidered determination.

(a) Notice to parties. A written notice of a PRO reconsidered determination must contain the following:

(1) The basis for the reconsidered determination.

(2) A detailed rationale for the reconsidered determination.
§ 473.42 Submitting a request for a hearing.

(a) Where to submit the written request. A beneficiary who wants to obtain a hearing under §473.40 must submit a written request to one of the following:

(1) A PRO must provide written notice of its reconsidered determination to the appropriate Medicare intermediary or carrier within 30 days if the initial determination is modified or reversed.

(2) This notice must contain adequate information to allow the intermediary or carrier to locate the claim file. This must include the name of the beneficiary, the Health Insurance Claim Number, the name of the provider, date of admission, and dates or services for which Medicare payment will not be made.

§ 473.36 Record of reconsideration.

(a) PRO requirements. A PRO must maintain the record of its reconsideration until the later of the following:

(1) Four years after the date on the notice of the PRO’s reconsidered determination.

(2) Completion of litigation and the passage of the time period for filing all appeals.

(b) Contents of the record. The record of the reconsideration must include:

(1) The initial determination.

(2) The basis for the initial determination.

(3) Documentation of the date of the receipt of the request for reconsideration.

(4) The detailed basis for the reconsidered determination.

(5) Evidence submitted by the parties.

(6) A copy of the notice of the reconsidered determination that was provided to the parties.

(7) Documentation of the delivery or mailing and, if appropriate, the receipt of the notice of the reconsidered determination by the parties.

(c) Confidentiality. The record of a PRO reconsidered determination is subject to prohibitions against disclosure of information as specified in section 1160 of the Act.

§ 473.38 Effect of a reconsidered determination.

A PRO reconsidered determination is binding upon all parties to the reconsideration unless—

(a) A hearing is requested in accordance with §473.40 and a final decision rendered; or

(b) The reconsidered determination is later reopened and revised in accordance with §473.48.

§ 473.40 Beneficiary's right to a hearing.

(a) Amount in controversy. If the amount in controversy is at least $200, a beneficiary (but not a provider or practitioner) who is dissatisfied with a PRO reconsidered determination may obtain a hearing by an administrative law judge (ALJ) of the Office of Hearings and Appeals of the SSA.

(b) Subject matter. A beneficiary has a right to a hearing on the following issues:

(1) Reasonableness of the services.

(2) Medical necessity of the services.

(3) Appropriateness of the setting in which the services were furnished.

(c) Governing provisions. The provisions of subpart G, Reconsiderations and Appeals under the Hospital Insurance Program, of part 405 of this chapter apply to hearings and appeals under this subpart unless they are inconsistent with specific provisions in this subpart. References in subpart G to initial and reconsidered determinations made by an intermediary, carrier, or HCFA should be read to mean initial and reconsidered determinations made by a PRO.

§ 473.44 Determining the amount in controversy for a hearing.

(a) After an individual appellant has submitted a request for a hearing, the ALJ determines the amount in controversy in accordance with §405.740(a) of this chapter for Part A services or §405.817(a) of this chapter for Part B services. When two or more appellants submit a request for hearing, the ALJ determines the amount in controversy in accordance with §405.740(b) of this chapter for Part A services and §405.817(b) of this chapter for Part B services.

(b) If the ALJ determines that the amount in controversy is less than $200, the ALJ, without holding a hearing, notifies the parties to the hearing that the parties have 15 calendar days to submit additional evidence to prove that the amount in controversy is at least $200.

(c) At the end of the 15-day period, if the ALJ determines that the amount in controversy is less than $200, the ALJ, without holding a hearing, dismisses the request for a hearing without ruling on the substantive issues involved in the appeal and notifies the parties to the hearing and the PRO that the PRO reconsidered determination is conclusive for Medicare payment purposes.

§ 473.46 Departmental Appeals Board and judicial review.

(a) The circumstances under which the DAB will review an ALJ hearing decision or dismissal are the same as those set forth at 20 CFR 404.970, (“Cases the Appeals Council will review”).

(b) If $2,000 or more is in controversy, a party may obtain judicial review of a Departmental Appeals Board decision, or an ALJ hearing decision if a request for review by the Departmental Appeals Board was denied, by filing a civil action under the Federal Rules of Civil Procedure within 60 days after the date the party received notice of the Departmental Appeals Board decision or denial.

§ 473.48 Reopening and revision of a reconsidered determination or a hearing decision.

(a) PRO reopenings—(1) General rule. A PRO or PRO subcontractor that made a reconsidered determination, or conducted a review of a DRG change as described in §473.15, that is otherwise binding, may reopen and revise the reconsidered determination or review, either on its own motion or at the request of a party, within one year from the date of the reconsidered determination or review.

(2) Extension of time limit. A PRO or PRO subcontractor may reopen and revise its reconsidered determination, or its review of a DRG change as described in §473.15, that is otherwise binding, after one year but within four years of the date of the determination or review if—

(i) The PRO receives new material evidence;

(ii) The PRO erred in interpretation or application of Medicare coverage policy;

(iii) There is an error apparent on the face of the evidence upon which the reconsidered determination was based; or
(iv) There is a clerical error in the statement of the reconsidered determination.

(b) ALJ and Departmental Appeals Board Reopening—Applicable procedures. The ALJ or the Departmental Appeals Board, whichever made the decision, may reopen and revise the decision in accordance with the procedures set forth in §405.750(b) of this chapter, which concerns reopenings and revisions under subpart G of part 405 of this chapter.

(c) Fraud or similar abusive practice. A reconsidered determination, a review of a DRG change, or a decision of an ALJ or the Departmental Appeals Board may be reopened and revised at any time, if the reconsidered determination, review, or decision was obtained through fraud or a similar abusive practice that does not support a formal finding of fraud.


PART 476—ACQUISITION, PROTECTION, AND DISCLOSURE OF PEER REVIEW INFORMATION

Subpart A—[Reserved]

Subpart B—Utilization and Quality Control Peer Review Organizations (PROs)

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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—Utilization and Quality Control Peer Review Organizations (PROs)

SOURCE: 50 FR 15359, Apr. 17, 1985, unless otherwise noted.

GENERAL PROVISIONS

§ 476.101 Scope and definitions.

(a) Scope. This subpart sets forth the policies and procedures governing—
(1) Disclosure of information collected, acquired or generated by a Utilization and Quality Control Peer Review Organization (PRO) (or the review component of a PRO subcontractor) in performance of its responsibilities under the Act and these regulations; and

(2) Acquisition and maintenance of information by a PRO to comply with its responsibilities under the Act.

(b) Definitions. As used in this part:

Abuse means any unlawful conduct relating to items or services for which payment is sought under Title XVIII of the Act.

Aggregate statistical data means any utilization, admission, discharge or diagnostic related group (DRG) data arrayed on a geographic, institutional or other basis in which the volume and frequency of services are shown without identifying any individual.

Confidential information means any of the following:

(1) Information that explicitly or implicitly identifies an individual patient, practitioner or reviewer.

(2) Sanction reports and recommendations.

(3) Quality review studies which identify patients, practitioners or institutions.

(4) PRO deliberations.

Health care facility or facility means an organization involved in the delivery of health care services or items for which reimbursement may be made in whole or in part under Title XVIII of the Act.

Implicitly identify(ies) means data so unique or numbers so small so that identification of an individual patient, practitioner or reviewer would be obvious.

Non-facility organization means a corporate entity that: (1) Is not a health care facility; (2) is not a 5 percent or more owner of a facility; and (3) is not owned by one or more health care facilities in the PRO area.

Patient representative means—(1) an individual designated by the patient, in writing, as authorized to request and receive PRO information that would otherwise be disclosable to that patient; or (2) an individual identified by the PRO in accordance with §476.132(c)(3) when the beneficiary is mentally, physically or legally unable to designate a representative.

Practitioner means an individual credentialed within a recognized health care discipline and involved in providing the services of that discipline to patients.

PRO deliberations means discussions or communications (within a PRO or between a PRO and a PRO subcontractor) including, but not limited to, review notes, minutes of meetings and any other records of discussions and judgments involving review matters regarding PRO review responsibilities and appeals from PRO determinations, in which the opinions of, or judgment about, a particular individual or institution can be discerned.

PRO information means any data or information collected, acquired or generated by a PRO in the exercise of its duties and functions under Title XI Part B or Title XVIII of the Act.

PRO interpretations and generalizations on the quality of health care means an assessment of the quality of care furnished by an individual provider or group of providers based on the PRO’s knowledge of the area gained from its medical review experience (e.g., quality review studies) and any other information obtained through the PRO’s review activities.

PRO review system means the PRO and those organizations and individuals who either assist the PRO or are directly responsible for providing medical care or for making determinations with respect to the medical necessity, appropriate level and quality of health care services that may be reimbursed under the Act. The system includes—

(1) The PRO and its officers, members and employees;

(2) PRO subcontractors;

(3) Health care institutions and practitioners whose services are reviewed;

(4) PRO reviewers and supporting staff; and

(5) Data support organizations.

Public information means information which has been disclosed to the public.

Quality review study means an assessment, conducted by or for a PRO, of a patient care problem for the purpose of improving patient care through peer analysis, intervention, resolution of the problem and follow-up.
§ 476.102 Statutory bases for acquisition and maintenance of information.

(a) Section 1154(a)(7)(C) of the Act requires PROs to the extent necessary and appropriate to examine the pertinent records of any practitioner or provider of health care services for which payment may be made under Title XVIII of the Act.

(b) Section 1154(a)(9) of the Act requires PROs to collect and maintain information necessary to carry out their responsibilities under the Act.

(c) Section 1156(a)(3) of the Act requires health care practitioners and providers to maintain evidence of the medical necessity and quality of health care services they provide to Medicare patients as required by PROs.

§ 476.103 Statutory bases for disclosure of information.

(a) Section 1154(a)(10) of the Act requires PROs to exchange information with intermediaries and carriers with contracts under sections 1816 and 1842 of the Act, other PROs, and other public or private review organizations as appropriate.

(b) Section 1160 of the Act provides that PRO information must be held in confidence and not be disclosed except where—

(1) Necessary to carry out the purpose of Title XI Part B of the Act;

(2) Specifically permitted or required under this subpart;

(3) Necessary, and in the manner prescribed under this subpart, to assist Federal and State agencies recognized by the Secretary as having responsibility for identifying and investigating cases or patterns of fraud or abuse;

(4) Necessary, and in the manner prescribed under the subpart to assist Federal or State agencies recognized by the Secretary as having responsibility for identifying cases or patterns involving risks to the public health;

(5) Necessary, and in the manner prescribed under this subpart to assist appropriate State agencies having responsibility for licensing or certification of providers or practitioners; or

(6) Necessary, and in the manner prescribed under this subpart to assist Federal or State health planning agencies by furnishing them aggregate statistical data on a geographical, institutional or other basis.

§ 476.104 Procedures for disclosure by a PRO.

(a) Notice to accompany disclosure.

(1) Any disclosure of information under the authority of this subpart is subject to the requirements in §476.105 relating to the providing of a notice of the disclosure.

(2) Disclosure of confidential information made under the authority of this subpart, except as provided in §476.106, must be accompanied by a written statement informing the recipient that the information may not be redisclosed except as provided under §476.107 that limits redisclosure.

(b) PRO interpretations. A PRO may provide a statement of comment, analysis, or interpretation to guide the recipient in using information disclosed under this subpart.

(c) Fees. A PRO may charge a fee to cover the cost of providing information authorized under this subpart. These

§ 476.105 Notice of information disclosure.

(a) Notice shall include the following information:

(1) A statement that the information is confidential and not to be disclosed except as provided under §476.107 that limits redisclosure.

(2) A statement identifying the purpose of the disclosure.

(3) A statement identifying the basis for the authority of the disclosure.

(4) A statement identifying the recipient of the information.

(5) A statement identifying the source of the information.

(6) A statement identifying the manner of the disclosure.

(b) A separate notice shall be provided to each recipient of information disclosed under this subpart.

(c) A separate notice shall be provided to each recipient of information disclosed under this subpart.

(d) A separate notice shall be provided to each recipient of information disclosed under this subpart.

(e) A separate notice shall be provided to each recipient of information disclosed under this subpart.

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§ 476.105 Notice of disclosures made by a PRO.

(a) Notification of the disclosure of non-confidential information. Except as permitted under §476.106, at least 30 calendar days before disclosure of nonconfidential information, the PRO must notify an identified institution of its intent to disclose information about the institution (other than reports routinely submitted to HCFA or Medicare fiscal intermediaries, or to or from PRO subcontractors, or to or from the institution) and provide the institution with a copy of the information. The institution may submit comments to the PRO that must be attached to the information disclosed if received before disclosure, or forwarded separately if received after disclosure.

(b) Notification of the disclosure of confidential information. (1) A PRO must notify the practitioner who has treated a patient, of a request for disclosure to the patient or patient representative in accordance with the requirements and exceptions to the requirements for disclosure specified under §476.132.

(2) A PRO must notify a practitioner or institution of the PRO’s intent to disclose information on the practitioner or institution to an investigative or licensing agency (§§476.137 and 476.138) except for cases specified in §476.106 involving fraud or abuse or imminent danger to individuals or the public health. The practitioner or institution must be notified and provided a copy of the information to be disclosed at least 30 calendar days before the PRO discloses the identifying information. The PRO must forward with the information any comments submitted by the practitioner or institution in response to the PRO notice if received before disclosure, or forwarded separately if received after disclosure.

[50 FR 15359, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985]

§ 476.106 Exceptions to PRO notice requirements.

(a) Imminent danger to individuals or public health. When the PRO determines that requested information is necessary to protect against an imminent danger to individuals or the public health, the notification required in §476.105 may be sent simultaneously with the disclosure.

(b) Fraud or Abuse. The notification requirement in §476.105 does not apply if—

(1) The disclosure is made in an investigation of fraud or abuse by the Office of the Inspector General or the General Accounting Office; or

(2) The disclosure is made in an investigation of fraud or abuse by any other Federal or State fraud or abuse agency and the investigative agency specifies in writing that the information is related to a potentially prosecutable criminal offense.

§ 476.107 Limitations on redisclosure.

Persons or organizations that obtain confidential PRO information must not further disclose the information to any other person or organization except—

(a) As directed by the PRO to carry out a disclosure permitted or required under a particular provision of this part;

(b) As directed by HCFA to carry out specific responsibilities of the Secretary under the Act;

(c) As necessary for HCFA to carry out its responsibilities for appeals under section 1155 of the Act or for HCFA to process sanctions under section 1156 of the Act;

(d) If the health care services furnished to an individual patient are reimbursed from more than one source, these sources of reimbursement may exchange confidential information as necessary for the payment of claims;

(e) If the information is acquired by the PRO from another source and the receiver of the information is authorized under its own authorities to acquire the information directly from the...
§ 476.111 PRO access to records and information of institutions and practitioners.

(a) A PRO is authorized to have access to and obtain records and information pertinent to the health care services furnished to Medicare patients, held by any institution or practitioner in the PRO area. The PRO may require the institution or practitioner to provide copies of such records or information to the PRO.

(b) A PRO may obtain non-Medicare patient records relating to review performed under a non-Medicare PRO contract if authorized by those patients in accordance with State law.

(c) In accordance with its quality review responsibilities under the Act, a PRO may have access to and obtain information from, the records of non-Medicare patients if authorized by the institution or practitioner.

[50 FR 15359, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985]

§ 476.112 PRO access to records and information of intermediaries and carriers.

A PRO is authorized to have access to and require copies of Medicare records or information held by intermediaries or carriers if the PRO determines that the records or information are necessary to carry out PRO review responsibilities.

[50 FR 15359, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985]

§ 476.113 PRO access to information collected for PRO purposes.

(a) Institutions and other entities must disclose to the PRO information collected by them for PRO purposes.

(b) Information collected or generated by institutions or practitioners to carry out quality review studies must be disclosed to the PRO.

[50 FR 15359, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985]

§ 476.114 Limitation on data collection.

A PRO or any agent, organization, or institution acting on its behalf, that is collecting information under authority of this part, must collect only that information which is necessary to accomplish the purposes of Title XI Part B of
§ 476.115 Requirements for maintaining confidentiality.

(a) Responsibilities of PRO officers and employees. The PRO must provide reasonable physical security measures to prevent unauthorized access to PRO information and to ensure the integrity of the information, including those measures needed to secure computer files. Each PRO must instruct its officers and employees and health care institution employees participating in PRO activities of their responsibility to maintain the confidentiality of information and of the legal penalties that may be imposed for unauthorized disclosure of PRO information.

(b) Responsible individuals within the PRO. The PRO must assign a single individual the responsibility for maintaining the system for assuring the confidentiality of information within the PRO review system. That individual must notify HCFA of any violations of these regulations.

(c) Training requirements. The PRO must train participants of the PRO review system in the proper handling of confidential information.

(d) Authorized access. An individual participating in the PRO review system on a routine or ongoing basis must not have authorized access to confidential PRO information unless that individual—

(1) Has completed a training program in the handling of PRO information in accordance with paragraph (c) of this section or has received comparable training from another source; and

(2) Has signed a statement indicating that he or she is aware of the legal penalties for unauthorized disclosure.

(e) Purging of personal identifiers. (1) The PRO must purge or arrange for purging computerized information, patient records and other noncomputerized files of all personal identifiers as soon as it is determined by HCFA that those identifiers are no longer necessary.

(2) The PRO must destroy or return to the facility from which it was collected confidential information generated from computerized information, patient records and other noncomputerized files when the PRO determines that the maintenance of hard copy is no longer necessary to serve the specific purpose for which it was obtained or generated.

(f) Data system procedures. The PRO must assure that organizations and consultants providing data services to the PRO have established procedures for maintaining the confidentiality of PRO information in accordance with requirements defined by the PRO and consistent with procedures established under this part.

§ 476.116 Notice to individuals and institutions under review.

The PRO must establish and implement procedures to provide patients, practitioners, and institutions under review with the following information—

(a) The title and address of the person responsible for maintenance of PRO information;

(b) The types of information that will be collected and maintained;

(c) The general rules governing disclosure of PRO information; and

(d) The procedures whereby patients, practitioners, and institutions may obtain access to information about themselves.

DISCLOSURE OF NONCONFIDENTIAL INFORMATION

§ 476.120 Information subject to disclosure.

Subject to the procedures for disclosure and notice of disclosure specified in §§ 476.104 and 476.105, the PRO must disclose—

(a) Nonconfidential information to any person upon request, including—

(1) The norms, criteria, and standards it uses for initial screening of cases, and for other review activities;

(2) Winning technical proposals for contracts from the Department, and winning technical proposals for subcontracts under those contracts (except for proprietary or business information);

(3) Copies of documents describing administrative procedures, agreed to between the PRO and institutions or
§ 476.132 Disclosure of information about patients.

(a) General requirements for disclosure.

 Except as specified in paragraph (b) of this section, a PRO must—

(1) Disclose patient identified information in its possession to the identified patient or the patient’s representative if—

(i) The patient or the patient’s representative requests the information in writing;

(ii) The request by a patient’s representative includes the designation, by the patient, of the representative; and

(iii) All other patient and practitioner identifiers have been removed.

(2) Seek the advice of the attending practitioner that treated the patient regarding the appropriateness of direct disclosure to the patient 15 days before the PRO provides the requested information. If the attending practitioner states that the released information could harm the patient, the PRO must act in accordance with paragraph (c)(2) of this section. The PRO must make disclosure to the patient or patient’s representative within 30 calendar days of receipt of the request.

(b) Exceptions. (1) If the request is in connection with an initial denial determination under section 1154(a)(3) of the Act, the PRO—

(i) Need not seek the advice of the practitioner that treated the patient regarding the appropriateness of direct disclosure to the patient; and

(ii) Must provide only the information used to support that determination in accordance with the procedures for disclosure of information relating to determinations under §473.24.

(2) A PRO must disclose information regarding PRO deliberations only as specified in §476.139(a).
(3) A PRO must disclose quality review study information only as specified in §476.140.

(c) Manner of disclosure. (1) The PRO must disclose the patient information directly to the patient unless knowledge of the information could harm the patient.

(2) If knowledge of the information could harm the patient, the PRO must disclose the information to the patient’s designated representative.

(3) If the patient is mentally, physically or legally unable to designate a representative, the PRO must disclose the information to a person whom the PRO determines is responsible for the patient.

The PRO must first attempt to make that determination based on the medical record. If the responsible person is not named in the medical record, then the PRO may rely on the attending practitioner for the information. If the practitioner is unable to provide a name, then the PRO must make a determination based on other reliable information.

[50 FR 15359, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985]

§476.133 Disclosure of information about practitioners, reviewers and institutions.

(a) General requirements for disclosure. Except as specified in paragraph (b) of this section, the following provisions are required of the PRO.

(1) Disclosure to the identified individual or institution. A PRO must disclose, to particular practitioners, reviewers and institutions, information about themselves, upon request, and may disclose it to them without a request.

(2) Disclosure to others. (i) A PRO must disclose to an institution, upon request, information on a practitioner to the extent that the information displays practice or performance patterns of the practitioner in that institution.

(ii) In accordance with section 1160 of the Act, a PRO must disclose information that displays practice or performance patterns of a practitioner or institution in accordance with the procedures for disclosures specified in §§476.137 and 476.138 to—

(A) Federal and State agencies that are responsible for the investigation of fraud and abuse of the Medicare or Medicaid programs, and

(B) Federal and State agencies that are responsible for licensing and certification of practitioners and providers.

(iii) A PRO may disclose to any person, agency or organization, information on a particular practitioner or reviewer with the consent of that practitioner or reviewer provided that the information does not identify other individuals.

(b) Exceptions. (1) If the request is in connection with an initial denial determination or a change resulting from a diagnostic related group (DRG) coding validation under Part 466 of this subchapter, the PRO must provide only the information used to support that determination in accordance with the procedures for disclosure of information relating to determinations under §473.24.

(2) A PRO must disclose information regarding PRO deliberations only as specified in §476.139(a).

(3) A PRO must disclose quality review study information only as specified in §476.140.


§476.134 Verification and amendment of PRO information.

(a) A PRO must verify the accuracy of its information concerning patients, practitioners, reviewers, and institutions and must permit the individual or institution to request an amendment of pertinent information that is in the possession of the PRO.

(b) If the PRO agrees with the request for amendment, the PRO must correct the information in its possession. If the information being amended has already been disclosed, the PRO must forward the amended information to the requester where it may affect decisions about a particular provider, practitioner or case under review.

(c) If the PRO disagrees with the request for amendment, a notation of the request, reasons for the request, and
§ 476.135 Disclosure necessary to perform review responsibilities.

(a) Disclosure to conduct review. The PRO must disclose or arrange for disclosure of information to individuals and institutions within the PRO review system as necessary to fulfill their particular duties and functions under Title XI Part B of the Act.

(b) Disclosure to consultants and subcontractors. The PRO must disclose to consultants or subcontractors the information they need to provide specified services to the PRO.

(c) Disclosure to other PRO and medical review boards. The PRO must disclose—

(1) To another PRO, information on patients and practitioners who are subject to review by the other PRO; and

(2) To medical review boards established under section 1881 of the Act, confidential information on patients, practitioners and institutions receiving or furnishing end stage renal disease services.

§ 476.136 Disclosure to intermediaries and carriers.

(a) Required disclosure. Except as specified in §§476.139(a) and 476.140 relating to disclosure of PRO deliberations and quality review study information, a PRO must disclose to intermediaries and carriers PRO information that relates to, or is necessary for, payment of claims for Medicare as follows:

(1) Review determinations and claims forms for health care services, furnished in the manner and form agreed to by the PRO and the intermediary or carrier.

(2) Upon request, copies of medical records acquired from practitioners or institutions for review purposes.

(3) PRO information about a particular patient or practitioner if the PRO and the intermediary or carrier (or HCFA if the PRO and the intermediary or carrier cannot agree) determine that the information is necessary for the administration of the Medicare program.

(b) Optional disclosure. The PRO may disclose the information specified in paragraph (a) of this section to intermediaries and carriers without a request.

§ 476.137 Disclosure to Federal and State enforcement agencies responsible for the investigation or identification of fraud or abuse of the Medicare or Medicaid programs.

(a) Required disclosure. Except as specified in §§476.139(a) and 476.140 relating to disclosure of PRO deliberations and quality review study information, the PRO must disclose confidential information relevant to an investigation of fraud or abuse of the Medicare or Medicaid programs, including PRO medical necessity determinations and other information that includes patterns of the practice or performance of a practitioner or institution, when a written request is received from a State or Federal enforcement agency responsible for the investigation or identification of fraud or abuse of the Medicare or Medicaid programs that—

(1) Identifies the name and title of the individual initiating the request,

(2) Identifies the physician or institution about which information is requested, and

(3) States affirmatively that the institution or practitioner is currently under investigation for fraud or abuse of the Medicare or Medicaid programs and that the information is needed in furtherance of that investigation.

(b) Optional disclosure. The PRO may provide the information specified in paragraph (a) of this section to Federal or State fraud and abuse enforcement agencies responsible for the investigation or identification of fraud or abuse of the Medicare or Medicaid programs, without a request.

§ 476.138 Disclosure for other specified purposes.

(a) General requirements for disclosure. Except as specified in paragraph (b) of this section, the following provisions are required of the PRO.

(1) Disclosure to licensing and certification bodies. (i) A PRO must disclose
§ 476.139 Disclosure of PRO deliberations and decisions.

(a) PRO deliberations. (1) A PRO must not disclose its deliberations except to—

(i) HCFA, at the PRO office or at a subcontracted organization;
(ii) HCFA, to the extent that the deliberations are incorporated in sanction and appeals reports; or
(iii) The Office of the Inspector General, and the General Accounting Office as necessary to carry out statutory responsibilities.

(2) PRO deliberations are not disclosable, either in written form or through oral testimony, in connection with the administrative hearing or review of a beneficiary’s claim.

(b) Reasons for PRO decisions. (1) A PRO may disclose to those who have access to PRO information under other provisions of this subpart, the reasons for PRO decisions pertaining to that information provided that the opinions or judgements of a particular individual or practitioner cannot be identified.

(2) A PRO must disclose, if requested in connection with the administrative hearing or review of a beneficiary’s claim, the reasons for PRO decisions. The PRO must include the detailed facts, findings and conclusions supporting the PRO’s determination. The PRO must insure that the opinions or judgements of a particular individual or practitioner cannot be identified through the materials that are disclosed.

§ 476.140 Disclosure of quality review study information.

(a) A PRO must disclose, onsite, quality review study information with identifiers of patients, practitioners or institutions to—

(1) Representatives of authorized licensure, accreditation or certification agencies as is required by the agencies in carrying out functions which are within the jurisdiction of such agencies under state law; to federal and state agencies responsible for identifying risks to the public health when there is substantial risk to the public health; HCFA; or to Federal and State fraud and abuse enforcement agencies;

(2) An institution or practitioner, if the information is limited to health care services furnished by the institution or practitioner; and

(3) A medical review board established under section 1881 of the Act pertaining to end-stage renal disease facilities, if the information is limited to health care services subject to its review.

[50 FR 15359, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985]

§ 476.139 Disclosure of confidential information upon request, to State or Federal licensing bodies responsible for the professional licensure of a practitioner or a particular institution. Confidential information, including PRO medical necessity determinations that display the practice or performance patterns of that practitioner, must be disclosed by the PRO but only to the extent that it is required by the agency to carry out a function within the jurisdiction of the agency under Federal or State law.

(ii) A PRO may provide the information specified in paragraph (a)(1)(i) of this section to the State or Federal licensing body without request.

(2) Disclosure to State and local public health officials. A PRO must disclose PRO information to State and local public health officials whenever the PRO determines that the disclosure of the information is necessary to protect against a substantial risk to the public health.

(3) Disclosure to the courts. Patient identified records in the possession of a PRO are not subject to subpoena or discovery in a civil action, including an administrative, judicial or arbitration proceeding.

(b) Exceptions. (1) The restriction set forth in paragraph (a)(3) of this section does not apply to HHS, including Inspector General, administrative subpoenas issued in the course of audits and investigations of Department programs, in the course of administrative hearings held under the Social Security Act or to disclosures to the General Accounting Office as necessary to carry out its statutory responsibilities.

(2) A PRO must disclose information regarding PRO deliberations and quality review study information only as specified in §§ 476.139(a) and 476.140.
§ 476.143 PRO involvement in shared health data systems.

(a) Information collected by a PRO. Except as prohibited in paragraph (b) of this section, information collected by a PRO may be processed and stored by a cooperative health statistics system established under the Public Health Service Act (42 U.S.C. 242k) or other State or Federally authorized shared data system.

(b) PRO participation. A PRO may not participate in a cooperative health statistics system or other shared health data system if the disclosure rules of the system would prevent the PRO from complying with the rules of this part.

(c) Disclosure of PRO information obtained by a shared health data system. PRO information must not be disclosed by the shared health data system unless—

(1) The source from which the PRO acquired the information consents to or requests disclosure; or

(2) The PRO requests the disclosure of the information to carry out a disclosure permitted under a provision of this part.

§ 476.142 Disclosure of sanction reports.

(a) The PRO must disclose sanction reports directly to the Office of the Inspector General and, if requested, to HCFA.

(b) The PRO must upon request, and may without a request, disclose sanction reports to State and Federal agencies responsible for the identification, investigation or prosecution of cases of fraud or abuse in accordance with § 476.137.

(c) HCFA will disclose sanction determinations in accordance with part 474 of this chapter.

§ 476.141 Disclosure of PRO interpretations on the quality of health care.

Subject to the procedures for disclosure and notice of disclosure specified in §§ 476.104 and 476.105, a PRO may disclose to the public PRO interpretations and generalizations on the quality of health care that identify a particular institution.
PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

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482.2 Provision of emergency services by nonparticipating hospitals.

Subpart B—Administration

482.11 Condition of participation: Compliance with Federal, State and local laws.
482.12 Condition of participation: Governing body.

Subpart C—Basic Hospital Functions

482.21 Condition of participation: Quality assurance.
482.22 Condition of participation: Medical staff.
482.23 Condition of participation: Nursing services.
482.24 Condition of participation: Medical record services.
482.25 Condition of participation: Pharmaceutical services.
482.26 Condition of participation: Radiologic services.
482.27 Condition of participation: Laboratory services.
482.28 Condition of participation: Food and dietetic services.
482.30 Condition of participation: Utilization review.
482.41 Condition of participation: Physical environment.
482.42 Condition of participation: Infection control.
482.43 Condition of participation: Discharge planning.
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Subpart D—Optional Hospital Services

482.51 Condition of participation: Surgical services.
482.52 Condition of participation: Anesthesia services.
482.53 Condition of participation: Nuclear medicine services.
482.54 Condition of participation: Outpatient services.
482.55 Condition of participation: Emergency services.
482.56 Condition of participation: Rehabilitation services.
482.57 Condition of participation: Respiratory care services.

Subpart E—Requirements for Specialty Hospitals

482.60 Special provisions applying to psychiatric hospitals.
482.61 Condition of participation: Special medical record requirements for psychiatric hospitals.
482.62 Condition of participation: Special staff requirements for psychiatric hospitals.
482.66 Special requirements for hospital providers of long-term care services ("swing-beds").

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).
SOURCE: 51 FR 22042, June 17, 1986, unless otherwise noted.

Subpart A—General Provisions

§ 482.1 Basis and scope.
(a) Statutory basis. (1) Section 1861(e) of the Act provides that—
(i) Hospitals participating in Medicare must meet certain specified requirements; and
(ii) The Secretary may impose additional requirements if they are found necessary in the interest of the health and safety of the individuals who are furnished services in hospitals.
(2) Section 1861(f) of the Act provides that an institution participating in Medicare as a psychiatric hospital must meet certain specified requirements imposed on hospitals under section 1861(e), must be primarily engaged in providing, by or under the supervision of a physician, psychiatric services for the diagnosis and treatment of mentally ill persons, must maintain clinical records and other records that the Secretary finds necessary, and must meet staffing requirements that the Secretary finds necessary to carry out an active program of treatment for individuals who are furnished services in the hospital. A distinct part of an institution can participate as a psychiatric hospital if the institution meets the specified 1861(e) requirements and is primarily engaged in providing psychiatric services, and if the distinct part meets the records and staffing requirements that the Secretary finds necessary.
(3) Sections 1861(k) and 1902(a)(30) of the Act provide that hospitals participating in Medicare and Medicaid must have a utilization review plan that meets specified requirements.

(4) Section 1883 of the Act sets forth the requirements for hospitals that provide long term care under an agreement with the Secretary.

(5) Section 1905(a) of the Act provides that “medical assistance” (Medicaid) payments may be applied to various hospital services. Regulations interpreting those provisions specify that hospitals receiving payment under Medicaid must meet the requirements for participation in Medicare (except in the case of medical supervision of nurse-midwife services. See §§440.10 and 440.165 of this chapter.).

(b) Scope. Except as provided in subpart A of part 488 of this chapter, the provisions of this part serve as the basis of survey activities for the purpose of determining whether a hospital qualifies for a provider agreement under Medicare and Medicaid.

[51 FR 22042, June 17, 1986, as amended at 60 FR 50442, Sept. 29, 1995]

§ 482.12 Condition of participation: Governing body.

(a) The hospital must have an effective governing body legally responsible for the conduct of the hospital as an institution. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body.

(b) Standard: Chief executive officer. The governing body must:

(1) Determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff;

(2) Appoint members of the medical staff after considering the recommendations of the existing members of the medical staff;

(3) Assure that the medical staff has bylaws;

(4) Approve medical staff bylaws and other medical staff rules and regulations;

(5) Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients;

(6) Ensure the criteria for selection are individual character, competence, training, experience, and judgment; and

(7) Ensure that under no circumstances is the appointment of staff membership or professional privileges in the hospital dependent solely upon certification, fellowship, or membership in a specialty body or society.


Subpart B—Administration

§ 482.11 Condition of participation: Compliance with Federal, State and local laws.

(a) The hospital must be in compliance with applicable Federal laws related to the health and safety of patients.

(b) The hospital must be—

(1) Licensed; or

(2) Approved as meeting standards for licensing established by the agency of the State or locality responsible for licensing hospitals.

(c) The hospital must assure that personnel are licensed or meet other applicable standards that are required by State or local laws.

§ 482.12 Condition of participation: Governing body.

The hospital must have an effective governing body legally responsible for the conduct of the hospital as an institution. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body.

(a) Standard: Medical staff. The governing body must:

(1) Determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff;

(2) Appoint members of the medical staff after considering the recommendations of the existing members of the medical staff;

(3) Assure that the medical staff has bylaws;

(4) Approve medical staff bylaws and other medical staff rules and regulations;

(5) Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients;

(6) Ensure the criteria for selection are individual character, competence, training, experience, and judgment; and

(7) Ensure that under no circumstances is the appointment of staff membership or professional privileges in the hospital dependent solely upon certification, fellowship, or membership in a specialty body or society.

(b) Standard: Chief executive officer. The governing body must appoint a chief executive officer who is responsible for managing the hospital.
(c) Standard: Care of patients. In accordance with hospital policy, the governing body must ensure that the following requirements are met:

(1) Every Medicare patient is under the care of:
   (i) A doctor of medicine or osteopathy (This provision is not to be construed to limit the authority of a doctor of medicine or osteopathy to delegate tasks to other qualified health care personnel to the extent recognized under State law or a State’s regulatory mechanism);
   (ii) A doctor of dental surgery or dental medicine who is legally authorized to practice dentistry by the State and who is acting within the scope of his or her license;
   (iii) A doctor of podiatric medicine, but only with respect to functions which he or she is legally authorized by the State to perform;
   (iv) A doctor of optometry who is legally authorized to practice optometry by the State in which he or she practices;
   (v) A chiropractor who is licensed by the State or legally authorized to perform the services of a chiropractor, but only with respect to treatment by means of manual manipulation of the spine to correct a subluxation demonstrated by x-ray to exist; and
   (vi) A clinical psychologist as defined in § 410.71 of this chapter, but only with respect to clinical psychologist services as defined in § 410.71 of this chapter and only to the extent permitted by State law.

(2) Patients are admitted to the hospital only on the recommendation of a licensed practitioner permitted by the State to admit patients to a hospital. If a Medicare patient is admitted by a practitioner not specified in paragraph (c)(1) of this section, that patient is under the care of a doctor of medicine or osteopathy.

(3) A doctor of medicine or osteopathy is on duty or on call at all times.

(4) A doctor of medicine or osteopathy is responsible for the care of each Medicare patient with respect to any medical or psychiatric problem that—
   (i) is present on admission or develops during hospitalization; and
   (ii) is not specifically within the scope of practice of a doctor of dental surgery, dental medicine, pediatric medicine, or optometry; a chiropractor; or clinical psychologist, as that scope is—
   (A) Defined by the medical staff;
   (B) Permitted by State law; and
   (C) Limited, under paragraph (c)(1)(v) of this section, with respect to chiropractors.

(d) Standard: Institutional plan and budget. The institution must have an overall institutional plan that meets the following conditions:

(1) The plan must include an annual operating budget that is prepared according to generally accepted accounting principles.

(2) The budget must include all anticipated income and expenses. This provision does not require that the budget identify item by item the components of each anticipated income or expense.

(3) The plan must provide for capital expenditures for at least a 3-year period, including the year in which the operating budget specified in paragraph (d)(2) of this section is applicable.

(4) The plan must include and identify in detail the objective of, and the anticipated sources of financing for, each anticipated capital expenditure in excess of $600,000 (or a lesser amount that is established, in accordance with section 1122(g)(1) of the Act, by the State in which the hospital is located) that relates to any of the following:
   (i) Acquisition of land;
   (ii) Improvement of land, buildings, and equipment; or
   (iii) The replacement, modernization, and expansion of buildings and equipment.

(5) The plan must be submitted for review to the planning agency designated in accordance with section 1122(b) of the Act, or if an agency is not designated, to the appropriate health planning agency in the State. (See part 100 of this title.) A capital expenditure is not subject to section 1122 review if 75 percent of the health care facility’s patients who are expected to use the service for which the capital expenditure is made are individuals enrolled in a health maintenance organization (HMO) or competitive medical plan (CMP) that meets the requirements of
section 1876(b) of the Act, and if the Department determines that the capital expenditure is for services and facilities that are needed by the HMO or CMP in order to operate efficiently and economically and that are not otherwise readily accessible to the HMO or CMP because—

(i) The facilities do not provide common services at the same site;

(ii) The facilities are not available under a contract of reasonable duration;

(iii) Full and equal medical staff privileges in the facilities are not available;

(iv) Arrangements with these facilities are not administratively feasible; or

(v) The purchase of these services is more costly than if the HMO or CMP provided the services directly.

(6) The plan must be reviewed and updated annually.

(7) The plan must be prepared—

(i) Under the direction of the governing body; and

(ii) By a committee consisting of representatives of the governing body, the administrative staff, and the medical staff of the institution.

(e) Standard: Contracted services. The governing body must be responsible for services furnished in the hospital whether or not they are furnished under contracts. The governing body must ensure that a contractor of services (including one for shared services and joint ventures) furnishes services that permit the hospital to comply with all applicable conditions of participation and standards for the contracted services.

(1) The governing body must ensure that the services performed under a contract are provided in a safe and effective manner.

(2) The hospital must maintain a list of all contracted services, including the scope and nature of the services provided.

(f) Standard: Emergency services. (1) If emergency services are provided at the hospital, the hospital must comply with the requirements of §482.55.

(2) If emergency services are not provided at the hospital, the governing body must assure that the medical staff has written policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate.


Subpart C—Basic Hospital Functions

§ 482.21 Condition of participation: Quality assurance.

The governing body must ensure that there is an effective, hospital-wide quality assurance program to evaluate the provision of patient care.

(a) Standard: Clinical plan. The organized, hospital-wide quality assurance program must be ongoing and have a written plan of implementation.

(1) All organized services related to patient care, including services furnished by a contractor, must be evaluated.

(2) Nosocomial infections and medication therapy must be evaluated.

(3) All medical and surgical services performed in the hospital must be evaluated as they relate to appropriateness of diagnosis and treatment.

(b) Standard: Medically-related patient care services. The hospital must have an ongoing plan, consistent with available community and hospital resources, to provide or make available social work, psychological, and educational services to meet the medically-related needs of its patients.

(c) Standard: Implementation. The hospital must take and document appropriate remedial action to address deficiencies found through the quality assurance program. The hospital must document the outcome of the remedial action.


§ 482.22 Condition of participation: Medical staff.

The hospital must have an organized medical staff that operates under by-laws approved by the governing body and is responsible for the quality of medical care provided to patients by the hospital.
§ 482.23

(a) Standard: Composition of the medical staff. The medical staff must be composed of doctors of medicine or osteopathy and, in accordance with State law, may also be composed of other practitioners appointed by the governing body.

(1) The medical staff must periodically conduct appraisals of its members.

(2) The medical staff must examine credentials of candidates for medical staff membership and make recommendations to the governing body on the appointment of the candidates.

(b) Standard: Medical staff organization and accountability. The medical staff must be well organized and accountable to the governing body for the quality of the medical care provided to patients.

(1) The medical staff must be organized in a manner approved by the governing body.

(2) If the medical staff has an executive committee, a majority of the members of the committee must be doctors of medicine or osteopathy.

(3) The responsibility for organization and conduct of the medical staff must be assigned only to an individual doctor of medicine or osteopathy or, when permitted by State law of the State in which the hospital is located, a doctor of dental surgery or dental medicine.

(c) Standard: Medical staff bylaws. The medical staff must adopt and enforce bylaws to carry out its responsibilities. The bylaws must:

(1) Be approved by the governing body.

(2) Include a statement of the duties and privileges of each category of medical staff (e.g., active, courtesy, etc.)

(3) Describe the organization of the medical staff.

(4) Describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body.

(5) Include a requirement that a physical examination and medical history be done no more than 7 days before or 48 hours after an admission for each patient by a doctor of medicine or osteopathy, or, for patients admitted only for oromaxillofacial surgery, by an oromaxillofacial surgeon who has been granted such privileges by the medical staff in accordance with State law.

(6) Include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges.

(d) Standard: Autopsies. The medical staff should attempt to secure autopsies in all cases of unusual deaths and of medical-legal and educational interest. The mechanism for documenting permission to perform an autopsy must be defined. There must be a system for notifying the medical staff, and specifically the attending practitioner, when an autopsy is being performed.


§ 482.23 Condition of participation: Nursing services.

The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse.

(a) Standard: Organization. The hospital must have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care. The director of the nursing service must be a licensed registered nurse. He or she is responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital.

(b) Standard: Staffing and delivery of care. The nursing service must have adequate numbers of licensed registered nurses, licensed practical (vocational) nurses, and other personnel to provide nursing care to all patients as needed. There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for bedside care of any patient.

(1) The hospital must provide 24-hour nursing services furnished or supervised by a registered nurse, and have a licensed practical nurse or registered nurse on duty at all times, except for rural hospitals that have in effect a 24-
hour nursing waiver granted under §405.1910(c) of this chapter.

(2) The nursing service must have a procedure to ensure that hospital nursing personnel for whom licensure is required have valid and current licensure.

(3) A registered nurse must supervise and evaluate the nursing care for each patient.

(4) The hospital must ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient.

(5) A registered nurse must assign the nursing care of each patient to other nursing personnel in accordance with the patient’s needs and the specialized qualifications and competence of the nursing staff available.

(6) Non-employee licensed nurses who are working in the hospital must adhere to the policies and procedures of the hospital. The director of nursing service must provide for the adequate supervision and evaluation of the clinical activities of non-employee nursing personnel which occur within the responsibility of the nursing service.

(c) Standard: Preparation and administration of drugs. Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient’s care as specified under §482.12(c), and accepted standards of practice.

(1) All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.

(2) All orders for drugs and biologicals must be in writing and signed by the practitioner or practitioners responsible for the care of the patient as specified under §482.12(c). When telephone or oral orders must be used, they must be—

(i) Accepted only by personnel that are authorized to do so by the medical staff policies and procedures, consistent with Federal and State law;

(ii) Signed or initialed by the prescribing practitioner as soon as possible; and

(iii) Used infrequently.

(3) Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures. If blood transfusions and intravenous medications are administered by personnel other than doctors of medicine or osteopathy, the personnel must have special training for this duty.

(4) There must be a hospital procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.

§ 482.24 Condition of participation: Medical record services.

The hospital must have a medical record service that has administrative responsibility for medical records. A medical record must be maintained for every individual evaluated or treated in the hospital.

(a) Standard: Organization and staffing. The organization of the medical record service must be appropriate to the scope and complexity of the services performed. The hospital must employ adequate personnel to ensure prompt completion, filing, and retrieval of records.

(b) Standard: Form and retention of record. The hospital must maintain a medical record for each inpatient and outpatient. Medical records must be accurately written, promptly completed, properly filed and retained, and accessible. The hospital must use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries.

(1) Medical records must be retained in their original or legally reproduced form for a period of at least 5 years.

(2) The hospital must have a system of coding and indexing medical records. The system must allow for timely retrieval by diagnosis and procedure, in order to support medical care evaluation studies.

(3) The hospital must have a procedure for ensuring the confidentiality of patient records. Information from or copies of records may be released only
§ 482.25 Condition of participation: Pharmaceutical services.

The hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital’s organized pharmaceutical service.

(a) Standard: Pharmacy management and administration. The pharmacy or drug storage area must be administered in accordance with accepted professional principles.

(1) A full-time, part-time, or consulting pharmacist must be responsible for developing, supervising, and coordinating all the activities of the pharmacy services.

(2) The pharmaceutical service must have an adequate number of personnel to ensure quality pharmaceutical services, including emergency services.

(3) Current and accurate records must be kept of the receipt and disposition of all scheduled drugs.

(b) Standard: Delivery of services. In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law.

(1) All compounding, packaging, and dispensing of drugs and biologicals must be under the supervision of a pharmacist and performed consistent with State and Federal laws.

(2) Drugs and biologicals must be kept in a locked storage area.

(3) Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use.

(4) When a pharmacist is not available, drugs and biologicals must be removed from the pharmacy or storage area only by personnel designated in the policies of the medical staff and pharmaceutical service, in accordance with Federal and State law.

(5) Drugs and biologicals not specifically prescribed as to time or number of doses must automatically be stopped after a reasonable time that is predetermined by the medical staff.

to authorized individuals, and the hospital must ensure that unauthorized individuals cannot gain access to or alter patient records. Original medical records must be released by the hospital only in accordance with Federal or State laws, court orders, or subpoenas.

(c) Standard: Content of record. The medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient’s progress and response to medications and services.

(1) All entries must be legible and complete, and must be authenticated and dated promptly by the person (identified by name and discipline) who is responsible for ordering, providing, or evaluating the service furnished.

(i) The author of each entry must be identified and must authenticate his or her entry.

(ii) Authentication may include signatures, written initials or computer entry.

(2) All records must document the following, as appropriate:

(i) Evidence of a physical examination, including a health history, performed no more than 7 days prior to admission or within 48 hours after admission.

(ii) Admitting diagnosis.

(iii) Results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient.

(iv) Documentation of complications, hospital acquired infections, and unfavorable reactions to drugs and anesthesia.

(v) Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent.

(vi) All practitioners’ orders, nursing notes, reports of treatment, medication records, radiology, and laboratory reports, and vital signs and other information necessary to monitor the patient’s condition.

(vii) Discharge summary with outcome of hospitalization, disposition of case, and provisions for follow-up care.

(viii) Final diagnosis with completion of medical records within 30 days following discharge.
§ 482.27 Condition of participation: Laboratory services.

(a) The hospital must maintain, or have available, adequate laboratory services to meet the needs of its patients. The hospital must ensure that all laboratory services provided to its patients are performed in a facility certified in accordance with part 493 of this chapter.

(b) Standard: Adequacy of laboratory services. The hospital must have laboratory services available, either directly or through a contractual agreement with a certified laboratory that meets requirements of part 493 of this chapter.

(1) Emergency laboratory services must be available 24 hours a day.

(2) A written description of services provided must be available to the medical staff.

(3) The laboratory must make provisions for proper receipt and reporting of tissue specimens.

§ 482.26 Condition of participation: Radiologic services.

The hospital must maintain, or have available, adequate radiologic services. If therapeutic services are also provided, they, as well as the diagnostic services, must meet professionally approved standards for safety and personnel qualifications.

(a) Standard: Radiologic services. The hospital must maintain, or have available, radiologic services according to needs of the patients.

(b) Standard: Safety for patients and personnel. The radiologic services, particularly ionizing radiology procedures, must be free from hazards for patients and personnel.

(1) Proper safety precautions must be maintained against radiation hazards. This includes adequate shielding for patients, personnel, and facilities, as well as appropriate storage, use, and disposal of radioactive materials.

(2) Periodic inspection of equipment must be made and hazards identified must be promptly corrected.

(3) Radiation workers must be checked periodically, by the use of exposure meters or badge tests, for amount of radiation exposure.

(4) Radiologic services must be provided only on the order of practitioners with clinical privileges or, consistent with State law, of other practitioners authorized by the medical staff and the governing body to order the services.

(c) Standard: Personnel. (1) A qualified full-time, part-time, or consulting radiologist must supervise the ionizing radiology services and must interpret only those radiologic tests that are determined by the medical staff to require a radiologist’s specialized knowledge. For purposes of this section, a radiologist is a doctor of medicine or osteopathy who is qualified by education and experience in radiology.

(2) Only personnel designated as qualified by the medical staff may use the radiologic equipment and administer procedures.

(d) Standard: Records. Records of radiologic services must be maintained.

(1) The radiologist or other practitioner who performs radiology services must sign reports of his or her interpretations.

(2) The hospital must maintain the following for at least 5 years:

(i) Copies of reports and printouts.

(ii) Films, scans, and other image records, as appropriate.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986]
(4) The medical staff and a pathologist must determine which tissue specimens require a macroscopic (gross) examination and which require both macroscopic and microscopic examinations.

(c) Standard: Potentially infectious blood and blood products—(1) Potentially HIV infectious blood and blood products are prior collections from a donor who tested negative at the time of donation but tests repeatedly reactive for the antibody to the human immunodeficiency virus (HIV) on a later donation, and the FDA-licensed, more specific test or other followup testing recommended or required by FDA is positive and the timing of seroconversion cannot be precisely estimated.

(2) Services furnished by an outside blood bank. If a hospital regularly uses the services of an outside blood bank, it must have an agreement with the blood bank that governs the procurement, transfer, and availability of blood and blood products. The agreement must require that the blood bank promptly notify the hospital of the following:

(i) If it supplied blood and blood products collected from a donor who tested negative at the time of donation but tests repeatedly reactive for the antibody to HIV on a later donation; and

(ii) The results of the FDA-licensed, more specific test or other followup testing recommended or required by FDA completed within 30 calendar days after the donor’s repeatedly reactive screening test. (FDA regulations concerning HIV testing and lookback procedures are set forth at 21 CFR 610.45–et seq.)

(3) Quarantine of blood and blood products pending completion of testing. If the blood bank notifies the hospital of the repeatedly reactive HIV screening test results as required by paragraph (c)(2)(i) of this section, the hospital must determine the disposition of the blood or blood product and quarantine all blood and blood products from previous donations in inventory.

(i) If the blood bank notifies the hospital that the result of the FDA-licensed, more specific test or other followup testing recommended or required by FDA is negative, absent other informative test results, the hospital may release the blood and blood products from quarantine.

(ii) If the blood bank notifies the hospital that the result of the FDA-licensed, more specific test or other followup testing recommended or required by FDA is positive, the hospital must dispose of the blood and blood products in accordance with 21 CFR 606.40 and notify patients in accordance with paragraph (c)(4) of this section.

(4) Patient notification. If the hospital has administered potentially HIV infectious blood or blood products (either directly through its own blood bank or under an agreement described in paragraph (c)(2) of this section) or released such blood or blood products to another entity or appropriate individual, the hospital must take the following actions:

(i) Promptly make at least three attempts to notify the patient’s attending physician (that is, the physician of record) or the physician who ordered the blood or blood product that potentially HIV infectious blood or blood products were transfused to the patient.

(ii) Ask the physician to immediately notify the patient, or other individual as permitted under paragraph (c)(8) of this section, of the need for HIV testing and counseling.

(iii) If the physician is unavailable, declines to make the notification, or later informs the hospital that he or she was unable to notify the patient, promptly make at least three attempts to notify the patient, or other individual as permitted under paragraph (c)(8) of this section, of the need for HIV testing and counseling.

(iv) Document in the patient’s medical record the notification or attempts to give the required notification.

(5) Timeframe for notification. The notification effort begins when the blood bank notifies the hospital that it received potentially HIV infectious blood and blood products and continues for 8 weeks unless—

(i) The patient is located and notified; or

(ii) The hospital is unable to locate the patient and documents in the patient’s medical record the extenuating circumstances beyond the hospital’s
control that caused the notification timeframe to exceed 8 weeks.

(6) Content of notification. The notification given under paragraphs (c)(4)(ii) and (iii) of this section must include the following information:

(i) A basic explanation of the need for HIV testing and counseling.

(ii) Enough oral or written information so that the transfused patient can make an informed decision about whether to obtain HIV testing and counseling.

(iii) A list of programs or places where the patient can obtain HIV testing and counseling, including any requirements or restrictions the program may impose.

(7) Policies and procedures. The hospital must establish policies and procedures for notification and documentation that conform to Federal, State, and local laws, including requirements for confidentiality and medical records.

(8) Notification to legal representative or relative. If the patient has been adjudged incompetent by a State court, the physician or hospital must notify a legal representative designated in accordance with State law. If the patient is competent, but State law permits a legal representative or relative to receive the information on the patient's behalf, the physician or hospital must notify the patient or his or her legal representative or relative. If the patient is deceased, the physician or hospital must continue the notification process and inform the deceased patient's legal representative or relative.

[57 FR 7136, Feb. 28, 1992, as amended at 61 FR 47433, Sept. 9, 1996]

§ 482.30 Condition of participation: Utilization review.

The hospital must have in effect a utilization review (UR) plan that provides for review of services furnished by the institution and by members of the medical staff to patients entitled to benefits under the Medicare and Medicaid programs.

(a) Applicability. The provisions of this section apply except in either of the following circumstances:

(1) A Utilization and Quality Control Peer Review Organization (PRO) has assumed binding review for the hospital.

(2) HCFA has determined that the UR procedures established by the State under title XIX of the Act are superior to the procedures required in this section, and has required hospitals in that State to meet the UR plan requirements under §§ 456.50 through 456.245 of this chapter.
§ 482.30

(b) Standard: Composition of utilization review committee. A UR committee consisting of two or more practitioners must carry out the UR function. At least two of the members of the committee must be doctors of medicine or osteopathy. The other members may be any of the other types of practitioners specified in § 482.12(c)(1).

(1) Except as specified in paragraphs (b) (2) and (3) of this section, the UR committee must be one of the following:

(i) A staff committee of the institution;

(ii) A group outside the institution—

(A) Established by the local medical society and some or all of the hospitals in the locality; or

(B) Established in a manner approved by HCFA.

(2) If, because of the small size of the institution, it is impracticable to have a properly functioning staff committee, the UR committee must be established as specified in paragraph (b)(1)(ii) of this section.

(3) The committee's or group's reviews may not be conducted by any individual who—

(i) Has a direct financial interest (for example, an ownership interest) in that hospital; or

(ii) Was professionally involved in the care of the patient whose case is being reviewed.

(c) Standard: Scope and frequency of review. (1) The UR plan must provide for review for Medicare and Medicaid patients with respect to the medical necessity of—

(i) Admissions to the institution;

(ii) The duration of stays; and

(iii) Professional services furnished, including drugs and biologicals.

(2) Review of admissions may be performed before, at, or after hospital admission.

(3) Except as specified in paragraph (e) of this section, reviews may be conducted on a sample basis.

(4) Hospitals that are paid for inpatient hospital services under the prospective payment system set forth in Part 412 of this chapter must conduct review of duration of stays and review of professional services as follows:

(i) For duration of stays, these hospitals need review only cases that they reasonably assume to be outlier cases based on extended length of stay, as described in § 412.80(a)(1)(i) of this chapter; and

(ii) For professional services, these hospitals need review only cases that they reasonably assume to be outlier cases based on extraordinarily high costs, as described in § 412.80(a)(1)(ii) of this chapter.

(d) Standard: Determination regarding admissions or continued stays. (1) The determination that an admission or continued stay is not medically necessary—

(i) May be made by one member of the UR committee if the practitioner or practitioners responsible for the care of the patient, as specified in § 482.12(c), concur with the determination or fail to present their views when afforded the opportunity; and

(ii) Must be made by at least two members of the UR committee in all other cases.

(2) Before making a determination that an admission or continued stay is not medically necessary, the UR committee must consult the practitioner or practitioners responsible for the care of the patient, as specified in § 482.12(c), and afford the practitioner or practitioners the opportunity to present their views.

(3) If the committee decides that admission to or continued stay in the hospital is not medically necessary, written notification must be given, no later than 2 days after the determination, to the hospital, the patient, and the practitioner or practitioners responsible for the care of the patient, as specified in § 482.12(c);

(e) Standard: Extended stay review. (1) In hospitals that are not paid under the prospective payment system, the UR committee must make a periodic review, as specified in the UR plan, of each current inpatient receiving hospital services during a continuous period of extended duration. The scheduling of the periodic reviews may—

(i) Be the same for all cases; or

(ii) Differ for different classes of cases.

(2) In hospitals paid under the prospective payment system, the UR committee must review all cases reasonably assumed by the hospital to be
outlier cases because the extended length of stay exceeds the threshold criteria for the diagnosis, as described in §412.80(a)(1)(i). The hospital is not required to review an extended stay that does not exceed the outlier threshold for the diagnosis.

(3) The UR committee must make the periodic review no later than 7 days after the day required in the UR plan.

(f) Standard: Review of professional services. The committee must review professional services provided, to determine medical necessity and to promote the most efficient use of available health facilities and services.

§ 482.41 Condition of participation: Physical environment.

The hospital must be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment and for special hospital services appropriate to the needs of the community.

(a) Standard: Buildings. The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients are assured.

(1) There must be emergency power and lighting in at least the operating, recovery, intensive care, and emergency rooms, and stairwells. In all other areas not serviced by the emergency supply source, battery lamps and flashlights must be available.

(2) There must be facilities for emergency gas and water supply.

(b) Standard: Life safety from fire. (1) Except as provided in paragraphs (b)(1)(i) through (b)(1)(iii) of this section, the hospital must meet the applicable provisions of the 1985 edition of the Life Safety Code of the National Fire Protection Association (which is incorporated by reference).¹

(i) Any hospital that on November 26, 1982, complied, with or without waivers, with the requirements of the 1967 edition of the Life Safety Code, or on May 9, 1988, complied with the 1981 edition of the Life Safety Code, is considered to be in compliance with this standard as long as the facility continues to remain in compliance with that edition of the Code.

(ii) After consideration of State survey agency findings, HCFA may waive specific provisions of the Life Safety Code which, if rigidly applied, would result in unreasonable hardship upon the facility, but only if the waiver does not adversely affect the health and safety of patients.

(iii) The provisions of the Life Safety Code do not apply in a State where HCFA finds that a fire and safety code imposed by State law adequately protects patients in hospitals.

(2) The hospital must have procedures for the proper routine storage and prompt disposal of trash.

(3) The hospital must have written fire control plans that contain provisions for prompt reporting of fires; extinguishing fires; protection of patients, personnel and guests; evacuation; and cooperation with fire fighting authorities.

(4) The hospital must maintain written evidence of regular inspection and approval by State or local fire control agencies.

(c) Standard: Facilities. The hospital must maintain adequate facilities for its services.

(1) Diagnostic and therapeutic facilities must be located for the safety of patients.

(2) Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.

(3) The extent and complexity of facilities must be determined by the services offered.

(4) There must be proper ventilation, light, and temperature controls in pharmaceutical, food preparation, and other appropriate areas.

[51 FR 22042, June 17, 1986, as amended at 53 FR 11509, Apr. 7, 1988]

§ 482.42 Condition of participation: Infection control.

The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.
§ 482.43  
(a) Standard: Organization and policies. A person or persons must be designated as infection control officer or officers to develop and implement policies governing control of infections and communicable diseases.

(1) The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infectious and communicable diseases of patients and personnel.

(2) The infection control officer or officers must maintain a log of incidents related to infections and communicable diseases.

(b) Standard: Responsibilities of chief executive officer, medical staff, and director of nursing services. The chief executive officer, the medical staff, and the director of nursing services must—

(1) Ensure that the hospital-wide quality assurance program and training programs address problems identified by the infection control officer or officers; and

(2) Be responsible for the implementation of successful corrective action plans in affected problem areas.

§ 482.43 Condition of participation: Discharge planning.

The hospital must have in effect a discharge planning process that applies to all patients. The hospital's policies and procedures must be specified in writing.

(a) Standard: Identification of patients in need of discharge planning. The hospital must identify at an early stage of hospitalization all patients who are likely to suffer adverse health consequences upon discharge if there is no adequate discharge planning.

(b) Standard: Discharge planning evaluation. (1) The hospital must provide a discharge planning evaluation to the patients identified in paragraph (a) of this section, and to other patients upon the patient's request, the request of a person acting on the patient's behalf, or the request of the physician.

(2) A registered nurse, social worker, or other appropriately qualified personnel must develop, or supervise the development of, the evaluation.

(3) The hospital must complete the evaluation on a timely basis so that appropriate arrangements for post-hospital care are made before discharge, and to avoid unnecessary delays in discharge.

(4) The hospital must include the discharge planning evaluation in the patient's medical record for use in establishing an appropriate discharge plan and must discuss the results of the evaluation with the patient or individual acting on his or her behalf.

(c) Standard: Discharge plan. (1) A registered nurse, social worker, or other appropriately qualified personnel must develop, or supervise the development of, a discharge plan if the discharge planning evaluation indicates a need for a discharge plan.

(2) In the absence of a finding by the hospital that a patient needs a discharge plan, the patient's physician may request a discharge plan. In such a case, the hospital must develop a discharge plan for the patient.

(3) The hospital must arrange for the initial implementation of the patient's discharge plan.

(4) The hospital must reassess the patient's discharge plan if there are factors that may affect continuing care needs or the appropriateness of the discharge plan.

(5) As needed, the patient and family members or interested persons must be counseled to prepare them for post-hospital care.

(d) Standard: Transfer or referral. The hospital must transfer or refer patients, along with necessary medical information, to appropriate facilities, agencies, or outpatient services, as needed, for followup or ancillary care.

(e) Standard: Reassessment. The hospital must reassess its discharge planning process on an on-going basis. The reassessment must include a review of
discharge plans to ensure that they are responsive to discharge needs.

§ 482.45 Condition of participation: Organ, tissue, and eye procurement.

(a) Standard: Organ procurement responsibilities. The hospital must have and implement written protocols that:

(1) Incorporate an agreement with an OPO designated under part 486 of this chapter, under which it must notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the hospital. The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the hospital, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the hospital for this purpose;

(2) Incorporate an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of tissues and eyes, as may be appropriate to assure that all usable tissues and eyes are obtained from potential donors, insofar as such an agreement does not interfere with organ procurement;

(3) Ensure, in collaboration with the designated OPO, that the family of each potential donor is informed of its options to donate organs, tissues, or eyes or to decline to donate. The individual designated by the hospital to initiate the request to the family must be an organ procurement representative or a designated requestor. A designated requestor is an individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community in the methodology for approaching potential donor families and requesting organ or tissue donation;

(4) Encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors;

(5) Ensure that the hospital works cooperatively with the designated OPO, tissue bank and eye bank in educating staff on donation issues, reviewing death records to improve identification of potential donors, and maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes take place.

(b) Standard: Organ transplantation responsibilities. (1) A hospital in which organ transplants are performed must be a member of the Organ Procurement and Transplantation Network (OPTN) established and operated in accordance with section 372 of the Public Health Service (PHS) Act (42 U.S.C. 274) and abide by its rules. The term “rules of the OPTN” means those rules provided for in regulations issued by the Secretary in accordance with section 372 of the PHS Act which are enforceable under 42 CFR 121.10. No hospital is considered to be out of compliance with section 1138(a)(1)(B) of the Act, or with the requirements of this paragraph, unless the Secretary has given the OPTN formal notice that he or she approves the decision to exclude the hospital from the OPTN and has notified the hospital in writing.

(2) For purposes of these standards, the term “organ” means a human kidney, liver, heart, lung, or pancreas.

(3) If a hospital performs any type of transplants, it must provide organ-transplant-related data, as requested by the OPTN, the Scientific Registry, and the OPOs. The hospital must also provide such data directly to the Department when requested by the Secretary.

§ 482.51 Condition of participation: Surgical services.

If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered, the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.

(a) Standard: Organization and staffing. The organization of the surgical services must be appropriate to the scope of the services offered.
(1) The operating rooms must be supervised by an experienced registered nurse or a doctor of medicine or osteopathy.

(2) Licensed practical nurses (LPNs) and surgical technologists (operating room technicians) may serve as "scrub nurses" under the supervision of a registered nurse.

(3) Qualified registered nurses may perform circulating duties in the operating room. In accordance with applicable State laws and approved medical staff policies and procedures, LPNs and surgical technologists may assist in circulatory duties under the supervision of a qualified registered nurse who is immediately available to respond to emergencies.

(4) Surgical privileges must be delineated for all practitioners performing surgery in accordance with the competencies of each practitioner. The surgical service must maintain a roster of practitioners specifying the surgical privileges of each practitioner.

(b) Standard: Delivery of service. Surgical services must be consistent with needs and resources. Policies governing surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care.

(1) There must be a complete history and physical work-up in the chart of every patient prior to surgery, except in emergencies. If this has been dictated, but not yet recorded in the patient's chart, there must be a statement to that effect and an admission note in the chart by the practitioner who admitted the patient.

(2) A properly executed informed consent form for the operation must be in the patient's chart before surgery, except in emergencies.

(3) The following equipment must be available to the operating room suites: call-in-system, cardiac monitor, resuscitator, defibrillator, aspirator, and tracheotomy set.

(4) There must be adequate provisions for immediate post-operative care.

(5) The operating room register must be complete and up-to-date.

(6) An operative report describing techniques, findings, and tissues removed or altered must be written or dictated immediately following surgery and signed by the surgeon.

§ 482.52 Condition of participation: Anesthesia services.

If the hospital furnishes anesthesia services, they must be provided in a well-organized manner under the direction of a qualified doctor of medicine or osteopathy. The service is responsible for all anesthesia administered in the hospital.

(a) Standard: Organization and staffing. The organization of anesthesia services must be appropriate to the scope of the services offered. Anesthesia must be administered by only—

(1) A qualified anesthesiologist;

(2) A doctor of medicine or osteopathy (other than an anesthesiologist);

(3) A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;

(4) A certified registered nurse anesthetist (CRNA), as defined in § 410.69(b) of this chapter, who is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed; or

(5) An anesthesiologist's assistant, as defined in § 410.69(b) of this chapter, who is under the supervision of an anesthesiologist who is immediately available if needed.

(b) Standard: Delivery of services. Anesthesia services must be consistent with needs and resources. Policies on anesthesia procedures must include the delineation of preanesthesia and post anesthesia responsibilities. The policies must ensure that the following are provided for each patient:

(1) A preanesthesia evaluation by an individual qualified to administer anesthesia under paragraph (a) of this section performed within 48 hours prior to surgery.

(2) An intraoperative anesthesia record.

(3) With respect to inpatients, a postanesthesia followup report by the individual who administers the anesthesia that is written within 48 hours after surgery.

(4) With respect to outpatients, a postanesthesia evaluation for proper
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§ 482.53 Condition of participation: Nuclear medicine services.

If the hospital provides nuclear medicine services, those services must meet the needs of the patients in accordance with acceptable standards of practice.

(a) Standard: Organization and staffing. The organization of the nuclear medicine service must be appropriate to the scope and complexity of the services offered.

(1) There must be a director who is a doctor of medicine or osteopathy qualified in nuclear medicine.

(2) The qualifications, training, functions, and responsibilities of nuclear medicine personnel must be specified by the service director and approved by the medical staff.

(b) Standard: Delivery of service. Radioactive materials must be prepared, labeled, used, transported, stored, and disposed of in accordance with acceptable standards of practice.

(1) In-house preparation of radiopharmaceuticals is by, or under, the direct supervision of an appropriately trained registered pharmacist or a doctor of medicine or osteopathy.

(2) There is proper storage and disposal of radioactive material.

(3) If laboratory tests are performed in the nuclear medicine service, the service must meet the applicable requirement for laboratory services specified in §482.27.

(c) Standard: Facilities. Equipment and supplies must be appropriate for the types of nuclear medicine services offered and must be maintained for safe and efficient performance. The equipment must be—

(1) Maintained in safe operating condition; and

(2) Inspected, tested, and calibrated at least annually by qualified personnel.

(d) Standard: Records. The hospital must maintain signed and dated reports of nuclear medicine interpretations, consultations, and procedures.

(1) The hospital must maintain copies of nuclear medicine reports for at least 5 years.

(2) The practitioner approved by the medical staff to interpret diagnostic procedures must sign and date the interpretation of these tests.

(3) The hospital must maintain records of the receipt and disposition of radiopharmaceuticals.

(4) Nuclear medicine services must be ordered only by practitioner whose scope of Federal or State licensure and whose defined staff privileges allow such referrals.

§ 482.54 Condition of participation: Outpatient services.

If the hospital provides outpatient services, the services must meet the needs of the patients in accordance with acceptable standards of practice.

(a) Standard: Organization. Outpatient services must be appropriately organized and integrated with inpatient services.

(b) Standard: Personnel. The hospitals must—

(1) Assign an individual to be responsible for outpatient services; and

(2) Have appropriate professional and nonprofessional personnel available.

§ 482.55 Condition of participation: Emergency services.

The hospital must meet the emergency needs of patients in accordance with acceptable standards of practice.

(a) Standard: Organization and direction. If emergency services are provided at the hospital—

(1) The services must be organized under the direction of a qualified member of the medical staff;

(2) The services must be integrated with other departments of the hospital;

(3) The policies and procedures governing medical care provided in the emergency service or department are established by and are a continuing responsibility of the medical staff.

(b) Standard: Personnel. (1) The emergency services must be supervised by a qualified member of the medical staff.

(2) There must be adequate medical and nursing personnel qualified in emergency care to meet the written...
emergency procedures and needs anticipated by the facility.

§ 482.56 Condition of participation: Rehabilitation services.

If the hospital provides rehabilitation, physical therapy, occupational therapy, audiology, or speech pathology services, the services must be organized and staffed to ensure the health and safety of patients.

(a) Standard: Organization and staffing. The organization of the service must be appropriate to the scope of the services offered.

(1) The director of the services must have the necessary knowledge, experience, and capabilities to properly supervise and administer the services.

(b) Standard: Delivery of services. Services must be furnished in accordance with a written plan of treatment. Services must be given in accordance with orders of practitioners who are authorized by the medical staff to order the services, and the orders must be incorporated in the patient's record.

§ 482.57 Condition of participation: Respiratory care services.

The hospital must meet the needs of the patients in accordance with acceptable standards of practice. The following requirements apply if the hospital provides respiratory care service.

(a) Standard: Organization and staffing. The organization of the respiratory care services must be appropriate to the scope and complexity of the services offered.

(1) There must be a director of respiratory care services who is a doctor of medicine or osteopathy with the knowledge, experience, and capabilities to supervise and administer the service properly. The director may serve on either a full-time or part-time basis.

(2) There must be adequate numbers of respiratory therapists, respiratory therapy technicians, and other personnel who meet the qualifications specified by the medical staff, consistent with State law.

(b) Standard: Delivery of Services. Services must be delivered in accordance with medical staff directives.

(1) Personnel qualified to perform specific procedures and the amount of supervision required for personnel to carry out specific procedures must be designated in writing.

(2) If blood gases or other laboratory tests are performed in the respiratory care unit, the unit must meet the applicable requirements for laboratory services specified in §482.27.

(3) Services must be provided only on, and in accordance with, the orders of a doctor of medicine or osteopathy.


Subpart E—Requirements for Specialty Hospitals

§ 482.60 Special provisions applying to psychiatric hospitals.

Psychiatric hospital must—

(a) Be primarily engaged in providing, by or under the supervision of a doctor of medicine or osteopathy, psychiatric services for the diagnosis and treatment of mentally ill persons;

(b) Meet the conditions of participation specified in §§482.1 through 482.23 and §§482.25 through 482.57;

(c) Maintain clinical records on all patients, including records sufficient to permit HCFA to determine the degree and intensity of treatment furnished to Medicare beneficiaries, as specified in §482.61; and

(d) Meet the staffing requirements specified in §482.62.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986]

§ 482.61 Condition of participation: Special medical record requirements for psychiatric hospitals.

The medical records maintained by a psychiatric hospital must permit determination of the degree and intensity of the treatment provided to individuals who are furnished services in the institution.

(a) Standard: 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 patient is hospitalized.

(1) The identification data must include the patient’s legal status.

(2) A provisional or admitting diagnosis must be made on every patient at the time of admission, and must include the diagnoses of intercurrent diseases as well as the psychiatric diagnoses.

(3) The reasons for admission must be clearly documented as stated by the patient and/or others significantly involved.

(4) The social service records, including reports of interviews with patients, family members, and others, must provide an assessment of home plans and family attitudes, and community resource contacts as well as a social history.

(5) When indicated, a complete neurological examination must be recorded at the time of the admission physical examination.

Standard: Psychiatric evaluation. Each patient must receive a psychiatric evaluation that must—

(1) Be completed within 60 hours of admission;

(2) Include a medical history;

(3) Contain a record of mental status;

(4) Note the onset of illness and the circumstances leading to admission;

(5) Describe attitudes and behavior;

(6) Estimate intellectual functioning, memory functioning, and orientation; and

(7) Include an inventory of the patient’s assets in descriptive, not interpretative, fashion.

Standard: Treatment plan. Each patient must have an individual comprehensive treatment plan that must include—

(i) A substantiated diagnosis;

(ii) Short-term and long-range goals;

(iii) The specific treatment modalities utilized;

(iv) The responsibilities of each member of the treatment team; and

(v) Adequate documentation to justify the diagnosis and the treatment and rehabilitation activities carried out.

(2) The treatment received by the patient must be documented in such a way to assure that all active therapeutic efforts are included.

(d) Standard: Recording progress. Progress notes must be recorded by the doctor of medicine or osteopathy responsible for the care of the patient as specified in §482.12(c), 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 patient but must be recorded at least weekly for the first 2 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 patient’s progress in accordance with the original or revised treatment plan.

(e) Standard: 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 patient’s hospitalization and recommendations from appropriate services concerning follow-up or aftercare as well as a brief summary of the patient’s condition on discharge.

§ 482.62 Condition of participation: Special staff requirements for psychiatric hospitals.

The hospital must have adequate numbers of qualified professional and supportive staff to evaluate patients, formulate written, individualized comprehensive treatment plans, provide active treatment measures, and engage in discharge planning.

(a) Standard: Personnel. The hospital must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to:

(1) Evaluate patients;

(2) Formulate written individualized, comprehensive treatment plans;

(3) Provide active treatment measures; and

(4) Engage in discharge planning.

(b) Standard: 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.

(1) 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.

(2) The director must monitor and evaluate the quality and appropriateness of services and treatment provided by the medical staff.

(c) Standard: Availability of medical personnel. Doctors of medicine or osteopathy and other appropriate professional personnel must be available to provide necessary medical and surgical diagnostic and treatment services. If medical and surgical diagnostic and treatment services are not available within the institution, the institution must have an agreement with an outside source of these services to ensure that they are immediately available or a satisfactory agreement must be established for transferring patients to a general hospital that participates in the Medicare program.

(d) Standard: Nursing services. The hospital 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 patient's active treatment program and to maintain progress notes on each patient.

(1) 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.

(2) The staffing pattern must insure the availability of a registered professional 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 patient's active treatment program.

(e) Standard: Psychological services. The hospital must provide or have available psychological services to meet the needs of the patients.

(f) Standard: 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.

(1) The director of the social work department or service must have a master's degree from an accredited school of social work or must be qualified by education and experience in the social services needs of the mentally ill. If the director does not hold a master's degree in social work, at least one staff member must have this qualification.

(2) 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.

(g) Standard: Therapeutic activities. The hospital must provide a therapeutic activities program.

(1) The program must be appropriate to the needs and interests of patients and be directed toward restoring and maintaining optimal levels of physical and psychosocial functioning.

(2) The number of qualified therapists, support personnel, and consultants must be adequate to provide comprehensive therapeutic activities consistent with each patient's active treatment program.
§ 482.66 Special requirements for hospital providers of long-term care services ("swing-beds").

A hospital that has a Medicare provider agreement must meet the following requirements in order to be granted an approval from HCFA to provide post-hospital extended care services, as specified in § 409.30 of this chapter, and be reimbursed as a swing-bed hospital, as specified in § 413.114 of this chapter:

(a) Eligibility. A hospital must meet the following eligibility requirements:

(1) The facility has fewer than 100 hospital beds, excluding beds for newborns and beds in intensive care type inpatient units (for eligibility of hospitals with distinct parts electing the optional reimbursement method, see § 413.24(d)(5) of this chapter).

(2) The hospital is located in a rural area. This includes all areas not delineated as "urbanized" areas by the Census Bureau, based on the most recent census.

(3) When required by State in which it is located, the hospital has been granted a certificate of need for the provision of long-term care services from the State health planning and development agency (designated under section 1521 of the Public Health Service Act).

(4) The hospital does not have in effect a 24-hour nursing waiver granted under § 488.54(a) of this chapter.

(5) The hospital has not had a swing-bed approval terminated within the two years previous to application.

(6) A hospital with more than 49 beds (but fewer than 100) approved under this section after March 31, 1988, must—

(i) Unless a Medicare-participating SNF is not available or the SNFs are not willing to enter into an agreement when one is offered, have an availability agreement with each SNF in its geographic region that requires the SNF to notify the hospital of the availability of posthospital SNF care beds and the dates when those beds will be available; and

(ii) Transfer the extended care patient within 5 days (excluding weekends and holidays) after learning that a SNF bed is available or in the case of prospective notification by the SNF, within 5 days of the date the bed becomes available, unless the patient's physician certifies, as required under § 424.20, that the transfer is not medically appropriate.

(7) The hospital must provide written assurance to HCFA that the hospital will not operate over 49 or over 99 beds except in connection with a catastrophic event. The hospital bed count is determined as follows:

(i) A hospital bed count is calculated by excluding from the count, beds that because of their special nature, such as newborn and intensive care beds, would not be available for swing-bed use. Also excluded from the bed count are beds in separately certified "distinct part" SNFs and NFs and beds in a psychiatric or rehabilitation unit that is excluded from the prospective payment system.

(ii) A hospital licensed for more than 49 or 99 beds, is considered to have the number of beds that it consistently utilizes and staffs. Hospitals, at a minimum, document their count by staffing schedules and census information for the previous 12 months before application to be a swing-bed hospital.

(b) Skilled nursing facility services. The facility is substantially in compliance with the following skilled nursing facility requirements contained in subpart B of part 483 of this chapter:

(1) Resident rights (§ 483.10 (b)(3), (b)(4), (b)(5), (b)(6), (d), (e), (h), (i), (j)(1)(vii), (j)(1)(viii), (l), and (m)).

(2) Admission, transfer, and discharge rights (§ 483.12 (a)(1), (a)(2), (a)(3), (a)(4), (a)(5), (a)(6), and (a)(7)).

(3) Resident behavior and facility practices (§ 483.13).

(4) Patient activities (§ 483.15(f)).

(5) Social services (§ 483.15(g)).

(6) Discharge planning (§ 483.20(e)).

(7) Specialized rehabilitative services (§ 483.45).

(8) Dental services (§ 483.55).

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

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

The resident has a right to a dignified existence, self-determination, and communication with and access to persons and services inside and outside the facility. A facility must protect and promote the rights of each resident, including each of the following rights:

(a) Exercise of rights. (1) The resident has the right to exercise his or her rights as a resident of the facility and as a citizen or resident of the United States.

(2) The resident has the right to be free of interference, coercion, discrimination, and reprisal from the facility in exercising his or her rights.

(b) Notice of rights and services. (1) The facility must inform the resident both orally and in writing in a language that the resident understands of his or her rights and all rules and regulations governing resident conduct and responsibilities during the stay in the facility.

(2) In the case of a resident adjudged incompetent under the laws of a State by a court of competent jurisdiction, the facility must inform the resident with the notice (if any) of the State developed under section 1919(e)(6) of the Act. Such notification must be made prior to or upon admission and during the resident’s stay. Receipt of such information, and any amendments to it, must be acknowledged in writing.

(2) The resident or his or her legal representative has the right—
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(i) Upon an oral or written request, to access all records pertaining to himself or herself including current clinical records within 24 hours (excluding weekends and holidays); and

(ii) After receipt of his or her records for inspection, to purchase at a cost not to exceed the community standard photocopies of the records or any portions of them upon request and 2 working days advance notice to the facility.

(3) The resident has the right to be fully informed in language that he or she can understand of his or her total health status, including but not limited to, his or her medical condition;

(4) The resident has the right to refuse treatment, to refuse to participate in experimental research, and to formulate an advance directive as specified in paragraph (8) of this section; and

(5) The facility must—

(i) Inform each resident who is entitled to Medicaid benefits, in writing, at the time of admission to the nursing facility or, when the resident becomes eligible for Medicaid of—

(A) The items and services that are included in nursing facility services under the State plan and for which the resident may not be charged;

(B) Those other items and services that the facility offers and for which the resident may be charged, and the amount of charges for those services; and

(ii) Inform each resident when changes are made to the items and services specified in paragraphs (5)(i) (A) and (B) of this section.

(6) The facility must inform each resident before, or at the time of admission, and periodically during the resident’s stay, of services available in the facility and of charges for those services, including any charges for services not covered under Medicare or by the facility’s per diem rate.

(7) The facility must furnish a written description of legal rights which includes—

(i) A description of the manner of protecting personal funds, under paragraph (c) of this section;

(ii) A description of the requirements and procedures for establishing eligibility for Medicaid, including the right to request an assessment under section 1924(c) which determines the extent of a couple’s non-exempt resources at the time of institutionalization and attributes to the community spouse an equitable share of resources which cannot be considered available for payment toward the cost of the institutionalized spouse’s medical care in his or her process of spending down to Medicaid eligibility levels;

(iii) A posting of names, addresses, and telephone numbers of all pertinent State client advocacy groups such as the State survey and certification agency, the State licensure office, the State ombudsman program, the protection and advocacy network, and the Medicaid fraud control unit; and

(iv) A statement that the resident may file a complaint with the State survey and certification agency concerning resident abuse, neglect, misappropriation of resident property in the facility, and non-compliance with the advance directives requirements.

(8) The facility must comply with the requirements specified in subpart I of part 489 of this chapter relating to maintaining written policies and procedures regarding advance directives. These requirements include provisions to inform and provide written information to all adult residents concerning the right to accept or refuse medical or surgical treatment and, at the individual’s option, formulate an advance directive. This includes a written description of the facility’s policies to implement advance directives and applicable State law. Facilities 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. If an adult individual is incapacitated at the time of admission 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 facility may give advance directive information to the individual’s family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated individual or to a surrogate or other concerned persons in accordance with State law. The facility is not relieved
of its obligation to provide this information to the individual once he or she is no longer incapacitated or unable to receive such information. Follow-up procedures must be in place to provide the information to the individual directly at the appropriate time.

(9) The facility must inform each resident of the name, specialty, and way of contacting the physician responsible for his or her care.

(10) The facility must prominently display in the facility written information, and provide to residents and applicants for admission oral and written information about how to apply for and use Medicare and Medicaid benefits, and how to receive refunds for previous payments covered by such benefits.

(11) Notification of changes. (i) A facility must immediately inform the resident; consult with the resident’s physician; and if known, notify the resident’s legal representative or an interested family member when there is—

(A) An accident involving the resident which results in injury and has the potential for requiring physician intervention;

(B) A significant change in the resident’s physical, mental, or psychosocial status (i.e., a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications);

(C) A need to alter treatment significantly (i.e., a need to discontinue an existing form of treatment due to adverse consequences, or to commence a new form of treatment); or

(D) A decision to transfer or discharge the resident from the facility as specified in §483.12(a).

(ii) The facility must also promptly notify the resident and, if known, the resident’s legal representative or an interested family member when there is—

(A) A change in room or roommate assignment as specified in §483.19(e)(2);

(B) A change in resident rights under Federal or State law or regulations as specified in paragraph (b)(1) of this section.

(iii) The facility must record and periodically update the address and phone number of the resident’s legal representative or interested family member.

(c) Protection of resident funds. (1) The resident has the right to manage his or her financial affairs, and the facility may not require residents to deposit their personal funds with the facility.

(2) Management of personal funds. Upon written authorization of a resident, the facility must hold, safeguard, manage, and account for the personal funds of the resident deposited with the facility, as specified in paragraphs (c)(3)-(8) of this section.

(3) Deposit of funds. (i) Funds in excess of $50. The facility must deposit any residents’ personal funds in excess of $50 in an interest bearing account (or accounts) that is separate from any of the facility’s operating accounts, and that credits all interest earned on resident’s funds to that account. (In pooled accounts, there must be a separate accounting for each resident’s share.)

(ii) Funds less than $50. The facility must maintain a resident’s personal funds that do not exceed $50 in a noninterest bearing account, interest-bearing account, or petty cash fund.

(4) Accounting and records. The facility must establish and maintain a system that assures a full and complete and separate accounting, according to generally accepted accounting principles, of each resident’s personal funds entrusted to the facility on the resident’s behalf.

(i) The system must preclude any commingling of resident funds with facility funds or with the funds of any person other than another resident.

(ii) The individual financial record must be available through quarterly statements and on request to the resident or his or her legal representative.

(5) Notice of certain balances. The facility must notify each resident that receives Medicaid benefits—

(i) When the amount in the resident’s account reaches $200 less than the SSI resource limit for one person, specified in section 1611(a)(3)(B) of the Act; and

(ii) That, if the amount in the account, in addition to the value of the resident’s other nonexempt resources, reaches the SSI resource limit for one person, the resident may lose eligibility for Medicaid or SSI.

(6) Conveyance upon death. Upon the death of a resident with a personal
fund deposited with the facility, the facility must convey within 30 days the resident's funds, and a final accounting of those funds, to the individual or probate jurisdiction administering the resident's estate.

(7) Assurance of financial security. The facility must purchase a surety bond, or otherwise provide assurance satisfactory to the Secretary, to assure the security of all personal funds of residents deposited with the facility.

(8) Limitation on charges to personal funds. The facility may not impose a charge against the personal funds of a resident for any item or service for which payment is made under Medicaid or Medicare (except for applicable deductible and coinsurance amounts). The facility may charge the resident for requested services that are more expensive than or in excess of covered services in accordance with §489.32 of this chapter. (This does not affect the prohibition on facility charges for items and services for which Medicaid has paid. See §447.15, which limits participation in the Medicaid program to providers who accept, as payment in full, Medicaid payment plus any deductible, coinsurance, or copayment required by the plan to be paid by the individual.)

(i) Services included in Medicare or Medicaid payment. During the course of a covered Medicare or Medicaid stay, facilities may not charge a resident for the following categories of items and services:

(A) Nursing services as required at §483.30 of this subpart.

(B) Dietary services as required at §483.35 of this subpart.

(C) An activities program as required at §483.15(f) of this subpart.

(D) Room/bed maintenance services.

(E) Routine personal hygiene items and services as required to meet the needs of residents, including, but not limited to, hair hygiene supplies, comb, brush, bath soap, disinfecting soaps or specialized cleansing agents when indicated to treat special skin problems or to fight infection, razor, shaving cream, toothbrush, toothpaste, denture adhesive, denture cleaner, dental floss, moisturizing lotion, tissues, cotton balls, cotton swabs, deodorant, incontinence care and supplies, sanitary napkins and related supplies, towels, washcloths, hospital gowns, over the counter drugs, hair and nail hygiene services, bathing, and basic personal laundry.

(F) Medically-related social services as required at §483.15(g) of this subpart.

(ii) Items and services that may be charged to residents’ funds. Listed below are general categories and examples of items and services that the facility may charge to residents’ funds if they are requested by a resident, if the facility informs the resident that there will be a charge, and if payment is not made by Medicare or Medicaid:

(A) Telephone.

(B) Television/radio for personal use.

(C) Personal comfort items, including smoking materials, notions and novelties, and confections.

(D) Cosmetic and grooming items and services in excess of those for which payment is made under Medicaid or Medicare.

(E) Personal clothing.

(F) Personal reading matter.

(G) Gifts purchased on behalf of a resident.

(H) Flowers and plants.

(I) Social events and entertainment offered outside the scope of the activities program, provided under §483.15(f) of this subpart.

(J) Noncovered special care services such as privately hired nurses or aides.

(K) Private room, except when therapeutically required (for example, isolation for infection control).

(L) Specially prepared or alternative food requested instead of the food generally prepared by the facility, as required by §483.35 of this subpart.

(iii) Requests for items and services. (A) The facility must not charge a resident (or his or her representative) for any item or service not requested by the resident.

(B) The facility must not require a resident (or his or her representative) to request any item or service as a condition of admission or continued stay.

(C) The facility must inform the resident (or his or her representative) requesting an item or service for which a charge will be made that there will be a charge for the item or service and what the charge will be.
(d) Free choice. The resident has the right to—
(1) Choose a personal attending physician;
(2) Be fully informed in advance about care and treatment and of any changes in that care or treatment that may affect the resident’s well-being; and
(3) Unless adjudged incompetent or otherwise found to be incapacitated under the laws of the State, participate in planning care and treatment or changes in care and treatment.
(e) Privacy and confidentiality. The resident has the right to personal privacy and confidentiality of his or her personal and clinical records.
   (1) Personal privacy includes accommodations, medical treatment, written and telephone communications, personal care, visits, and meetings of family and resident groups, but this does not require the facility to provide a private room for each resident;
   (2) Except as provided in paragraph (e)(3) of this section, the resident may approve or refuse the release of personal and clinical records to any individual outside the facility;
   (3) The resident's right to refuse release of personal and clinical records does not apply when—
      (i) The resident is transferred to another health care institution; or
      (ii) Record release is required by law.
(f) Grievances. A resident has the right to—
(1) Voice grievances without discrimination or reprisal. Such grievances include those with respect to treatment which has been furnished as well as that which has not been furnished; and
(2) Prompt efforts by the facility to resolve grievances the resident may have, including those with respect to the behavior of other residents.
(g) Examination of survey results. A resident has the right to—
(1) Examine the results of the most recent survey of the facility conducted by Federal or State surveyors and any plan of correction in effect with respect to the facility. The facility must make the results available for examination in a place readily accessible to residents, and must post a notice of their availability; and
(2) Receive information from agencies acting as client advocates, and be afforded the opportunity to contact these agencies.
(h) Work. The resident has the right to—
(1) Refuse to perform services for the facility;
(2) Perform services for the facility, if he or she chooses, when—
      (i) The facility has documented the need or desire for work in the plan of care;
      (ii) The plan specifies the nature of the services performed and whether the services are voluntary or paid;
      (iii) Compensation for paid services is at or above prevailing rates; and
      (iv) The resident agrees to the work arrangement described in the plan of care.
(i) Mail. The resident has the right to privacy in written communications, including the right to—
(1) Send and promptly receive mail that is unopened; and
(2) Have access to stationery, postage, and writing implements at the resident’s own expense.
(j) Access and visitation rights. (1) The resident has the right and the facility must provide immediate access to any resident by the following:
   (i) Any representative of the Secretary;
   (ii) Any representative of the State;
   (iii) The resident's individual physician;
   (iv) The State long term care ombudsman (established under section 307(a)(12) of the Older Americans Act of 1965);
   (v) The agency responsible for the protection and advocacy system for developmentally disabled individuals (established under part C of the Developmental Disabilities Assistance and Bill of Rights Act);
   (vi) The agency responsible for the protection and advocacy system for mentally ill individuals (established under the Protection and Advocacy for Mentally Ill Individuals Act);
   (vii) Subject to the resident’s right to deny or withdraw consent at any time, immediate family or other relatives of the resident; and
   (viii) Subject to reasonable restrictions and the resident’s right to deny
§ 483.12 Admission, transfer and discharge rights.

(a) Transfer and discharge—

(1) Definition: Transfer and discharge includes movement of a resident to a bed outside of the certified facility whether that bed is in the same physical plant or not. Transfer and discharge does not refer to movement of a resident to a bed within the same certified facility.

(2) Transfer and discharge requirements.

The facility must permit each resident to remain in the facility, and not transfer or discharge the resident from the facility unless—

(i) The transfer or discharge is necessary for the resident’s welfare and the resident’s needs cannot be met in the facility;

(ii) The transfer or discharge is appropriate because the resident’s health has improved sufficiently so the resident no longer needs the services provided by the facility;

(iii) The safety of individuals in the facility is endangered;

(iv) The health of individuals in the facility would otherwise be endangered;

(v) The resident has failed, after reasonable and appropriate notice, to pay for (or to have paid under Medicare or Medicaid) a stay at the facility. For a resident who becomes eligible for Medicaid after admission to a facility, the facility may charge a resident only allowable charges under Medicaid; or

(vi) The facility ceases to operate.

(3) Documentation. When the facility transfers or discharges a resident under any of the circumstances specified in paragraphs (a)(2)(i) through (v) of this section, the resident’s clinical record must be documented. The documentation must be made by—

(i) The resident’s physician when transfer or discharge is necessary under paragraph (a)(2)(i) or paragraph (a)(2)(ii) of this section; and

or withdraw consent at any time, others who are visiting with the consent of the resident.

(2) The facility must provide reasonable access to any resident by any entity or individual that provides health, social, legal, or other services to the resident, subject to the resident’s right to deny or withdraw consent at any time.

(3) The facility must allow representatives of the State Ombudsman, described in paragraph (j)(1)(iv) of this section, to examine a resident’s clinical records with the permission of the resident or the resident’s legal representative, and consistent with State law.

(k) Telephone. The resident has the right to have reasonable access to the use of a telephone where calls can be made without being overheard.

(l) Personal property. The resident has the right to retain and use personal possessions, including some furnishings, and appropriate clothing, as space permits, unless to do so would infringe upon the rights or health and safety of other residents.

(m) Married couples. The resident has the right to share a room with his or her spouse when married residents live in the same facility and both spouses consent to the arrangement.

(n) Self-Administration of Drugs. An individual resident may self-administer drugs if the interdisciplinary team, as defined by §483.20(d)(2)(ii), has determined that this practice is safe.

(o) Refusal of certain transfers. (1) An individual has the right to refuse a transfer to another room within the institution, if the purpose of the transfer is to relocate—

(i) A resident of a SNF from the distinct part of the institution that is a SNF to a part of the institution that is not a SNF, or

(ii) A resident of a NF from the distinct part of the institution that is a NF to a distinct part of the institution that is a SNF.

(2) A resident’s exercise of the right to refuse transfer under paragraph (o)(1) of this section does not affect the individual’s eligibility or entitlement to Medicare or Medicaid benefits.

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(ii) A physician when transfer or discharge is necessary under paragraph (a)(2)(iv) of this section.

(4) Notice before transfer. Before a facility transfers or discharges a resident, the facility must—

(i) Notify the resident and, if known, a family member or legal representative of the resident of the transfer or discharge and the reasons for the move in writing and in a language and manner they understand.

(ii) Record the reasons in the resident's clinical record; and

(iii) Include in the notice the items described in paragraph (a)(6) of this section.

(5) Timing of the notice. (i) Except when specified in paragraph (a)(5)(ii) of this section, the notice of transfer or discharge required under paragraph (a)(4) of this section must be made by the facility at least 30 days before the resident is transferred or discharged.

(ii) Notice may be made as soon as practicable before transfer or discharge when—

(A) the safety of individuals in the facility would be endangered under paragraph (a)(2)(iii) of this section;

(B) The health of individuals in the facility would be endangered, under paragraph (a)(2)(iv) of this section;

(C) The resident's health improves sufficiently to allow a more immediate transfer or discharge, under paragraph (a)(2)(ii) of this section;

(D) An immediate transfer or discharge is required by the resident's urgent medical needs, under paragraph (a)(2)(i) of this section; or

(E) A resident has not resided in the facility for 30 days.

(6) Contents of the notice. The written notice specified in paragraph (a)(4) of this section must include the following:

(i) The reason for transfer or discharge;

(ii) The effective date of transfer or discharge;

(iii) The location to which the resident is transferred or discharged;

(iv) A statement that the resident has the right to appeal the action to the State;

(v) The name, address and telephone number of the State long term care ombudsman;

(vi) For nursing facility residents with developmental disabilities, the mailing address and telephone number of the agency responsible for the protection and advocacy of developmentally disabled individuals established under Part C of the Developmental Disabilities Assistance and Bill of Rights Act; and

(vii) For nursing facility residents who are mentally ill, the mailing address and telephone number of the agency responsible for the protection and advocacy of mentally ill individuals established under the Protection and Advocacy for Mentally Ill Individuals Act.

(7) Orientation for transfer or discharge. A facility must provide sufficient preparation and orientation to residents to ensure safe and orderly transfer or discharge from the facility.

(b) Notice of bed-hold policy and readmission—(1) Notice before transfer. Before a nursing facility transfers a resident to a hospital or allows a resident to go on therapeutic leave, the nursing facility must provide written information to the resident and a family member or legal representative that specifies—

(i) The duration of the bed-hold policy under the State plan, if any, during which the resident is permitted to return and resume residence in the nursing facility; and

(ii) The nursing facility's policies regarding bed-hold periods, which must be consistent with paragraph (b)(3) of this section, permitting a resident to return.

(2) Bed-hold notice upon transfer. At the time of transfer of a resident for hospitalization or therapeutic leave, a nursing facility must provide to the resident and a family member or legal representative written notice which specifies the duration of the bed-hold policy described in paragraph (b)(1) of this section.

(3) Permitting resident to return to facility. A nursing facility must establish and follow a written policy under which a resident, whose hospitalization or therapeutic leave exceeds the bed-hold period under the State plan, is re-admitted to the facility immediately upon the first availability of a bed in a semi-private room if the resident—
§ 483.13 Resident behavior and facility practices.

(a) Restraints. The resident has the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident’s medical symptoms.

(b) Abuse. The resident has the right to be free from verbal, sexual, physical, and mental abuse, corporal punishment, and involuntary seclusion.

(c) Staff treatment of residents. The facility must develop and implement written policies and procedures that prohibit mistreatment, neglect, and abuse of residents and misappropriation of resident property.

(1) The facility must—

(i) Not use verbal, mental, sexual, or physical abuse, corporal punishment, or involuntary seclusion;

(ii) Not employ individuals who have been—

(A) Found guilty of abusing, neglecting, or mistreating residents by a court of law; or

(B) Have had a finding entered into the State nurse aide registry concerning abuse, neglect, mistreatment of residents or misappropriation of their property; and

(iii) Report any knowledge it has of actions by a court of law against an employee, which would indicate
unfitness for service as a nurse aide or other facility staff to the State nurse aide registry or licensing authorities. 

(2) The facility must ensure that all alleged violations involving mistreatment, neglect, or abuse, including injuries of unknown source, and misappropriation of resident property are reported immediately to the administrator of the facility and to other officials in accordance with State law through established procedures (including to the State survey and certification agency). 

(3) The facility must have evidence that all alleged violations are thoroughly investigated, and must prevent further potential abuse while the investigation is in progress. 

(4) The results of all investigations must be reported to the administrator or his designated representative and to other officials in accordance with State law (including to the State survey and certification agency) within 5 working days of the incident, and if the alleged violation is verified appropriate corrective action must be taken.

§ 483.15 Quality of life.

A facility must care for its residents in a manner and in an environment that promotes maintenance or enhancement of each resident’s quality of life.

(a) Dignity. The facility must promote care for residents in a manner and in an environment that maintains or enhances each resident’s dignity and respect in full recognition of his or her individuality.

(b) Self-determination and participation. The resident has the right to—

(1) Choose activities, schedules, and health care consistent with his or her interests, assessments, and plans of care;

(2) Interact with members of the community both inside and outside the facility; and

(3) Make choices about aspects of his or her life in the facility that are significant to the resident.

(c) Participation in resident and family groups. (1) A resident has the right to organize and participate in resident groups in the facility;

(2) A resident’s family has the right to meet in the facility with the families of other residents in the facility;

(3) The facility must provide a resident or family group, if one exists, with private space;

(4) Staff or visitors may attend meetings at the group’s invitation;

(5) The facility must provide a designated staff person responsible for providing assistance and responding to written requests that result from group meetings;

(6) When a resident or family group exists, the facility must listen to the views and act upon the grievances and recommendations of residents and families concerning proposed policy and operational decisions affecting resident care and life in the facility.

(d) Participation in other activities. A resident has the right to participate in social, religious, and community activities that do not interfere with the rights of other residents in the facility.

(e) Accommodation of needs. A resident has the right to—

(1) Reside and receive services in the facility with reasonable accommodation of individual needs and preferences, except when the health or safety of the individual or other residents would be endangered; and

(2) Receive notice before the resident’s room or roommate in the facility is changed.

(f) Activities. (1) The facility must provide for an ongoing program of activities designed to meet, in accordance with the comprehensive assessment, the interests and the physical, mental, and psychosocial well-being of each resident.

(2) The activities program must be directed by a qualified professional who—

(i) is a qualified therapeutic recreation specialist or an activities professional who—

(A) is licensed or registered, if applicable, by the State in which practicing; and

(B) is eligible for certification as a therapeutic recreation specialist or as an activities professional by a recognized accrediting body on or after October 1, 1990; or

(ii) has 2 years of experience in a social or recreational program within the
§ 483.20 Resident assessment.

The facility must conduct initially and periodically a comprehensive, accurate, standardized, reproducible assessment of each resident's functional capacity.

(a) Admission orders. At the time each resident is admitted, the facility must have physician orders for the resident's immediate care.

(b) Comprehensive assessments.

(1) Resident assessment instrument. A facility must make a comprehensive assessment of a resident's needs, using the resident assessment instrument (RAI) specified by the State. The assessment must include at least the following:

(i) Identification and demographic information.
(ii) Customary routine.
(iii) Cognitive patterns.
(iv) Communication.
(v) Vision.
(vi) Mood and behavior patterns.
(vii) Psychosocial well-being.
(viii) Physical functioning and structural problems.
(ix) Continence.
(x) Disease diagnoses and health conditions.
(xi) Dental and nutritional status.
(xii) Skin condition.
(xiii) Activity pursuit.
(xiv) Medications.
(xv) Special treatments and procedures.
(xvi) Discharge potential.
(xvii) Documentation of summary information regarding the additional assessment performed through the resident assessment protocols.
(xviii) Documentation of participation in assessment.

The assessment process must include direct observation and communication with the resident, as well as communication with licensed and nonlicensed direct care staff members on all shifts.

(2) When required. Subject to the timeframes prescribed in §413.343(b) of this chapter, a facility must conduct a comprehensive assessment of a resident as follows:

(i) Within 14 calendar days after admission, excluding readmissions in which there is no significant change in the resident's physical or mental condition. (For purposes of this section, "readmission" means a return to the facility following a temporary absence for hospitalization or for therapeutic leave.)
(ii) Within 14 calendar days after the facility determines, or should have determined, that there has been a significant change in the resident's physical or mental condition. (For purposes of this section, a "significant change" means a major decline or improvement in the resident's status that will not normally resolve itself without further intervention by staff or by implementing standard disease-related clinical interventions, that has an impact on more than one area of the resident's health status, and requires interdisciplinary review or revision of the care plan, or both.)

(iii) Not less often than once every 12 months.

(c) Quarterly review assessment. A facility must assess a resident using the quarterly review instrument specified by the State and approved by HCFA not less frequently than once every 3 months.

(d) Use. A facility must maintain all resident assessments completed within the previous 15 months in the resident's active record and use the results of the assessments to develop, review, and revise the resident's comprehensive plan of care.

(e) Coordination. A facility must coordinate assessments with the preadmission screening and resident review program under Medicaid in part 483, subpart C to the maximum extent practicable to avoid duplicative testing and effort.

(f) Automated data processing requirement. (1) Encoding data. Within 7 days after a facility completes a resident's assessment, a facility must encode the following information for each resident in the facility:

   (i) Admission assessment.
   (ii) Annual assessment updates.
   (iii) Significant change in status assessments.

   (2) Transferring data. Within 7 days after a facility completes a resident's assessment, a facility must be capable of transmitting to the State information for each resident contained in the MDS in a format that conforms to standard record layouts and data dictionaries, and that passes standardized edits defined by HCFA and the State.

   (3) Monthly transmittal requirements. A facility must electronically transmit, at least monthly, encoded, accurate, complete MDS data to the State for all assessments conducted during the previous month, including the following:

      (i) Admission assessment.
      (ii) Annual assessment.
      (iii) Significant change in status assessment.

      (iv) Significant correction of prior full assessment.
      (v) Significant correction of prior quarterly assessment.
      (vi) Quarterly review.
      (vii) A subset of items upon a resident's transfer, reentry, discharge, and death.

      (viii) Background (face-sheet) information, for an initial transmission of MDS data on a resident that does not have an admission assessment.

   (4) Data format. The facility must transmit data in the format specified by HCFA or, for a State which has an alternate RAI approved by HCFA, in the format specified by the State and approved by HCFA.

   (5) Resident-identifiable information. (i) A facility may not release information that is resident-identifiable to the public.

      (ii) The facility may release information that is resident-identifiable to an agent only in accordance with a contract under which the agent agrees not to use or disclose the information except to the extent the facility itself is permitted to do so.

   (g) Accuracy of assessments. The assessment must accurately reflect the resident's status.

   (h) Coordination. A registered nurse must conduct or coordinate each assessment with the appropriate participation of health professionals.

   (i) Certification. (1) A registered nurse must sign and certify that the assessment is completed.

      (2) Each individual who completes a portion of the assessment must sign and certify the accuracy of that portion of the assessment.
(j) Penalty for falsification. (1) Under Medicare and Medicaid, an individual who willfully and knowingly—

   (i) Certifies a material and false statement in a resident assessment is subject to a civil money penalty of not more than $1,000 for each assessment; or

   (ii) Causes another individual to certify a material and false statement in a resident assessment is subject to a civil money penalty of not more than $5,000 for each assessment.

(2) Clinical disagreement does not constitute a material and false statement.

(k) Comprehensive care plans. (1) The facility must develop a comprehensive care plan for each resident that includes measurable objectives and timetables to meet a resident's medical, nursing, and mental and psychosocial needs that are identified in the comprehensive assessment. The care plan must describe the following—

   (i) The services that are to be furnished to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being as required under §483.25; and

   (ii) Any services that would otherwise be required under §483.25 but are not provided due to the resident's exercise of rights under §483.10, including the right to refuse treatment under §483.10(b)(4).

(2) A comprehensive care plan must be—

   (i) Developed within 7 days after completion of the comprehensive assessment;

   (ii) Prepared by an interdisciplinary team, that includes the attending physician, a registered nurse with responsibility for the resident, and other appropriate staff in disciplines as determined by the resident's needs, and, to the extent practicable, the participation of the resident, the resident's family or the resident's legal representative; and

   (iii) Periodically reviewed and revised by a team of qualified persons after each assessment.

(3) The services provided or arranged by the facility must—

   (i) Meet professional standards of quality; and

   (ii) Be provided by qualified persons in accordance with each resident's written plan of care.

(l) Discharge summary. When the facility anticipates discharge a resident must have a discharge summary that includes—

   (1) A recapitulation of the resident's stay;

   (2) A final summary of the resident's status to include items in paragraph (b)(2) of this section, at the time of the discharge that is available for release to authorized persons and agencies, with the consent of the resident or legal representative; and

   (3) A post-discharge plan of care that is developed with the participation of the resident and his or her family, which will assist the resident to adjust to his or her new living environment.

(m) Preadmission screening for mentally ill individuals and individuals with mental retardation. (1) A nursing facility must not admit, on or after January 1, 1989, any new resident with—

   (i) Mental illness as defined in paragraph (f)(2)(i) of this section, unless the State mental health authority has determined, based on an independent physical and mental evaluation performed by a person or entity other than the State mental health authority, prior to admission—

      (A) That, because of the physical and mental condition of the individual, the individual requires the level of services provided by a nursing facility; and

      (B) If the individual requires such level of services, whether the individual requires specialized services; or

   (ii) Mental retardation, as defined in paragraph (f)(2)(ii) of this section, unless the State mental retardation or developmental disability authority has determined prior to admission—

      (A) That, because of the physical and mental condition of the individual, the individual requires the level of services provided by a nursing facility; and

      (B) If the individual requires such level of services, whether the individual requires specialized services for mental retardation.

(2) Definition. For purposes of this section—

   (i) An individual is considered to have mental illness if the individual has
§ 483.25 Quality of care.

Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.

(a) Activities of daily living. Based on the comprehensive assessment of a resident, the facility must ensure that—

1. A resident’s abilities in activities of daily living do not diminish unless circumstances of the individual’s clinical condition demonstrate that diminution was unavoidable. This includes the resident’s ability to—
   (i) Bathe, dress, and groom;
   (ii) Transfer and ambulate;
   (iii) Toilet;
   (iv) Eat; and
   (v) Use speech, language, or other functional communication systems.

2. A resident is given the appropriate treatment and services to maintain or improve his or her abilities specified in paragraph (a)(1) of this section; and

3. A resident who is unable to carry out activities of daily living receives the necessary services to maintain good nutrition, grooming, and personal and oral hygiene.

(b) Vision and hearing. To ensure that residents receive proper treatment and assistive devices to maintain vision and hearing abilities, the facility must, if necessary, assist the resident—

1. In making appointments, and

2. By arranging for transportation to and from the office of a practitioner specializing in the treatment of vision or hearing impairment or the office of a professional specializing in the provision of vision or hearing assistive devices.

(c) Pressure sores. Based on the comprehensive assessment of a resident, the facility must ensure that—

1. A resident who enters the facility without pressure sores does not develop pressure sores unless the individual’s clinical condition demonstrates that they were unavoidable; and

2. A resident having pressure sores receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing.

(d) Urinary incontinence. Based on the resident’s comprehensive assessment, the facility must ensure that—

1. A resident who enters the facility without an indwelling catheter is not catheterized unless the resident’s clinical condition demonstrates that catheterization was necessary; and

2. A resident who is incontinent of bladder receives appropriate treatment and services to prevent urinary tract infections and to restore as much normal bladder function as possible.

(e) Range of motion. Based on the comprehensive assessment of a resident, the facility must ensure that—

1. A resident who enters the facility without a limited range of motion does not experience reduction in range of motion unless the resident’s clinical condition demonstrates that a reduction in range of motion is unavoidable; and

2. A resident with a limited range of motion receives appropriate treatment and services to increase range of motion and/or to prevent further decrease in range of motion.

(f) Mental and Psychosocial functioning. Based on the comprehensive assessment of a resident, the facility must ensure that—

1. A resident who displays mental or psychosocial adjustment difficulty, receives appropriate treatment and services to correct the assessed problem,
§ 483.30 Nursing services.

(A) Resident whose assessment did not reveal a mental or psychosocial adjustment difficulty does not display a pattern of decreased social interaction and/or increased withdrawn, angry, or depressive behaviors, unless the resident’s clinical condition demonstrates that such a pattern was unavoidable.

(2) Naso-gastric tubes. Based on the comprehensive assessment of a resident, the facility must ensure that—

(1) A resident who has been able to eat enough alone or with assistance is not fed by naso-gastric tube unless the resident’s clinical condition demonstrates that use of a naso-gastric tube was unavoidable; and

(2) A resident who is fed by a naso-gastric or gastrostomy tube receives the appropriate treatment and services to prevent aspiration pneumonia, diarrhea, vomiting, dehydration, metabolic abnormalities, and nasal-pharyngeal ulcers and to restore, if possible, normal eating skills.

(h) Accidents. The facility must ensure that—

(1) The resident environment remains as free of accident hazards as is possible; and

(2) Each resident receives adequate supervision and assistance devices to prevent accidents.

(i) Nutrition. Based on a resident’s comprehensive assessment, the facility must ensure that a resident—

(1) Maintains acceptable parameters of nutritional status, such as body weight and protein levels, unless the resident’s clinical condition demonstrates that this is not possible; and

(2) Receives a therapeutic diet when there is a nutritional problem.

(j) Hydration. The facility must provide each resident with sufficient fluid intake to maintain proper hydration and health.

(k) Special needs. The facility must ensure that residents receive proper treatment and care for the following special services:

(1) Injections;

(2) Parenteral and enteral fluids;

(3) Colostomy, urostomy, or ileostomy care;

(4) Tracheostomy care;

(5) Tracheal suctioning;

(6) Respiratory care;

(7) Foot care; and

(8) Prostheses.

(l) Unnecessary drugs—(1) General. Each resident’s drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used:

(i) In excessive dose (including duplicate drug therapy); or

(ii) For excessive duration; or

(iii) Without adequate monitoring; or

(iv) Without adequate indications for its use; or

(v) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or

(vi) Any combinations of the reasons above.

(2) Antipsychotic Drugs. Based on a comprehensive assessment of a resident, the facility must ensure that—

(i) Residents who have not used antipsychotic drugs are not given these drugs unless antipsychotic drug therapy is necessary to treat a specific condition as diagnosed and documented in the clinical record; and

(ii) Residents who use antipsychotic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.

(m) Medication Errors. The facility must ensure that—

(1) It is free of medication error rates of five percent or greater; and

(2) Residents are free of any significant medication errors.


§ 483.30 Nursing services.

The facility must have sufficient nursing staff to provide nursing and related services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care.

(a) Sufficient staff. (1) The facility must provide services by sufficient numbers of each of the following types of personnel on a 24-hour basis to provide nursing care to all residents in accordance with resident care plans:

(i) Except when waived under paragraph (c) of this section, licensed nurses; and

(ii) Other nursing personnel.

(2) Except when waived under paragraph (c) of this section, the facility
must designate a licensed nurse to serve as a charge nurse on each tour of duty.

(b) Registered nurse. (1) Except when waived under paragraph (c) or (d) of this section, the facility must use the services of a registered nurse for at least 8 consecutive hours a day, 7 days a week.

(2) Except when waived under paragraph (c) or (d) of this section, the facility must designate a registered nurse to serve as the director of nursing on a full time basis.

(3) The director of nursing may serve as a charge nurse only when the facility has an average daily occupancy of 60 or fewer residents.

(c) Nursing facilities: Waiver of requirement to provide licensed nurses on a 24-hour basis. To the extent that a facility is unable to meet the requirements of paragraphs (a)(2) and (b)(1) of this section, a State may waive such requirements with respect to the facility if—

(1) The facility demonstrates to the satisfaction of the State that the facility has been unable, despite diligent efforts (including offering wages at the community prevailing rate for nursing facilities), to recruit appropriate personnel;

(2) The State determines that a waiver of the requirement will not endanger the health or safety of individuals staying in the facility;

(3) The State finds that, for any periods in which licensed nursing services are not available, a registered nurse or a physician is obligated to respond immediately to telephone calls from the facility;

(4) A waiver granted under the conditions listed in paragraph (c) of this section is subject to annual State review;

(5) In granting or renewing a waiver, a facility may be required by the State to use other qualified, licensed personnel;

(6) The State agency granting a waiver of such requirements provides notice of the waiver to the State long term care ombudsman (established under section 307(a)(12) of the Older Americans Act of 1965) and the protection and advocacy system in the State for the mentally ill and mentally retarded; and

(7) The nursing facility that is granted such a waiver by a State notifies residents of the facility (or, where appropriate, the guardians or legal representatives of such residents) and members of their immediate families of the waiver.

(d) SNFs: Waiver of the requirement to provide services of a registered nurse for more than 40 hours a week.

(1) The Secretary may waive the requirement that a SNF provide the services of a registered nurse for more than 40 hours a week, including a director of nursing specified in paragraph (b) of this section, if the Secretary finds that—

(i) The facility is located in a rural area and the supply of skilled nursing facility services in the area is not sufficient to meet the needs of individuals residing in the area;

(ii) The facility has one full-time registered nurse who is regularly on duty at the facility 40 hours a week; and

(iii) The facility either—

(A) Has only patients whose physicians have indicated (through physicians' orders or admission notes) that they do not require the services of a registered nurse or a physician for a 48-hours period, or

(B) Has made arrangements for a registered nurse or a physician to spend time at the facility, as determined necessary by the physician, to provide necessary skilled nursing services on days when the regular full-time registered nurse is not on duty;

(iv) The Secretary provides notice of the waiver to the State long term care ombudsman (established under section 307(a)(12) of the Older Americans Act of 1965) and the protection and advocacy system in the State for the mentally ill and mentally retarded; and

(v) The facility that is granted such a waiver notifies residents of the facility (or, where appropriate, the guardians or legal representatives of such residents) and members of their immediate families of the waiver.

(2) A waiver of the registered nurse requirement under paragraph (d)(1) of this section is subject to annual renewal by the Secretary.

§ 483.35 Dietary services.

The facility must provide each resident with a nourishing, palatable, well-balanced diet that meets the daily nutritional and special dietary needs of each resident.

(a) Staffing. The facility must employ a qualified dietitian either full-time, part-time, or on a consultant basis.

(1) If a qualified dietitian is not employed full-time, the facility must designate a person to serve as the director of food service who receives frequently scheduled consultation from a qualified dietitian.

(2) A qualified dietitian is one who is qualified based upon either registration by the Commission on Dietetic Registration of the American Dietetic Association, or on the basis of education, training, or experience in identification of dietary needs, planning, and implementation of dietary programs.

(b) Sufficient staff. The facility must employ sufficient support personnel competent to carry out the functions of the dietary service.

(c) Menus and nutritional adequacy. Menus must—

(1) Meet the nutritional needs of residents in accordance with the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences;

(2) Be prepared in advance; and

(3) Be followed.

(d) Food. Each resident receives and the facility provides—

(1) Food prepared by methods that conserve nutritive value, flavor, and appearance;

(2) Food that is palatable, attractive, and at the proper temperature;

(3) Food prepared in a form designed to meet individual needs; and

(4) Substitutes offered of similar nutritive value to residents who refuse food served.

(e) Therapeutic diets. Therapeutic diets must be prescribed by the attending physician.

(f) Frequency of meals. (1) Each resident receives and the facility provides at least three meals daily, at regular times comparable to normal mealtimes in the community.

(2) There must be no more than 14 hours between a substantial evening meal and breakfast the following day, except as provided in (4) below.

(3) The facility must offer snacks at bedtime daily.

(4) When a nourishing snack is provided at bedtime, up to 16 hours may elapse between a substantial evening meal and breakfast the following day if a resident group agrees to this meal span, and a nourishing snack is served.

(g) Assistive devices. The facility must provide special eating equipment and utensils for residents who need them.

(h) Sanitary conditions. The facility must—

(1) Procure food from sources approved or considered satisfactory by Federal, State, or local authorities;

(2) Store, prepare, distribute, and serve food under sanitary conditions; and

(3) Dispose of garbage and refuse properly.

[56 FR 48874, Sept. 26, 1991]

§ 483.40 Physician services.

A physician must personally approve in writing a recommendation that an individual be admitted to a facility. Each resident must remain under the care of a physician.

(a) Physician supervision. The facility must ensure that—

(1) The medical care of each resident is supervised by a physician; and

(2) Another physician supervises the medical care of residents when their attending physician is unavailable.

(b) Physician visits. The physician must—

(1) Review the resident’s total program of care, including medications and treatments, at each visit required by paragraph (c) of this section;

(2) Write, sign, and date progress notes at each visit; and

(3) Sign and date all orders.

(c) Frequency of physician visits.

(1) The resident must be seen by a physician at least once every 30 days for the first 90 days after admission, and at least once every 60 days thereafter.

(2) A physician visit is considered timely if it occurs not later than 10 days after the date the visit was required.
§ 483.60 Pharmacy services.

The facility must provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in §483.75(h) of this part.

(3) Except as provided in paragraphs (c)(4) and (f) of this section, all required physician visits must be made by the physician personally.

(4) At the option of the physician, required visits in SNFs after the initial visit may alternate between personal visits by the physician and visits by a physician assistant, nurse practitioner, or clinical nurse specialist in accordance with paragraph (e) of this section.

(d) Availability of physicians for emergency care. The facility must provide or arrange for the provision of physician services 24 hours a day, in case of an emergency.

(e) Physician delegation of tasks in SNFs. (1) Except as specified in paragraph (e)(2) of this section, a physician may delegate tasks to a physician assistant, nurse practitioner, or clinical nurse specialist who—

(i) Meets the applicable definition in §491.2 of this chapter or, in the case of a clinical nurse specialist, is licensed as such by the State;

(ii) Is acting within the scope of practice as defined by State law; and

(iii) Is under the supervision of the physician.

(2) A physician may not delegate a task when the regulations specify that the physician must perform it personally, or when the delegation is prohibited under State law or by the facility's own policies.

(f) Performance of physician tasks in NFs. At the option of the State, any required physician task in NFs (including tasks which the regulations specify must be performed personally by the physician) may also be satisfied when performed by a nurse practitioner, clinical nurse specialist, or physician assistant who is not an employee of the facility but who is working in collaboration with a physician.

§ 483.55 Dental services.

The facility must assist residents in obtaining routine and 24-hour emergency dental care.

(a) Skilled nursing facilities. A facility—

(1) Must provide or obtain from an outside resource, in accordance with §483.75(h) of this part, routine and emergency dental services to meet the needs of each resident;

(2) May charge a Medicare resident an additional amount for routine and emergency dental services;

(3) Must, if necessary, assist the resident—

(i) In making appointments; and

(ii) By arranging for transportation to and from the dentist's office;

(4) Promptly refer residents with lost or damaged dentures to a dentist.

(b) Nursing facilities. The facility—

(1) Must provide or obtain from an outside resource, in accordance with §483.75(h) of this part, the following dental services to meet the needs of each resident:

(i) Routine dental services (to the extent covered under the State plan); and

(ii) Emergency dental services;

(2) Must, if necessary, assist the resident—

(i) In making appointments; and

(ii) By arranging for transportation to and from the dentist's office;

(3) Must promptly refer residents with lost or damaged dentures to a dentist.

§ 483.45 Specialized rehabilitative services.

(a) Provision of services. If specialized rehabilitative services such as but not limited to physical therapy, speech-language pathology, occupational therapy, and mental health rehabilitative services for mental illness and mental retardation, are required in the resident's comprehensive plan of care, the facility must—

(1) Provide the required services; or

(2) Obtain the required services from an outside resource (in accordance with §483.75(h) of this part) from a provider of specialized rehabilitative services.

(b) Qualifications. Specialized rehabilitative services must be provided under the written order of a physician by qualified personnel.

§ 483.65  Infection control.

The facility must establish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of disease and infection.

(a) Infection control program. The facility must establish an infection control program under which it—

(1) Investigates, controls, and prevents infections in the facility; and
(2) Decides what procedures, such as isolation, should be applied to an individual resident; and
(3) Maintains a record of incidents and corrective actions related to infections.

(b) Preventing spread of infection. (1) When the infection control program determines that a resident needs isolation to prevent the spread of infection, the facility must isolate the resident.

(2) The facility must prohibit employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease.

(3) The facility must require staff to wash their hands after each direct resident contact for which handwashing is indicated by accepted professional practice.

(c) Linens. Personnel must handle, store, process, and transport linens so as to prevent the spread of infection.


§ 483.70  Physical environment.

The facility must be designed, constructed, equipped, and maintained to protect the health and safety of residents, personnel and the public.

(a) Life safety from fire. Except as provided in paragraph (a)(1) or (a)(3) of this section, the facility must meet the applicable provisions of the 1985 edition of the Life Safety Code of the National Fire Protection Association (which is incorporated by reference). Incorporation of the 1985 edition of the National
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Fire Protection Association's Life Safety Code (published February 7, 1985; ANSI/NFPA) was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 that govern the use of incorporations by reference.1

(1) A facility is considered to be in compliance with this requirement as long as the facility—
(i) On November 26, 1982, complied with or without waivers, with the requirements of the 1967 or 1973 editions of the Life Safety Code and continues to remain in compliance with those editions of the Code; or

(2) After consideration of State survey agency findings, HCFA may waive specific provisions of the Life Safety Code which, if rigidly applied would result in unreasonable hardship upon the facility, but only if the waiver does not adversely affect the health and safety of residents or personnel.

(3) The provisions of the Life Safety Code do not apply in a State where HCFA finds, in accordance with applicable provisions of sections 1819(d)(2)(B)(ii) and 1919(d)(2)(B)(ii) of the Act, that a fire and safety code imposed by State law adequately protects patients, residents and personnel in long term care facilities.

(b) Emergency power. (1) An emergency electrical power system must supply power adequate at least for lighting all entrances and exits; equipment to maintain the fire detection, alarm, and extinguishing systems; and life support systems in the event the normal electrical supply is interrupted.

(2) When life support systems are used, the facility must provide emergency electrical power with an emergency generator (as defined in NFPA 99, Health Care Facilities) that is located on the premises.

(c) Space and equipment. The facility must—
(1) Provide sufficient space and equipment in dining, health services, recreation, and program areas to enable staff to provide residents with needed services as required by these standards and as identified in each resident's plan of care; and
(2) Maintain all essential mechanical, electrical, and patient care equipment in safe operating condition.

(d) Resident rooms. Resident rooms must be designed and equipped for adequate nursing care, comfort, and privacy of residents.

(1) Bedrooms must—
(i) Accommodate no more than four residents;
(ii) Measure at least 80 square feet per resident in multiple resident bedrooms, and at least 100 square feet in single resident rooms;
(iii) Have direct access to an exit corridor;
(iv) Be designed or equipped to assure full visual privacy for each resident;
(v) In facilities initially certified after March 31, 1992, except in private rooms, each bed must have ceiling suspended curtains, which extend around the bed to provide total visual privacy in combination with adjacent walls and curtains;
(vi) Have at least one window to the outside; and
(vii) Have a floor at or above grade level.

(2) The facility must provide each resident with—
(i) A separate bed of proper size and height for the convenience of the resident;
(ii) A clean, comfortable mattress;
(iii) Bedding appropriate to the weather and climate; and
(iv) Functional furniture appropriate to the resident's needs, and individual closet space in the resident's bedroom with clothes racks and shelves accessible to the resident.

(3) HCFA, or in the case of a nursing facility the survey agency, may permit variations in requirements specified in paragraphs (d)(1) (i) and (ii) of this section relating to rooms in individual

1The Code is available for inspection at the Office of the Federal Register Information Center, room 8301, 1110 L Street NW., Washington, DC Copies may be obtained from the National Fire Protection Association, Batterymarch Park, Quincy, MA 02269. If any changes in this code are also to be incorporated by reference, a notice to that effect will be published in the Federal Register.
§ 483.75 Administration.

A facility must be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.

(a) Licensure. A facility must be licensed under applicable State and local law.

(b) Compliance with Federal, State, and local laws and professional standards. The facility must operate and provide services in compliance with all applicable Federal, State, and local laws, regulations, and codes, and with accepted professional standards and principles that apply to professionals providing services in such a facility.

(c) Relationship to other HHS regulations. In addition to compliance with the regulations set forth in this subpart, facilities are obliged to meet the applicable provisions of other HHS regulations, including but not limited to those pertaining to nondiscrimination on the basis of race, color, or national origin (45 CFR part 80); nondiscrimination on the basis of handicap (45 CFR part 84); nondiscrimination on the basis of age (45 CFR part 91); protection of human subjects of research (45 CFR part 46); and fraud and abuse (42 CFR part 455). Although these regulations are not in themselves considered requirements under this part, their violation may result in the termination or suspension of, or the refusal to grant or continue payment with Federal funds.

(d) Governing body. (1) The facility must have a governing body, or designated persons functioning as a governing body, that is legally responsible for establishing and implementing policies regarding the management and operation of the facility; and

(2) The governing body appoints the administrator who is—

(i) Licensed by the State where licensing is required; and

(ii) Responsible for management of the facility.

(e) Required training of nursing aides—

(1) Definitions.

Licensed health professional means a physician; physician assistant; nurse practitioner; physical, speech, or occupational therapist; physical or occupational therapy assistant; registered professional nurse; licensed practical nurse; or licensed or certified social worker.

Nurse aide means any individual providing nursing or nursing-related services to residents in a facility who is not a licensed health professional, a registered dietitian, or someone who volunteers to provide such services without pay.
§ 483.75  
(2) General rule. A facility must not use any individual working in the facility as a nurse aide for more than 4 months, on a full-time basis, unless:
   (i) That individual is competent to provide nursing and nursing related services; and
   (ii) That individual has completed a training and competency evaluation program, or a competency evaluation program approved by the State as meeting the requirements of §§ 483.151-483.154 of this part; or
(3) Non-permanent employees. A facility must not use on a temporary, per diem, leased, or any basis other than a permanent employee any individual who does not meet the requirements in paragraphs (e)(2) (i) and (ii) of this section.
(4) Competency. A facility must not use any individual who has worked less than 4 months as a nurse aide in that facility unless the individual—
   (i) Is a full-time employee in a State-approved training and competency evaluation program;
   (ii) Has demonstrated competence through satisfactory participation in a State-approved nurse aide training and competency evaluation program or competency evaluation program; or
   (iii) Has been deemed or determined competent as provided in § 483.150 (a) and (b).
(5) Registry verification. Before allowing an individual to serve as a nurse aide, a facility must receive registry verification that the individual has met competency evaluation requirements unless—
   (i) The individual is a full-time employee in a training and competency evaluation program approved by the State; or
   (ii) The individual can prove that he or she has recently successfully completed a training and competency evaluation program approved by the State and has not yet been included in the registry. Facilities must follow up to ensure that such an individual actually becomes registered.
(6) Multi-State registry verification. Before allowing an individual to serve as a nurse aide, a facility must seek information from every State registry established under sections 1819(e)(2)(A) or 1919(e)(2)(A) of the Act the facility believes will include information on the individual.
(7) Required retraining. If, since an individual’s most recent completion of a training and competency evaluation program, there has been a continuous period of 24 consecutive months during which the individual provided nursing or nursing-related services for monetary compensation, the individual must complete a new training and competency evaluation program or a new competency evaluation program.
(8) Regular in-service education. The facility must complete a performance review of every nurse aide at least once every 12 months, and must provide regular in-service education based on the outcome of these reviews. The in-service training must—
   (i) Be sufficient to ensure the continuing competence of nurse aides, but must be no less than 12 hours per year;
   (ii) Address areas of weakness as determined in nurse aides’ performance reviews and may address the special needs of residents as determined by the facility staff; and
   (iii) For nurse aides providing services to individuals with cognitive impairments, also address the care of the cognitively impaired.
(f) Proficiency of Nurse aides. The facility must ensure that nurse aides are able to demonstrate competency in skills and techniques necessary to care for residents’ needs, as identified through resident assessments, and described in the plan of care.
(g) Staff qualifications. (1) The facility must employ on a full-time, part-time or consultant basis those professionals necessary to carry out the provisions of these requirements.
   (2) Professional staff must be licensed, certified, or registered in accordance with applicable State laws.
   (3) If the facility does not employ a qualified professional person to furnish a specific service to be provided by the facility, the facility must have that service furnished to residents by a person or agency outside the facility under an arrangement described in section 1861(w).
of the Act or (with respect to services furnished to NF residents and dental services furnished to SNF residents) an agreement described in paragraph 

(h)(2) of this section.

(2) Arrangements as described in section 1861(w) of the Act or agreements pertaining to services furnished by outside resources must specify in writing that the facility assumes responsibility for—

(i) Obtaining services that meet professional standards and principles that apply to professionals providing services in such a facility; and

(ii) The timeliness of the services.

(i) Medical director. (1) The facility must designate a physician to serve as medical director.

(2) The medical director is responsible for—

(i) Implementation of resident care policies; and

(ii) The coordination of medical care in the facility.

(j) Level B requirement: Laboratory services. (1) The facility must provide or obtain laboratory services to meet the needs of its residents. The facility is responsible for the quality and timeliness of the services.

(i) If the facility provides its own laboratory services, the services must meet the applicable requirements for laboratories specified in part 493 of this chapter.

(ii) If the facility provides blood bank and transfusion services, it must meet the applicable requirements for laboratories specified in part 493 of this chapter.

(iii) If the laboratory chooses to refer specimens for testing to another laboratory, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the requirements of part 493 of this chapter.

(iv) If the facility does not provide laboratory services on site, it must have an agreement to obtain these services from a laboratory that meets the applicable requirements of part 493 of this chapter.

(2) The facility must—

(i) Provide or obtain laboratory services only when ordered by the attending physician;

(ii) Promptly notify the attending physician of the findings;

(iii) Assist the resident in making transportation arrangements to and from the source of service, if the resident needs assistance; and

(iv) File in the resident’s clinical record laboratory reports that are dated and contain the name and address of the testing laboratory.

(k) Radiology and other diagnostic services. (1) The facility must provide or obtain radiology and other diagnostic services to meet the needs of its residents. The facility is responsible for the quality and timeliness of the services.

(i) If the facility provides its own diagnostic services, the services must meet the applicable conditions of participation for hospitals contained in §482.26 of this subchapter.

(ii) If the facility does not provide its own diagnostic services, it must have an agreement to obtain these services from a provider or supplier that is approved to provide these services under Medicare.

(2) The facility must—

(i) Provide or obtain radiology and other diagnostic services only when ordered by the attending physician;

(ii) Promptly notify the attending physician of the findings;

(iii) Assist the resident in making transportation arrangements to and from the source of service, if the resident needs assistance; and

(iv) File in the resident’s clinical record signed and dated reports of x-ray and other diagnostic services.

(l) Clinical records. (1) The facility must maintain clinical records on each resident in accordance with accepted professional standards and practices that are—

(i) Complete;

(ii) Accurately documented;

(iii) Readily accessible; and

(iv) Systematically organized.

(2) Clinical records must be retained for—

(i) The period of time required by State law; or

(ii) Five years from the date of discharge when there is no requirement in State law; or
(iii) For a minor, three years after a resident reaches legal age under State law.

(3) The facility must safeguard clinical record information against loss, destruction, or unauthorized use;

(4) The facility must keep confidential all information contained in the resident’s records, regardless of the form or storage method of the records, except when release is required by—

(i) Transfer to another health care institution;

(ii) Law;

(iii) Third party payment contract; or

(iv) The resident.

(5) The clinical record must contain—

(i) Sufficient information to identify the resident;

(ii) A record of the resident’s assessments;

(iii) The plan of care and services provided;

(iv) The results of any preadmission screening conducted by the State; and

(v) Progress notes.

(m) Disaster and emergency preparedness. (1) The facility must have detailed written plans and procedures to meet all potential emergencies and disasters, such as fire, severe weather, and missing residents.

(2) The facility must train all employees in emergency procedures when they begin to work in the facility, periodically review the procedures with existing staff, and carry out unannounced staff drills using those procedures.

(n) Transfer agreement. (1) In accordance with section 1861(l) of the Act, the facility (other than a nursing facility which is located in a State on an Indian reservation) must have in effect a written transfer agreement with one or more hospitals approved for participation under the Medicare and Medicaid programs that reasonably assures that—

(i) Residents will be transferred from the facility to the hospital, and ensured of timely admission to the hospital when transfer is medically appropriate as determined by the attending physician; and

(ii) Medical and other information needed for care and treatment of residents will be exchanged between the institutions.

(2) The facility is considered to have a transfer agreement in effect if the facility has attempted in good faith to enter into an agreement with a hospital sufficiently close to the facility to make transfer feasible.

(o) Quality assessment and assurance. (1) A facility must maintain a quality assessment and assurance committee consisting of—

(i) The director of nursing services;

(ii) A physician designated by the facility; and

(iii) At least 3 other members of the facility’s staff.

(2) The quality assessment and assurance committee—

(i) Meets at least quarterly to identify issues with respect to which quality assessment and assurance activities are necessary; and

(ii) Develops and implements appropriate plans of action to correct identified quality deficiencies.

(3) A State or the Secretary may not require disclosure of the records of such committee except in so far as such disclosure is related to the compliance of such committee with the requirements of this section.

(4) Good faith attempts by the committee to identify and correct quality deficiencies will not be used as a basis for sanctions.

(p) Disclosure of ownership. (1) The facility must comply with the disclosure requirements of §§420.206 and 455.104 of this chapter.

(2) The facility must provide written notice to the State agency responsible for licensing the facility at the time of change, if a change occurs in—

(i) Persons with an ownership or control interest, as defined in §§420.201 and 455.101 of this chapter;

(ii) The officers, directors, agents, or managing employees;

(iii) The corporation, association, or other company responsible for the management of the facility; or

(iv) The facility’s administrator or director of nursing.

(3) The notice specified in paragraph (p)(2) of this section must include the
§ 483.100 Basis.

The requirements of §§ 483.100 through 483.138 governing the State's responsibility for preadmission screening and annual resident review (PASARR) of individuals with mental illness and mental retardation are based on section 1919(e)(7) of the Act.

§ 483.102 Applicability and definitions.

(a) This subpart applies to the screening or reviewing of all individuals with mental illness or mental retardation who apply to or reside in Medicaid certified NFs regardless of the source of payment for the NF services, and regardless of the individual's or resident's known diagnoses.

(b) Definitions. As used in this subpart—

(1) An individual is considered to have a serious mental illness (MI) if the individual meets the following requirements on diagnosis, level of impairment and duration of illness:

(i) Diagnosis. The individual has a major mental disorder diagnosable under the Diagnostic and Statistical Manual of Mental Disorders, 3rd edition, revised in 1987.

The incorporation of the 1987 edition of the Diagnostic and Statistical Manual of Mental Disorders, 3rd edition, was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 that govern the use of incorporation by reference.¹

(ii) Level of impairment. The disorder results in functional limitations in major life activities within the past 3 to 6 months that would be appropriate for the individual's developmental stage. An individual typically has at least one of the following characteristics on a continuing or intermittent basis:

(A) Interpersonal functioning. The individual has serious difficulty interacting appropriately and communicating effectively with other persons, has a possible history of altercations, evictions, firing, fear of strangers, avoidance of interpersonal relationships and social isolation;

(B) Concentration, persistence, and pace. The individual has serious difficulty in sustaining focused attention for a long enough period to permit the completion of tasks commonly found in work settings or in work-like structured activities occurring in school or home settings, manifests difficulties in concentration, inability to complete simple tasks within an established time period, makes frequent errors, or requires assistance in the completion of these tasks; and

(C) Adaptation to change. The individual has serious difficulty in adapting to typical changes in circumstances associated with work, school, family, or social interaction, manifests agitation, exacerbated signs and symptoms associated with the illness, or withdrawal

¹The Diagnostic and Statistical Manual of Mental Disorders is available for inspection at the Health Care Financing Administration, room 132, East High Rise Building, 6225 Security Boulevard, Baltimore, Maryland, or at the Office of the Federal Register, suite 700, 800 North Capitol St. NW., Washington, DC. Copies may be obtained from the American Psychiatric Association, Division of Publications and Marketing, 1400 K Street, NW., Washington, DC 20005.
from the situation, or requires intervention by the mental health or judicial system.

(iii) Recent treatment. The treatment history indicates that the individual has experienced at least one of the following:
(A) Psychiatric treatment more intensive than outpatient care more than once in the past 2 years (e.g., partial hospitalization or inpatient hospitalization); or
(B) Within the last 2 years, due to the mental disorder, experienced an episode of significant disruption to the normal living situation, for which supportive services were required to maintain functioning at home, or in a residential treatment environment, or which resulted in intervention by housing or law enforcement officials.

(2) An individual is considered to have dementia if he or she has a primary diagnosis of dementia, as described in the Diagnostic and Statistical Manual of Mental Disorders, 3rd edition, revised in 1987, or a non-primary diagnosis of dementia unless the primary diagnosis is a major mental disorder as defined in paragraph (b)(1)(i)(A) of this section.

(3) An individual is considered to have mental retardation (MR) if he or she has—
(i) A level of retardation (mild, moderate, severe or profound) described in the American Association on Mental Retardation’s Manual on Classification in Mental Retardation (1983). Incorporation by reference of the 1983 edition of the American Association on Mental Retardation’s Manual on Classification in Mental Retardation was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 that govern the use of incorporations by reference; or
(ii) A related condition as defined by §435.1009 of this chapter.

§ 483.104 State plan requirement.
As a condition of approval of the State plan, the State must operate a preadmission screening and annual resident review program that meets the requirements of §§483.100 through 438.138.

§ 483.106 Basic rule.
(a) Requirement. The State PASARR program must require—
(1) Preadmission screening of all individuals with mental illness or mental retardation who apply as new admissions to Medicaid NFs on or after January 1, 1989;
(2) Initial review, by April 1, 1990, of all current residents with mental retardation or mental illness who entered Medicaid NFs prior to January 1, 1989; and
(3) At least annual review, as of April 1, 1990, of all residents with mental illness or mental retardation, regardless of whether they were first screened under the preadmission screening or annual resident review requirements.

(b) Admissions, readmissions and interfacility transfers—
(1) New admission. An individual is a new admission if he or she is admitted to any NF for the first time or does not qualify as a readmission. With the exception of certain hospital discharges described in paragraph (b)(2) of this section, new admissions are subject to preadmission screening.

(2) Exempted hospital discharge. (i) An exempted hospital discharge means an individual—
(A) Who is admitted to any NF directly from a hospital after receiving acute inpatient care at the hospital; (B) Who requires NF services for the condition for which he or she received care in the hospital; and (C) Whose attending physician has certified before admission to the facility that the individual is likely to require less than 30 days nursing facility services.

(ii) If an individual who enters a NF as an exempted hospital discharge is later found to require more than 30 days of NF care, the State mental
§ 483.108 Relationship of PASARR to other Medicaid processes.

(a) PASARR determinations made by the State mental health or mental retardation authorities cannot be countermanded by the State Medicaid agency, either in the claims process or through other utilization control/review processes or by the State survey and certification agency. Only appeals determinations made through the system specified in subpart E of this part may overturn a PASARR determination made by the State mental health or mental retardation authorities.

(b) In making their determinations, however, the State mental health and mental retardation authorities must not use criteria relating to the need for NF care or specialized services that are inconsistent with this regulation and any supplementary criteria adopted by the State Medicaid agency under its approved State plan.
§ 483.114 Out-of-State arrangements.

(a) Basic rule. The State in which the individual is a State resident (or would be a State resident at the time he or she becomes eligible for Medicaid), as defined in §435.403 of this chapter, must pay for the PASARR and make the required determinations, in accordance with §431.52(b).

(b) Agreements. A State may include arrangements for PASARR in its provider agreements with out-of-State facilities or reciprocal interstate agreements.

§ 483.112 Preadmission screening of applicants for admission to NFs.

(a) Determination of need for NF services. For each NF applicant with MI or MR, the State mental health or mental retardation authority (as appropriate) must determine, in accordance with §483.130, whether, because of the resident’s physical and mental condition, the individual requires the level of services provided by a NF.

(b) Determination of need for specialized services. If the individual with mental illness or mental retardation is determined to require a NF level of care, the State mental health or mental retardation authority (as appropriate) must also determine, in accordance with §483.130, whether the individual requires specialized services for the mental illness or mental retardation, as defined in §483.120.

(c) Timeliness—(1) Except as specified in paragraph (c)(4) of this section, a preadmission screening determination must be made in writing within an annual average of 7 to 9 working days of referral of the individual with MI or MR by whatever agent performs the Level I identification, under §483.128(a) of this part, to the State mental health or mental retardation authority for screening. (See §483.128(a) for discussion of Level I evaluation.)

(2) The State may conduct determinations verbally to nursing facilities and the individual and confirm them in writing.

(3) The State may compute separate annual averages for the mentally ill and the mentally retarded/developmentally disabled populations.

(4) The Secretary may grant an exception to the timeliness standard in paragraph (c)(1) of this section when the State—

(i) Exceeds the annual average; and

(ii) Provides justification satisfactory to the Secretary that a longer time period was necessary.

§ 483.114 Annual review of NF residents.

(a) Individuals with mental illness. For each resident of a NF who has mental illness, the State mental health authority must determine in accordance with §483.130 whether, because of the resident’s physical and mental condition, the resident requires—

(1) The level of services provided by—

(i) A NF;

(ii) An inpatient psychiatric hospital for individuals under age 21, as described in section 1905(h) of the Act; or

(iii) An institution for mental diseases providing medical assistance to individuals age 65 or older; and

(2) Specialized services for mental illness, as defined in §483.120.

(b) Individuals with mental retardation. For each resident of a NF who has mental retardation, the State mental retardation or developmental disability authority must determine in accordance with §483.130 whether, because of his or her physical or mental condition, the resident requires—

(1) The level of services provided by a NF or an intermediate care facility for the mentally retarded; and

(2) Specialized services for mental retardation as defined in §483.120.

(c) Frequency of review—(1) A review and determination must be conducted for each resident of a Medicaid NF who has mental illness or mental retardation not less often than annually.

(2) “Annually” is defined as occurring within every fourth quarter after the previous preadmission screen or annual resident review.

(d) April 1, 1990 deadline for initial reviews. The first set of annual reviews on residents who entered the NF prior
§ 483.116 Residents and applicants determined to require NF level of services.

(a) Individuals needing NF services. If the State mental health or mental retardation authority determines that a resident or applicant for admission to a NF requires a NF level of services, the NF may admit or retain the individual.

(b) Individuals needing NF services and specialized services. If the State mental health or mental retardation authority determines that a resident or applicant for admission requires both a NF level of services and specialized services for the mental illness or mental retardation—

(1) The NF may admit or retain the individual; and

(2) The State must provide or arrange for the provision of the specialized services needed by the individual while he or she resides in the NF.

§ 483.118 Residents and applicants determined not to require NF level of services.

(a) Applicants who do not require NF services. If the State mental health or mental retardation authority determines that an applicant for admission to a NF does not require NF services, the applicant cannot be admitted. NF services are not a covered Medicaid service for that individual, and further screening is not required.

(b) Residents who require neither NF services nor specialized services for MI or MR. If the State mental health or mental retardation authority determines that a resident requires neither the level of services provided by a NF nor specialized services for MI or MR, regardless of the length of stay in the facility, the State must—

(1) Arrange for the safe and orderly discharge of the resident from the facility in accordance with §483.12(a); and

(2) Prepare and orient the resident for discharge.

(c) Residents who do not require NF services but require specialized services for MI or MR—(1) Long term residents. Except as otherwise may be provided in an alternative disposition plan adopted under section 1919(e)(7)(E) of the Act, for any resident who has continuously resided in a NF for at least 30 months before the date of the determination, and who requires only specialized services as defined in §483.120, the State must, in consultation with the resident’s family or legal representative and caregivers—

(i) Offer the resident the choice of remaining in the facility or of receiving services in an alternative appropriate setting;

(ii) Inform the resident of the institutional and noninstitutional alternatives covered under the State Medicaid plan for the resident;

(iii) Clarify the effect on eligibility for Medicaid services under the State plan if the resident chooses to leave the facility, including its effect on re-admission to the facility; and

(iv) Regardless of the resident’s choice, provide for, or arrange for the provision of specialized services for the mental illness or mental retardation.

(2) Short term residents. Except as otherwise may be provided in an alternative disposition plan adopted under section 1919(e)(7)(E) of the Act, for any resident who requires only specialized services, as defined in §483.120, and who has not continuously resided in a NF for at least 30 months before the date of the determination, the State must, in consultation with the resident’s family or legal representative and caregivers—

(i) Arrange for the safe and orderly discharge of the resident from the facility in accordance with §483.12(a);

(ii) Prepare and orient the resident for discharge; and

(iii) Provide for, or arrange for the provision of, specialized services for the mental illness or mental retardation.

(3) For the purpose of establishing length of stay in a NF, the 30 months of continuous residence in a NF or longer—

(i) Is calculated back from the date of the first annual resident review determination which finds that the individual is not in need of NF level of services;

(ii) May include temporary absences for hospitalization or therapeutic leave; and
§ 483.120 Specialized services.

(a) Definition—(1) For mental illness, specialized services means the services specified by the State which, combined with services provided by the NF, results in the continuous and aggressive implementation of an individualized plan of care that—
   (i) Is developed and supervised by an interdisciplinary team, which includes a physician, qualified mental health professionals and, as appropriate, other professionals. 
   (ii) Prescribes specific therapies and activities for the treatment of persons experiencing an acute episode of serious mental illness, which necessitates supervision by trained mental health personnel; and
   (iii) Is directed toward diagnosing and reducing the resident’s behavioral symptoms that necessitated institutionalization, improving his or her level of independent functioning, and achieving a functioning level that permits reduction in the intensity of mental health services to below the level of specialized services at the earliest possible time.

(2) For mental retardation, specialized services means the services specified by the State which, combined with services provided by the NF or other service providers, results in treatment which meets the requirements of § 483.440(a)(1).

(b) Who must receive specialized services. The State must provide or arrange for the provision of specialized services, in accordance with this subpart, to all NF residents with MI or MR whose needs are such that continuous supervision, treatment and training by qualified mental health or mental retardation personnel is necessary, as identified by the screening provided in § 483.130 or §§ 483.134 and 483.136.

(c) Services of lesser intensity than specialized services. The NF must provide mental health or mental retardation services which are of a lesser intensity than specialized services to all residents who need such services.

§ 483.122 FFP for NF services.

(a) Basic rule. Except as otherwise may be provided in an alternative disposition plan adopted under section 1919(e)(7)(E) of the Act, FFP is available in State expenditures for NF services provided to a Medicaid eligible individual subject to the requirements of this part only if the individual has been determined—
   (1) To need NF care under §483.116(a) or
   (2) Not to need NF services but to need specialized services, meets the requirements of §483.118(c)(1), and elects to stay in the NF.

(b) FFP for late reviews. When a preadmission screening has not been performed prior to admission or an annual review is not performed timely, in accordance with §483.114(c), but either is performed at a later date, FFP is available only for services furnished after the screening or review has been performed, subject to the provisions of paragraph (a) of this section.

§ 483.124 FFP for specialized services.

FFP is not available for specialized services furnished to NF residents as NF services.

§ 483.126 Appropriate placement.

Placement of an individual with MI or MR in a NF may be considered appropriate only when the individual’s needs are such that he or she meets the minimum standards for admission and the individual’s needs for treatment do not exceed the level of services which can be delivered in the NF to which the individual is admitted either through NF services alone or, where necessary, through NF services supplemented by specialized services provided by or arranged for by the State.

§ 483.128 PASARR evaluation criteria.

(a) Level I: Identification of individuals with MI or MR. The State’s PASARR program must identify all individuals who are suspected of having MI or MR as defined in §483.102. This identification function is termed Level I. Level II is the function of evaluating and determining whether NF services and specialized services are needed. The State’s performance of the Level I
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identification function must provide at least, in the case of first time identifications, for the issuance of written notice to the individual or resident and his or her legal representative that the individual or resident is suspected of having MI or MR and is being referred to the State mental health or mental retardation authority for Level II screening.

(b) Adaptation to culture, language, ethnic origin. Evaluations performed under PASARR and PASARR notices must be adapted to the cultural background, language, ethnic origin and means of communication used by the individual being evaluated.

(c) Participation by individual and family. PASARR evaluations must involve—

(1) The individual being evaluated;

(2) The individual's legal representative, if one has been designated under State law; and

(3) The individual's family if—

(i) Available; and

(ii) The individual or the legal representative agrees to family participation.

(d) Interdisciplinary coordination. When parts of a PASARR evaluation are performed by more than one evaluator, the State must ensure that there is interdisciplinary coordination among the evaluators.

(e) The State's PASARR program must use at least the evaluative criteria of §483.130 (if one or both determinations can easily be made categorically as described in §483.130) or of §§483.132 and 483.134 or §483.136 (or, in the case of individuals with both MI and MR, §§483.132, 483.134 and 483.136 if a more extensive individualized evaluation is required).

(f) Data. In the case of individualized evaluations, information that is necessary for determining whether it is appropriate for the individual with MI or MR to be placed in an NF or in another appropriate setting should be gathered throughout all applicable portions of the PASARR evaluation (§§483.132 and 483.134 and/or §483.136). The two determinations relating to the need for NF level of care and specialized services are interrelated and must be based upon a comprehensive analysis of all data concerning the individual.

(g) Preexisting data. Evaluators may use relevant evaluative data, obtained prior to initiation of preadmission screening or annual resident review, if the data are considered valid and accurate and reflect the current functional status of the individual. However, in the case of individualized evaluations, to supplement and verify the currency and accuracy of existing data, the State's PASARR program may need to gather additional information necessary to assess proper placement and treatment.

(h) Findings. For both categorical and individualized determinations, findings of the evaluation must correspond to the person's current functional status as documented in medical and social history records.

(i) Evaluation report: Individualized determinations. For individualized PASARR determinations, findings must be issued in the form of a written evaluative report which—

(1) Identifies the name and professional title of person(s) who performed the evaluation(s) and the date on which each portion of the evaluation was administered;

(2) Provides a summary of the medical and social history, including the positive traits or developmental strengths and weaknesses or developmental needs of the evaluated individual;

(3) If NF services are recommended, identifies the specific services which are required to meet the evaluated individual's needs, including services required in paragraph (i)(5) of this section;

(4) If specialized services are not recommended, identifies any specific mental retardation or mental health services which are of a lesser intensity than specialized services that are required to meet the evaluated individual's needs;

(5) If specialized services are recommended, identifies the specific mental retardation or mental health services required to meet the evaluated individual's needs; and

(6) Includes the bases for the report's conclusions.
(j) Evaluation report: Categorical determinations. For categorical PASARR determinations, findings must be issued in the form of an abbreviated written evaluative report which—

(1) Identifies the name and professional title of the person applying the categorical determination and the data on which the application was made;

(2) Explains the categorical determination(s) that has (have) been made and, if only one of the two required determinations can be made categorically, describes the nature of any further screening which is required;

(3) Identifies, to the extent possible, based on the available data, NF services, including any mental health or specialized psychiatric rehabilitative services, that may be needed; and

(4) Includes the bases for the report’s conclusions.

(k) Interpretation of findings to individual. For both categorical and individualized determinations, findings of the evaluation must be interpreted and explained to the individual and, where applicable, to a legal representative designated under State law.

(l) Evaluation report. The evaluator must send a copy of the evaluation report to the—

(1) Individual or resident and his or her legal representative;

(2) Appropriate State authority in sufficient time for the State authorities to meet the times identified in §483.112(c) for PASs and §483.114(c) for ARRs;

(3) Admitting or retaining NF;

(4) Individual’s attending physician; and

(5) The discharging hospital if the individual is seeking NF admission from a hospital.

(m) The evaluation may be terminated if the evaluator finds at any time during the evaluation that the individual being evaluated—

(1) Does not have MI or MR; or

(2) Has—

(i) A primary diagnosis of dementia (including Alzheimer's Disease or a related disorder); or

(ii) A non-primary diagnosis of dementia without a primary diagnosis that is a serious mental illness, and does not have a diagnosis of MR or a related condition.

§ 483.130 PASARR determination criteria.

(a) Basis for determinations. Determinations made by the State mental health or mental retardation authority as to whether NF level of services and specialized services are needed must be based on an evaluation of data concerning the individual, as specified in paragraph (b) of this section.

(b) Types of determinations. Determinations may be—

(1) Advance group determinations, in accordance with this section, by category that take into account that certain diagnoses, levels of severity of illness, or need for a particular service clearly indicate that admission to or residence in a NF is normally needed, or that the provision of specialized services is not normally needed; or

(2) Individualized determinations based on more extensive individualized evaluations as required in §483.132, §483.134, or §483.136 (or, in the case of an individual having both MR and MI, §§483.134 and 483.136).

(c) Group determinations by category. Advance group determinations by category developed by the State mental health or mental retardation authorities may be made applicable to individuals by the NF or other evaluator following Level I review only if existing data on the individual appear to be current and accurate and are sufficient to allow the evaluator readily to determine that the individual fits into the category established by the State authorities (see §483.132(c)). Sources of existing data on the individual that could form the basis for applying a categorical determination by the State authorities would be hospital records, physician’s evaluations, election of hospice status, records of community mental health centers or community mental retardation or developmental disability providers.

(d) Examples of categories. Examples of categories for which the State mental health or mental retardation authority
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may make an advance group determination that NF services are needed are—

(1) Convalescent care from an acute physical illness which—

(i) Required hospitalization; and

(ii) Does not meet all the criteria for an exempt hospital discharge, which is not subject to preadmission screening, as specified in §483.106(b)(2).

(2) Terminal illness, as defined for hospice purposes in §418.3 of this chapter;

(3) Severe physical illnesses such as coma, ventilator dependence, functioning at a brain stem level, or diagnoses such as chronic obstructive pulmonary disease, Parkinson's disease, Huntington's disease, amyotrophic lateral sclerosis, and congestive heart failure which result in a level of impairment so severe that the individual could not be expected to benefit from specialized services;

(4) Provisional admissions pending further assessment in cases of delirium where an accurate diagnosis cannot be made until the delirium clears;

(5) Provisional admissions pending further assessment in emergency situations requiring protective services, with placement in a nursing facility not to exceed 7 days; and

(6) Very brief and finite stays of up to a fixed number of days to provide respite to in-home caregivers to whom the individual with MI or MR is expected to return following the brief NF stay.

(e) Time limits. The State may specify time limits for categorical determinations that NF services are needed and in the case of paragraphs (d)(4), (5) and (6) of this section, must specify a time limit which is appropriate for provisional admissions pending further assessment and for emergency situations and respite care. If an individual is later determined to need a longer stay than the State's time limit allows, the individual must be subjected to an annual resident review before continuation of the stay may be permitted and payment made for days of NF care beyond the State's time limit.

(f) The State mental health and mental retardation authorities may make categorical determinations that specialized services are not needed in the provisional, emergency and respite admission situations identified in §483.130(d)(4)–(6). In all other cases, except for §483.130(h), a determination that specialized services are not needed must be based on a more extensive individualized evaluation under §483.134 or §483.136.

(g) Categorical determinations: No positive specialized treatment determinations. The State mental health and mental retardation authorities must not make categorical determinations that specialized services are needed. Such a determination must be based on a more extensive individualized evaluation under §483.134 or §483.136 to determine the exact nature of the specialized services that are needed.

(h) Categorical determinations: Dementia and MR. The State mental retardation authority may make categorical determinations that individuals with dementia, which exists in combination with mental retardation or a related condition, do not need specialized services.

(i) If a State mental health or mental retardation authority determines NF needs by category, it may not waive the specialized services determination. The appropriate State authority must also determine whether specialized services are needed either by category (if permitted) or by individualized evaluations, as specified in §483.134 or §483.136.

(j) Recording determinations. All determinations made by the State mental health and mental retardation authority, regardless of how they are arrived at, must be recorded in the individual’s record.

(k) Notice of determination. The State mental health or mental retardation authority must notify in writing the following entities of a determination made under this subpart:

(1) The evaluated individual and his or her legal representative;

(2) The admitting or retaining NF;

(3) The individual or resident’s attending physician; and

(4) The discharging hospital, unless the individual is exempt from preadmission screening as provided for at §483.106(b)(2).

(l) Contents of notice. Each notice of the determination made by the State
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mental health or mental retardation authority must include—

(1) Whether a NF level of services is needed;
(2) Whether specialized services are needed;
(3) The placement options that are available to the individual consistent with these determinations; and
(4) The rights of the individual to appeal the determination under subpart E of this part.

(m) Placement options. Except as otherwise may be provided in an alternative disposition plan adopted under section 1919(e)(7)(E) of the Act, the placement options and the required State actions are as follows:

(1) Can be admitted to a NF. Any applicant for admission to a NF who has MI or MR and who requires the level of services provided by a NF, regardless of whether specialized services are also needed, may be admitted to a NF, if the placement is appropriate, as determined in §483.126. If specialized services are also needed, the State is responsible for providing or arranging for the provision of the specialized services.

(2) Cannot be admitted to a NF. Any applicant for admission to a NF who has MI or MR and who does not require the level of services provided by a NF, regardless of whether specialized services are also needed, is inappropriate for NF placement and must not be admitted.

(3) Can be considered appropriate for continued placement in a NF. Any NF resident with MI or MR who requires the level of services provided by a NF, regardless of the length of his or her stay or the need for specialized services, can continue to reside in the NF, if the placement is appropriate, as determined in §483.126.

(4) May choose to remain in the NF even though the placement would otherwise be inappropriate. Any NF resident with MI or MR who does not require the level of services provided by a NF but does require specialized services and who has continuously resided in a NF for at least 30 consecutive months before the date of determination may choose to continue to reside in the facility or to receive covered services in an alternative appropriate institutional or noninstitutional setting. Wherever the resident chooses to reside, the State must meet his or her specialized services needs. The determination notice must provide information concerning how, when, and by whom the various placement options available to the resident will be fully explained to the resident.

(5) Cannot be considered appropriate for continued placement in a NF and must be discharged (short-term residents). Any NF resident with MI or MR who does not require the level of services provided by a NF but does require specialized services and who has resided in a NF for less than 30 consecutive months must be discharged in accordance with §483.12(a) to an appropriate setting where the State must provide specialized services. The determination notice must provide information on how, when, and by whom the resident will be advised of discharge arrangements and of his/her appeal rights under both PASARR and discharge provisions.

(6) Cannot be considered appropriate for continued placement in a NF and must be discharged (short or long-term residents). Any NF resident with MI or MR who does not require the level of services provided by a NF and does not require specialized services regardless of his or her length of stay, must be discharged in accordance with §483.12(a). The determination notice must provide information on how, when, and by whom the resident will be advised of discharge arrangements and of his or her appeal rights under both PASARR and discharge provisions.

(n) Specialized services needed in a NF. If a determination is made to admit or allow to remain in a NF any individual who requires specialized services, the determination must be supported by assurances that the specialized services that are needed can and will be provided or arranged for by the State while the individual resides in the NF.

(o) Record retention. The State PASARR system must maintain records of evaluations and determinations, regardless of whether they are performed categorically or individually, in order to support its determinations and actions and to protect the appeal rights of individuals subjected to PASARR; and
§ 483.132 Evaluating the need for NF services and NF level of care (PASARR/NF).

(a) Basic rule. For each applicant for admission to a NF and each NF resident who has MI or MR, the evaluator must assess whether—

(1) The individual’s total needs are such that his or her needs can be met in an appropriate community setting;

(2) The individual’s total needs are such that they can be met only on an inpatient basis, which may include the option of placement in a home and community-based services waiver program, but for which the inpatient care would be required;

(3) If inpatient care is appropriate and desired, the NF is an appropriate institutional setting for meeting those needs in accordance with §483.126; or

(4) If the inpatient care is appropriate and desired but the NF is not the appropriate setting for meeting the individual’s needs in accordance with §483.126, another setting such as an ICF/MR (including small, community-based facilities), an IMD providing services to individuals aged 65 or older, or a psychiatric hospital is an appropriate institutional setting for meeting those needs.

(b) Determining appropriate placement. In determining appropriate placement, the evaluator must prioritize the physical and mental needs of the individual being evaluated, taking into account the severity of each condition.

(c) Data. At a minimum, the data relied on to make a determination must include:

(1) Evaluation of physical status (for example, diagnoses, date of onset, medical history, and prognosis);

(2) Evaluation of mental status (for example, diagnoses, date of onset, medical history, likelihood that the individual may be a danger to himself/herself or others); and

(3) Functional assessment (activities of daily living).

(d) Based on the data compiled in §483.132 and, as appropriate, in §§483.134 and 483.136, the State mental health or mental retardation authority must determine whether an NF level of services is needed.

§ 483.134 Evaluating whether an individual with mental illness requires specialized services (PASARR/MI).

(a) Purpose. The purpose of this section is to identify the minimum data needs and process requirements for the State mental health authority, which is responsible for determining whether or not the applicant or resident with MI, as defined in §483.102(b)(1) of this part, needs a specialized services program for mental illness as defined in §483.120.

(b) Data. Minimum data collected must include—

(1) A comprehensive history and physical examination of the person. The following areas must be included (if not previously addressed):

(i) Complete medical history;

(ii) Review of all body systems;

(iii) Specific evaluation of the person’s neurological system in the areas of motor functioning, sensory functioning, gait, deep tendon reflexes, cranial nerves, and abnormal reflexes; and

(iv) In case of abnormal findings which are the basis for an NF placement, additional evaluations conducted by appropriate specialists.

(2) A comprehensive drug history including current or immediate past use of medications that could mask symptoms or mimic mental illness.

(3) A psychosocial evaluation of the person, including current living arrangements and medical and support systems.

(4) A comprehensive psychiatric evaluation including a complete psychiatric history, evaluation of intellectual functioning, memory functioning, and orientation, description of current attitudes and overt behaviors, affect, suicidal or homicidal ideation, paranoia, and degree of reality testing (presence and content of delusions) and hallucinations.
§ 483.135 Evaluating whether an individual with mental retardation requires specialized services (PASARR/MR).

(a) Purpose. The purpose of this section is to identify the minimum data needs and process requirements for the State mental retardation authority to determine whether or not the applicant or resident with mental retardation, as defined in §483.102(b)(3) of this part, needs a continuous specialized services program, which is analogous to active treatment, as defined in §§435.1009 and 483.440 of this chapter.

(b) Data. Minimum data collected must include the individual's comprehensive history and physical examination results to identify the following information or, in the absence of data, must include information that permits a reviewer specifically to assess:

1. The individual's medical problems;
2. The level of impact these problems have on the individual's independent functioning;
3. All current medications used by the individual and the current response of the individual to any prescribed medications in the following drug groups:
   (i) Hypnotics,
   (ii) Antipsychotics (neuroleptics),
   (iii) Mood stabilizers and antidepressants,
   (iv) Antianxiety-sedative agents, and
   (v) Anti-Parkinson agents.
4. Self-monitoring of health status;
5. Self-administering and scheduling of medical treatments;
6. Self-monitoring of nutritional status;
7. Self-help development such as toileting, dressing, grooming, and eating;
8. Sensorimotor development, such as ambulation, positioning, transfer skills, gross motor dexterity, visual motor perception, fine motor dexterity, eye-hand coordination, and extent to which prosthetic, orthotic, corrective or mechanical supportive devices can improve the individual's functional capacity;
9. Speech and language (communication) development, such as expressive language (verbal and nonverbal), receptive language (verbal and nonverbal), extent to which non-oral communication systems can improve the individual's function capacity, auditory functioning, and extent to which amplification devices (for example, hearing aid) or a program of amplification can improve the individual's functional capacity;
10. Social development, such as interpersonal skills, recreation-leisure skills, and relationships with others;
§ 483.138 Maintenance of services and availability of FFP.

(a) Maintenance of services. If a NF mails a 30 day notice of its intent to transfer or discharge a resident, under §483.12(a) of this chapter, the agency may not terminate or reduce services until—

(1) The expiration of the notice period; or

(2) A subpart E appeal, if one has been filed, has been resolved.

(b) Availability of FFP. FFP is available for expenditures for services provided to Medicaid recipients during—

(1) The 30 day notice period specified in §483.12(a) of this chapter; or

(2) During the period an appeal is in progress.

Subpart D—Requirements That Must Be Met by States and State Agencies: Nurse Aide Training and Competency Evaluation

§ 483.150 Statutory basis; Deemed meeting or waiver of requirements.

(a) Statutory basis. This subpart is based on sections 1819(b)(5) and 1919(b)(5) of the Act, which establish standards for training nurse-aides and for evaluating their competency.
§ 483.151 State review and approval of nurse aide training and competency evaluation programs and competency evaluation programs.

(a) State review and administration. (1) The State—
(i) Must specify any nurse aide training and competency evaluation programs that the State approves as meeting the requirements of §483.152 and/or competency evaluations programs that the State approves as meeting the requirements of §483.154; and
(ii) May choose to offer a nurse aide training and competency evaluation program that meets the requirements of §483.152 and/or a competency evaluation program that meets the requirements of §483.154.
(2) If the State does not choose to offer a nurse aide training and competency evaluation program or competency evaluation program, the State must review and approve or disapprove nurse aide training and competency evaluation programs and nurse aide competency evaluation programs upon request.
(3) The State survey agency must in the course of all surveys, determine whether the nurse aide training and competency evaluation requirements of §483.75(e) are met.

(b) Requirements for approval of programs. (1) Before the State approves a nurse aide training and competency evaluation program or competency evaluation program, the State must—
(i) Determine whether the nurse aide training and competency evaluation program meets the course requirements of §§483.152:
(ii) Determine whether the nurse aide competency evaluation program meets the requirements of §483.154; and
(iii) In all reviews other than the initial review, visit the entity providing the program.
(2) The State may not approve a nurse aide training and competency evaluation program or competency evaluation program offered by or in a facility which, in the previous two years—
(i) In the case of a skilled nursing facility, has operated under a waiver under section 1819(b)(4)(C)(i)(II) of the Act;
(ii) In the case of a nursing facility, has operated under a waiver under section 1919(b)(4)(C)(ii) of the Act that was granted on the basis of a demonstration that the facility is unable to provide nursing care required under section 1919(b)(4)(C)(i) of the Act for a period in excess of 48 hours per week;
(iii) Has been subject to an extended (or partial extended) survey under sections 1819(g)(2)(B)(i) or 1919(g)(2)(B)(i) of the Act;
§ 483.152 Requirements for approval of a nurse aide training and competency evaluation program.

(a) For a nurse aide training and competency evaluation program to be approved by the State, it must, at a minimum—

(1) Conist of no less than 75 clock hours of training;

(2) Include at least the subjects specified in paragraph (b) of this section;

(3) Include at least 16 hours of supervised practical training.

(b) Duration of approval. The State may not grant approval of a nurse aide training and competency evaluation program for a period longer than 2 years. A program must notify the State and the State must review the program when there are substantive changes made to the program within the 2-year period.

(c) Withdrawal of approval. (1) The State must withdraw approval of a nurse aide training and competency evaluation program or nurse aide competency evaluation program if the State determines that any of the applicable requirements of §§ 483.152 or 483.154 are not met by the program.

(2) The State may withdraw approval of a nurse aide training and competency evaluation program if the entity providing the program refuses to permit unannounced visits by the State.

(d) If a State withdraws approval of a nurse aide training and competency evaluation program or competency evaluation program—

(i) The State must notify the program in writing, indicating the reason(s) for withdrawal of approval of the program.

(ii) The State must withdraw approval of a nurse aide training and competency evaluation program from which approval has been withdrawn if the State determines that any of the applicable requirements of §§ 483.152 or 483.154 are not met by the program.

(e) If a State withdraws approval of a nurse aide training and competency evaluation program—

(i) The State must notify the program in writing, indicating the reason(s) for withdrawal of approval of the program.

(ii) Students who have started a training and competency evaluation program from which approval has been withdrawn must be allowed to complete the course.
supervision of a registered nurse who possesses a minimum of 2 years of nursing experience, at least 1 year of which must be in the provision of long term care facility services;

(ii) Instructors must have completed a course in teaching adults or have experience in teaching adults or supervising nurse aides;

(iii) In a facility-based program, the training of nurse aides may be performed under the general supervision of the director of nursing for the facility who is prohibited from performing the actual training; and

(iv) Other personnel from the health professions may supplement the instructor, including, but not limited to, registered nurses, licensed practical/vocational nurses, pharmacists, dietitians, social workers, sanitarians, fire safety experts, nursing home administrators, gerontologists, psychologists, physical and occupational therapists, activities specialists, speech/language/hearing therapists, and resident rights experts. Supplemental personnel must have at least 1 year of experience in their fields;

(6) Contain competency evaluation procedures specified in §483.154.

(b) The curriculum of the nurse aide training program must include—

(1) At least a total of 64 hours of training in the following areas prior to any direct contact with a resident:

(i) Communication and interpersonal skills;

(ii) Infection control;

(iii) Safety/emergency procedures, including the Heimlich maneuver;

(iv) Promoting residents' independence; and

(v) Respecting residents' rights.

(2) Basic nursing skills:

(i) Taking and recording vital signs;

(ii) Measuring and recording height and weight;

(iii) Caring for the residents' environment;

(iv) Recognizing abnormal changes in body functioning and the importance of reporting such changes to a supervisor; and

(v) Caring for residents when death is imminent.

(3) Personal care skills, including, but not limited to—

(i) Bathing;

(ii) Grooming, including mouth care;

(iii) Dressing;

(iv) Toileting;

(v) Assisting with eating and hydration;

(vi) Proper feeding techniques;

(vii) Skin care; and

(viii) Transfers, positioning, and turning.

(4) Mental health and social service needs:

(i) Modifying aide's behavior in response to residents' behavior;

(ii) Awareness of developmental tasks associated with the aging process;

(iii) How to respond to resident behavior;

(iv) Allowing the resident to make personal choices, providing and reinforcing other behavior consistent with the resident's dignity; and

(v) Using the resident's family as a source of emotional support.

(5) Care of cognitively impaired residents:

(i) Techniques for addressing the unique needs and behaviors of individual with dementia (Alzheimer's and others);

(ii) Communicating with cognitively impaired residents;

(iii) Understanding the behavior of cognitively impaired residents;

(iv) Appropriate responses to the behavior of cognitively impaired residents; and

(v) Methods of reducing the effects of cognitive impairments.

(6) Basic restorative services:

(i) Training the resident in self care according to the resident's abilities;

(ii) Use of assistive devices in transferring, ambulation, eating, and dressing;

(iii) Maintenance of range of motion;

(iv) Proper turning and positioning in bed and chair;

(v) Bowel and bladder training; and

(vi) Care and use of prosthetic and orthotic devices.

(7) Residents' Rights:

(i) Providing privacy and maintenance of confidentiality;

(ii) Promoting the residents' right to make personal choices to accommodate their needs;

(iii) Giving assistance in resolving grievances and disputes;
(iv) Providing needed assistance in getting to and participating in resident and family groups and other activities;
(v) Maintaining care and security of residents' personal possessions;
(vi) Promoting the resident's right to be free from abuse, mistreatment, and neglect and the need to report any instances of such treatment to appropriate facility staff;
(vii) Avoiding the need for restraints in accordance with current professional standards.

(c) Prohibition of charges. (1) No nurse aide who is employed by, or who has received an offer of employment from, a facility on the date on which the aide begins a nurse aide training and competency evaluation program may be charged for any portion of the program (including any fees for textbooks or other required course materials).
(2) If an individual who is not employed, or does not have an offer to be employed, as a nurse aide becomes employed by, or receives an offer of employment from, a facility not later than 12 months after completing a nurse aide training and competency evaluation program, the State must provide for the reimbursement of costs incurred in completing the program on a pro rata basis during the period in which the individual is employed as a nurse aide.

§ 483.154 Nurse aide competency evaluation.

(a) Notification to Individual. The State must advise in advance any individual who takes the competency evaluation that a record of the successful completion of the evaluation will be included in the State's nurse aid registry.
(b) Content of the competency evaluation program—(1) Written or oral examinations. The competency evaluation must:
(i) Allow an aide to choose between a written and an oral examination;
(ii) Address each course requirement specified in § 483.152(b);
(iii) Be developed from a pool of test questions, only a portion of which is used in any one examination;
(iv) Use a system that prevents disclosure of both the pool of questions and the individual competency evaluations; and
(v) If oral, must be read from a prepared text in a neutral manner.
(2) Demonstration of skills. The skills demonstration must consist of a demonstration of randomly selected items drawn from a pool consisting of the tasks generally performed by nurse aides. This pool of skills must include all of the personal care skills listed in § 483.152(b)(3).
(c) Administration of the competency evaluation. (1) The competency examination must be administered and evaluated only by—
(i) The State directly; or
(ii) A State approved entity which is neither a skilled nursing facility that participates in Medicare nor a nursing facility that participates in Medicaid.
(2) No nurse aide who is employed by, or who has received an offer of employment from, a facility on the date on which the aide begins a nurse aide competency evaluation program may be charged for any portion of the program.
(3) If an individual who is not employed, or does not have an offer to be employed, as a nurse aide becomes employed by, or receives an offer of employment from, a facility not later than 12 months after completing a nurse aide competency evaluation program, the State must provide for the reimbursement of costs incurred in completing the program on a pro rata basis during the period in which the individual is employed as a nurse aide.
(4) The skills demonstration part of the evaluation must be—
(i) Performed in a facility or laboratory setting comparable to the setting in which the individual will function as a nurse aide; and
(ii) Administered and evaluated by a registered nurse with at least one year's experience in providing care for the elderly or the chronically ill of any age.
(d) Facility proctoring of the competency evaluation. (1) The competency evaluation may, at the nurse aide's option, be conducted at the facility in which the nurse aide is or will be employed unless the facility is described in § 483.151(b)(2).
(2) The State may permit the competency evaluation to be proctored by facility personnel if the State finds that the procedure adopted by the facility assures that the competency evaluation program—
(i) is secure from tampering;
(ii) is standardized and scored by a testing, educational, or other organization approved by the State; and
(iii) requires no scoring by facility personnel.
(3) The State must retract the right to proctor nurse aide competency evaluations from facilities in which the State finds any evidence of impropriety, including evidence of tampering by facility staff.
(e) Successful completion of the competency evaluation program. (1) The State must establish a standard for satisfactory completion of the competency evaluation. To complete the competency evaluation successfully an individual must pass both the written or oral examination and the skills demonstration.
(2) A record of successful completion of the competency evaluation must be included in the nurse aide registry provided in §483.156 within 30 days of the date if the individual is found to be competent.
(f) Unsatisfactory completion of the competency evaluation program. (1) If the individual does not complete the evaluation satisfactorily, the individual must be advised—
(i) Of the areas which he or she did not pass; and
(ii) That he or she has at least three opportunities to take the evaluation.
(2) The State may impose a maximum upon the number of times an individual upon the number of times an individual may attempt to complete the competency evaluation successfully, but the maximum must be no less than three.
§ 483.156 Registry of nurse aides.
(a) Establishment of registry. The State must establish and maintain a registry of nurse aides that meets the requirements of this section. The registry—
(1) Must include as a minimum the information contained in paragraph (c) of this section:
(2) Must be sufficiently accessible to meet the needs of the public and health care providers promptly;
(3) May include home health aides who have successfully completed a home health aide competency evaluation program approved by the State if home health aides are differentiated from nurse aides; and
(4) Must provide that any response to an inquiry that includes a finding of abuse, neglect, or misappropriation of property also include any statement disputing the finding made by the nurse aide, as provided under paragraph (c)(1)(ix) of this section.
(b) Registry operation. (1) The State may contract the daily operation and maintenance of the registry to a non-State entity. However, the State must maintain accountability for overall operation of the registry and compliance with these regulations.
(2) Only the State survey and certification agency may place on the registry findings of abuse, neglect, or misappropriation of property.
(3) The State must determine which individuals who (i) have successfully completed a nurse aide training and competency evaluation program or nurse aide competency evaluation program; (ii) have been deemed as meeting these requirements; or (iii) have had these requirements waived by the State do not qualify to remain on the registry because they have performed no nursing or nursing-related services for a period of 24 consecutive months.
(4) The State may not impose any charges related to registration on individuals listed in the registry.
(5) The State must provide information on the registry promptly.
(c) Registry Content. (1) The registry must contain at least the following information on each individual who has successfully completed a nurse aide training and competency evaluation program which meets the requirements of §483.152 or a competency evaluation which meets the requirements of §483.154 and has been found by the State to be competent to function as a nurse aide or who may function as a nurse aide because of meeting criteria in §483.150:
(i) The individual’s full name.
§ 483.158 FFP for nurse aide training and competency evaluation.

(a) State expenditures for nurse aide training and competency evaluation programs and competency evaluation programs are administrative costs. They are matched as indicated in §433.15(b)(8) of this chapter.

(b) FFP is available for State expenditures associated with nurse aide training and competency evaluation programs and competency evaluation programs only for—

(1) Nurse aides employed by a facility;

(2) Nurse aides who have an offer of employment from a facility;

(3) Nurse aides who become employed by a facility not later than 12 months after completing a nurse aide training and competency evaluation program or competency evaluation program;

(4) Nurse aides who receive an offer of employment from a facility not later than 12 months after completing a nurse aide training and competency evaluation program or competency evaluation program.

Subpart E—Appeals of Discharges, Transfers, and Preadmission Screening and Annual Resident Review (PASARR) Determinations

SOURCE: 57 FR 56514, Nov. 30, 1992, unless otherwise noted.

§ 483.200 Statutory basis.

This subpart is based on sections 1819(e)(3) and (f)(3) and 1919(e)(3) and (f)(3) of the Act, which require States to make available, to individuals who are discharged or transferred from SNFs or NFs, an appeals process that complies with guidelines issued by the Secretary.

[60 FR 50443, Sept. 29, 1995]

§ 483.202 Definitions.

For purposes of this subpart and subparts B and C—

Discharge means movement from an entity that participates in Medicare as a skilled nursing facility, a Medicare certified distinct part, an entity that participates in Medicaid as a nursing
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§ 483.315 Specification of resident assessment instrument.

(a) Statutory basis. Sections 1819(e)(5) and 1919(e)(5) of the Act require that a State specify the resident assessment instrument (RAI) to be used by long term care facilities in the State when conducting initial and periodic assessments of each resident’s functional capacity, in accordance with §483.20.

(b) State options in specifying an RAI. The RAI that the State specifies must be one of the following:

1. The instrument designated by HCFA.
2. An alternate instrument specified by the State and approved by HCFA, using the criteria specified in the State Operations Manual issued by HCFA (HCFA Pub. 7) which is available for purchase through the National Technical Information Service, 5285 Port Royal Rd., Springfield, VA 22151.

(c) State requirements in specifying an RAI.

1. Within 30 days after HCFA notifies the State of the HCFA-designated RAI or changes to it, the State must do one of the following:
   - (i) Specify the HCFA-designated RAI.
   - (ii) Notify HCFA of its intent to specify an alternate instrument.

2. Within 60 days after receiving HCFA approval of an alternate RAI, the State must specify the RAI for use by all long term care facilities participating in the Medicare and Medicaid programs.

3. After specifying an instrument, the State must provide periodic educational programs for facility staff to assist with implementation of the RAI.

4. A State must audit implementation of the RAI through the survey process.

5. A State must obtain approval from HCFA before making any modifications to its RAI.

6. A State must adopt revisions to the RAI that are specified by HCFA.
(d) HCFA-designated RAI. The HCFA-designated RAI is published in the State Operations Manual issued by HCFA (HCFA Pub. 7), as updated periodically, and consists of the following:

1. The minimum data set (MDS) and common definitions.
2. The resident assessment protocols (RAPs) and triggers that are necessary to accurately assess residents, established by HCFA.
3. The quarterly review, based on a subset of the MDS specified by HCFA.
4. The requirements for use of the RAI that appear at § 483.20.

(e) Minimum data set (MDS). The MDS includes assessment in the following areas:

1. Identification and demographic information, which includes information to identify the resident and facility, the resident's residential history, education, the reason for the assessment, guardianship status and information regarding advance directives, and information regarding mental health history.
2. Customary routine, which includes the resident's lifestyle prior to admission to the facility.
3. Cognitive patterns, which include memory, decision making, consciousness, behavioral measures of delirium, and stability of condition.
4. Communication, which includes scales for measuring hearing and communication skills, information on how the resident expresses himself or herself, and stability of communicative ability.
5. Vision pattern, which includes a scale for measuring vision and vision problems.
6. Mood and behavior patterns, which include scales for measuring behavioral indicators and symptoms, and stability of condition.
7. Psychosocial well-being, which includes the resident's interpersonal relationships and adjustment factors.
8. Physical functioning and structural problems, which contains scales for measuring activities of daily living, mobility, potential for improvement, and stability of functioning.
10. Disease diagnoses and health conditions, which includes active medical diagnoses, physical problems, pain assessment, and stability of condition.
11. Dental and nutritional status, which includes information on height and weight, nutritional problems and accommodations, oral care and problems, and measure of nutritional intake.
12. Skin condition, which includes current and historical assessment of skin problems, treatments, and information regarding foot care.
13. Activity pursuit, which gathers information on the resident's activity preferences and the amount of time spent participating in activities.
14. Medications, which contains information on the types and numbers of medications the resident receives.
15. Special treatments and procedures, which includes measurements of therapies, assessment of rehabilitation/restorative care, special programs and interventions, and information on hospital visits and physician involvement.
16. Discharge potential, which assesses the possibility of discharging the resident and discharge status.
17. Documentation of summary information regarding the additional assessment performed through the resident assessment protocols.
18. Documentation of participation in assessment.

(f) Resident assessment protocols (RAPs). At a minimum, the RAPs address the following domains:

1. Delirium.
2. Cognitive loss.
5. ADL functional/rehabilitation potential.
6. Urinary incontinence and indwelling catheter.
7. Psychosocial well-being.
8. Mood state.
10. Activities.
11. Falls.
13. Feeding tubes.
15. Dental care.
16. Pressure ulcers.
§ 483.405 Relationship to other HHS regulations.

In addition to compliance with the regulations set forth in this subpart, facilities are obliged to meet the applicable provisions of other HHS regulations, including but not limited to those pertaining to nondiscrimination.
§ 483.410 Condition of participation: Governing body and management.

(a) Standard: Governing body. The facility must identify an individual or individuals to constitute the governing body of the facility. The governing body must—

1. Exercise general policy, budget, and operating direction over the facility;

2. Set the qualifications (in addition to those already set by State law, if any) for the administrator of the facility; and

3. Appoint the administrator of the facility.

(b) Standard: Compliance with Federal, State, and local laws. The facility must be in compliance with all applicable provisions of Federal, State and local laws, regulations and codes pertaining to health, safety, and sanitation.

(c) Standard: Client records. (1) The facility must develop and maintain a recordkeeping system that includes a separate record for each client and that documents the client’s health care, active treatment, social information, and protection of the client’s rights.

2. The facility must keep confidential all information contained in the clients’ records, regardless of the form or storage method of the records.

3. The facility must develop and implement policies and procedures governing the release of any client information, including consents necessary from the client, or parents (if the client is a minor) or legal guardian.

4. Any individual who makes an entry in a client’s record must make it legibly, date it, and sign it.

5. The facility must provide a legend to explain any symbol or abbreviation used in a client’s record.

6. The facility must provide each identified residential living unit with appropriate aspects of each client’s record.

(d) Standard: Services provided under agreements with outside sources. (1) If a service required under this subpart is not provided directly, the facility must have a written agreement with an outside program, resource, or service to furnish the necessary service, including emergency and other health care.

2. The agreement must—

i. Contain the responsibilities, functions, objectives, and other terms agreed to by both parties; and

ii. Provide that the facility is responsible for assuring that the outside services meet the standards for quality of services contained in this subpart.

3. The facility must assure that outside services meet the needs of each client.

4. If living quarters are not provided in a facility owned by the ICF/MR, the ICF/MR remains directly responsible for the standards relating to physical environment that are specified in §483.470 (a) through (g), (j) and (k).

(e) Standard: Licensure. The facility must be licensed under applicable State and local law.

§ 483.420 Condition of participation: Client protections.

(a) Standard: Protection of clients’ rights. The facility must ensure the rights of all clients. Therefore, the facility must—

1. Inform each client, parent (if the client is a minor), or legal guardian, of the client’s rights and the rules of the facility;

2. Inform each client, parent (if the client is a minor), or legal guardian, of the client’s medical condition, developmental and behavioral status, attendant risks of treatment, and of the right to refuse treatment;

3. Allow and encourage individual clients to exercise their rights as clients of the facility, and as citizens of the United States, including the right
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(4) Allow individual clients to manage their financial affairs and teach them to do so to the extent of their capabilities;

(5) Ensure that clients are not subjected to physical, verbal, sexual or psychological abuse or punishment;

(6) Ensure that clients are free from unnecessary drugs and physical restraints and are provided active treatment to reduce dependency on drugs and physical restraints;

(7) Provide each client with the opportunity for personal privacy and ensure privacy during treatment and care of personal needs;

(8) Ensure that clients are not compelled to perform services for the facility and ensure that clients who do work for the facility are compensated for their efforts at prevailing wages and commensurate with their abilities;

(9) Ensure clients the opportunity to communicate, associate and meet privately with individuals of their choice, and to send and receive unopened mail;

(10) Ensure that clients have access to telephones with privacy for incoming and outgoing local and long distance calls except as contraindicated by factors identified within their individual program plans;

(11) Ensure clients the opportunity to participate in social, religious, and community group activities;

(12) Ensure that clients have the right to retain and use appropriate personal possessions and clothing, and ensure that each client is dressed in his or her own clothing each day; and

(13) Permit a husband and wife who both reside in the facility to share a room.

(b) Standard: Client finances. (1) The facility must establish and maintain a system that—

(i) Assures a full and complete accounting of clients’ personal funds entrusted to the facility on behalf of clients; and

(ii) Precludes any commingling of client funds with facility funds or with the funds of any person other than another client.

(2) The client’s financial record must be available on request to the client, parents (if the client is a minor) or legal guardian.

(c) Standard: Communication with clients, parents, and guardians. The facility must—

(1) Promote participation of parents (if the client is a minor) and legal guardians in the process of providing active treatment to a client unless their participation is unobtainable or inappropriate;

(2) Answer communications from clients’ families and friends promptly and appropriately;

(3) Promote visits by individuals with a relationship to the client (such as family, close friends, legal guardians and advocates) at any reasonable hour, without prior notice, consistent with the right of that client’s and other clients’ privacy, unless the interdisciplinary team determines that the visit would not be appropriate;

(4) Promote visits by parents or guardians to any area of the facility that provides direct client care services to the client, consistent with the right of that client’s and other clients’ privacy;

(5) Promote frequent and informal leaves from the facility for visits, trips, or vacations; and

(6) Notify promptly the client’s parents or guardian of any significant incidents, or changes in the client’s condition including, but not limited to, serious illness, accident, death, abuse, or unauthorized absence.

(d) Standard: Staff treatment of clients. (1) The facility must develop and implement written policies and procedures that prohibit mistreatment, neglect or abuse of the client.

(i) Staff of the facility must not use physical, verbal, sexual or psychological abuse or punishment.

(ii) Staff must not punish a client by withholding food or hydration that contributes to a nutritionally adequate diet.

(iii) The facility must prohibit the employment of individuals with a conviction or prior employment history of child or client abuse, neglect or mistreatment.

(2) The facility must ensure that all allegations of mistreatment, neglect or abuse, as well as injuries of unknown source, are reported immediately to
§ 483.430 Condition of participation: Facility staffing.

(a) Standard: Qualified mental retardation professional. Each client’s active treatment program must be integrated, coordinated and monitored by a qualified mental retardation professional who—

(1) Has at least one year of experience working directly with persons with mental retardation or other developmental disabilities; and

(2) Is one of the following:

(i) A doctor of medicine or osteopathy.
(ii) A registered nurse.
(iii) An individual who holds at least a bachelor’s degree in a professional category specified in paragraph (b)(5) of this section.

(b) Standard: Professional program services. (1) Each client must receive the professional program services needed to implement the active treatment program defined by each client’s individual program plan. Professional program staff must work directly with clients and with paraprofessional, non-professional and other professional program staff who work with clients.

(2) The facility must have available enough qualified professional staff to carry out and monitor the various professional interventions in accordance with the stated goals and objectives of every individual program plan.

(3) Professional program staff must participate as members of the interdisciplinary team in relevant aspects of the active treatment process.

(4) Professional program staff must participate in on-going staff development and training in both formal and informal settings with other professional, paraprofessional, and nonprofessional staff members.

(5) Professional program staff must be licensed, certified, or registered, as applicable, to provide professional services by the State in which he or she practices. Those professional program staff who do not fall under the jurisdiction of State licensure, certification, or registration requirements, specified in §483.410(b), must meet the following qualifications:

(i) To be designated as an occupational therapist, an individual must be eligible for certification as an occupational therapist by the American Occupational Therapy Association or another comparable body.

(ii) To be designated as an occupational therapy assistant, an individual must be eligible for certification as a certified occupational therapy assistant by the American Occupational Therapy Association or another comparable body.

(iii) To be designated as a physical therapist, an individual must be eligible for certification as a physical therapist by the American Physical Therapy Association or another comparable body.

(iv) To be designated as a physical therapy assistant, an individual must be eligible for registration by the American Physical Therapy Association or be a graduate of a two year college-level program approved by the American Physical Therapy Association or another comparable body.

(v) To be designated as a psychologist, an individual must have at least a master’s degree in psychology from an accredited school.

(vi) To be designated as a social worker, an individual must—

(A) Hold a graduate degree from a school of social work accredited or approved by the Council on Social Work Education or another comparable body; or

(B) Hold a Bachelor of Social Work degree from a college or university accredited or approved by the Council on Social Work Education or another comparable body.
(vii) To be designated as a speech-language pathologist or audiologist, an individual must—

(A) Be eligible for a Certificate of Clinical Competence in Speech-Language Pathology or Audiology granted by the American Speech-Language-Hearing Association or another comparable body; or

(B) Meet the educational requirements for certification and be in the process of accumulating the supervised experience required for certification.

(viii) To be designated as a professional recreation staff member, an individual must have a bachelor’s degree in recreation or in a specialty area such as art, dance, music or physical education.

(ix) To be designated as a professional dietitian, an individual must be eligible for registration by the American Dietetics Association.

(x) To be designated as a human services professional, an individual must have at least a bachelor’s degree in a human services field (including, but not limited to: sociology, special education, rehabilitation counseling, and psychology).

(xi) If the client’s individual program plan is being successfully implemented by facility staff, professional program staff meeting the qualifications of paragraph (b)(5)(i) through (x) of this section are not required—

(A) Except for qualified mental retardation professionals;

(B) Except for the requirements of paragraph (b)(2) of this section concerning the facility’s provision of enough qualified professional program staff; and

(C) Unless otherwise specified by State licensure and certification requirements.

(c) Standard: Facility staffing.

(1) The facility must not depend upon clients or volunteers to perform direct care services for the facility.

(2) There must be responsible direct care staff on duty and awake on a 24-hour basis, when clients are present, to take prompt, appropriate action in case of injury, illness, fire or other emergency, in each defined residential living unit housing—

(i) Clients for whom a physician has ordered a medical care plan;

(ii) Clients who are aggressive, assaultive or security risks;

(iii) More than 16 clients; or

(iv) Fewer than 16 clients within a multi-unit building.

(3) There must be a responsible direct care staff person on duty on a 24-hour basis (when clients are present) to respond to injuries and symptoms of illness, and to handle emergencies, in each defined residential living unit housing—

(i) Clients for whom a physician has not ordered a medical care plan;

(ii) Clients who are not aggressive, assaultive or security risks; and

(iii) Sixteen or fewer clients.

(4) The facility must provide sufficient support staff so that direct care staff are not required to perform support services to the extent that these duties interfere with the exercise of their primary direct client care duties.

(d) Standard: Direct care (residential living unit) staff.

(1) The facility must provide sufficient direct care staff to manage and supervise clients in accordance with their individual program plans.

(2) Direct care staff are defined as the present on-duty staff calculated over all shifts in a 24-hour period for each defined residential living unit.

(3) Direct care staff must be provided by the facility in the following minimum ratios of direct care staff to clients:

(i) For each defined residential living unit serving children under the age of 12, severely and profoundly retarded clients, clients with severe physical disabilities, or clients who are aggressive, assaultive, or security risks, or who manifest severely hyperactive or psychotic-like behavior, the staff to client ratio is 1 to 3.2.

(ii) For each defined residential living unit serving moderately retarded clients, the staff to client ratio is 1 to 4.

(iii) For each defined residential living unit serving clients who function within the range of mild retardation, the staff to client ratio is 1 to 6.4.

(4) When there are no clients present in the living unit, a responsible staff member must be available by telephone.
§ 483.440 Condition of participation: Active treatment services.

(a) Standard: Active treatment. (1) Each client must receive a continuous active treatment program, which includes aggressive, consistent implementation of a program of specialized and generic training, treatment, health services and related services described in this subpart, that is directed toward—
   (i) The acquisition of the behaviors necessary for the client to function with as much self determination and independence as possible; and
   (ii) The prevention or deceleration of regression or loss of current optimal functional status.

(2) Active treatment does not include services to maintain generally independent clients who are able to function with little supervision or in the absence of a continuous active treatment program.

(b) Standard: Admissions, transfers, and discharge. (1) Clients who are admitted by the facility must be in need of and receiving active treatment services.

(2) Admission decisions must be based on a preliminary evaluation of the client that is conducted or updated by the facility or by outside sources.

(3) A preliminary evaluation must contain background information as well as currently valid assessments of functional, developmental, behavioral, social, health and nutritional status to determine if the facility can provide for the client's needs and if the client is likely to benefit from placement in the facility.

(4) If a client is to be either transferred or discharged, the facility must—
   (i) Have documentation in the client's record that the client was transferred or discharged for good cause; and
   (ii) Provide a reasonable time to prepare the client and his or her parents or guardian for the transfer or discharge (except in emergencies).

(5) At the time of the discharge, the facility must—
   (i) Develop a final summary of the client's developmental, behavioral, social, health and nutritional status and, with the consent of the client, parents (if the client is a minor) or legal guardian, provide a copy to authorized persons and agencies; and
   (ii) Provide a post-discharge plan of care that will assist the client to adjust to the new living environment.

(c) Standard: Individual program plan. (1) Each client must have an individual program plan developed by an interdisciplinary team that represents the professions, disciplines or service areas that are relevant to—
   (i) Identifying the client's needs, as described by the comprehensive functional assessments required in paragraph (c)(3) of this section; and
   (ii) Designing programs that meet the client's needs.

(2) Appropriate facility staff must participate in interdisciplinary team meetings. Participation by other agencies serving the client is encouraged. Participation by the client, his or her parent (if the client is a minor), or the client's legal guardian is required unless that participation is unobtainable or inappropriate.

(3) Within 30 days after admission, the interdisciplinary team must perform accurate assessments or reassessments as needed to supplement the preliminary evaluation conducted prior to admission. The comprehensive functional assessment must take into consideration the client's age (for example, child, young adult, elderly person) and the implications for active treatment at each stage, as applicable, and must—
(i) Identify the presenting problems and disabilities and where possible, their causes;
(ii) Identify the client’s specific developmental strengths;
(iii) Identify the client’s specific developmental and behavioral management needs;
(iv) Identify the client’s need for services without regard to the actual availability of the services needed; and
(v) Include physical development and health, nutritional status, sensorimotor development, affective development, speech and language development and auditory functioning, cognitive development, social development, adaptive behaviors or independent living skills necessary for the client to be able to function in the community, and as applicable, vocational skills.

(4) Within 30 days after admission, the interdisciplinary team must prepare for each client an individual program plan that states the specific objectives necessary to meet the client’s needs, as identified by the comprehensive assessment required by paragraph (c)(3) of this section, and the planned sequence for dealing with those objectives. These objectives must—
(i) Be stated separately, in terms of a single behavioral outcome;
(ii) Be assigned projected completion dates;
(iii) Be expressed in behavioral terms that provide measurable indices of performance;
(iv) Be organized to reflect a developmental progression appropriate to the individual; and
(v) Be assigned priorities.

(5) Each written training program designed to implement the objectives in the individual program plan must specify:
(i) The methods to be used;
(ii) The schedule for use of the method;
(iii) The person responsible for the program;
(iv) The type of data and frequency of data collection necessary to be able to assess progress toward the desired objectives;
(v) The inappropriate client behavior(s), if applicable; and
(vi) Provision for the appropriate expression of behavior and the replacement of inappropriate behavior, if applicable, with behavior that is adaptive or appropriate.

(6) The individual program plan must also:
(i) Describe relevant interventions to support the individual toward independence.
(ii) Identify the location where program strategy information (which must be accessible to any person responsible for implementation) can be found.
(iii) Include, for those clients who lack them, training in personal skills essential for privacy and independence (including, but not limited to, toilet training, personal hygiene, dental hygiene, self-feeding, bathing, dressing, grooming, and communication of basic needs), until it has been demonstrated that the client is developmentally incapable of acquiring them.
(iv) Identify mechanical supports, if needed, to achieve proper body position, balance, or alignment. The plan must specify the reason for each support, the situations in which each is to be applied, and a schedule for the use of each support.
(v) Provide that clients who have multiple disabling conditions spend a major portion of each waking day out of bed and outside the bedroom area, moving about by various methods and devices whenever possible.
(vi) Include opportunities for client choice and self-management.

(7) A copy of each client’s individual program plan must be made available to all relevant staff, including staff of other agencies who work with the client, and to the client, parents (if the client is a minor) or legal guardian.

(d) Standard: Program implementation.
(1) As soon as the interdisciplinary team has formulated a client’s individual program plan, each client must receive a continuous active treatment program consisting of needed interventions and services in sufficient number and frequency to support the achievement of the objectives identified in the individual program plan.

(2) The facility must develop an active treatment schedule that outlines the current active treatment program.
§ 483.450 Condition of participation: Client behavior and facility practices.

(a) Standard: Facility practices—Conduct toward clients. (1) The facility must develop and implement written policies and procedures for the management of conduct between staff and clients. These policies and procedures must—
   (i) Promote the growth, development and independence of the client;
   (ii) Address the extent to which client choice will be accommodated in daily decision-making, emphasizing self-determination and self-management, to the extent possible;
   (iii) Specify client conduct to be allowed or not allowed; and
   (iv) Be available to all staff, clients, parents of minor children, and legal guardians.

(2) To the extent possible, clients must participate in the formulation of these policies and procedures.

(3) Clients must not discipline other clients, except as part of an organized system of self-government, as set forth in facility policy.

(b) Standard: Management of inappropriate client behavior. (1) The facility must develop and implement written policies and procedures that govern the inappropriate behavior and other programs that, in the opinion of the committee, involve risks to client protection and rights;

(2) Insure that these programs are conducted only with the written informed consent of the client, parent (if the client is a minor), or legal guardian; and

(3) Review, monitor and make suggestions to the facility about its practices and programs as they relate to drug usage, physical restraints, time-out rooms, application of painful or noxious stimuli, control of inappropriate behavior, protection of client rights and funds, and any other area that the committee believes need to be addressed.

(4) The provisions of paragraph (f)(3) of this section may be modified only if, in the judgment of the State survey agency, Court decrees, State law or regulations provide for equivalent client protection and consultation.

§ 483.450 Condition of participation: Client behavior and facility practices.

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(2) Insure that these programs are conducted only with the written informed consent of the client, parent (if the client is a minor), or legal guardian; and

(3) Review, monitor and make suggestions to the facility about its practices and programs as they relate to drug usage, physical restraints, time-out rooms, application of painful or noxious stimuli, control of inappropriate behavior, protection of client rights and funds, and any other area that the committee believes need to be addressed.

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§ 483.450 Condition of participation: Client behavior and facility practices.

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(2) Insure that these programs are conducted only with the written informed consent of the client, parent (if the client is a minor), or legal guardian; and

(3) Review, monitor and make suggestions to the facility about its practices and programs as they relate to drug usage, physical restraints, time-out rooms, application of painful or noxious stimuli, control of inappropriate behavior, protection of client rights and funds, and any other area that the committee believes need to be addressed.

(4) The provisions of paragraph (f)(3) of this section may be modified only if, in the judgment of the State survey agency, Court decrees, State law or regulations provide for equivalent client protection and consultation.
management of inappropriate client behavior. These policies and procedures must be consistent with the provisions of paragraph (a) of this section. These procedures must—

(i) Specify all facility approved interventions to manage inappropriate client behavior;

(ii) Designate these interventions on a hierarchy to be implemented, ranging from most positive or least intrusive, to least positive or most intrusive;

(iii) Insure, prior to the use of more restrictive techniques, that the client’s record documents that programs incorporating the use of less intrusive or more positive techniques have been tried systematically and demonstrated to be ineffective; and

(iv) Address the following:
(A) The use of time-out rooms.
(B) The use of physical restraints.
(C) The use of drugs to manage inappropriate behavior.
(D) The application of painful or noxious stimuli.
(E) The staff members who may authorize the use of specified interventions.
(F) A mechanism for monitoring and controlling the use of such interventions.

(2) Interventions to manage inappropriate client behavior must be employed with sufficient safeguards and supervision to ensure that the safety, welfare and civil and human rights of clients are adequately protected.

(3) Techniques to manage inappropriate client behavior must never be used for disciplinary purposes, for the convenience of staff or as a substitute for an active treatment program.

(4) The use of systematic interventions to manage inappropriate client behavior must be incorporated into the client’s individual program plan, in accordance with §483.440(c) (4) and (5) of this subpart.

(5) Standing or as needed programs to control inappropriate behavior are not permitted.

(c) Standard: Time-out rooms. (1) A client may be placed in a room from which egress is prevented only if the following conditions are met:

(i) The placement is a part of an approved systematic time-out program as required by paragraph (b) of this section. (Thus, emergency placement of a client into a time-out room is not allowed.)
(ii) The client is under the direct constant visual supervision of designated staff.
(iii) The door to the room is held shut by staff or by a mechanism requiring constant physical pressure from a staff member to keep the mechanism engaged.

(2) Placement of a client in a time-out room must not exceed one hour.

(3) Clients placed in time-out rooms must be protected from hazardous conditions including, but not limited to, presence of sharp corners and objects, uncovered light fixtures, unprotected electrical outlets.

(4) A record of time-out activities must be kept.

(d) Standard: Physical restraints. (1) The facility may employ physical restraint only—

(i) As an integral part of an individual program plan that is intended to lead to less restrictive means of managing and eliminating the behavior for which the restraint is applied;
(ii) As an emergency measure, but only if absolutely necessary to protect the client or others from injury; or
(iii) As a health-related protection prescribed by a physician, but only if absolutely necessary during the conduct of a specific medical or surgical procedure, or only if absolutely necessary for client protection during the time that a medical condition exists.

(2) Authorizations to use or extend restraints as an emergency must be:

(i) In effect no longer than 12 consecutive hours; and
(ii) Obtained as soon as the client is restrained or stable.

(3) The facility must not issue orders for restraint on a standing or as needed basis.

(4) A client placed in restraint must be checked at least every 30 minutes by staff trained in the use of restraints, released from the restraint as quickly as possible, and a record of these checks and usage must be kept.

(5) Restraints must be designed and used so as not to cause physical injury to the client and so as to cause the least possible discomfort.
§ 483.460 Condition of participation: Health care services.

(a) Standard: Physician services.

(1) The facility must ensure the availability of physician services 24 hours a day.

(2) The physician must develop, in coordination with licensed nursing personnel, a medical care plan of treatment for a client if the physician determines that an individual client requires 24-hour licensed nursing care. This plan must be integrated in the individual program plan.

(3) The facility must provide or obtain preventive and general medical care as well as annual physical examinations of each client that at a minimum include the following:

(i) Evaluation of vision and hearing.

(ii) Immunizations, using as a guide the recommendations of the Public Health Service Advisory Committee on Immunization Practices or of the Committee on the Control of Infectious Diseases of the American Academy of Pediatrics.

(iii) Routine screening laboratory examinations as determined necessary by the physician, and special studies when needed.

(iv) Tuberculosis control, appropriate to the facility's population, and in accordance with the recommendations of the American College of Chest Physicians or the section of diseases of the chest of the American Academy of Pediatrics, or both.

(4) To the extent permitted by State law, the facility may utilize physician assistants and nurse practitioners to provide physician services as described in this section.

(b) Standard: Physician participation in the individual program plan. A physician must participate in—

(1) The establishment of each newly admitted client's initial individual program plan as required by §456.380 of this chapter that specified plan of care requirements for ICFs; and

(2) If appropriate, physicians must participate in the review and update of an individual program plan as part of the interdisciplinary team process either in person or through written report to the interdisciplinary team.

(c) Standard: Nursing services. The facility must provide clients with nursing services in accordance with their needs. These services must include—

(1) Participation as appropriate in the development, review, and update of an individual program plan as part of the interdisciplinary team process;

(2) The development, with a physician, of a medical care plan of treatment for a client when the physician has determined that an individual client requires such a plan;

(3) For those clients certified as not needing a medical care plan, a review of their health status which must—

(i) Be by a direct physical examination;

(ii) Be by a licensed nurse;
(iii) Be on a quarterly or more frequent basis depending on client need;
(iv) Be recorded in the client’s record; and
(v) Result in any necessary action (including referral to a physician to address client health problems).

(4) Other nursing care as prescribed by the physician or as identified by client needs; and
(5) Implementing, with other members of the interdisciplinary team, appropriate protective and preventive health measures that include, but are not limited to—

(i) Training clients and staff as needed in appropriate health and hygiene methods;
(ii) Control of communicable diseases and infections, including the instruction of other personnel in methods of infection control; and
(iii) Training direct care staff in detecting signs and symptoms of illness or dysfunction, first aid for accidents or illness, and basic skills required to meet the health needs of the clients.

(d) Standard: Nursing staff.

(1) Nurses providing services in the facility must have a current license to practice in the State.

(2) The facility must employ or arrange for licensed nursing services sufficient to care for clients health needs including those clients with medical care plans.

(3) The facility must utilize registered nurses as appropriate and required by State law to perform the health services specified in this section.

(4) If the facility utilizes only licensed practical or vocational nurses to provide health services, it must have a formal arrangement with a registered nurse to be available for verbal or on-site consultation to the licensed practical or vocational nurse.

(5) Non-licensed nursing personnel who work with clients under a medical care plan must do so under the supervision of licensed persons.

(e) Standard: Dental services.

(1) The facility must provide or make arrangements for comprehensive diagnostic and treatment services for each client from qualified personnel, including licensed dentists and dental hygienists either through organized dental services in-house or through arrangement.

(2) If appropriate, dental professionals must participate, in the development, review and update of an individual program plan as part of the interdisciplinary process either in person or through written report to the interdisciplinary team.

(3) The facility must provide education and training in the maintenance of oral health.

(f) Standard: Comprehensive dental diagnostic services. Comprehensive dental diagnostic services include—

(1) A complete extraoral and intraoral examination, using all diagnostic aids necessary to properly evaluate the client’s oral condition, not later than one month after admission to the facility (unless the examination was completed within twelve months before admission);

(2) Periodic examination and diagnosis performed at least annually, including radiographs when indicated and detection of manifestations of systemic disease; and

(3) A review of the results of examination and entry of the results in the client’s dental record.

(g) Standard: Comprehensive dental treatment. The facility must ensure comprehensive dental treatment services that include—

(1) The availability for emergency dental treatment on a 24-hour-a-day basis by a licensed dentist; and

(2) Dental care needed for relief of pain and infections, restoration of teeth, and maintenance of dental health.

(h) Standard: Documentation of dental services. (1) If the facility maintains an in-house dental service, the facility must keep a permanent dental record for each client, with a dental summary maintained in the client’s living unit.

(2) If the facility does not maintain an in-house dental service, the facility must obtain a dental summary of the results of dental visits and maintain the summary in the client’s living unit.

(i) Standard: Pharmacy services. The facility must provide or make arrangements for the provision of routine and emergency drugs and biologicals to its clients. Drugs and biologicals may be
obtained from community or contract pharmacists or the facility may maintain a licensed pharmacy.

(j) Standard: Drug regimen review. (1) A pharmacist with input from the interdisciplinary team must review the drug regimen of each client at least quarterly.

(2) The pharmacist must report any irregularities in clients' drug regimens to the prescribing physician and interdisciplinary team.

(3) The pharmacist must prepare a record of each client's drug regimen reviews and the facility must maintain that record.

(4) An individual medication administration record must be maintained for each client.

(5) As appropriate the pharmacist must participate in the development, implementation, and review of each client's individual program plan either in person or through written report to the interdisciplinary team.

(k) Standard: Drug administration. The facility must have an organized system for drug administration that identifies each drug up to the point of administration. The system must assure that—

(1) All drugs are administered in compliance with the physician's orders;

(2) All drugs, including those that are self-administered, are administered without error;

(3) Unlicensed personnel are allowed to administer drugs only if State law permits;

(4) Clients are taught how to administer their own medications if the interdisciplinary team determines that self administration of medications is an appropriate objective, and if the physician does not specify otherwise;

(5) The client's physician is informed of the interdisciplinary team's decision that self-administration of medications is an objective for the client;

(6) No client self-administers medications until he or she demonstrates the competency to do so;

(7) Drugs used by clients while not under the direct care of the facility are packaged and labeled in accordance with State law; and

(8) Drug administration errors and adverse drug reactions are recorded and reported immediately to a physician.

(l) Standard: Drug storage and record-keeping. (1) The facility must store drugs under proper conditions of sanitation, temperature, light, humidity, and security.

(2) The facility must keep all drugs and biologicals locked except when being prepared for administration. Only authorized persons may have access to the keys to the drug storage area. Clients who have been trained to self administer drugs in accordance with §483.460(k)(4) may have access to keys to their individual drug supply.

(3) The facility must maintain records of the receipt and disposition of all controlled drugs.

(4) The facility must, on a sample basis, periodically reconcile the receipt and disposition of all controlled drugs in schedules II through IV (drugs subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. 801 et seq., as implemented by 21 CFR part 308).

(5) If the facility maintains a licensed pharmacy, the facility must comply with the regulations for controlled drugs.

(m) Standard: Drug labeling. (1) Labeling of drugs and biologicals must—

(i) Be based on currently accepted professional principles and practices; and

(ii) Include the appropriate accessory and cautionary instructions, as well as the expiration date, if applicable.

(2) The facility must remove from use—

(i) Outdated drugs; and

(ii) Drug containers with worn, illegible, or missing labels.

(3) Drugs and biologicals packaged in containers designated for a particular client must be immediately removed from the client's current medication supply if discontinued by the physician.

(n) Standard: Laboratory services. (1) If a facility chooses to provide laboratory services, the laboratory must meet the requirements specified in part 493 of this chapter.

(2) If the laboratory chooses to refer specimens for testing to another laboratory, the referral laboratory must
be certified in the appropriate specialties and subspecialties of service in accordance with the requirements of part 493 of this chapter.

[53 FR 20496, June 3, 1988, as amended at 57 FR 7136, Feb. 28, 1992]

§ 483.470 Condition of participation: Physical environment.

(a) Standard: Client living environment. (1) The facility must not house clients of grossly different ages, developmental levels, and social needs in close physical or social proximity unless the housing is planned to promote the growth and development of all those housed together.

(2) The facility must not segregate clients solely on the basis of their physical disabilities. It must integrate clients who have ambulation deficits or who are deaf, blind, or have seizure disorders, etc., with others of comparable social and intellectual development.

(b) Standard: Client bedrooms. (1) Bedrooms must—

(i) Be rooms that have at least one outside wall;

(ii) Be equipped with or located near toilet and bathing facilities;

(iii) Accommodate no more than four clients unless granted a variance under paragraph (b)(3) of this section;

(iv) Measure at least 60 square feet per client in multiple client bedrooms and at least 80 square feet in single client bedrooms; and

(v) In all facilities initially certified, or in buildings constructed or with major renovations or conversions on or after October 3, 1988, have walls that extend from floor to ceiling.

(2) If a bedroom is below grade level, it must have a window that—

(i) Is usable as a second means of escape by the client(s) occupying the room; and

(ii) Is no more than 44 inches (measured to the window sill) above the floor unless the facility is surveyed under the Health Care Occupancy Chapter of the Life Safety Code, in which case the window must be no more than 36 inches (measured to the window sill) above the floor.

(3) The survey agency may grant a variance from the limit of four clients per room only if a physician who is a member of the interdisciplinary team and who is a qualified mental retardation professional—

(i) Certifies that each client to be placed in a bedroom housing more than four persons is so severely medically impaired as to require direct and continuous monitoring during sleeping hours; and

(ii) Documents the reasons why housing in a room of only four or fewer persons would not be medically feasible.

(4) The facility must provide each client with—

(i) A separate bed of proper size and height for the convenience of the client;

(ii) A clean, comfortable mattress;

(iii) Bedding appropriate to the weather and climate; and

(iv) Functional furniture appropriate to the client's needs, and individual closet space in the client's bedroom with clothes racks and shelves accessible to the client.

(c) Standard: Storage space in bedroom. The facility must provide—

(1) Space and equipment for daily out-of-bed activity for all clients who are not yet mobile, except those who have a short-term illness or those few clients for whom out-of-bed activity is a threat to health and safety; and

(2) Suitable storage space, accessible to clients, for personal possessions, such as TVs, radios, prosthetic equipment and clothing.

(d) Standard: Client bathrooms. The facility must—

(1) Provide toilet and bathing facilities appropriate in number, size, and design to meet the needs of the clients;

(2) Provide for individual privacy in toilets, bathtubs, and showers; and

(3) In areas of the facility where clients who have not been trained to regulate water temperature are exposed to hot water, ensure that the temperature of the water does not exceed 110°Fahr.

(e) Standard: Heating and ventilation. (1) Each client bedroom in the facility must have—

(i) At least one window to the outside; and

(ii) Direct outside ventilation by means of windows, air conditioning, or mechanical ventilation.

(2) The facility must—
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(i) Maintain the temperature and humidity within a normal comfort range by heating, air conditioning or other means; and

(ii) Ensure that the heating apparatus does not constitute a burn or smoke hazard to clients.

(f) Standard: Floors. The facility must have—

(1) Floors that have a resilient, non-abrasive, and slip-resistant surface;

(2) Nonabrasive carpeting, if the area used by clients is carpeted and serves clients who lie on the floor or ambulate with parts of their bodies, other than feet, touching the floor; and

(3) Exposed floor surfaces and floor coverings that promote mobility in areas used by clients, and promote maintenance of sanitary conditions.

(g) Standard: Space and equipment. The facility must—

(1) Provide sufficient space and equipment in dining, living, health services, recreation, and program areas (including adequately equipped and sound treated areas for hearing and other evaluations if they are conducted in the facility) to enable staff to provide clients with needed services as required by this subpart and as identified in each client’s individual program plan.

(2) Furnish, maintain in good repair, and teach clients to use and to make informed choices about the use of dentures, eyeglasses, hearing and other communications aids, braces, and other devices identified by the interdisciplinary team as needed by the client.

(3) Provide adequate clean linen and dirty linen storage areas.

(h) Standard: Emergency plan and procedures. (1) The facility must develop and implement detailed written plans and procedures to meet all potential emergencies and disasters such as fire, severe weather, and missing clients.

(2) The facility must communicate, periodically review, make the plan available, and provide training to the staff.

(i) Standard: Evacuation drills. (1) The facility must hold evacuation drills at least quarterly for each shift of personnel and under varied conditions to—

(ii) Ensure that all personnel on all shifts are trained to perform assigned tasks; and

(iii) Evaluate the effectiveness of emergency and disaster plans and procedures.

(2) The facility must—

(i) Actually evacuate clients during at least one drill each year on each shift;

(ii) Make special provisions for the evacuation of clients with physical disabilities;

(iii) File a report and evaluation on each evacuation drill;

(iv) Investigate all problems with evacuation drills, including accidents, and take corrective action; and

(v) During fire drills, clients may be evacuated to a safe area in facilities certified under the Health Care Occupancies Chapter of the Life Safety Code.

(j) Standard: Fire protection—(1) General. (i) Except as specified in paragraph (j)(2) of this section, the facility must meet the applicable provisions of either the Health Care Occupancies Chapters or the Residential Board and Care Occupancies Chapter of the Life Safety Code (LSC) of the National Fire Protection Association, 1985 edition, which is incorporated by reference.2

(ii) The State survey agency may apply a single chapter of the LSC to the entire facility or may apply different chapters to different buildings.

2Incorporation of the 1985 edition of the National Fire Protection Association’s Life Safety Code (published February 7, 1985; ANSI/NFPA 101) was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 that govern the use of incorporations by reference. The Code is available for inspection at the Office of the Federal Register Information Center, 800 North Capitol Street, NW., suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, Batterymarch Park, Quincy, Mass. 02269.

If any changes in this Code are also to be incorporated by reference, a notice to that effect will be published in the Federal Register.
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or parts of buildings as permitted by the LSC.

(iii) A facility that meets the LSC definition of a residential board and care occupancy and that has 16 or fewer beds, must have its evacuation capability evaluated in accordance with the Evacuation Difficulty Index of the LSC (appendix F).

(2) Exceptions. (i) For facilities that meet the LSC definition of a health care occupancy:

(A) The State survey agency may waive, for a period it considers appropriate, specific provisions of the LSC if—

(1) The waiver would not adversely affect the health and safety of the clients; and

(2) Rigid application of specific provisions would result in an unreasonable hardship for the facility.

(B) The State survey agency may apply the State's fire and safety code instead of the LSC if the Secretary finds that the State has a code imposed by State law that adequately protects a facility's clients.

(C) Compliance on November 26, 1982 with the 1967 edition of the LSC or compliance on April 18, 1986 with the 1981 edition of the LSC, with or without waivers, is considered to be compliance with this standard as long as the facility continues to remain in compliance with that edition of the Code.

(ii) For facilities that meet the LSC definition of a residential board and care occupancy and that have more than 16 beds, the State survey agency may apply the State's fire and safety code as specified in paragraph (j)(2)(B) of this section.

(k) Standard: Paint. The facility must—

(1) Use lead-free paint inside the facility; and

(2) Remove or cover interior paint or plaster containing lead so that it is not accessible to clients.

(l) Standard: Infection control.

(1) The facility must provide a sanitary environment to avoid sources and transmission of infections. There must be an active program for the prevention, control, and investigation of infection and communicable diseases.

(2) The facility must implement successful corrective action in affected problem areas.

(3) The facility must maintain a record of incidents and corrective actions related to infections.

(4) The facility must prohibit employees with symptoms or signs of a communicable disease from direct contact with clients and their food.

§ 483.480 Condition of participation: Dietetic services.

(a) Standard: Food and nutrition services. (1) Each client must receive a nourishing, well-balanced diet including modified and specially-prescribed diets.

(2) A qualified dietitian must be employed either full-time, part-time, or on a consultant basis at the facility's discretion.

(3) If a qualified dietitian is not employed full-time, the facility must designate a person to serve as the director of food services.

(4) The client's interdisciplinary team, including a qualified dietitian and physician, must prescribe all modified and special diets including those used as a part of a program to manage inappropriate client behavior.

(5) Foods proposed for use as a primary reinforcement of adaptive behavior are evaluated in light of the client's nutritional status and needs.

(6) Unless otherwise specified by medical needs, the diet must be prepared at least in accordance with the latest edition of the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences, adjusted for age, sex, disability and activity.

(b) Standard: Meal services. (1) Each client must receive at least three meals daily, at regular times comparable to normal mealtimes in the community with—

(i) Not more than 14 hours between a substantial evening meal and breakfast of the following day, except on weekends and holidays when a nourishing snack is provided at bedtime, 16 hours may elapse between a substantial evening meal and breakfast; and

(ii) Not less than 10 hours between breakfast and the evening meal of the
same day, except as provided under paragraph (b)(1)(i) of this section.

(2) Food must be served—
(i) In appropriate quantity;
(ii) At appropriate temperature;
(iii) In a form consistent with the developmental level of the client; and
(iv) With appropriate utensils.

(3) Food served to clients individually and uneaten must be discarded.

(c) Standard: Menus. (1) Menus must—
(i) Be prepared in advance;
(ii) Provide a variety of foods at each meal;
(iii) Be different for the same days of each week and adjusted for seasonal changes; and
(iv) Include the average portion sizes for menu items.

(2) Menus for food actually served must be kept on file for 30 days.

(d) Standard: Dining areas and service. The facility must—
(1) Serve meals for all clients, including persons with ambulation deficits, in dining areas, unless otherwise specified by the interdisciplinary team or a physician;
(2) Provide table service for all clients who can and will eat at a table, including clients in wheelchairs;
(3) Equip areas with tables, chairs, eating utensils, and dishes designed to meet the developmental needs of each client;
(4) Supervise and staff dining rooms adequately to direct self-help dining procedure, to assure that each client receives enough food and to assure that each client eats in a manner consistent with his or her developmental level; and
(5) Ensure that each client eats in an upright position, unless otherwise specified by the interdisciplinary team or a physician.

PART 484—CONDITIONS OF PARTICIPATION: HOME HEALTH AGENCIES

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) unless otherwise indicated.

Source: 54 FR 33367, Aug. 14, 1989, unless otherwise noted.

Editorial Note: Nomenclature changes affecting part 484 appear at 56 FR 32973, July 18, 1991.

Subpart A—General Provisions

§ 484.1 Basis and scope.

(a) Basis and scope. This part is based on the indicated provisions of the following sections of the Act:

(1) Sections 1861(o) and 1891 establish the conditions that an HHA must meet in order to participate in Medicare.

(2) Section 1861(z) specifies the Institutional planning standards that HHAs must meet.

(b) This part also sets forth additional requirements that are considered necessary to ensure the health and safety of patients.

[60 FR 50443, Sept. 29, 1995]
§ 484.2 Definitions.

As used in this part, unless the context indicates otherwise—Bylaws or equivalent means a set of rules adopted by an HHA for governing the agency’s operation.

Branch office means a location or site from which a home health agency provides services within a portion of the total geographic area served by the parent agency. The branch office is part of the home health agency and is located sufficiently close to share administration, supervision, and services in a manner that renders it unnecessary for the branch independently to meet the conditions of participation as a home health agency.

Clinical note means a notation of a contact with a patient that is written and dated by a member of the health team, and that describes signs and symptoms, treatment and drugs administered and the patient’s reaction, and any changes in physical or emotional condition.


Parent home health agency means the agency that develops and maintains administrative controls of subunits and/or branch offices.

Primary home health agency means the agency that is responsible for the services furnished to patients and for implementation of the plan of care.

Progress note means a written notation, dated and signed by a member of the health team, that summarizes facts about care furnished and the patient’s response during a given period of time.

Proprietary agency means a private profit-making agency licensed by the State.

Public agency means an agency operated by a State or local government.

Subdivision means a component of a multi-function health agency, such as the home care department of a hospital or the nursing division of a health department, which independently meets the conditions of participation for HHAs. A subdivision that has subunits or branch offices is considered a parent agency.

Subunit means a semi-autonomous organization that—
(1) Serves patients in a geographic area different from that of the parent agency; and
(2) Must independently meet the conditions of participation for HHAs because it is too far from the parent agency to share administration, supervision, and services on a daily basis.

Summary report means the compilation of the pertinent factors of a patient’s clinical notes and progress notes that is submitted to the patient’s physician.

Supervision means authoritative procedural guidance by a qualified person for the accomplishment of a function or activity. Unless otherwise specified in this part, the supervisor must be on the premises to supervise an individual who does not meet the qualifications specified in § 484.4.

§ 484.4 Personnel qualifications.

Staff required to meet the conditions set forth in this part are staff who meet the qualifications specified in this section.

Administrator, home health agency. A person who:
(a) Is a licensed physician; or
(b) Is a registered nurse; or
(c) Has training and experience in health service administration and at least 1 year of supervisory or administrative experience in home health care or related health programs.

Audiologist. A person who:
(a) Meets the education and experience requirements for a Certificate of Clinical Competence in audiology granted by the American Speech-Language-Hearing Association; or
(b) Meets the educational requirements for certification and is in the process of accumulating the supervised experience required for certification.

Home health aide. Effective for services furnished after August 14, 1990, a person who has successfully completed a State-established or other training program that meets the requirements of § 484.36(a) and a competency evaluation program or State licensure program that meets the requirements of § 484.36(b) or (e), or a competency evaluation program or State licensure program that meets the requirements of...
§ 484.36 (b) or (e). An individual is not considered to have completed a training and competency evaluation program, or a competency evaluation program if, since the individual's most recent completion of this program(s), there has been a continuous period of 24 consecutive months during none of which the individual furnished services described in § 409.40 of this chapter for compensation.

Occupational therapist. A person who:

(a) Is a graduate of an occupational therapy curriculum accredited jointly by the Committee on Allied Health Education and Accreditation of the American Medical Association and the American Occupational Therapy Association; or

(b) Is eligible for the National Registration Examination of the American Occupational Therapy Association; or

(c) Has 2 years of appropriate experience as an occupational therapist, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as an occupational therapist after December 31, 1977.

Occupational therapy assistant. A person who:

(a) Meets the requirements for certification as an occupational therapy assistant established by the American Occupational Therapy Association; or

(b) Has 2 years of appropriate experience as an occupational therapy assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as an occupational therapy assistant after December 31, 1977.

Physical therapist. A person who is licensed as a physical therapist, if applicable, by the State in which practicing, and

(a) Has graduated from a physical therapy curriculum approved by:

(1) The American Physical Therapy Association, or

(2) The Committee on Allied Health Education and Accreditation of the American Medical Association, or

(3) The Council on Medical Education of the American Medical Association and the American Physical Therapy Association; or

(b) Prior to January 1, 1966,

(1) Was admitted to membership by the American Physical Therapy Association, or

(2) Was admitted to registration by the American Registry of Physical Therapist, or

(3) Has graduated from a physical therapy curriculum in a 4-year college or university approved by a State department of education; or

(c) Has 2 years of appropriate experience as a physical therapist, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking qualification as a physical therapist after December 31, 1977; or

(d) Was licensed or registered prior to January 1, 1966, and prior to January 1, 1970, had 15 years of full-time experience in the treatment of illness or injury through the practice of physical therapy in which services were rendered under the order and direction of attending and referring doctors of medicine or osteopathy; or

(e) If trained outside the United States,

(1) Was graduated since 1928 from a physical therapy curriculum approved in the country in which the curriculum was located and in which there is a member organization of the World Confederation for Physical Therapy.

(2) Meets the requirements for membership in a member organization of the World Confederation for Physical Therapy.

Physical therapy assistant. A person who is licensed as a physical therapy assistant, if applicable, by the State in which practicing, and

(a) Has graduated from a 2-year college-level program approved by the American Physical Therapy Association; or
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(2) Has 2 years of appropriate experience as a physical therapy assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that these determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as a physical therapy assistant after December 31, 1977.

Physician. A doctor of medicine, osteopathy or podiatry legally authorized to practice medicine and surgery by the State in which such function or action is performed.

Practical (vocational) nurse. A person who is licensed as a practical (vocational) nurse by the State in which practicing.

Public health nurse. A registered nurse who has completed a baccalaureate degree program approved by the National League for Nursing for public health nursing preparation or postregistered nurse study that includes content approved by the National League for Nursing for public health nursing preparation.

Registered nurse (RN). A graduate of an approved school of professional nursing, who is licensed as a registered nurse by the State in which practicing.

Social work assistant. A person who:

(1) Has a baccalaureate degree in social work, psychology, sociology, or other field related to social work, and has had at least 1 year of social work experience in a health care setting; or

(2) Has 2 years of appropriate experience as a social work assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that these determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as a social work assistant after December 31, 1977.

Social worker. A person who has a master's degree from a school of social work accredited by the Council on Social Work Education, and has 1 year of social work experience in a health care setting.

Speech-language pathologist. A person who:

(1) Meets the education and experience requirements for a Certificate of Clinical Competence in (speech pathology or audiology) granted by the American Speech-Language-Hearing Association; or

(2) Meets the educational requirements for certification and is in the process of accumulating the supervised experience required for certification.

[54 FR 33367, August 14, 1989, as amended at 56 FR 32973, July 18, 1991]

Subpart B—Administration

§ 484.10 Condition of participation: Patient rights.

The patient has the right to be informed of his or her rights. The HHA must protect and promote the exercise of these rights.

(a) Standard: Notice of rights. (1) The HHA must provide the patient with a written notice of the patient's rights in advance of furnishing care to the patient or during the initial evaluation visit before the initiation of treatment.

(2) The HHA must maintain documentation showing that it has complied with the requirements of this section.

(b) Standard: Exercise of rights and respect for property and person. (1) The patient has the right to exercise his or her rights as a patient of the HHA.

(2) The patient's family or guardian may exercise the patient's rights when the patient has been judged incompetent.

(3) The patient has the right to have his or her property treated with respect.

(4) The patient has the right to voice grievances regarding treatment or care that is (or fails to be) furnished, or regarding the lack of respect for property by anyone who is furnishing services on behalf of the HHA and must not be subjected to discrimination or reprisal for doing so.

(5) The HHA must investigate complaints made by a patient or the patient's family or guardian regarding treatment or care that is (or fails to be) furnished, or regarding the lack of respect for the patient's property by anyone furnishing services on behalf of the HHA, and must document both the
existence of the complaint and the resolution of the complaint.

(c) Standard: Right to be informed and to participate in planning care and treatment. (1) The patient has the right to be informed, in advance about the care to be furnished, and of any changes in the care to be furnished.

(i) The HHA must advise the patient in advance of the disciplines that will furnish care, and the frequency of visits proposed to be furnished.

(ii) The HHA must advise the patient in advance of the plan of care before the change is made.

(2) The patient has the right to participate in the planning of the care.

(i) The HHA must advise the patient in advance of the right to participate in planning the care or treatment and in planning changes in the care or treatment.

(ii) The HHA complies with the requirements of subpart I of part 489 of this chapter relating to maintaining advance directives. The HHA must inform and distribute written information to the patient, in advance, concerning its policies on advance directives, including a description of applicable State law. The HHA may furnish advance directives information to a patient at the time of the first home visit, as long as the information is furnished before care is provided.

(d) Standard: Confidentiality of medical records. The patient has the right to confidentiality of the clinical records maintained by the HHA. The HHA must advise the patient of the agency’s policies and procedures regarding disclosure of clinical records.

(e) Standard: Patient liability for payment. (1) The patient has the right to be advised, before care is initiated, of the extent to which payment for the HHA services may be expected from Medicare or other sources, and the extent to which payment may be required from the patient. Before the care is initiated, the HHA must inform the patient, orally and in writing, of—

(i) The extent to which payment may be expected from Medicare, Medicaid, or any other Federal, State, or local law.

(ii) The charges for services that will not be covered by Medicare; and

(iii) The charges that the individual may have to pay.

(2) The patient has the right to be advised orally and in writing of any changes in the information provided in accordance with paragraph (e)(1) of this section when they occur. The HHA must advise the patient of these changes orally and in writing as soon as possible, but no later than 30 calendar days from the date that the HHA becomes aware of a change.

(f) Standard: Home health hotline. The patient has the right to be advised of the availability of the toll-free HHA hotline in the State. When the agency accepts the patient for treatment or care, the HHA must advise the patient in writing of the telephone number of the home health hotline established by the State, the hours of its operation, and that the purpose of the hotline is to receive complaints or questions about local HHAs. The patient also has the right to use this hotline to lodge complaints concerning the implementation of the advance directives requirements.

[54 FR 33367, August 14, 1989, as amended at 56 FR 32973, July 18, 1991; 57 FR 8203, Mar. 6, 1992; 60 FR 33293, June 27, 1995]

§ 484.12 Condition of participation: Compliance with Federal, State, and local laws, disclosure and ownership information, and accepted professional standards and principles.

(a) Standard: Compliance with Federal, State, and local laws and regulations. The HHA and its staff must operate and furnish services in compliance with all applicable Federal, State, and local laws and regulations. If State or applicable local law provides for the licensure of HHAs, an agency not subject to licensure is approved by the licensing authority as meeting the standards established for licensure.

(b) Standard: Disclosure of ownership and management information. The HHA must comply with the requirements of Part 420, Subpart C of this chapter. The HHA also must disclose the following information to the State survey agency at the time of the HHA’s initial request for certification, for each survey, and at the time of any change in ownership or management:
(1) The name and address of all persons with an ownership or control interest in the HHA as defined in §§420.201, 420.202, and 420.206 of this chapter.

(2) The name and address of each person who is an officer, a director, an agent or a managing employee of the HHA as defined in §§420.201, 420.202, and 420.206 of this chapter.

(3) The name and address of the corporation, association, or other company that is responsible for the management of the HHA, and the name and address of the chief executive officer and the chairman of the board of directors of that corporation, association, or other company responsible for the management of the HHA.

(c) Standard: Compliance with accepted professional standards and principles. The HHA and its staff must comply with accepted professional standards and principles that apply to professionals furnishing services in an HHA.

§ 484.14 Condition of participation: Organization, services, and administration.

Organization, services furnished, administrative control, and lines of authority for the delegation of responsibility down to the patient care level are clearly set forth in writing and are readily identifiable. Administrative and supervisory functions are not delegated to another agency or organization and all services not furnished directly, including services provided through subunits are monitored and controlled by the parent agency. If an agency has subunits, appropriate administrative records are maintained for each subunit.

(a) Standard: Services furnished. Part-time or intermittent skilled nursing services and at least one other therapeutic service (physical, speech, or occupational therapy; medical social services; or home health aide services) are made available on a visiting basis, in a place of residence used as a patient’s home. An HHA must provide at least one of the qualifying services directly through agency employees, but may provide the second qualifying service and additional services under arrangements with another agency or organization.

(b) Standard: Governing body. A governing body (or designated persons so functioning) assumes full legal authority and responsibility for the operation of the agency. The governing body appoints a qualified administrator, arranges for professional advice as required under §484.16, adopts and periodically reviews bylaws or an acceptable equivalent, and oversees the management and fiscal affairs of the agency.

(c) Standard: Administrator. The administrator, who may also be the supervising physician or registered nurse required under paragraph (d) of this section, organizes and directs the agency’s ongoing functions; maintains ongoing liaison among the governing body, the group of professional personnel, and the staff; employs qualified personnel and ensures adequate staff education and evaluations; ensures the accuracy of public information materials and activities; and implements an effective budgeting and accounting system. A qualified person is authorized in writing to act in the absence of the administrator.

(d) Standard: Supervising physician or registered nurse. The skilled nursing and other therapeutic services furnished are under the supervision and direction of a physician or a registered nurse (who preferably has at least 1 year of nursing experience and is a public health nurse). This person, or similarly qualified alternate, is available at all times during operating hours and participates in all activities relevant to the professional services furnished, including the development of qualifications and the assignment of personnel.

(e) Standard: Personnel policies. Personnel practices and patient care are supported by appropriate, written personnel policies. Personnel records include qualifications and licensure that are kept current.

(f) Standard: Personnel under hourly or per visit contracts. If personnel under hourly or per visit contracts are used by the HHA, there is a written contract between those personnel and the agency that specifies the following:

(1) Patients are accepted for care only by the primary HHA.

(2) The services to be furnished.
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(3) The necessity to conform to all applicable agency policies, including personnel qualifications.

(4) The responsibility for participating in developing plans of care.

(5) The manner in which services will be controlled, coordinated, and evaluated by the primary HHA.

(6) The procedures for submitting clinical and progress notes, scheduling of visits, periodic patient evaluation.

(7) The procedures for payment for services furnished under the contract.

(g) Standard: Coordination of patient services. All personnel furnishing services maintain liaison to ensure that their efforts are coordinated effectively and support the objectives outlined in the plan of care. The clinical record or minutes of case conferences establish that effective interchange, reporting, and coordination of patient care does occur. A written summary report for each patient is sent to the attending physician at least every 62 days.

(h) Standard: Services under arrangements. Services furnished under arrangements are subject to a written contract conforming with the requirements specified in paragraph (f) of this section and with the requirements of section 1861(w) of the Act (42 U.S.C. 1320x(w)).

(i) Standard: Institutional planning. The HHA, under the direction of the governing body, prepares an overall plan and a budget that includes an annual operating budget and capital expenditure plan.

(1) Annual operating budget. There is an annual operating budget that includes all anticipated income and expenses related to items that would, under generally accepted accounting principles, be considered income and expense items. However, it is not required that there be prepared, in connection with any budget, an item by item identification of the components of each type of anticipated income or expense.

(2) Capital expenditure plan. (i) There is a capital expenditure plan for at least a 3-year period, including the operating budget year. The plan includes and identifies in detail the anticipated sources of financing for, and the objectives of, each anticipated expenditure of more than $600,000 for items that would under generally accepted accounting principles, be considered capital items. In determining if a single capital expenditure exceeds $600,000, the cost of studies, surveys, designs, plans, working drawings, specifications, and other activities essential to the acquisition, improvement, modernization, expansion, or replacement of land, plant, building, and equipment are included. Expenditures directly or indirectly related to capital expenditures, such as grading, paving, broker commissions, taxes assessed during the construction period, and costs involved in demolishing or razing structures on land are also included. Transactions that are separated in time, but are components of an overall plan or patient care objective, are viewed in their entirety without regard to their timing. Other costs related to capital expenditures include title fees, permit and license fees, broker commissions, architect, legal, accounting, and appraisal fees; interest, finance, or carrying charges on bonds, notes and other costs incurred for borrowing funds.

(ii) If the anticipated source of financing is, in any part, the anticipated payment from title V (Maternal and Child Health and Crippled Children's Services) or title XVIII (Medicare) or title XIX (Medicaid) of the Social Security Act, the plan specifies the following:

(A) Whether the proposed capital expenditure is required to conform, or is likely to be required to conform, to current standards, criteria, or plans developed in accordance with the Public Health Service Act or the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963.

(B) Whether a capital expenditure proposal has been submitted to the designated planning agency for approval in accordance with section 1122 of the Act (42 U.S.C. 1320a-1) and implementing regulations.

(C) Whether the designated planning agency has approved or disapproved the proposed capital expenditure if it was presented to that agency.

(3) Preparation of plan and budget. The overall plan and budget is prepared under the direction of the governing
body of the HHA by a committee consisting of representatives of the governing body, the administrative staff, and the medical staff (if any) of the HHA.

(4) Annual review of plan and budget. The overall plan and budget is reviewed and updated at least annually by the committee referred to in paragraph (i)(3) of this section under the direction of the governing body of the HHA.

(j) Standard: Laboratory services. (1) If the HHA 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 HHA 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.

§ 484.18 Condition of participation: Acceptance of patients, plan of care, and medical supervision.

Patients are accepted for treatment on the basis of a reasonable expectation that the patient's medical, nursing, and social needs can be met adequately by the agency in the patient's place of residence. Care follows a written plan of care established and periodically reviewed by a doctor of medicine, osteopathy, or podiatric medicine.

(a) Standard: Plan of care. The plan of care developed in consultation with the agency staff covers all pertinent diagnoses, including mental status, types of services and equipment required, frequency of visits, prognosis, rehabilitation potential, functional limitations, activities permitted, nutritional requirements, medications and treatments, any safety measures to protect against injury, instructions for timely discharge or referral, and any other appropriate items. If a physician refers a patient under a plan of care that cannot be completed until after an evaluation visit, the physician is consulted to approve additions or modifications to the original plan. Orders for therapy services include the specific procedures and modalities to be used and the amount, frequency, and duration. The therapist and other agency personnel participate in developing the plan of care.

(b) Standard: Periodic review of plan of care. The total plan of care is reviewed by the attending physician and HHA personnel as often as the severity of the patient's condition requires, but at least once every 62 days. Agency professional staff promptly alert the physician to any changes that suggest a need to alter the plan of care.

(c) Standard: Conformance with physician orders. Drugs and treatments are administered by agency staff only as ordered by the physician. Oral orders are put in writing and signed and dated with the date of receipt by the registered nurse or qualified therapist (as
§ 484.30 Condition of participation: Skilled nursing services.

The HHA furnishes skilled nursing services by or under the supervision of a registered nurse and in accordance with the plan of care.

(a) Standard: Duties of the registered nurse. The registered nurse makes the initial evaluation visit, regularly re-evaluates the patient’s nursing needs, initiates the plan of care and necessary revisions, furnishes those services requiring substantial and specialized nursing skill, initiates appropriate preventive and rehabilitative nursing procedures, prepares clinical and progress notes, coordinates services, informs the physician and other personnel of changes in the patient’s condition and needs, counsels the patient and family in meeting nursing and related needs, participates in in-service programs, and supervises and teaches other nursing personnel.

(b) Standard: Duties of the licensed practical nurse. The licensed practical nurse furnishes services in accordance with agency policies, prepares clinical and progress notes, assists the physician and registered nurse in performing specialized procedures, prepares equipment and materials for treatments observing aseptic technique as required, and assists the patient in learning appropriate self-care techniques.

§ 484.32 Condition of participation: Therapy services.

Any therapy services offered by the HHA directly or under arrangement are given by a qualified therapist or by a qualified therapy assistant under the supervision of a qualified therapist and in accordance with the plan of care. The qualified therapist assists the physician in evaluating level of function, helps develop the plan of care (revising it as necessary), prepares clinical and progress notes, advises and consults with the family and other agency personnel, and participates in in-service programs.

(a) Standard: Supervision of physical therapy assistant and occupational therapy assistant. Services furnished by a qualified physical therapy assistant or qualified occupational therapy assistant may be furnished under the supervision of a qualified physical or occupational therapist. A physical therapy assistant or occupational therapy assistant performs services planned, delegated, and supervised by the therapist, assists in preparing clinical notes and progress reports, and participates in educating the patient and family, and in in-service programs.

(b) Standard: Supervision of speech therapy services. Speech therapy services are furnished only by or under supervision of a qualified speech pathologist or audiologist.

§ 484.34 Condition of participation: Medical social services.

If the agency furnishes medical social services, those services are given by a qualified social worker or by a qualified social work assistant under the supervision of a qualified social worker, and in accordance with the plan of care. The social worker assists the physician and other team members in understanding the significant social and emotional factors related to the health problems, participates in the development of the plan of care, prepares clinical and progress notes, works with the family, uses appropriate community resources, participates in discharge planning and in-service programs, and acts as a consultant to other agency personnel.
§ 484.36 Condition of participation: Home health aide services.

Home health aides are selected on the basis of such factors as a sympathetic attitude toward the care of the sick, ability to read, write, and carry out directions, and maturity and ability to deal effectively with the demands of the job. They are closely supervised to ensure their competence in providing care. For home health services furnished (either directly or through arrangements with other organizations) after August 14, 1990, the HHA must use individuals who meet the personnel qualifications specified in §484.4 for “home health aide”.

(a) Standard: Home health aide training—(1) Content and duration of training. The aide training program must address each of the following subject areas through classroom and supervised practical training totalling at least 75 hours, with at least 16 hours devoted to supervised practical training. The individual being trained must complete at least 16 hours of classroom training before beginning the supervised practical training.

(i) Communications skills.
(ii) Observation, reporting and documentation of patient status and the care or service furnished.
(iii) Reading and recording temperature, pulse, and respiration.
(iv) Basic infection control procedures.
(v) Basic elements of body functioning and changes in body function that must be reported to an aide’s supervisor.
(vi) Maintenance of a clean, safe, and healthy environment.
(vii) Recognizing emergencies and knowledge of emergency procedures.
(viii) The physical, emotional, and developmental needs of and ways to work with the populations served by the HHA, including the need for respect for the patient, his or her privacy and his or her property.
(ix) Appropriate and safe techniques in personal hygiene and grooming that include—
(A) Bed bath.
(B) Sponge, tub, or shower bath.
(C) Shampoo, sink, tub, or bed.
(D) Nail and skin care.
(E) Oral hygiene.
(F) Toileting and elimination.
(x) Safe transfer techniques and ambulation.
(xi) Normal range of motion and positioning.
(xii) Adequate nutrition and fluid intake.
(xiii) Any other task that the HHA may choose to have the home health aide perform.

“Supervised practical training” means training in a laboratory or other setting in which the trainee demonstrates knowledge while performing tasks on an individual under the direct supervision of a registered nurse or licensed practical nurse.

(2) Conduct of training—(i) Organizations. A home health aide training program may be offered by any organization except an HHA that, within the previous 2 years has been found—

(A) Out of compliance with requirements of this paragraph (a) or paragraph (b) of this section;
(B) To permit an individual that does not meet the definition of “home health aide” as specified in §484.4 to furnish home health aide services (with the exception of licensed health professionals and volunteers);
(C) Has been subject to an extended (or partial extended) survey as a result of having been found to have furnished substandard care (or for other reasons at the discretion of the HCFA or the State);
(D) Has been assessed a civil monetary penalty of not less than $5,000 as an intermediate sanction;
(E) Has been found to have compliance deficiencies that endanger the health and safety of the HHA’s patients and has had a temporary management appointed to oversee the management of the HHA;
(F) Has had all or part of its Medicare payments suspended; or
(G) Under any Federal or State law within the 2-year period beginning on October 1, 1988—

(1) Has had its participation in the Medicare program terminated;
(2) Has been assessed a penalty of not less than $5,000 for deficiencies in Federal or State standards for HHAs;
(3) Was subject to a suspension of Medicare payments to which it otherwise would have been entitled;
(4) Had operated under a temporary management that was appointed to oversee the operation of the HHA and to ensure the health and safety of the HHA’s patients; or
(5) Was closed or had its residents transferred by the State.

(ii) Qualifications for instructors. The training of home health aides and the supervision of home health aides during the supervised practical portion of the training must be performed by or under the general supervision of a registered nurse who possesses a minimum of 2 years of nursing experience, at least 1 year of which must be in the provision of home health care. Other individuals may be used to provide instruction under the supervision of a qualified registered nurse.

(3) Documentation of training. The HHA must maintain sufficient documentation to demonstrate that the requirements of this standard are met.

(b) Standard: Competency evaluation and in-service training—(1) Applicability. An individual may furnish home health aide services on behalf of an HHA only after that individual has successfully completed a competency evaluation program as described in this paragraph. The HHA is responsible for ensuring that the individuals who furnish home health aide services on its behalf meet the competency evaluation requirements of this section.

(2) Content and frequency of evaluations and amount of in-service training. (i) The competency evaluation must address each of the subjects listed in paragraph (a)(1)(ii) through (xiii) of this section.

(ii) The HHA must complete a performance review of each home health aide no less frequently than every 12 months.

(iii) The home health aide must receive at least 12 hours of in-service training during each 12-month period. The in-service training may be furnished while the aide is furnishing care to the patient.

(3) Conduct of evaluation and training—(i) Organizations. A home health aide competency evaluation program may be offered by any organization except as specified in paragraph (a)(2)(i) of this section.

The in-service training may be offered by any organization.

(ii) Evaluators and instructors. The competency evaluation must be performed by a registered nurse. The in-service training generally must be supervised by a registered nurse who possesses a minimum of 2 years of nursing experience at least 1 year of which must be in the provision of home health care.

(iii) Subject areas. The subject areas listed at paragraphs (a)(1) (iii), (ix), (x), and (xi) of this section must be evaluated after observation of the aide’s performance of the tasks with a patient. The other subject areas in paragraph (a)(1) of this section may be evaluated through written examination, oral examination, or after observation of a home health aide with a patient.

(4) Competency determination. (i) A home health aide is not considered competent in any task for which he or she is evaluated as “unsatisfactory”. The aide must not perform that task without direct supervision by a licensed nurse until after he or she receives training in the task for which he or she was evaluated as “unsatisfactory” and passes a subsequent evaluation with “satisfactory”.

(ii) A home health aide is not considered to have successfully passed a competency evaluation if the aide has an “unsatisfactory” rating in more than one of the required areas.

(5) Documentation of competency evaluation. The HHA must maintain documentation which demonstrates that the requirements of this standard are met.

(6) Effective date. The HHA must implement a competency evaluation program that meets the requirements of this paragraph before February 14, 1990. The HHA must provide the preparation necessary for the individual to successfully complete the competency evaluation program. After August 14, 1990, the HHA may use only those aides that have been found to be competent in accordance with §484.36(b).

(c) Standard: Assignment and duties of the home health aide—(1) Assignment. The home health aide is assigned to a specific patient by the registered nurse. Written patient care instructions for the home health aide must be
prepared by the registered nurse or other appropriate professional who is responsible for the supervision of the home health aide under paragraph (d) of this section.

(2) Duties. The home health aide provides services that are ordered by the physician in the plan of care and that the aide is permitted to perform under State law. The duties of a home health aide include the provision of hands-on personal care, performance of simple procedures as an extension of therapy or nursing services, assistance in ambulation or exercises, and assistance in administering medications that are ordinarily self-administered. Any home health aide services offered by an HHA must be provided by a qualified home health aide.

(d) Standard: Supervision. (1) If the patient receives skilled nursing care, the registered nurse must perform the supervisory visit required by paragraph (d)(2) of this section. If the patient is not receiving skilled nursing care, but is receiving another skilled service (that is, physical therapy, occupational therapy, or speech-language pathology services), supervision may be provided by the appropriate therapist.

(2) The registered nurse (or another professional described in paragraph (d)(1) of this section) must make an on-site visit to the patient’s home no less frequently than every 2 weeks.

(3) If home health aide services are provided to a patient who is not receiving skilled nursing care, physical or occupational therapy or speech-language pathology services, the registered nurse must make a supervisory visit to the patient’s home no less frequently than every 62 days. In these cases, to ensure that the aide is properly caring for the patient, each supervisory visit must occur while the home health aide is providing patient care.

(4) If home health aide services are provided by an individual who is not employed directly by the HHA (or hospice), the services of the home health aide must be provided under arrangements, as defined in section 1861(w)(1) of the Act. If the HHA (or hospice) chooses to provide home health aide services under arrangements with another organization, the HHA’s (or hospice’s) responsibilities include, but are not limited to—

(i) Ensuring the overall quality of the care provided by the aide;

(ii) Supervision of the aide’s services as described in paragraphs (d)(1) and (d)(2) of this section; and

(iii) Ensuring that home health aides providing services under arrangements have met the training requirements of paragraphs (a) and (b) of this section.

(e) Personal care attendant: Evaluation requirements—(1) Applicability. This paragraph applies to individuals who are employed by HHAs exclusively to furnish personal care attendant services under a Medicaid personal care benefit.

(2) Rule. An individual may furnish personal care services, as defined in §440.170 of this chapter, on behalf of an HHA after the individual has been found competent by the State to furnish those services for which a competency evaluation is required by paragraph (b) of this section and which the individual is required to perform. The individual need not be determined competent in those services listed in paragraph (a) of this section that the individual is not required to furnish.

§ 484.38 Condition of participation: Qualifying to furnish outpatient physical therapy or speech pathology services.

An HHA that wishes to furnish outpatient physical therapy or speech pathology services must meet all the pertinent conditions of this part and also meet the additional health and safety requirements set forth in §§485.711, 485.713, 485.715, 485.719, 485.723, and 485.727 of this chapter to implement section 1861(p) of the Act.

§ 484.48 Condition of participation: Clinical records.

A clinical record containing pertinent past and current findings in accordance with accepted professional standards is maintained for every patient receiving home health services.
§ 484.52 Condition of participation: Evaluation of the agency’s program.

The HHA has written policies requiring an overall evaluation of the agency’s total program at least once a year by the group of professional personnel (or a committee of this group), HHA staff, and consumers, or by professional people outside the agency working in conjunction with consumers. The evaluation consists of an overall policy and administrative review and a clinical record review. The evaluation assesses the extent to which the agency’s program is appropriate, adequate, effective, and efficient. Results of the evaluation are reported to and acted upon by those responsible for the operation of the agency and are maintained separately as administrative records.

(a) Standard: Policy and administrative review. As a part of the evaluation process the policies and administrative practices of the agency are reviewed to determine the extent to which they promote patient care that is appropriate, adequate, effective, and efficient. Mechanisms are established in writing for the collection of pertinent data to assist in evaluation.

(b) Standard: Clinical record review. At least quarterly, appropriate health professionals, representing at least the scope of the program, review a sample of both active and closed clinical records to determine whether established policies are followed in furnishing services directly or under arrangement. There is a continuing review of clinical records for each 62-day period that a patient receives home health services to determine adequacy of the plan of care and appropriateness of continuation of care.
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§ 485.54 Condition of participation: Compliance with State and local laws.

485.608 Condition of participation: Compliance with Federal, State, and local laws and regulations.
485.610 Condition of participation: Status and location.
485.612 Condition of participation: Compliance with hospital requirements at time of application.
485.614 Condition of participation: Agreements.
485.616 Condition of participation: Emergency services.
485.620 Condition of participation: Number of beds and length of stay.
485.623 Condition of participation: Physical plant and environment.
485.627 Condition of participation: Organizational structure.
485.631 Condition of participation: Staffing and staff responsibilities.
485.635 Condition of participation: Provision of services.
485.638 Condition of participation: Clinical records.
485.639 Condition of participation: Surgical services.
485.641 Condition of participation: Periodic evaluation and quality assurance review.
485.645 Special requirements for CAH providers of long-term care services ("swing-beds").

Subpart H—Conditions of Participation for Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services

§ 485.701 Basis and scope.

As used in this subpart, unless the context indicates otherwise, "comprehensive outpatient rehabilitation facility", "CORF", or "facility" means a nonresidential facility that—

(a) Is established and operated exclusively for the purpose of providing diagnostic, therapeutic, and restorative services to outpatients for the rehabilitation of injured, disabled, or sick persons, at a single fixed location, by or under the supervision of a physician; and

(b) Meets all the requirements of this subpart.

§ 485.703 Definitions.

§ 485.705 Personnel qualifications.

§ 485.707 Condition of participation: Compliance with Federal, State, and local laws.

§ 485.709 Condition of participation: Administrative management.

§ 485.711 Condition of participation: Plan of care and physician involvement.

§ 485.713 Condition of participation: Physical therapy services.

§ 485.715 Condition of participation: Speech pathology services.

§ 485.717 Condition of participation: Rehabilitation program.

§ 485.719 Condition of participation: Arrangements for physical therapy and speech pathology services to be performed by other than salaried organization personnel.

§ 485.721 Condition of participation: Clinical records.

§ 485.723 Condition of participation: Physical environment.

§ 485.725 Condition of participation: Infection control.

§ 485.727 Condition of participation: Disaster preparedness.

§ 485.729 Condition of participation: Program evaluation.

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

licensed, certified, or registered in accordance with applicable State and local laws.

§ 485.56 Condition of participation: Governing body and administration.

The facility must have a governing body that assumes full legal responsibility for establishing and implementing policies regarding the management and operation of the facility.

(a) Standard: Disclosure of ownership. The facility must comply with the provisions of part 420, subpart C of this chapter that require health care providers and fiscal agents to disclose certain information about ownership and control.

(b) Standard: Administrator. The governing body must appoint an administrator who—

(1) Is responsible for the overall management of the facility under the authority delegated by the governing body;

(2) Implements and enforces the facility’s policies and procedures;

(3) Designates, in writing, an individual who, in the absence of the administrator, acts on behalf of the administrator; and

(4) Retains professional and administrative responsibility for all personnel providing facility services.

(c) Standard: Group of professional personnel. The facility must have a group of professional personnel associated with the facility that—

(1) Develops and periodically reviews policies to govern the services provided by the facility; and

(2) Consists of at least one physician and one professional representing each of the services provided by the facility.

(d) Standard: Institutional budget plan. The facility must have an institutional budget plan that meets the following conditions:

(1) It is prepared, under the direction of the governing body, by a committee consisting of representatives of the governing body and the administrative staff.

(2) It provides for—

(i) An annual operating budget prepared according to generally accepted accounting principles;

(ii) A 3-year capital expenditure plan if expenditures in excess of $100,000 are anticipated, for that period, for the acquisition of land; the improvement of land, buildings, and equipment; and the replacement, modernization, and expansion of buildings and equipment; and

(iii) Annual review and updating by the governing body.

(e) Standard: Patient care policies. The facility must have written patient care policies that govern the services it furnishes. The patient care policies must include the following:

(1) A description of the services the facility furnishes through employees and those furnished under arrangements.

(2) Rules for and personnel responsibilities in handling medical emergencies.

(3) Rules for the storage, handling, and administration of drugs and biologicals.

(4) Criteria for patient admission, continuing care, and discharge.

(5) Procedures for preparing and maintaining clinical records on all patients.

(6) A procedure for explaining to the patient and the patient’s family the extent and purpose of the services to be provided.

(7) A procedure to assist the referring physician in locating another level of care for—patients whose treatment has terminated and who are discharged.

(8) A requirement that patients accepted by the facility must be under the care of a physician.

(9) A requirement that there be a plan of treatment established by a physician for each patient.

(10) A procedure to ensure that the group of professional personnel reviews and takes appropriate action on recommendations from the utilization review committee regarding patient care policies.

(f) Standard: Delegation of authority. The responsibility for overall administration, management, and operation must be retained by the facility itself and not delegated to others.

(1) The facility may enter into a contract for purposes of assistance in financial management and may delegate
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§ 485.58 Condition of participation: Comprehensive rehabilitation program.

The facility must provide a coordinated rehabilitation program that includes, at a minimum, physicians' services, physical therapy services, and social or psychological services. The services must be furnished by personnel that meet the qualifications set forth in §485.70 and must be consistent with the plan of treatment and the results of comprehensive patient assessments.

(a) Standard: Physician services. (1) A facility physician must be present in the facility for a sufficient time to—

(i) Provide, in accordance with accepted principles of medical practice, medical direction, medical care services, and consultation;

(ii) Establish the plan of treatment in cases where a plan has not been established by the referring physician;

(iii) Assist in establishing and implementing the facility's patient care policies; and

(iv) Participate in plan of treatment reviews, patient case review conferences, comprehensive patient assessment and reassessments, and utilization review.

(2) The facility must provide for emergency physician services during the facility operating hours.

(b) Standard: Plan of treatment. For each patient, a physician must establish a plan of treatment before the facility initiates treatment. The plan of treatment must meet the following requirements:

(1) It must delineate anticipated goals and specify the type, amount, frequency and duration of services to be provided.

(2) It must be promptly evaluated after changes in the patient's condition and revised when necessary.

(3) It must, if appropriate, be developed in consultation with the facility physician and the appropriate facility professional personnel.

(4) It must be reviewed at least every 60 days by a facility physician who, when appropriate, consults with the professional personnel providing services. The results of this review must be communicated to the patient's referring physician for concurrence before treatment is continued or discontinued.

(5) It must be revised if the comprehensive reassessment of the patient's status or the results of the patient case review conference indicate the need for revision.

(c) Standard: Coordination of services. The facility must designate, in writing, a qualified professional to ensure that professional personnel coordinate their related activities and exchange information about each patient under their care. Mechanisms to assist in the coordination of services must include—

(1) Providing to all personnel associated with the facility, a schedule indicating the frequency and type of services provided at the facility;
(2) A procedure for communicating to all patient care personnel pertinent information concerning significant changes in the patient's status;

(3) Periodic clinical record entries, noting at least the patient's status in relationship to goal attainment; and

(4) Scheduling patient case review conferences for purposes of determining appropriateness of treatment, when indicated by the results of the initial comprehensive patient assessment, reassessment(s), the recommendation of the facility physician (or other physician who established the plan of treatment), or upon the recommendation of one of the professionals providing services.

(d) Standard: Provision of services. (1) All patients must be referred to the facility by a physician who provides the following information to the facility before treatment is initiated:

(i) The patient's significant medical history.

(ii) Current medical findings.

(iii) Diagnosis(es) and contraindications to any treatment modality.

(iv) Rehabilitation goals, if determined.

(2) Services may be provided by facility employees or by others under arrangements made by the facility.

(3) The facility must have on its premises the necessary equipment to implement the plan of treatment and sufficient space to allow adequate care.

(4) The services must be furnished by personnel that meet the qualifications of §485.70 and the number of qualified personnel must be adequate for the volume and diversity of services offered. Personnel that do not meet the qualifications specified in §485.70 may be used by the facility in assisting qualified staff. When a qualified individual is assisted by these personnel, the qualified individual must be on the premises, and must instruct these personnel in appropriate patient care service techniques and retain responsibility for their activities.

(5) A qualified professional must initiate and coordinate the appropriate portions of the plan of treatment, monitor the patient's progress, and recommend changes, in the plan, if necessary.

(6) A qualified professional representing each service made available at the facility must be either on the premises of the facility or must be available through direct telecommunication for consultation and assistance during the facility's operating hours. At least one qualified professional must be on the premises during the facility's operating hours.

(7) All services must be provided consistent with accepted professional standards and practice.

(e) Standard: Scope and site of services—(1) Basic requirements. The facility must provide all the CORF services required in the plan of treatment and, except as provided in paragraph (e)(2) of this section, must provide the services on its premises.

(2) Exceptions. Physical therapy, occupational therapy, and speech pathology services furnished away from the premises of the CORF may be covered as CORF services if Medicare payment is not otherwise made for these services. In addition, a single home visit is covered if there is need to evaluate the potential impact of the home environment on the rehabilitation goals.

(f) Standard: Patient assessment. Each qualified professional involved in the patient's care, as specified in the plan of treatment, must—

(1) Carry out an initial patient assessment; and

(2) In order to identify whether or not the current plan of treatment is appropriate, perform a patient reassessment after significant changes in the patient's status.

(g) Standard: Laboratory services. (1) If the facility provides its own laboratory services, the services must meet the applicable requirements for laboratories specified in part 493 of this chapter.

(2) If the facility chooses to refer specimens for laboratory testing, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the requirements of part 493 of this chapter.
§ 485.60 Condition of participation:
Clinical records.

The facility must maintain clinical records on all patients in accordance with accepted professional standards and practice. The clinical records must be completely, promptly, and accurately documented, readily accessible, and systematically organized to facilitate retrieval and compilation of information.

(a) Standard: Content. Each clinical record must contain sufficient information to identify the patient clearly and to justify the diagnosis and treatment. Entries in the clinical record must be made as frequently as is necessary to insure effective treatment and must be signed by personnel providing services. All entries made by assistant level personnel must be countersigned by the corresponding professional. Documentation on each patient must be consolidated into one clinical record that must contain—

(1) The initial assessment and subsequent reassessments of the patient’s needs;
(2) Current plan of treatment;
(3) Identification data and consent or authorization forms;
(4) Pertinent medical history, past and present;
(5) A report of pertinent physical examinations if any;
(6) Progress notes or other documentation that reflect patient reaction to treatment, tests, or injury, or the need to change the established plan of treatment; and
(7) Upon discharge, a discharge summary including patient status relative to goal achievement, prognosis, and future treatment considerations.

(b) Standard: Protection of clinical record information. The facility must safeguard clinical record information against loss, destruction, or unauthorized use. The facility must have procedures that govern the use and removal of records and the conditions for release of information. The facility must obtain the patient’s written consent before releasing information not required to be released by law.

(c) Standard: Retention and preservation. The facility must retain clinical record information for 5 years after patient discharge and must make provision for the maintenance of such records in the event that it is no longer able to treat patients.

§ 485.62 Condition of participation:
Physical environment.

The facility must provide a physical environment that protects the health and safety of patients, personnel, and the public.

(a) Standard: Safety and comfort of patients. The physical premises of the facility and those areas of its surrounding physical structure that are used by the patients (including at least all stairwells, corridors and passageways) must meet the following requirements:

(1) Applicable Federal, State, and local building, fire, and safety codes must be met.
(2) Fire extinguishers must be easily accessible and fire regulations must be prominently posted.
(3) A fire alarm system with local (inhouse) capability must be functional, and where power is generated by electricity, an alternate power source with automatic triggering must be present.
(4) Lights, supported by an emergency power source, must be placed at exits.
(5) A sufficient number of staff to evacuate patients during a disaster must be on the premises of the facility whenever patients are being treated.
(6) Lighting must be sufficient to carry out services safely; room temperature must be maintained at comfortable levels; and ventilation through windows, mechanical means, or a combination of both must be provided.
(7) Safe and sufficient space must be available for the scope of services offered.

(b) Standard: Sanitary environment. The facility must maintain a sanitary environment and establish a program to identify, investigate, prevent, and control the cause of patient infections.

(1) The facility must establish written policies and procedures designed to control and prevent infection in the facility and to investigate and identify possible causes of infection.
(2) The facility must monitor the infection control program to ensure that the staff implement the policies and procedures and that the policies and
§ 485.64 Condition of participation: Disaster procedures.

The facility must have written policies and procedures that specifically define the handling of patients, personnel, records, and the public during disasters. All personnel associated with the facility must be knowledgeable with respect to these procedures, be trained in their application, and be assigned specific responsibilities.

(a) Standard: Disaster plan. The facility’s written disaster plan must be developed and maintained with assistance of qualified fire, safety, and other appropriate experts. The plan must include—

(1) Procedures for prompt transfer of casualties and records;
(2) Procedures for notifying community emergency personnel (for example, fire department, ambulance, etc.);
(3) Instructions regarding the location and use of alarm systems and signals and fire fighting equipment; and
(4) Specification of evacuation routes and procedures for leaving the facility.

(b) Standard: Drills and staff training.

(1) The facility must provide ongoing training and drills for all personnel associated with the facility in all aspects of disaster preparedness.
(2) All new personnel must be oriented and assigned specific responsibilities regarding the facility’s disaster plan within two weeks of their first workday.

§ 485.66 Condition of participation: Utilization review plan.

The facility must have in effect a written utilization review plan that is implemented at least each quarter, to assess the necessity of services and promotes the most efficient use of services provided by the facility.

(a) Standard: Utilization review committee. The utilization review committee, consisting of the group of professional personnel specified in § 485.56(c), a committee of this group, or a group of similar composition, comprised by professional personnel not associated with the facility, must carry out the utilization review plan.

(b) Standard: Utilization review plan. The utilization review plan must contain written procedures for evaluating—

(1) All equipment is properly maintained and equipment needing periodic calibration is calibrated consistent with the manufacturer’s recommendations; and
(2) The interior of the facility, the exterior of the physical structure housing the facility, and the exterior walkways and parking areas are clean and orderly and maintained free of any defects that are a hazard to patients, personnel, and the public.

(d) Standard: Access for the physically impaired. The facility must ensure the following:

(1) Doorways, stairwells, corridors, and passageways used by patients are—
   (i) Of adequate width to allow for easy movement of all patients (including those on stretchers or in wheelchairs); and
   (ii) In the case of stairwells, equipped with firmly attached handrails on at least one side.
(2) At least one toilet facility is accessible and constructed to allow utilization by ambulatory and non-ambulatory individuals.
(3) At least one entrance is usable by individuals in wheelchairs.
(4) In multi-story buildings, elevators are accessible to and usable by the physically impaired on the level that they use to enter the building and all levels normally used by the patients of the facility.
(5) Parking spaces are large enough and close enough to the facility to allow safe access by the physically impaired.
§ 485.70 Personnel qualifications.

This section sets forth the qualifications that must be met, as a condition of participation, under §485.58, and as a condition of coverage of services under §410.100 of this chapter.

(a) A facility physician must be a doctor of medicine or osteopathy who—

(1) Is licensed under State law to practice medicine or surgery; and

(2) Has had, subsequent to completing a 1-year hospital internship, at least 1 year of training in the medical management of patients requiring rehabilitation services; or

(3) Has had at least 1 year of full-time or part-time experience in a rehabilitation setting providing physicians' services similar to those required in this subpart.

(b) A licensed practical nurse must be licensed as a practical or vocational nurse by the State in which practicing, if applicable.

(c) An occupational therapist and an occupational therapist assistant must meet the qualifications set forth in §405.1202(f) and (g) of this chapter.

(d) An orthotist must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Have successfully completed a training program in orthotics that is jointly recognized by the American Council on Education and the American Board for Certification in Orthotics and Prosthetics; and

(3) Be eligible to take that Board's certification examination in orthotics.

(e) A physical therapist and a physical therapist assistant must meet the qualifications set forth in paragraphs (b) and (c) of this section.

(f) A prosthetist must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Have successfully completed a training program in prosthetics that is jointly recognized by the American Council on Education and the American Board for Certification in Orthotics and Prosthetics; and

(3) Be eligible to take that Board's certification examination in prosthetics.

(g) A psychologist must be certified or licensed by the State in which he or she is practicing, if that State requires certification or licensing, and must hold a master's degree in psychology from and educational institution approved by the State in which the institution is located.

(h) A registered nurse must be a graduate of an approved school of nursing and be licensed as a registered nurse by the State in which practicing, if applicable.

(i) A rehabilitation counselor must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Hold at least a bachelor's degree; and

(3) Be eligible to take the certification examination administered by the Commission on Rehabilitation Counselor Certification.

(j) A respiratory therapist must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Have successfully completed a training program accredited by the Committee on Allied Health Education and Accreditation (CAHEA) in collaboration with the Joint Review Committee for Respiratory Therapy Education; and

(3) Either—

(i) Be eligible to take the registry examination for respiratory therapists administered by the National Board for Respiratory Therapy, Inc.; or

(ii) Have equivalent training and experience as determined by the National Board for Respiratory Therapy, Inc.

(k) A respiratory therapy technician must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Have successfully completed a training program accredited by the Committees on Allied Health Education and Accreditation (CAHEA) in
§ 485.74 Appeal rights.
The appeal provisions set forth in part 498 of this chapter, for providers, are applicable to any entity that is participating or seeks to participate in the Medicare program as a CORF.


Subparts C-E—[Reserved]

Subpart F—Conditions of Participation: Critical Access Hospitals (CAHs)

Source: 58 FR 30671, May 26, 1993, unless otherwise noted.

§ 485.601 Basis and scope.

(a) Statutory basis. This subpart is based on section 1820 of the Act which sets forth the conditions for designating certain hospitals as CAHs.

(b) Scope. This subpart sets forth the conditions that a hospital must meet to be designated as a CAH.


§ 485.602 Definitions.

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

Direct services means services provided by employed staff of the CAH, not services provided through arrangements or agreements.


§ 485.603 Rural health network.

A rural health network is an organization that meets the following specifications:

(a) It includes—

(1) At least one hospital that the State has designated or plans to designate as a CAH; and

(2) At least one hospital that furnishes acute care services.

(b) The members of the organization have entered into agreements regarding—

(1) Patient referral and transfer;

(2) The development and use of communications systems, including, where feasible, telemetry systems and systems for electronic sharing of patient data; and

(3) The provision of emergency and nonemergency transportation among members.

(c) Each CAH has an agreement with respect to credentialing and quality assurance with at least—

(1) One hospital that is a member of the network when applicable;

(2) One PRO or equivalent entity; or

(3) One other appropriate and qualified entity identified in the State rural health care plan.


§ 485.604 Personnel qualifications.

Staff that furnish services in a CAH must meet the applicable requirements of this section.

(a) Clinical nurse specialist. A clinical nurse specialist must be a person who performs the services of a clinical nurse specialist as authorized by the State, in accordance with State law or the State regulatory mechanism provided by State law.
(b) Nurse practitioner. A nurse practitioner must be a registered professional nurse who is currently licensed to practice in the State, who meets the State’s requirements governing the qualification of nurse practitioners, and who meets one of the following conditions:

(1) Is currently certified as a primary care nurse practitioner by the American Nurses’ Association or by the National Board of Pediatric Nurse Practitioners and Associates.

(2) Has successfully completed a 1 academic year program that—
   (i) Prepares registered nurses to perform an expanded role in the delivery of primary care;
   (ii) Includes at least 4 months (in the aggregate) of classroom instruction and a component of supervised clinical practice; and
   (iii) Awards a degree, diploma, or certificate to persons who successfully complete the program.

(3) Has successfully completed a formal educational program (for preparing physician assistants) that does not meet the requirements of paragraph (c)(2) of this section and has been assisting primary care physicians for a total of 12 months during the 18-month period immediately preceding June 25, 1993.


§ 485.606 Designation and certification of CAHs.

(a) Criteria for State designation. (1) A State that has established a Medicare rural hospital flexibility program described in section 1820(c) of the Act may designate one or more facilities as CAHs if each facility meets the CAH conditions of participation in this subpart F.

(2) The State must not deny any hospital that is otherwise eligible for designation as a CAH under this paragraph (a) solely because the hospital has entered into an agreement under which the hospital may provide posthospital SNF care as described in §482.66 of this chapter.

(b) Criteria for HCFA certification. HCFA certifies a facility as a CAH if—

(1) The facility is designated as a CAH by the State in which it is located and has been surveyed by the State survey agency or by HCFA and found to meet all conditions of participation in this Part and all other applicable requirements for participation in Part 489 of this chapter.

(2) The facility is a medical assistance facility operating in Montana or a rural primary care hospital designated by HCFA before August 5, 1997, and is otherwise eligible to be designated as a CAH by the State under the rules in this subpart.


§ 485.608 Condition of participation: Compliance with Federal, State, and local laws and regulations.

The CAH and its staff are in compliance with applicable Federal, State and local laws and regulations.
§ 485.610 Condition of participation: Status and location.

(a) Standard: Status. The facility is a public or nonprofit hospital.

(b) Standard: Location. The CAH meets the following requirements:

1. The CAH 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 the regulations in §412.230(e) of this chapter.

2. The CAH is not deemed to be located in an urban area under §412.63(b) of this chapter.

3. The CAH has not been classified as an urban hospital for purposes of the standardized payment amount by HCFA or the Medicare Geographic Classification Review Board under §412.232 of this chapter, and is not among a group of hospitals that have been redesignated to an adjacent urban area under §412.232 of this chapter.

4. The CAH is located more than a 35-mile drive (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from a hospital or another CAH, or the CAH is certified by the State as being a necessary provider of health care services to residents in the area.


§ 485.612 Condition of participation: Compliance with hospital requirements at time of application.

The hospital has a provider agreement to participate in the Medicare program as a hospital at the time the hospital applies for designation as a CAH.


§ 485.616 Condition of participation: Agreements.

(a) Standard: Agreements with network hospitals. In the case of a CAH that is a member of a rural health network as defined in §485.603 of this chapter, the CAH has in effect an agreement with at least one hospital that is a member of the network for—

1. Patient referral and transfer;

2. The development and use of communications systems of the network, including the network’s system for the electronic sharing of patient data, and telemetry and medical records, if the network has in operation such a system; and

3. The provision of emergency and nonemergency transportation between the facility and the hospital.

(b) Standard: Agreements for credentialing and quality assurance. Each CAH that is a member of a rural health network shall have an agreement with respect to credentialing and quality assurance with at least—

1. One hospital that is a member of the network;

2. One PRO or equivalent entity; or

3. One other appropriate and qualified entity identified in the State rural health care plan.


§ 485.618 Condition of participation: Emergency services.

The CAH provides emergency care necessary to meet the needs of its inpatients and outpatients.

(a) Standard: Availability. Emergency services are available on a 24-hours a day basis.

(b) Standard: Equipment, supplies, and medication. Equipment, supplies, and medication used in treating emergency cases are kept at the CAH and are readily available for treating emergency
cases. The items available must include the following:

1. **Drugs and biologicals** commonly used in life-saving procedures, including analgesics, local anesthetics, antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids, antiarhythmic, cardiac glycosides, antihypertensives, diuretics, and electrolytes and replacement solutions.

2. **Equipment and supplies** commonly used in life-saving procedures, including airways, endotracheal tubes, ambu bag/valve/mask, oxygen, tourniquets, immobilization devices, splints, IV therapy supplies, suction machine, defibrillator, cardiac monitor, chest tubes, and indwelling urinary catheters.

3. **Standard: Blood and blood products.** The facility provides, either directly or under arrangements, the following:
   - (1) Services for the procurement, safekeeping, and transfusion of blood, including the availability of blood products needed for emergencies on a 24-hours a day basis.
   - (2) Blood storage facilities that meet the requirements of 42 CFR part 493, subpart K, and are under the control and supervision of a pathologist or other qualified doctor of medicine or osteopathy. If blood banking services are provided under an arrangement, the arrangement is approved by the facility's medical staff and by the persons directly responsible for the operation of the facility.

4. **Personnel**—(1) There must be a practitioner with training or experience in emergency care on call and immediately available by telephone or radio contact, and available on site within 30 minutes, on a 24-hours a day basis.

5. **Emergency procedures.** The CAH assures the safety of patients in non-medical emergencies by—
   - (1) Training staff in handling emergencies, including prompt reporting of fires, extinguishing of fires, protection and, where necessary, evacuation of patients, personnel, and guests, and cooperation with fire fighting and disaster authorities;
   - (2) Provide information on treatment of emergency patients, and refer patients to the CAH or other appropriate locations for treatment.


§ 485.620 Condition of participation: Number of beds and length of stay.

(a) **Standard: Number of beds.** Except as permitted for CAHs having swing-bed agreements under §485.645 of this chapter, the CAH maintains no more than 15 inpatient beds.

(b) **Standard: Length of stay.** The CAH discharges or transfers each inpatient within 96 hours after admission, unless a longer period is required because transfer to a hospital is precluded because of inclement weather or other emergency conditions. A PRO or equivalent entity may also, on request, waive the 96-hour restriction on a case-by-case basis.


§ 485.623 Condition of participation: Physical plant and environment.

(a) **Standard: Construction.** The CAH is constructed, arranged, and maintained to ensure access to and safety of patients, and provides adequate space for the provision of direct services.

(b) **Maintenance.** The CAH has housekeeping and preventive maintenance programs to ensure that—
   - (1) All essential mechanical, electrical, and patient-care equipment is maintained in safe operating condition;
   - (2) There is proper routine storage and prompt disposal of trash;
   - (3) Drugs and biologicals are appropriately stored;
   - (4) The premises are clean and orderly; and
   - (5) There is proper ventilation, lighting, and temperature control in all pharmaceutical, patient care, and food preparation areas.

(c) **Standard: Emergency procedures.** The CAH assures the safety of patients in non-medical emergencies by—
   - (1) Training staff in handling emergencies, including prompt reporting of fires, extinguishing of fires, protection and, where necessary, evacuation of patients, personnel, and guests, and cooperation with fire fighting and disaster authorities;
   - (2) Provide information on treatment of emergency patients, and refer patients to the CAH or other appropriate locations for treatment.
§ 485.627 Condition of participation: 
Organizational structure.

(a) Standard: Governing body or responsible individual. The CAH has a governing body or an individual that assumes full legal responsibility for determining, implementing and monitoring policies governing the CAH's total operation and for ensuring that those policies are administered so as to provide quality health care in a safe environment.

(b) Standard: Disclosure. The CAH discloses the names and addresses of—
(1) Its owners, or those with a controlling interest in the CAH or in any subcontractor in which the CAH directly or indirectly has a 5 percent or more ownership interest, in accordance with subpart C of part 420 of this chapter;
(2) The person principally responsible for the operation of the CAH; and
(3) The person responsible for medical direction.

§ 485.631 Condition of participation: 
Staffing and staff responsibilities.

(a) Standard: Staffing—(1) The CAH has a professional health care staff that includes one or more doctors of medicine or osteopathy, and may include one or more physician assistants, nurse practitioners, or clinical nurse specialists.

(2) Any ancillary personnel are supervised by the professional staff.

(3) The staff is sufficient to provide the services essential to the operation of the CAH.

(4) A doctor of medicine or osteopathy, nurse practitioner, clinical nurse specialist, or physician assistant is available to furnish patient care services at all times the CAH operates.

(5) A registered nurse, clinical nurse specialist, or licensed practical nurse is...
on duty whenever the CAH has one or more inpatients.

(b) Standard: Responsibilities of the doctor of medicine or osteopathy.

(1) The doctor of medicine or osteopathy—

(i) Provides medical direction for the CAH's health care activities and consultation for, and medical supervision of, the health care staff;

(ii) In conjunction with the physician assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the CAH's written policies governing the services it furnishes.

(iii) In conjunction with the physician assistant and/or nurse practitioner members, periodically reviews the CAH's patient records, provides medical orders, and provides medical care services to the patients of the CAH; and

(iv) Periodically reviews and signs the records of patients cared for by nurse practitioners, clinical nurse specialists, or physician assistants.

(2) A doctor of medicine or osteopathy is present for sufficient periods of time, at least once in every 2 week period (except in extraordinary circumstances) to provide the medical direction, medical care services, consultation, and supervision described in this paragraph, and is available through direct radio or telephone communication for consultation, assistance with medical emergencies, or patient referral. The extraordinary circumstances are documented in the records of the CAH. A site visit is not required if no patients have been treated since the latest site visit.

(c) Standard: Physician assistant, nurse practitioner, and clinical nurse specialist responsibilities.

(1) The physician assistant, the nurse practitioner, or clinical nurse specialist members of the CAH's staff—

(i) Participate in the development, execution and periodic review of the written policies governing the services the CAH furnishes; and

(ii) Participate with a doctor of medicine or osteopathy in a periodic review of the patients' health care records.

(2) The physician assistant, nurse practitioner, or clinical nurse specialist performs the following functions to the extent they are not being performed by a doctor of medicine or osteopathy:

(i) Provides services in accordance with the CAH's policies.

(ii) Arranges for, or refers patients to, needed services that cannot be furnished at the CAH, and assures that adequate patient health records are maintained and transferred as required when patients are referred.

(3) Whenever a patient is admitted to the CAH by a nurse practitioner, physician assistant, or clinical nurse specialist, a doctor of medicine or osteopathy on the staff of the CAH is notified of the admission.


§ 485.635 Condition of participation: Provision of services.

(a) Standard: Patient care policies.

(1) The CAH's health care services are furnished in accordance with appropriate written policies that are consistent with applicable State law.

(2) The policies are developed with the advice of a group of professional personnel that includes one or more doctors of medicine or osteopathy and one or more physician assistants, nurse practitioners, or clinical nurse specialists, if they are on staff under the provisions of §485.631(a)(1); at least one member is not a member of the CAH staff.

(3) The policies include the following:

(i) A description of the services the CAH furnishes directly and those furnished through agreement or arrangement.

(ii) Policies and procedures for emergency medical services.

(iii) Guidelines for the medical management of health problems that include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the CAH.

(iv) Rules for the storage, handling, dispensation, and administration of drugs and biologicals. These rules must provide that there is a drug storage area that is administered in accordance with accepted professional principles, that current and accurate records are kept of the receipt and disposition of
all scheduled drugs, and that outdated, mislabeled, or otherwise unusable drugs are not available for patient use.

(v) Procedures for reporting adverse drug reactions and errors in the administration of drugs.

(vi) A system for identifying, reporting, investigating and controlling infections and communicable diseases of patients and personnel.

(vii) If the CAH furnishes inpatient services, procedures that ensure that the nutritional needs of inpatients are met in accordance with recognized dietary practices and the orders of the practitioner responsible for the care of the patients, and that the requirement of §483.25(i) is met with respect to inpatients receiving posthospital SNF care.

(4) These policies are reviewed at least annually by the group of professional personnel required under paragraph (a)(2) of this section, and reviewed as necessary by the CAH.

(b) Standard: Direct services—(1) General. The CAH staff furnishes, as direct services, those diagnostic and therapeutic services and supplies that are commonly furnished in a physician’s office or at another entry point into the health care delivery system, such as a low intensity hospital outpatient department or emergency department. These direct services include medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions.

(2) Laboratory services. The CAH provides, as direct services, basic laboratory services essential to the immediate diagnosis and treatment of the patient that meet the standards imposed under section 353 of the Public Health Service Act (42 U.S.C. 236a). (See the laboratory requirements specified in part 493 of this chapter.) The services provided include:

(i) Chemical examination of urine by stick or tablet method or both (including urine ketones);

(ii) Hemoglobin or hematocrit;

(iii) Blood glucose;

(iv) Examination of stool specimens for occult blood;

(v) Pregnancy tests; and

(vi) Primary culturing for transmittal to a certified laboratory.

(3) Radiology services. Radiology services furnished at the CAH are provided as direct services by staff qualified under State law, and do not expose CAH patients or staff to radiation hazards.

(4) Emergency procedures. In accordance with the requirements of §485.618, the CAH provides as direct services medical emergency procedures as a first response to common life-threatening injuries and acute illness.

(c) Standard: Services provided through agreements or arrangements. (1) The CAH has agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including—

(i) Inpatient hospital care;

(ii) Services of doctors of medicine or osteopathy; and

(iii) Additional or specialized diagnostic and clinical laboratory services that are not available at the CAH.

(iv) Food and other services to meet inpatients’ nutritional needs to the extent these services are not provided directly by the CAH.

(2) If the agreements or arrangements are not in writing, the CAH is able to present evidence that patients referred by the CAH are being accepted and treated.

(3) The CAH maintains a list of all services furnished under arrangements or agreements. The list describes the nature and scope of the services provided.

(4) The person principally responsible for the operation of the CAH under §485.627(b)(2) of this chapter is also responsible for the following:

(i) Services furnished in the CAH whether or not they are furnished under arrangements or agreements.

(ii) Ensuring that a contractor of services (including one for shared services and joint ventures) furnishes services that enable the CAH to comply with all applicable conditions of participation and standards for the contracted services.

(d) Standard: Nursing services. Nursing services must meet the needs of patients.
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(1) A registered nurse must provide (or assign to other personnel) the nursing care of each patient, including patients at a SNF level of care in a swing-bed CAH. The care must be provided in accordance with the patient's needs and the specialized qualifications and competence of the staff available.

(2) A registered nurse or, where permitted by State law, a physician assistant, must supervise and evaluate the nursing care for each patient, including patients at a SNF level of care in a swing-bed CAH.

(3) All drugs, biologicals, and intravenous medications must be administered by or under the supervision of a registered nurse, a doctor of medicine or osteopathy, or, where permitted by State law, a physician assistant, in accordance with written and signed orders, accepted standards of practice, and Federal and State laws.

(4) A nursing care plan must be developed and kept current for each inpatient.

§ 485.638 Conditions of participation: Clinical records.

(a) Standard: Records system.—(1) The CAH maintains a clinical records system in accordance with written policies and procedures.

(2) The records are legible, complete, accurately documented, readily accessible, and systematically organized.

(3) A designated member of the professional staff is responsible for maintaining the records and for ensuring that they are completely and accurately documented, readily accessible, and systematically organized.

(4) For each patient receiving health care services, the CAH maintains a record that includes, as applicable—

(i) Identification and social data, evidence of properly executed informed consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient;

(ii) Reports of physical examinations, diagnostic and laboratory test results, including clinical laboratory services, and consultative findings;

(iii) All orders of doctors of medicine or osteopathy or other practitioners, reports of treatments and medications, nursing notes and documentation of complications, and other pertinent information necessary to monitor the patient's progress, such as temperature graphics, progress notes describing the patient's response to treatment; and

(iv) Dated signatures of the doctor of medicine or osteopathy or other health care professional.

(b) Standard: Protection of record information.—(1) The CAH maintains the confidentiality of record information and provides safeguards against loss, destruction, or unauthorized use.

(2) Written policies and procedures govern the use and removal of records from the CAH and the conditions for the release of information.

(3) The patient's written consent is required for release of information not required by law.

(c) Standard: Retention of records. The records are retained for at least 6 years from date of last entry, and longer if required by State statute, or if the records may be needed in any pending proceeding.

§ 485.639 Condition of participation: Surgical services.

Surgical procedures must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body of the CAH in accordance with the designation requirements under paragraph (a) of this section.

(a) Designation of qualified practitioners. The CAH designates the practitioners who are allowed to perform surgery for CAH patients, in accordance with its approved policies and procedures, and with State scope of practice laws. Surgery is performed only by—

(1) A doctor of medicine or osteopathy, including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;

(2) A doctor of dental surgery or dental medicine; or

(3) A doctor of podiatric medicine.
§ 485.641 Condition of participation: Periodic evaluation and quality assurance review.

(a) Standard: Periodic evaluation—(1) The CAH carries out or arranges for a periodic evaluation of its total program. The evaluation is done at least once a year and includes review of—
   (i) The utilization of CAH services, including at least the number of patients served and the volume of services;
   (ii) A representative sample of both active and closed clinical records; and
   (iii) The CAH’s health care policies.

2. The purpose of the evaluation is to determine whether the utilization of services was appropriate, the established policies were followed, and any changes are needed.

(b) Standard: Quality assurance. The CAH has an effective quality assurance program to evaluate the quality and appropriateness of the diagnosis and treatment furnished in the CAH and of the treatment outcomes. The program requires that—
   (1) All patient care services and other services affecting patient health and safety, are evaluated;
   (2) Nosocomial infections and medication therapy are evaluated;
   (3) The quality and appropriateness of the diagnosis and treatment furnished by nurse practitioners, clinical nurse specialists, and physician assistants at the CAH are evaluated by a member of the CAH staff who is a doctor of medicine or osteopathy or by another doctor of medicine or osteopathy under contract with the CAH;
   (4) The quality and appropriateness of the diagnosis and treatment furnished by doctors of medicine or osteopathy at the CAH are evaluated by—
      (i) One hospital that is a member of the network, when applicable;
      (ii) One PRO or equivalent entity; or
      (iii) One other appropriate and qualified entity identified in the State rural health care plan; and
   (5) The CAH staff considers the findings of the evaluations, including any findings or recommendations of the PRO, and takes corrective action if necessary.

   (ii) The CAH also takes appropriate remedial action to address deficiencies found through the quality assurance program.
§ 485.645 Special requirements for CAH providers of long-term care services ("swing-beds")

A CAH must meet the following requirements in order to be granted an approval from HCFA to provide post-hospital SNF care, as specified in § 409.30 of this chapter, and to be paid for SNF-level services, in accordance with paragraph (c) of this section.

(a) Eligibility. A CAH must meet the following eligibility requirements:

(1) The facility has been certified as a CAH by HCFA under § 485.606(b) of this subpart; and

(2) The facility provides not more than 25 inpatient beds, and the number of beds used at any time for acute care inpatient services does not exceed 15 beds. Any bed of a unit of the facility that is licensed as distinct-part SNF at the time the facility applies to the State for designation as a CAH is not counted under paragraph (a) of this section.

(b) Facilities participating as rural primary care hospitals (RPCHs) on September 30, 1997. These facilities must meet the following requirements:

(1) Notwithstanding paragraph (a) of this section, a CAH that participated in Medicare as a RPCH on September 30, 1997, and on that date had in effect an approval from HCFA to use its inpatient facilities to provide post-hospital SNF care, may continue in that status under the same terms, conditions and limitations that were applicable at the time those approvals were granted.

(2) A CAH that was granted swing-bed approval under paragraph (b)(1) of this section may request that its application to be a CAH and swing-bed provider be reevaluated under paragraph (a) of this section. If this request is approved, the approval is effective not earlier than October 1, 1997. As of the date of approval, the CAH no longer has any status under paragraph (b)(1) of this section and may not request reinstatement under paragraph (b)(1) of this section.

(c) Payment. Payment for inpatient RPCH services to a CAH that has qualified as a CAH under the provisions in paragraph (a) of this section is made in accordance with § 413.70 of this chapter. Payment for post-hospital SNF-level of care services is made in accordance with the payment provisions in § 413.114 of this chapter.

(d) SNF services. The CAH is substantially in compliance with the following SNF requirements contained in subpart B of part 483 of this chapter:

(1) Residents rights (§483.10(b)(3) through (b)(6), (d) (e), (h), (l), (j)(1)(vii) and (viii), (l), and (m) of this chapter).

(2) Admission, transfer, and discharge rights (§483.12(a) of this chapter).

(3) Resident behavior and facility practices (§483.13 of this chapter).

(4) Patient activities (§483.15(f) of this chapter), except that the services may be directed either by a qualified professional meeting the requirements of §483.15(f)(2), or by an individual on the facility staff who is designated as the activities director and who serves in consultation with a therapeutic recreation specialist, occupational therapist, or other professional with experience or education in recreational therapy.

(5) Social services (§483.15(g) of this chapter).

(6) Comprehensive assessment, comprehensive care plan, and discharge planning (§483.20(b), (d), and (e) of this chapter).

(7) Specialized rehabilitative services (§483.45 of this chapter).

(8) Dental services (§483.55 of this chapter).

(9) Nutrition (§483.25(i) of this chapter).

[63 FR 26359, May 12, 1998]
§ 485.701   Basis and scope.

This subpart implements section 1861(p)(4) of the Act, which—
(a) Defines outpatient physical therapy and speech pathology services;
(b) Imposes requirements with respect to adequate program, facilities, policies, staffing, and clinical records; and
(c) Authorizes the Secretary to establish by regulation other health and safety requirements.

[60 FR 2327, Jan. 9, 1995]

§ 485.703   Definitions.

Clinic. A facility that is established primarily to furnish outpatient physician services and that meets the following tests of physician involvement:
(1) The medical services are furnished by a group of three or more physicians practicing medicine together.
(2) A physician is present during all hours of operation of the clinic to furnish medical services, as distinguished from purely administrative services.

Organization. A clinic, rehabilitation agency, or public health agency.

Public health agency. An official agency established by a State or local government, the primary function of which is to maintain the health of the population served by performing environmental health services, preventive medical services, and in certain cases, therapeutic services.

Rehabilitation agency. An agency that—
(1) Provides an integrated multidisciplinary rehabilitation program designed to upgrade the physical functioning of handicapped disabled individuals by bringing specialized rehabilitation staff together to perform as a team; and
(2) Provides at least the following services:

(i) Physical therapy or speech-language pathology services.
(ii) Social or vocational adjustment services.

Supervision. Authoritative procedural guidance that is for the accomplishment of a function or activity and that—
(1) Includes initial direction and periodic observation of the actual performance of the function or activity; and
(2) Is furnished by a qualified person—
(i) Whose sphere of competence encompasses the particular function or activity; and
(ii) Who (unless otherwise provided in this subpart) is on the premises if the person performing the function or activity does not meet the assistant-level practitioner qualifications specified in § 485.705.


§ 485.705   Personnel qualifications.

The training, experience, and membership requirements for personnel involved in the furnishing of outpatient physical therapy and speech-language pathology services are as follows:
(a) Administrator. A person who has a bachelor's degree and:
(1) Has experience or specialized training in the administration of health institutions or agencies; or
(2) Is qualified and has experience in one of the professional health disciplines.

(b) Physical therapist. A person who is licensed as a physical therapist by the State in which he or she is practicing if the State licenses physical therapists, and—
(1) Has graduated from a physical therapy curriculum approved by the American Physical Therapy Association, or by the Council on Medical Education and Hospitals of the American Medical Association, or jointly by the Council on Medical Education of the American Medical Association and the American Physical Therapy Association; or
(2) Prior to January 1, 1966.
(i) Was admitted to membership by the American Physical Therapy Association; or
(ii) Was admitted to registration by the American Registry of Physical Therapists; or
(iii) Has graduated from a physical therapy curriculum in a 4-year college or university approved by a State department of education; or
(3) Has 2 years of appropriate experience as a physical therapist and has achieved a satisfactory grade on a proficiency examination approved by the Secretary, except that such determinations of proficiency shall not apply with respect to persons initially licensed by a State after December 31, 1977, or seeking qualification as a physical therapist after such date; or
(4)(i) Was licensed or registered prior to January 1, 1966, and
(ii) Prior to January 1, 1970, had 15 years of full-time experience in the treatment of illness or injury through the practice of physical therapy in which services were rendered under the order and direction of attending and referring doctors of medicine or osteopathy; or
(5) If trained outside the United States;
(i) Was graduated since 1928 from a physical therapy curriculum approved in the country in which the curriculum was located and in which there is a member organization of the World Confederation for Physical Therapy.
(ii) Meets the requirements for membership in a member organization of the World Confederation for Physical Therapy.
(iii) Has 1 year of experience under the supervision of an active member of the American Physical Therapy Association, and
(iv) Has successfully completed a qualifying examination as prescribed by the American Physical Therapy Association.
(6) Physician. A person who is—
(1) A doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he or she performs those functions or actions; or
(2) A doctor of podiatric medicine, but only with respect to the functions which he or she is legally authorized to perform by the State in which he or she performs them.
(e) Psychologist. A person who:
(1) Holds a doctoral degree in psychology from a training program approved by the American Psychological Association; or
(2) Has attained certification or licensing by the State, or non-statutory certification by the State psychological association.
(f) Social worker. A person who is licensed by the State in which he is practicing if the State licenses social workers, is a graduate of a school of social work accredited or approved by the Council on Social Work Education, and has 1 year of social work experience in a health-care setting.
(g) Speech pathologist. A person who is licensed by the State in which he is practicing, if the State licenses speech pathologists, and
(1) Is eligible for a certificate of clinical competence in speech pathology granted by the American Speech and Hearing Association under its requirements in effect on January 17, 1974; or
(2) Meets the educational requirements for certification, and is in the process of accumulating the supervised clinical experience required for certification.
(h) Vocational specialist. A person who has a baccalaureate degree and:
(1) Two years experience in vocational counseling in a rehabilitation setting such as a sheltered workshop, State employment service agency, etc.; or
(2) At least 18 semester hours in vocational rehabilitation, educational or vocational guidance, psychology, social work, special education or personnel administration, and 1 year of experience in vocational counseling in a rehabilitation setting; or
§ 485.707 Condition of participation:
Compliance with Federal, State, and local laws.

The organization and its staff are in compliance with all applicable Federal, State, and local laws and regulations.

(a) Standard: Licensure of organization.
In any State in which State or applicable local law provides for the licensing of organizations, a clinic, rehabilitation agency, or public health agency is licensed in accordance with applicable laws.

(b) Standard: Licensure or registration of personnel.
Staff of the organization are licensed or registered in accordance with applicable laws.

§ 485.711 Condition of participation:
Plan of care and physician involvement.

For each patient in need of outpatient physical therapy or speech pathology services there is a written plan of care established and periodically reviewed by a physician, or by a physical therapist or speech pathologist respectively. The organization has a physician available to furnish necessary medical care in case of emergency.

(a) Standard: Medical history and prior treatment.
The following are obtained by the organization before or at the time of initiation of treatment:
(1) The patient's significant past history.
(2) Current medical findings, if any.
(3) Diagnosis(es), if established.
§ 485.713 Condition of participation: Physical therapy services.

If the organization offers physical therapy services, it provides an adequate program of physical therapy and has an adequate number of qualified personnel and the equipment necessary to carry out its program and to fulfill its objectives.

(a) Standard: Adequate program. (1) The organization is considered to have an adequate outpatient physical therapy program if it can:
   (i) Provide services using therapeutic exercise and the modalities of heat, cold, water, and electricity;
   (ii) Conduct patient evaluations; and
   (iii) Administer tests and measurements of strength, balance, endurance, range of motion, and activities of daily living.

(2) A qualified physical therapist is present or readily available to offer supervision when a physical therapist assistant furnishes services.
   (i) If a qualified physical therapist is not on the premises during all hours of operation, patients are scheduled so as to ensure that the therapist is present when special skills are needed, for example, for evaluation and reevaluation.
   (ii) When a physical therapist assistant furnishes services off the organization’s premises, those services are supervised by a qualified physical therapist who makes an onsite supervisory visit at least once every 30 days.

(b) Standard: Facilities and equipment. The organization has the equipment and facilities required to provide the range of services necessary in the treatment of the types of disabilities it accepts for service.

(c) Standard: Personnel qualified to provide physical therapy services. Physical therapy services are provided by, or under the supervision of, a qualified physical therapist. The number of qualified physical therapists and qualified physical therapist assistants is adequate for the volume and diversity of physical therapy services offered. A qualified physical therapist is on the premises or readily available during the operating hours of the organization.

(d) Standard: Supportive personnel. If personnel are available to assist qualified physical therapists by performing

(4) Physician’s orders, if any.
(5) Rehabilitation goals, if determined.
(6) Contraindications, if any.
(7) The extent to which the patient is aware of the diagnosis(es) and prognosis.
(8) If appropriate, the summary of treatment furnished and results achieved during previous periods of rehabilitation services or institutionalization.

(b) Standard: Plan of care. (1) For each patient there is a written plan of care established by the physician or by the physical therapist or speech-language pathologist who furnishes the services.

(2) The plan of care for physical therapy or speech pathology services indicates anticipated goals and specifies for those services the—
   (i) Type;
   (ii) Amount;
   (iii) Frequency; and
   (iv) Duration.

(3) The plan of care and results of treatment are reviewed by the physician or by the individual who established the plan at least as often as the patient’s condition requires, and the indicated action is taken. (For Medicare patients, the plan must be reviewed by a physician at least every 30 days in accordance with §410.61(e) of this chapter.)

(4) Changes in the plan of care are noted in the clinical record. If the patient has an attending physician, the therapist or speech-language pathologist who furnishes the services promptly notifies him or her of any change in the patient’s condition or in the plan of care.

(c) Standard: Emergency care. The organization provides for one or more doctors of medicine or osteopathy to be available on call to furnish necessary medical care in case of emergency. The established procedures to be followed by personnel in an emergency cover immediate care of the patient, persons to be notified, and reports to be prepared.

[54 FR 36769, Sept. 20, 1989. Redesignated and amended at 60 FR 2326, 2327, Jan. 9, 1995]
§ 485.715 Condition of participation: Speech pathology services.

If speech pathology services are offered, the organization provides an adequate program of speech pathology and has an adequate number of qualified personnel and the equipment necessary to carry out its program and to fulfill its objectives.

(a) Standard: Adequate program. The organization is considered to have an adequate outpatient speech pathology program if it can provide the diagnostic and treatment services to effectively treat speech disorders.

(b) Standard: Facilities and equipment. The organization has the equipment and facilities required to provide the range of services necessary in the treatment of the types of speech disorders it accepts for service.

(c) Standard: Personnel qualified to provide speech pathology services. Speech pathology services are given or supervised by a qualified speech pathologist and the number of qualified speech pathologists is adequate for the volume and diversity of speech pathology services offered. At least one qualified speech pathologist is present at all times when speech pathology services are furnished.

§ 485.717 Condition of participation: Rehabilitation program.

This condition and its standards apply only to a rehabilitation agency's own patients, not to patients of hospitals, skilled nursing facilities (SNFs), or Medicaid nursing facilities (NFs) to whom the agency furnishes services. (The hospital, SNF, or NF is responsible for ensuring that qualified staff furnish services for which they arrange or contract for their patients.) The rehabilitation agency provides, in addition to physical therapy and speech-language pathology services, social or vocational adjustment services to all of its patients who need them. The agency provides for special qualified staff to evaluate the social and vocational factors, to counsel and advise on the social or vocational problems that arise from the patient's illness or injury, and to make appropriate referrals for needed services.

(a) Standard: Qualification of staff. The agency's social or vocational adjustment services are furnished as appropriate, by qualified psychologists, qualified social workers, or qualified vocational specialists. Social or vocational adjustment services may be performed by a qualified psychologist or qualified social worker. Vocational adjustment services may be furnished by a qualified vocational specialist.

(b) Standard: Arrangements for social or vocational adjustment services. (1) If a rehabilitation agency does not provide social or vocational adjustment services through salaried employees, it may provide those services through a written contract with others who meet the requirements and responsibilities set forth in this subpart for salaried personnel.

(2) The contract must specify the term of the contract and the manner of termination or renewal and provide that the agency retains responsibility for the control and supervision of the services.

§ 485.719 Condition of participation: Arrangements for physical therapy and speech pathology services to be performed by other than salaried organization personnel.

(a) Conditions. If an organization provides outpatient physical therapy or speech pathology services under an arrangement with others, the services are to be furnished in accordance with the terms of a written contract, which provides that the organization retains
§ 485.723 Condition of participation: Physical environment.

The building housing the organization is constructed, equipped, and maintained to protect the health and safety of patients, personnel, and the public and provides a functional, sanitary, and comfortable environment.

§ 485.721 Condition of participation: Clinical records.

The organization maintains clinical records on all patients in accordance with accepted professional standards, and practices. The clinical records are completely and accurately documented, readily accessible, and systematically organized to facilitate retrieving and compiling information.

(a) Standard: Protection of clinical record information. The organization recognizes the confidentiality of clinical record information and provides safeguards against loss, destruction, or unauthorized use. Written procedures govern the use and removal of records and the conditions for release of information. The patient’s written consent is required for release of information not authorized by law.

(b) Standard: Content. The clinical record contains sufficient information to identify the patient clearly, to justify the diagnosis(es) and treatment, and to document the results accurately. All clinical records contain the following general categories of data:

(1) Documented evidence of the assessment of the needs of the patient, of an appropriate plan of care, and of the care and services furnished.

(2) Identification data and consent forms.

(3) Medical history.

(4) Report of physical examinations, if any.

(5) Observations and progress notes.

(6) Reports of treatments and clinical findings.

(7) Discharge summary including final diagnosis(es) and prognosis.

(c) Standard: Completion of records and centralization of reports. Current clinical records and those of discharged patients are completed promptly. All clinical information pertaining to a patient is centralized in the patient’s clinical record. Each physician signs the entries that he or she makes in the clinical record.

(d) Standard: Retention and preservation. Clinical records are retained for at least:

(1) The period determined by the respective State statute, or the statute of limitations in the State; or

(2) In the absence of a State statute—

(i) Five years after the date of discharge; or

(ii) In the case of a minor, 3 years after the patient becomes of age under State law or 5 years after the date of discharge, whichever is longer.

(e) Standard: Indexes. Clinical records are indexed at least according to name of patient to facilitate acquisition of statistical medical information and retrieval of records for research or administrative action.

(f) Standard: Location and facilities. The organization maintains adequate facilities and equipment, conveniently located, to provide efficient processing of clinical records (reviewing, indexing, filing, and prompt retrieval).

§ 485.725 Condition of participation: Infection control.

(a) Standard: Safety of patients. The organization satisfies the following requirements:

(1) It complies with all applicable State and local building, fire, and safety codes.

(2) Permanently attached automatic fire-extinguishing systems of adequate capacity are installed in all areas of the premises considered to have special fire hazards. Fire extinguishers are conveniently located on each floor of the premises. Fire regulations are prominently posted.

(3) Doorways, passageways and stairwells negotiated by patients are:

   (i) Of adequate width to allow for easy movement of all patients (including those on stretchers or in wheelchairs), (ii) free from obstruction at all times, and (iii) in the case of stairwells, equipped with firmly attached handrails on at least one side.

(4) Lights are placed at exits and in corridors used by patients and are supported by an emergency power source.

(5) A fire alarm system with local alarm capability and, where applicable, an emergency power source, is functional.

(6) At least two persons are on duty on the premises of the organization whenever a patient is being treated.

(7) No occupancies or activities undesirable or injurious to the health and safety of patients are located in the building.

(b) Standard: Maintenance of equipment, building, and grounds. The organization establishes a written preventive-maintenance program to ensure that—

(1) The equipment is operative, and is properly calibrated; and

(2) The interior and exterior of the building are clean and orderly and maintained free of any defects that are a potential hazard to patients, personnel, and the public.

(c) Standard: Other environmental considerations. The organization provides a functional, sanitary, and comfortable environment for patients, personnel, and the public.

(1) Provision is made for adequate and comfortable lighting levels in all areas; limitation of sounds at comfort levels; a comfortable room temperature; and adequate ventilation through windows, mechanical means, or a combination of both.

(2) Toilet rooms, toilet stalls, and lavatories are accessible and constructed so as to allow use by non-ambulatory and semiambulatory individuals.

(3) Whatever the size of the building, there is an adequate amount of space for the services provided and disabilities treated, including reception area, staff space, examining room, treatment areas, and storage.


# 485.725 Condition of participation: Infection control.

The organization that provides outpatient physical therapy services establishes an infection-control committee of representative professional staff with responsibility for overall infection control. All necessary housekeeping and maintenance services are provided to maintain a sanitary and comfortable environment and to help prevent the development and transmission of infection.

(a) Standard: Infection-control committee. The infection-control committee establishes policies and procedures for investigating, controlling, and preventing infections in the organization and monitors staff performance to ensure that the policies and procedures are executed.

(b) All personnel follow written procedures for effective aseptic techniques. The procedures are reviewed annually and revised if necessary to improve them.

(c) Standard: Housekeeping. (1) The organization employs sufficient housekeeping personnel and provides all necessary equipment to maintain a safe, clean, and orderly interior. A full-time employee is designated as the one responsible for the housekeeping services and for supervision and training of housekeeping personnel.

(2) An organization that has a contract with an outside resource for housekeeping services may be found to be in compliance with this standard provided the organization or outside resource or both meet the requirements of the standard.
§ 485.727 Condition of participation: Disaster preparedness.

The organization has a written plan, periodically rehearsed, 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 a disaster.

(a) Standard: Disaster plan. The organization has a written plan in operation, with procedures to be followed in the event of fire, explosion, or other disaster. The plan is developed and maintained with the assistance of qualified fire, safety, and other appropriate experts, and includes:

(1) Transfer of casualties and records;
(2) The location and use of alarm systems and signals;
(3) Methods of containing fire;
(4) Notification of appropriate persons; and
(5) Evacuation routes and procedures.

(b) Standard: Staff training and drills. All employees are trained, as part of their employment orientation, in all aspects of preparedness for any disaster. The disaster program includes orientation and ongoing training and drills for all personnel in all procedures so that each employee promptly and correctly carries out his assigned role in case of a disaster.

§ 485.729 Condition of participation: Program evaluation.

The organization has procedures that provide for a systematic evaluation of its total program to ensure appropriate utilization of services and to determine whether the organization’s policies are followed in providing services to patients through employees or under arrangements with others.

(a) Standard: Clinical-record review. A sample of active and closed clinical records is reviewed quarterly by the appropriate health professionals to ensure that established policies are followed in providing services.

(b) Standard: Annual statistical evaluation. An evaluation is conducted annually of statistical data such as number of different patients treated, number of patient visits, condition on admission and discharge, number of new patients, number of patients by diagnosis(es), sources of referral, number and cost of units of service by treatment given, and total staff days or work hours by discipline.

§ 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

Subpart A—General Provisions

Sec. 486.1 Basis and scope.

Subpart B—[Reserved]

Subpart C—Conditions for Coverage: Portable X-Ray Services

486.100 Condition for coverage: Compliance with Federal, State, and local laws and regulations.
486.102 Condition for coverage: Supervision by a qualified physician.
486.104 Condition for coverage: Qualifications, orientation, and health of technical personnel.
486.106 Condition for coverage: Referral for service and preservation of records.
486.108 Condition for coverage: Safety standards.
§ 486.110 Condition for coverage: Inspection of equipment.

Subpart D—Conditions for Coverage: Outpatient Physical Therapy Services Furnished by Physical Therapists in Independent Practice

486.150 Condition for coverage: General requirements.
486.151 Condition for coverage: Supervision.
486.153 Condition for coverage: Compliance with Federal, State, and local laws.
486.155 Condition for coverage: Plan of care.
486.157 Condition for coverage: Physical therapy services.
486.159 Condition for coverage: Coordination of services with other organizations, agencies, or individuals.
486.161 Condition for coverage: Clinical records.
486.163 Condition for coverage—physical environment.

Subparts E-F—[Reserved]

Subpart G—Conditions for Coverage: Organ Procurement Organizations

486.301 Basis and scope.
486.304 General requirements.
486.306 Qualifications for designation as an OPO.
486.307 OPO service area size designation and documentation requirements.
486.308 Condition: Participation in organ procurement and transplantation network.
486.310 Condition: Adherence to performance standards.
486.314 Effect of failure to meet requirements.
486.316 Designation of one OPO for each service area.
486.318 Changes in ownership or service area.
486.325 Termination of agreement with HCFA.

Appendix A to Subpart G of Part 486—Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs

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

Subpart A—General Provisions

§ 486.1 Basis and scope.

(a) Statutory basis. This part is based on the following sections of the Act:

1138(b)—for coverage of organ procurement services.
1861(p)—for coverage of outpatient physical therapy services furnished by physical therapists in independent practice.
1861(s) (3), (15), and (17)—for coverage of portable X-ray services.

(b) Scope. (1) This part sets forth the conditions for coverage of certain specialized services that are furnished by suppliers and that are not specified in other portions of this chapter.
(2) The conditions for coverage of other specialized services furnished by suppliers are set forth in the following regulations which, unless otherwise indicated, are part of this chapter:
(i) Ambulatory surgical center (ASC) services—Part 416.
(ii) Ambulance services—Part 410, subpart B.
(iii) ESRD services—Part 405, subpart U.
(iv) Laboratory services—Part 403.
(v) Mammography services—Part 410, subpart B (§410.34) and 21 CFR Part 900, subpart B, of the Food and Drug Administration regulations.
(vi) Rural health clinic and Federally qualified health center services—Part 491, subpart A.

[60 FR 50447, Sept. 29, 1995]
X-ray services, the supplier is (1) licensed or registered pursuant to such law, or (2) approved by the agency of the State or locality responsible for licensure or registration as meeting the standards established for such licensure or registration.

(b) Standard—licensure or registration of personnel. All personnel engaged in operating portable X-ray equipment are currently licensed or registered in accordance with all applicable State and local laws.

(c) Standard—licensure or registration of equipment. All portable X-ray equipment used in providing portable X-ray services is licensed or registered in accordance with all applicable State and local laws.

(d) Standard—conformity with other Federal, State, and local laws and regulations. The supplier of portable X-ray services agrees to render such services in conformity with Federal, State, and local laws relating to safety standards.

§ 486.104 Condition for coverage: Qualifications, orientation and health of technical personnel.

Portable X-ray services are provided by qualified technologists.

(a) Standard—qualifications of technologists. All operators of the portable X-ray equipment meet the requirements of paragraph (a) (1), (2), or (3) of this section:

(1) Successful completion of a program of formal training in X-ray technology of not less than 24 months’ duration in a school approved by the Council on Education of the American Medical Association or by the American Osteopathic Association, or have earned a bachelor’s or associate degree in radiologic technology from an accredited college or university.

(2) The supervising physician certifies annually that he periodically checks the procedural manuals and observes the operators’ performance, that he has verified that equipment and personnel meet applicable Federal, State, and local licensure and registration requirements and that safe operating procedures are used.

(b) Standard—qualifications of the physician supervisor. Portable X-ray services are provided under the supervision of a licensed doctor of medicine or licensed doctor of osteopathy who is qualified by advanced training and experience in the use of X-rays for diagnostic purposes, i.e., he (1) is certified in radiology by the American Board of Radiology or by the American Osteopathic Board of Radiology or possesses qualifications which are equivalent to those required for such certification, or (2) is certified or meets the requirements for certification in a medical specialty in which he has become qualified by experience and training in the use of X-rays for diagnostic purposes, or (3) specializes in radiology and is recognized by the medical community as a specialist in radiology.
§ 486.106

[42 CFR Ch. IV (10-1-98 Edition)]

(a) Standard—personnel orientation.
The supplier of portable X-ray services has an orientation program for personnel, based on a procedural manual which is: Available to all members of the staff, incorporates relevant portions of professionally recognized documents, and includes instruction in all of the following:

1. Precautions to be followed to protect the patient from unnecessary exposure to radiation;
2. Precautions to be followed to protect an individual supporting the patient during X-ray procedures from unnecessary exposure to radiation;
3. Precautions to be followed to protect other individuals in the surrounding environment from exposure to radiation;
4. Precautions to be followed to protect the operator of portable X-ray equipment from unnecessary exposure to radiation;
5. Considerations in determining the area which will receive the primary beam;
6. Determination of the time interval at which to check personnel radiation monitors;
7. Use of the personnel radiation monitor in providing an additional check on safety of equipment;
8. Proper use and maintenance of equipment;
9. Proper maintenance of records;
10. Technical problems which may arise and methods of solution;
11. Protection against electrical hazards;
12. Hazards of excessive exposure to radiation.

(b) Standard—preservation of records.
Such reports are maintained for a period of at least 2 years, or for the period of time required by State law for such records (as distinguished from requirements as to the radiograph itself), whichever is longer.

§ 486.108 Condition for coverage: Safety standards.

X-ray examinations are conducted through the use of equipment which is free of unnecessary hazards for patients, personnel, and other persons in the immediate environment, and through operating procedures which provide minimum radiation exposure to patients, personnel, and other persons in the immediate environment.

(a) Standard—tube housing and devices to restrict the useful beam. The tube housing is of diagnostic type. Diaphragms, cones, or adjustable collimators capable of restricting the useful beam to the area of clinical interest are used and provide the same degree of protection as is required of the housing.

(b) Standard—total filtration. (1) The aluminum equivalent of the total filtration in the primary beam is not less than that shown in the following table except when contraindicated for a particular diagnostic procedure.

<table>
<thead>
<tr>
<th>Operating kVp</th>
<th>Total filtration (inherent plus added)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Below 50 kVp</td>
<td>0.5 millimeters aluminum.</td>
</tr>
<tr>
<td>50–70 kVp</td>
<td>1.5 millimeters aluminum.</td>
</tr>
<tr>
<td>Above 70 kVp</td>
<td>2.5 millimeters aluminum.</td>
</tr>
</tbody>
</table>

(2) If the filter in the machine is not accessible for examination or the total filtration is unknown, it can be assumed that the requirements are met if the half-value layer is not less than that shown in the following table:

<table>
<thead>
<tr>
<th>Operating kVp</th>
<th>Half-value layer</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 kVp</td>
<td>0.6 millimeters aluminum.</td>
</tr>
<tr>
<td>70 kVp</td>
<td>1.6 millimeters aluminum.</td>
</tr>
<tr>
<td>90 kVp</td>
<td>2.6 millimeters aluminum.</td>
</tr>
<tr>
<td>100 kVp</td>
<td>2.8 millimeters aluminum.</td>
</tr>
<tr>
<td>110 kVp</td>
<td>3.0 millimeters aluminum.</td>
</tr>
<tr>
<td>120 kVp</td>
<td>3.3 millimeters aluminum.</td>
</tr>
</tbody>
</table>

(c) Standard—termination of exposure. A device is provided to terminate the exposure after a preset time or exposure.

(d) Standard—control panel. The control panel provides a device (usually a milliammeter or a means for an audible signal) to give positive indication of the production of X-rays whenever the X-ray tube is energized. The control panel includes appropriate indicators (labelled control settings and/or meters) which show the physical factors (such as kVp, mA, exposure time or whether timing is automatic) used for the exposure.

(e) Standard—exposure control switch. The exposure control switch is of the dead-man type and is so arranged that the operator can stand at least 6 feet from the patient and well away from the useful beam.

(f) Standard—protection against electrical hazards. Only shockproof equipment is used. All electrical equipment is grounded.

(g) Standard—mechanical supporting or restraining devices. Mechanical supporting or restraining devices are provided so that such devices can be used when a patient must be held in position for radiography.

(h) Standard—protective gloves and aprons. Protective gloves and aprons are provided so that when the patient must be held by an individual, that individual is protected with these shielding devices.

(i) Standard—restriction of the useful beam. Diaphragms, cones, or adjustable collimators are used to restrict the useful beam to the area of clinical interest.

(j) Standard—personnel monitoring. A device which can be worn to monitor radiation exposure (e.g., a film badge) is provided to each individual who operates portable X-ray equipment. The device is evaluated for radiation exposure to the operator at least monthly and appropriate records are maintained by the supplier of portable X-ray services of radiation exposure measured by such a device for each individual.

(k) Standard—personnel and public protection. No individual operationally exposed to radiation is permitted to hold patients during exposures except during emergencies, nor is any other individual regularly used for this service. Care is taken to assure that pregnant women do not assist in portable X-ray examinations.

§ 486.110 Condition for coverage: Inspection of equipment.

Inspections of all X-ray equipment and shielding are made by qualified individuals at intervals not greater than every 24 months.

(a) Standard—qualified inspectors. Inspections are made at least every 24 months by a radiation health specialist who is on the staff of or approved by an appropriate State or local government agency.

(b) Standard—records of inspection and scope of inspection. The supplier maintains records of current inspections which include the extent to which equipment and shielding are in compliance with the safety standards outlined in § 486.108.


Subpart D—Conditions for Coverage: Outpatient Physical Therapy Services Furnished by Physical Therapists in Independent Practice

§ 486.150 Condition for coverage: General requirements.

In order to be covered under Medicare as a supplier of outpatient physical therapy services, a physical therapist in independent practice must meet the following requirements:

(a) Be licensed in the State in which he or she practices.

(b) Meet one of the personnel qualifications specified in § 485.705(b).

(c) Furnish services under the circumstances described in § 410.60 of this chapter.

(d) Meet the requirements of this subpart.

[60 FR 2329, Jan. 9, 1995]

§ 486.151 Condition for coverage: Supervision.

The services are furnished by or under the direct supervision of a qualified physical therapist in independent practice.

[60 FR 2329, Jan. 9, 1995]

§ 486.153 Condition for coverage: Compliance with Federal, State, and local laws.

The physical therapist in independent practice and staff, if any, are in compliance with all applicable Federal, State, and local laws and regulations.

(a) Standard: Licensure of facility. In any State in which State or applicable local law provides for the licensing of the facility of a physical therapist, such facility is:

(1) Licensed pursuant to such law; or

(2) If not subject to licensure, is approved (by the agency of such State or locality responsible for licensing) as meeting the standards established for such licensing.

(b) Standard: Licensure or registration of personnel. The physical therapist in independent practice and staff, if any, are licensed or registered in accordance with applicable laws.

[41 FR 20865, May 21, 1976, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated and amended at 60 FR 2326, 2329, Jan. 9, 1995]

§ 486.155 Condition for coverage: Plan of care.

For each patient, a written plan of care is established and periodically reviewed by the individual who established it.

(a) Standard: Medical history and prior treatment. The physical therapist obtains the following information before or at the time of initiation of treatment:

(1) The patient’s significant past history.

(2) Diagnosis(es), if established.

(3) Physician’s orders, if any.

(4) Rehabilitation goals and potential for their achievement.

(5) Contraindications, if any.

(6) The extent to which the patient is aware of the diagnosis(es) and prognosis.

(7) If appropriate, the summary of treatment provided and results achieved during previous periods of physical therapy services or institutionalization.

(b) Standard: Plan of care. (1) For each patient there is a written plan of care that is established by the physician or by the physical therapist who furnishes the services.
§ 486.161 Condition for coverage: Clinical records.

The physical therapist in independent practice maintains clinical records on all patients in accordance with accepted professional standards and practices. The clinical records are completely and accurately documented, readily accessible, and systematically organized to facilitate retrieving and compiling information.

(a) Standard: Protection of clinical record information. Clinical-record information is recognized as confidential and is safeguarded against loss, destruction, or unauthorized use. Written procedures govern use and removal of records and include conditions for release of information. A patient’s written consent is required for release of information not authorized by law.

(b) Standard: Content. The clinical record contains sufficient information to identify the patient clearly, to justify the diagnosis(es) and treatment, and to document the results accurately. All clinical records contain the following general categories of data:

(2) The plan indicates anticipated goals and specifies for physical therapy services the—
(i) Type;
(ii) Amount;
(iii) Frequency; and
(iv) Duration.

(3) The plan of care and results of treatment are reviewed by the physician or by the therapist at least as often as the patient’s condition requires, and the indicated action is taken.

(4) Changes in the plan of care are noted in the clinical record. If the patient has an attending physician, the therapist who furnishes the services promptly notifies him or her of any change in the patient’s condition or in the plan of care. (For Medicare patients, the plan must be reviewed by a physician in accordance with §410.61(e).)
§ 486.163 Condition for coverage—physical environment.

The physical environment of the office or facility of the physical therapist in independent practice affords a functional, sanitary, safe, and comfortable surrounding for patients, personnel, and the public.

(a) Standard: Building construction.

The construction of the building housing the physical therapy office meets all applicable State and local building, fire, and safety codes.

(b) Standard: Maintenance of the physical therapy office and equipment. There is a written preventive-maintenance program to ensure that equipment is operative and that the physical therapy office is clean and orderly. All essential mechanical, electrical, and patient-care equipment is maintained in safe operating condition, and is properly calibrated.

(c) Standard: Other environmental considerations. The building housing the physical therapy office is accessible to, and functional for, patients, personnel, and the public. Written effective procedures in aseptic techniques are followed by all personnel and the procedures are reviewed annually, and when necessary, revised.

(d) The physical therapist is alert to the possibility of fire and other nonmedical emergencies and has written plans that include—

(1) The means for leaving the office and the building safely, demonstrated, for example, by fire exit signs; and

(2) Other provisions necessary to ensure the safety of patients.

42 CFR Ch. IV (10-1-98 Edition)
§ 486.302 Definitions.

As used in this subpart, the following definitions apply:

Certification or recertification means a HCFA determination that an entity meets the standards for a qualified OPO at § 486.304 of this subpart and is eligible for designation if it meets the additional conditions for designation at §§ 486.306 and 486.308. No payment ensues from certification alone.

Designation or redesignation means HCFA approval of an OPO for Medicare and Medicaid payment purposes under section 1138(b)(1)(F) of the Act. The terms are used interchangeably except when otherwise specifically indicated.

Entire standard metropolitan statistical area means a metropolitan statistical area, a consolidated metropolitan statistical area, or a primary statistical area listed in the State and Metropolitan Area Data Book published by the U.S. Bureau of the Census.

Open area means a service area for which HCFA has notified the public that it is accepting applications for designation.

Organ means a human kidney, liver, heart, lung, or pancreas.

Organ procurement organization means an organization that performs or coordinates the performance of retrieving, preserving and transporting organs and maintains a system of locating prospective recipients for available organs.

Potential donor means a person who dies in circumstances (causes and conditions of death, and age at death) that are generally acceptable for donation of at least one solid organ if the donor can be identified timely and permission for donation can be obtained.

Service area means a geographical area of sufficient size to assure maximum effectiveness in the procurement and equitable distribution of organs and that, either includes an entire standard metropolitan statistical area or does not include any part of such an area and that meets the standards of this subpart.

Transplant center means a hospital certified by Medicare to furnish directly, for a specific organ(s), transplant and other medical and surgical specialty services required for the care of transplant patients.

§ 486.304 General requirements.

(a) Designation—A condition for payment. Payment may be made under the Medicare and Medicaid programs for organ procurement costs attributable to payments made by an OPO only if the organization has been designated by the Secretary as an OPO, payment to which may be treated as organ procurement costs for reimbursement of hospitals under Medicare and Medicaid.

(b) Requirements for designated status.

To be the designated OPO for a service area, an entity must do the following:

(1) Submit to HCFA a written application for designation, using the application form prescribed by HCFA.

(2) Be certified as a qualified OPO.

(3) Participate in the Organ Procurement and Transplantation Network as specified in § 486.308.

(4) Enter into an agreement with HCFA that meets the requirements set forth in paragraph (c) of this section.

(5) Upon its initial designation, meet the requirements at § 486.310(a)(3) or § 486.310(b)(4), as appropriate, concerning working relationships with hospitals or transplant centers. During the initial designation period, the OPO is not required to demonstrate compliance with §§ 486.310(a)(1) and (a)(2) or §§ 486.310(b)(1), which set forth performance standards for OPDs.

(6) To be redesignated after an initial designation period, comply with all the requirements of this subpart, including those at § 486.310, which set forth performance standards for OPOs.

(7) Obtain HCFA approval before entering into any change of ownership, merger, consolidation, or change in its service area (see § 486.318, which sets forth requirements concerning approval for changes in ownership and...
(8) Enter into a working relationship with any hospitals, including transplant centers, in the OPO's service area that request a working relationship.

c) Agreement with HCFA. An OPO must enter into an agreement with HCFA. The agreement is effective upon submission by the OPO and acceptance by HCFA, but may be terminated by either party. If an OPO agreement is terminated, payment for organ procurement services attributable to that OPO will not be made for services furnished on or after the effective date of termination. In the agreement, the OPO must agree to do the following:

(1) Maintain compliance with the requirements of titles XVIII and XIX of the Act, section 1138 of the Act, and applicable regulations, including the conditions set forth in this subpart, and the regulations of the OPTN approved and issued by the Secretary, and to report promptly to the Secretary any failure to do so.

(2) File a cost report in accordance with §413.24(f) of this chapter within 3 months after the end of each fiscal year.

(3) Permit HCFA to designate an intermediary to determine the interim payment rate payable to the transplant hospitals for services provided by the OPO and to make a determination of reasonable cost based on the cost report it files.

(4) Provide budget or cost projection information as may be required to establish an initial interim payment rate.

(5) Pay to HCFA amounts that have been paid by HCFA to transplant hospitals as Medicare payment for organ recovery fees and that are determined to be in excess of the reasonable cost of the services provided by the OPO.

(6) Not charge an individual for items or services for which that individual is entitled to have payment made under the Medicare program.

(7) Maintain and make available to HCFA, the Comptroller General, or their designee data that show the number of organs procured and transplanted.

(8) Maintain data in a format that can be readily continued by a successor OPO and turn over to HCFA copies of all records, data, and software necessary to ensure uninterrupted service by a successor OPO that may be designated for all or part of its service area. Records and data subject to this requirement include records on individual donors (including identifying data and data on organs retrieved), records on transplant candidates (including identifying data and data on immune system and other medical indications), and procedural manuals and other materials used in conducting OPO operations. Donor records must include at least information identifying the donor (for example, name, address, date of birth, social security number), the organs and tissues (when applicable) retrieved, date of the organ retrieval, and test results.

d) When OPOs may apply for designation. Entities may apply for designation whenever a service area becomes an open area.

e) Designation periods—

(1) General. An OPO is normally designated for 2 years. A designation period may not exceed 2 years but may be shorter.

(2) Redesignation. Redesignation must occur at least every 2 years and be completed before the end of an existing designation period.

(3) Interim designation. HCFA may designate an organization for an interim designation period if the period is needed in order for HCFA to make a final designation determination.

(i) The interim designee may be either the OPO previously designated for the service area or another organization.

(ii) The interim designation period does not exceed 180 days after the normal designation period has expired.

(iii) The interim designee must meet all requirements of section 371(b) of the Public Health Service Act (42 U.S.C. 273(b)) regarding qualified OPOs and must not be out of compliance with the requirements of section 1138(b)(1) (B) through (E) of the Act regarding requirements for payment of organ procurement costs under title XVIII or title XIX of the Act.

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§ 486.306 Qualifications for designation as an OPO.

To be designated as the OPO for a service area, an organization must, at the time of application and throughout the period of its designation, meet the following requirements:

(a) Be a nonprofit entity that is exempt from Federal income taxation under section 501 of the Internal Revenue Code of 1986.

(b) Have accounting and other fiscal procedures necessary to assure the fiscal stability of the organization, including procedures to obtain payment for kidneys and non-renal organs provided to transplant centers.

(c) Have an agreement with the Secretary to be reimbursed under Medicare for the procurement of covered organs.

(d) Document that it has a defined service area that meets the requirements of § 486.307.

(e) Have a director and such other staff, including an organ donation coordinator and an organ procurement specialist, necessary to obtain organs effectively from donors in its service area.

(f) Have a board of directors or an advisory board that has the authority to recommend policies relating to the donation, procurement, and distribution of organs. While an OPO may have more than one board, the members specified in paragraphs (f)(1) through (f)(5) of this section must be members of a single board. The board of directors or advisory board must be composed of the following:

(1) Members who represent hospital administrators, tissue banks, voluntary health associations in its service area and either intensive care or emergency room personnel.

(2) Members who represent the public residing in that area.

(3) A physician with knowledge, experience, or skill in the field of human histocompatibility, or an individual with a doctorate degree in a biological science and with knowledge, experience, or skills in the field of human histocompatibility.

(4) A neurosurgeon or another physician with knowledge or skills in the field of neurology.

(5) A transplant surgeon from each transplant center in its service area with which the OPO has arrangements to coordinate its activities.

(g) To identify potential organ donors, have documented evidence that—

(1) It has a working relationship with at least 75 percent of the hospitals that participate in the Medicare and Medicaid programs in its service area and that have an operating room and the equipment and personnel for retrieving organs; and

(2) It conducts systematic efforts intended to acquire all usable organs from potential donors.

(h) Arrange for the appropriate tissue typing of donated organs.

(i) Have a system to equitably allocate donated organs among transplant patients that is consistent with—

(1) “Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs” issued by the Centers for Disease Control and Prevention (CDC) that are appended to this subpart; and

(2) Rules of the Organ Procurement and Transplantation Network (OPTN), see § 486.308.

(j) Provide or arrange for the transportation of donated organs to transplant centers.

(k) Have arrangements to coordinate its activities with transplant centers in the area.

(l) Have arrangements to cooperate with tissue banks for the retrieval, processing, preservation, storage and distribution of tissues as may be appropriate to assure that all usable tissues are obtained from potential donors.

(m) Maintain and make available upon request of the Secretary, the Comptroller General, or their designees data that relate to the performance standards.

(n) Maintain data in a format that can be readily used by a successor OPO and agree to turn over to the Secretary copies of all records and data necessary to assure uninterrupted service by a successor OPO newly designated by HCFA.

(o) Have a procedure for ensuring the confidentiality of patient records. Information from or copies of records
may be released only to authorized individuals and the OPO must ensure that unauthorized individuals cannot gain access to or alter patient records. Original medical records may be released by the OPO only in accordance with Federal or State laws, court orders, or subpoenas.

(p) Conduct and participate in professional education concerning organ procurement.

(q) Ensure that appropriate donor screening and infection tests, consistent with OPTN standards and the CDC guidelines that are appended to this subpart, are performed by a laboratory that is certified in the appropriate specialty or subspecialty of service in accordance with part 493 of this chapter, including tests to prevent the acquisition of organs that are infected with the etiologic agent for acquired immunodeficiency syndrome.

(r) Assist hospitals in establishing and implementing protocols for making routine inquiries about organ donation by potential donors.

(s) Ensure that donors are tested for human immunodeficiency viral markers consistent with OPTN rules and the CDC guidelines appended to this subpart for solid organ donation.

(t) Submit accurate data to HCFA within 15 days following the end of a calendar year (unless otherwise notified) giving information on the following:

(1) Population of designated service area based on the most recent U.S. Bureau of the Census data.
(2) Number of actual donors.
(3) Number of kidneys procured.
(4) Number of kidneys transplanted.
(5) Number of extrarenal organs by type procured.
(6) Number of extrarenal organs by type transplanted.


§ 486.307 OPO service area size designation and documentation requirements.

(a) General documentation requirement. An OPO must make available to HCFA documentation verifying that the OPO meets the requirements of paragraphs (b) through (d) of this section at the time of application and throughout the period of its designation.

(b) Boundary designation. The defined service area either includes an entire Metropolitan Statistical Area or a New England County Metropolitan Area as specified by the Director of the Office of Management and Budget or does not include any part of such an area.

(c) Service area location and characteristics. An OPO must precisely define and document a proposed service area’s location through the following information:

(1) The names of counties (or parishes in Louisiana) served or, if the service area includes an entire State, the name of the State.
(2) Geographic boundaries of the service area for which U.S. population statistics are available.
(3) Total population in service area.
(4) The number of and the names of acute care hospitals in the service area with an operating room and the equipment and personnel to retrieve organs.

(d) Sufficient size requirements. (1) Before January 1, 1996, an OPO must demonstrate that it can procure organs from at least 50 potential donors per calendar year or that its service area comprises an entire State.

(2) Beginning January 1, 1996, an OPO must meet at least one of the following requirements:

(i) Its service area must include an entire State or official U.S. territory.

(ii) It must either procure organs from an average of at least 24 donors per calendar year in the 2 years before the year of redesignation or request and be granted an exception to this requirement under paragraph (d)(3) or (d)(4) of this section.

(iii) In the case of an OPO operating exclusively in a noncontiguous U.S. State, a U.S. territory, or a U.S. commonwealth, such as Hawaii or Puerto Rico, it must procure organs at the rate of 50 percent of the national average of all OPOs for kidney procurement per million population and for kidney transplantation per million population.

(iv) If it is an entity that has not been previously designated as an OPO,
it must demonstrate that it can procure organs from at least 50 potential donors per calendar year.

(3) HCFA may grant an OPO an exception to paragraph (d)(2)(ii) of this section if the OPO can demonstrate that—

(i) It failed to meet the requirement because of unusual circumstances beyond its control;
(ii) It has historically maintained a service area of sufficient size to meet the criterion in paragraph (d)(2)(ii) of this section; and
(iii) It has a specific plan to meet the service area size criterion in paragraph (d)(2)(ii) of this section in the future.

(4) During the 1996 redesignation process only, HCFA may grant an exception to paragraph (d)(2)(ii) of this section to an OPO that can demonstrate that—

(i) It meets the performance criteria in §486.310(b); and
(ii) It has a specific plan to meet the service area size criterion in paragraph (d)(2)(ii) of this section by the 1998 redesignation period.

§ 486.308 Condition: Participation in organ procurement and transplantation network.

In order to be designated as the OPO for its service area, and to continue to be the designated OPO once designated, an OPO must be a member of, have a written agreement with, and abide by the rules of the OPTN established and operated in accordance with section 372 of the Public Health Service (PHS) Act (42 U.S.C. 274). The term “rules of the OPTN” means those rules provided for in regulations issued by the Secretary in accordance with section 372 of the PHS Act. No OPO is considered to be out of compliance with section 1138(b)(1)(D) of the Act or this section unless the Secretary has given the OPTN formal notice that he or she approves the decision to exclude the entity from the OPTN and also has notified the entity in writing.

§ 486.310 Condition: Adherence to performance standards.

(a) Standards before January 1, 1996. Before January 1, 1996, OPOs must meet the following performance standards:

(1) Each OPO must procure within its service area a minimum ratio of 23 cadaveric kidneys per million population of its service area for each 12-month period surveyed.

(2) Each OPO must provide a minimum ratio of cadaveric kidneys procured in its service area and transplanted (either locally or exported and transplanted) of 19 cadaveric kidneys per million population of its service area for each 12-month period surveyed.

(b) Standards beginning on January 1, 1996. Except as specified in paragraph (c) of this section, each OPO must achieve at least 75 percent of the national mean for four of the following five performance categories, averaged over the 2 calendar years before the year of redesignation:

(1) Number of actual donors per million population.

(2) Number of kidneys recovered per million population.

(3) Number of extrarenal organs recovered per million population.

(4) Number of kidneys transplanted per million population.

(5) Number of extrarenal organs transplanted per million population.

(c) Exceptions and exemptions—(1) Exception based on location. OPOs operating exclusively in a noncontiguous U.S. State, a U.S. territory, or a U.S. commonwealth, such as Hawaii or Puerto Rico, may be granted an exception from the performance standards of paragraph (b) of this section because of special geographically related characteristics, such as difficulty in transporting organs to the mainland, that impede satisfaction of the national rate of organ procurement. They must meet a standard of 50 percent of the national average of all OPOs for kidneys recovered and transplanted per million population.

(2) Exception because of lack of competition for a service area. HCFA may continue to designate an OPO that does not meet the standards under paragraph (b) of this section for a service area.
§ 486.314 Effect of failure to meet requirements.

Failure to continue to meet any of the requirements in §§ 486.306 and 486.308 or to meet the performance standards in § 486.310 may result in termination of the OPO's agreement with HCFA.


§ 486.316 Designation of one OPO for each service area.

(a) HCFA designates only one OPO per service area. Applications for designation are accepted only during a period when the service area is an open area. A service area is open for competition once the existing designation period has expired, when the existing designated status of the OPO for that service area has been terminated, or when no OPO has been designated for the area. HCFA may also declare the service area open in the event an OPO ceases to operate or HCFA has reasonable ground for anticipating it will cease to operate. In cases of urgent need (such as evidence of medically or ethically unsound practices), HCFA may terminate its agreement with an OPO immediately. The service area remains open until an OPO is designated for it. If more than one organization applies and substantially meets the requirements of § 486.306 in a given service area, HCFA considers other factors in reaching a decision concerning which organization to designate. These factors follow:

(1) Prior performance, including the previous year’s experience in terms of the number of organs retrieved and wasted and the average cost per organ;
(2) Actual number of donors compared to the number of potential donors;
(3) The nature of relationships and degree of involvement with hospitals in the organization's service area;
(4) Bed capacity associated with the hospitals with which the organizations have a working relationship;
(5) Willingness and ability to place organs within the service area; and
(6) Proximity of the organization to the donor hospitals.
(b) An organization that applies to HCFA to be the designated OPO for its service area and that is not designated may appeal its nondesignation under part 498 of this chapter.

(c) After January 1, 1996, a hospital must enter into an agreement only with the OPO designated to serve the area in which the hospital is located unless HCFA has granted the hospital a waiver under paragraphs (d) through (g) of this section to be serviced by another OPO.

(d) If HCFA changes the OPO designated for an area, hospitals located in that area must enter into agreements with the newly designated OPO or submit a request for a waiver in accordance with paragraph (e) of this section within 30 days of notice of the change in designation.

(e) A hospital may request and HCFA may grant a waiver permitting the hospital to have an agreement with a designated OPO other than the OPO designated for the service area in which the hospital is located. To qualify for a waiver, the hospital must submit data to HCFA establishing that—

1. The waiver is expected to increase organ donations; and
2. The waiver will ensure equitable treatment of patients referred for transplants within the service area served by the hospital's designated OPO and within the service area served by the OPO with which the hospital seeks to enter into an agreement.

(f) In making a determination on waiver requests, HCFA considers:

1. Cost effectiveness;
2. Improvements in quality;
3. Changes in a hospital's designated OPO due to changes in the metropolitan service area designations, if applicable; and
4. The length and continuity of a hospital's relationship with an OPO other than the hospital's designated OPO.

(g) A hospital may continue to operate under its existing agreement with an out-of-area OPO while HCFA is processing the waiver request. If a waiver request is denied, a hospital must enter into an agreement with the designated OPO within 30 days of notification of the final determination.

§ 486.318 Changes in ownership or service area.

(a) OPO requirements. (1) A designated OPO considering a change in ownership or in its service area must notify HCFA before putting it into effect. This notification is required to ensure that the entity, as changed, will continue to satisfy Medicare and Medicaid requirements. A change in ownership takes place if there is the merger of one entity into another or the consolidation of one entity with another.

(2) A designated OPO considering a change in its service area must obtain prior HCFA approval. In the case of a service area change that results from a change of ownership due to merger or consolidation, the entities must submit anew the information required in an application for designation, or other written documentation HCFA determines to be necessary for designation.

(b) HCFA requirements. (1) If HCFA finds that the entity has changed to such an extent that it no longer satisfies the prerequisites for OPO designation, HCFA may terminate the OPO's agreement and declare the OPO's service area to be an open area.

(2) If HCFA finds that the changed entity continues to satisfy the prerequisites for OPO designation, the period of designation of the changed entity is the remaining designation term of the OPO that was reorganized. If more than one designated OPO is involved in the reorganization, the remaining designation term is ordinarily the longest of the remaining periods. HCFA may determine, however, that a shorter period applies if it decides that a shorter period is in the best interest of the Medicare and Medicaid programs. The performance standards of §486.310 apply at the end of this remaining period.
§ 486.325 Terminations of agreement with HCFA.

(a) Types—(1) Voluntary termination. If an OPO wishes to terminate its agreement, it must send written notice of its intention with the proposed effective date to HCFA. HCFA may approve the proposed date, set a different date no later than 6 months after the proposed effective date, or set a date less than 6 months after the proposed date if it determines that it would not disrupt services to the service area or otherwise interfere with the effective and efficient administration of the Medicare and Medicaid programs. If HCFA determines that a designated OPO has ceased to furnish organ procurement services to its service area, the cessation of services is deemed to constitute a voluntary termination by the OPO, effective on a date determined by HCFA.

(2) Involuntary termination. HCFA may terminate an agreement if it finds that an OPO no longer meets the conditions for coverage in this subpart, or is not in substantial compliance with any other applicable Federal regulations or provisions of titles XI, XVIII, or title XIX of the Act. HCFA may also terminate an agreement immediately in cases of urgent need, such as the discovery of unsound medical practices.

(b) Notice to OPO. HCFA gives notice of termination to an OPO at least 90 days before the effective date stated in the notice.

(c) Appeal right. The OPO may appeal the termination in accordance with the provisions set forth in part 498, which sets forth appeals procedures for determinations that affect participation in the Medicare and Medicaid programs.

(d) Effects of termination. When an OPO agreement is terminated—

(1) Medicare and Medicaid payments may not be made for organ procurement services the OPO furnishes on or after the effective date of termination; and

(2) HCFA will accept applications from any entity to be the designated OPO for that area.

(e) Public notice. In the case of voluntary termination, the OPO must give prompt public notice of the date of termination, and such information regarding the effect of that termination as HCFA may require, through publication in local newspapers in the service area. In the case of involuntary termination, HCFA gives notice of the date of termination.

(f) Reinstatement. HCFA may, at its discretion, designate an OPO whose agreement was previously terminated if HCFA finds that the cause for termination has been removed, is satisfied that it is not likely to recur, has not designated another OPO for the service area, and finds that the OPO meets all the necessary requirements for designation.

Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs

Summary

Although previous recommendations for preventing transmission of human immunodeficiency virus (HIV) through transplantation of human tissue and organs have markedly reduced the risk for this type of transmission, a case of HIV transmission from a screened, antibody-negative donor to several recipients raised questions about the need for additional federal oversight of transplantation of organs and tissues. A working group formed by the Public Health Service (PHS) in 1991 to address these issues concluded that further recommendations should be made to reduce the already low risk of HIV transmission by transplantation of organs and tissues. In revising these recommendations, the PHS sought assistance from public and private health professionals and representatives of transplant, public health, and other organizations. The revised guidelines address issues such as donor screening, testing, and exclusionary criteria; quarantine of tissue from living donors; inactivation or elimination of infectious organisms in organs and tissues before transplantation; timely detection, reporting, and tracking of potentially infected tissues, organs, and recipients; and recall of stored tissues from donors found after donation to have been infected. Factors considered in the development of these guidelines include differences between the screening of living and cadaveric donors; time constraints due to organ/tissue viability that may preclude performing certain screening procedures; differences in the risk of HIV transmission from various organs and tissues; differences between systems for procuring and distributing organs and tissues; the effect of screening practices on the limited availability of organs and some tissues; and the benefit of the transplant to the recipient.

INTRODUCTION

Exclusion of prospective blood donors based on their acknowledged risk behaviors for human immunodeficiency virus (HIV) infection began in 1983 (1). In 1985, when tests for HIV antibody became available, screening prospective donors of blood, organs, and other tissues also began (2,3). Both measures have reduced markedly the transmission of HIV via these routes.

A 1991 investigation determined that several recipients had been infected with HIV by an organ/tissue donor who had tested negative for HIV antibody at the time of donation (4). This occurrence raised questions about the need for additional federal oversight of transplantation of organs and tissues. To address these questions, the Public Health Service (PHS) formed a working group comprising representatives from several federal agencies. The working group concluded that, although existing recommendations are largely sufficient, revisions should be made to reduce the already low risk of HIV transmission via transplantation of organs and tissues. Adequate federal
regulations, recommendations, and guidelines for blood and plasma are already established and are not addressed in this document.

Those developing guidelines for other organs and tissues should consider donor screening and testing; quarantine of tissue from living donors; inactivation or elimination of infectious organisms in organs and tissues before transplantation; timely detection, reporting, and tracking of potentially infected organs, tissues, and recipients; and recall of stored tissue from donors found after donation to have been infected.

These guidelines apply largely to donation and transplantation of organs and solid tissues. Although they also apply generally to donation of human milk and semen, some modifications may be needed because donors of human milk and semen are living and often donate repeatedly. Additionally, donor milk should be pasteurized (a heating procedure that inactivates HIV) before dispensing. This document can serve as a general guide to facilities that bank breast milk or semen and should be followed where feasible.

In revising these recommendations for transplantation of organs and tissues, PHS sought assistance from public and private health professionals and representatives of transplant, public health, and other organizations (see pages iii-v). These guidelines do not supersede existing state laws but are to be implemented in accordance with existing statutes.

BACKGROUND

Epidemiology of HIV Infection in Recipients of Organs and Tissues

Most transmission of HIV to organ/tissue recipients occurred before 1985, before the implementation of donor screening. In addition to HIV transmission through blood and blood products, reports of HIV infection following transplantation have implicated the kidney, liver, heart, pancreas, bone, and possibly skin as sources of infection (4). HIV has also been transmitted from infected semen during artificial insemination (5). Several studies and case reports indicate that HIV can be transmitted through breast milk from HIV-infected women to their children (6,7); these investigations include several prospective studies indicating that breast-fed infants are at greater risk of acquiring HIV from their infected mothers than are bottle-fed infants (8,9).

Reports of transmission from screened, HIV-antibody-negative donors of organs or tissues have been rare. In one instance, hemodilution from multiple transfusions given to the organ/tissue donor before collection of the blood sample resulted in an HIV-antibody test result that was initially false negative (10). Serum samples taken on admission, before the transfusions, and 2 days after the transfusions later tested positive for antibody to HIV. In another instance, a kidney donor tested HIV-antibody negative 8 months before donation but seroconverted between the time of testing and donation (11). The donor was not retested at the time of donation. In a third instance, an organ from an HIV-infected donor was transplanted under emergency conditions before results of the HIV-antibody test were known (12).

A fourth case involved transmission from an organ/tissue donor whose HIV-antibody test was negative at the time of donation (4). Most likely, the donation occurred sometime between infection and antibody seroconversion, which, for most
infected persons, ranges from 4 weeks to 6 months (13). Six years after the donor's
death and ensuing donation, HIV infection in the stored donor material was confirmed
by virus culture and polymerase chain reaction (PCR) of stored donor lymphocytes
(4). Among the 41 recipients identified and tested, those who received the solid
organs and unprocessed, fresh-frozen bone acquired HIV infection from the allografts
(one recipient of a heart, two recipients of kidneys, one recipient of a liver, and three
recipients of fresh-frozen bone). The recipients of other processed bone and relatively
avascular soft tissue (fascia lata, tendons, ligaments, dura mater, and corneas) did not
become HIV infected (4).

Current Use of Organ and Tissue Transplants

The number of transplants has grown considerably over the last several years, a
phenomenon attributable to many factors, including the availability of improved im-
munosuppressant drugs. Approximately 66 Organ Procurement Organizations (OPOs)
and 260 organ transplant centers are members of the Organ Procurement and Trans-
plantation Network (OPTN). In 1990 these centers recovered approximately 15,000
organs (e.g., kidney, liver, heart, lung, and pancreas) from 4,500 donors.

OPOs and tissue banks also recovered tissues (other than the organs listed above)
from an estimated 7,500–10,000 donors in 1990. These tissues were used in approxi-
ately 250,000–300,000 (mostly bone) allografts.

In 1990, member banks of the Eye Bank Association of America (EBAA) retrieved
ocular tissue from more than 40,000 donors. These tissues are used for corneal trans-
plantation and are also processed into epikeratophakia lenticules (EBAA Statistical

More than 400 establishments either bank or commercially process one or more
human tissues. Approximately 100 eye banks and 125 bone banks operate in the
United States (although the number of hospitals that store bone for future transplan-
tation is difficult to estimate). Also, several hospitals may retrieve and store bone from
living donors. Seven human milk banks operating in the United States process donor
breast milk.

The American Fertility Society is aware of approximately 100 semen banks in the
United States. Slightly fewer than half of artificial inseminations performed in the
United States involve unrelated-donor semen used to inseminate approximately
75,000 women per year. In addition to these 100 semen banks, an undetermined num-
ber of smaller banks are hospital based or located in the offices of individual
physicians.

The National Heart, Lung, and Blood Institute (NHLBI) within the National Institutes
of Health (NIH) is aware of 99 bone marrow transplant centers, of which 41 participate
in programs involving bone marrow transplants from unrelated donors. Many addi-
tional facilities are equipped to obtain marrow from donors. About 2,200 bone marrow
transplants involving allogeneic marrow took place in the United States in 1991. Of
those, approximately 435 were provided by donors who were not related to the recipi-
ents. Peripheral blood stem cells are being used for autologous transplantation and, in
the future, may be useful for allogeneic use. Furthermore, cord blood stem cells are
being used for both related- and unrelated-donor allogeneic transplantation.
Current Guidelines and Recommendations

Procedures for procurement and transplantation of organs and tissues are addressed by a) federal laws, regulations, and guidelines; b) state laws and regulations; and c) voluntary industry standards. Several federal agencies either directly or indirectly regulate procurement and transplantation of organs and tissues. These activities range from the publication of guidelines that address the transmission of communicable diseases through transplantation to regulatory requirements for registration and premarket product licensure or approval (blood and certain other tissue products).

The Health Resources and Services Administration (HRSA), through the United Network for Organ Sharing (UNOS), administers the contract for OPTN as required by Section 372 of the Public Health Service Act and as amended (42 USC 274). The contract covers specified solid organs (kidney, liver, heart, lung, and pancreas) but does not cover corneas, eyes, or other tissues. Technically, all UNOS policies are voluntary; however, HRSA is currently developing regulations dealing with OPTN membership and operation.

Under a separate contract with HRSA, UNOS maintains a Scientific Registry for Transplant Recipients that includes information on all solid-organ transplant recipients (since October 1, 1987) from the date of transplantation until failure of the graft or death of the patient. In addition, HRSA informally conveys recommendations to organizations involved in procurement and transplantation of organs. Through OPTN and the Scientific Registry for Transplant Recipients, HRSA has the capacity to link organ donors and their recipients.

FDA regulates a limited number of specific tissues as either "biological products" or "medical devices." Examples of tissues include blood, dura mater, corneal lenticules, umbilical veins, nonautologous cultured skin, and heart valves. In addition, FDA has recently published regulations regarding behavioral screening and infectious disease testing (HIV-1, HIV-2, hepatitis B virus, and hepatitis C virus) for donors of human tissue for transplantation (14). FDA also regulates certain agents and devices for processing bone marrow, although bone marrow transplants from unrelated donors are under the auspices of NHLBI.

NHLBI manages the federal contract for the National Marrow Donor Program. Two bone marrow donor registries currently exist: one independent registry and one registry managed through the NHLBI contractor. Each registry group has voluntary guidelines/standards that resemble blood-banking standards. Although federal regulations have not yet been promulgated, the current practice of bone marrow acquisition and transplantation includes procedures to reduce the risk of HIV transmission. NHLBI is preparing regulations that will set forth criteria, standards, and procedures for entities involved in bone marrow collection, processing, and transplantation. These entities include the National Marrow Donor Registry, individual donor centers, donor registries, marrow-collection centers, and marrow-transplant centers. The regulations will include donor-selection criteria to prevent the transmission of infectious diseases, including HIV infection.

Donor Screening

PHS has made recommendations for preventing HIV transmission through organ/tissue transplantation and artificial insemination (1-3,15,16). These
recommendations include screening for behaviors that are associated with acquisition of HIV infection, a physical examination for signs and symptoms related to HIV infection, and laboratory screening for antibody to HIV.

PHS has made no specific recommendations for donation and banking of human milk, although HIV-infected women in the United States are advised to avoid breastfeeding their infants because of the risk of HIV transmission through breast milk (17). The Human Milk Banking Association of North America has issued guidelines for the establishment and operation of human milk banks (18). These guidelines state that all human milk donors should be screened according to the American Association of Blood Banks' standards for screening blood donors. All milk accepted for donation should be pasteurized unless the recipient's condition requires fresh-frozen milk, in which case the milk bank director should consult with the medical director and advisory board to approve the dispensing of microbiologically screened, fresh-frozen milk from suitable donors.

Since March 1985, the FDA has licensed a number of screening and supplemental tests for detection and confirmation of HIV antibody. All these tests are intended for use on either fresh or freezer-stored samples of serum or plasma. The FDA has not required manufacturers to submit data showing that HIV-1 antigen and antibody-detection kits produce accurate results when applied to postmortem blood samples. Postmortem blood samples are often hemolyzed, which may affect the specificity of screening assays for HIV antibody (19,20).

The screening tests include enzyme immunoassays (EIAs), several of which are also approved for testing blood spots dried onto a specific filter paper, which may provide a method for storing samples. Rapid screening assays for HIV antibody that use a latex-agglutination or EIA (microparticle-based) format have also been approved for screening serum, plasma, or whole blood. A licensed EIA for detecting antibodies to HIV-2 is also commercially available, as are "combination tests" that simultaneously detect antibodies to HIV-1 and HIV-2 (21). FDA has also licensed one manufacturer to make and distribute a test for detection of HIV-1 p24 antigen for patient diagnosis and prognosis of HIV infection but not for screening blood donors.

Western blot tests and an immunofluorescence assay for HIV-1 are approved for supplemental, more specific testing of serum, plasma, and whole-blood samples found reactive by HIV-1 antibody screening tests. No additional, more specific test is approved that confirms either antibodies to HIV-2 (21) or eluted, dried blood-spot results. The licensed p24-antigen test includes a neutralization procedure that is to be used for specific testing of samples with repeatedly reactive test results. Federal regulations already require that all donations of blood, blood components, and plasma intended for further processing into injectable products ("source plasma") be screened with a licensed test that detects HIV antibody. Since June 1992, PHS has also required that all blood and plasma donations be screened for HIV-2 antibody.

PHS has not recommended the use of the licensed HIV-1 p24-antigen assay for screening donated blood or source plasma, nor has the kit been approved for use in donor screening. This position is based on findings from several studies indicating that a blood donor with a positive test for antigen and a negative test for antibody is rare (22,23). Such rarity is probably attributable to the effectiveness of the donor-qualification procedures, including donor education, voluntary exclusion, and
antibody testing that together operate to prevent donation by persons at increased risk for HIV infection.

Limited studies have been conducted to examine the use of the p24-antigen assay to screen organ/tissue donors (19,20,24). Among approximately 1,000 samples from HIV-1 antibody-negative donors, no donors had detectable HIV-1 p24 antigen.

**Recipient Screening**

Until recently, PHS had made no recommendations regarding routine testing of recipients of organs, tissues, semen, or donated human milk. However, in response to the July 18, 1991, report of the PHS Workgroup on Organ and Tissue Transplantation, HRSA asked UNOS to request that transplant centers implement an interim voluntary HIV-testing policy for organ recipients. HRSA has requested that recipients be tested for HIV-1 antibody immediately before transplantation and at 3, 6, and 12 months after transplantation. If HIV infection is diagnosed in an organ recipient, the results of the HIV test are reported by the transplant center to the Scientific Registry for Transplant Recipients and to the procuring OPO, in accordance with existing state laws. No comparable registry exists for recipients of tissues, semen, or donated human milk. However, the National Marrow Donor Program routinely tracks both donors and recipients of bone marrow for unrelated-donor transplants. This program reports no known seroconversions among either donors or recipients, although recipients are not routinely screened for HIV.

Routine testing of recipients after transplantation has several potential benefits. First, early identification of HIV infection in a recipient allows for early intervention before signs and symptoms develop. Both antiviral therapy to prevent progression to acquired immunodeficiency syndrome (AIDS) (25) and prophylactic therapy to prevent opportunistic infections (26,27) have been recommended for HIV-infected patients, based on CD4+ T-lymphocyte levels. Second, early identification of HIV infection in a transplant recipient allows for early intervention to prevent further transmission from the recipient to sex or needle-sharing partners and to future offspring (through vertical transmission from mother to infant). Third, early identification of HIV infection in a recipient potentially identifies an infectious donor. Should further investigation indicate that the donor is the source of the HIV infection in the recipient, other recipients of tissue from that same donor can be notified and stored tissue can be retrieved, preventing further transmission through transplantation.

Concern has been expressed that linking HIV infection in a transplant recipient to the transplantation may be difficult because many recipients may have also received blood or blood products or have other risk factors. However, identification of multiple HIV-infected recipients of tissue from the same donor strongly implicates the donor as the source of the HIV infection in the recipients. In addition, stored blood or lymphoid samples from the donor (when available) can be tested for the presence of virus to confirm the HIV-infection status of the donor (4).

Questions have been raised about whether transplant recipients who may be receiving immunosuppressive therapy to prevent rejection are capable of producing antibody against HIV if transmission occurs. Several reports now indicate that the HIV-antibody response is not delayed in transplant recipients receiving antirejection therapy, which primarily affects cellular immunity (4).
The additional costs of routine screening for HIV in recipients must be considered as well. The Institute of Medicine has estimated that laboratory costs are approximately $4 for a patient who tests negative and $35 for a patient who tests positive. (The latter cost includes the added expense of repeat EIAs and Western blot or other supplemental tests.) These costs may be underestimates, however. The time required for pretest and posttest counseling was estimated to be approximately 0.5–1.0 hour for an HIV-seronegative patient and 1.5–2.0 hours for an HIV-seropositive patient (28).

**Inactivation of HIV in Tissues**

Thorough donor screening is considered the most effective method for preventing HIV transmission through transplantation; however, the use of chemical or physical inactivating or sterilizing agents to reduce further the already low risk of transmission has been considered. If such agents are to be useful, they must either inactivate or eliminate the virus while maintaining the functional integrity of the tissue or organ.

No mechanism for inactivating virus in whole organs currently exists. However, several agents have been suggested as possible disinfectants for tissues such as bone fragments (4). Pasteurization has been shown to inactivate HIV in human milk without substantially compromising nutritional and immunologic characteristics (29).

Although some physical and chemical agents have been shown to reduce the likelihood of isolating virus from treated solid tissues, conclusive evidence that those processes render solid tissue completely safe yet structurally intact is lacking. In the recent case of an HIV-infected donor who was antibody negative (4), tissues that had been processed in a variety of ways did not transmit HIV. These tissues included a) lyophilized fascia lata, tendons, or ligaments; b) dura mater that was lyophilized and irradiated with 3.0–3.4 Mrad of gamma radiation through a cobalt-60 source; c) bone fragments that were treated with ethanol and lyophilized; and d) one sample of fresh-frozen long bone with the marrow elements evacuated (4). However, because most of these tissues were relatively avascular, it is unclear whether the absence of HIV transmission was due to processing, avascularity, or both.

**General Considerations**

In developing guidelines for preventing HIV transmission from organ/tissue donors to recipients, several factors were considered: a) differences between the screening of living, brain-dead, and cadaveric donors; b) time constraints due to organ/tissue viability that may preclude performing certain screening procedures; c) differences in the risk for HIV transmission from various organs and tissues; d) differences between systems in place for procuring and distributing organs and tissues; e) the effect of screening practices on the limited availability of organs and some tissues; and f) the benefit of the transplant to the recipient (i.e., some transplants are lifesaving, whereas others are life enhancing).

Living donors can be interviewed about potential high-risk behavior, whereas deceased donors cannot. In the case of brain-dead or cadaveric donors, family members and others may be unable to provide an accurate risk history. Therefore, exclusion of potentially infected brain-dead or cadaveric donors relies even more heavily on laboratory screening and physical examinations than on interviews regarding high-risk behavior.
Screening procedures that require more than 24 hours to complete may not be feasible for brain-dead or cadaveric donors of organs and certain tissues. Most tissues must be recovered and most organs must be recovered and transplanted shortly after cessation of circulatory function of the donor. Whereas some tissues can be stored for months, others must be transplanted within a few days after procurement. These time constraints may limit the ability to interview certain family members or significant life partners who are not nearby and may preclude the use of certain laboratory screening tests that cannot be performed within these time constraints.

The precise risk of HIV transmission from various tissues is not known, yet some organs and tissues clearly present a higher risk for HIV transmission than others (4). For example, studies indicate that the risk for transmission from an organ of an HIV-infected donor is nearly 100%. Fresh-frozen, unprocessed bone also appears to carry a high risk for transmission, particularly if marrow elements and adherent tissue are not removed. Relatively avascular solid tissue, some of which is also processed by using techniques that might inactivate HIV, appears to carry a lower risk for HIV transmission.

As noted earlier in these guidelines, there is considerable variability in the role of federal agencies regarding transplantation of organs and tissues and the procurement and distribution systems. Oversight for, existence of, and compliance with recommendations also vary between these systems. When organs and tissues are procured from a single donor, tracking systems must involve multiple distribution systems that may be difficult to link.

Donor-screening practices must also consider the already inadequate supply of most organs and tissues needed for transplantation. However, even though attempts should be made to ensure the highest level of safety, donor-screening practices should not unnecessarily exclude acceptable potential donors. Those involved in developing guidelines should consider that some transplants are lifesaving (e.g., a heart transplant), whereas others are life enhancing. Some physicians may be willing to offer the patient a transplant of a lifesaving organ from a donor whose HIV risk status is questionable but would not use life-enhancing tissue from such a donor.

RECOMMENDATIONS

Donor Screening

1. All prospective living donors or next of kin or significant life partners accompanying brain-dead or cadaveric donors should be informed of the general nature of the donor-evaluation process, including a review of medical and behavioral history, physical examination, and blood tests to exclude infectious agents that might be transmitted by organ or tissue transplant.

2. Prospective living donors or next of kin or significant life partners accompanying brain-dead or cadaveric donors should be informed about modes of transmission and risk factors for HIV infection, emphasizing that HIV can be transmitted via transplanted organs and tissues. They should be told that a negative test for HIV antibody does not guarantee that the donor is free of HIV infection because of the
rare situation of donation after infection but before seroconversion. Therefore, organs and tissue must not be transplanted from persons who may have engaged in activities that placed them at increased risk for HIV infection. This information should be presented in simple language to ensure that the donor, next of kin, or significant life partner understands what is considered high-risk behavior and the importance of excluding persons who have engaged in this behavior. Persons soliciting the donation should not place undue pressure to donate on potential living donors and those persons providing permission for potential brain-dead or cadaveric donors who might otherwise decline to donate or give permission because of high-risk behavior.

3. To ascertain risk factors, all prospective living donors should be interviewed in a confidential and sensitive manner by a health-care professional competent to elicit information about behaviors that place persons at risk for HIV infection. Interviewers should ask direct questions about high-risk behavior.

4. For potential pediatric donors for whom maternal transmission of HIV is a consideration, the mother and, if possible, the father should be interviewed about behaviors that may have placed them at risk for acquiring HIV infection that could have been transmitted to their child.

5. Except where retrieval occurs by legal authorization, the next of kin or significant life partner of brain-dead or cadaveric donors should be interviewed in a confidential and sensitive manner by a health-care professional regarding potential HIV risk factors in the donor. Other family members, friends, and sex partners may also need to be interviewed, if available. When consent for removal of organs/tissue is required, at least the person signing the consent form should be interviewed. Other possible sources of information about behavioral risk factors may include hospital, police, and coroner’s records, if available. When an interview is not performed, as allowed by legal authorization, the transplant surgeon should be fully informed that the donation was accepted, even though a direct interview with the next of kin or significant life partner was not performed.

6. If available, the medical records, including autopsy reports of all donors, should be reviewed for signs and symptoms associated with HIV infection and for evidence of high-risk behavior (e.g., male-to-male sexual contact, acquisition of sexually transmitted diseases, exchange of sex for money or drugs, injecting-drug use, or birth to a mother either at risk for or infected with HIV).

7. All prospective donors of organs, solid tissue, and semen should undergo a physical examination as close as possible before donation, with special attention to physical signs of HIV disease and injecting-drug use. The extent of the physical examination should be determined by the responsible medical officials according to the context of organ/tissue donation. Human milk banks should obtain a release from the primary health-care provider certifying that the prospective donor is in good health and does not constitute a risk to potential recipients.

8. As with donors of blood and plasma, prospective living organ, tissue, semen, and milk donors found after careful screening to be acceptable donors should sign
Donor Testing

1. For all prospective donors, a blood sample obtained before any transfusions were administered (during the current hospital admission for inpatients) should be collected as close to the time of retrieval of tissue as possible. Bone marrow donors must provide blood samples far enough in advance of marrow harvest to permit the tests to be performed and results reported before the recipient's preparative regimen (marrow ablation) is begun. Samples should be tested for antibodies to both HIV-1 and HIV-2 by using FDA-licensed tests. Separate tests or a combination test for HIV-1 and HIV-2 may be used. All antibody-screening tests should be performed by EIA unless the condition of the recipient or donor dictates the use of a more rapid screening assay.

2. Transfusions and infusion of other fluids to the prospective donor might produce false-negative results because of hemodilution. Efforts should be made to perform HIV-antibody testing on the most recent pretransfusion/infusion specimen for which identity and quality can be ensured. Specimens should not be drawn immediately downstream from an intravenous site to prevent dilution with intravenous fluids.

Posttransfusion/infusion specimens may be considered for testing after efforts to obtain a pretransfusion/infusion sample have been exhausted and posttransfusion/infusion samples have been assessed for evidence of dilution. The suitability of posttransfusion/infusion samples must consider a) the volume of the material transfused as a percentage of the patient's total blood volume and b) the amount of time between the last transfusion/infusion and the collection of the sample to be tested. An exchange of one total blood volume will reduce the concentration of an intravascular substance such as IgG to 35% of initial levels if there is no replacement from the extravascular space. More than 50% of total body IgG is extravascular, and reequilibration to normal levels of IgG should be nearly complete within 24 hours of a total blood volume exchange of albumin (30).
3. The HIV p24-antigen assay may identify a few of the rare donors who are HIV-infected, yet antibody-negative; however, studies examining the utility of this assay for screening organ/tissue donors are limited and currently do not allow a definitive recommendation on the use of this test (19, 24). The utility of other assays such as PCR, which are currently experimental, should be considered for evaluation as they become available for clinical use. Those institutions choosing to use the HIV-1 p24-antigen assay should be aware that in populations with low prevalence (e.g., organ/tissue donors), a large percentage of persons who test repeatedly reactive (without confirmation with the neutralization assay) will be false positive. Consideration should also be given to the potential problems with decreased specificity when the assay is used to test postmortem samples (19).

4. The testing algorithm for HIV-antibody assays should be performed as described in the package insert with an initial test and, if reactive, a retest on the same specimen. However, the time constraints of some situations may not accommodate the delay of repeat testing by EIA as described in the package insert. In such extreme cases of lifesaving organ transplantation, the sample should be set up in triplicate in the initial EIA. A repeatedly reactive result (positive screening test) is defined as reactivity above the test cutoff in two or more of the three assays. When testing by EIA is impractical, a more rapid licensed test should be performed in triplicate. Testing by the conventional algorithm should be performed as early as possible, even if it follows the procurement and/or transplant of the organs or tissues.

5. Results of HIV testing for organ/tissue donors should be handled confidentially, in accordance with general medical practices and applicable federal and state statutes, regulations, and guidelines.

6. Prospective living donors should be notified if they are found through the screening process to be HIV infected. Because of the possibility of sexual or parenteral transmission, the spouse or known sex partners of brain-dead or cadaveric donors should be notified in accordance with state law. All notifications should be handled in a manner congruent with current recommendations regarding counseling, testing, and partner notification (31, 32). Before the notification of these persons, transplant and procurement organizations should consult with their state health department concerning local notification policies.

    Also before notification, the repeatedly reactive screening assay should be confirmed with more specific supplemental tests. An aliquot of the original sample should be analyzed by using the following, more specific tests. For repeatedly reactive HIV-1 antibody EIAs, an HIV-1 Western blot or immunofluorescence assay should be performed. For repeatedly reactive HIV-1 antigen assays (if performed), a neutralization procedure must be performed. For HIV-2, no licensed supplemental test is available; however, consideration may be given to the use of research assays such as Western blot, immunofluorescence, radioimmune precipitation, and synthetic peptide-based EIA. Arrangements for HIV-2 supplemental testing may need to be made with either the state or local health department. For repeatedly reactive combination HIV-1 and HIV-2 assays, the published testing algorithm should be followed (21). When the results of any supplemental tests are unclear, the use of research assays should be considered.
Notification of HIV-infected prospective living donors or spouses/known sex partners of cadaveric donors should be done in accordance with state law and in a confidential and sensitive manner by staff competent in counseling and discussing positive HIV results and their implications. If such staff are not available in the organ/tissue procurement organization, arrangements should be made with other organizations such as health departments or clinics to provide appropriate notification.

7. When it is possible to properly obtain and store samples, one or more of the following samples from the donor should be saved for at least 5 years after the expiration date of the tissue: dried blood spots, a frozen buffy coat, spleen cells, lymph node cells, bone marrow, and an aliquot of serum. These samples can be examined if subsequent information indicates that the donor may have donated during the period after infection but before antibody seroconversion.

8. Confirmed positive HIV test results in a prospective organ/tissue donor should be reported to state health agencies if required by state law or regulation.

Donor Exclusion Criteria

Regardless of their HIV antibody test results, persons who meet any of the criteria listed below should be excluded from donation of organs or tissues unless the risk to the recipient of not performing the transplant is deemed to be greater than the risk of HIV transmission and disease (e.g., emergent, life-threatening illness requiring transplantation when no other organs/tissues are available and no other lifesaving therapies exist). In such a case, informed consent regarding the possibility of HIV transmission should be obtained from the recipient.

Behavior/History Exclusionary Criteria

1. Men who have had sex with another man in the preceding 5 years.

2. Persons who report nonmedical intravenous, intramuscular, or subcutaneous injection of drugs in the preceding 5 years.

3. Persons with hemophilia or related clotting disorders who have received human-derived clotting factor concentrates

4. Men and women who have engaged in sex in exchange for money or drugs in the preceding 5 years.

5. Persons who have had sex in the preceding 12 months with any person described in items 1–4 above or with a person known or suspected to have HIV infection.

6. Persons who have been exposed in the preceding 12 months to known or suspected HIV-infected blood through percutaneous inoculation or through contact with an open wound, nonintact skin, or mucous membrane.

7. Inmates of correctional systems. (This exclusion is to address issues such as difficulties with informed consent and increased prevalence of HIV in this population.)
Specific Exclusionary Criteria for Pediatric Donors

1. Children meeting any of the exclusionary criteria listed above for adults should not be accepted as donors.

2. Children born to mothers with HIV infection or mothers who meet the behavioral or laboratory exclusionary criteria for adult donors (regardless of their HIV status) should not be accepted as donors unless HIV infection can be definitely excluded in the child as follows:

   Children >18 months of age who are born to mothers with or at risk for HIV infection, who have not been breast fed within the last 12 months, and whose HIV antibody tests, physical examination, and review of medical records do not indicate evidence of HIV infection can be accepted as donors.

3. Children ≤18 months of age who are born to mothers with or at risk for HIV infection or who have been breast fed within the past 12 months should not be accepted as donors regardless of their HIV test results.

Laboratory and Other Medical Exclusionary Criteria

1. Persons who cannot be tested for HIV infection because of refusal, inadequate blood samples (e.g., hemodilution that could result in false-negative tests), or any other reasons.

2. Persons with a repeatedly reactive screening assay for HIV-1 or HIV-2 antibody regardless of the results of supplemental assays.

3. Persons whose history, physical examination, medical records, or autopsy reports reveal other evidence of HIV infection or high-risk behavior, such as a diagnosis of AIDS, unexplained weight loss, night sweats, blue or purple spots on the skin or mucous membranes typical of Kaposi's sarcoma, unexplained lymphadenopathy lasting >1 month, unexplained temperature >100.5 F (38.6 C) for >10 days, unexplained persistent cough and shortness of breath, opportunistic infections, unexplained persistent diarrhea, male-to-male sexual contact, sexually transmitted diseases, or needle tracks or other signs of parenteral drug abuse.

Inactivation of HIV in Organs/Tissues

Definitive recommendations cannot yet be made regarding inactivation of HIV in organs and tissues because of lack of information about potentially effective inactivation measures. Research should continue in this area. Efforts to evaluate the effect of certain processing techniques on tissue sterility and quality should be expanded to include virologic studies for HIV. Thus, until more is known, it is prudent to process bone and bone fragments and carefully evacuate all marrow components from whole bone whenever feasible.

Quarantine

For semen donations and, when possible, for tissue donations from living donors, the collection should be placed in frozen quarantine and the donor retested for
antibodies to HIV-1 and HIV-2 after 6 months (15). The quarantined material should be released only if the follow-up test results have been obtained and are negative.

**Record Keeping for Tracking of Recipients and Tissues**

1. Each establishment involved in the acquisition, processing, distribution, or storage of organs or tissues should have a graft identification system that allows the tracking of organs and tissues from the donor source to the recipient institution and vice versa. Furthermore, each establishment involved in the acquisition of organs or tissues from a single donor should have mechanisms in place to facilitate the communication between establishments for the purposes of tracking organs and tissues to recipients who should be notified if HIV transmission from donor source material is confirmed. Procurement, processing, distribution, and storage centers should keep accurate records of the distribution of each organ/tissue according to the donor identification number, tissue type and identifying number, and identifying information for the receiving center, along with dates of procurement and distribution. Records should be kept a minimum of 10 years after expiration of tissue.

2. The transplantation center, hospital, physician, or dentist should keep accurate records of all organs/tissues received and the disposition of each. These records must be separate from patients' medical records (e.g., in a log book) so that this information is easily obtainable should tracking be necessary. Recorded information should include the organ/tissue type; donor identification number; name of procurement or distribution center supplying the organ/tissue; recipient-identifying information: name of recipient's physician or dentist; and dates of a) receipt by the center and b) either transplantation to the recipient or further distribution.

3. The donor identification number and organ or tissue type should be recorded in the recipient's transplant/medical/dental record.

**Testing and Reporting of Recipients**

1. Health-care providers for transplant recipients and the recipients themselves should be aware of the small but potential risk of infections, including HIV, from transplanted organs and tissues. The recipient's informed consent to the transplant should include acknowledgment of the risks, including transmission of HIV and other infections.

2. Until the risk for HIV transmission from screened donors has been clarified, recipients of solid organs should be routinely advised to be tested for HIV immediately before transplantation and at 3 months following the transplant. Testing of recipients should be done with consent of the recipient and should not be mandatory. Recipients of tissues other than solid organs do not require routine testing for HIV following receipt of the tissue from appropriately screened donors. Results of HIV testing of organ recipients should be collected and analyzed by the Scientific Registry for Transplant Recipients. (If data indicate no benefit from recipient testing, then this recommendation for recipient testing may be omitted in a revision of these guidelines.)
3. If a transplant recipient is found to be infected with HIV, the transplant center or health-care provider should, consistent with state law, immediately notify the state health department and the organization from which the tissue was obtained. HIV infection in a solid-organ recipient should also be reported to the Scientific Registry for Transplant Recipients.

Recall of Stored Tissue and Tracking of Recipients of Organs/Tissue from HIV-Infected Donors

1. Upon being notified that an organ/tissue recipient is infected with HIV, the organ/tissue collection center, in collaboration with the state or local health department and with assistance from CDC, is responsible for determining as soon as possible whether the donor was HIV-infected. This is done by determining the HIV-infection status of other recipients of organs/tissues (particularly those recipients of organs and fresh-frozen bone) and by laboratory testing of stored donor material. Experimental diagnostic laboratory assays such as PCR may be useful in these situations and should be used when they become available.

2. If evidence suggests HIV infection in the donor either from testing of stored donor specimens or by finding HIV infection in other recipients, all other recipients of that donor's tissue or organs should be notified through their transplanting physician and informed of the likelihood of HIV exposure and advised to undergo HIV testing.

3. HIV-infected recipients should be counseled about their need for medical evaluation and about prevention of HIV transmission to others. They should also be advised to inform their sex or needle-sharing partners of their potential risk and need for HIV counseling and testing. HIV-infected women should be informed of the risk of transmission of HIV to their children born after the transplant and be advised to have these children evaluated and to avoid breast-feeding. Pregnant women should receive pregnancy counseling about HIV.

4. All stored organs/tissues from a donor found to be HIV-infected should be retrieved and quarantined immediately and either used only for research purposes or destroyed, except when the transplantation of an indispensable organ/tissue is necessary to save the patient's life.

[61 FR 19745, May 2, 1996]

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

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Accredited provider or supplier means a provider or supplier that has voluntarily applied for and has been accredited by a national accreditation program meeting the requirements of and approved by HCFA in accordance with §488.5 or §488.6.

Act means the Social Security Act.

AOA stands for the American Osteopathic Association.

Certification is a recommendation made by the State survey agency on the compliance of providers and suppliers with the conditions of participation, requirements (for SNFs and NFs), and conditions of coverage.

Conditions for coverage means the requirements suppliers must meet to participate in the Medicare program.

Conditions of participation means the requirements providers other than skilled nursing facilities must meet to participate in the Medicare program and includes conditions of certification for rural health clinics.

Full review means a survey of a hospital for compliance with all conditions of participation for hospitals.

JCAHO stands for the Joint Commission on Accreditation of Healthcare Organizations.

Medicare condition means any condition of participation or for coverage, including any long term care requirements.

Provider of services or provider means a hospital, critical access hospital, skilled nursing facility, nursing facility, home health agency, hospice, comprehensive outpatient rehabilitation facility, or provider of outpatient physical therapy or speech pathology services.

Rate of disparity means the percentage of all sample validation surveys for which a State survey agency finds non-compliance with one or more Medicare conditions and no comparable condition level deficiency was cited by the accreditation organization, where it is reasonable to conclude that the deficiencies were present at the time of the accreditation organization’s most recent surveys of providers or suppliers of the same type.

Example: Assume that during a validation review period State survey agencies perform validation surveys at 200 facilities of the same type (for example, ambulatory surgical centers, home health agencies) accredited by the same accreditation organization. The State survey agencies find 60 of the facilities out of compliance with one or more Medicare conditions, and it is reasonable to conclude that these deficiencies were present at the time of the most recent survey by an accreditation organization. The accreditation organization, however, has found deficiencies comparable to the condition level deficiencies at only 22 of the 60 facilities. These validation results would yield ((60−22)/200) a rate of disparity of 19 percent.

Reasonable assurance means that an accreditation organization has demonstrated to HCFA’s satisfaction that its requirements, taken as a whole, are at least as stringent as those established by HCFA, taken as a whole.

State includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa.

State survey agency means the State health agency or other appropriate State or local agency used by HFCA to perform survey and review functions for Medicare.

Substantial allegation of noncompliance means a complaint from any of a variety of sources (including complaints submitted in person, by telephone, through written correspondence, or in newspaper or magazine articles) that, if substantiated, would affect the health and safety of patients and raises doubts as to a provider’s or supplier’s noncompliance with any Medicare condition.

Supplier means any of the following: independent laboratory; portable X-ray services; physical therapist independent practice; ESRD facility; rural health clinic; Federally qualified health center; or chiropractor.

Validation review period means the one year period during which HCFA conducts a review of the validation surveys and evaluates the results of the most recent surveys performed by the accreditation organization.

§ 488.2 Statutory basis.

This part is based on the indicated provisions of the following sections of the Act:

1128—Exclusion of entities from participation in Medicare.
1128A—Civil money penalties.
1814—Conditions for, and limitations on, payment for Part A services.
1819—Requirements for SNFs.
1861(f)—Requirements for psychiatric hospitals.
1861(z)—Institutional planning standards that hospitals and SNFs must meet.
1861(ee)—Discharge planning guidelines for hospitals.
1864—Use of State survey agencies.
1865—Effect of accreditation.
1902—Requirements for participation in the Medicaid program.
1913—Medicaid requirements for hospitals that provide NF care.
1919—Medicaid requirements for NFs.

[60 FR 50443, Sept. 29, 1995]

§ 488.3 Conditions of participation; conditions for coverage; and long-term care requirements.

(a) Basic rules. In order to be approved for participation in or coverage under the Medicare program, a prospective provider or supplier must:

(1) Meet the applicable statutory definitions in section 1138(b), 1819, 1832(a)(2)(F), 1861, 1881, or 1919 of the Act; and

(2) Be in compliance with the applicable conditions or long-term care requirements prescribed in subpart N, Q or U of part 405, part 416, subpart C of part 418, part 482, part 483, part 484, part 485, subpart A of part 491, or part 494 of this chapter.

(b) Special Conditions. (1) The Secretary, after consultation with the JCAH0 or AOA, may issue conditions of participation for hospitals higher or more precise than those of either those accrediting bodies.

(2) The Secretary may, at a State’s request, approve health and safety requirements for providers and suppliers in that State, which are higher than those otherwise applied in the Medicare program.

(3) If a State or political subdivision imposes higher requirements on institutions as a condition for the purchase of health services under a State Medicaid Plan approved under Title XIX of the Act, (or if Guam, Puerto Rico, or the Virgin Islands does so under a State plan for Old Age Assistance under Title I of the Act, or for Aid to the Aged, Blind, and Disabled under the original Title XVI of the Act), the Secretary is required to impose similar requirements as a condition for payment under Medicare in that State or political subdivision.

[54 FR 22859, June 17, 1988, as amended at 58 FR 61838, Nov. 23, 1993]

§ 488.4 Application and reapplication procedures for accreditation organizations.

(a) A national accreditation organization applying for approval of deeming authority for Medicare requirements under §488.5 or 488.6 of this subpart must furnish to HCFA the information and materials specified in paragraphs (a)(1) through (10) of this section. A national accreditation organization reapplying for approval must furnish to HCFA whatever information and materials from paragraphs (a)(1) through (10) of this section that HCFA requests. The materials and information are—

(1) The types of providers and suppliers for which the organization is requesting approval;

(2) A detailed comparison of the organization’s accreditation requirements and standards with the applicable Medicare requirements (for example, a crosswalk);

(3) A detailed description of the organization’s survey process, including—

(i) Frequency of the surveys performed;

(ii) Copies of the organization’s survey forms, guidelines and instructions to surveyors;

(iii) Accreditation survey review process and the accreditation status decision-making process;

(iv) Procedures used to notify accredited facilities of deficiencies and the procedures used to monitor the correction of deficiencies in accredited facilities; and
(v) Whether surveys are announced or unannounced;
(4) Detailed information about the individuals who perform surveys for the accreditation organization, including—
   (i) The size and composition of accreditation survey teams for each type of provider and supplier accredited;
   (ii) The education and experience requirements surveyors must meet;
   (iii) The content and frequency of the in-service training provided to survey personnel;
   (iv) The evaluation systems used to monitor the performance of individual surveyors and survey teams; and
   (v) Policies and procedures with respect to an individual's participation in the survey or accreditation decision process of any facility with which the individual is professionally or financially affiliated;
(5) A description of the organization's data management and analysis system with respect to its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system;
(6) The organization's procedures for responding to and for the investigation of complaints against accredited facilities, including policies and procedures regarding coordination of these activities with appropriate licensing bodies and ombudsmen programs;
(7) The organization's policies and procedures with respect to the withholding or removal of accreditation status for facilities that fail to meet the accreditation organization's standards or requirements, and other actions taken by the organization in response to noncompliance with its standards and requirements;
(8) A description of all types (for example, full, partial, type of facility, etc.) and categories (provisional, conditional, temporary, etc.) of accreditation offered by the organization, the duration of each type and category of accreditation and a statement specifying the types and categories of accreditation for which approval of deeming authority is sought;
(9) A list of all currently accredited facilities, the type and category of accreditation currently held by each facility, and the expiration date of each facility's current accreditation; and
(10) A list of all full and partial accreditation surveys scheduled to be performed by the organization.
(b) The accreditation organization must also submit the following supporting documentation—
   (1) A written presentation that demonstrates the organization's ability to furnish HCFA with electronic data in ASCII comparable code;
   (2) A resource analysis that demonstrates that the organization's staffing, funding and other resources are adequate to perform the required surveys and related activities; and
   (3) A statement acknowledging that as a condition for approval of deeming authority, the organization will agree to—
       (i) Notify HCFA in writing of any facility that has had its accreditation revoked, withdrawn, or revised, or that has had any other remedial or adverse action taken against it by the accreditation organization within 30 days of any such action taken;
       (ii) Notify all accredited facilities within 10 days of HCFA's withdrawal of the organization's approval of deeming authority;
       (iii) Notify HCFA in writing at least 30 days in advance of the effective date of any proposed changes in accreditation requirements;
       (iv) Within 30 days of a change in HCFA requirements, submit to HCFA an acknowledgement of HCFA's notification of the change as well as a revised crosswalk reflecting the new requirements and inform HCFA about how the organization plans to alter its requirements to conform to HCFA's new requirements;
       (v) Permit its surveyors to serve as witnesses if HCFA takes an adverse action based on accreditation findings;
       (vi) [Reserved]
       (vii) Notify HCFA in writing within ten days of a deficiency identified in any accreditation entity where the deficiency poses an immediate jeopardy to the entity's patients or residents or a hazard to the general public; and
       (viii) Conform accreditation requirements to changes in Medicare requirements.
(c) If HCFA determines that additional information is necessary to make a determination for approval or
§ 488.5 Effect of JCAHO or AOA accreditation of hospitals.

(a) Deemed to meet. Institutions accredited as hospitals by the JCAHO or AOA are deemed to meet all of the Medicare conditions of participation for hospitals, except—

(1) The requirement for utilization review as specified in section 1861(e)(6) of the Act and in § 482.30 of this chapter;

(2) The additional special staffing and medical records requirements that are considered necessary for the provision of active treatment in psychiatric hospitals (section 1861(f) of the Act) and implementing regulations; and

(3) Any requirements under section 1861(e) of the Act and implementing regulations that HCFA, after consulting with JCAHO or AOA, identifies as being higher or more precise than the requirements for accreditation (section 1865(a)(4) of the Act).

(b) Deemed status for providers and suppliers that participate in the Medicaid program. Eligibility for Medicaid participation can be established through Medicare deemed status for providers and suppliers that are not required under Medicaid regulations to comply with any requirements other than Medicare participation requirements for that provider or supplier type.

(c) Release and use of hospital accreditation surveys.

(1) A hospital deemed to meet program requirements must authorize its accreditation organization to release to HCFA and the State survey agency a copy of its most current accreditation survey together with any other information related to the survey that HCFA may require (including corrective action plans).

(2) HCFA may use a validation survey, an accreditation survey or other information related to the survey to determine that a hospital does not meet the Medicare conditions of participation.

(3) HCFA may disclose the survey and information related to the survey to the extent that the accreditation survey and related survey information are related to an enforcement action taken by HCFA.

[58 FR 61840, Nov. 23, 1993]
§ 488.6 Other national accreditation programs for hospitals and other providers and suppliers.

(a) In accordance with the requirements of this subpart, a national accreditation program for hospitals; psychiatric hospitals; SNFs; HHAS; ASCs; RHCs; CORFs; hospices; screening mammography services; critical access hospitals; or clinic, rehabilitation agency, or public health agency providers of outpatient physical therapy, occupational therapy or speech pathology services may provide reasonable assurance to HCFA that it requires the providers or suppliers it accredits to meet requirements that are at least as stringent as the Medicare conditions when taken as a whole. In such a case, HCFA may deem the providers or suppliers the program accredits to be in compliance with the appropriate Medicare conditions. These providers and suppliers are subject to validation surveys under § 488.7 of this subpart. HCFA will publish notices in the FEDERAL REGISTER in accordance with § 488.8(b) identifying the programs and deeming authority of any national accreditation program and the providers or suppliers it accredits. The notice will describe how the accreditation organization's accreditation program provides reasonable assurance that entities accredited by the organization meet Medicare requirements. (See § 488.5 for requirements concerning hospitals accredited by JCAHO or AOA.)

(b) Eligibility for Medicaid participation can be established through Medicare deemed status for providers and suppliers that are not required under Medicaid regulations to comply with any requirements other than Medicare participation requirements for that provider or supplier type.

(c)(1) A provider or supplier deemed to meet program requirements under paragraph (a) of this section must authorize its accreditation organization to release to HCFA and the State survey agency a copy of its most current accreditation survey, together with any information related to the survey that HCFA may require (including corrective action plans).

(2) HCFA may determine that a provider or supplier does not meet the Medicare conditions on the basis of its own investigation of the accreditation survey or any other information related to the survey.

(3) Upon written request, HCFA may disclose the survey and information related to the survey—

(i) Of any HHA; or

(ii) Of any other provider or supplier specified at paragraph (a) of this section if the accreditation survey and related survey information relate to an enforcement action taken by HCFA.

§ 488.7 Validation survey.

(a) Basis for survey. HCFA may require a survey of an accredited provider or supplier to validate its organization's accreditation process. These surveys will be conducted on a representative sample basis, or in response to substantial allegations of noncompliance.

(1) When conducted on a representative sample basis, the survey is comprehensive and addresses all Medicare conditions or is focused on a specific condition or conditions.

(2) When conducted in response to a substantial allegation, the State survey agency surveys for any condition that HCFA determines is related to the allegations.

(3) If the State survey agency substantiates a deficiency and HCFA determines that the provider or supplier is out of compliance with any Medicare condition, the State survey agency conducts a full Medicare survey.

(b) Effect of selection for survey. A provider or supplier selected for a validation survey must—

(1) Authorize the validation survey to take place; and

(2) Authorize the State survey agency to monitor the correction of any deficiencies found through the validation survey.

(c) Refusal to cooperate with survey. If a provider or supplier selected for a validation survey fails to comply with the requirements specified in paragraph (b) of this section, it will no longer be deemed to meet the Medicare conditions but will be subject to full review by the State survey agency in accordance with § 488.11, and may be subject to termination of its provider status.
§ 488.8 Federal review of accreditation organizations.

(a) Review and approval of national accreditation organization. HCFA’s review and evaluation of a national accreditation organization will be conducted in accordance with, but will not necessarily be limited to, the following general criteria—

(1) The equivalency of an accreditation organization’s accreditation requirements of an entity to the comparable HCFA requirements for the entity;

(2) The organization’s survey process to determine—

(i) The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training;

(ii) The comparability of survey procedures to those of State survey agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities;

(iii) The organization’s procedures for monitoring providers or suppliers found by the organization to be out of compliance with program requirements. These monitoring procedures are to be used only when the organization identifies noncompliance. If noncompliance is identified through validation surveys, the State survey agency monitors corrections as specified at § 488.7(b)(3);

(iv) The ability of the organization to report deficiencies to the surveyed facilities and respond to the facility’s plan of correction in a timely manner;

(v) The ability of the organization to provide HCFA with electronic data in ASCII comparable code and reports necessary for effective validation and assessment of the organization survey process;

(vi) The adequacy of staff and other resources;

(vii) The organization’s ability to provide adequate funding for performing required surveys; and

(viii) The organization’s policies with respect to whether surveys are announced or unannounced; and

(3) The accreditation organization’s agreement to provide HCFA with a copy of the most current accreditation survey together with any other information related to the survey as HCFA may require (including corrective action plans).

(b) Notice and comment. (1) HCFA will publish a proposed notice in the Federal Register whenever it contemplates approving an accreditation organization’s application for deeming authority. The proposed notice will specify the basis for granting approval of deeming authority and the types of providers and suppliers accredited by
the organization for which deeming authority would be approved. The proposed notice will also describe how the accreditation organization’s accreditation program provides reasonable assurance that entities accredited by the organization meet Medicare requirements. The proposed notice will also provide opportunity for public comment.

(2) HCFA will publish a final notice in the Federal Register whenever it grants deeming authority to a national accreditation organization. Publication of the final notice will follow publication of the proposed notice by at least six months. The final notice will specify the effective date of the approval of deeming authority and the term of approval (which will not exceed six years).

(c) Effects of approval of an accreditation organization. HCFA will deem providers and suppliers accredited by an approved accreditation organization to meet the Medicare conditions for which the approval of deeming authority has specifically been granted. The deeming authority will take effect 90 days following the publication of the final notice.

(d) Continuing Federal oversight of equivalency of an accreditation organization and removal of deeming authority. This paragraph establishes specific criteria and procedures for continuing oversight and for removing the approval of deeming authority of a national accreditation organization.

(1) Comparability review. HCFA will compare the equivalency of an accreditation organization’s accreditation requirements to the comparable HCFA requirements if—

(i) HCFA imposes new requirements or changes its survey process;

(ii) An accreditation organization proposes to adopt new requirements or change its survey process. An accreditation organization must provide written notification to HCFA at least 30 days in advance of the effective date of any proposed changes in its accreditation requirements or survey process; and

(iii) An accreditation organization’s approval has been in effect for the maximum term specified by HCFA in the final notice.

(2) Validation review. Following the end of a validation review period, HCFA will identify any accreditation programs for which—

(i) Validation survey results indicate a rate of disparity between certifications of the accreditation organization and certification of the State agency of 20 percent or more; or

(ii) Validation survey results, irrespective of the rate of disparity, indicate widespread or systematic problems in an organization’s accreditation process that provide evidence that there is no longer reasonable assurance that accredited entities meet Medicare requirements.

(3) Reapplication procedures. (i) Every six years, or sooner as determined by HCFA, an approved accreditation organization must reapply for continued approval of deeming authority. HCFA will notify the organization of the materials the organization must submit as part of the reapplication procedure.

(ii) An accreditation organization that is not meeting the requirements of this subpart, as determined through a comparability review, must furnish HCFA, upon request and at any time, with the reapplication materials. HCFA will establish a deadline by which the materials are to be submitted.

(e) Notice. If a comparability or validation review reveals documentation that an accreditation organization is not meeting the requirements of this subpart, HCFA will provide written notice to the organization indicating that its deeming authority approval may be in jeopardy and that a deeming authority review is being initiated. The notice provides the following information—

(1) A statement of the requirements, instances, rates or patterns of discrepancies that were found as well as other related documentation;

(2) An explanation of HCFA’s deeming authority review on which the final determination is based;

(3) A description of the process available if the accreditation organization wishes an opportunity to explain or justify the findings made during the comparability or validation review;

(4) A description of the possible actions that may be imposed by HCFA.
based on the findings from the validation review; and

(5) The reaplication materials the organization must submit and the deadline for their submission.

(f) Deeming authority review. (1) HCFA will conduct a review of an accreditation organization’s accreditation program if the comparability or validation review produces findings as described at paragraph (d)(1) or (2), respectively, of this section. HCFA will review as appropriate either or both—

(i) The requirements of the accreditation organization; or

(ii) The criteria described in paragraph (a)(1) of this section to reevaluate whether the accreditation organization continues to meet all these criteria.

(2) If HCFA determines, following the deeming authority review, that the accreditation organization has failed to adopt requirements comparable to HCFA’s or submit new requirements timely, the accreditation organization may be given a conditional approval of its deeming authority for a probationary period of up to 180 days to adopt comparable requirements.

(3) If HCFA determines, following the deeming authority review, that the rate of disparity identified during the validation review meets either of the criteria set forth in paragraph (d)(2) of this section HCFA—

(i) May give the accreditation organization conditional approval of its deeming authority during a probationary period of up to one year (whether or not there are also noncomparable requirements) that will be effective 30 days following the date of this determination;

(ii) Will require the accreditation organization to release to HCFA upon its request any facility-specific data that is required by HCFA for continued monitoring;

(iii) Will require the accreditation organization to provide HCFA with a survey schedule for the purpose of intermittent onsite monitoring by HCFA staff, State surveyors, or both; and

(iv) Will publish in the Medicare Annual Report to Congress the name of any accreditation organization given a probationary period by HCFA.

(4) Within 60 days after the end of any probationary period, HCFA will make a final determination as to whether or not an accreditation program continues to meet the criteria described at paragraph (a)(1) of this section and will issue an appropriate notice (including reasons for the determination) to the accreditation organization and affected providers or suppliers. This determination will be based on any of the following—

(i) The evaluation of the most current validation survey and review findings. The evaluation must indicate an acceptable rate of disparity of less than 20 percent between the certifications of the accreditation organization and the certifications of the State agency as described at paragraph (d)(2)(i) of this section in order for the accreditation organization to retain its approval;

(ii) The evaluation of facility-specific data, as necessary, as well as other related information;

(iii) The evaluation of an accreditation organization’s surveyors in terms of qualifications, ongoing training composition of survey team, etc.;

(iv) The evaluation of survey procedures; or

(v) The accreditation requirements.

(5) If the accreditation program has not made improvements acceptable to HCFA during the probationary period, HCFA may remove recognition of deemed authority effective 30 days from the date that it provides written notice to the organization that its deeming authority will be removed.

(6) The existence of any validation review, deeming authority review, probationary period, or any other action by HCFA, does not affect or limit the conducting of any validation survey.

(7) HCFA will publish a notice in the Federal Register containing a justification of the basis for removing the deeming authority from an accreditation organization. The notice will provide the reasons the accreditation organization’s accreditation program no longer meets Medicare requirements.

(8) After HCFA removes approval of an accreditation organization’s deeming authority, an affected provider’s or supplier’s deemed status continues in effect 60 days after the removal of approval. HCFA may extend the period
§ 488.10 State survey agency review: Statutory provisions.

(a) Section 1864(a) of the Act requires the Secretary to enter into an agreement with any State that is able and willing to do so, under which appropriate State or local survey agencies will determine whether:

(1) Providers or prospective providers meet the Medicare conditions of participation or requirements (for SNFs and NFs);

(2) Suppliers meet the conditions for coverage; and

(3) Rural health clinics meet the conditions of certification.

(b) Section 1865(a) of the Act provides that if an institution is accredited as a hospital by the JCAHO, it will be deemed to meet the conditions of participation:

(1) Except those specified in §488.5;

(2) Provided that such hospital, if it is included within a validation survey, authorizes the JCAHO to release to HCFA (on a confidential basis) upon request a copy of the most current JCAHO accreditation survey.

(c) Section 1864(c) of the Act authorizes the Secretary to enter into agreements with State survey agencies for the purpose of conducting validation surveys in hospitals accredited by the JCAHO. Section 1865(b) provides that an accredited hospital which is found after a validation survey to have significant deficiencies related to the health and safety of patients will no longer be deemed to meet the conditions of participation.

(d) Section 1865(a) of the Act also provides that if HCFA finds that accreditation of a hospital; psychiatric hospital; SNF; HHA; hospice; ASC; RHC; CORF; laboratory; screening mammography service; critical access hospital; or clinic, rehabilitation agency, or public health agency provider of outpatient physical therapy, occupational therapy, or speech pathology services by any national accreditation organization provides reasonable assurance that any or all Medicare conditions are met, HCFA may treat the provider or supplier as meeting the conditions.

§ 488.9 Onsite observation of accreditation organization operations.

As part of the application review process, the validation review process, or the continuing oversight of an accreditation organization's performance, HCFA may conduct an onsite inspection of the accreditation organization's operations and offices to verify the organization's representations and to assess the organization's compliance with its own policies and procedures. The onsite inspection may include, but is not limited to, the review of documents, auditing meetings concerning the accreditation process, the evaluation of survey results or the accreditation decision-making process, and interviews with the organization's staff.

[58 FR 61842, Nov. 23, 1993]
§ 488.11  State survey agency functions.

State and local agencies that have agreements under section 1864(a) of the Act perform the following functions:

(a) Survey and make recommendations regarding the issues listed in § 488.10.

(b) Conduct validation surveys of accredited facilities as provided in § 488.7.

(c) Perform other surveys and carry out other appropriate activities and certify their findings to HCFA.

(d) Make recommendations regarding the effective dates of provider agreements and supplier approvals in accordance with § 489.13 of this chapter.


§ 488.12  Effect of survey agency certification.

Certifications by the State survey agency represent recommendations to HCFA.

(a) On the basis of these recommendations, HCFA will determine whether:

(1) A provider or supplier is eligible to participate in or be covered under the Medicare program; or

(2) An accredited hospital is deemed to meet the Medicare conditions of participation or is subject to full review by the State survey agency.

(b) Notice of HCFA’s determination will be sent to the provider or supplier.

§ 488.14  Effect of PRO review.

When a PRO is conducting review activities under section 1154 of the Act and part 466 of this chapter, its activities are in lieu of the utilization review and evaluation activities required of health care institutions under sections 1861(e)(6), and 1861(k) of the Act.

[59 FR 56237, Nov. 10, 1994]

§ 488.18  Documentation of findings.

(a) The findings of the State agency with respect to each of the conditions of participation, requirements (for SNFs and NFs), or conditions for coverage must be adequately documented. When the State agency certifies to the Secretary that a provider or supplier is not in compliance with the conditions or requirements (for SNFs and NFs), and therefore not eligible to participate in the program, such documentation includes, in addition to the description of the specific deficiencies which resulted in the agency’s recommendation, any provider or supplier response.

(b) If a provider or supplier is certified by the State agency as in compliance with the conditions or participation requirements (for SNFs and NFs) or as meeting the requirements for special certification (see § 488.54), with deficiencies not adversely affecting the health and safety of patients, the following information will be incorporated into the finding:

(1) A statement of the deficiencies that were found.

(2) A description of further action that is required to remove the deficiencies.

(3) A time-phased plan of correction developed by the provider and supplier and concurred with by the State agency.

(4) A scheduled time for a resurvey of the institution or agency to be conducted by the State agency within 90 days following the completion of the survey.

(c) If, on the basis of the State certification, the Secretary determines that the provider or supplier is eligible to participate, the information described in paragraph (b) of this section will be incorporated into a notice of eligibility to the provider or supplier.

(d) If the State agency receives information to the effect that a hospital or a critical access hospital (as defined in section 1861(mm)(1) of the Act) has violated § 489.24 of this chapter, the State agency is to report the information to HCFA promptly.


EFFECTIVE DATE NOTE: At 59 FR 32120, June 22, 1994, in § 488.18, paragraph (d) was added, and will not become effective until the information collection requirements are approved by the Office of Management and Budget. A document will be published in the Federal Register once approval has been obtained.
§ 488.20 Periodic review of compliance and approval.

(a) Determinations by HCFA to the effect that a provider or supplier is in compliance with the conditions of participation, or requirements (for SNFs and NFs), or the conditions for coverage are made as often as HCFA deems necessary and may be more or less than a 12-month period, except for SNFs, NFs and HHAs. (See § 488.308 for special rules for SNFs and NFs.)

(b) The responsibilities of State survey agencies in the review and certification of compliance are as follows:

(1) Resurvey providers or suppliers as frequently as necessary to ascertain compliance and confirm the correction of deficiencies;

(2) Review reports prepared by a Professional Standards Review Organization (authorized under Part B Title XI of the Act) or a State inspection of care team (authorized under Title XIX of the Act) regarding the quality of a facility’s care;

(3) Evaluate reports that may pertain to the health and safety of patients; and

(4) Take appropriate actions that may be necessary to achieve compliance or certify noncompliance to HCFA.

(c) A State survey agency certification to HCFA that a provider or supplier is no longer in compliance with the conditions of participation or conditions for coverage will supersede the State survey agency's previous certification.

§ 488.24 Certification of noncompliance.

(a) Special rules for certification of noncompliance for SNFs and NFs are set forth in § 488.330.

(b) The State agency will certify that a provider or supplier is not or is no longer in compliance with a particular requirement, condition of participation, or condition for coverage where the deficiencies are of such character as to substantially limit the provider's or supplier's capacity to furnish adequate care or which adversely affect the health and safety of patients; or

(c) If HCFA determines that an institution or agency does not qualify for participation or coverage because it is not in compliance with the conditions of participation or conditions for coverage, or if a provider’s agreement is terminated for that reason, the institution or agency has the right to request that the determination be reviewed. (Appeals procedures are set forth in Part 498 of this chapter.)

§ 488.26 Determining compliance.

(a) Additional rules for certification of compliance for SNFs and NFs are set forth in § 488.330.

(b) The decision as to whether there is compliance with a particular requirement, condition of participation, or condition for coverage depends upon the manner and degree to which the provider or supplier satisfies the various standards within each condition. Evaluation of a provider's or supplier's performance against these standards enables the State survey agency to document the nature and extent of deficiencies, if any, with respect to a particular function, and to assess the need for improvement in relation to the prescribed conditions.

(c) The State survey agency must adhere to the following principles in determining compliance with participation requirements:

(1) The survey process is the means to assess compliance with Federal health, safety and quality standards;

(2) The survey process uses resident outcomes as the primary means to establish the compliance status of facilities. Specifically surveyors will directly observe the actual provision of care and services to residents, and the effects of that care, to assess whether the care provided meets the needs of individual residents;

(3) Surveyors are professionals who use their judgment, in concert with Federal forms and procedures, to determine compliance;
§ 488.28 Providers or suppliers, other than SNFs and NFs, with deficiencies.

(a) If a provider or supplier is found to be deficient with respect to one or more of the standards in the conditions of participation or conditions for coverage, it may participate in or be covered under the Health Insurance for the Aged and Disabled Program only if the facility has submitted an acceptable plan of correction for achieving compliance within a reasonable period of time acceptable to the Secretary.

(b) The existing deficiencies noted either individually or in combination neither jeopardize the health and safety of patients nor are of such character as to seriously limit the provider’s capacity to render adequate care.

(c)(1) If it is determined during a survey that a provider or supplier is not in compliance with one or more of the standards, it is granted a reasonable time to achieve compliance.

(2) The amount of time depends upon the —

(i) Nature of the deficiency; and

(ii) State survey agency’s judgment as to the capabilities of the facility to provide adequate and safe care.

(d) Ordinarily a provider or supplier is expected to take the steps needed to achieve compliance within 60 days of being notified of the deficiencies but the State survey agency may recommend that additional time be granted by the Secretary in individual situations, if in its judgment, it is not reasonable to expect compliance within 60 days, for example, a facility must obtain the approval of its governing body, or engage in competitive bidding.

[59 FR 56237, Nov. 10, 1994]

Subpart B—Special Requirements

§ 488.52 [Reserved]

§ 488.54 Temporary waivers applicable to hospitals.

(a) General provisions. If a hospital is found to be out of compliance with one or more conditions of participation for hospitals, as specified in part 482 of this chapter, a temporary waiver may be granted by HCFA. HCFA may extend a temporary waiver only if such a waiver would not jeopardize or adversely affect the health and safety of patients. The waiver may be issued for any one year period or less under certain circumstances. The waiver may be withdrawn earlier if HCFA determines this action is necessary to protect the health and safety of patients. A waiver may be granted only if:

(1) The hospital is located in a rural area. This includes all areas not delineated as “urban” by the Bureau of the Census, based on the most recent census;

(2) The hospital has 50 or fewer inpatient hospital beds;

(3) The character and seriousness of the deficiencies do not adversely affect the health and safety of patients; and

(4) The hospital has made and continues to make a good faith effort to comply with personnel requirements consistent with any waiver.

(b) Minimum compliance requirements. Each case will have to be decided on its individual merits, and while the degree and extent of compliance will vary, the institution must, as a minimum, meet all of the statutory conditions in section 1861(e)(1)-(8), in addition to meeting such other requirements as the Secretary finds necessary under section 1861(e)(9). (For further information relating to the exception in section 1861(e)(5) of the Act, see paragraph (c) of this section.)

(c) Temporary waiver of 24-hour nursing requirement of 24-hour registered nurse requirement. HCFA may waive the requirement contained in section 1861(e)(5) that a hospital must provide
24-hour nursing service furnished or supervised by a registered nurse. Such a waiver may be granted when the following criteria are met:

1. The hospital’s failure to comply fully with the 24-hour nursing requirement is attributable to a temporary shortage of qualified nursing personnel in the area in which the hospital is located.
2. A registered nurse is present on the premises to furnish or supervise the nursing services during at least the daytime shift, 7 days a week.
3. The hospital has in charge, on all tours of duty not covered by a registered nurse, a licensed practical (vocational) nurse.
4. The hospital complies with all requirements specified in paragraph (a) of this section.

(d) Temporary waiver for technical personnel. HCFA may waive technical personnel requirements, issued under section 1861(e)(9) of the Act, contained in the Conditions of Participation; Hospitals (part 482 of this chapter). Such a waiver must take into account the availability of technical personnel and the educational opportunities for technical personnel in the area in which the hospital is located. HCFA may also limit the scope of services furnished by a hospital in conjunction with the waiver in order not to adversely affect the health and safety of the patients. In addition, the hospital must also comply with all requirements specified in paragraph (a) of this section.

§ 488.56 Temporary waivers applicable to skilled nursing facilities.

(a) Waiver of 7-day registered nurse requirement. To the extent that §483.30 of this chapter requires any skilled nursing facility to engage the services of a registered nurse more than 40 hours a week, the Secretary may waive such requirement for such periods as he deems appropriate if, based upon documented findings of the State agency, he determines that:

1. Such facility is located in a rural area and the supply of skilled nursing facility services in such area is not sufficient to meet the needs of individual patients therein,
2. Such facility has at least one fulltime registered nurse who is regularly on duty at such facility 40 hours a week, and
3. Such facility (i) has only patients whose attending physicians have indicated (through physicians’ orders or admission notes) that each such patient does not require the services of a registered nurse for a 48-hour period, or (ii) has made arrangements for a registered nurse or a physician to spend such time at the facility as is determined necessary by the patient’s attending physician to provide necessary services on days when the regular fulltime registered nurse is not on duty.
4. Such facility has made and continues to make a good faith effort to comply with the more than 40-hour registered nurse requirement, but such compliance is impeded by the unavailability of registered nurses in the area.

(b) Waiver of medical director requirement. To the extent that §488.75(i) of this chapter requires any skilled nursing facility to engage the services of a medical director either part-time or full-time, the Secretary may waive such requirement for such periods as he deems appropriate if, based upon documented findings of the State agency, he determines that:

1. Such facility is located in an area where the supply of physicians is not sufficient to permit compliance with this requirement without seriously reducing the availability of physician services within the area, and
2. Such facility has made and continues to make a good faith effort to comply with §488.75(i) of this chapter, but such compliance is impeded by the unavailability of physicians in the area.

§ 488.60 Special procedures for approving end stage renal disease facilities.

(a) Considerations for approval. An ESRD facility which wishes to be approved for coverage, or which wishes any expansion of dialysis services to be approved for coverage in accordance with subpart U of part 405, must secure the Secretary's determination thereunder. In addition to the certification by the State agency referred to in §488.12 of this part, data furnished by network organizations and recommendations of the Public Health Service, concerning the contribution of a facility to the furnishing of end-stage renal disease services in its network and concerning the facility's compliance with professional norms and standards (see subpart U of part 405), shall be considered by the Secretary in determining whether to approve a facility for coverage or for any expansion of services under the End-Stage Renal Disease Program. The facility will also be required to submit data pertaining to its qualifications for approval or for any expansion of services, for consideration in the Secretary's determination.

(b) Determining compliance with minimal utilization rates: Time limitations—(1) Unconditional status. A facility which meets minimal utilization requirements will be assigned this status as long as it continues to meet these requirements. (2) Conditional status. A facility which meets minimal utilization requirements will be assigned this status as long as it continues to meet these requirements. (3) Exception status. Under unusual circumstances (see §405.2122(b) of this chapter) the Secretary may grant a time-limited exception to a facility which is not in compliance with the minimal utilization rate(s) for either unconditional status or conditional status. This exception status may be granted, and may be renewed on an annual basis, under circumstances where rigid application of minimal utilization rate requirements would adversely affect the achievement of ESRD program objectives.

(c) New applicant. A facility which has not previously participated in the ESRD program must submit a plan detailing how it expects to meet the conditional minimal utilization rate status by the end of the second calendar year of its operation under the program and meet the unconditional minimal utilization rate status by the end of the fourth calendar year of its operation under the program.

(d) Notification. The Secretary will notify each facility and its network coordinating council of its initial and its subsequent minimal utilization rate classification.

(e) Failure to meet minimal utilization rate. A facility failing to meet standards for unconditional status or conditional status, or if applicable, for exception status, will be so notified at the time of such classification.

(f) Interim regulations participant. A facility previously participating under the interim regulations will not be approved under the program established by subpart U until it has demonstrated that it meets all the applicable requirements of this subpart, including the appropriate minimal utilization rate. It may continue under the interim program only for a period not to exceed 1 year from the effective date of these amendments (see §405.2100(c) of this chapter). During this period it may demonstrate its ability to meet the appropriate minimal utilization rate. Failure to qualify under this subpart will automatically terminate coverage of such facility's services under the ESRD program at the end of such year.

§ 488.64 Remote facility variances for utilization review requirements.

(a) As used in this section:

(1) An "available" individual is one who:

(i) Possesses the necessary professional qualifications;

(ii) Is not precluded from participating by reason of financial interest in any such facility or direct responsibility for the care of the patients being reviewed or, in the case of a skilled
Health Care Financing Administration, HHS § 488.64

Nursing facility, employment by the facility; and

(iii) Is not precluded from effective participation by the distance between the facility and his residence, office, or other place of work. An individual whose residence, office, or other place of work is more than approximately one hour’s travel time from the facility shall be considered precluded from effective participation.

(2) "Adjacent facility" means a health care facility located within a 50-mile radius of the facility which requests a variance.

(b) The Secretary may grant a requesting facility a variance from the time frames set forth in §§405.1137(d) of this chapter and 482.30 as applicable, within which reviews all of cases must be commenced and completed, upon a showing satisfactory to the Secretary that the requesting facility has been unable to meet one or more of the requirements of §405.1137 of this chapter or §482.30 of this chapter, as applicable, by reason of insufficient medical and other professional personnel available to conduct the utilization review required by §405.1137 of this chapter or §482.30 of this chapter, as applicable.

(c) The request for variance shall document the requesting facility’s inability to meet the requirements for which a variance is requested and the facility’s good faith efforts to comply with the requirements contained in §405.1137 of this chapter or §482.30 of this chapter, as applicable.

(d) The request shall include an assurance by the requesting facility that it will continue its good faith efforts to meet the requirements contained in §405.1137 of this chapter or §482.30 of this chapter, as applicable.

(e) A revised utilization review plan for the requesting facility shall be submitted concurrently with the request for a variance. The revised plan shall specify the methods and procedures which the requesting facility will use, if a variance is granted, to assure:

(1) That effective and timely control will be maintained over the utilization of services; and

(2) That reviews will be conducted so as to improve the quality of care provided to patients.

(f) The request for a variance shall include:

(1) The name, location, and type (e.g., hospital, skilled nursing facility) of the facility for which the variance is requested;

(2) The total number of patient admissions and average daily patient census at the facility within the previous six months;

(3) The total number of title XVIII and title XIX patient admissions and the average daily patient census of title XVIII and title XIX patients in the facility within the previous six months;

(4) As relevant to the request, the names of all physicians on the active staff of the facility and the names of all other professional personnel on the staff of the facility, or both;

(5) The name, location, and type of each adjacent facility (e.g., hospital, skilled nursing facility);

(6) The distance and average travel time between the facility and each adjacent facility;

(7) As relevant to the request, the location of practice of available physicians and the estimated number of other available professional personnel, or both (see paragraph (a)(3)(iii) of this section);

(8) Documentation by the facility of its attempt to obtain the services of available physicians or other professional personnel, or both; and

(9) A statement of whether a PRO exists in the area where the facility is located.

(g) The Secretary shall promptly notify the facility of the action taken on the request. Where a variance is in effect, the validation of utilization review pursuant to §405.1137 of this chapter or §482.30 shall be made with reference to the revised utilization review plan submitted with the request for variance.

(h) The Secretary, in granting a variance, will specify the period for which the variance has been granted; such period will not exceed one year. A request for a renewal shall be submitted not later than 30 days prior to the expiration of the variance and shall contain all information required by paragraphs (c), (d), and (f) of this section. Renewal of the variance will be contingent upon
the facility’s continuing to meet the provisions of this section.

§ 488.100 Long term care survey forms, Part A.

**PART A — ADMINISTRATIVE AND PROCEDURAL REQUIREMENTS**

**MEDICARE / MEDICAID SKILLED NURSING FACILITY AND INTERMEDIATE CARE FACILITY SURVEY REPORT**

<table>
<thead>
<tr>
<th>PROVIDER NUMBER</th>
<th>FACILITY NAME AND ADDRESS (City, State, Zip Code)</th>
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</thead>
<tbody>
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<thead>
<tr>
<th>VENDOR NUMBER</th>
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<table>
<thead>
<tr>
<th>SURVEY DATE</th>
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<table>
<thead>
<tr>
<th>SURVEYORS’ NAMES</th>
<th>TITLES</th>
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<tr>
<td>CODE</td>
<td>COMPLIANCE WITH STATE AND LOCAL LAWS</td>
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<tr>
<td>------</td>
<td>-------------------------------------</td>
</tr>
<tr>
<td>F500</td>
<td>Compliance with State and Local Laws (Condition of Participation)</td>
</tr>
<tr>
<td>F501</td>
<td>SNF (405.1120) (Standard)</td>
</tr>
<tr>
<td>F502</td>
<td>ICF (442.251) (Standard)</td>
</tr>
<tr>
<td>F503</td>
<td>The facility has a current State License (Number _____________)</td>
</tr>
<tr>
<td>F504</td>
<td>SNF (405.1120(b)) (Standard)</td>
</tr>
<tr>
<td>F505</td>
<td>ICF (442.302) (Standard)</td>
</tr>
<tr>
<td>F506</td>
<td>Staff of the facility are licensed or registered in accordance with applicable State laws.</td>
</tr>
<tr>
<td>F507</td>
<td>SNF (405.1120(c)) (Standard)</td>
</tr>
<tr>
<td>F508</td>
<td>ICF (442.252) (Standard)</td>
</tr>
<tr>
<td>F509</td>
<td>ICF (442.315) (Standard)</td>
</tr>
<tr>
<td>F510</td>
<td>The facility is in compliance with applicable Federal, State and local laws and regulations relating to fire and safety, sanitation, communicable and reportable diseases, postmortem procedures and other relevant health and safety requirements.</td>
</tr>
<tr>
<td>CODE</td>
<td>COMPLIANCE WITH STATE AND LOCAL LAWS/GOVERNING BODY AND MANAGEMENT</td>
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<tr>
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<td>---------------------------------------------------------------</td>
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<tr>
<td></td>
<td>The facility is in compliance with applicable regulations pertaining to:</td>
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<tr>
<td>F511</td>
<td>Buying, dispensing, safeguarding, administering, and disposing of medications and controlled substances.</td>
</tr>
<tr>
<td></td>
<td><strong>Exception:</strong> Not applicable to SNFs.</td>
</tr>
<tr>
<td>F512</td>
<td>Construction, maintenance and equipment.</td>
</tr>
<tr>
<td></td>
<td><strong>Exception:</strong> Not applicable to SNFs.</td>
</tr>
<tr>
<td>F513</td>
<td>Current reports from all responsible governmental agencies are retained at the facility.</td>
</tr>
<tr>
<td>F514</td>
<td>Governing Body and Management <em>(Condition of Participation)</em></td>
</tr>
<tr>
<td></td>
<td>SNF (405.1121)</td>
</tr>
<tr>
<td></td>
<td>The facility has a governing body with full legal authority and responsibility for operation of the facility.</td>
</tr>
<tr>
<td></td>
<td><strong>A. Disclosure</strong></td>
</tr>
<tr>
<td></td>
<td>SNF (405.1121(a)) <em>(Standard)</em></td>
</tr>
<tr>
<td></td>
<td>Full disclosure of ownership has been made in accordance with requirements at 42 CFR 420.206.</td>
</tr>
<tr>
<td></td>
<td><strong>B. Administration</strong></td>
</tr>
<tr>
<td></td>
<td>SNF (405.1121(c)) <em>(Standard)</em></td>
</tr>
<tr>
<td></td>
<td>1. Written bylaws address the operation of the facility.</td>
</tr>
<tr>
<td></td>
<td>2. Written bylaws and policies address effective resident care.</td>
</tr>
<tr>
<td></td>
<td>3. Bylaws are reviewed and revised as necessary.</td>
</tr>
</tbody>
</table>
### C. Independent Medical Review

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Met</th>
<th>Not Met</th>
<th>N/A</th>
<th>Explanatory Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>F520</td>
<td>ICF (442.301) (Standard)</td>
<td>☐</td>
<td>☓</td>
<td>☐</td>
<td>The facility has policies which ensure that the facility cooperates in an effective program for regular independent medical evaluation and audit of residents in the facility to the extent required by the programs in which the facility participates.</td>
</tr>
</tbody>
</table>

### D. Administrator

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Met</th>
<th>Not Met</th>
<th>N/A</th>
<th>Explanatory Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>F522</td>
<td>SNF (405.1121(d)) (Standard)</td>
<td>☐</td>
<td>☓</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>F523</td>
<td>ICF (442.303) (Standard)</td>
<td>☐</td>
<td>☓</td>
<td>☐</td>
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</tr>
<tr>
<td>F524</td>
<td>The facility has a licensed administrator who has authority for the overall operation of the facility. (Administrator’s license or registration number</td>
<td>☐</td>
<td>☓</td>
<td>☐</td>
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</tr>
</tbody>
</table>

### E. Resident Care Director

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Met</th>
<th>Not Met</th>
<th>N/A</th>
<th>Explanatory Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>F525</td>
<td>ICF (442.304) (Standard)</td>
<td>☐</td>
<td>☓</td>
<td>☐</td>
<td>1. The administrator or another professional staff member is the resident care director (RSD).</td>
</tr>
<tr>
<td>F526</td>
<td></td>
<td></td>
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<td></td>
<td>2. The RSD coordinates and monitors each resident’s care.</td>
</tr>
<tr>
<td>CODE</td>
<td>GOVERNING BODY AND MANAGEMENT</td>
<td>YES</td>
<td>NO</td>
<td>N/A</td>
<td>EXPLANATORY STATEMENT</td>
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<tr>
<td>F526</td>
<td>SNF (405.1121(g)) (Standard)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
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</tr>
<tr>
<td>F529</td>
<td>1. The facility has an overall plan and budget prepared by a committee of representatives from the governing body, administrative staff, and the organized medical staff (if any).</td>
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<tr>
<td>F530</td>
<td>2. The overall plan and budget is reviewed and updated at least annually.</td>
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<tr>
<td>F531</td>
<td>3. The plan includes a capital expenditures plan, if necessary.</td>
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<tr>
<td>G</td>
<td>G. Personnel Policies and Procedures</td>
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</tr>
<tr>
<td>F532</td>
<td>SNF (405.1121(g)) (Standard)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F533</td>
<td>1. The facility has written policies and procedures that support sound resident care and personnel practices and address, at least:</td>
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<tr>
<td>F534</td>
<td>a. Control of communicable disease;</td>
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<tr>
<td>F535</td>
<td>b. The review of employee incidents and accidents to identify health and safety hazards; and</td>
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<tr>
<td>F536</td>
<td>c. The existence of a safe and sanitary environment.</td>
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<tr>
<td>F537</td>
<td>2. Personnel records are current, available to each employee, and contain sufficient information to support placement in the position to which assigned.</td>
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<tr>
<td>F537</td>
<td>3. Referral or provision for periodic health examinations to ensure freedom from communicable disease.</td>
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</tbody>
</table>
### NAME OF FACILITY

<table>
<thead>
<tr>
<th>CODE</th>
<th>GOVERNING BODY AND MANAGEMENT</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>H. Outside Resources/Consultant Agreements</td>
<td></td>
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</tr>
<tr>
<td>F538</td>
<td>SNF (405.1121(j)) (Standard)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
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<tr>
<td>F539</td>
<td>ICF (442.317) (Standard)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
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<tr>
<td></td>
<td>F540 The facility has written agreements with qualified persons to render a service (if it does not employ a qualified professional person to do so). The agreements:</td>
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<tr>
<td></td>
<td>F541 1. Address the responsibilities, functions, objectives, and terms (including financial arrangements and charges);</td>
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<td>F542 2. Are signed by an authorized representative of the facility and the outside resource; and</td>
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<tr>
<td></td>
<td>F543 3. Specify that the facility retains ultimate responsibility for the services rendered.</td>
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<tr>
<td></td>
<td>I. Notification of Change in Resident Status</td>
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</tr>
<tr>
<td>F544</td>
<td>SNF (405.1121(j)) (Standard)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
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</tr>
<tr>
<td>F545</td>
<td>The facility has policies and procedures to notify physicians and other responsible persons in the event of an accident involving the resident, or resident's physical, mental or emotional status, or resident charges, billings or related administrative matter.</td>
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</table>
### NAME OF FACILITY

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<thead>
<tr>
<th>CODE</th>
<th>GOVERNING BODY AND MANAGEMENT</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>J. Resident Rights</td>
<td>SNF (405.1121(b)) (Standard)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
<td></td>
<td>Indicators 1 thru 12 apply to SNFs.</td>
</tr>
<tr>
<td>F547</td>
<td>ICF (442.311) (Standard)</td>
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<tr>
<td>1. Information</td>
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<tr>
<td>F548</td>
<td>a. The facility informs each resident, before or at the time of admission, of his rights and responsibilities.</td>
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<tr>
<td>F549</td>
<td>b. The facility informs each resident, before or at the time of admission, of all rules governing resident conduct.</td>
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<tr>
<td>F550</td>
<td>c. The facility informs each resident of amendments to their policies on residents' rights and responsibilities and rules governing conduct.</td>
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<tr>
<td>F551</td>
<td>d. Each resident acknowledges in writing receipt of residents' rights information and any amendment to it.</td>
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<tr>
<td>F552</td>
<td>e. The resident must be informed in writing of all services and charges for services.</td>
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</tr>
<tr>
<td>F553</td>
<td>f. The resident must be informed in writing of all changes in services and charges before or at the time of admission and on a continuing basis.</td>
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<tr>
<td>F554</td>
<td>g. The resident must be informed of services not covered by Medicare or Medicaid in the basic rate.</td>
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</table>
### NAME OF FACILITY

<table>
<thead>
<tr>
<th>CODE</th>
<th>GOVERNING BODY AND MANAGEMENT</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Medical Condition and Treatment</td>
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</tr>
<tr>
<td>F555 a. Each resident is informed by a physician of his health and medical condition unless the physician decides that informing the resident is medically contraindicated.</td>
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<tr>
<td>F556 b. Each resident is given an opportunity to participate in planning his total care and medical treatment.</td>
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<tr>
<td>F557 c. Each resident is given an opportunity to refuse treatment.</td>
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<tr>
<td>F558 d. Each resident gives informed, written consent before participating in experimental research.</td>
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</tr>
<tr>
<td>F559 e. If the physician decides that informing the resident of his health and medical condition is medically contraindicated, the physician has documented this decision in the resident's medical record.</td>
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<tr>
<td>3. Transfer and Discharge</td>
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<tr>
<td>F560 a. Medical reasons.</td>
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</tr>
<tr>
<td>F561 b. His/her welfare or that of other residents.</td>
<td></td>
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<tr>
<td>F562 c. Nonpayment except as prohibited by the Medicare or Medicaid program.</td>
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<tr>
<td>4. Exercising Rights</td>
<td></td>
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</tr>
<tr>
<td>F563 a. Each resident is encouraged and assisted to exercise his/her rights as a resident of the facility and as a citizen.</td>
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</tr>
<tr>
<td>F564 b. Each resident is allowed to submit complaints and recommendations concerning the policies and services of the facility to staff or to outside representatives of the resident's choice or both.</td>
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<tr>
<td>F565 c. Such complaints are submitted free from restraint, coercion, discrimination, or reprisal.</td>
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</tr>
<tr>
<td>CODE</td>
<td>GOVERNING BODY AND MANAGEMENT</td>
<td>YES</td>
<td>NO</td>
<td>N/A</td>
<td>EXPLANATORY STATEMENT</td>
</tr>
<tr>
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<tr>
<td></td>
<td>5. Financial Affairs</td>
<td></td>
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</tr>
<tr>
<td>F566</td>
<td>a. Residents are allowed to manage their own personal financial affairs.</td>
<td></td>
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</tr>
<tr>
<td>F567</td>
<td>b. The facility establishes and maintains a system that assures full and complete accounting of residents' personal funds. An accounting report is made to residents in skilled nursing facilities at least on a quarterly basis.</td>
<td></td>
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</tr>
<tr>
<td>F568</td>
<td>c. The facility does not commingle resident funds with any other funds other than resident funds.</td>
<td></td>
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</tr>
<tr>
<td>F569</td>
<td>d. If a resident requests assistance from the facility in managing his personal financial affairs, resident's delegation is in writing.</td>
<td></td>
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<tr>
<td></td>
<td>e. The facility system of accounting includes written receipts for:</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>F570</td>
<td>1. All personal possessions and funds received by or deposited with the facility.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>F571</td>
<td>2. All disbursement made to or for the resident.</td>
<td></td>
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</tr>
<tr>
<td>F572</td>
<td>f. The financial record must be available to the resident and his/her family.</td>
<td></td>
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<tr>
<td></td>
<td>6. Freedom from Abuse and Restraints</td>
<td></td>
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</tr>
<tr>
<td>F573</td>
<td>a. Each resident is free from mental and physical abuse</td>
<td></td>
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</tr>
<tr>
<td>F574</td>
<td>b. Chemical and physical restraints are only used when authorized by a physician in writing for a specified period of time or in emergencies.</td>
<td></td>
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<tr>
<td>F575</td>
<td>c. If used in emergencies, they are necessary to protect the resident from injury to himself or others.</td>
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<td></td>
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</tr>
<tr>
<td>CODE</td>
<td>GOVERNING BODY AND MANAGEMENT</td>
<td>YES</td>
<td>NO</td>
<td>N/A</td>
<td>EXPLANATORY STATEMENT</td>
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<tr>
<td>F576</td>
<td>d. The use is authorized by a professional staff member identified in the written policies and procedures of the facility.</td>
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</tr>
<tr>
<td>F577</td>
<td>e. The use is reported promptly to the resident's physician by the staff member.</td>
<td></td>
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</tr>
<tr>
<td>F578</td>
<td>7. Privacy</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>F579</td>
<td>a. Each resident is treated with respect, consideration and full recognition of his/her dignity and individuality.</td>
<td></td>
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<tr>
<td>F580</td>
<td>b. Each resident is given privacy during treatment and care of personal needs.</td>
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</tr>
<tr>
<td>F581</td>
<td>c. Each resident's records, including information in an automated data bank, are treated confidentially.</td>
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</tr>
<tr>
<td>F582</td>
<td>d. Each resident must give written consent before the facility releases information from his/her record to someone not otherwise authorized to receive it.</td>
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<tr>
<td>F583</td>
<td>e. Married residents are given privacy during visits by their spouses.</td>
<td></td>
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<tr>
<td>F584</td>
<td>f. Married residents are permitted to share a room.</td>
<td></td>
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</tr>
<tr>
<td>F585</td>
<td>8. Work</td>
<td></td>
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<tr>
<td>F586</td>
<td>No resident may be required to perform services for the facility.</td>
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<tr>
<td></td>
<td>9. Freedom of Association and Correspondence</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>a. Each resident is allowed to communicate, associate and meet privately with individuals of his choice unless this infringes upon the rights of another resident.</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>b. Each resident is allowed to send and receive personal mail unopened.</td>
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</tbody>
</table>
### NAME OF FACILITY

<table>
<thead>
<tr>
<th>CODE</th>
<th>GOVERNING BODY AND MANAGEMENT</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>F587</td>
<td>10. Activities</td>
<td></td>
<td></td>
<td></td>
<td>Each resident is allowed to participate in social, religious, and community group activities.</td>
</tr>
<tr>
<td>F588</td>
<td>11. Personal Possessions</td>
<td></td>
<td></td>
<td></td>
<td>Each resident is allowed to retain and use his personal possessions and clothing as space permits.</td>
</tr>
<tr>
<td>F589</td>
<td>12. Written Policies and Procedures: Delegation of Rights and Responsibilities</td>
<td></td>
<td></td>
<td></td>
<td>ICF (442.312) (Standard) ☐ MET ☐ NOT MET</td>
</tr>
<tr>
<td></td>
<td>a. The facility has written policies and procedures that provide that all the rights and responsibilities of a resident pass to the resident's guardian, next of kin or sponsoring agency or agencies if the resident is adjudicated incompetent under State law or is determined by his physician to be incapable of understanding his rights and responsibilities.</td>
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<tr>
<td></td>
<td>b. Physician determinations of incapability and the specific reasons thereof are recorded by the physician in the resident's record.</td>
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</tr>
<tr>
<td>F592</td>
<td>K. Resident Care Policies</td>
<td></td>
<td></td>
<td></td>
<td>SNF (405.1121)(b) (Standard) ☐ MET ☐ NOT MET</td>
</tr>
<tr>
<td></td>
<td>1. The facility has written policies to govern the continuing skilled nursing care and related medical or other services provided.</td>
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<tr>
<td></td>
<td>2. These policies reflect awareness of and provision for meeting the total medical and psychosocial needs of residents including admission, transfer, discharge planning, and the range of services available to residents; and</td>
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Form HCFA-522 (3-96)
<table>
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<tr>
<th>CODE</th>
<th>GOVERNING BODY AND MANAGEMENT</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>F595</td>
<td>3. The protection of residents' personal and property rights.</td>
<td></td>
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</tr>
<tr>
<td>F596</td>
<td>4. The policies are developed by a group of professional personnel, including the Medical Director or the organized medical staff, and are periodically reviewed and revised (if necessary).</td>
<td></td>
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<tr>
<td>F597</td>
<td>5. These policies are available to admitting physicians, sponsoring agencies, residents, and the public.</td>
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</tr>
<tr>
<td>F598</td>
<td>6. The Medical Director or a registered nurse is designated as responsible for the execution of the policies.</td>
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<tr>
<td></td>
<td>L. Public Availability</td>
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<tr>
<td>F599</td>
<td>ICF (442.305) (Standard)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
<td></td>
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</tr>
<tr>
<td>F600</td>
<td>1. The facility has written policies and procedures governing all the services it provides.</td>
<td></td>
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<tr>
<td>F601</td>
<td>2. The policies and procedures are available to the staff and residents, members of the family, the public, and legal representatives of residents.</td>
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<tr>
<td></td>
<td>M. Admissions</td>
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<tr>
<td>F602</td>
<td>ICF (442.306) (Standard)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
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<tr>
<td></td>
<td>The facility has written policies and procedures that ensure that it admits as residents only those residents whose needs can be met by:</td>
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<tr>
<td>F603</td>
<td>1. the facility itself.</td>
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<tr>
<td>F604</td>
<td>2. the facility in cooperation with community resources.</td>
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</tr>
<tr>
<td>F605</td>
<td>3. the facility in cooperation with other providers of care affiliated with or under contract to the facility.</td>
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</table>

Form HCFA-525 (2.66)
<table>
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<tr>
<th>CODE</th>
<th>GOVERNING BODY AND MANAGEMENT</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
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</thead>
<tbody>
<tr>
<td>F606</td>
<td>ICF (442.307) (Standard)</td>
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<tr>
<td></td>
<td>N. Transfers</td>
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<tr>
<td>F607</td>
<td></td>
<td>MET</td>
<td></td>
<td></td>
<td>1. The facility has written policies and procedures to ensure that residents are transferred promptly to a hospital, SNF, or other appropriate facility when a change is necessary.</td>
</tr>
<tr>
<td></td>
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<td></td>
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<td></td>
<td>2. Except in emergencies, the facility consults the resident, his next of kin, the attending physician, and the responsible agency, if any, at least five days before discharge.</td>
</tr>
<tr>
<td>F608</td>
<td></td>
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<td></td>
<td>3. The facility uses casework services and other means to ensure that adequate arrangements are made to meet resident's needs through other resources.</td>
</tr>
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<td>F609</td>
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<tr>
<td>F610</td>
<td>ICF (442.308) (Standard)</td>
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<tr>
<td></td>
<td>O. Restraints</td>
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<td></td>
<td>The facility has written policies and procedures that:</td>
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<tr>
<td>F611</td>
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<td></td>
<td>1. Define the uses of chemical and physical restraints.</td>
</tr>
<tr>
<td>F612</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2. Identify the professional personnel who may authorize the use of restraints in emergencies under 442.311(f).</td>
</tr>
<tr>
<td>F613</td>
<td></td>
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<td></td>
<td></td>
<td>3. Describe procedures for monitoring and controlling the use of these restraints.</td>
</tr>
<tr>
<td>F614</td>
<td>ICF (442.309) (Standard)</td>
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<tr>
<td></td>
<td>P. Complaints</td>
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<td></td>
<td>The facility has written policies and procedures that:</td>
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<tr>
<td>F615</td>
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<td></td>
<td></td>
<td></td>
<td>1. Describe the procedures the facility uses to receive complaints and recommendations from residents.</td>
</tr>
<tr>
<td>F616</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2. Ensure that the facility responds to complaints and recommendations.</td>
</tr>
<tr>
<td>CODE</td>
<td>GOVERNING BODY AND MANAGEMENT</td>
<td>YES</td>
<td>NO</td>
<td>N/A</td>
<td>EXPLANATORY STATEMENT</td>
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<tr>
<td>F617</td>
<td>SNF (405.1121(b)(i)(ii)) (Standard)</td>
<td>☐</td>
<td>☑</td>
<td>☐</td>
<td>1. The facility conducts an orientation program for all new employees that includes a review of all its policies.</td>
</tr>
<tr>
<td>F618</td>
<td>ICF (442.314) (Standard)</td>
<td>☐</td>
<td>☑</td>
<td>☐</td>
<td>2. The facility plans and conducts an inservice staff development program for all personnel to assist them in developing and improving their skills.</td>
</tr>
<tr>
<td>F619</td>
<td></td>
<td></td>
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<td></td>
<td>3. The facility maintains a record of the orientation and staff development programs it conducts.</td>
</tr>
<tr>
<td>F620</td>
<td></td>
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<td></td>
<td>4. The record includes the content of the program and the names of participants.</td>
</tr>
<tr>
<td>F621</td>
<td></td>
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<td>5. Inservice training includes at least prevention and control of infections, fire prevention and safety, confidentiality of resident information, and preservation of resident dignity including protection of resident’s privacy and personal and property rights.</td>
</tr>
<tr>
<td>CODE</td>
<td>MEDICAL DIRECTION</td>
<td>YES</td>
<td>NO</td>
<td>N/A</td>
<td>EXPLANATORY STATEMENT</td>
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<tr>
<td>F624</td>
<td><strong>Medical Direction (Condition of Participation)</strong></td>
<td></td>
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<td></td>
<td>The facility has a written agreement with a licensed physician to serve as Medical Director on a part-time or full-time basis as is appropriate to the needs of the residents and the facility. (See 405.1911(b) regarding waiver of this requirement.)</td>
</tr>
<tr>
<td>F625</td>
<td>SNF (405.1122) (Standard)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F626</td>
<td>1. Medical direction and coordination of medical care in the facility are provided by a Medical Director.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>F627</td>
<td>2. The Medical Director is responsible for development of policies approved by the governing body.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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</tr>
<tr>
<td>F628</td>
<td>3. Coordination of medical care includes liaison with attending physicians to ensure their written orders are promptly executed upon admission of a resident, and periodic evaluation of the adequacy and appropriateness of health professional and supportive staff and services.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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</tr>
<tr>
<td>F629</td>
<td>SNF (405.1122)(b) (Standard)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
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</tr>
<tr>
<td>F630</td>
<td>1. The Medical Director is responsible for surveillance of the health status of the facility’s employees.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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</tr>
<tr>
<td>F631</td>
<td>2. Incidents and accidents that occur on the premises are reviewed by the Medical Director to identify hazards to health and safety.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>CODE</td>
<td>PHYSICIAN SERVICES</td>
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<tr>
<td>F632</td>
<td>SNF (405.1123)</td>
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<td></td>
<td></td>
<td>Physician Services (Condition of Participation)</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>Residents in need of skilled or rehabilitative care are admitted to the facility only upon the recommendation of, and remain under the care of, a physician. To the extent feasible, each resident designates a personal physician.</td>
</tr>
<tr>
<td>A.</td>
<td>Physician Supervision</td>
<td></td>
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</tr>
<tr>
<td>F633</td>
<td>SNF (405.1123(b)) (Standard)</td>
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<tr>
<td>F634</td>
<td>ICF (442.346) (Standard)</td>
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<tr>
<td>F635</td>
<td>1. The facility has a policy that the health care of every resident must be under the supervision of a physician.</td>
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</tr>
<tr>
<td>F636</td>
<td>2. All attending physicians must make arrangements for the medical care of their residents in their absence.</td>
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</tr>
<tr>
<td>B.</td>
<td>Emergency Services</td>
<td></td>
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</tr>
<tr>
<td>F637</td>
<td>SNF (405.1123(d)) (Standard)</td>
<td></td>
<td></td>
<td></td>
<td>The facility has written procedures available at each nurses' station, that provide for having a physician available to furnish necessary medical care in case of emergency.</td>
</tr>
</tbody>
</table>
### NAME OF FACILITY

<table>
<thead>
<tr>
<th>CODE</th>
<th>NURSING SERVICES</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>F638</td>
<td>Nursing Services (Condition of Participation) SNF (405.1124)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
<td>The facility provides 24-hour service by licensed nurses, including the services of a registered nurse at least during the day tour of duty, 7 days a week. There is an organized nursing service with a sufficient number of qualified nursing personnel to meet the total nursing needs of all residents (See 405.1911(a) regarding waiver of the 7-day registered nurse requirement).</td>
<td></td>
</tr>
<tr>
<td>F639</td>
<td>ICF (442.342) (Standard)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
<td>The facility provides nursing care as needed including restorative nursing care.</td>
<td></td>
</tr>
</tbody>
</table>

**A. Director of Nursing Services**

<table>
<thead>
<tr>
<th>CODE</th>
<th>NURSING SERVICES</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>F640</td>
<td>SNF (405.1124(a)) (Standard)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
<td></td>
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</tr>
<tr>
<td>F641</td>
<td>1. The director of nursing services is a qualified registered nurse employed full-time.</td>
<td></td>
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</tr>
<tr>
<td>F642</td>
<td>2. The director of nursing services has, in writing, administrative authority, responsibility, and accountability for the functions, activities, and training of the nursing services staff, and serves only one facility in this capacity.</td>
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</tr>
<tr>
<td>F643</td>
<td>3. If the director of nursing services has other institutional responsibilities, a qualified registered nurse serves as assistant so that there is the equivalent of a full-time director of nursing services on duty.</td>
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</tbody>
</table>
NAME OF FACILITY

<table>
<thead>
<tr>
<th>CODE</th>
<th>NURSING SERVICES</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>B. Health Services Supervision</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>F644</td>
<td>ICF (442.339) (Standard)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F645</td>
<td>1. The facility has a full-time registered nurse, or a licensed practical or vocational nurse to supervise the health services 7 days a week on the day shift.</td>
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<tr>
<td>F646</td>
<td>2. The nurse has a current State license.</td>
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</tr>
<tr>
<td>F647</td>
<td>3. If the supervisor of health services is a licensed practical or vocational nurse, the facility has a formal contract with a registered nurse to serve as a consultant no less than 4 hours a week.</td>
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<tr>
<td>F648</td>
<td>4. To qualify to serve as a health services supervisor, a licensed practical or vocational nurse must:</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>a. Have graduated from a State-approved school of practical nursing, or</td>
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</tr>
<tr>
<td>F649</td>
<td>b. Have education or other training that the State authority responsible for licensing practical nurses considered equal to graduation from a State-approved school of practical nursing, or</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>F650</td>
<td>c. Have passed the Public Health Service examination for waived licensed practical or vocational nurses.</td>
<td></td>
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</tr>
<tr>
<td>F651</td>
<td>5. If the nurse in charge is licensed by the State in a category other than registered nurse or licensed practical or vocational nurse:</td>
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</tr>
<tr>
<td></td>
<td>a. The individual has completed a training program to get the license that includes at least the same number of classroom and practice hours in all nursing subjects as in the program of a State-approved school of practical or vocational nursing, and</td>
<td></td>
<td></td>
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</tbody>
</table>
NAME OF FACILITY

<table>
<thead>
<tr>
<th>CODE</th>
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<th>YES</th>
<th>NO</th>
<th>NIA</th>
<th>EXPLANATORY STATEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>F652</td>
<td>b. The State agency responsible for licensing the individual submits a report to the Medicaid agency comparing State-licensed practical nurse or vocational nurse course requirements with those for the program completed by the individual.</td>
<td></td>
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<tr>
<td>C. Twenty-four Hour Nursing Service</td>
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</tr>
<tr>
<td>F653</td>
<td>SNF (405.1124(e)) (Standard)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
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<tr>
<td>F654</td>
<td>ICF (442.338) (Standard)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
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</tr>
<tr>
<td>F655</td>
<td>1. 24-Hour Nursing</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Nursing policies and procedures address the total nursing needs of the residents.</td>
<td></td>
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<tr>
<td>F656</td>
<td>The policies are designed to ensure that each resident receives:</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Treatment.</td>
<td></td>
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<tr>
<td>F657</td>
<td>Medications as prescribed.</td>
<td></td>
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<tr>
<td>F658</td>
<td>Diet as prescribed.</td>
<td></td>
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<tr>
<td>F659</td>
<td>Rehabilitative nursing care as needed.</td>
<td></td>
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<tr>
<td>F660</td>
<td>Proper care to prevent decubitus ulcers and deformities.</td>
<td></td>
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<tr>
<td>F661</td>
<td>Proper care to ensure that residents are clean, well-groomed and comfortable.</td>
<td></td>
<td></td>
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<tr>
<td>F662</td>
<td>Protection from accident and injury.</td>
<td></td>
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<tr>
<td>F663</td>
<td>Protection from infection.</td>
<td></td>
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<tr>
<td>F664</td>
<td>Encouragement, assistance, and training in self-care and group activities.</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>CODE</td>
<td>NURSING SERVICES</td>
<td>YES</td>
<td>NO</td>
<td>N/A</td>
<td>EXPLANATORY STATEMENT</td>
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<tr>
<td>F665</td>
<td>2. Weekly time schedules are maintained and indicate the number and classifications of nursing personnel including relief personnel, who worked on each unit for each tour of duty</td>
<td></td>
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<tr>
<td></td>
<td>D. Rehabilitative Nursing Care</td>
<td></td>
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</tr>
<tr>
<td>F666</td>
<td>SNF (405.1124(d)) (Standard)</td>
<td>MET</td>
<td>NOT MET</td>
<td></td>
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</tr>
<tr>
<td>F667</td>
<td>Nursing personnel are trained in rehabilitative nursing</td>
<td></td>
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<tr>
<td></td>
<td>E. Supervision of Resident Nutrition</td>
<td></td>
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</tr>
<tr>
<td>F668</td>
<td>SNF (405.1124(f)) (Standard)</td>
<td>MET</td>
<td>NOT MET</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F669</td>
<td>A procedure is established to inform dietary service of physicians' diet orders and of residents' dietary problems</td>
<td></td>
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<tr>
<td></td>
<td>F. Administration of Drugs</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>F670</td>
<td>SNF (405.1124(g)) (Standard)</td>
<td>MET</td>
<td>NOT MET</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F671</td>
<td>Procedures are established by the Pharmaceutical Services Committee (see 405.1127(d)) to ensure that drugs are checked against physicians' orders</td>
<td></td>
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<tr>
<td></td>
<td>G. Conformance with Physicians' Drug Orders</td>
<td></td>
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</tr>
<tr>
<td>F672</td>
<td>SNF (405.1124(h)) (Standard)</td>
<td>MET</td>
<td>NOT MET</td>
<td></td>
<td>Indicators 1 thru 4 apply to SNFs.</td>
</tr>
<tr>
<td></td>
<td>ICF (442.333) (Standard)</td>
<td>MET</td>
<td>NOT MET</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F674</td>
<td>1. Drugs not specifically limited as to time or number of doses when ordered are controlled by automatic stop orders or other methods in accordance with written policies</td>
<td></td>
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</tbody>
</table>
### NAME OF FACILITY

<table>
<thead>
<tr>
<th>CODE</th>
<th>NURSING SERVICES</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>F675</td>
<td>2. The attending physician is notified of an automatic stop order prior to the last dose so that the physician may decide if the administration of the drug or biological is to be continued or altered.</td>
<td></td>
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<tr>
<td>F676</td>
<td>ICF (442.334) (Standard)</td>
<td>☑ MET</td>
<td>☑ NOT MET</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F677</td>
<td>3. Physicians' verbal orders for drugs are given only to a licensed nurse, pharmacist, or physician and are immediately recorded and signed by the person receiving the order. (Verbal orders for Schedule II drugs are permitted only in the case of a bona fide emergency situation.)</td>
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<tr>
<td>F678</td>
<td>4. Such orders are countersigned by the attending physician within a reasonable time.</td>
<td></td>
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#### H. Storage of Drugs and Biologicals

<table>
<thead>
<tr>
<th>CODE</th>
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<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>F679</td>
<td>SNF (405.1124)(i) (Standard)</td>
<td>☑ MET</td>
<td>☑ NOT MET</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F680</td>
<td>1. Procedures for storing and disposing of drugs and biologicals are established by the pharmaceutical services committee.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>F681</td>
<td>2. In accordance with State and Federal laws, all drugs and biologicals are stored in locked compartments under proper temperature controls.</td>
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<tr>
<td>F682</td>
<td>3. Only authorized personnel have access to the keys.</td>
<td></td>
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</tr>
<tr>
<td>F683</td>
<td>4. Separately locked, permanently affixed compartments are provided for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention &amp; Control Act of 1970 and other drugs subject to abuse, except under single unit dosage distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.</td>
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<tr>
<td>F684</td>
<td>5. An emergency medication kit approved by the pharmaceutical services committee is kept readily available.</td>
<td></td>
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</tbody>
</table>
NAME OF FACILITY

<table>
<thead>
<tr>
<th>CODE</th>
<th>DIETETIC SERVICES</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Dietetic Services (Condition of Participation)</td>
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</tr>
<tr>
<td>F685</td>
<td>SNF (405.1125)</td>
<td></td>
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<tr>
<td></td>
<td>The facility provides a hygienic dietetic service that meets the daily nutritional needs of patients, ensures that special dietary needs are met, and provides palatable and attractive meals. A facility that has a contract with an outside food management company may be found to be in compliance with this condition provided the facility and/or company meets the standards listed herein.</td>
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<td></td>
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<td></td>
<td></td>
<td>A. Staffing</td>
</tr>
<tr>
<td>F686</td>
<td>SNF (405.1125(a))</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>(Standard)</td>
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<tr>
<td>F687</td>
<td>Overall supervisory responsibility for the dietetic service is assigned to a full-time qualified dietetic service supervisor.</td>
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</tr>
<tr>
<td>F688</td>
<td>1. If the dietetic service supervisor is not a qualified dietitian, the dietetic service supervisor functions with frequent, regularly scheduled consultation from a person so qualified. (§405.1101(e).)</td>
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<tr>
<td>F689</td>
<td>3. In addition, the facility employs sufficient supportive personnel competent to carry out the functions of the dietetic service.</td>
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<tr>
<td>F690</td>
<td>4. If consultant dietetic services are used, the consultant’s visits are at appropriate times, and of sufficient duration and frequency to provide continuing liaison with medical and nursing staffs, advice to the administrator, resident counseling, guidance to the supervisor and staff of the dietetic service, approval of all menus, and participation in the development or revisions of dietetic policies and procedures. (See §405.1121(i).)</td>
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<td>CODE</td>
<td>DETERMINATION</td>
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<tr>
<td>F691</td>
<td>ICF (442.332) (Standard)</td>
<td>□ MET</td>
<td>□ NOT MET</td>
<td></td>
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</tr>
<tr>
<td>F692</td>
<td>1. The facility has a staff member trained or experienced in food management or nutrition who is responsible for:</td>
<td></td>
<td></td>
<td></td>
<td>a. Planning meals that meet the nutritional needs of each resident.</td>
</tr>
<tr>
<td>F693</td>
<td>b. Following the orders of the resident's physician.</td>
<td></td>
<td></td>
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<tr>
<td>F694</td>
<td>c. To the extent medically possible, following the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences (Recommended Dietary Allowances, 8th Ed., 1974).</td>
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<tr>
<td>F695</td>
<td>d. Supervising the meal preparation and service to ensure that the menu plan is followed.</td>
<td></td>
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<tr>
<td>F696</td>
<td>2. For residents who required medically prescribed special diets, the facility:</td>
<td></td>
<td></td>
<td></td>
<td>a. Has menus for those residents planned by a professionally qualified dietitian or reviewed and approved by the attending physician; and</td>
</tr>
<tr>
<td>F697</td>
<td>b. Supervises the preparation and serving of meals to ensure that the resident accepts the special diet.</td>
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<tr>
<td>F698</td>
<td>3. The facility keeps for 30 days a record of each menu as served.</td>
<td></td>
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<tr>
<td>CODE</td>
<td>CODE DESCRIPTOR</td>
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<td>N/A</td>
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<tr>
<td>F699</td>
<td>SNF (405.1125(d)) (Standard)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
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</tr>
<tr>
<td>F700</td>
<td>In the event food service employees are assigned duties outside the dietary service, these duties do not interfere with the sanitation, safety, or the time required for dietary work assignments. (See §405.1121(g).)</td>
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<tr>
<td>F701</td>
<td>SNF (405.1125(g)) (Standard)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
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</tr>
<tr>
<td>F702</td>
<td>Written reports of inspections by State and local health authorities are on file at the facility, with notation made of action taken by the facility to comply with any recommendations.</td>
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<tr>
<td>F703</td>
<td>SNF (405.1126)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
<td></td>
<td>The facility provides, or arranges for, under written agreement, specialized rehabilitative services by qualified personnel (i.e., physical therapy, speech pathology and audiology, and occupational therapy) as needed by residents to improve and maintain functioning. Safe and adequate space and equipment are available, commensurate with the services offered. If the facility does not offer such services directly, it does not admit nor retain residents in need of this care unless provision is made for such services under arrangement with qualified outside resources under which the facility assumes professional responsibility for the services rendered. (See §405.1121(h).)</td>
</tr>
<tr>
<td>CODE</td>
<td>SPECIALIZED REHABILITATION SERVICES</td>
<td>YES</td>
<td>NO</td>
<td>N/A</td>
<td>EXPLANATORY STATEMENT</td>
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<tr>
<td>F704</td>
<td>A. Staffing and Organization</td>
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<tr>
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<td>SNF (405.112(a)) (Standard)</td>
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<tr>
<td></td>
<td>Indicators 1 thru 3 apply to SNFs</td>
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<tr>
<td>F705</td>
<td>ICF (442.343) (Standard)</td>
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<tr>
<td>F706</td>
<td>1. Specialized rehabilitative services are provided, in accordance with accepted professional practices, by qualified therapists or by qualified assistants or other supportive personnel under the supervision of qualified therapists.</td>
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<tr>
<td>F707</td>
<td>2. Other rehabilitative services also may be provided, but must be in a facility where all rehabilitative services are provided through an organized rehabilitative service under the supervision of a physician qualified in physical medicine who determines the goals and limitations of these services and assigns duties appropriate to the training and experience of those providing such services.</td>
<td></td>
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<td></td>
<td>Exception: Does not apply to ICFs.</td>
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</tbody>
</table>
| F708 | 3. Written administrative and resident care policies and procedures are developed for rehabilitative services by appropriate therapists and representatives of the medical, administrative, and nursing staffs. |     |    |     | Exception: Does not apply to ICF's  
See General Requirements 442.305 |
### NAME OF FACILITY

<table>
<thead>
<tr>
<th>CODE</th>
<th>SPECIALIZED REHABILITATION SERVICES/PHARMACEUTICAL SERVICES</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
</tr>
</thead>
</table>
| F709 | *B. Documentation of Services*  
SNF (405.1126(d))  
(Standard)  
☐ MET  
☐ NOT MET  
The physician's order, the plan of rehabilitative care, services rendered, evaluations of progress, and other pertinent information are recorded in the patient’s medical record, and are dated and signed by the physician ordering the service and the person who provided the service. | | | | |
| F710 | *C. Qualifying to Provide Outpatient Physical Therapy Services*  
SNF (405.1126(d))  
(Standard)  
☐ MET  
☐ NOT MET  
If the facility provides outpatient physical therapy services, it meets the applicable health and safety regulations pertaining to such services as are included in Subpart Q of this part. (See §405.1719, 405.1720, 405.1722(a) and (b)(1)(2)(3)(4), (5), (6), (7), and (8); and 405.1725.) | | | | |
| F711 | *Pharmaceutical Services (Condition of Participation)*  
SNF (405.1127)  
☐ MET  
☐ NOT MET  
The facility has appropriate methods and procedures for the dispensing and administering of drugs and biologics. The facility is responsible for providing such drugs and biologics for its residents, insofar as they are covered under the programs, and for ensuring that pharmaceutical services are provided in accordance with accepted professional principles. | | | | |
<table>
<thead>
<tr>
<th>CODE</th>
<th>PHARMACEUTICAL SERVICES</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Supervision of Services</td>
<td></td>
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</tr>
<tr>
<td>F712</td>
<td>SNF (405.1127(a)) (Standard)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
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<tr>
<td>F713</td>
<td>1. The pharmaceutical services are under the general supervision of a qualified pharmacist.</td>
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<tr>
<td>F714</td>
<td>2. The pharmacist is responsible to the administrative staff for developing, coordinating, and supervising all pharmaceutical services.</td>
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</tr>
<tr>
<td>F715</td>
<td>3. The pharmacist (if not a full-time employee) devotes a sufficient number of hours, based upon the needs of the facility, during regularly scheduled visits to carry out these responsibilities.</td>
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<tr>
<td>B. Control and Accountability</td>
<td></td>
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<tr>
<td>F716</td>
<td>ICF (442.333) (Standard)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
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</tr>
<tr>
<td>F717</td>
<td>1. The facility employs a licensed pharmacist, or</td>
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<tr>
<td>F718</td>
<td>2. The facility has formal arrangements with a licensed pharmacist to advise the facility on ordering, storage, administration, disposal and recordkeeping of drugs and biologicals.</td>
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<tr>
<td>F719</td>
<td>SNF (405.1127(b)) (Standard)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
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</tr>
<tr>
<td>F720</td>
<td>1. The pharmaceutical service has procedures for control and accountability of all drugs and biologicals throughout the facility.</td>
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<tr>
<td>F721</td>
<td>2. Only approved drugs and biologicals are used in the facility.</td>
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<tr>
<td>F722</td>
<td>3. Records of receipt and disposition of all controlled drugs are maintained in sufficient detail to enable an accurate reconciliation.</td>
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</tr>
<tr>
<td>CODE</td>
<td>PHARMACEUTICAL SERVICES: LABORATORY AND RADILOGIC SERVICES</td>
<td>YES</td>
<td>NO</td>
<td>N/A</td>
<td>EXPLANATORY STATEMENT</td>
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</tr>
<tr>
<td>C. Pharmaceutical Services Committee</td>
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<tr>
<td>F723</td>
<td>SNF (405.1127(d)) (Standard) □ MET □ NOT MET</td>
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<tr>
<td>F724</td>
<td>1. A pharmaceutical services committee or its equivalent develops written policies and procedures for safe and effective drug therapy, distribution, control and use.</td>
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<td>F725</td>
<td>2. The committee is comprised of at least the pharmacist, the director of nursing services, the administrator, and one physician.</td>
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<tr>
<td>F726</td>
<td>3. The committee oversees pharmaceutical services in the facility, makes recommendations for improvement, and monitors the service to ensure its accuracy and adequacy.</td>
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<tr>
<td>Laboratory and Radiologic Services (Condition of Participation)</td>
<td></td>
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<tr>
<td>F727</td>
<td>SNF (405.1128) □ MET □ NOT MET</td>
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<tr>
<td>F728</td>
<td>The facility has provision for promptly obtaining required laboratory, X-ray, and other diagnostic services.</td>
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<tr>
<td>A. Provision for Services</td>
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<tr>
<td>F729</td>
<td>SNF (405.1128(a)) (Standard) □ MET □ NOT MET</td>
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<tr>
<td>F729</td>
<td>1. If the facility provides its own laboratory and X-ray services, these meet the applicable conditions established for certification of hospitals that are contained in 405.1028 and 405.1029, respectively.</td>
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<tr>
<td>NAME OF FACILITY</td>
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<tr>
<td><strong>CODE</strong></td>
<td><strong>LABORATORY AND RADIOLOGIC SERVICES/ DENTAL SERVICES</strong></td>
<td><strong>YES</strong></td>
<td><strong>NO</strong></td>
<td><strong>N/A</strong></td>
<td><strong>EXPLANATORY STATEMENT</strong></td>
</tr>
<tr>
<td>F730</td>
<td>2. If the facility itself does not provide such services, arrangements are made for obtaining these services from a physician's office, a participating hospital or skilled nursing facility, or a portable X-ray supplier or independent laboratory which is approved to provide these services under the program.</td>
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<tr>
<td>F731</td>
<td>3. The facility assists the resident, if necessary, in arranging for transportation to and from the source of service.</td>
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<tr>
<td></td>
<td><strong>B. Blood and Blood Products</strong></td>
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<tr>
<td>F732</td>
<td>SNF (405.1129(b)) (Standard)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
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<tr>
<td>F733</td>
<td>1. Blood handling and storage facilities are safe, adequate, and properly supervised.</td>
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<tr>
<td>F734</td>
<td>2. If the facility provides for maintaining and transfusing blood and blood products, it meets the conditions established for certification of hospitals that are contained in §405.1028(j).</td>
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<tr>
<td>F735</td>
<td>3. If the facility does not provide its own facility but does provide transfusion services alone, it meets at least the requirements of §405.1028(j)(1), (3), (4), (6), and (9).</td>
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<tr>
<td></td>
<td><strong>Dental Services (Condition of Participation)</strong></td>
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<tr>
<td>F736</td>
<td>SNF (405.1129)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
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</tbody>
</table>

The facility has satisfactory arrangements to assist residents to obtain routine and emergency dental care (See §405.1121(i)). (The basic Hospital Insurance Program does not cover the services of a dentist in a skilled nursing facility in connection with the care, treatment, filling, removal, or replacement of teeth or structures supporting the teeth; and only certain oral surgery is included in the Supplemental Medical Insurance Program.)
### NAME OF FACILITY

#### CODE: DENTAL SERVICES/SOCIAL SERVICES: YES NO N/A EXPLANATORY STATEMENT

<table>
<thead>
<tr>
<th>CODE</th>
<th>DENTAL SERVICES/SOCIAL SERVICES</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>F737</td>
<td>SNF (405.1129(a)) (Standard)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
<td></td>
<td>A. Advisory Dentist</td>
</tr>
<tr>
<td>F738</td>
<td></td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
<td></td>
<td>The facility has a cooperative agreement with a dentist, and</td>
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<tr>
<td></td>
<td>A dentist recommends oral hygiene policies and practices for the care of residents. (§405.1121(h).)</td>
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<tr>
<td>F739</td>
<td>SNF (405.1129(b)) (Standard)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
<td></td>
<td>B. Arrangements of Outside Services</td>
</tr>
<tr>
<td>F740</td>
<td></td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
<td></td>
<td>1. The facility has a cooperative agreement with a dentist, and</td>
</tr>
<tr>
<td>F741</td>
<td></td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
<td></td>
<td>2. Maintains a list of dentists in the community for residents who do not have a private dentist.</td>
</tr>
<tr>
<td>F742</td>
<td></td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
<td></td>
<td>3. The facility assists the resident, if necessary, in arranging for transportation to and from the dentist’s office.</td>
</tr>
<tr>
<td></td>
<td>Social Services (Condition of Participation)</td>
<td></td>
<td></td>
<td></td>
<td>The facility has satisfactory arrangements for identifying the medically related social and emotional needs of the resident. It is not mandatory that the skilled nursing facility itself provide social services in order to participate in the program. If the facility does not provide social services, it has written procedures for referring residents in need of social services to appropriate social agencies. If social services are offered by the facility, they are provided under a clearly defined plan, by qualified persons, to assist each resident to adjust to the social and emotional aspects of the resident’s illness, treatment, and stay in the facility.</td>
</tr>
<tr>
<td>NAME OF FACILITY</td>
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<table>
<thead>
<tr>
<th>CODE</th>
<th>SOCIAL SERVICES</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
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</thead>
<tbody>
<tr>
<td>F744</td>
<td>A. Social Service Functions</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>SNF (405.1130(a)) (Standard)</td>
<td>❑ MET</td>
<td>❑ NOT MET</td>
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</tbody>
</table>

Services are provided to meet the social and emotional needs of residents by qualified staff of the facility, or by referral, based on established procedures, to appropriate social agencies.

| F745 | | | | | |
| F746 | ICF (442.344(b)) | ❑ MET | ❑ NOT MET | | |

The facility either provides these services itself or arranges for them with qualified outside resources.

| F747 | B. Staffing | | | | |
| F748 | SNF (405.1130(b)) (Standard) | ❑ MET | ❑ NOT MET | | |

1. If the facility offers social services, a member of the staff of the facility is designated as responsible for social services.

2. If the designated person is not a qualified social worker, the facility has a written agreement with a qualified social worker or recognized social agency for consultation and assistance on a regularly scheduled basis. (See §405.1101(b).)

3. The social service also has sufficient supportive personnel to meet resident needs.

4. Facilities are adequate for social service personnel, easily accessible to residents and medical and other staff, and ensure privacy for interviews.
### NAME OF FACILITY

<table>
<thead>
<tr>
<th>CODE</th>
<th>SOCIAL SERVICES/ACTIVITIES</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
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</thead>
<tbody>
<tr>
<td>F752</td>
<td>ICF (442.344(c))</td>
<td></td>
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<tr>
<td>F753</td>
<td>The facility designates one staff member, qualified by training or experience, to be responsible for:</td>
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<tr>
<td></td>
<td>a. Arranging for social services; and</td>
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<tr>
<td>F754</td>
<td>b. Integrating social services with other elements of the plan of care.</td>
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<tr>
<td></td>
<td><strong>C. Records and Confidentiality</strong></td>
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<tr>
<td>F755</td>
<td>SNF (405.1130(c)) (Standard)</td>
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<tr>
<td>F756</td>
<td>Records of pertinent social data about personal and family problems medically related to the resident's illness and care, and of action taken to meet the resident's needs, are maintained in the resident's medical records.</td>
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<tr>
<td>F757</td>
<td>If social services are provided by an outside resource, a record is maintained of each referral to such resource.</td>
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<tr>
<td></td>
<td><strong>Activities (Condition of Participation)</strong></td>
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<tr>
<td>F758</td>
<td>SNF (405.1131)</td>
<td></td>
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<tr>
<td></td>
<td>The facility provides for an activities program, appropriate to the needs and interests of each resident, to encourage self care, resumption of normal activities, and maintenance of an optimal level of psychosocial functioning.</td>
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<tr>
<td>CODE</td>
<td>ACTIVITIES/MEDICAL RECORDS</td>
<td>YES</td>
<td>NO</td>
<td>N/A</td>
<td>EXPLANATORY STATEMENT</td>
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</tr>
<tr>
<td>A. Staffing</td>
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<td></td>
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<tr>
<td>F759</td>
<td>SNF (405.1131(a)) (Standard)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
<td></td>
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<tr>
<td>F760</td>
<td>A member of the facility's staff is designated as responsible for the activities program.</td>
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<tr>
<td>F761</td>
<td>If not a qualified activities coordinator, this staff member functions with frequent, regularly scheduled consultation from a person so qualified. (See §405.1101(c).)</td>
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<tr>
<td>F762</td>
<td>ICF (442.345(b))</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
<td></td>
<td>The facility designates one staff member, qualified by training or experience in directing group activity, to be responsible for activity service.</td>
</tr>
<tr>
<td>Medical Records (Condition of Participation)</td>
<td></td>
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<tr>
<td>F763</td>
<td>SNF (405.1132)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
<td></td>
<td>The facility maintains clinical (medical) records on all residents in accordance with accepted professional standards and practices. The medical record service has sufficient staff, facilities, and equipment to provide medical records that are completely and accurately documented, readily accessible, and systematically organized to facilitate retrieving and compiling information.</td>
</tr>
<tr>
<td>F764</td>
<td>ICF (442.318(a))</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
<td></td>
<td>The facility maintains an organized resident record system that contains a record for each resident.</td>
</tr>
</tbody>
</table>
### NAME OF FACILITY

<table>
<thead>
<tr>
<th>CODE</th>
<th>MEDICAL RECORDS</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
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</tbody>
</table>

#### A. Staffing

- **F765** SNF (405.1132(a)) (Standard)
  - MET
  - NOT MET

- **F766** 1. Overall supervisory responsibility for the medical record service is assigned to a full-time employee of the facility.
- **F767** 2. The facility also employs sufficient supportive personnel competent to carry out the functions of the medical record service.
- **F768** 3. If the medical record supervisor is not a qualified medical record practitioner, this person functions with consultation from a person qualified. (See §405.1101(b)).

#### B. Protection of Medical Record Information

- **F769** SNF (405.1132(b)) (Standard)
  - MET
  - NOT MET

- **F770** ICF (442.318(d))
  - MET
  - NOT MET

- **F771** The facility safeguards medical record information against loss, destruction, or unauthorized use.

#### C. Physician Documentation

- **F772** SNF (405.1132(c)) (Standard)
  - MET
  - NOT MET

- **F773** 1. Only physicians enter or authenticate in medical records operations that require medical judgment (in accordance with medical staff bylaws, rules, and regulations, if applicable).
- **F774** 2. All physicians sign their entries into the medical record.
## Name of Facility

<table>
<thead>
<tr>
<th>Code</th>
<th>Medical Records</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
<th>Explanatory Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>D. Completion of Records and Centralization of Reports</td>
<td></td>
<td></td>
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<tr>
<td>F775</td>
<td>SNF (405.1132(e)) (Standard)</td>
<td>MET</td>
<td>NOT MET</td>
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<tr>
<td>F776</td>
<td>1. Current medical records and those of discharged residents are completed promptly.</td>
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<tr>
<td>F777</td>
<td>2. All clinical information pertaining to a resident's stay is centralized in the resident's medical record.</td>
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<tr>
<td>E. Retention and Preservation</td>
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<tr>
<td>F778</td>
<td>SNF (405.1132(k)) (Standard)</td>
<td>MET</td>
<td>NOT MET</td>
<td></td>
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<tr>
<td></td>
<td>Medical records are retained for a period of time not less than that determined by the respective State statute, the statute of limitations in the State, or 5 years from the date of discharge in the absence of a State statute, or, in the case of a minor, 3 years after the resident becomes of age under State law.</td>
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<tr>
<td>F779</td>
<td>ICF (442.318(h))</td>
<td>MET</td>
<td>NOT MET</td>
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<tr>
<td></td>
<td>The facility must keep a resident's record for at least 3 years after the resident is discharged.</td>
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<tr>
<td>F. Location and Facilities</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>F780</td>
<td>SNF (405.1132(h)) (Standard)</td>
<td>MET</td>
<td>NOT MET</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>The facility maintains adequate facilities and equipment, conveniently located to provide efficient processing of medical records (reviewing, indexing, filing, and prompt retrieval).</td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
### NAME OF FACILITY

##### CODE Transfer Agreement (Condition of Participation) YES NO N/A EXPLANATORY STATEMENT

<table>
<thead>
<tr>
<th>Transfer Agreement (Condition of Participation)</th>
<th>MET</th>
<th>NOT MET</th>
</tr>
</thead>
<tbody>
<tr>
<td>F781 SNF (405.1133)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F782 ICF (442.316) (Standard)</td>
<td></td>
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</tr>
<tr>
<td>F783 The facility has in effect a transfer agreement with one or more hospitals approved for participation under the programs, which provides the basis for effective working arrangements under which inpatient hospital care or other hospital services are available promptly to the facility's residents when needed. (A facility that has been unable to establish a transfer agreement with the hospital(s) in the community or service area after documented attempts to do so is considered to have such an agreement in effect.) Exception: A facility that has been unable to establish a written agreement after documented attempts to do so, is considered to have such an agreement.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Resident Transfer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F784 SNF (405.1133)(a) (Standard)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| F785 A hospital and a skilled nursing facility shall be considered to have a transfer agreement in effect if, by reason of a written agreement between them or (in case of two institutions are under common control) by reason of a written undertaking by the person or body which controls them, there is reasonable assurance that:  

1. Transfer of patients will be effected between the hospital and the skilled nursing facility, ensuring timely admission, whenever such transfer is medically appropriate as determined by the attending physician. |     |         |
<table>
<thead>
<tr>
<th>CODE</th>
<th>TRANSFER AGREEMENT/PHYSICAL ENVIRONMENT</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>F786</td>
<td>2. There will be interchange of medical and other information necessary or useful in the care and treatment of individuals transferred between institutions, or in determining whether such individuals can be adequately cared for otherwise than in either of such institutions.</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>F787</td>
<td>3. Security and accountability for residents' personal effects are provided on transfer.</td>
<td></td>
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</tr>
<tr>
<td></td>
<td><strong>Physical Environment (Condition of Participation)</strong></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>F788</td>
<td>SNF (405.1134)</td>
<td>☐  MET ☐ NOT MET</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>The facility is constructed, equipped, and maintained to protect the health and safety of residents, personnel, and the public.</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td><strong>A. Life Safety from Fire</strong></td>
<td></td>
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<td></td>
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</tr>
<tr>
<td></td>
<td>SNF (405.1134(a)) <strong>(Standard)</strong> ☐ MET ☐ NOT MET</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>ICF (442.321) <strong>(Standard)</strong> ☐ MET ☐ NOT MET</td>
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</tr>
<tr>
<td></td>
<td>(See appropriate HCFA Fire Safety survey form.)</td>
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</tr>
<tr>
<td></td>
<td><strong>B. Maintenance of Equipment, Building, and Grounds</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F789</td>
<td>SNF (405.1134(b)) <strong>(Standard)</strong> ☐ MET ☐ NOT MET</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>F790</td>
<td>The facility establishes a written preventative maintenance program to ensure that all equipment is operative.</td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
**NAME OF FACILITY**

<table>
<thead>
<tr>
<th>CODE</th>
<th>INFECTION CONTROL</th>
<th>YES</th>
<th>NO</th>
<th>NIA</th>
<th>EXPLANATORY STATEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>F791</td>
<td>Infection Control (Condition of Participation)</td>
<td>☐ MET ☐ NOT MET</td>
<td></td>
<td></td>
<td>The facility establishes an infection control committee of representative professional staff with responsibility for overall infection control in the facility. All necessary housekeeping and maintenance services are provided to maintain a sanitary and comfortable environment and to help prevent the development and transmission of infection.</td>
</tr>
<tr>
<td>F792</td>
<td>SNF (405.1135)</td>
<td>☐ MET ☐ NOT MET</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F793</td>
<td>1. The infection control committee is composed of members of the medical and nursing staffs, administration, and the dietary, pharmacy, housekeeping, maintenance, and other services.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>F794</td>
<td>2. The committee establishes policies and procedures for investigating, controlling, and preventing infection in the facility.</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>F795</td>
<td>3. The committee monitors staff performance to ensure that the policies and procedures are executed.</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>F796</td>
<td>B. Aseptic and Isolation Techniques</td>
<td>☐ MET ☐ NOT MET</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F797</td>
<td>1. The facility has written procedures for aseptic and isolation techniques.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F798</td>
<td>2. These procedures are reviewed and revised for effectiveness and improvement as necessary.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CODE</td>
<td>INFECTION CONTROL</td>
<td>YES</td>
<td>NO</td>
<td>N/A</td>
<td>EXPLANATORY STATEMENT</td>
</tr>
<tr>
<td>------</td>
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</tr>
<tr>
<td>C. Housekeeping</td>
<td>SNF 405.1135(c) (Standard)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
<td></td>
<td>1. The facility employs sufficient housekeeping personnel.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2. Provides all necessary equipment to maintain a safe, clean and orderly interior.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3. A full-time employee is designated responsible for the services and for supervision and training of personnel.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>4. If a facility has a contract with an outside resource for housekeeping services, the facility and/or outside resource meets the requirements of the standards.</td>
</tr>
<tr>
<td>D. Pest Control</td>
<td>SNF 405.1135(e) (Standard)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
<td></td>
<td>The facility has an ongoing pest control program.</td>
</tr>
<tr>
<td>CODE</td>
<td>DISASTER PREPAREDNESS</td>
<td>YES/NO</td>
<td>EXPLANATORY STATEMENT</td>
<td></td>
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</tr>
<tr>
<td>F805</td>
<td>Disaster Preparedness (Condition of Participation)</td>
<td></td>
<td>The facility has a written plan, periodically rehearsed, with procedures to be followed in the event of an internal or external disaster and for the care of casualties (residents and personnel) arising from such disasters.</td>
<td></td>
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</tr>
<tr>
<td>F806</td>
<td>ICF (442.313) (Standard)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>F807</td>
<td>1. The facility has a written plan for staff and residents to follow in case of emergencies such as fire or explosion.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>F808</td>
<td>2. The facility rehearses the plan regularly.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>F809</td>
<td>3. The facility has written procedures for the staff to follow in case of an emergency involving an individual resident.</td>
<td></td>
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</tr>
<tr>
<td>F810</td>
<td>4. These procedures include:</td>
<td></td>
<td>a. Caring for the resident.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F811</td>
<td>b. Notifying the attending physician and other individuals responsible for the resident.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>F812</td>
<td>c. Arranging for transportation, hospitalization, and other appropriate services.</td>
<td></td>
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<tr>
<td>F813</td>
<td>SNF (405.1136(a)) (Standard)</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>F814</td>
<td>1. The facility has an acceptable written plan in operation, with procedures to be followed in the event of fire, explosion, or other disaster.</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>F815</td>
<td>2. The plan is developed and maintained with the assistance of qualified fire, safety, and other appropriate experts.</td>
<td></td>
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</tr>
</tbody>
</table>
## NAME OF FACILITY

<table>
<thead>
<tr>
<th>CODE</th>
<th>DISASTER PREPAREDNESS/UTILIZATION REVIEW</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>F816</td>
<td>3. Includes procedures for prompt transfer of casualties and records.</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>F817</td>
<td>4. Instructions regarding the location and use of alarm systems and signals and of fire-fighting equipment.</td>
<td></td>
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</tr>
<tr>
<td>F818</td>
<td>5. Information regarding methods of containing fire.</td>
<td></td>
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<tr>
<td>F819</td>
<td>6. Procedures for notification of appropriate persons.</td>
<td></td>
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<tr>
<td>F820</td>
<td>7. Specifications of evacuation routes and procedures. (See §405.1134(a).)</td>
<td></td>
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</tr>
</tbody>
</table>

### B. Orientation and training

<table>
<thead>
<tr>
<th>F821</th>
<th>SNF (405.1136(b)) (Standard)</th>
<th>MET</th>
<th>NOT MET</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>The disaster program includes orientation and ongoing training and drills for all personnel in all procedures so that each employee promptly and correctly carries out a specific role in case of a disaster (See §405.1121(h).)</td>
<td></td>
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</table>

### Utilization Review (Condition of Participation)

<table>
<thead>
<tr>
<th>F823</th>
<th>SNF (405.1137)</th>
<th>MET</th>
<th>NOT MET</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>The facility carries out utilization review of the services provided in the facility to residents who are entitled to benefits under the program(s). Utilization review assures the maintenance of high quality care and appropriate and efficient utilization of facility services. There are two elements to utilization review: medical care evaluation studies and review of extended duration cases.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CODE</td>
<td>UTILIZATION REVIEW</td>
<td>YES</td>
<td>NO</td>
<td>N/A</td>
</tr>
<tr>
<td>------</td>
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</tr>
<tr>
<td>F831</td>
<td>b. A group outside the facility which is similarly composed and which is established by the local medical or osteopathic society and some or all of the hospitals and skilled nursing facilities in the locality; or (indicate name of the outside group and briefly describe the organization.)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>F832</td>
<td>c. A group established and organized in a manner approved by the Secretary that is capable of performing such function.</td>
<td></td>
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</tr>
<tr>
<td>F833</td>
<td>2. The medical care evaluation studies, educational duties of the review program, and the review of admissions and long-stay cases are performed by:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>a. the same committee or group;</td>
<td></td>
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<tr>
<td>F834</td>
<td>b. or more committees or groups.</td>
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<tr>
<td></td>
<td>Briefly explain who performs these functions.</td>
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</tr>
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</table>

C. Medical Care Evaluation Studies

F855 SNF (405.1137)(c) (Standard) [ ] MET [ ] NOT MET

<table>
<thead>
<tr>
<th>CODE</th>
<th>UTILIZATION REVIEW</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>F856</td>
<td>1. Medical care evaluation studies are performed to promote the most effective and efficient use of available health facilities and services consistent with resident needs and professionally recognized standards of health care.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>F857</td>
<td>2. Studies emphasize identification and analysis of patterns of resident care and suggest, where appropriate, possible changes for maintaining consistently high quality care and effective and efficient use of services.</td>
<td></td>
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</tr>
</tbody>
</table>
### NAME OF FACILITY

<table>
<thead>
<tr>
<th>CODE</th>
<th>UTILIZATION REVIEW</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>FB38</td>
<td>3. Each medical care evaluation study identifies and analyzes factors related to the care rendered in the facility and where indicated, results in recommendations for change beneficial to residents, staff, the facility, and the community.</td>
<td></td>
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</tr>
<tr>
<td>FB39</td>
<td>4. Studies, on a sample or other basis, include, but need not be limited to, admissions, durations of stay, ancillary services furnished (including drugs and biologics), and professional services performed on premises.</td>
<td></td>
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</tr>
<tr>
<td>FB40</td>
<td>At least one study was completed during the last year. Type of study last completed:</td>
<td></td>
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</tr>
</tbody>
</table>

**D. Extended Stay Review**

<p>| FB41 | SNF (405.137(d)) (Standard) | ☐ MET | ☐ NOT MET | |
|------|-----------------------------|-------|-----------| |
| FB42 | 1. Periodic review is made of each current inpatient skilled nursing facility beneficiary case of continuous extended duration, and the length of which is defined in the utilization review plan to determine whether further inpatient stay is necessary. |  |  |  | |
| FB43 | 2. The review is based on the attending physician's reasons for and plan for continued stay and any other documentation the committee or group deems appropriate. |  |  |  | |
| FB44 | 3. Cases are screened by: a. A qualified non-physician representative of the committee. b. The group. c. The reviewer uses criteria established by the physician members of the committee. |  |  |  | |</p>
<table>
<thead>
<tr>
<th>CODE</th>
<th>UTILIZATION REVIEW</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>F847</td>
<td></td>
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<td>4. In instances when non-physician members are utilized, those cases are referred to a physician member for further review when it appears that the resident no longer requires further inpatient care.</td>
</tr>
<tr>
<td>F848</td>
<td></td>
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<td></td>
<td>5. Non-physician representatives used to screen extended stay review cases, have experience in such screening or appropriate training in the application of the screening criteria used, or both.</td>
</tr>
<tr>
<td>F849</td>
<td></td>
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<td></td>
<td>6. Before the expiration of each new period, the case must be reviewed again in like manner with such reviews being repeated as long as the stay continues beyond the scheduled review dates and notice has not been given pursuant to paragraph (e) of this section.</td>
</tr>
<tr>
<td></td>
<td>E. Further Stay Not Medically Necessary</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>F850</td>
<td>SNF (405.1137(c)) (Standard)</td>
<td>□</td>
<td>MET</td>
<td>□ NOT MET</td>
<td></td>
</tr>
<tr>
<td>F851</td>
<td>1. A final determination of the committee or group that continued stay is not medically necessary is made by at least two physician members of the committee or group, except that the final determination may be made by one physician where the attending physician, when given an opportunity to express his views, does not do so, or does not contest the finding that the continued stay is not medically necessary.</td>
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</tr>
<tr>
<td>F852</td>
<td>2. If the committee or group, or its nonphysician representative where a physician member concurs, has reason to believe from the review of an extended duration case or a case reviewed as part of a medical care evaluation study that further stay is no longer medically necessary, the committee or group shall notify the individual's attending physician and afford him an opportunity to present his views before it makes a final determination.</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>CODE</td>
<td>UTILIZATION REVIEW</td>
<td>YES</td>
<td>NO</td>
<td>N/A</td>
<td>EXPLANATORY STATEMENT</td>
</tr>
<tr>
<td>-------</td>
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<td>--------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>F853</td>
<td>3. If the final determination of the committee or group is that further stay is no longer medically necessary, written notification of the finding is given to the facility, the attending physician, and the individual (or where appropriate, his next of kin) no later than 2 days after such final determination is made and, in no event in the case of an extended duration case, later than 3 working days after the end of the extended duration period specified pursuant to paragraph (d) of this section.</td>
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**F. Administrative Responsibilities**

<table>
<thead>
<tr>
<th>CODE</th>
<th>UTILIZATION REVIEW</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
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<tbody>
<tr>
<td>F854</td>
<td>SNF (405.1137(i)) (Standard)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
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<table>
<thead>
<tr>
<th>CODE</th>
<th>UTILIZATION REVIEW</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>F855</td>
<td>The administrative staff of the facility is kept directly and fully informed of committee activities to facilitate support and assistance. (Explain)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**G. Utilization Review Records**

<table>
<thead>
<tr>
<th>CODE</th>
<th>UTILIZATION REVIEW</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
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<tbody>
<tr>
<td>F856</td>
<td>SNF (405.1137(g)) (Standard)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
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</table>

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<thead>
<tr>
<th>CODE</th>
<th>UTILIZATION REVIEW</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>F857</td>
<td>1. Written records of committee activities are maintained.</td>
<td></td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>CODE</th>
<th>UTILIZATION REVIEW</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>F858</td>
<td>2. Appropriate reports, signed by the committee chairman, are made regularly to the medical staff, administrative staff, governing body, and sponsors (if any).</td>
<td></td>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CODE</th>
<th>UTILIZATION REVIEW</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>F859</td>
<td>3. Minutes of each committee meeting is maintained and include at least: a. Name of committee.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CODE</th>
<th>UTILIZATION REVIEW</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>F860</td>
<td>b. Date and duration of meeting.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CODE</th>
<th>UTILIZATION REVIEW</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>F861</td>
<td>c. Names of committee members present and absent.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CODE</td>
<td>UTILIZATION REVIEW</td>
<td>YES</td>
<td>NO</td>
<td>N/A</td>
<td>EXPLANATORY STATEMENT</td>
</tr>
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</tr>
<tr>
<td>F962</td>
<td>4. Description of activities presently in progress to satisfy the requirements for medical care evaluation studies, including the subject, reason for study, dates of commencement and expected completion, summary of studies completed since the last meeting, conclusions and follow-up on implementation of recommendations made from previous studies.</td>
<td></td>
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</tr>
<tr>
<td>F963</td>
<td>5. Summary of extended duration cases reviewed including the number of cases, identification number, admission and review dates, and decision reached, including the basis for each determination and action taken for each case not approved for extended care.</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>F864</td>
<td>H. Discharge Planning</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>SNF (405.1137(h)) (Standard)</td>
<td>□ MET</td>
<td>□ NOT MET</td>
<td></td>
<td>The facility maintains a centralized, coordinated program to ensure that each resident has a planned program of continuing care which meets his postdischarge needs.</td>
</tr>
<tr>
<td>F865</td>
<td>1. The facility has in operation an organized discharge planning program.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F866</td>
<td>The utilization review committee, in its evaluation of the current status of each extended duration case, has available to it the results of such discharge planning and information on alternative available community resources to which the resident may be referred.</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>F867</td>
<td>2. The facility maintains written discharge planning procedures which describe:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>a. How the discharge coordinator will function, and his authority and relationships with the facility’s staff.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F868</td>
<td>b. The maximum time period after which reevaluation of each resident’s discharge plan is made.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Form HCA-AD5 (3-99)
<table>
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<tr>
<th>CODE</th>
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<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>F869</td>
<td>c. Local resources available to the facility, the resident, and the attending physician to assist in developing and implementing individual discharge plans; and</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F870</td>
<td>d. Provisions for periodic review and reevaluation of the facility's discharge planning program.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F871</td>
<td>3. At the time of discharge, the facility provides those responsible for the resident's post discharge care with appropriate summary of information about the discharged resident to ensure the optimal continuity of care.</td>
<td></td>
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<tr>
<td></td>
<td>The discharge summary includes at least the following:</td>
<td></td>
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</tr>
<tr>
<td>F872</td>
<td>a. Current information relative to diagnoses.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F873</td>
<td>b. Rehabilitation potential.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F874</td>
<td>c. A summary of the course of prior treatment.</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>F875</td>
<td>d. Physician orders for the immediate care of the resident.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F876</td>
<td>e. Pertinent social information.</td>
<td></td>
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</tr>
</tbody>
</table>
§ 488.105 Long term care survey forms, Part B.

PART B

MEDICARE / MEDICAID SKILLED NURSING FACILITY AND INTERMEDIATE CARE FACILITY SURVEY REPORT

<table>
<thead>
<tr>
<th>PROVIDER NUMBER</th>
<th>FACILITY NAME AND ADDRESS (City, State, Zip)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| VENDOR NUMBER   |                                             |
|-----------------|                                             |

<table>
<thead>
<tr>
<th>SURVEY DATE</th>
<th></th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SURVEYORS’ NAMES</th>
<th>TITLES</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SURVEY TEAM COMPOSITION

F1 Indicate the Number of Surveyors According to Discipline:

A. Administrator  H. Life Safety Code Specialist
B. Nurse          I. Laboratory
C. Dietitian      J. Sanitarian
D. Pharmacist     K. Therapist
E. Records Admin.  L. Physician
F. Social Worker  M. National Institute of Mental Health
G. Qualified Mental Health Professional  N. Other

Note: More than one discipline may be marked for surveyors qualified in multiple disciplines.

F2 Indicate the Total Number of Surveyors Onsite: __________________________

Form HCFA-619 (2-98)  (CONTINUED ON REVERSE)  Page 1
<table>
<thead>
<tr>
<th>PROVIDER NO.</th>
<th>F3</th>
<th>F4</th>
<th>F5</th>
<th>F6</th>
<th>TOTAL RESIDENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BATHING</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>F7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Number of residents requiring assistance in bathing more than one part of body—or does not bathe self.</td>
</tr>
<tr>
<td>F8</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Number of residents requiring assistance in bathing only a single part (as back or disabled extremity) or bathes self completely.</td>
</tr>
<tr>
<td>F9</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>TOTAL</strong></td>
</tr>
<tr>
<td><strong>DRESSING</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F10</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Number of residents totally dressed by another person.</td>
</tr>
<tr>
<td>F11</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Number of residents needing assistance to dress self or remain partly dressed. (Exclude those residents totally dressed.)</td>
</tr>
<tr>
<td>F12</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Number of residents able to get clothes from closets and drawers puts on clothes, outer garments, braces manages fasteners. Act of tying shoes is excluded.</td>
</tr>
<tr>
<td>F13</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>TOTAL</strong></td>
</tr>
<tr>
<td><strong>TOILETTING</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F14</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Number of residents not toileted. (Use protective padding, catheter.)</td>
</tr>
<tr>
<td>F15</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Number of residents who must use a bedpan or commode and/or receive assistance in getting to and using a toilet.</td>
</tr>
<tr>
<td>F16</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Number of residents able to get to toilet gets on and off toilet—cleans self—arranges clothes.</td>
</tr>
<tr>
<td>F17</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>TOTAL</strong></td>
</tr>
<tr>
<td><strong>TRANSFERRING</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F18</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Number of residents needing assistance in all transfers (moving in or out of bed and/or chair, toilet, tub or wheelchair).</td>
</tr>
<tr>
<td>F19</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Number of residents needing assistance in transferring to toilet and tub only.</td>
</tr>
<tr>
<td>F20</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Number of residents able to complete all transfers independently (may or may not be using mechanical support).</td>
</tr>
<tr>
<td>F21</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>TOTAL</strong></td>
</tr>
<tr>
<td><strong>CONTINENCE</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F22</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Number of residents with indwelling or external catheters.</td>
</tr>
<tr>
<td>F23</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Number of residents with partial or total incontinence in urination or defecation—partial or total control by suppositories or enemas, regulated use of urinals and/or bedpans.</td>
</tr>
<tr>
<td>F24</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Number of residents with urination and defecation entirely self-controlled.</td>
</tr>
<tr>
<td>F25</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>TOTAL</strong></td>
</tr>
<tr>
<td><strong>FEEDING</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F26</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Number of residents who receive enteral/parenteral feedings.</td>
</tr>
<tr>
<td>F27</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Number of residents who receive NG tube feedings.</td>
</tr>
<tr>
<td>F28</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Number of residents who require assistance in act of eating.</td>
</tr>
<tr>
<td>F29</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Number of residents who get food from plate or its equivalent into mouth—pre-cutting, boiling and preparing of food, buttering bread, opening cans, removing plate covers, etc., are excluded from evaluation.</td>
</tr>
<tr>
<td>F30</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>TOTAL</strong></td>
</tr>
</tbody>
</table>

* MUST EQUAL TOTAL NUMBER OF RESIDENTS IN FACILITY
### NAME OF FACILITY

<table>
<thead>
<tr>
<th>CODE</th>
<th>GOVERNING BODY (CONDITION OF PARTICIPATION)</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>F50</td>
<td>SNF (405.1121)</td>
<td>☐</td>
<td>☐</td>
<td>☑</td>
<td></td>
</tr>
</tbody>
</table>

#### RESIDENT RIGHTS

<table>
<thead>
<tr>
<th>F51</th>
<th>SNF (405.1121)(k) (Standard)</th>
<th>☐</th>
<th>☐</th>
<th>☑</th>
<th>Indicators A thru K apply to this standard for SNFs.</th>
</tr>
</thead>
<tbody>
<tr>
<td>F52</td>
<td>ICF (442.311) (Standard)</td>
<td>☐</td>
<td>☐</td>
<td>☑</td>
<td>Indicators A thru K apply to this standard for ICFs.</td>
</tr>
</tbody>
</table>

#### A. Information

1. The facility informs each resident, before or at the time of admission, of his/her rights and responsibilities.

2. The facility informs each resident, before or at the time of admission, of all rules governing resident conduct.

3. The facility informs each resident of amendments to their policies on residents' rights and responsibilities and rules governing conduct.

4. Each resident acknowledges in writing receipt of residents' rights information and any amendment to it.

5. The resident must be informed in writing of all services and charges for services.

6. The resident must be informed in writing of all changes in services and charges before or at the time of admission and on a continuing basis.

7. The resident must be informed of services not covered by Medicare or Medicaid and not covered in the basic rate.
<table>
<thead>
<tr>
<th>CODE</th>
<th>GOVERNING BODY</th>
</tr>
</thead>
<tbody>
<tr>
<td>B. Medical Condition and Treatment</td>
<td></td>
</tr>
<tr>
<td>F60</td>
<td>1. Each resident is informed by a physician of his/her health and medical condition unless the physician decides that informing the resident is medically contraindicated.</td>
</tr>
<tr>
<td>F61</td>
<td>2. Each resident is given an opportunity to participate in planning his/her total care and medical treatment.</td>
</tr>
<tr>
<td>F62</td>
<td>3. Each resident is given an opportunity to refuse treatment.</td>
</tr>
<tr>
<td>F63</td>
<td>4. Each resident gives informed, written consent before participating in experimental research.</td>
</tr>
<tr>
<td>F64</td>
<td>5. If the physician decides that informing the resident of his/her health and medical condition is medically contraindicated, the physician has documented this decision in the resident's medical record.</td>
</tr>
<tr>
<td>C. Transfer and Discharge</td>
<td></td>
</tr>
<tr>
<td>F65</td>
<td>Each resident is transferred or discharged only for:</td>
</tr>
<tr>
<td>F66</td>
<td>1. Medical reasons.</td>
</tr>
<tr>
<td>F67</td>
<td>2. His/her welfare or that of other residents.</td>
</tr>
<tr>
<td>F68</td>
<td>3. Payment which is prohibited by the Medicare or Medicaid program.</td>
</tr>
<tr>
<td>F69</td>
<td>4. Each resident is given reasonable advance notice to assure orderly transfer or discharge. EXCEPTION: Not required for ICU residents.</td>
</tr>
<tr>
<td>D. Exercising Rights</td>
<td></td>
</tr>
<tr>
<td>F70</td>
<td>1. Each resident is encouraged and assisted to exercise his/her rights as a resident of the facility and as a citizen.</td>
</tr>
<tr>
<td></td>
<td>2. Each resident is allowed to submit complaints and recommendations concerning the policies and services of the facility to staff or to outside representatives of the resident's choice or both.</td>
</tr>
<tr>
<td>CODE</td>
<td>GOVERNING BODY</td>
</tr>
<tr>
<td>------</td>
<td>----------------</td>
</tr>
<tr>
<td>71</td>
<td>3. Such complaints are submitted free from restraint, coercion, discrimination, or reprisal.</td>
</tr>
<tr>
<td>72</td>
<td>E. Financial Affairs</td>
</tr>
<tr>
<td>73</td>
<td>1. Residents are allowed to manage their own personal financial affairs.</td>
</tr>
<tr>
<td>73</td>
<td>2. The facility establishes and maintains a system that assures full and complete accounting of residents' personal funds. An accounting report is made to each resident in a skilled nursing facility at least on a quarterly basis.</td>
</tr>
<tr>
<td>74</td>
<td>3. The facility does not commingle resident funds with any other funds.</td>
</tr>
<tr>
<td>75</td>
<td>4. If a resident requests assistance from the facility in managing his/her personal financial affairs, resident's delegation is in writing.</td>
</tr>
<tr>
<td>76</td>
<td>5. The facility system of accounting includes written receipts for:</td>
</tr>
<tr>
<td>77</td>
<td>All personal possessions and funds received by or deposited with the facility.</td>
</tr>
<tr>
<td>78</td>
<td>All disbursements made to or for the resident.</td>
</tr>
<tr>
<td>79</td>
<td>F. Freedom from Abuse and Restraints</td>
</tr>
<tr>
<td>80</td>
<td>1. Each resident is free from mental and physical abuse.</td>
</tr>
<tr>
<td>80</td>
<td>2. Chemical and physical restraints are only used when authorized by a physician in writing for a specified period of time or in emergencies.</td>
</tr>
<tr>
<td>CODE</td>
<td>GOVERNING BODY</td>
</tr>
<tr>
<td>------</td>
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</tr>
<tr>
<td>F81</td>
<td>3. If used in emergencies, they are necessary to protect the resident from injury to himself/herself or others.</td>
</tr>
<tr>
<td>F82</td>
<td>4. The emergency use is authorized by a professional staff member identified in the written policies and procedures of the facility.</td>
</tr>
<tr>
<td>F83</td>
<td>5. The emergency use is reported promptly to the resident's physician by the staff member.</td>
</tr>
<tr>
<td>G. Privacy</td>
<td></td>
</tr>
<tr>
<td>F84</td>
<td>1. Each resident is treated with respect, consideration and full recognition of his/her dignity and individuality.</td>
</tr>
<tr>
<td>F85</td>
<td>2. Each resident is given privacy during treatment and care of personal needs.</td>
</tr>
<tr>
<td>F86</td>
<td>3. Each resident's records, including information in an automated data bank, are treated confidentially.</td>
</tr>
<tr>
<td>F87</td>
<td>4. Each resident must give written consent before the facility releases information from his/her record to someone not otherwise authorized to receive it.</td>
</tr>
<tr>
<td>F88</td>
<td>5. Married residents are given privacy during visits by their spouses.</td>
</tr>
<tr>
<td>F90</td>
<td>6. Married residents are permitted to share a room.</td>
</tr>
<tr>
<td>H. Work</td>
<td></td>
</tr>
<tr>
<td>F90</td>
<td>No resident may be required to perform services for the facility.</td>
</tr>
<tr>
<td>CODE</td>
<td>GOVERNING BODY</td>
</tr>
<tr>
<td>------</td>
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<td>F91</td>
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<td>F92</td>
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<td>F93</td>
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<td>F95</td>
<td></td>
</tr>
<tr>
<td>ICF (442.312) (Standard)</td>
<td>☐ MET</td>
</tr>
<tr>
<td>F96</td>
<td></td>
</tr>
<tr>
<td>F97</td>
<td></td>
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</table>
## NAME OF FACILITY

<table>
<thead>
<tr>
<th>CODE</th>
<th>GOVERNING BODY</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>F98</td>
<td>SNF (405.1121)(N) (Standard)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F99</td>
<td>ICF (442.314) (Standard)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
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</tr>
<tr>
<td>F100</td>
<td>1. Facility staff are knowledgeable about the problems and needs of the aged, ill, and disabled.</td>
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</tr>
<tr>
<td>F101</td>
<td>2. Facility staff practices proper techniques in providing care to the aged, ill, and disabled.</td>
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</tr>
<tr>
<td>F102</td>
<td>3. Facility staff practice proper technique for prevention and control of infection, fire prevention and safety, accident prevention, confidentiality of resident information, and preservation of resident dignity, including protection of privacy and personal and property rights.</td>
<td>☐</td>
<td>☐</td>
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</tr>
</tbody>
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## STATUS CHANGE NOTIFICATIONS

<table>
<thead>
<tr>
<th>CODE</th>
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<th>YES</th>
<th>NO</th>
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<th>EXPLANATORY STATEMENT</th>
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<tbody>
<tr>
<td>F103</td>
<td>SNF (405.1121)(B) (Standard)</td>
<td>☐ MET</td>
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<td>F104</td>
<td>ICF (442.307) (Standard)</td>
<td>☐ Met</td>
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<tr>
<td>F105</td>
<td>1. The facility notifies the resident's attending physician and other responsible persons in the event of an accident involving the resident, or other significant change in the resident's physical, mental, or emotional status, or resident charges, billings, and related administrative matters.</td>
<td>☐</td>
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</tr>
<tr>
<td>F106</td>
<td>2. Except in a medical emergency, a resident is not transferred or discharged, nor is treatment altered radically, without consultation with the resident or, if the resident is incompetent, without prior notification of next of kin or sponsor.</td>
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<td>☐</td>
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<td>CODE</td>
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<td>N/A</td>
<td>EXPLANATORY STATEMENT</td>
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<tr>
<td>P107</td>
<td>SNF (405.1123)</td>
<td></td>
<td>MET</td>
<td></td>
<td>NOT MET</td>
</tr>
</tbody>
</table>

**A. Medical Findings and Orders at Time of Admission**

| P108 | SNF (405.1123)(a)(Standards) | MET | NO | N/A | |

1. There is made available to the facility prior to or at the time of admission, resident information which includes current medical findings, diagnoses, and orders from a physician for immediate care of the resident.

2. Information about the rehabilitation potential of the resident and a summary of prior treatment are made available to the facility at the time of admission or within 48 hours thereafter.
<table>
<thead>
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<th>NO</th>
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<th>EXPLANATORY STATEMENT</th>
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<tbody>
<tr>
<td>FL1</td>
<td>Resident Supervision by Physician</td>
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<tr>
<td>FL11</td>
<td>SNF (405.112b)(j) (Standard)</td>
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<tr>
<td>FL12</td>
<td>ICF (442.346) (Standard)</td>
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<tr>
<td></td>
<td>Indicators B and C apply to</td>
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<tr>
<td></td>
<td>Full standard for ICFs.</td>
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</tr>
<tr>
<td>FL13</td>
<td>1. Every resident must be under the</td>
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<tr>
<td></td>
<td>supervision of a physician.</td>
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<tr>
<td>FL14</td>
<td>2. A physician prescribes a planned</td>
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<tr>
<td></td>
<td>regimen of care based on a medical</td>
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<tr>
<td></td>
<td>evaluation of each resident's</td>
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</tr>
<tr>
<td></td>
<td>immediate and long-term care needs.</td>
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<td>Exception: Not required for ICF</td>
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<tr>
<td></td>
<td>residents</td>
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<tr>
<td>FL15</td>
<td>3. A physician is available to</td>
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<tr>
<td></td>
<td>provide care in the absence of any</td>
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<tr>
<td></td>
<td>resident's attending physician.</td>
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<td>FL16</td>
<td>4. Medical evaluation is done within</td>
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<td></td>
<td>48 hours of admission unless done</td>
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<td>within 5 days prior to admission.</td>
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<td>Exception: Not required for ICF</td>
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<td>residents</td>
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<tr>
<td>FL17</td>
<td>5. Each resident is seen by their</td>
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<td>attending physician at least once</td>
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<td>every 30 days for the first 60 days</td>
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<td>after admission.</td>
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<td>Exception: ICF residents must be seen</td>
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<tr>
<td></td>
<td>every 60 days unless otherwise</td>
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<td>justified and documented by the</td>
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<td>attending physician.</td>
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<td>FL18</td>
<td>6. Each resident's total program of</td>
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<td>care including medications and</td>
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<td>treatments is reviewed during a visit</td>
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<td>by the attending physician at least</td>
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<td>once every 30 days for the first 90</td>
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<td>days and revised as necessary.</td>
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<td>Exception: Only medications must be</td>
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<td>reviewed quarterly for ICF residents.</td>
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<td>F119</td>
<td>7. Progress notes are written and signed by the physician at the time of each visit, and all orders are signed by the physician.</td>
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<tr>
<td>F120</td>
<td>8. Alternate physician visit schedules that exceed a 30-day schedule adopted after the 90th day following admission are justified by the attending physician in the medical record. These visits cannot exceed 60 days or apply to residents who require specialized rehabilitation schedules. <strong>EXCEPTION:</strong> Not required for ICF residents.</td>
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<td>F121</td>
<td>C. Emergency Services</td>
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<td>SNF (405.1123(c)) (Standard)</td>
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<td>F122</td>
<td>Emergency services from a physician are available and provided to each resident who requires emergency care.</td>
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<td>SNF (405.1124(c)) (Standard)</td>
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<td>Indicators A and B apply to this standard for SNFs</td>
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<td>F125</td>
<td>ICF (440.338)</td>
<td>□ Met</td>
<td>□ Not Met</td>
<td></td>
<td>Indicators A thru E apply to this standard for ICFs except where noted.</td>
</tr>
<tr>
<td></td>
<td>A. The facility provides nursing services which are sufficient to meet nursing needs of all residents all hours of each day.</td>
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<tr>
<td>F126</td>
<td>1. Each resident receives all treatments, medications and diet as prescribed. Deviations are reported and appropriate action is taken.</td>
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<td>CODE</td>
<td>NURSING SERVICES</td>
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<td>NO</td>
<td>N/A</td>
<td>EXPLANATORY STATEMENT</td>
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<tr>
<td>F127</td>
<td>2. Each resident receives daily personal hygiene as needed to assure cleanliness, good skin care, good grooming, and oral hygiene taking into account individual preferences. Residents are encouraged to engage in self care activity.</td>
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<tr>
<td>F128</td>
<td>3. Each resident receives care necessary to prevent skin breakdown.</td>
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<tr>
<td>F129</td>
<td>4. Each resident with a decubitus receives care necessary to promote the healing of the decubitus including proper dressing.</td>
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<tr>
<td>F130</td>
<td>5. When residents require restraints the application is ordered by the physician, applied properly, and released at least every 2 hours.</td>
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<tr>
<td>F131</td>
<td>6. Each resident with incontinence is provided with care necessary to encourage continence including frequent toileting and opportunities for rehabilitative training.</td>
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<tr>
<td>F132</td>
<td>7. Each resident with a urinary catheter receives proper routine care including periodic evaluation.</td>
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<tr>
<td>F133</td>
<td>8. Each resident receives proper care for the following needs:</td>
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<tr>
<td></td>
<td>Injections</td>
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<tr>
<td></td>
<td>Parenteral fluids</td>
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<tr>
<td></td>
<td>Colostomy/Ileostomy</td>
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<tr>
<td></td>
<td>Respiratory Care</td>
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<td>Tracheostomy Care</td>
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<td></td>
<td>Suctioning</td>
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<td>Tube Feeding</td>
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<tr>
<td>F134</td>
<td>9. Infection Control Techniques are properly carried out in the provision of care to each resident.</td>
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<tr>
<td>CODE</td>
<td>NURSING SERVICES</td>
<td>YES</td>
<td>NO</td>
<td>N/A</td>
<td>EXPLANATORY STATEMENT</td>
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<tr>
<td>F135</td>
<td>10. Proper nursing and sanitary procedures and techniques are used when medications are given to residents.</td>
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<tr>
<td>F136</td>
<td>11. Adequate resident care supplies are available for providing treatments.</td>
<td></td>
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<tr>
<td>F137</td>
<td><strong>B. Twenty-Four Hour Nursing Service</strong>&lt;br&gt;1. Nursing personnel, including registered nurses, licensed practical (vocational) nurses, nurse aides, orderlies, and ward clerks, are assigned duties consistent with their education and experience, and based on the characteristics of the resident load&lt;br&gt;<strong>EXCEPTION:</strong> Not required for ICFs.</td>
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<tr>
<td>F138</td>
<td>2. Weekly time schedules are maintained and indicate the number and classifications of nursing personnel including relief personnel, who worked on each unit for each tour of duty.&lt;br&gt;(If a distinct part certification, show the staffing for the DP and, if appropriate, any nonparticipating remainder and explain any sharing of nursing personnel.)&lt;br&gt;&lt;br&gt;<strong>Exception:</strong> Not required for Freestanding ICFs.</td>
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<tr>
<td>F139</td>
<td>3. There is a sufficient number of nursing staff available to meet the total needs of all residents.</td>
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<tr>
<td>F140</td>
<td>4. There is a registered nurse on the day tour of duty 7 days a week.&lt;br&gt;&lt;br&gt;<strong>Exception:</strong> Not required for ICF residents.</td>
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<tr>
<td>CODE</td>
<td>NURSING SERVICES</td>
<td>YES</td>
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<td>N/A</td>
<td>EXPLANATORY STATEMENT</td>
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<tr>
<td>F141</td>
<td>C. Charge Nurse</td>
<td>☐ MET</td>
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</tbody>
</table>

1. A registered nurse or a qualified licensed practical (or vocational) nurse is designated as charge nurse by the director of nursing for each tour of duty.

   Exception: Not required for ICFs.

2. The director of nursing services does not serve as charge nurse in a facility with an average daily total occupancy of 60 or more residents.

   Exception: Not required for ICFs.

3. The ICF must have a registered nurse, or a licensed practical or vocational nurse full-time, 7 days a week, on the day shift.

   Exception: Not required for SNFs.
List the number of full-time equivalents of RN's, LPN's, Aides/Orderlies assigned to nursing duty from the last 3 complete weeks. (Note only actual staff on duty.)

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<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
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NAME OF FACILITY

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<th>Day 5</th>
<th>Day 6</th>
<th>Day 7</th>
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<td>F155</td>
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STAFFING PATTERN WORKSHEETS DAY OF SURVEY (OPTIONAL)

ENTIRE FACILITY STAFFING PATTERN (DAY OF SURVEY)

<table>
<thead>
<tr>
<th>DAY</th>
<th>CODE</th>
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<td>F158</td>
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<tr>
<td>EVENING</td>
<td>F159</td>
<td>REPORT</td>
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<td>F162</td>
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UNIT STAFFING PATTERN WORKSHEET (DAY OF SURVEY)

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<th>DAY</th>
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<td>F163</td>
<td>RN</td>
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<td>EVENING</td>
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<tr>
<td>NIGHT</td>
<td>F165</td>
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<tr>
<td>CENSUS</td>
<td>F166</td>
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<tr>
<td>CODE</td>
<td>NURSING SERVICES</td>
<td>YES</td>
<td>NO</td>
<td>N/A</td>
<td>EXPLANATORY STATEMENT</td>
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<tr>
<td>P167</td>
<td>SNF (405.1124(e)) (Standard)</td>
<td>☐ MET</td>
<td>☐</td>
<td>☐</td>
<td>1. Each resident’s needs are addressed in a written plan of care which demonstrates that the plans of all services are integrated, consonant with the physician’s plan of medical care, and implemented shortly after admission.</td>
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<tr>
<td>P168</td>
<td>ICF (442.341) (Standard)</td>
<td>☐ MET</td>
<td>☐</td>
<td>☐</td>
<td>2. Each professional service identifies needs, goals, plans, and evaluates the effectiveness of interventions, plus institutes changes in the plan of care in a timely manner.</td>
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<tr>
<td>P169</td>
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<td></td>
<td>3. Rehabsitive Nursing Services are performed daily, and recorded for those residents who require such service.</td>
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<tr>
<td>P170</td>
<td>SNF (405.1124(e)) (Standard)</td>
<td>☐ MET</td>
<td>☐</td>
<td>☐</td>
<td>4. Each resident receives rehabilitative nursing care to promote maximum physical functioning to prevent immobility, deformities, and contractures.</td>
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<tr>
<td>P171</td>
<td>ICF (442.342) (Standard)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>5. There is an ongoing evaluation of each resident’s rehabilitative nursing needs. This may include:</td>
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<tr>
<td>P172</td>
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<td></td>
<td></td>
<td>a) Range of motion, ambulation, turning and positioning and other activities;</td>
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<td>P173</td>
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<td>b) Assistance and instruction in the activities of daily living such as feeding, dressing, grooming, oral hygiene and toilet activities;</td>
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<td>P174</td>
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<td></td>
<td>c) Remotivation therapy and/or reality orientation when appropriate.</td>
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</tbody>
</table>
| P175 | | | | | 3. These activities are coordinated with other resident care services.
NAME OF FACILITY

<table>
<thead>
<tr>
<th>CODE</th>
<th>NURSING SERVICES</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td>y. The facility has an awareness of nutritional needs and fluid intake of residents and provides prompt assistance where necessary in feeding residents.</td>
</tr>
<tr>
<td>1180</td>
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<td></td>
<td></td>
<td>SNF (405.112G)(f) (Standard)</td>
</tr>
<tr>
<td>1180</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1. Each resident is provided with the amount of food and fluid on a daily basis necessary to maintain their appropriate minimum average weight. Between meal feedings are offered and the amount consumed is observed. Daily food and fluid intake is observed and encouraged.</td>
</tr>
<tr>
<td>1180</td>
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<td>2. Each resident needing assistance in eating or drinking is provided prompt assistance. Specific self-help devices are available when necessary.</td>
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<tr>
<td>1180</td>
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<td>3. Deviations from normal food and fluid intake are recorded and reported to the charge nurse and the attending physician.</td>
</tr>
<tr>
<td>NAME OF FACILITY</td>
<td>COMMENTS</td>
<td>EXPLANATORY STATEMENT</td>
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</tbody>
</table>

- **F103** Administration of Drugs
  - SNF 480.111(g)(4) (Standard) [MET] [MET] [MET] [MET]
  - ICF 442.2301 (Standard) [MET] [MET] [MET] [MET]

- **F104** Drugs and biologics are administered as soon as possible after doses are prepared.
  - SNF 480.111(g)(4) (Standard) [MET] [MET] [MET] [MET]
  - ICF 442.2301 (Standard) [MET] [MET] [MET] [MET]

- **F105** ICF residents may self-administer medication only with their physician's permission.
  - SNF 480.111(g)(4) (Standard) [MET] [MET] [MET] [MET]
  - ICF 442.2301 (Standard) [MET] [MET] [MET] [MET]

- **F106** Medication administered in accordance with written orders of the physician.
  - SNF 480.111(g)(4) (Standard) [MET] [MET] [MET] [MET]
  - ICF 442.2301 (Standard) [MET] [MET] [MET] [MET]

(See Fina 4828-522)”

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*Section 488.105*
NAME OF FACILITY

<table>
<thead>
<tr>
<th>CODE</th>
<th>DIETETIC SERVICES (CONDITION OF PARTICIPATION)</th>
<th>YES</th>
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<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
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<tbody>
<tr>
<td>F193</td>
<td>SNF (405.1125)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
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<tr>
<td>F194</td>
<td>ICF (422.332) (Standard)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
<td></td>
<td>Indicators A and B apply to this standard for ICFS.</td>
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<tr>
<td></td>
<td>A. Menus and Nutritional Adequacy</td>
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<tr>
<td>F195</td>
<td>SNF (405.1125)(00) (Standard)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
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</tr>
<tr>
<td>F196</td>
<td>Menus are planned and followed to meet the nutritional needs of each resident in accordance with physicians' orders and, to the extent medically possible, based on the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences.</td>
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<tr>
<td></td>
<td>B. Therapeutic Diets</td>
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<tr>
<td>F197</td>
<td>SNF (405.1125)(c) (Standard)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
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<tr>
<td>F198</td>
<td>1. Therapeutic diets are prescribed by the attending physician.</td>
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<tr>
<td>F199</td>
<td>2. Therapeutic menus are planned in writing, prepared, and served as ordered with supervision from the dietician and advice from the physician whenever necessary.</td>
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<tr>
<td>F200</td>
<td>Number of Regular Diets.</td>
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<tr>
<td>F201</td>
<td>Number of Therapeutic Diets</td>
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<td>F202</td>
<td>Number of Mechanically Altered Diets</td>
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<td>F203</td>
<td>Number of Tube Feedings</td>
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<tr>
<td>CODE</td>
<td>CODE DESCRIPTION</td>
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</table>
| F204 | SNF (405.1125(e)) | MET | NOT MET | C. Preparation
| F205 | 1. Food is prepared by methods that conserve its nutritive value and flavor. | | |
| F206 | 2. Meals are palatable, served at proper temperatures. They are cut, ground, chopped, pureed or in a form which meets individual resident needs. | | |
| F207 | 3. If a resident refuses food served, appropriate substitutes of similar nutritive value are offered. | | |
| F208 | SNF (405.1125(dd)) | MET | NOT MET | D. Frequency
| F209 | ICF (442.331) | MET | NOT MET | |
| F210 | 1. At least three meals are served daily at regular hours with not more than a 14-hour span between a substantial evening meal and breakfast. | | |
| F211 | 2. To the extent medically possible, bedtime nourishments are offered to all residents. | | Exception: Not required for ICF Residents. |
| F212 | SNF (405.1125(46)) | MET | NOT MET | E. Staffing
| F213 | 1. Food service personnel are on duty daily over a period of 12 or more hours. | | |
NAME OF FACILITY

<table>
<thead>
<tr>
<th>CODE</th>
<th>SPECIALIZED REHABILITATIVE SERVICES (CONDITION OF PARTICIPATION)</th>
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<td>F214</td>
<td>SNF (405-1126)</td>
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<tr>
<td>F215</td>
<td>SNF (405-1126) (Standard)</td>
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<td>F216</td>
<td>ICF (442-343) (Standard)</td>
<td>☐</td>
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</table>

A. Plan of Care

- Rehabilitative services are provided under a written plan of care, initiated by the attending physician and developed in consultation with appropriate therapist(s) and the nursing service.

B. Therapy

- Therapy is provided according to orders of the attending physician in accordance with accepted professional practices by qualified therapists or qualified assistants.

C. Progress

1. A report of the resident's progress is communicated to the attending physician within 2 weeks of the initiation of specialized rehabilitative services.

   Exception: ICF resident's progress must be reviewed regularly.
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<th>CODE</th>
<th>SPECIALIZED REHABILITATIVE SERVICES/PHARMACEUTICAL SERVICES</th>
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<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
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<tbody>
<tr>
<td>F220</td>
<td>2. The resident’s progress is thereafter reviewed regularly, and the plan of rehabilitative care is reevaluated as necessary, but at least every 30 days, by the physician and the therapist. Exceptions: ICF residents’ plans must be revised as necessary.</td>
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<td>F221</td>
<td><strong>PHARMACEUTICAL SERVICES (CONDITION OF PARTICIPATION)</strong></td>
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<tr>
<td>F222</td>
<td>A. Supervision</td>
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<td>F224</td>
<td>The pharmacist reviews the drug regimen of each resident at least monthly and reports any irregularities to the medical director and administrator.</td>
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<td>LABORATORY AND RADIOLOGIC SERVICES/SOCIAL SERVICES</td>
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<td>ICF (442.333) (Standard)</td>
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<tr>
<td>F227</td>
<td>The labeling of drugs and biologicals is based on currently accepted professional principles and includes the appropriate accessory and cautionary instructions as well as an expiration date when applicable.</td>
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<tr>
<td>F228</td>
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<td>☐ MET ☐ NOT MET</td>
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</table>

**Provision of Services**

1. All services are provided only on the orders of a physician.
2. The attending physician is notified promptly of diagnostic findings.
3. Signed and dated reports of a clinical laboratory, X-ray and other diagnostic services are filed with the resident's medical record.
<table>
<thead>
<tr>
<th>Code</th>
<th>Social Services/Activities</th>
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<th>Explanatory Statement</th>
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<td>SNF (405.1130)</td>
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<tr>
<td>P224</td>
<td>SNF (405.1130(a)) (Standard)</td>
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<tr>
<td>P225</td>
<td>ICF (442.344)</td>
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</tbody>
</table>

A. Plan

The medically related social and emotional needs of the resident are identified.

B. Provision of Services

1. Services are provided to meet the social and emotional needs by the facility or by referral to an appropriate social agency.

2. If financial assistance is indicated, arrangements are made promptly for referral to an appropriate agency.
<table>
<thead>
<tr>
<th>CODE</th>
<th>ACTIVITIES</th>
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<th>NOT</th>
<th>EXPLANATORY STATEMENT</th>
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<tbody>
<tr>
<td>F241</td>
<td>ICF (442-245) (standard)</td>
<td>[ ]</td>
<td>[ ]</td>
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<tr>
<td>F242</td>
<td>1. An ongoing program of meaningful activities is provided based on identified needs and interests of each resident. It is designed to promote opportunities for engaging in normal pursuits, including religious activities of their choice, if any.</td>
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<td>F243</td>
<td>2. Unless contraindicated by the attending physicians each resident is encouraged to participate in the activities program.</td>
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<tr>
<td>F244</td>
<td>3. The activities promote the physical, social and mental well-being of the resident.</td>
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<td>F245</td>
<td>4. Equipment is maintained in good working order.</td>
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<tr>
<td>F246</td>
<td>5. Supplies and equipment are available.</td>
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<tr>
<td>CODE</td>
<td>MEDICAL RECORDS</td>
<td>YES</td>
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<td>F247</td>
<td>SNF (405.1132)</td>
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<td>F248</td>
<td>SNF (405.1132(c)(Standard)</td>
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<tr>
<td>F249</td>
<td>ICF (442.31E) (Standard)</td>
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<tr>
<td>F250</td>
<td>1. The medical record contains sufficient information to identify the resident clearly, to justify diagnoses and treatment, and to document results accurately.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CODE</td>
<td>MEDICAL RECORDS</td>
<td>YES</td>
<td>NO</td>
<td>N/A</td>
</tr>
<tr>
<td>--------</td>
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</tr>
<tr>
<td>F251</td>
<td>2. The medical record contains the following information:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>a. Identification information</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F252</td>
<td>b. Admission data including past medical and social history</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F253</td>
<td>c. Transfer form, discharge summary from any transferring facility</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F254</td>
<td>d. Report of resident's attending physician</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>F255</td>
<td>e. Report of physical examinations</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F256</td>
<td>f. Reports of physicians' periodic evaluations and progress notes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F257</td>
<td>g. Diagnostic reports and therapeutic orders</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F258</td>
<td>h. Reports of treatments</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F259</td>
<td>i. Medications administered</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F260</td>
<td>j. An overall plan of care setting forth goals to be accomplished through each service's designated activities, therapies and treatments.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F261</td>
<td>k. Assessments and goals of each service's plan of care</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F262</td>
<td>l. Treatments and services rendered</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F263</td>
<td>m. Progress notes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F264</td>
<td>n. All symptoms and other indications of illness or injury including date, time and action taken regarding each problem.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NAME OF FACILITY</td>
<td>CODE</td>
<td>TRANSFER AGREEMENT (CONDITION OF PARTICIPATION)</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>------------------</td>
<td>------</td>
<td>-----------------------------------------------</td>
<td>-----</td>
<td>----</td>
</tr>
<tr>
<td></td>
<td>F265</td>
<td>SNF (405.1133)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
</tr>
<tr>
<td></td>
<td>F266</td>
<td>SNF (405.1133)(a) (Standard)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
</tr>
<tr>
<td></td>
<td>F267</td>
<td>ICF (442.316) (Standard)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
</tr>
</tbody>
</table>

F268 A. Whenever the attending physician determines that a transfer is medically appropriate between a hospital or a facility providing more specialized care and the nursing facility, admission to the new facility shall be effected in a timely manner.

F269 B. Information necessary for providing care and treatment to transferred individuals is provided.
<table>
<thead>
<tr>
<th>CODE</th>
<th>PHYSICAL ENVIRONMENT</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>F270</td>
<td>SNF (405.1134)</td>
<td></td>
<td></td>
<td></td>
<td>PHYSICAL ENVIRONMENT (CONDITION OF PARTICIPATION)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>A. Nursing Unit</td>
</tr>
<tr>
<td>F271</td>
<td>SNF (405.1134(d)) (Standard)</td>
<td></td>
<td></td>
<td></td>
<td>1. The unit is properly equipped for preparation and storage of drugs and biologicals.</td>
</tr>
<tr>
<td>F272</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2. Utility and storage rooms are adequate in size.</td>
</tr>
<tr>
<td>F273</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3. The unit is equipped to register resident calls with a functioning communication system from resident areas including resident rooms and toilet and bathing facilities.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>B. Dining and Activities Area</td>
</tr>
<tr>
<td>F275</td>
<td>SNF (405.1134(g)) (Standard)</td>
<td></td>
<td></td>
<td></td>
<td>1. The facility provides one or more clean, orderly and appropriately furnished rooms of adequate size designated for resident dining and resident activities.</td>
</tr>
<tr>
<td>F276</td>
<td>ICF (442.329) (Standard)</td>
<td></td>
<td></td>
<td></td>
<td>2. Dining and activity rooms are well lighted and ventilated.</td>
</tr>
<tr>
<td>F277</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3. Any multipurpose room used for dining and resident activities has sufficient space to accommodate all activities and prevent their interference with each other.</td>
</tr>
</tbody>
</table>
### C. Resident Rooms

<table>
<thead>
<tr>
<th>Code</th>
<th>Standard</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>Explanatory Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>F280</td>
<td>SNF (405.1134(e))</td>
<td>☐</td>
<td>☑</td>
<td>☑</td>
<td>N/A</td>
</tr>
<tr>
<td>F281</td>
<td>ICF (442.325)</td>
<td>☐</td>
<td>☑</td>
<td>☑</td>
<td>N/A</td>
</tr>
</tbody>
</table>

1. Single resident rooms have at least 100 square feet.
2. Multiple resident rooms have no more than four residents and at least 80 square feet per resident.
3. Each room is equipped with or conveniently located near toilet and bathing facilities.
4. There is capability of maintaining privacy in each.
5. There is adequate storage space for each resident.
6. There is a comfortable and functioning bed and chair plus a functional cabinet and light.
7. The resident call system functions in resident rooms.
8. Each room is designed and equipped for adequate nursing care and the comfort and privacy of the residents.
9. Each room is at or above grade level.
10. Each room has direct access to a corridor and outside exposure.

Exception: Not required for ICF residents.
### NAME OF FACILITY

<table>
<thead>
<tr>
<th>CODE</th>
<th>PHYSICAL ENVIRONMENT</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>D. Toilet and Bath Facilities</td>
<td>ICF (442.326) (Standard)</td>
<td>☐ MET ☐ NOT MET</td>
<td>☑</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F292</td>
<td>1. Facilities are clean, sanitary and free of odors.</td>
<td>☑</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F293</td>
<td>2. Facilities have safe and comfortable hot water temperatures.</td>
<td>☑</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F294</td>
<td>3. Facilities maintain privacy.</td>
<td>☑</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F295</td>
<td>4. Facilities have grab bars and other safeguards against slipping.</td>
<td>☑</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F296</td>
<td>5. Facilities have fixtures in good condition.</td>
<td>☑</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F297</td>
<td>6. The resident call system functions in toilet and bath facilities.</td>
<td>☑</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E. Social Service Area</td>
<td>SNF (405.1130(d)) (Standard)</td>
<td>☐ MET ☐ NOT MET</td>
<td>☑</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F299</td>
<td>1. Ensures privacy for social service interviewing.</td>
<td>☑</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F300</td>
<td>2. Adequate space for clerical and interviewing functions is provided.</td>
<td>☑</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F301</td>
<td>3. Facilities are easily accessible to residents and staff.</td>
<td>☑</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CODE</td>
<td>PHYSICAL ENVIRONMENT</td>
<td>YES</td>
<td>NO</td>
<td>N/A</td>
<td>EXPLANATORY STATEMENT</td>
</tr>
<tr>
<td>------</td>
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</tr>
<tr>
<td>F303</td>
<td>SNF (405.1129(a)) (Standard)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F304</td>
<td>ICF (442.328(a))</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
<td></td>
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</tr>
<tr>
<td>F305</td>
<td>1. Space is adequate for proper use of equipment by all residents receiving treatments.</td>
<td></td>
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</tr>
<tr>
<td>F306</td>
<td>2. Equipment is safe and in proper working condition.</td>
<td></td>
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</tr>
<tr>
<td>F307</td>
<td>SNF (405.1134(1)) (Standard)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F308</td>
<td>ICF (442.328(b))</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F309</td>
<td>1. Single rooms with private toilet and handwashing facilities are available for isolating residents.</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>F310</td>
<td>2. Precautionary signs are used to identify these rooms when in use.</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>F311</td>
<td>SNF (405.1134(2)) (Standard)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F312</td>
<td>ICF (442.324) (Standard)</td>
<td>☐ MET</td>
<td>☐ NOT MET</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F313</td>
<td>1. All common resident areas are clean, sanitary and free of odors.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F314</td>
<td>2. Provision is made for adequate and comfortable lighting levels in all areas.</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>F315</td>
<td>3. There is limitation of sounds at comfort levels.</td>
<td></td>
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</tr>
</tbody>
</table>
### NAME OF FACILITY

<table>
<thead>
<tr>
<th>CODE</th>
<th>PHYSICAL ENVIRONMENT</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>F316</td>
<td>4. A comfortable room temperature is maintained.</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>F317</td>
<td>5. There is adequate ventilation through windows or mechanical means or a combination of both.</td>
<td></td>
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</tr>
<tr>
<td>F318</td>
<td>6. Corridors are equipped with firmly secured handrails on each side.</td>
<td></td>
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</tr>
<tr>
<td>F319</td>
<td>7. Staff are aware of procedures to ensure water to all essential areas in the event of loss of normal supply.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>F320</td>
<td>I. Maintenance of Building and Equipment</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>SNF (405.1134(h)) (Standard)</td>
<td>☑</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>F321</td>
<td>1. The interior and exterior of the building are clean and orderly.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F322</td>
<td>2. All essential mechanical and electrical equipment is maintained in safe operating condition.</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>F323</td>
<td>3. Sufficient storage space is available and used for equipment to ensure that the facility is orderly and safe.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>F324</td>
<td>4. Resident care equipment is clean and maintained in safe operating condition.</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>F325</td>
<td>ICF (442.331(h))</td>
<td>☑</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Indicators J thru L apply to ICFs.</td>
<td></td>
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</tr>
<tr>
<td>F326</td>
<td>J. Dietary Service Area</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>SNF (405.1134(h)) (Standard)</td>
<td>☑</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>F327</td>
<td>1. Kitchen and dietary service areas are adequate to insure proper, timely food services for all residents</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F328</td>
<td>2. Kitchen areas are properly ventilated, arranged, and equipped for storage and preparation of food as well as for dish and utensil cleaning, and refuse storage and removal.</td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
### NAME OF FACILITY

<table>
<thead>
<tr>
<th>CODE</th>
<th>PHYSICAL ENVIRONMENT/INFECTION CONTROL</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>F329</td>
<td>SNF (405.1125(f)) (Standard)</td>
<td>Met</td>
<td>Not Met</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F330</td>
<td>Diabetic service personnel practice hygienic food handling techniques.</td>
<td></td>
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</tr>
<tr>
<td>F331</td>
<td>SNF (405.1125(g)) (Standard)</td>
<td>Met</td>
<td>Not Met</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F332</td>
<td>Food is stored, refrigerated, prepared, distributed, and served under sanitary conditions.</td>
<td></td>
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</tr>
<tr>
<td>F333</td>
<td>Waste is disposed of properly.</td>
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</tr>
</tbody>
</table>

### Emergency Power

<table>
<thead>
<tr>
<th>CODE</th>
<th>PHYSICAL ENVIRONMENT/INFECTION CONTROL</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>F334</td>
<td>SNF (405.1134(b)) (Standard)</td>
<td>Met</td>
<td>Not Met</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F335</td>
<td>An emergency source of electrical power necessary to protect the health and safety of residents is available in the event the normal electrical supply is interrupted.</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>F336</td>
<td>Emergency power is adequate at least for lighting in all means of egress; equipment to maintain fire detection, alarm, and extinguishing systems; and life safety support systems.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>F337</td>
<td>Emergency power is provided by an emergency electrical generator located on the premises where life support systems are used.</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

### INFECTION CONTROL (CONDITION OF PARTICIPATION)

<table>
<thead>
<tr>
<th>CODE</th>
<th>PHYSICAL ENVIRONMENT/INFECTION CONTROL</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>F338</td>
<td>SNF (405.1135)</td>
<td>Met</td>
<td>Not Met</td>
<td></td>
<td></td>
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</tbody>
</table>

### Infection Control

<table>
<thead>
<tr>
<th>CODE</th>
<th>PHYSICAL ENVIRONMENT/INFECTION CONTROL</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>F339</td>
<td>SNF (405.1136(b)) (Standard)</td>
<td>Met</td>
<td>Not Met</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F340</td>
<td>Aseptic and isolation techniques are followed by all personnel.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# NAME OF FACILITY

<table>
<thead>
<tr>
<th>CODE</th>
<th>INFECTION CONTROL/DISASTER PREPAREDNESS</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>598</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>42 CFR Ch. IV (10-1-98 Edition)</td>
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<tr>
<td></td>
<td>§ 488.105</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**B. Sanitation**

- **F341**
  - SNF (405.1135(d)) (Standard)
  - The facility maintains a safe, clean, and orderly interior.

- **F342**
  - The facility maintains a safe, clean, and orderly interior.

**C. Linen**

- **F343**
  - SNF (405.1135(d)) (Standard)

- **F344**
  - ICF (442.327) (Standard)

- **F345**
  - The facility has available at all times a quantity of linen essential for proper care and comfort of residents.

- **F346**
  - Linens are handled, stored, processed, and transported in such a manner as to prevent the spread of infection.

**D. PEST CONTROL**

- **F347**
  - SNF (405.1135(e)) (Standard)

- **F348**
  - ICF (442.315(c)) (Standard)

- **F349**
  - The facility is maintained free from insects and rodents.

**DISASTER PREPAREDNESS (CONDITION OF PARTICIPATION)**

- **F350**
  - SNF (405.1136)

- **F351**
  - SNF (405.1136(f)) (Standard)

- **F352**
  - ICF (442.313) (Standard)

- **F353**
  - Disaster Plan

1. Facility staff are aware of plans, procedures to be followed for fire, explosion or other disaster.
<table>
<thead>
<tr>
<th>CODE</th>
<th>DISASTER PREPAREDNESS</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>EXPLANATORY STATEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>F354</td>
<td>2. Facility staff are knowledgeable about evacuation routes.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F355</td>
<td>3. Facility staff are aware of their specific responsibilities in regard to evaluation and protection of residents.</td>
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<tr>
<td>F356</td>
<td>4. Facility staff are aware of methods of containing fire.</td>
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<tr>
<td></td>
<td>B. Drills</td>
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<td>F357</td>
<td>SNF (405.1136(b))(Standard)</td>
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<tr>
<td>F358</td>
<td>1. All employees are trained, as part of their employment orientation in all aspects of preparedness for any disaster.</td>
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<tr>
<td>F359</td>
<td>2. Facility staff participate in ongoing training and drills in all procedures so that each employee promptly and correctly carries out a specific role in the case of a disaster.</td>
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**SKILLED NURSING FACILITY & INTERMEDIATE CARE FACILITY**

**SURVEY REPORT — PART B**

(To be used with 2-88 Revision of Form HCFA-515)

<table>
<thead>
<tr>
<th>PROVIDER NO.</th>
<th>FACILITY NAME</th>
<th>SURVEY DATE</th>
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**SURVEY TEAM COMPOSITION**

*F1: Indicate the number of surveyors according to discipline:

A. _______ ADMINISTRATOR
B. _______ NURSE
C. _______ DIETITIAN
D. _______ PHARMACIST
E. _______ RECORDS ADMINISTRATOR
F. _______ SOCIAL WORKER
G. _______ QUALIFIED MENTAL RETARDATION PROFESSIONAL
H. _______ LIFE SAFETY CODE SPECIALIST
I. _______ LABORATORIAN
J. _______ SANITARIAN
K. _______ THERAPIST
L. _______ PHYSICIAN
M. _______ NATIONAL INSTITUTE OF MENTAL HEALTH
N. _______ OTHER

NOTE: More than one discipline may be marked for surveyors qualified in multiple disciplines.

*F2: Indicate the total number of surveyors on site: ____

**F193: Drug Error Rate: ____%** (Round % to nearest whole number.)

*SFS Survey Form Indicator (Check one)

Traditional Survey
(1) __

New LTC Survey
(2) __

NOTE: Please attach copy of pages 2, 14 and 15.

*Mandatory

**Form HCFA-415E (2-89)**

U.S. GOVERNMENT PRINTING OFFICE: 1996 O - 153-203 : 03 3
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<th>NAME</th>
<th>ROOM NUMBER</th>
<th>REASON FOR SELECTION</th>
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</table>
TOUR NOTES WORKSHEET

INSTRUCTIONS

1. Note care and problems in care on all units.
2. Report deficiencies directly to survey report form or evaluate further during in-depth sample review.
3. Select residents for in-depth review.
4. Select a proportionate number from each section.

INDEPTH SAMPLE

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<thead>
<tr>
<th>Facility</th>
<th>Census</th>
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<td>(Min 10)</td>
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OBSERVE RESIDENTS FOR THE FOLLOWING CARE PROBLEMS

GROOMING/PERSONAL HYGIENE

POSITIONING

ASSISTIVE DEVICES

AMBULATION

RESTRAINTS

HYDRATION

INFECTION CONTROL

PATIENT RIGHTS

OTHER

FORM HCPA-P2T (2-96)

42 CFR Ch. IV (10-1-98 Edition)
<table>
<thead>
<tr>
<th>PROVIDER NUMBER</th>
<th>SURVEY DATE</th>
<th>OBSERVATION INTERVIEW OF: RESIDENT IDENTIFIER</th>
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</table>

**INSTRUCTIONS**

1. Observe each resident in the sample to identify ADL needs and potential problems. Check appropriate boxes.
2. Interview only residents in the sample who are capable and willing.
3. Review each resident's record to ensure assessments, plans, interventions, and evaluations are appropriate and current.
4. Note deficiencies on survey report form after reviewing all residents in sample.

**ADL'S**

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<td>Toileting</td>
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<tr>
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<tr>
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<tr>
<td>Eating</td>
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**GROOMING/HYGIENE**

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**GROUNDRY/VOCATIONS**

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**FEEDING**

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**FINANCIAL PLANS**

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**BOWEL/LAVERAGE**

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**ASSISTANT'S**

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**PAIN RELIEF**

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**DIETARY NEEDS**

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**SOCIAL SERVICE NEEDS**

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**PERSONALITY DISORDERS**

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**PROGRESSIVE PROBLEMS**

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**DIAPERING**

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**RATING**

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**TRACH/OSTOMY**

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**URINE/FAECAL**

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**URINE/FAECAL**

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**OBSTETRICS**

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**BREATHING**

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**SURGICAL**

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**MEDICATIONS**

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**FAMILY/HUSBAND**

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**ACTIVITY NEEDS**

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**PATIENT RIGHTS**

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**FEEDING**

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**INJECTIONS**

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**NOTES:**
## Drug Pass Worksheet

**InSTRUCTIONS**

2. Record Observation of each Opportunity.
3. Compare Observation Notes with Physician Orders.
4. Calculate and Note Error Rate.
5. Note Deficiencies on Survey Report Form.

**DEFICIENCY FORMULA**

\[
\text{Deficiency} = \frac{\text{Significant + Non-magnify}}{\text{Dosage Given + Dosage Ordered But Not Given}} \times 100 \times \frac{\text{Error Rate}}{2}
\]

<table>
<thead>
<tr>
<th>IDENTIFIER</th>
<th>POOR</th>
<th>PASS</th>
<th>RECORD</th>
</tr>
</thead>
<tbody>
<tr>
<td>RESIDENT'S FULL NAME, ROOM NUMBER, TIME</td>
<td>DRUG PRESCRIPTION NAME, DOSE AND FORM</td>
<td>OBSERVATION OF ADMINISTRATION</td>
<td>DRUG ORDER WRITTEN AS (IF DIFFERS FROM ADAMS ONLY)</td>
</tr>
</tbody>
</table>

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Health Care Financing Administration, HHS 
§ 488.105
DRUG ERROR CALCULATION
(SEE SOM Appendix N Part 2)

How to Calculate a Medication Error Rate—in calculating the percentage of errors, the numerator in the ratio is the total number of errors that you observe, both significant and non-significant. The denominator is all the doses observed being administered plus the doses ordered but not administered. The equation for calculating a medication error rate is as follows:

\[
\text{Medication Error Rate} = \frac{\text{Number of errors observed}}{\text{Opportunities for errors}} \times 100
\]

Where: Opportunities for errors equals the number of doses administered plus the number of doses ordered but not administered.

Comments

For example, you observed the administration of drugs to 20 patients. There were a total of 47 drugs administered (47 opportunities for errors). At the completion of the reconciliation of your Observations with the physicians' orders, you find that three medication errors were made in administration and one medication was omitted (ordered but not administered). The omitted dose is included in both the numerator and the denominator. Therefore, following the above formula, your equation would be as follows:

\[
\frac{3}{47 + 1} \times 100 = 8.3\%
\]
**DINING AREA & EATING ASSISTANCE WORKSHEET**

**INSTRUCTIONS**

1. **DINING AREA AND MEALS**
   a. Size does not restrict movement.
   b. Accommodates all residents.
   c. Cleanliness.
   d. Adequate/comfortable lighting.
   e. Adequate/comfortable ventilation.

2. **SERVING OF MEALS**
   a. Number of mealtime span between meals.
   b. Conformance to physicians order.
   c. Nutritional adequacy.
   d. Adequacy of portions.
   e. Residents eat approximately 75% of meals.
   f. Puree dishes served individually.
   g. Food cut, chopped or ground for individual resident needs.
   h. Acceptable taste.
   i. Proper temperature.
   j. Plates covered.

---

[Form Approval Details]

Health Care Financing Administration, HHS 1340-0060

Section 488.105
2. SERVING OF MEALS * (continued)
   k. Served promptly.
   l. Residents ready for meal when served.
   m. Attractive.
   n. Utensils available.
   o. Functional trays for bedfast residents.
   p. Salt, pepper, sugar, other condiments on resident's trays unless contraindicated.
   q. Medically able residents eating in dining area.
   r. Bedtime nourishment offered.

3. SUPERVISION OF RESIDENT NUTRITION
   a. Prompt assistance.
   b. Proper assistance (spoon-feeding, supervision or instruction to develop eating skills).
   c. Courteous and unhurried assistance.
   d. Self-help devices present (straws, easy grip utensils, special cup, etc.).
   e. Intake recorded/deviations from normal are reported.
§ 488.110 Procedural guidelines.

SNF/ICF Survey Process. The purpose for implementing a new SNF/ICF survey process is to assess whether the quality of care, as intended by the law and regulations, and as needed by the resident, is actually being provided in nursing homes. Although the onsite review procedures have been changed, facilities must continue to meet all applicable Conditions/Standards, in order to participate in Medicare/Medicaid programs. That is, the methods used to compile information about compliance with law and regulations are changed; the law and regulations themselves are not changed. The new process differs from the traditional process, principally in terms of its emphasis on resident outcomes. In ascertaining whether resident grooming and personal hygiene needs are met, for example, surveyors will no longer routinely evaluate a facility’s written policies and procedures. Instead, surveyors will observe residents in order to make that determination. In addition, surveyors will confirm, through interviews with residents and staff, that such needs are indeed met on a regular basis. In most reviews, then, surveyors will ascertian whether the facility is actually providing the required and needed care and services, rather than whether the facility is capable of providing the care and services.

The Outcome-Oriented Survey Process—Skilled Nursing Facilities (SNFs) and Intermediate Care Facilities (ICFs)

(a) General. A complete SNF/ICF facility survey consists of three components:
• Life Safety Code requirements;
• Administrative and structural requirements (Part A of the Survey Report, Form HCFA-525); and
• Direct resident care requirements (Part B of the Survey Report, Form HCFA-519), along with the related worksheets (HCFA-520 through 524).

Use this survey process for all surveys of SNFs and ICFs—whether freestanding, distinct parts, or dually certified. Do not use this process for surveys of Intermediate Care Facilities for Mentally Retarded (ICFs/MR), swing-bed hospitals or skilled nursing sections of hospitals that are not separately certified as SNF distinct parts. Do not announce SNF/ICF surveys ahead of time.

(b) The Survey Tasks. Listed below are the survey tasks for easy reference:
• Task 1. Entrance Conference.
• Task 2. Resident Sample—Selection Methodology.
• Task 4. Observation/Interview/Medical Record Review of Each Individual in the Resident Sample (including drug regimen review).
• Task 5. Drug Pass Observation.
• Task 6. Dining Area and Eating Assistance Observation.
• Task 7. Forming the Deficiency Statement (if necessary).
• Task 8. Exit Conference.

(c) Task 1—Entrance Conference. Perform these activities during the entrance conference in every certification and recertification survey:
• Introduce all members of the team to the facility staff, if possible, even though the whole team may not be present for the entire entrance conference. (All surveyors wear identification tags.)
§ 488.110  42 CFR Ch. IV (10-1-98 Edition)

• Explain the SNF/ICF survey process as resident centered in focus, and outline the basic steps.
  • Ask the facility for a list showing names of residents by room number with each of the following care needs/treatments identified for each resident to whom they apply:
    — Decubitus care
    — Restraints
    — Catheters
    — Injections
    — Parenteral fluids
    — Rehabilitation service
    — Colostomy/ileostomy care
    — Respiratory care
    — Tracheostomy care
    — Suctioning
    — Tube feeding
  Use this list for selecting the resident sample.
  • Ask the facility to complete page 2 of Form HCFA-519 (Resident Census) as soon as possible, so that the information can further orient you to the facility’s population. In a survey of a SNF with a distinct part ICF, you may collect two sets of census data. However, consolidate the information when submitting it to the regional office. You may modify the Resident Census Form to include the numbers of licensed and certified beds, if necessary.
  • Ask the facility to post signs on readily viewed areas (at least one on each floor) announcing that State surveyors are in the facility performing an “inspection,” and are available to meet with residents in private. Also indicate the name and telephone number of the State agency. Hand-printed signs with legible, large letters are acceptable.
  • If the facility has a Resident Council, make mutually agreeable arrangements to meet privately with the president and officers and other individuals they might invite.
  • Inform the facility that interviews with residents and Resident Councils are conducted privately, unless they independently request otherwise, in order to enhance the development of rapport as well as to allay any resident anxiety. Tell the facility that information is gathered from interviews, the tour, observations, discussions, record review, and facility officials. Point out that the facility will be given an opportunity to respond to all findings.

(d) Task 2—Resident Sample—Selection Methodology. This methodology is aimed at formulating a sample that reflects the actual distribution of care needs/treatments in the facility population. Primarily performed on a random basis, it also ensures representation in the sample of certain care needs and treatments that are assessed during the survey.

(1) Sample Size. Calculate the size of the sample according to the following guide:

<table>
<thead>
<tr>
<th>Number of residents in facility</th>
<th>Number of residents in sample¹</th>
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<tbody>
<tr>
<td>0–60 residents</td>
<td>25% of residents (minimum—10).</td>
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<tr>
<td>61–120 residents</td>
<td>20% of residents (minimum—15).</td>
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<tr>
<td>121–200 residents</td>
<td>15% of residents (minimum—24).</td>
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<tr>
<td>201+ residents</td>
<td>10% of residents (minimum—30).</td>
</tr>
<tr>
<td>¹ Maximum—50.</td>
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Note that the calculation is based on the resident census, not beds. After determining the appropriate sample size, select residents for the sample in a random manner. You may, for example, select every fifth resident from the resident census, beginning at a random position on the list. For surveys of dually certified facilities or distinct part SNFs/ICFs, first use the combined SNF/ICF population to calculate the size of the sample, and then select a sample that reflects the proportions of SNF and ICF residents in the facility’s overall population.

(2) Special Care Needs/Treatments. The survey form specifies several care needs/treatments that must always be reviewed when they apply to any facility residents. These include:

• Decubitus Care
• Restraints
• Catheters
• Injections, Parenteral Fluids, Colostomy/Ileostomy, Respiratory Care, Tracheostomy Care, Suctioning, Tube Feeding
• Rehabilitative Services (physical therapy, speech pathology and audiology services, occupational therapy)

Due to the relatively low prevalence of these care needs/treatments, appropriate residents may be either under-
represented or entirely omitted from the sample. Therefore, determine during the tour how many residents in the random selection fall into each of these care categories. Then, compare the number of such residents in the random selection with the total number of residents in the facility with each specified care need/treatment (based on either the resident census or other information provided by the facility).

Review no less than 25 percent of the residents in each of these special care needs/treatments categories. For example, if the facility has 10 residents with decubitus ulcers, but only one of these residents is selected randomly, review two more residents with decubitus ulcers (25% of 10 equals 2.5, so review a total of 3). Or, if the facility has two residents who require tube feeding, neither of whom is in the random selection, review the care of at least one of the these residents. This can be accomplished in the following manner:

Conduct in-depth reviews of the randomly selected residents and then perform limited reviews of additional residents as needed to cover the specified care categories. Such reviews are limited to the care and services related to the pertinent care areas only, e.g., catheters, restraints, or colostomy. Utilize those worksheets or portions of worksheets which are appropriate to the limited review. Refer to the Care Guidelines, as a resource document, when appropriate.

Always keep in mind that neither the random selection approach nor the review of residents within the specified care categories precludes investigation of other resident care situations that you believe might pose a serious threat to a resident’s health or safety. Add to the sample, as appropriate.

(e) Task 3—Tour of the Facility. (1) Purpose. Conduct the tour in order to:
   • Develop an overall picture of the types and patterns of care delivery present within the facility;
   • View the physical environment; and
   • Ascertain whether randomly selected residents are communicative and willing to be interviewed.

   (2) Protocol. You may tour the entire facility as a team or separately, as long as all areas of the facility are examined by at least one team member. Success of the latter approach, however, is largely dependent on open intra-team communication and the ability of each team member to identify situations for further review by the team member of the appropriate discipline. You may conduct the tour with or without facility staff accompanying you, as you prefer. Facilities, however, vary in staff member availability. Record your notes on the Tour Notes Worksheet, Form HCFA–521.

   Allow approximately three hours for the tour. Converse with residents, family members/significant others (if present), and staff, asking open-ended questions in order to confirm observations, obtain additional information, (e.g., accidents, odors, apparent inappropriate dress, adequacy and appropriateness of activities). Converse sufficiently with residents selected for in-depth review to ascertain whether they are willing to be interviewed and are communicative. Observe staff interactions with other staff members as well as with residents for insight into matters such as resident rights and assignments of staff responsibilities.

   Always knock and/or get permission before entering a room or interrupting privacy. If you wish to inspect a resident’s skin, observe a treatment procedure, or observe a resident who is exposed, courteously ask permission from the resident if she/he comprehends, or ask permission from the staff nurse if the resident cannot communicate. Do not do “hands-on” monitoring such as removal of dressings; ask staff to remove a dressing or handle a resident.

   (3) Resident Needs. While touring, focus on the residents’ needs—physical, emotional, psychosocial, or spiritual—and whether those needs are being met. Refer to the following list as needed:
   —Personal hygiene, grooming, and appropriate dress
   —Position
   —Assistive and other restorative devices
   —Rehabilitation issues
   —Functional limitations in ADL
   —Functional limitations in gait, balance and coordination
   —Hydration and nutritional status
   —Resident rights
§ 488.110

Activity for time of day (appropriate or inappropriate)
Emotional status
Level of orientation
Awareness of surroundings
Behaviors
Cleanliness of immediate environment (wheelchair, bed, bedside table, etc.)
Odors
Adequate clothing and care supplies as well as maintenance and cleanliness of same

(4) Review of the Physical Environment. As you tour each resident's room and auxiliary rooms, also examine them in connection with the physical environment requirements. You need not document physical environment on the Tour Notes Worksheet. Instead, you may note any negative findings directly on the Survey Report Form in the remarks section.

(5) Meeting With Resident Council Representatives. If a facility has a Resident Council, one or more surveyors meet with the representatives in a private area. Facility staff members do not attend unless specifically requested by the Council. Explain the purpose of the survey and briefly outline the steps in the survey process, i.e., entrance conference * * * exit conference. Indicate your interest in learning about the strengths of the facility in addition to any complaints or shortcomings. State that this meeting is one part of the information gathering; the findings have not yet been completed nor the conclusions formulated. Explain further, however, that the official survey findings are usually available within three months after the completion of the survey, and give the telephone number of the State agency office.

Use this meeting to ascertain strengths and/or problems, if any, from the consumer's perspective, as well as to develop additional information about aspects of care and services gleaned during the tour that were possibly substandard.

Conduct the meeting in a manner that allows for comments about any aspect of the facility. (See the section on Interview Procedures.) Use open-ended questions such as:
- "What is best about this home?"
- "What is worst?"
- "What would you like to change?"
- "What can anyone else tell me about this?"

In order to get more detail, use questions such as:
- "Can you be more specific?"
- "Can you give me an example?"
- "What is negative about the care/staff/cleanliness here?"
- "What would make it better?"
- "What don't you like? What do you like?"

If you wish to obtain information about a topic not raised by the residents, use an approach like the following:
- "Tell me what you think about the food/staff/cleanliness here."
- "What would you like to change?"
- "What do you like? What don't you like?"

(6) Tour Summation and Focus of Remaining Survey Activity. When the tour is completed, review the resident census data provided by the facility. Determine if the care categories specified in the section on Resident Sample are sufficiently represented in the random selection, make adjustments as needed, and complete the listing of residents on the worksheet labeled "Residents Selected for In-depth Review", Form HCFA-520.

Transcribe notes of a negative nature onto the SRF in the “Remarks” column under the appropriate rule. Findings from a later segment in the survey or gathered by another surveyor may combine to substantiate a deficiency. You need not check "met" or "not met" at this point in the survey. Discuss significant impressions/conclusions at the completion of each subsequent survey task, and transfer any negative findings onto the Survey Report Form in the Remarks section.

(f) Task 4—Observation/Interview/Medical Record Review (including drug regimen review). Perform the in-depth review of each individual in the resident sample in order to ascertain whether the facility is meeting resident needs. Evaluate specific indicators for each resident, utilizing the front and back of the “Observation/Interview/Record Review (OIRR)” worksheet, Form HCFA-524. You may prefer to perform the record review first, complete resident/staff/family observations and interviews, and finally, return to the record for any final unresolved issues. On the other hand, you may prefer to do the
interviews first. Either method is acceptable. Whenever possible, however, complete one resident’s observation/interview/medical record review and document the OIRR before moving onto another resident. If because of the facility layout, it is more efficient to do more than one record review at a time, limit such record review to two or three residents so your familiarity with the particular resident and continuity of the OIRR are not compromised.

(1) Observation. Conduct observations concurrently with interviews of residents, family/significant others, and discussions with direct care staff [of the various disciplines involved. In multi-facility operations, whenever possible, observe staff that is regularly assigned to the facility in order to gain an understanding of the care and services usually provided.] Maintain respect for resident privacy. Minimize disruption of the operations of the facility or impositions upon any resident as much as possible. Based upon your observations of the residents’ needs, gather information about any of the following areas, as appropriate:

- Bowel and bladder training
- Catheter care
- Restraints
- Injections
- Parenteral fluids
- Tube feeding/gastrostomy
- Colostomy/ileostomy
- Respiratory therapy
- Tracheostomy care
- Suctioning

(2) Interviews. Interview each resident in private unless he/she independently requests that a facility staff member or other individual be present. Conduct the in-depth interview in a non-threatening and noninvasive fashion so as to decrease anxiety and defensiveness. The open-ended approach described in the section on the Resident Council is also appropriate for the in-depth interview. While prolonged time expenditure is not usually a worthwhile use of resources or the resident’s time, do allow time initially to establish rapport.

At each interview:
- Introduce yourself.
- Address the resident by name.
- Explain in simple terms the reason for your visit (e.g., to assure that the care and services are adequate and appropriate for each resident).
- Briefly outline the process—entrance conference, tour, interviews, observations, review of medical records, resident interviews, and exit conference.
- Mention that the selection of a particular resident for an interview is not meant to imply that his/her care is substandard or that the facility provides substandard care. Also mention that most of those interviewed are selected randomly.
- Assure that you will strive for anonymity for the resident and that the interview is used in addition to medical records, observations, discussions, etc., to capture an accurate picture of the treatment and care provided by the facility. Explain that the official findings of the survey are usually available to the public about three months after completion of the survey, but resident names are not given to the public.
- When residents experience difficulty expressing themselves:
  - Avoid pressuring residents to verbalize
  - Accept and respond to all communication
  - Ignore mistakes in word choice
  - Allow time for recollection of words
  - Encourage self-expression through any means available
- When interviewing residents with decreased receptive capacity:
  - Speak slowly and distinctly
  - Speak at conversational voice level
  - Sit within the resident’s line of vision
- Listen to all resident information/allegations without judgment. Information gathered subsequently may substantiate or repudiate an allegation.

The length of the interview varies, depending on the condition and wishes of the resident and the amount of information supplied. Expect the average interview, however, to last approximately 15 minutes. Courteously terminate an interview whenever the resident is unable or unwilling to continue, or is too confused or disoriented to continue. Do, however, perform the
other activities of this task (observation and record review). If, in spite of your conversing during the tour, you find that less than 40 percent of the residents in your sample are sufficiently alert and willing to be interviewed, try to select replacements so that a complete OIRR is performed for a group this size, if possible. There may be situations, however, where the resident population has a high percentage of confused individuals and this percentage is not achievable. Expect that the information from confused individuals can be, but is not necessarily, less reliable than that from more alert individuals.

Include the following areas in the interview of each resident in the sample:

- Activities of daily living
- Grooming/hygiene
- Nutrition/dietary
- Restorative/rehabilitation care and services
- Activities
- Social services
- Resident rights

Refer to the Care Guidelines “evaluation factors” as a resource for possible elements to consider when focusing on particular aspects of care and resident needs.

Document information obtained from the interviews/observations on the OIRR Worksheet. Record in the “Notes” section any additional information you may need in connection with substandard care or services. Unless the resident specifically requests that he/she be identified, do not reveal the source of the information gleaned from the interview.

(3) Medical Record Review. The medical record review is a three-part process, which involves first reconciling the observation/interview findings with the record, then reconciling the record against itself, and lastly performing the drug regimen review.

Document your findings on the OIRR Worksheet, as appropriate, and summarize on the Survey Report Form the findings that are indicative of problematic or substandard care. Be alert for repeated similar instances of substandard care developing as the number of completed OIRR Worksheets increases.

**NOTE:** The problems related to a particular standard or condition could range from identical (e.g., meals not in accordance with dietary plan) to different but related (e.g., nursing services—lapse in care provided to residents with catheters, to residents with contractures, to residents needing assistance for personal hygiene and residents with improperly applied restraints).

(i) Reconciling the observation/interview findings with the record. Determine if:

- An assessment has been performed.
- A plan with goals has been developed.
- The interventions have been carried out.
- The resident has been evaluated to determine the effectiveness of the interventions.

For example, if a resident has developed a decubitus ulcer while in the facility, record review can validate staff and resident interviews regarding the facility’s attempts at prevention. Use your own judgment; review as much of the record(s) as necessary to evaluate the care planning. Note that facilities need not establish specific areas in the record stating “Assessment,” “Plan,” “Intervention,” or “Evaluation” in order for the documentation to be considered adequate.

(ii) Reconciling the record with itself. Determine:

- If the resident has been properly assessed for all his/her needs.
- That normal and routine nursing practices such as periodic weights, temperatures, blood pressures, etc., are performed as required by the resident’s conditions.

(iii) Performing the drug regimen review. The purpose of the drug regimen review is to determine if the pharmacist has reviewed the drug regimen on a monthly basis. Follow the procedures in Part One of Appendix N, Surveyor Procedures for Pharmaceutical Service Requirements in Long-Term Care Facilities. Fill in the appropriate boxes on the top left hand corner of the reverse side of the OIRR Worksheet, Form HCFA-524. Appendix N lists many irregularities that can occur. Review at least six different indicators on each survey. However, the same six indicators need not be reviewed on every survey.
NOTE: If you detect irregularities and the documentation demonstrates that the pharmacist has notified the attending physician, do not cite a deficiency. Do, however, bring the irregularity to the attention of the medical director or other facility official, and note the official’s name and date of notification on the Survey Report Form.

(g) Task 5—Drug Pass Observation. The purpose of the drug pass observation is to observe the actual preparation and administration of medications to residents. With this approach, there is no doubt that the errors detected, if any, are errors in drug administration, not documentation. Follow the procedure in Part Two of Appendix N, Surveyor Procedures for Pharmaceutical Service Requirements in Long-Term Care Facilities, and complete the Drug Pass Worksheet, Form HCFA-522. Be as neutral and unobtrusive as possible during the drug pass observation. Whenever possible, select one surveyor, who is a Registered Nurse or a pharmacist, to observe the drug pass of approximately 20 residents. In facilities where fewer than 20 residents are receiving medications, review as many residents receiving medications as possible. Residents selected for the in-depth review need not be included in the drug pass observation; however, their whole or partial inclusion is acceptable. In order to get a balanced view of a facility’s practices, observe more than one person administering a drug pass, if feasible. This might involve observing the morning pass one day in Wing A, for example, and the morning pass the next day in Wing B.

Transfer findings noted on the “Drug Pass” worksheet to the SRF under the appropriate rule. If your team concludes that the facility’s medication error rate is 5 percent or more, cite the deficiency under Nursing Services/Administration of Drugs. Report the error rate under F.200. If the deficiency is at the standard level, cite it in Nursing Services, rather than Pharmacy.

(h) Task 6—Dining Area and Eating Assistance Observation. The purpose of this task is to ascertain the extent to which the facility meets dietary needs, particularly for those who require eating assistance. This task also yields information about staff interaction with residents, appropriateness of dress and hygiene for meals, usage and availability, as well as appropriateness of dress and hygiene for meals.

For this task, use the worksheet entitled “Dining Area and Eating Assistance Observation” (Form HCFA-523). Observe two meals; for a balanced view, try to observe meals at different times of the day. For example, try to observe a breakfast and a dinner rather than two breakfasts. Give particular care to performing observations as unobtrusively as possible. Chatting with residents and sitting down nearby may help alleviate resident anxiety over the observation process.

Select a minimum of five residents for each meal observation and include residents who have their meals in their rooms. Residents selected for the in-depth review need not be included in the dining and eating assistance observation; however, their whole or partial inclusion is acceptable. Ascertain the extent to which the facility assesses, plans, and evaluates the nutritional care of residents and eating assistance needs by reviewing the sample of 10 or more residents. If you are unable to determine whether the facility meets the standards from the sample reviewed, expand the sample and focus on the specific area(s) in question, until you can formulate a conclusion about the extent of compliance. As with the other survey tasks, transfer the findings noted on the “Dining & Eating Assistance Observation” worksheet to the Survey Report Form.

(i) Task 7—Forming the Deficiency Statement. (1) General. The Survey Report Form contains information about all of the negative findings of the survey. Be sure to transfer to the Survey Report Form data from the tour, drug pass observation, dining area and eating assistance observation, as well as in-depth review of the sample of residents. Transfer only those findings which could possibly contribute to a determination that the facility is deficient in a certain area.

Meet as a group in a pre-exit conference to discuss the findings and make conclusions about the deficiencies, subject to information provided by facility officials that may further explain the situation. Review the summaries/conclusions from each task...
§ 488.110

and decide whether any further information and documentation is necessary to substantiate a deficiency. As
the facility for additional information for clarification about particular findings, if necessary. Always consider in-
formation provided by the facility. If the facility considers as acceptable, practices which you believe are not ac-
ceptable, ask the facility to back up its contention with suitable reference material or sources and submit them for
your consideration.

(2) Analysis. Analyze the findings on the Survey Report Form for the degree of severity, frequency of occurrence
and impact on delivery of care or quality of life. The threshold at which the frequency of occurrences amounts to a
deficiency varies from situation to situation. One occurrence directly related to a life-threatening or fatal outcome
can be cited as a deficiency. On the other hand, a few sporadic occurrences may have so slight an impact on deliv-
ery of care or quality of life that they do not warrant a deficiency citation. Review carefully all the information
gathered. What may appear during observation as a pattern, may or may not be corroborated by records, staff, and
residents. For example, six of the 32 residents in the sample are dressed in mismatched, poorly buttoned clothes.
A few of the six are wearing slippers without socks. A few others are wearing worn clothes. Six occurrences
might well be indicative of a pattern of substandard care. Close scrutiny of records, discussions with staff, and
interviews reveal, however, that the six residents are participating in dressing retraining programs. Those residents
who are without socks, chose to do so. The worn clothing items were also chosen—they are favorites.

Combinations of substandard care such as poor grooming of a number of residents, lack of ambulation of a num-
ber of residents, lack of attention to positioning, poor skin care, etc., can yield a deficiency in nursing services
just as 10 out of 10 residents receiving substandard care for decubiti yields a deficiency.

(3) Deficiencies Alleged by Staff or Residents. If staff or residents allege deficiencies, but records, interviews, and
observation fail to confirm the situa-
tion, it is unlikely that a deficiency ex-
ists. Care and services that are indeed confirmed by the survey to be in com-
pliance with the regulatory require-
ments, but considered deficient by resi-
dents or staff, cannot be cited as defi-
cient for certification purposes. On the
other hand, if an allegation is of a very
serious nature (e.g., resident abuse)
and the tools of record review and ob-
servation are not effective because the
problem is concealed, obtain as much
information as possible or necessary to
ascertain compliance, and cite accord-
ingly. Residents, family, or former em-
ployees may be helpful for information
gathering.

(4) Composing the Deficiency Statement. Write the deficiency statement in terms specific enough to allow a rea-
sonably knowledgeable person to un-
derstand the aspect(s) of the require-
ment(s) that is (are) not met. Do not
delve into the facility's policies and
procedures to determine or speculate
on the root cause of a deficiency, or
sift through various alternatives in an
effort to prescribe an acceptable rem-
edy. Indicate the data prefix tag and
regulatory citation, followed by a sum-
mary of the deficiency and supporting
findings using resident identifiers, not
resident names, as in the following ex-
ample.

F102 SNF 405.1123(b).—Each resident has
not had a physician's visit at least once
every 30 days for the first 90 days after ad-
mission. Resident 1602 has not been seen by
a physician since she was admitted 50 days
ago. Her condition has deteriorated since
that time (formulation of decubiti, infec-
tions).

When the data prefix tag does not re-
peal the regulations, also include a
short phrase that describes the prefix
tag (e.g., F117 decubitus ulcer care).
List the data tags in numerical order,
whenever possible.

(j) Task 8—Exit Conference. The pur-
pose of the exit conference is to inform
the facility of survey findings and to
arrange for a plan of correction, if
needed. Keep the tone of the exit con-
ference consistent with the character of
the survey process—inspection and
enforcement. Tactful, business-like,
professional presentation of the findings is of paramount importance. Recognize that the facility may wish to respond to various findings. Although deficiency statements continue to depend, in part, on surveyor professional judgment, support your conclusions with resident-specific examples (identifiers other than names) whenever you can do so without compromising confidentiality. Before formally citing deficiencies, discuss any allegations or findings that could not be substantiated during earlier tasks in the process. For example, if information is gathered that suggests a newly hired R.N. is not currently licensed, ask the facility officials to present current licensure information for the nurse in question. Identify residents when the substandard care is readily observed or discerned through record review. Ensure that the facility improves the care provided to all affected residents, not only the identified residents. Make clear to the facility that during a follow-up visit the surveyors may review residents other than those with significant problems from the original sample, in order to see that the facility has corrected the problems overall. Do not disclose the source of information provided during interviews, unless the resident has specifically requested you to inform the facility of his/her comments or complaints. In accordance with your Agency’s policy, present the Statement of Deficiencies, form HCFA-2567, on site or after supervisory review, no later than 10 calendar days following the survey.

(k) Plan of Correction. Explain to the facility that your role is to identify care and services which are not consistent with the regulatory requirements, rather than to ascertain the root causes of deficiencies. Each facility is expected to review its own care delivery. Subsequent to the exit conference, each facility is required to submit a plan of correction that identifies necessary changes in operation that will assure correction of the cited deficiencies. In reviewing and accepting a proposed plan of correction, apply these criteria:

- Does the facility have a reasonable approach for correcting the deficiencies?
- Is there a high probability that the planned action will result in compliance?
- Is compliance expected timely?

Plans of correction specific to residents identified on the deficiency statement are acceptable only where the deficiency is determined to be unique to that resident and not indicative of a possible systemic problem. For example, as a result of an aide being absent, two residents are not ambulated three times that day as called for in their care plans. A plan of correction that says “Ambulate John Jones and Mary Smith three times per day,” is not acceptable. An acceptable plan of correction would explain changes made to the facility’s staffing and scheduling in order to guarantee that staff is available to provide all necessary services for all residents.

Acceptance of the plan of correction does not absolve the facility of the responsibility for compliance should the implementation not result in correction and compliance. Acceptance indicates the State agency’s acknowledgement that the facility indicated a willingness and ability to make corrections adequately and timely.

 Allow the facility up to 10 days to prepare and submit the plan of correction to the State agency, however, follow your SA policy if the timeframe is shorter. Retain the various survey worksheets as well as the Survey Report Form at the State agency. Forward the deficiency statement to the HCFA regional office.

(l) Follow-up Surveys. The purpose of the follow-up survey is to re-evaluate the specific types of care or care delivery patterns that were cited as deficient during the original survey. Ascertain the corrective status of all deficiencies cited on the HCFA-2567. Because this survey process focuses on the actual provision of care and services, revisits are almost always necessary to ascertain whether the deficiencies have indeed been corrected. The nature of the deficiencies dictates the scope of the follow-up visit. Use as many tasks or portions of the Survey Report Form(s) as needed to ascertain compliance status. For example, you need not perform another drug pass if no drug related deficiencies
§ 488.110  
were cited on the initial survey. Similarly, you need not repeat the dining area and eating assistance observations if no related problems were identified. All or some of the aspects of the observation/interview/medical record review, however, are likely to be appropriate for the follow-up survey.

When selecting the resident sample for the follow-up, determine the sample size using the same formula as used earlier in the survey, with the following exceptions:

- The maximum sample size is 30 residents, rather than 50.
- The minimum sample size of 10 residents does not apply if only one care category was cited as deficient and the total number of residents in that category was less than 10 (e.g., deficiency cited under catheter care and only five residents have catheters).

Include in the sample those residents who, in your judgment, are appropriate for reviewing vis-a-vis the cited substandard care. If possible, include some residents identified as receiving substandard care during the initial survey. If after completing the follow-up activities you determine that the cited deficiencies were not corrected, initiate adverse action procedures, as appropriate.

When you find substandard care or services in the course of a survey, carefully document your findings. Explain the deficiency in sufficient detail so that the facility officials understand your rationale. If the cause of the deficiency is obvious, share the information with the provider. For example, if you cite a deficiency for restraints (F 118), indicate that restraints were applied backwards on residents 1621, 1634, 1646, etc.

In those instances where the cause is not obvious, do not delve into the facility's policies and procedures to determine the root cause of any deficiency. Do not recommend or prescribe an acceptable remedy. The provider is responsible for deciding on and implementing the action(s) necessary for achieving compliance. For the restraint situation in the example above, you would not ascertain whether the improper application was due to improper training or lack of training, nor would you attempt to identify the staff member who applied the restraints. It is the provider's responsibility to make the necessary changes or corrections to ensure that the restraints are applied properly.

A secondary role for the surveyor is to provide general consultation to the provider/consumer community. This includes meeting with provider/consumer associations and other groups as well as participating in seminars. It also includes informational activities, whereby you respond to oral or written inquiries about required outcomes in care and services.

(n) Confidentiality and Respect for Resident Privacy. Conduct the survey in a manner that allows for the greatest degree of confidentiality for residents, particularly regarding the information gathered during the in-depth interviews. When recording observations about care and resident conditions, protect the privacy of all residents. Use a code such as resident identifier number rather than names on worksheets whenever possible. Never use a resident's name on the Deficiency Statement, Form HCFA-2567. Block out resident names, if any, from any document that is disclosed to the facility, individual or organization.

When communicating to the facility about substandard care, fully identify the resident(s) by name if the situation was identified through observation or record review. Improperly applied restraints, expired medication, cold food, gloves not worn for a sterile procedure, and diet inconsistent with order, are examples of problems which can be identified to the facility by resident name. Information about injuries due to broken equipment, prolonged use of restraints, and opened mail is less likely to be obtained through observation or record review. Do not reveal the source of information unless actually
observed, discovered in the record review, or requested by the resident or family.

(o) Team Composition. Whenever possible, use the following survey team model:

SNF/ICF Survey Team Model

In facilities with 200 beds or less, the team size may range from 2 to 4 members. If the team size is:

- 2 members: The team has at least one RN plus another RN or a dietitian or a pharmacist.
- 3-4 member: In addition to the composition described above, the team has one or two members of any discipline such as a social worker, sanitarian, etc.

If the facility has over 200 beds and the survey will last more than 2 days, the team size may be greater than 4 members. Select additional disciplines as appropriate to the facility’s compliance history.

Average onsite time per survey: 60 person hours (Number of surveyors multiplied by the number of hours on site)

Preferably, team members have gerontological training and experience. Any member may serve as the team leader, consistent with State agency procedures. In followup surveys, select disciplines based on major areas of correction. Include a social worker, for example, if the survey revealed major psychosocial problems. This model does not consider integrated survey and inspection of care review teams, which typically would be larger.

(p) Type of Facility—Application of SNF or ICF Regulations. Apply the regulations to the various types of facilities in the following manner:

- Freestanding Skilled Nursing Facility (SNF)
- Freestanding Intermediate Care Facility (ICF)
- SNF Distinct Part of a Hospital
- ICF Distinct Part of a Hospital
- Dually Certified SNF/ICF
- Freestanding SNF with ICF Distinct Part (Regardless of the proportion of SNF and ICF beds, the facility type is determined by the higher level of care. Therefore, LTC facilities with distinct parts are defined as SNFs with ICF distinct parts.)

(q) Use of Part A and Part B of the Survey Report. (i) Use of Part A (HCFA-525).—Use Part A for initial certification surveys only, except under the following circumstances:

- When a terminated facility requests program participation 60 days or more after termination. Treat this situation as a request for initial certification and complete Part A of the survey report in addition to Part B.
- If an ICF with a favorable compliance history requests to covert a number of beds to SNF level, complete both Part A and Part B for compliance with the SNF requirements. If distinct part status is at issue, also examine whether it meets the criteria for certification as a distinct part.

(ii) Resurvey of Participating Facilities. Do not use Part A for resurveys of participating SNFs and ICFs. A determination of compliance, based on documented examination of the written policies and procedures and other pertinent documents during the initial survey, establishes the facility’s compliance status with Part A requirements. This does not preclude citing deficiencies if they pertain to administrative or structural requirements from Part A that are uncovered incidental to a Part B survey. As an assurance measure, however, each facility at the time of recertification must complete an affidavit (on the HCFA-1516) attesting that no substantive changes have occurred that would affect compliance. Each facility must also agree to notify...
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the State agency immediately of any upcoming changes in its organization or management which may affect its compliance status. If a new administrator is unable to complete the affidavit, proceed with the survey using the Part B form and worksheets; do not use the Part A form. The survey cannot be considered complete, however, until the affidavit is signed. If the facility fails to complete the affidavit, it cannot participate in the program.

(iii) Substantial Changes in a Facility's Organization and Management. If you receive such information, review the changes to ensure compliance with the regulations. Request copies of the appropriate documents (e.g., written policies and procedures, personnel qualifications, or agreements) if they were not submitted. If the changes have made continued compliance seem doubtful, determine through a Part B survey whether deficiencies have resulted. Cite any deficiencies on the HCFA-2567 and follow the usual procedures.

(2) Use of Part B (HCFA-519). Use Part B and the worksheets for all types of SNF and ICF surveys—initials, recertifications, followup, complaints, etc. The worksheets are:

- HCFA-520—Residents Selected for In-depth Review
- HCFA-521—Tour Notes Worksheet
- HCFA-522—Drug Pass Worksheet
- HCFA-523—Dining Area and Eating Assistance Worksheet
- HCFA-5245—Observation/Interview/Record Review Worksheet

For complaint investigations, perform a full or partial Part B survey based on the extent of the allegations. If the complaint alleges substandard care in a general fashion or in a variety of services and care areas, perform several tasks or a full Part B survey, as needed. If the complaint is of a more specific nature, such as an allegation of improper medications, perform an appropriate partial Part B survey, such as a drug pass review and a review of selected medical records.
### §488.115 Care guidelines.

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<thead>
<tr>
<th>Survey Area</th>
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<td><strong>Resident Rights</strong></td>
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<tr>
<td>FS3</td>
<td>SNF 405.1321(k)(1)</td>
<td>ICF 442.311(a)</td>
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<td>FS4</td>
<td>SNF 405.1321(h)(1)</td>
<td>ICF 442.311(a)(1)</td>
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<td><strong>A. Information</strong></td>
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<td>FS5</td>
<td>SNF 405.1321(h)(1)</td>
<td>ICF 442.311(a)(2)</td>
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<tr>
<td>1. Rights and Responsibilities</td>
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<td>FS6</td>
<td>SNF 405.1321(k)(1)</td>
<td>ICF 442.311(a)(3)</td>
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<td>2. Rules of Residency Conduct</td>
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<td>FS7</td>
<td>SNF 405.1321(h)(2)</td>
<td>ICF 442.311(a)(4)</td>
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<td>3. Resident Acknowledgment</td>
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**Intent:**
To assure that the resident maintains, in so far as possible, those personal rights that are a part of normal, adult life, and including the right to personal dignity.

*Information concerning incompetent residents is given in L. Delegation of Rights and Responsibilities.*
LONG TERM CARE SURVEY

<table>
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<tr>
<td>F58 SRF 485.132(a)(1)</td>
<td>Ask Resident:</td>
<td>- If there are changes in services or costs does someone explain these?</td>
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<td></td>
<td>Ask Administrative Staff:</td>
<td>- How do residents learn what is expected of them?</td>
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<td>4. Resident informed in writing of changes in services and charges for services.</td>
<td>- How do they learn about any changes in the facility's procedures and/or costs?</td>
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<tr>
<td>F59 SRF 485.132(a)(2)</td>
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<td>5. Information to resident of services not covered by Medicare or Medicaid and not covered in the basic rate.</td>
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### LONG TERM CARE SURVEY

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</table>
| B. Medical Condition & Treatment | **Ask Resident:**  
- Has your doctor discussed your health with you?  
- How is it, what’s wrong, and what you can expect in the future?  
- Have you had the opportunity to help plan what you need and how you are taken care of?  
- Do you know that you can refuse treatment or medication?  
- Have you ever refused medication or treatment?  
- What happened when you did?  

**Ask Staff:**  
- Is the facility participating in any experimental research?  
- If yes, ask what residents are involved.  
- Interview a sample of these residents.  

**Ask Resident (or Guardian):**  
- Are you participating in the study?  
- Was this explained to you well enough so that you understand what the study is about and any risks that may be involved? |  
- If the resident has not been informed of his/her medical condition, physician notes should document that the resident was not informed because it was medically contraindicated.  
- Do care plans or other documentation reflect resident participation in care planning?  
  - If resident states he/she has refused treatment or medication does documentation indicate adherence to violation of resident rights.  
  - Review records of residents identified as participating in a clinical research study. Are informed consent forms signed? Do these signed forms list all known risks for the resident?  
  - All needed informed consent statements are present and properly signed. | **Unless there is documentation that the resident’s medical condition should not be discussed with his/her resident interview/record review should indicate that the resident and physician have discussed his/her medical condition.**  
- If you cannot confirm that this has occurred, interview staff to get further clarification.  
- Almost all residents who are able to participate to some extent in their care planning do so.  
- You should find evidence of this for the majority of the residents (e.g., care planning interview, nurses notes, social worker progress notes). | **Patient Care Management**  
465.112(d)  
442.1319  
442.341 |

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Health Care Financing Administration, HHS

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<tr>
<td>F60-64 (cont'd)</td>
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<td>However, except in an emergency situation force should never be used to compel a resident to accept medication or treatment.</td>
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<td>Deceit is also a violation of resident rights, except in the case of therapeutically indicated placebos ordered by the physician.</td>
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<td>Any resident participating in research studies should fully understand the implication of the study.</td>
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<td>The facility is not in compliance with the resident rights regulation if the resident consents to participate in a clinical study without full knowledge of the study. (Record review only as other nonclinical studies may not require informed consent).</td>
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## Long Term Care Survey

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</table>
| C. Transfer and Discharge | Look for residents that may be inappropriately placed physically—an alert resident roaming with a confused, noisy resident; very ill resident placed far from the nurses station; residents not compatible with each other, (e.g., different life-styles, habits, etc.). | **Ask Resident:** | Nursing, physician, and/or social service progress notes should indicate reasons for transfer and discussion with resident and/or family/guardian. | To be in compliance with transfer and discharge regulations the facility must be able to confirm that all discharges/transfers were for medical or resident welfare reasons, or non-payment. Welfare reasons include physical, emotional, social issues. | [Status Change Notification](#) [485.112][1][j] 
[Medical Records](#) [485.113][c][e] 
[Transfer Agreement](#) [485.113][a][2] |
| F65-04 | **SNF 485.112(1)(4)** | **ICF 442.318(c)** | If staff interviews give a cause to feel that transfers and discharges may be in violation of these regulations, review a sample of closed records for transfer information on how it was handled. | Transfers and discharges made solely for the convenience of the facility are unacceptable. Relocation to accommodate contagious or other disorders requiring isolation procedures are not for the convenience of the facility. | [Status Change Notification](#) [485.112][1][j] 
[Medical Records](#) [485.113][c][e] 
[Transfer Agreement](#) [485.113][a][2] |

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**Note:**
- **Status Change Notification** [485.112][1][j]
- **Medical Records** [485.113][c][e]
- **Transfer Agreement** [485.113][a][2]
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<tr>
<td>F65-6B (cont'd)</td>
<td>+ cost factors</td>
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<td>+ resident welfare</td>
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<td>+ resident's reason for requesting the move</td>
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<td></td>
<td>+ facility's assessment of whether the move would be beneficial or not for the resident</td>
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<td>SURVEY AREA</td>
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<td>D. Exercising Rights</td>
<td>Do residents appear comfortable when speaking to the surveyor so as opposed to being afraid that someone may see them or overhear their conversation?</td>
<td><strong>Ask Resident:</strong>&lt;br&gt;- Do you belong to, or have representation on the resident council?&lt;br&gt;- Are you informed of changes in the facility that will affect you?&lt;br&gt;- Are you given a chance to express views on these changes prior to their implementation?&lt;br&gt;- Does the facility assist in arranging for you to vote either at the polls or via absentee ballot?&lt;br&gt;- Are you assisted in obtaining legal or Social Services if needed?&lt;br&gt;- Do you feel comfortable in expressing yourself freely or are you concerned about retaliation?&lt;br&gt;- Is staff/administration responsive to complaints? Do you know who to complain to?&lt;br&gt;<strong>Ask Staff:</strong>&lt;br&gt;- What arrangements are made for residents to vote?&lt;br&gt;- How do you handle it if someone needs a lawyer or other service that you don't provide?</td>
<td>Review resident council documentation, as available, to determine level of activity.</td>
<td>Compliance determinations will be made based primarily on resident/staff interviews and correlation of interview information with documentation in the Medical record.</td>
<td>Social Services 482.1130 442.264</td>
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<tr>
<td>E. Financial</td>
<td>Ask Residents:</td>
<td></td>
<td>A copy of the statement should be in the resident's financial record and given to the resident at least quarterly.</td>
<td>Residents should have reasonable access to their funds (may not be available at 2 A.M.) and should have at least a quarterly accounting of their funds.</td>
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<tr>
<td>Affairs</td>
<td>- Are you able to take care of your own financial affairs?</td>
<td></td>
<td>Receipts, account logs showing deposits/withdrawals, authorization/ reason for withdrawals, and interest earned should be reviewed. If resident indicates there may be a problem, an in-depth interview should be conducted.</td>
<td>If questions arise they should be resolved.</td>
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<td>- Does the facility keep some money for you that you can have when you request it?</td>
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<td>Personal possessions and funds received from the residents should be protected from theft and other loss. If losses do occur there should be: 1. a procedure which is implemented to investigate the loss, and 2. a plan to prevent recurrence.</td>
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<tr>
<td></td>
<td>- When you ask for this money, how quickly do you get it?</td>
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<td></td>
<td>- Do you know the amount of money you have available at this time?</td>
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<td></td>
<td>- If the facility pays bills for you do they periodically provide an itemized listing of the transactions they have made?</td>
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<td></td>
<td>- When did you receive the last itemized statement?</td>
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<td>- Are you comfortable that your funds are taken care of correctly?</td>
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<td>- If you deposit money or valuables with the facility, do you receive a receipt for this deposit?</td>
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<td>- Are you or your family able to review your financial records when you request to do so?</td>
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<td></td>
<td>- Have you ever had money or anything else stolen? If so, what was done about it?</td>
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<td>F72-78</td>
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<td>SNF 485.1121(k)(b)</td>
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<td>485.1121(m)</td>
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<td>ICF 442.311(e)</td>
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<td>442.328</td>
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Social Services 485.1130(a)
### Long Term Care Survey

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<tbody>
<tr>
<td>F72-7B (cont'd)</td>
<td>- Does the home provide safe-keeping for valuables? &lt;br&gt;- Have they ever lost anything of yours? &lt;br&gt;<strong>Ask Staff:</strong> &lt;br&gt;- What is the procedure when residents lose personal belongings? Valuables? &lt;br&gt;- How are resident personal funds handled? &lt;br&gt;- What is your procedure when a resident asks to get an accounting of their funds? &lt;br&gt;<em>The special needs of residents with Alzheimer's disease who &quot;lose&quot; personal possessions should be noted. Individuals in stages 2 and 3 of Alzheimer's disease sometimes believe their personal possessions were stolen.</em></td>
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<td>SURVEY AREA</td>
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<tr>
<td>F. Freedom from Abuse and Restraints</td>
<td>- How many residents are physically restrained?</td>
<td>Ask Resident:</td>
<td>Look for a physician's order for the restraint.</td>
<td>There must be a physician's order for all restraints, including</td>
<td>Nursing Services 485.1124(c)(5)</td>
</tr>
<tr>
<td>F79-B3</td>
<td>- What type of restraints are used?</td>
<td>- Why are you wearing this?</td>
<td>Review nurses', physicians' progress notes re: reason for restraints and resident reaction.</td>
<td>&quot;safety devices&quot; which are defined in some State laws.</td>
<td>Rehab Nursing 485.1124(e)</td>
</tr>
<tr>
<td>SNF 485.1124(4)(17)</td>
<td>- Are they applied correctly?</td>
<td>- How often is it worn?</td>
<td>Also any alternative methods tried.</td>
<td>Progress notes should show evidence that methods other than restraints were initially used to protect the resident from injury, and that restraints were used only when other methods were not adequate.</td>
<td>Patient Care Management 485.1124(d)</td>
</tr>
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<td>CF 442.317(f)</td>
<td>- What is the apparent physical/mental condition of those residents restrained?</td>
<td>- What is done for you when the restraint is removed?</td>
<td>- What time of day are restraints most often applied?</td>
<td>If used in an &quot;emergency&quot; the reason for use must be documented and show that:</td>
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<td></td>
<td>- Do you observe the release of restraints every 2 hours and the provision of at least 10 minutes exercise for the resident?</td>
<td>- For nonrestrained resident:</td>
<td>- Review schedule of releasing restraints.</td>
<td>a. Its use was necessary to protect the resident from injury.</td>
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<td></td>
<td>- Do staff respond to request for water, assistance to bathroom, etc., from a resident who is restrained?</td>
<td>- Have you ever been restrained?</td>
<td>- Care plans:</td>
<td>b. Its use was necessary to protect others from injury.</td>
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<td></td>
<td>- What is the interval between request and response?</td>
<td>- For what reason?</td>
<td>- When restraint is to be used.</td>
<td>The resident must be observed by a staff member at least every 30 mins.</td>
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<td></td>
<td>- What explanation was given for the restraint?</td>
<td>- For how long?</td>
<td>while restrained.</td>
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<td></td>
<td>- Do you ever feel that you receive medication when you don't need it?</td>
<td>- Are plans for alternative measures.</td>
<td>The restraints must be released and the resident exercised, toileted, etc., at least every 2 hours.</td>
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<tr>
<td>F79-83 (cont'd)</td>
<td>How often are restrained residents observed by staff?</td>
<td>Ask Staff: What is the facility policy regarding restraints?</td>
<td>Who authorizes the use of restraints in an emergency?</td>
<td>The restraint must be applied correctly.</td>
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<td></td>
<td>Observe effect on residents. Do you see what may be signs of overmedication?</td>
<td>- What is considered an &quot;emergency&quot; need for restraints?</td>
<td>Do progress notes indicate that a professional staff member authorized the use of &quot;emergency&quot; restraints?</td>
<td>If the use of restraints increased during evening and night hours, review progress notes, nurses' notes, and staffing to make a determination as to whether the restraints are justified or if they are for staff convenience.</td>
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<td></td>
<td>How often is this observed?</td>
<td>- What is the most common reason for use of restraints?</td>
<td>There should be documentation that the use of &quot;emergency&quot; restraint has been promptly reported to the residents physician.</td>
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<td></td>
<td>Residents should be free from mental and physical abuse.</td>
<td>- Do you try any alternative measures before using restraints? Review incident and accident reports to identify any problematic trends.</td>
<td>Care plans should plan not only for care while the resident is restrained but should show effort to find alternative treatments to restraints, or there should be documentation in the medical record that no alternative is appropriate.</td>
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<td></td>
<td>Observe interaction of staff and residents for any sign of harassment, humiliation or threats.</td>
<td>- What information do you give the physician to help him make the decision to order restraints?</td>
<td>An appropriate drug regimen review should be conducted on the resident.</td>
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<td></td>
<td>Do residents appear comfortable with staff?</td>
<td>- What do you routinely do for the resident when you periodically release the restraints? Your observations should show interaction between residents and staff to be, except in unusual situations, free from tension and hostility.</td>
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<td>Look for numbers of residents with bruises or other injuries (skin of the elderly bruises easily, so do not automatically assume abuse or injury).</td>
<td>- Does use of restraints increase on evenings or nights when there are fewer staff members? Staff should step into situation where one resident may be abusing another.</td>
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<td>Observe resident to resident interactions and staff response to any physical or mental abuse of one resident to another.</td>
<td>- Have you had any accidents or incidents in the last year while residents were restrained?</td>
<td>Are there resident complaints documented?</td>
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<td></td>
<td>- How do you define the difference between a &quot;safety device&quot; and a &quot;restraint&quot;?</td>
<td>What is the resolution of these complaints?</td>
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<tr>
<td>F79-83 (cont'd)</td>
<td>- Observe for evidence of resident neglect, residents left in urine/feces without cleaning.</td>
<td>- Ask Resident: - Do you feel safe in the facility? - Do you ever feel intimidated, harassed, or otherwise abused? - How are confused residents treated? - Is anyone ever hit or treated roughly? - Do you feel as if you are treated with respect/dignity? - Is the staff/administration responsive to complaints? - Do you know who to complain to?</td>
<td></td>
<td>Resident should feel free to voice complaints. If no complaints are noted in records or on record review, why not? Residents should seem comfortable in relating how they are treated.</td>
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| G. Privacy  | - Observe interactions between staff and residents for indications of respect, consideration, dignity and individuality. | Ask Resident:  
- Do you feel that you are treated as a worthwhile, adult individual? -  
- when you are being cared for, are you comfortable?  
- What is the degree of privacy and respect you receive?  
- Do you feel comfortable that if the door to your room is closed staff will knock or otherwise make their presence known before entry?  
- Do you have a private place to make telephone calls?  
- Can you see your record if/when you ask?  
- Has any information about your condition been given to someone outside of the facility without your permission? | Review progress notes for indications that staff see resident as an individual, i.e., resident eats breakfast in bed because he/she enjoys it. Signed consent for release of information. Do maintenance of and content of medical records indicate that confidentiality is practiced? | Observations and interviews will give you information to determine if residents are respected and treated as individuals. In privacy available—e.g., access to a private place to meet or make phone calls, ability to shut door when having visitors, etc. | Medical Records  
483.1132(b)  
442.318(d)  
Married residents should not be left where unauthorized personnel can read them and there should be identification codes needed to access computerized records. Married residents should be sharing rooms if they desire to do so unless there are appropriate contradictions. |
## LONG TERM CARE SURVEY

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<tbody>
<tr>
<td>184-89 (cont'd)</td>
<td>- Are medical records kept in their assigned spots not carelessly left for unauthorized persons to view?</td>
<td>- Are married residents sharing rooms?</td>
<td>- Observe for negative attitudes toward aging-infantilization and patronizing of residents.</td>
<td>- If residents undress in public area, how does staff handle this?</td>
<td>- Listen to staff conversation in public places (elevator, lobby). Are resident issues being discussed?</td>
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<tr>
<td></td>
<td>- For Married Residents:</td>
<td>- When your husband/wife visits can you shut your door and be assured of privacy?</td>
<td>- Can you ask that you not be disturbed and have that request respected?</td>
<td>- Ask Staff:</td>
<td>- What is done to assure that each resident maintains his/her dignity and individuality?</td>
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<td></td>
<td>- How are medical records kept secure? Who has access?</td>
<td>- Do you have married couples here?</td>
<td>- Do they share rooms?</td>
<td>- If not, why?</td>
<td>- What arrangements do you make for spouses or significant others to visit?</td>
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<td></td>
<td>- Do you allow their door to be closed?</td>
<td>- Can you adhere to a request that they not be disturbed?</td>
<td>- How are residents' medical records and conditions kept confidential?</td>
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<tr>
<td>M. Work</td>
<td>Are residents doing any type of work such as picking up dirty trays,</td>
<td>If residents are performing services for the</td>
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<tr>
<td>F90</td>
<td>pushing laundry hampers, etc.?</td>
<td>facility such as pick up dirty trays or stamp</td>
<td>If appropriate does the family concur?</td>
<td>Services performed by a resident should be part of the resident’s plan of care and</td>
<td>405.1124(d)</td>
</tr>
<tr>
<td>SWF 405.1123(k)(10)</td>
<td>What about clerical work?</td>
<td>mail?</td>
<td>Are results documented in progress notes?</td>
<td>should be done only if the resident is in full agreement.</td>
<td>662.341</td>
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<tr>
<td>ICF 402.311(h)</td>
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<td>Service rewards are specifically identified and not obtained using the residents'</td>
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<td>Ask Resident: Are you ever asked to help put in the facility such as pick up</td>
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<td>own funds.</td>
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<td>dirty trays or stamp mail?</td>
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<td>If yes, do you do this?</td>
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<td>- Do you want to, or do you feel it is expected of you?</td>
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<td>- Do you feel you can say “no”?</td>
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<td>Ask Staff: Are residents asked to help with facility staff?</td>
<td>If residents are performing services for the</td>
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<tr>
<td></td>
<td>- Are you shorthanded?</td>
<td>facility such as pick up dirty trays or stamp</td>
<td>If appropriate does the family concur?</td>
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<td></td>
<td>- What is their reaction?</td>
<td>mail?</td>
<td>Are results documented in progress notes?</td>
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<td></td>
<td>- What useful work is available for residents who want/need to be</td>
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<td>useful work “employed”?</td>
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| § 488.115 |                                                                 |                                                                 |                                                                                      |                                                                                      |                 |
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</table>
| 1. Freedom of Association and Correspondence   | - Are there areas in the facility—e.g., small lounges, etc., where residents can and do meet privately?  | Ask Residents:  
- Have you visited anyone?  
- Can you find a private place to visit?  
- Do you receive your mail unopened unless you request otherwise?  
- Are there telephones you have access to?  
- Do the staff or volunteers assist you in reading or sending mail, if needed?  
- How timely is your mail delivered?  
- How do you receive incoming calls?  
- Ask Staff:  
- Where do residents go when they want privacy?  
- What telephones are available to residents?  
- What is the facility visiting policy? | Physician orders and care plans for indicators of restrictions on visitors and/or receiving and sending mail. | All residents may have access to and maintain contact with the community and members of that community have access to them.  
Subject to reasonable scheduling restrictions, residents may receive visits from anyone they wish. A particular visitor may be restricted by the facility for one of the following reasons:  
- The resident refuses to see the visitor.  
- The resident's physician documents specific reasons why such a visit would be harmful to the resident's health.  
- The visitor's behavior is reasonably disruptive of the functioning of the facility (reasons are documented and kept on file).  
Decisions to restrict a visitor are reviewed and reevaluated each time the resident's plan of care and medical orders are reviewed by the physician and nursing staff or at the resident's request. | Resident Rights 489.121(b)(6) 442.311(g) |
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<tr>
<td>F91-92 (cont'd)</td>
<td>Do the available telephones accommodate the physically handicapped (e.g., wheelchair bound, hearing impaired, etc.).</td>
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Space is provided for residents to receive visitors in reasonable comfort and privacy.

Telephones, consistent with ANSI standards (45.1134(c)), are made available and accessible for residents to make and receive calls with privacy. Residents who need help are assisted in using the phone. The fact that telephone communication is possible, as well as any restrictions, is made known to residents.

Arrangements are made to provide assistance to residents who require help in reading or sending mail.
### LONG TERM CARE SURVEY

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| J. Activities | - What planned activities are occurring?  
- What unplanned activities are occurring—individual, 2 or 3 persons or a larger group.  
- If there is a facility chapel, is it open?  
- Are activities posted at wheelchair level and kept up to date?  
- Are residents lined up in front of a T.V. in a common room for hours?  
- Are activities offered during the evening and on weekends. | Ask Residents:  
- What do you like to do?  
- What did you do yesterday? (Compare answers)  
- Is participation in activities optional?  
- Are you encouraged to participate?  
- Is pressure exerted on you to attend specific activities?  
- Which ones? (Surveyors should be aware of special encouragement—gentle persuasion, which might be important for the depressed or withdrawn resident.)  
- Are residents notified of community activities?  
- Are arrangements made for transportation, etc., so that residents can participate?  
- Can residents go to religious services if they wish?  
- What opportunities are you given to make choices in your life within the facility? (e.g., are all residents "put to bed" at the same time)? | Care plans or other documentation should indicate resident preferences for both facility and non-facility planned activities.  
Progress notes of responses to activities. | Compliance with this element is determined by evidence that residents are given the opportunity to participate in available activities they choose unless medically contraindicated.  
Residents must not be forced to participate against their wishes. | Patient Activities  
482.133(o)  
482.305(a)(c) |
| F93 | SNF 485.133(4)(12)  
ICF 482.305(a)(3) | | | | |

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<tr>
<td>K. Personal</td>
<td>- Are residents wearing their own clothing or facility nightgowns, robes, etc.?</td>
<td>- Ask Residents:</td>
<td>- Admission notes on personal property inventory, e.g., the record should indicate a list of any personal property secured by the facility. The record should indicate how personal clothing will be laundered.</td>
<td>- Residents are permitted to keep reasonable amounts of personal clothing and possessions for their use, while in the facility. Such personal property is kept in a safe location which is convenient to the resident. The amount that is reasonable will be dependent on space available in the facility.</td>
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<td>Possessions</td>
<td>- In resident rooms observe for personal belongings.</td>
<td>- Ask Staff:</td>
<td></td>
<td>Patients are advised, prior to or at admission, of the kinds and amounts of clothing and possessions permitted for personal use, and whether the facility will accept responsibility for maintaining these items (e.g., cleaning and laundry).</td>
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<td></td>
<td>- Ask residents if you can look in the closet for personal clothing in there?</td>
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<td>Any personal clothing or possessions retained by the facility for the patient during his stay is identified.</td>
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<td>- Ask residents if belongings such as clothing are identified with name tags or other identifying methods?</td>
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<td>The facility is responsible for secure storage of such items, and they are returned to the patient promptly upon request or upon discharge from the facility.</td>
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<td></td>
<td>- Is there enough space to store clothing?</td>
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<tr>
<td>L. Delegation of Rights and Responsibilities</td>
<td><strong>Ask Administrative Staff:</strong> - When do you have relatives make decisions for residents—i.e., how do you decide when the resident isn’t capable of making decisions himself? - Have any legal steps been taken?</td>
<td>Review physician progress notes—incapability must be documented. Is there clear documentation as to whom rights and responsibilities have been assigned? Are pertinent consents/documents signed by appointed guardian?</td>
<td>The fact that a resident has been judged incompetent, is medically incapable of understanding, or exhibits a communication barrier, does not absolve the facility from advising the resident of their rights to the extent the patient is able to understand them. If the resident is incapable of understanding their rights, the facility advises the guardian or sponsor and acquires a statement indicating an understanding of resident’s rights. The surveyor reviews records of residents selected for indepth review who are classified either incompetent, medically incapable of understanding their rights, or have a communication barrier to verify documented evidence (signed acknowledgment) that the guardian or other sponsor has been advised of these resident rights and understand their role in acting on behalf of the resident.</td>
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<td>F95-97</td>
<td>SNF 485.112(l)(k)</td>
<td>ICF 442.312</td>
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<td>Resident Rights 485.112(l)(k)(l) 442.312(a)</td>
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<td>EVALUATION FACTORS</td>
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<tr>
<td><strong>F100</strong> 1. Facility staff are knowledgeable about the problems and needs of the aged, ill, and disabled.</td>
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<tr>
<td><strong>F101</strong> 2. Facility staff practices proper techniques in providing care to the aged, ill, and disabled.</td>
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<td><strong>F102</strong> 3. Facility staff practices proper techniques for prevention and control of infection, fire prevention</td>
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<tr>
<td>How do staff relate to residents?</td>
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<td>Does the facility reflect adaptations for the elderly, i.e., information given in large print, floors covered with materials that allow for ease of movement with walkers, wheelchair, etc.?</td>
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<tr>
<td>Ask Residents</td>
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<tr>
<td>- Does staff know how to take care of you?</td>
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<td>- What things do they do to help you accommodate your (poor vision, unsteady walking, arthritis, etc.)?</td>
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<td>Ask Staff</td>
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<td>- What, if any, training have you had here to learn about unique problems and needs of the aged?</td>
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<td>- What training have you had during the last 12 months?</td>
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<td>- How have you learned about facility policies and procedures?</td>
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<td>- Does the facility ask your needs when they develop a training program?</td>
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<td>- In what areas would you like to have training?</td>
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<td>Care plans reflect staff's knowledge of the problems and needs of the residents and special adaptations that are needed.</td>
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<td>Progress notes indicate that the special needs are considered in implementing planned care.</td>
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<tr>
<td>facility staff adjusts care to needs/problems of resident.</td>
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<td>Staff is knowledgeable concerning facility policies and procedures.</td>
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<td>Staff practices correct techniques, i.e., infection control, rehabilitation nursing techniques, etc.</td>
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<tr>
<td>Staff interacts and treats residents in a kind, caring way.</td>
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Residents Rights
SNF 405.1121(a) ICF 442.311
Infection Control
405.1135(a)(b)(c) 442.315(b)(c)
442.326(a)(c)
Physical Environment
405.1134(a)
442.315(b)(c)
442.326(a)(c)
Nursing Services
405.1124(a)(c)(e) 442.338(b)(c)
Social Services
405.1138(a)
<table>
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<tr>
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<tr>
<td>F102 (cont'd) and safety, prevention, confidentiality of resident information, and preservation of resident dignity, including protection of privacy and personal property rights.</td>
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**INTENT**

To assure that facility provides ongoing training to staff so that they will be knowledgeable in current practices, use proper techniques, and interact with residents in a kind, caring way.
## Long Term Care Survey

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<tr>
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<tr>
<td>Status Change Notifications</td>
<td>Note residents condition: - Clean - Well groomed - Well adjusted - Casts - Bruises - Decubitus Ulcer - Multiple sites of edema - Abnormal behavior, e.g., abusive, disruptive, not reasonable, etc.</td>
<td>Ask Resident: - Have you been injured since you have been in the facility? - If you are injured or become ill, is your physician notified? - Are your relatives notified? - Do you know who is notified if administrative changes such as changes in charges, billings, etc. occur?</td>
<td>- Progress note should document injury/change in condition plus notification of physician and appropriate family member/guardian. - Changes in charges should be documented. Ask facility where this is located. - Review accident and incident reports for in-depth sample.</td>
<td>- All injuries and changes in condition must be documented. The resident's physician and family must be notified of significant changes. This should be documented, but this notification should be confirmed by the resident if possible.</td>
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<td>Emergency Services</td>
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*Note: The facility notifies the resident's attending physician and other responsible persons in the event of an accident involving the resident, other significant change in the resident's physical, mental, or emotional status, or patient charges, billings, and related administrative matters.*
### LONG TERM CARE SURVEY

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</thead>
</table>
| F06         | Ask Resident:  
- Have you ever been or do you know if others have been transferred or discharged without discussing it with you first?  
- Nursing, physician and social work progress notes should be reviewed for evidence of discussion of transfer/discharge with resident or other designated person.  
- Except in an emergency, all transfers or discharges are first discussed with the resident or next of kin as evidenced by documentation in the medical record or confirmed by asking resident. |              |               |                   |                 |

**INTENT**

To assure that:
- the resident receives proper treatment in the event of an accident or change of condition.
- resident and/or next of kin or responsible party is aware in advance of any changes.
- resident is not discharged to gain a higher source payment for that bed or facility convenience.
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<tbody>
<tr>
<td>Physician's Services</td>
<td>F103</td>
<td>A. Medical Findings and Orders at Time of Admission</td>
<td>Ask Staff: - Interview nursing staff to determine if they receive transfer information and admission orders on day of admission. - Ask Administrator and Director of Nursing to explain procedure if a resident arrives without sufficient medical information and/or orders.</td>
<td>Review records of residents selected for indepth review to ascertain that: - There is a referral form from the transferring facility that was received in advance of admission or on date of admission that includes current medical findings, diagnosis and orders from a physician for the immediate care of the resident. - If the medical orders were not obtained from the resident attending physician, there are temporary orders from the emergency care physician. - Information on the rehabilitation potential (prognosis) of the resident and a summary of the course of treatment followed in the transferring facility were transmitted within 48 hours of admission. - The summary of treatment should include discharge summaries from therapies, or special services when appropriate. - For residents admitted directly from other facilities.</td>
<td>Examine medical records of the residents selected for indepth review to determine if date of orders, medical data and other required information is the date of admission or within 48 hours of admission. The facility should receive sufficient information and orders to provide continuity of care of all residents.</td>
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<tr>
<td>FLG (cont'd)</td>
<td>the resident and a summary of prior treatments are made available to the facility at the time of admission, or within 48 hours thereafter.</td>
<td></td>
<td>community, the attending physician provided current medical findings, diagnosis, prognosis, and orders.</td>
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<td>SURVEY AREA</td>
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<tr>
<td>Resident Supervision by Physician</td>
<td>Observe resident for any problem/conditions that should be addressed by physician, e.g., edema, loss of appetite, weight loss, etc.</td>
<td>Ask Resident: - How often physician visits. - If physician has discussed plan of care and medical treatment. - If resident feels treatment and/or plan of care meets his/her needs. - What kind of questions do you ask the physician about your health problem? (Give examples.)</td>
<td>Review medical records of selected for in-depth review for: - A current plan of care that is based upon physician’s orders and resident needs. - Evidence that the plan is reviewed and revised as needed. - Evidence through physician’s progress notes, nurses notes, physician’s orders, that the physician participates in the resident’s overall plan of care. - Evidence that rehabilitation potential is addressed. - Long range plans include an estimate of the length of time for skilled nursing care and a discharge plan. - Physician’s orders for medications and treatments on admission and during stay. - A medical evaluation completed within 48 hours of admission unless done within 5 days prior to admission that includes attention to needs such as diet, vision, hearing, speech</td>
<td>Medical records should provide evidence that the residents are under the supervision of a physician by the coordination of physician’s orders and progress notes with the resident’s plan of care and observations of residents needs. There is evidence that the physician reviews and revises the plan of care as needed. There is evidence that the physician services are available to the residents when the residents need such services. An alternate schedule for physician visit may be established if the attending physician determine that the resident need not be seen every 30 days. Justification for the decision is placed in the resident’s medical record and is reviewed by the U.S. Committee and State medical review team. Where there is a change in the resident’s condition and the physician has failed to document his findings or evaluation of the condition, the physician has failed to provide</td>
<td>F111 SFH 405.112(b) F112 ICF 442.346</td>
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<tr>
<td>F114</td>
<td>A physician prescribes a planned regimen of care based on a medical evaluation of each resident’s immediate and long-term care needs.</td>
<td>Ask Licensed Nursing Staff: - How often physician visits and is it often enough to meet resident’s need? - Does physician participate in evaluation and re-evaluation of resident’s plan of care? - Does plan of care meet resident’s needs? - Is physician available in an emergency? - Is physician available to discuss resident’s treatment and care?</td>
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<tr>
<td>F116</td>
<td></td>
<td>Ask Administrator: - Facility’s policy regarding a physician to provide care in the absence of the resident’s own physician. - Facility’s policy on physician visits.</td>
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<td>F114 (cont'd)</td>
<td>level of activity, emotional adjustment. - Evidence in care plans and treatment records that physician's orders are being implemented. - Discrepancies in medication record, diet order, intake and output records. - Evidence that an alternate physician provided care if applicable. - Progress notes by physician at least every 30 days for first 90 days (ICT at least every 60 days). - Review of medications and treatments every 30 days or 60 days if an alternate schedule of visits has been approved. - Documentation of physician observations, actions and plans for treatment. - Justification for alternate schedule of visits.</td>
<td>evidence of his evaluation of resident needs and supervised care. A physician is available to respond within a reasonable time when a resident needs medical attention.</td>
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<td>F115</td>
<td>3. A physician is available to provide care in the absence of any resident's attending physician.</td>
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<td>F116</td>
<td>4. Medical evaluation is done within 48 hours of admission unless done within 5 days prior to admission. NOT ICFs.</td>
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<tr>
<td>F117</td>
<td>5. Each SNF resident is seen by their attending physician at least once every 30 days for the first 90 days after admission.</td>
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<td>A few closed records should be reviewed to determine if residents were appropriately discharged by an order written by the attending physician. Also review</td>
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<td>Although medical evaluation can be noted as a revision of the previous H&amp;P. A statement such as “no change” when in conflict with the status of the</td>
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<td>F117 (cont'd)</td>
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<tr>
<td><strong>Exception:</strong> ICF residents must be seen every 60 days unless otherwise justified and documented by the attending physician.</td>
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<tr>
<td>F118 6. Each resident's total program of care including medications and treatments is reviewed during a visit by the attending physician at least once every 30 days for the first 90 days and reviewed as necessary.</td>
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<td></td>
<td></td>
<td>discharge plans to assure that they were adequate and implemented. Verbal medication orders are countersigned by a physician. Physician is reviewing all medication orders every quarter.</td>
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<td>resident on this admission to the facility, does not constitute a medical evaluation. Verbal medication orders must be countersigned with 48 hours.</td>
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### Long Term Care Survey

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<tr>
<td><strong>Exclusion:</strong> Only medications must be reviewed quarterly for ICF residents.</td>
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<td><strong>F119</strong></td>
<td>7. Progress notes are written and signed by the physician at the time of each visit, and all orders are signed by the physician.</td>
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<td><strong>F120</strong></td>
<td>8. Alternate physician visit schedules that exceed a 30-day schedule adopted after the 90th day following admission are justified by the attending physician in</td>
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<td>F120 (cont'd)</td>
<td>the medical record.</td>
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<td>These visits cannot exceed 60 days or apply to patients who require specialized rehabilitation schedules.</td>
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<td>Exception RCF residents must be seen every 60 days unless justified otherwise documented by the attending physician.</td>
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<td>C. Emergency Services</td>
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<td>F122</td>
<td>Emergency services from a physician are available and provided to each resident who requires emergency care.</td>
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<td>Ask Staff:</td>
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<td>- Are you aware of physician reporting procedures and medical protocols to be followed during a fire emergency?</td>
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<td>- Do you know where names and telephone numbers are of physicians to be called in case of emergency?</td>
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<td>- If records document an accident or a medical emergency, was the patient seen by a physician or was the physician notified promptly of the emergency?</td>
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<td>- Review physician's orders to see if specific medications or treatments were ordered to treat emergency situation if applicable.</td>
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<td>- Surveyor verifies that there are readily available written procedures for securing a physician in case of emergency.</td>
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<td>- Names and telephone numbers are posted or on rolodex.</td>
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<td>- An alternate physician is designated.</td>
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<tr>
<td>F122 (cont'd)</td>
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<td>- Review physicians progress notes to see if emergency situation was addressed.</td>
<td>- There is provision for:  + Notification of attending physician/emergency and other responsible person.  + Arrangements for transportation.  + Preparation of reports.  + There is evidence in the medical records that proper procedures have been carried out.  + Residents with sudden changes in condition have been evaluated by the physician.</td>
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<td>Nursing Services</td>
<td>F124 SNF 405.1124(c)</td>
<td>F125</td>
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<tr>
<td>Grooming and Personal Hygiene</td>
<td>F127 SNF 405.1124(c)</td>
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Basic care provided to residents:
Surveyors should observe the basic care provided by staff to the residents. Listed below are suggested areas of attention which may provide evidence of the quality of personal care:
- Eyes/Ears/Mouth
  Presence/absence of:
  - Secretions, tearing around eyelids, redness or irritation of eyes
  - Eyeglasses worn when appropriate are clean, in good repair and fit properly
  - Backs of ears scaly, obvious wax buildup, discharge, odor
  - Hearing aid worn when appropriate, is in good repair and working
  - Dried food particles or drool, etc. around mouth

Ask Resident:
- If the resident's clothing is inappropriate, ask:
  - Did you choose your clothing today?
  - Is this what you want to wear?
  - Do you have other clothing available?
  - If the resident is not clean, poorly groomed, or inappropriately groomed, ask the resident:
    - Have you had any help in caring for yourself today (e.g., washing your face, brushing your teeth, etc.)?
    - How often do you have a bath/shower?
    - How often is your hair washed?
    - How often do you brush your teeth/clean your dentures?
    - Were there extenuating circumstances (e.g.,

Nursing notes, flow sheets or bathing records should indicate that the care plan for grooming and personal hygiene is being followed. For example:
- Bathing schedules are being followed (including the use of any soaps or special lotions)
- Assistance instruction and/or supervision is being provided as identified for each activity

Nursing documentation should also indicate resident response or any changes in the resident's behavior, reaction to an activity, or the ability to carry out grooming and personal hygiene activities. Look for indications of progress toward a goal or further determination of resident functioning.

Refer to information on observation. A pattern of evidence of poor personal care indicates noncompliance unless the care plan specifically deals with this and appropriate planning and implementation is occurring.

The regulations require that individual preferences are taken into account when providing for grooming and personal hygiene and that residents are encouraged in self-care activity. Do your patient interviews substantiate compliance with the regulations?
LONG TERM CARE SURVEY

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<tr>
<td>F127 (cont'd)</td>
<td>Dentures worn when appropriate and in good repair.</td>
<td>- Oral hygiene.</td>
<td>- resident being partaking in dressing retraining program?</td>
<td>- Special consideration might be given to the dementia patient who frequently &quot;borrows&quot; clothes and for whom removal may elicit catastrophic reaction whether clothing &quot;matches&quot; may not be the most important issue in the care of these patients.</td>
<td>Ask Direct Care Staff: - How do you choose what clothing each of your residents wear each day? - Do you have a specific schedule for washing residents' hair? - How did you learn to bathe resident? - How did you learn to wash residents hair? - How do you learn to shave residents? - How do you handle situations when residents want to wear dirty clothes, or mismatched clothes? - How much care do you let the residents do on their own?</td>
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<tr>
<td>Skin Condition</td>
<td>F126-129</td>
<td>Observe with residents' permission:</td>
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<tr>
<td></td>
<td></td>
<td>General condition of skin</td>
<td>Look at nursing notes and P.O.C. for evidence of:</td>
<td>Preventable pressure sores are not occurring. Ulcers present are treated on a routine basis according to P.O.C. Is skin clean? Is resident dry? Is turning schedule adhered to? Are lines clean and smooth? Do personnel know preventive measures and practice them? Has a nutritional assessment been done, and if appropriate, recommendations implemented?</td>
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<td></td>
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<td>Redness</td>
<td>Planned preventive measures.</td>
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<td></td>
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<td>Blanching</td>
<td>Treatments/intervention including nutrition.</td>
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<td>Soak/dry/rough etc.</td>
<td>Routine assessment/evaluation of skin condition.</td>
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<td></td>
<td></td>
<td>Rashes/irritation</td>
<td>Documentation of specific skin problems with location, number, severity, measurements as appropriate, and cause.</td>
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<td></td>
<td></td>
<td>Bruises</td>
<td>Progress or lack of progress in healing.</td>
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<td></td>
<td></td>
<td>Scabs</td>
<td>Assessment/Reevaluation of interventions with alterations in plan.</td>
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<td></td>
<td></td>
<td>Free of above</td>
<td>Appropriate nutritional plan.</td>
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<td></td>
<td></td>
<td>Measures taken to prevent skin breakdown.</td>
<td>Methods to control edema of lower extremities.</td>
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<td>Pressure sores</td>
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<td></td>
<td></td>
<td>Factors contributing to prevention of pressure sores</td>
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<td></td>
<td></td>
<td>Overall cleanliness and maintenance of dry and aerated skin (uncompromised by urine/vomit/perspiration)</td>
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<td></td>
<td></td>
<td>Pillows for pressure points and bony prominences including padding on bed/chair</td>
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<td></td>
<td>Proper gentle massage to bony areas several times a day.</td>
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</table>
### Long Term Care Survey

<table>
<thead>
<tr>
<th>Survey Area</th>
<th>Observation</th>
<th>Interviewing</th>
<th>Record Review</th>
<th>Evaluation Factors</th>
<th>Cross Reference</th>
</tr>
</thead>
</table>
| F128-129 (cont'd) | + Regular assistance for resident to turn or shift weight (bed rails, footboards, trapeze). | Ask Direct Care Staff:  
- What can you tell me about [Mr./Mrs.]' swelling/feet/wounds/bruises/etc.?  
- What do you do for them? |             |                   | Resident Supervision by Physician 483.112(g) |
|             | + Bed linens, clothing, underpads smooth and free from wrinkles.  
+ Elastic bandages or hose are smooth and wrinkle free.  
+ Elastic bandages wrapped smooth with appropriate overlap.  
+ Dietary/Nutritional support for skin integrity. [See Guidelines for Dietary/Nutrition.]  
+ Prevention of shearing force when resident's position altered by staff.  
+ Turning and repositioning as needed.  
+ Care and treatment:  
- Turning and repositioning every two hours or as needed (e.g., alternative approach that is justified by the facility.)  
- Positioning of the ulcer site or protection of affected areas.  
- Use of effective pressure relief devices. |             |                   |                   |
<table>
<thead>
<tr>
<th>SURVEY AREA</th>
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</thead>
<tbody>
<tr>
<td>Wounds/Wound Dressing F126 SMF 485.1124(c)</td>
<td>- Condition of dressing - i.e., clean, firmly secured unless contraindicated. - Observe, if possible, and with resident's permission, a dressing change. - Pre-dressing Removal of all equipment and supplies organized. - Hands washed. - Residents provided with privacy. - Dressing is: - Old dressing observed for drainage. - Wound examined. - Appropriate technique used. - Proper disposal of old dressing. - Post dressing. - Does staff member wash hands? - Return resident to comfortable position or previous activity.</td>
<td>Ask Resident: - How often is the dressing changed? - By whom is the dressing changed? - Does it seem dressing changes are frequent enough? - Are there any odors from the dressing? - Is the dressing change always done in a similar way? - If not, what are the differences? - Do you feel confident that the wound is being well cared for? - Is the area/wound healing? - What caused the ulcer, wound, etc.? Is it healing? Does the staff keep you informed of its status?</td>
<td>Physician orders for wound care. - Progress notes detailing condition of wound - i.e., size, drainage, surrounding tissue, odor - Treatment provided. - Progress/change. - Plan of Care (POC). - The plan of care should address: - Area in need of treatment, treatment to be performed, frequency, and responsible staff. - All necessary solutions, ointments, irrigations, types of dressings, and materials. - Any necessary precautions, drainage, if present, sutures, and tubing. - Specific goals of treatment as well as any problems or limitations imposed as a result of treatment.</td>
<td>Physician orders, your observations, progress notes and POC should reflect the same information. Treatment provided over a period of time with no improvement and no re-evaluation also would represent non-compliance, unless nursing/physician progress notes address the “no improvement” problem. Compliance is evidenced by: - treatment given according to doctor's orders and POC - use of appropriate technique when caring for wound/changing dressing (e.g., follows facility's written procedures) - periodic evaluation of healing process and revision of care plan as needed.</td>
<td>Physician Services 485.1124 442.346 Infection Control 485.1135(b) Pt. Care Management 485.1124 442.341 Dietetic Services 485.1125(b)(1)(a) 442.352(a)(1)(b)(1) Medical Records 485.1122 442.318</td>
</tr>
</tbody>
</table>
### Long Term Care Survey

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</thead>
<tbody>
<tr>
<td>Restraints</td>
<td>Direct to evidence of:</td>
<td>Use of restraints may be precipitated by an &quot;emergency&quot; situation in which there is a threat to the resident's health or safety, or a threat to the health and safety of others due to the resident's behavior. Restrained residents may not be coherent or rational enough to respond to questions and caution in interviewing, therefore, must be oversold. However, observation of a resident in a geri-chair or sliding tray in place for restraints, or in a wheelchair (with vest restraints) for several hours would warrant appropriate questions as to when the staff last assisted him or her to move about or whether the resident would like to get out of the chair. Staff interviews focus on the reason why the resident is restrained.</td>
<td>- Physician orders for restraint: reason, length of time, type, - Progress notes; - Describe the resident's status/behavior which prompted the use of the restraint. - If a chemical restraint, the order should indicate a specific time period for its use as well as a stop date. - Plan of Care should include other methods or therapies that are being used in conjunction with restraints. - What alternatives to restraints have been considered? - Identify staff responsible for observing the resident (every 30 minutes), and releasing and exercising/assisting the resident (every 2 hours for at least 10 minutes). Time intervals should be identified.</td>
<td>- Is there a physician's order, including the circumstances in which they will be used, the length of use, and the type of restraint? - Is the restraint applied properly? - Is it released at least every two hours and the resident provided with exercise and toilet facilities if needed? - Does the staff observe the resident frequently while he/she is restrained? - Are chemical restraints administered in accordance with physician's orders? - Is the order for restraints renewed only after a reassessment of the patient?</td>
<td>Patient Rights 484.121(k)(1)(7) 442.31(f)(2)</td>
</tr>
<tr>
<td>F130</td>
<td>- Proper application, - Proper use, - Maintenance of good body alignment - Resident observation, release and exercise</td>
<td>Ask Direct Care Staff and Charge Nurse: - When, why, and how to release and apply restraints? - Why is the resident...</td>
<td>- Indicate involvement and input of other disciplines necessary to overcome the problem. - Indicate a specific period of time for...</td>
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When residents require restraints, the application is ordered by the physician, applied properly, and reevaluated at least every two hours. (See also information under Resident rights and freedom from abuse & restraints.)
<table>
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<tr>
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<tr>
<td>F130 (cont'd)</td>
<td>rubbing and blistering or impeded circulation</td>
<td>- Body alignment and support: use of pillows, footboards, and wheelchair footrests to maintain appropriate posture, circulation, and to prevent skin injury or breakdown. - Periodic release and exercise: exercise may include ambulation, range of motion, massage, or other opportunities for motion (at least 10 minutes every 2 hours during day and evening hours). - Chemical restraints: residents appear drowsy throughout the day (may indicate that tranquilizers or other drugs are being used to limit or control behavior for staff convenience).</td>
<td>- Restraint? - Was the resident given an option of restraint? - When were you taught the use of restraints? - By whom? - If chemically restrained excessively sedated? - Why is this done? - Whether alternate means of restraint have been attempted, for how long this will continue, etc. This should elucidate from staff whether the chemical restraint is necessary, or whether it is done for staff convenience by controlling resident behavior. - Do you ask the resident for permission before using restraints? - How does the restrained resident request assistance? - What is the usual timeframe for assistance to reach the restrained resident? Ask resident: - Why are you restrained? - What would happen if the restraint were removed? - When do you use bed rails? - What purpose do they serve? - How do you gain assistance?</td>
<td>using the restraint.</td>
<td>- Indication of assessment of factors which precipitate resident behavior which has warranted restraints and plans to intervene early enough to prevent occurrence. - Type, duration and frequency of exercise should be documented. - An assessment of why restraints are continued should be documented.</td>
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<tr>
<td>Bowel and Bladder Incontinence</td>
<td>Each resident with incontinence is provided with care necessary to encourage continence, including frequent toileting and opportunities for rehabilitative training.</td>
<td>- There should be a chart/record in the resident's room on which the program is documented accurately.</td>
<td>- Both the resident and direct care staff should be interviewed and should exhibit a good understanding of the importance of maintaining a regular schedule of elimination.</td>
<td>- Physician orders if required by facility policy.</td>
<td>Nursing Services 485.1124(a)</td>
</tr>
<tr>
<td>SNF 405.1124(c)</td>
<td></td>
<td>- If the room is located a distance from the toileting room or for residents with problems ambulating, a commode may be present in the room.</td>
<td>- If neither are aware of the intake and toileting schedule, then determine whether they are appropriately panning the resident or carrying out a retraining program.</td>
<td>- Nursing notes for documentation of techniques and progress reevaluation.</td>
<td>Dietetic Services 405.1125(c)</td>
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<td></td>
<td></td>
<td>- Verify that a call light is available to the resident if non-ambulatory or restrained.</td>
<td>- Verify that the resident is aware of his/her participation in the program.</td>
<td>- Plan of care</td>
<td></td>
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<td></td>
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<td>- Are fluids available at bedside?</td>
<td>- Are fluids available at bedside?</td>
<td>- The plan of care should clearly address:</td>
<td></td>
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<td></td>
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<td>- Is there roughage on meal tray?</td>
<td>- Diet is appropriate to enhance elimination?</td>
<td>- Goals that resident will aim for.</td>
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<td>- Methods to accomplish the goals.</td>
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<td>- Schedule for fluid intake.</td>
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<td>- Schedule for toileting.</td>
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<td>- Responsible staff</td>
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<td>- Any limitations the resident may encounter as a result of either incontinence or the training program.</td>
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<td></td>
<td>- Progress notes/physician orders for cause of incontinence.</td>
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<td>- Laboratory tests of kidney function when available.</td>
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<td>- Treatment for diarrhea/constipation.</td>
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<td>- Residents preference for treatment of constipation.</td>
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<td>Long Term Care Survey</td>
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<td>SURVEY AREA</td>
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<td>F131 (cont’d)</td>
<td></td>
<td>Ask Nurse Aides and Charge Nurse:</td>
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<td>at least 7 days for the cause of incontinence</td>
<td>§ 488.115</td>
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<td></td>
<td></td>
<td>- Will you describe this resident's bowel/bladder (B/B) training program?</td>
<td></td>
<td>and when appropriate an intensive bowel and bladder B/B training program should be instituted.</td>
<td>HHS</td>
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<td></td>
<td></td>
<td>- How long has it been in effect?</td>
<td></td>
<td>A trial B/B training program is suggested for all residents with incontinence problems.</td>
<td>1 &amp; 6</td>
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<td>- When will you evaluate the results?</td>
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<td>- If this program is not successful</td>
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<td></td>
<td>- What assessment was done to determine B/B status</td>
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<td></td>
<td>- For residents not on B/B retraining programs</td>
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<td></td>
<td></td>
<td>what is the facility program for managing incontinence?</td>
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<tr>
<td>Catheter Care</td>
<td></td>
<td>The indwelling catheter should promote a continuous flow of urine unless ordered otherwise. The surveyor should also observe for the following:</td>
<td></td>
<td>The facility should follow accepted professional standards in their catheter care.</td>
<td>§ 488.115(c)</td>
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<tr>
<td>F132 SNF 405.1124(c)</td>
<td></td>
<td>- Appropriate catheter insertion and care.</td>
<td></td>
<td>There should be medical reasons for catheter insertion - staff convenience cannot be justification.</td>
<td>§ 488.115(c)</td>
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<tr>
<td>Each resident with a urinary catheter receives proper routine care including periodic evaluation</td>
<td></td>
<td>- Proper positioning of the catheter and drainage bag.</td>
<td></td>
<td>Direct care staff should know signs and symptoms of urinary tract</td>
<td>§ 488.115(c)</td>
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<td></td>
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<td>- Cleanliness of the</td>
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<tr>
<td>F132 (cont'd)</td>
<td>Tubing and drainage bag.</td>
<td>Ask Nursing Aide and Charge Nurse:</td>
<td>- Assessment should address:</td>
<td>Infections (U.T.I.s) and these should be reported and treated promptly.</td>
<td>*The Center for Disease Control has developed standards for catheter care which may be used but it is not a requirement.</td>
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<td></td>
<td>- Color and consistency of urine in bag.</td>
<td>- How do you routinely position and secure catheters and drainage bags?</td>
<td>- Need for an indwelling catheter.</td>
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<td></td>
<td>- Availability and accuracy of documentation on the N/A sheet if ordered or policy.</td>
<td>- How often is each part of the system changed?</td>
<td>- Resultant problems or limitations.</td>
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<td>- Proper equipment for ambulation - Teg bag if resident is ambulating (if ordered).</td>
<td>- What are the indications for insertion of the catheter?</td>
<td>- Plan of care should address:</td>
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<td></td>
<td>- Availability of fluids.</td>
<td>- What is the facility's procedure for routine catheter care?</td>
<td>- Type of catheter and type and frequency of care.</td>
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<td></td>
<td>- When indicated monitor intake to ensure adequate intake and output or conformance with physician orders.</td>
<td>- How do you observe for U.T.I.'s in residents with indwelling catheters?</td>
<td>- For irrigation, the rationale, the type of solution, amount, and frequency of irrigation.</td>
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<td></td>
<td>- How many observed residents are on catheter care?</td>
<td>- What is the facility's procedure for the cleansing and storage of reusable catheter equipment and drainage receptacles?</td>
<td>- Frequency of symptoms which would precipitate catheter change.</td>
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<td>- How do you care for catheter tubing?</td>
<td>- Time frames of catheter change and responsible staff.</td>
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<td>- Appropriate increase in oral fluid intake.</td>
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<td>- Interventions:</td>
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<tr>
<td>F132 (cont'd)</td>
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- Indwelling catheter.
- The specific type and size of equipment used should be noted.
- Signs and symptoms of urinary tract infections (UTI) should be acted upon and documented as to follow-up.
- Evaluation/Reevaluation
  - The record should reflect that the resident:
  - Is assessed for UTI.
  - Has no abdominal distention.
  - Notes should also include:
  - The color and odor of urine and the development of any problems after insertion of indwelling catheter.
  - Verify that catheter is patent.
## Survey Area

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<tr>
<th>Injections</th>
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</tr>
</thead>
<tbody>
<tr>
<td>F151</td>
<td>- Observe for preparation of injection — i.e., maintenance of sterility; correct dilution, handwashing, before preparation, etc.</td>
<td>- Observe injection site for:</td>
<td>- Physician order sheet:</td>
<td>- Is the medication administered according to the physicians order?</td>
<td>Staff Development 405.1121(b) 402.314</td>
</tr>
<tr>
<td>SNF 1124(c)</td>
<td>- Resident response to medication if appropriate</td>
<td>- Ask Nurse:</td>
<td>- Nursing notes for:</td>
<td></td>
<td>Infection Control 405.1135(b)</td>
</tr>
<tr>
<td></td>
<td>- What is your plan for alternating injection sites? Show me.</td>
<td>+ Does the nurse administering the medication know the expected action of the drug?</td>
<td>+ Any problems noted at injection site</td>
<td>- If infection control reports show infections at injection sites.</td>
<td></td>
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<tr>
<td></td>
<td>- What is the medication for and what are potential adverse reactions?</td>
<td>+ Any other adverse reactions.</td>
<td>+ Site of injection</td>
<td>- Is the resident's response to the medication noted in the progress notes?</td>
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<td></td>
<td>- Is there nonspecific pain at the injection site or shooting pains down a limb?</td>
<td>+ Site of injection</td>
<td>+ Plan of care</td>
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<td></td>
<td>- Is there skin irritation or lumps under the skin?</td>
<td>+ Rotation of injection site</td>
<td>+ Care for any special problems related to the injection.</td>
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<td></td>
<td>- If adverse reaction occur, how soon are they reported?</td>
<td>+ Care for any special problems related to the injection.</td>
<td>- Infection Control: reports for any infections connected with injections.</td>
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<td>- Could this be given by any other route?</td>
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<td>Ask Resident:</td>
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<td>Suggested questions are:</td>
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<tr>
<td></td>
<td>1. What kind of medicine do you receive by injection/shot? Why do you need that medicine?</td>
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<td></td>
<td>2. Do you have pain or numbness at or around your injection site?</td>
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<td>3. Who gives the injection?</td>
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<td>4. Do you receive your injection according to a schedule?</td>
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### Long Term Care Survey

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<th>Survey Area</th>
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<th>Evaluation Factors</th>
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</thead>
<tbody>
<tr>
<td>Parenteral Fluids F133 SNF 405.1124(c)</td>
<td>The surveyor should observe that parenteral fluids are administered with safe, aseptic technique providing fluids as ordered by the physician. Safety and comfort measures are to be taken insuring maximum protection and optimum hydration of the resident. The surveyor should note the following items: - Labeling of the solution bottle/bag, - Rate of infusion (cc/ml per hour). - Date and time started, - Any signs of swelling or redness at site, - Site dressing is clean, dry and dated, - Accurate I&amp;D of parenteral and P.O. fluids, - If splint (armboard) is used, it is applied to prevent movement but not impede circulation, - Positioning of I.V. tubing, - Comfort of restraint used to allow for maximum resident freedom while preventing movement of I.V. site.</td>
<td>Ask Resident: - Why do you have this tube in your arm/leg? - Is it comfortable? - Is there a way it would be more comfortable? - How long has it been in? - How much longer will it stay in?</td>
<td>Ask Appropriate Staff: - Why the resident is receiving I.V. therapy? - What is the rate of infusion? - How often is the dressing changed? - How often is the tubing changed? - What are possible side effects? - How often is the site changed? - How often is the infusion checked for drip rate and the remaining volume to be administered? Ask Nursing Aide: - What are your responsibilities when caring for a resident receiving I.V. fluids? - What training have you had?</td>
<td>- Physician's order for parenteral therapy. - Specifying type of fluid, rate of infusion/hour, and additives, if any, is available and current. - Twenty-four hour I&amp;D record. - Nursing documentation indicates physician's orders are being followed. - Any adverse reactions are noted in the medical record. - Record indicates: + Infusion started by whom, at what time, and rate of flow + Note is made of observation of pain or swelling at infusion site. + The need or reason for parenteral fluids. + The plan of care includes a plan of care should include + Type, rate of infusion, hour, and additives (if ordered).</td>
<td>- Is the parenteral fluid administered according to the physician's order and in accordance with accepted nursing practice? - Are infusions noted in a timely manner before a large amount of fluid is infused? - Is the facility procedure for care of the I.V. site and tubing changes followed for all patients unless contraindicated? - Does documentation reflect what the patient received, any problems, and his/her response to the parenteral fluid? - Have any adverse effects been caused by administration of I.V. fluid? - If yes, were they preventable?</td>
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<td>SURVEY AREA</td>
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<td>RECORD REVIEW</td>
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<tr>
<td>F133 (cont'd)</td>
<td>The surveyor should ascertain that the facility is providing appropriate nursing care to those residents who have had bowel surgery resulting in a colostomy or ileostomy. It is recommended that the surveyor, with the resident,</td>
<td>specified goals for correction, time frame, and responsible staff. Documentation must include time administered and by whom, the amount of fluid infused, and any other special care administered as a result of IV therapy (i.e., wound care, assistance with ADLs, etc.).</td>
<td>The record must reflect:</td>
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<td></td>
<td>Ask Resident:</td>
<td><em>Plan of care would not be modified for a one-time IV infusion.</em></td>
<td>Conditions of site and any complications, phlebitis, necrosis, etc. noted, along with measures taken to correct these.</td>
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<tr>
<td>Colectomy/Ileostomy</td>
<td>[F133 ( \text{SNF 405.1124(c)} )]</td>
<td>The surveyor should determine that:</td>
<td>The resident's response to therapy and changes in laboratory studies.</td>
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<td></td>
<td></td>
<td>- Why was the ostomy performed?</td>
<td>Compliance would be indicated if residents are physically and emotionally comfortable with the ostomy with minimal or no skin problems. If residents are not comfortable with the ostomy, are having skin or other problems, the facility</td>
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<td></td>
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<td>- How do you feel about the ostomy?</td>
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<td>- Does it ever cause you problems (e.g., pain, skin problems, odor, accidents)? If so, what</td>
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<td>Colostomy/Ecstomy F133 (cont’d)</td>
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<td></td>
<td>Consent permission, observe care being given to determine that proper techniques are being used. The following steps should be taken to assure that proper ostomy care is being provided.</td>
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<td>- The ostomy dressing should be changed or the bag emptied and thoroughly cleaned promptly after each bowel evacuation or more frequently, if drainage continues.</td>
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<td>- The peristomal skin should be cleansed and dried, and appropriate measures taken to prevent excoriation and infection.</td>
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<td>- The resident's privacy should be considered while providing care.</td>
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<td>- The resident should be provided with information and instruction in self-care at the appropriate level of understanding.</td>
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<td></td>
<td>- The resident should be observed for signs of withdrawal, distress, anxiety, or other emotional responses which may be related to his/her condition.</td>
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<td></td>
<td>- Does staff do anything that the resident or family would like to see done differently?</td>
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<td></td>
<td>- What does the staff generally do with or for the ostomy? Are they consistent and timely?</td>
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<td>- Has staff talked to you about doing some of the care for this? If so, what was the outcome? If not, is this something you'd be interested in learning more about?</td>
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<td>Ask Staff:</td>
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<td>- If nurses aid:</td>
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<td>+ How did you learn to take care of colostomies?</td>
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<td>+ What do you do if the skin around the colostomy becomes red or sore?</td>
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<td>+ Do you ever teach the residents to care for their own colostomies?</td>
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<td>- If nurse (RN or LPN)</td>
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<td>+ What is the procedure if the resident becomes constipated?</td>
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<td>Ask Other Nursing Staff:</td>
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<td>- Is there a facility procedure for ostomy care?</td>
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<td>- Do you have skin problems with your ostomy?</td>
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<td>documented as established through management of diet, fluid intake, exercise, and the use of prescribed laxatives, suppositories, and/or irrigations.</td>
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<td>- Ostomy care is documented in the resident's medical record along with a description of the contents.</td>
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<td>- Problems in irregularity, skin breakdown, or other observable concerns are documented and reported to the physician.</td>
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<td>- Documentation indicates that nursing measures are taken to assist the resident who is experiencing problems in understanding and/or accepting the presence of the ostomy.</td>
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<td>- Documentation of nursing measures to maintain skin integrity.</td>
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<td>- Assessment:</td>
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<td></td>
<td>+ Needs, problems, and limitations as a result of an ostomy.</td>
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<td>+ Specific degree of</td>
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<td>SURVEY AREA</td>
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<td>Colostomy/Illeostomy F133 (cont'd)</td>
<td>her acceptance of the colostomy/illeostomy. The surveyor should observe the staff giving ostomy care to verify that proper technique is used.</td>
<td>ostomy residents? - What do you do when skin becomes excoriated? - What teaching do you do with the residents? - What in general is the response to this teaching?</td>
<td>self-care performed or assistance needed. - Special skin care needs. - Special dietary needs. - (emotional) support. - Medications and treatments if needed. - Plan of Care The plan of care should clearly address: - Specific goals to overcome or improve the problem(s) identified. - Methods to accomplish the goal (training, assistance, supervision, treatments, emotional support). - Services necessary and who will perform the services. - Time frame for accomplishing goals.</td>
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Social Services
489.1150(a)
442.334(a)(b)
<table>
<thead>
<tr>
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<tr>
<td>Respiratory Therapy</td>
<td>In Aerosol Compressor or IPPB (Intermittent Positive Pressure Breathing Machine)</td>
<td>The surveyor must determine that the facility is providing respiratory therapy as ordered by the physician. Observation for this indicator should focus on the necessary equipment as well as on the resident. In order to determine that the necessary equipment is available, the surveyor must look for the following:</td>
<td>- Respiratory oxygen therapy is performed or administered by appropriately trained staff.</td>
<td>- Only qualified (trained) personnel should administer respiratory therapy. Therapy must be provided as ordered.</td>
<td>Staff Development 489.1121 (b)</td>
</tr>
<tr>
<td>F133</td>
<td>SNF 489.1124(c)</td>
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<td>Infection Control 489.1135(b)</td>
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<td>Patent Care Management 489.1124(d)</td>
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<td>442.341</td>
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<p>| ONLY QUALIFIED TRAINED PERSONNEL SHOULD ADMINISTER RESPIRATORY THERAPY. THERAPY MUST BE PROVIDED AS ORDERED. THE EFFECTIVENESS OF THE THERAPY MUST BE PERIODICALLY EVALUATED AND THERAPY REVISED AS APPROPRIATE. EFFECTIVE INFECTION CONTROL MEASURES MUST BE PRACTICED. NEEDED SAFETY PRECAUTION FOR THE USE OF OXYGEN MUST BE PRACTICED. EQUIPMENT SHOULD BE AVAILABLE AND IN WORKING ORDER. | |</p>
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</table>
| Respiratory Therapy F155 (cont'd) | stored wet. If it is not attached to the tubing, ask to see it. The mouthpiece is connected to the nebulizer cup. The surveyor should also check that all involved equipment is clean. **Oxygen Therapy** The surveyor must establish that the facility is meeting the oxygen needs of the resident. When the facility does not have wall units, check that:  
  - There are enough cylinders for oxygen delivery.  
  - There should be flow meters and regulators for tanks in use.  
  - A wrench should be attached or stored close by.  
  - If using large cylinders (size G or H), look for a carrier since these tanks cannot be transported without it.  
  - The cylinder at the resident's bedside should either be on | pulmonary equipment?  
  - What training was given you in the use of this equipment?  
  - Where is the emergency oxygen supply? | problems and/or limitations.  
  - Specific methods to accomplish the goals (observation, supervision, training, etc.).  
  - Who is responsible to perform therapy or assist in accomplishment of goal.  
  - Intervention - The record should display evidence that:  
    - The plan of care is functional.  
    - The therapy was administered in accordance with physician's order for the specified reason(s) by an appropriately trained staff member.  
    - Change in condition is documented and acted upon promptly.  
  - Evaluation/Reevaluation The record should reflect:  
    - The resident's response to therapy.  
    - If response was undesirable, evidence of further intervention.  
    - Any progress, deterioration, or development of new problems. | Physical Equipment 465.133 (i)  
Medical Records 465.133  
462.318 |
### Short-Term Care Survey

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<thead>
<tr>
<th>Area</th>
<th>Observation</th>
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<tbody>
<tr>
<td>Resident</td>
<td>If resident is not in good condition, check for good eating habits.</td>
<td>- Resident cannot eat.</td>
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<tr>
<td>Call</td>
<td>Call is not answered in a reasonable time.</td>
<td>- Call not answered in a reasonable time.</td>
</tr>
<tr>
<td>Medicare</td>
<td>Medicare is not being billed appropriately.</td>
<td>- Medicare not billed appropriately.</td>
</tr>
<tr>
<td>Medication</td>
<td>Medication is not being administered as prescribed.</td>
<td>- Medication not administered as prescribed.</td>
</tr>
<tr>
<td>Equipment</td>
<td>Equipment is not being used or maintained properly.</td>
<td>- Equipment not used or maintained properly.</td>
</tr>
<tr>
<td>Housing</td>
<td>Housing is not adequate or safe.</td>
<td>- Housing not adequate or safe.</td>
</tr>
<tr>
<td>Hygiene</td>
<td>Hygiene is not being maintained.</td>
<td>- Hygiene not maintained.</td>
</tr>
<tr>
<td>toileting</td>
<td>Toileting is not being done properly.</td>
<td>- Toileting not done properly.</td>
</tr>
<tr>
<td>Personal Care</td>
<td>Personal care is not being done properly.</td>
<td>- Personal care not done properly.</td>
</tr>
<tr>
<td>Transportation</td>
<td>Transportation is not being provided.</td>
<td>- Transportation not provided.</td>
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<tr>
<td>Social Programs</td>
<td>Social programs are not being provided.</td>
<td>- Social programs not provided.</td>
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* Based on the above, make any necessary modifications of goals.
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| Respiratory Therapy F133 (cont'd) | - Is sufficient Oxygen supply available?  
- Is the ventilator accessible to an emergency outlet?  
- Is the resident in a location that allows for frequent observation by staff?  
- How does the resident communicate with staff?  
- What level of staff (aide, LPN, RN) is caring for the resident?  
- Is such equipment at bedside?  
- Is there reserve back-up equipment?  
- What is the condition of the residents skin around intubation tube/tracheostomy?  
- Does the care given use appropriate technique in caring of the patient? | residents on respira- 
- tors?  
- Can you show me how the alarm system works?  
- What is your procedure for pulmonary care?  
- What is your procedure for changing tubing and the water reservoir?  
- What happens if the power goes off? | | | |
### Long Term Care Survey

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<th>Survey Area</th>
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| Tracheostomy Care            | Satisfactory tracheostomy care is a procedure which promotes a clean, unobstructed air passageway and maintains the skin integrity surrounding the tracheostomy site. The surveyor should determine whether: Adequate supplies are available for the care of the tracheostomy such as tracheostomy kits, hydrogen peroxide, normal saline or sterile water, suction machine, catheter, sterile gloves, and clean dressings. The patient is breathing without difficulty and is comfortable. The dressing is clean, dry, and intact; the cannula is clean, in the proper position, and secured. The skin surrounding the trach is clean and dry with no redness or inflammation. The resident has adequate oral hygiene. An extra tube, the same size as the one in use, is available. Resident interviews must be guided by the resident’s communication ability. Ask Resident: - How long will you have it? - What care can you do for yourself? - What do you need help with? - Who helps you? - Is someone always available to suction his/her when needed? - Is the suction equipment always available in working order? - Is the dressing kept clean and comfortable? - Is the tube kept clean and changed as needed? - How often are the tubes and dressings changed? Does he/she feel confident in the personnel caring for his/her trach? - What is communicating with staff and other residents like? - Are staff patient and do they allow you enough time to express your needs/thoughts/feelings? May I observe your tracheostomy care? Ask Staff: - why does resident have

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|                              | - The surveyor should determine that tracheostomy care is done as scheduled and as needed following the proper procedure. Any special solutions that are needed should be addressed in the physician’s orders. Assessment – The record should reflect that the need for tracheostomy care was assessed in terms of: - Frequency - Skin integrity surrounding the tracheostomy, noting redness, inflammation, and/or excoriation. Plan of Care should include: - Specific times of trach care and the responsible, appropriate trained person performing this task. - Specific problems relating to skin and breathing as well as the goals set to overcome these problems listing the appropriate personnel responsible. - Time frames for resolving problems

### Evaluation Factors

Stoma and surrounding skin should be in good condition and if not, there should be treatment directed to resolving this problem. All staff caring for the tracheostomy must be trained and emergency procedures must be known. All needed equipment must be available and in working order. Residents must at all times have readily available a means of communicating with the staff in an emergency.

### Cross Reference

- Infection Control 405.1135 (b)
- Training 405.1121(h)
- Patient Care Management 405.1124(d)
- Physicians Services 405.1122(i)
- Social Services 405.1130(a)
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<td>Tracheostomy Care F133 (cont'd)</td>
<td>place, is available at bedside. - Does resident have an adequate method of communicating with the staff? - Does staff allow enough time for residents to communicate?</td>
<td>tracheostomy? - What training were you given to enable you to care for tracheostomies? - What is the procedure for tracheostomy care? - How often is the tube changed? - What do you do if the tube comes out? - May I watch you do a dressing change? - If not convenient, describe what you do? - How do you communicate with a tracheostomized resident?</td>
<td>listed in goals. + Plan for periodic assessment of appropriateness of resident's own self care re: teaching or nursing assuming more responsibility as appropriate. - Intervention - The surveyor should look for documentation of: + Trach care and oral hygiene administration, including responsible personnel, time and date, and effects. + Any problems or changes noted in resident condition (e.g., redness, swelling, tracheal obstruction). + Emotional response to tracheostomy. + Evaluation/Reevaluation - Resident is or is not benefiting from trach care and skin care. + If problems are noted, the progress notes and plans for care should indicate changes in treatment. + Resident's emotional response to care of the tracheostomy should be evaluated.</td>
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<td>SURVEY AREA</td>
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<td>Tracheostomy Care F133 (cont'd)</td>
<td>Suctioning is necessary for any resident who is unable to cough up secretions that are obstructing his airway. Suctioning may occur via the oral or nasal route, or sputum route with sterile technique. Attempts should be made to observe a resident being suctioned should such an opportunity arise. If so, observe that a clean/aseptic technique is observed throughout and that the resident tolerated the procedure. There should not be bloody aspirant, cyanosis, or broncho-spasm. Check that equipment is in good working order, frequency of procedure, etc.</td>
<td>Ask Resident: - How are you feeling now after the suctioning? Does the suctioning seem to help? - Has staff explained to you the need for suctioning? Why do you need to be suctioned? How often? - Who performs the suctioning (i.e., nurses or nurses aides)? Do you feel safe with the staff performing the suctioning? - Does everyone do it about the same way?</td>
<td>- Assessment - The record should reflect that: - The resident is frequently observed for suctioning needs. - Any limitations a resident has as a result of his suctioning needs should be specifically noted. - Any problems resulting must be specified. - Plan of Care should include: - Awareness of the resident's suctioning needs, goals, approaches, and responsible staff needed to improve the problem or at least maintain the resident at his present status without further deterioration. The plan must clearly indicate specific approaches towards: - Prevention of skin problems around the trach if one exists. - Correction of any existing skin pro-</td>
<td>- All equipment must be available and in working order. - All staff caring for the resident must know what to do in an emergency. - Current professionally accepted standards of care must be maintained.</td>
<td>Infection Control 489.1125(b) Patient Care Management 489.1124(a)</td>
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<tr>
<td>Suctioning F133 SNF 489.1124(c)</td>
<td>Resident observations which indicate need for intervention include: - Secretions are draining from a resident's mouth or trach, and the resident is unable to</td>
<td></td>
<td>since this may require additional care planning.</td>
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</tbody>
</table>
LONG TERM CARE SURVEY

<table>
<thead>
<tr>
<th>SURVEY AREA</th>
<th>OBSERVATION</th>
<th>INTERVIEWING</th>
<th>RECORD REVIEW</th>
<th>EVALUATION FACTORS</th>
<th>CROSS REFERENCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suctioning</td>
<td>cough or clear nose.</td>
<td>- Where are your emergency electrical outlets?</td>
<td>Snuiss.</td>
<td>- Provision of good oral hygiene including a rigid schedule for mouth care, schedules, or procedures for maintaining clean equipment at bedside, as well as disposal of used (dirty) equipment.</td>
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</tr>
<tr>
<td>F133 (cont')</td>
<td>- There are audible crackles or wheezes and/or diminished breath sounds.</td>
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<td></td>
<td>- Route of suctioning (i.e., oral/nasal/ tracheal).</td>
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<td></td>
<td>- The resident is dyspneic.</td>
<td>- How often does Mrs./Mr. need to be suctioned?</td>
<td></td>
<td>- Interventions - The route should indicate clearly that:</td>
<td></td>
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<tr>
<td></td>
<td>- Restlessness or agitation may also be an indication that suctioning is needed.</td>
<td>- May I observe you when you suction Mrs./Mr.?</td>
<td></td>
<td>* The plan of care is being implemented. Documentation should reflect:</td>
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<tr>
<td></td>
<td>Upon completion of suctioning above symptoms should, in most cases, be relieved.</td>
<td></td>
<td></td>
<td>+ The number of times the resident required suctioning, for what specific reason, and by whom the resident was suctioned.</td>
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<td></td>
<td>The surveyor should observe that the resident is positioned to facilitate breathing (usually at a 45 degree angle). Check to see that the facility has an ample supply of suction machines and suction catheters to meet the needs of residents requiring them and that they are clean and properly stored.</td>
<td></td>
<td></td>
<td>+ Any specific treatment the resident received in conjunction with suctioning</td>
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<tr>
<td>Suctioning</td>
<td></td>
<td></td>
<td>(i.e., oral hygiene, skin care, etc.).</td>
<td>- Evaluation/Reevaluation</td>
<td></td>
</tr>
<tr>
<td>F155 (cont'd)</td>
<td></td>
<td></td>
<td>- The record should reflect.</td>
<td>- How well the resident tolerates suctioning procedures.</td>
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<td></td>
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<td></td>
<td>- Any bloody aspirate, cardiac arrhythmia, cyanosis, or bronchospasm.</td>
<td>- Any progress or lack of progress, deterioration, and/or the development of new problems.</td>
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<td></td>
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<td>- Further interventions utilized to overcome or improve these.</td>
<td>- The evaluation should determine whether goals are being reached or if new goals must be addressed.</td>
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<tr>
<td>Tube Feedings</td>
<td>- Staff use proper technique in administering feedings and medications.</td>
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<tr>
<td>F153</td>
<td>Check to see that staff checks for location of tube before feeding and that tubing</td>
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<td>SNF 405.1324(c)</td>
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<td></td>
<td>If the resident is able to be interviewed, suggested questions may be:</td>
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<td>Do you feel comfortable/safe with all the staff who perform the feeding?</td>
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<tr>
<td>Tube Feeding</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Review</td>
<td>- Plan of care</td>
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<tr>
<td>- Must document tube placement and formula potency prior to each feeding.</td>
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<td>§ 488.115</td>
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<tr>
<td>Nursing Services</td>
<td>- Has the feeding been ordered by a physician?</td>
<td></td>
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<tr>
<td>405.1324(d)(1)(f)</td>
<td>- Is tube feeding nutritionally adequate?</td>
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<tr>
<td>442.330(a)(1)</td>
<td>- Have attempts been made to discontinue tube feeding if indicated?</td>
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<tr>
<td>442.333(c)</td>
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<tr>
<td>Tube Feedings</td>
<td>is irritated before and after addition of medication.</td>
<td>- The tube is clean and formula flows freely.</td>
<td>- In the case of continuous feeding, tube placement must be documented at least every 4 hours.</td>
<td>- Is skin free from irritation; mouth care is given several times daily? (More frequent mouth care in the case of continuous feeding.)</td>
<td>Genetic Services 483.125(c)</td>
</tr>
<tr>
<td>F133 (cont'd)</td>
<td>- The equipment is clean and protected. If dressings are ordered, they are in place, clean, and dry.</td>
<td>- The nasal tube is securely but comfortably secured on the face with skin maintained intact and without irritation.</td>
<td>- Nasal gastric tube must be secured in a manner that avoids creating pressure on the nose and nasopharynx.</td>
<td>- Have changes in resident condition been noted and addressed? (Weight loss, constipation, diarrhea, skin condition?)</td>
<td></td>
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<td></td>
<td>- The skin around the gastrostomy is kept clean and free from irritation or infection. It should be checked carefully for leakage of gastric contents.</td>
<td>- Identify frequency, amount of feeding based on the physician's order and time span over which each feeding is accomplished.</td>
<td>- Medication and treatment records.</td>
<td>- Have observed problems been coordinated with other departments and resolved?</td>
<td></td>
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<td></td>
<td>- A resident who has a N/G tube for a prolonged period of time should be observed for possible complications, such as naso erosions, sinusitis, esophagitis, gastric ulceration, and pulmonary infection.</td>
<td>- Fluid intake records.</td>
<td>- Number of calories as well as amount of additional water.</td>
<td>- Is feeding being monitored to ensure that feeding is occurring at the ordered/appropriate rate?</td>
<td></td>
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<tr>
<td></td>
<td>- Resident is fed slowly with head elevated to 45° during feeding and at least 1 hour post-feeding.</td>
<td>- Documentation present regarding removal and reinsertion of tubes.</td>
<td>- Record should indicate measures taken to prevent diarrhea and constipation and to treat if they have developed.</td>
<td>- Varied supplements as preferences allow.</td>
<td></td>
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<tr>
<td>Tube Feedings F133 (cont'd)</td>
<td>Supplies for mouth care are in evidence, observe if possible for technique, mouth shows evidence of good care (i.e., moist, clean.)</td>
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<tr>
<td>Nursing Services</td>
<td>Are personnel performing duties that are allowed under the State Nurse Practice Act?</td>
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<tr>
<td>FL17</td>
<td>Do you observe care being rendered in an appropriate, competent manner?</td>
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<td>Does the time schedule posted indicate that at least the minimum required personnel are scheduled and actually on duty?</td>
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<td></td>
<td>What is the usual response time before a call bell is answered?</td>
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<td>FL18</td>
<td>In SNF's is an RN on duty during the day?</td>
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<td></td>
<td>Are licensed staff and aide staff functioning in appropriate roles?</td>
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<td></td>
<td>Where are staff spending their time?</td>
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<td>Ask Resident:</td>
<td>Do residents generally feel that people taking care of them know what they are doing?</td>
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<td></td>
<td>Are your treatments done in a consistent manner?</td>
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<td></td>
<td>Do you feel that there are enough people here to take care of you?</td>
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<td></td>
<td>How long do you usually wait for help when you put your call light on?</td>
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<td>Is there anything that doesn't get done as often as it should?</td>
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<tr>
<td>Ask Staff:</td>
<td>Do you feel qualified to do all the work you are assigned to do?</td>
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<td></td>
<td>Do you feel you have enough training to keep up with the care the residents require?</td>
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<tr>
<td>All nursing personnel must function within their State Nursing Practice Act. Levels of staffing meet at least minimum requirements. Nursing care needs must be identified by the facility &amp; documentation, resident and staff interviews should determine if these needs are met. All nursing staff should have education or training to prepare them for the care they perform.</td>
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<tr>
<td>F139 (contd)</td>
<td>Check for staff who are actually on duty.</td>
<td>- If no, what else do you need?</td>
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<td>available to meet the total needs of all residents.</td>
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<tr>
<td>F140</td>
<td>There is a registered nurse on the day tour of duty 7 days a week (for SNF only).</td>
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<td></td>
<td>Intent</td>
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<td>that all residents are cared for by personnel qualified to provide the care &amp; that sufficient numbers &amp; classifications of personnel are available.</td>
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<tr>
<td>Patient Care Management</td>
<td>Observe resident level of physical, mental, emotional and social functioning. Note problems, potential problems, needs, using observation/interview/record review work sheet.</td>
<td>Ask Resident:</td>
<td>Review:</td>
<td>- Are all resident's needs/problems identified?</td>
<td>Physician Services</td>
</tr>
<tr>
<td>F167</td>
<td></td>
<td></td>
<td>- Are you aware that you have a plan of care?</td>
<td>485.1123</td>
<td>442.346</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Did you participate in developing a plan of care?</td>
<td>Medical Records</td>
<td>442.318</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Did you or your family know what the plan is and details? (e.g., diet, ambulation, dressing, etc.)</td>
<td>Resident Rights</td>
<td>442.311</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Do you attend and participate in plan of care meetings?</td>
<td>24-Hour Nursing Service</td>
<td>442.338</td>
</tr>
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<td></td>
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<td></td>
<td>- Who also attends the plan of care meetings?</td>
<td>Specialized Rehabilitation Services</td>
<td>442.347</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td>- When did you last attend the meeting for your plan of care?</td>
<td>Training</td>
<td>442.314</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Does the staff assist you in achieving the goals on the plan of care?</td>
<td>Resident Rooms</td>
<td>442.324</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- If not, who does or why not?</td>
<td>Infectious Control</td>
<td>442.325</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Do you have all necessary assistive devices and equipment?</td>
<td></td>
<td>442.326</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Is there anything that is not part of your plan of care that you think should be included?</td>
<td></td>
<td>442.324</td>
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<td></td>
<td></td>
<td></td>
<td>- What happens if you question any treatment or procedure? Can you give an example?</td>
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## Long Term Care Survey

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<tr>
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<td>F 170 (cont'd)</td>
<td>Ask Staff: - What is your input into resident's plan of care? - What aspect of the resident plan of care are you carrying out? - What is this particular resident's plan of care? - How do you assist the resident in carrying out the plan of care? - Who attends the care planning meeting? - Is the plan of care useful to you in caring for the resident? - Is there anything the resident needs that is not addressed in the plan of care? - How often is it reassessed?</td>
<td></td>
<td></td>
<td></td>
<td>Social Services 485.113B 440.1138G(d) Activities 442.345 Dietetic Services 442.332</td>
</tr>
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### Long Term Care Survey

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| Restorative Nursing Activities of Daily Living | A. Observe residents in need of assistance.  
1. Is needed assistance provided?  
2. Is resident provided assistance and instruction, as appropriate, in all ADL's to increase his/her level of independence?  
3. Does staff minimize pain/discomfort while assisting resident?  
4. Is resident taught transfer techniques?  
5. Is resident assisted to toilet in timely manner?  
6. Resident personal equipment available & within reach? | Ask Resident:  
- What assistance do you need with bathing and/or dressing? Who helps you?  
- Does the staff plan with you your dressing/bathing schedule?  
- Do the nursing and activities staff coordinate your schedule so that you have the opportunity to participate in favorite activities?  
- Are you able to dress/bathe at time convenient for you?  
- Are you bathed consistently? I.e., on the days scheduled does the bath get performed?  
- Where are you bathed? (bed, shower, tub?)  
- Are there adequate clothes available for you to wear?  
- Do they come back from laundry in appropriate condition?  
- How do you get in and out of bed?  
- If staff exists you, do they seem to be able to do their job appropriately? Do you always feel safe when | Review:  
- Plan of care  
+ Reflects assessment, goals, methods to reach goals, service providers, evaluation, and achievement.  
+ Addresses restorative nursing assessment, program initiation, implementation and evaluation of the progress over a reasonable time period.  
+ Professional judge's opinion determines the assessment of appropriate time frame.  
+ Identifies planning for potential discharge for all residents to determine a disposition on home care or an alternate level of care.  
- Nursing Notes  
+ Demonstrate evidence of assessment, intervention, response to treatments/teaching and their progress towards independence, a maintenance level or a deterioration.  
+ Provide evidence of interdisciplinary conferences. | Are patient needs identified?  
Verify that the plan of care addresses resident needs and is implemented as scheduled and that all appropriate information is documented.  
If goals are not reached, has a reevaluation been performed and goals revised?  
Does restorative nursing assist the resident to acquire a higher level of independence?  
Is sufficient time allowed to resident for learning to increase his/her level of independence?  
Are assistive devices used regularly as per plan and are they in good repair?  
Is there an assessment, and if appropriate, a plan for each ADL that the resident needs to gain independence?  
Maintenance goals should be noted as appropriate. |
| ICF 442.342 442.343(a)(b)(c) | Glasses  
Hearing aids  
Ventures  
[Artificial Larynx] | | | |
## Long Term Care Survey

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<tr>
<td>Prosthetic devices (eg. braces, artificial extremities).</td>
<td>Being helped?</td>
<td>Are staff members encouraging you to do things for yourself?</td>
</tr>
<tr>
<td>Adaptive equipment (eg. built-up spoon, reachers).</td>
<td>Do you have any problems getting to the bathroom on time?</td>
<td>Do you have any problems with leakage when you sneeze, laugh or at any other particular time?</td>
</tr>
<tr>
<td>Orthotic devices (eg. splints, AFO's).</td>
<td>How does the staff help you with these problems?</td>
<td>Are they aware of the problems?</td>
</tr>
<tr>
<td>Restraints (eg. vest, waist, wrist, ankle, wrists, nets, geri-chairs).</td>
<td>Do you move regularly?</td>
<td>If not, what do you/ staff do about this? Are you able to feed yourself?</td>
</tr>
<tr>
<td>Grooming items (eg. comb, brush, shaver).</td>
<td>Are you able to get to the dining room by yourself? If not, why? In that case, what does staff do about this?</td>
<td>How long have you been up today? Do you usually lie down for a rest?</td>
</tr>
<tr>
<td>Oral hygiene items (eg. toothbrush, toothpaste, mouthwash, denture cup).</td>
<td>If you need help getting into or out of bed, is staff available to help you when you need it?</td>
<td>Where do you spend most of your time - in your chair, wheelchair or in bed?</td>
</tr>
<tr>
<td>Self-feeding devices. Assistive devices for special sensory loss needs (eg. communication boards, large print books, magnifiers, writing tablets, picture cards, talking books).</td>
<td>Training/pre-training</td>
<td>Prosthetic management Stroke adapted ADL's Self-injections of medications Bowel/bladder Self-feeding Self grooming Ambulation</td>
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<tr>
<td>F171-176 (cont'd)</td>
<td>Colostomy/ileostomy Care Respiratory Care Oxygen inhalation Speech Mobility Upper extremity dressing Lower extremity dressing</td>
<td>Does anyone move your arms or legs or help you with exercises? Have your sleeping habits changed since you came to the nursing home? If yes, in what way? Are you able to get help during the night if needed? What kind of help is needed? Is staff response timely? Do you feel there are adequate care supplies at this facility? If not, can you give me an example of why you feel this way? Is your family involved in assisting you or if learning to help you? Do you feel there is adequate staff at this facility? If not, can you give me an example of why you feel this way? Does staff assist and/or encourage activities (e.g., R.N., ambulation A.D.L., communication programs, feeding)? How often does staff assist in activities? Is there anything resident would like to do</td>
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<td>F171-176 (cont'd)</td>
<td>for himself/herself that staff is doing? Is resident comfortable (e.g., free from pain)? Is your cane/walker/crutches comfortable for you to use? Did anyone measure you so you have the right size cane/walker/crutches? Did anyone show you the correct way to use your cane/walker/crutches? If the facility arranged so that you can get around easily?</td>
<td>Ask Activities Staff. Do you provide information to nursing staff about time and place of activities, plus names of residents who are to attend or those who might be interested in attending? <strong>Chair-bound Resident</strong> Ask Resident: Does he/she know why he/she is in a chair? Is resident assisted to use bathroom? Is resident comfortable? Does he/she see therapist (O.T., Speech, P.T.) and how often? Does resident go to a</td>
</tr>
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</tr>
<tr>
<td>F171-376 (cont'd)</td>
<td>therapy area or does therapist come to resident?</td>
<td>- Is able to reach items needed?</td>
</tr>
</tbody>
</table>

Ask Nurse Aide
- Who gives you information about the time and place of activities and which residents are to attend? How are you given this information?
- How do you encourage a resident to do the most for themselves?

Wheelchair Resident
Ask Resident:
- Does he/she know why he/she needs a wheelchair?
- Is resident trained and/or encouraged in independent wheelchair ambulation and activity?
- Does resident know how to lock and unlock wheelchair?

Ask Staff:
- How is a resident set up for independent wheelchair ambulation?
- Nurse Aide - has resident received instruction in transfer techniques?

For Bed Bound Resident
In addition to appropriate interview questions above:
### Long Term Care Survey

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<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>F111-176 (cont'd)</td>
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</table>

**Ask Resident:**
- How do you spend your day?
- Can you do some things for yourself?
- Does the staff give you a chance to learn self-care skills?

**Ask Nurse:**
- If the resident had access to a recliner chair, would he/she be able to be out of bed?
- Is the time out of bed coordinated with the activity schedule and necessary care?

**Ask Nurse Aide:**
- Does this resident do any self-care? Why not?
- If no, has anyone tried to teach him/her to do some care?
### Long Term Care Survey

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</thead>
</table>
| Positioning | Observe residents in bed, chairs, restrained, or 
               | - body alignment 
               | - contractures (when did they occur and what is 
               | - rehabilitation 
               | - MD orders for non-neg 
               | Rehabilitation 
               | 442.113(h) 
               | 442.133(c)(2) 
               | MD Orders 
               | Activities 
               | Resident Rights 
               | Nursing Staffing 
               | Social Service 
               | Dietary |
| FTSP 
               | SWF 405.1124(a) 
               | - positioning 
               | - contractures (when did they occur and what is 
               | - ROM program (observe 
               | - contractures) 
               | - what kinds of exercise 
               | - range of motion (ROM) 
               | - how often do you 
               | - resident teaching 
               | - resident teaching 
               | - services responsible 
               | - plan has been imple 
               | - progress toward goals 
               | - response to information 
               | - look for actual turning 
               | - positioning schedule |

To assure that the resident is 
positioned at all 
times to promote 
maximum therapeu 
tic benefit and 
comfort, as well 
as safety.

**Specific Observations** for the Bed Resident 
(as appropriate to condition), 
Positioning/Body alignment 
Resting splints & correct 
application 
Foot positioning boards 
Trapeze 
Hand rails 
Elbow/leg splints & 
correct application 
Restraints 
Siderails (padded) 
Special mattresses
### Long Term Care Survey

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<tbody>
<tr>
<td>F175 (cont'd)</td>
<td>Blankets/pillows Clean, smooth linen Clean, appropriate bed wear Turning schedules ROM schedule O.B.O. (as tolerated) Water available All adaptive devices are clean and in good repair. All assistive supportive devices are clean and in good repair. Specific Observation for the 008 Resident in Chair (ergo-chair, lounge chair in room, as appropriate to condition) Arrangement of room facilities includes optimal independence (e.g., independent eating, grooming, I.V., radio, water). Positioning/body alignment Blankets/hap robe, pillows, foot stool Hand rails, splints. Clean, dry, sterile Pressure relief device, Restraints, with release &amp; activity schedule. Call bell available.</td>
<td>- When? - Does staff answer call bell promptly? How soon? - Is resident able to reach items (e.g., water, call bell), urinal, emesis basin, tissues? - How much confidence do you have when the nurses are helping you transfer, or turn and sit? - Does resident go to therapy area or does therapist come to resident?</td>
<td></td>
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### Long Term Care Survey

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</table>
| F175 (cont'd) | Specific Observation for the Wheel Chair Resident (as appropriate to condition, including deliberate alterations made to equipment for specific reasons.) | - Proper fit  
- Good working condition  
- Appropriate arm rest, footrest, leg support, lap tray  
- Proper positioning  
- Pressure relief aids, (e.g., gel flotation pads, egg crate mattress, sheepskin)  
- Set up for independent ambulation  
- Functional adapted toilet area  
- Transfer techniques  
- Observe how staff wheel the resident (e.g., do they inform before starting movement)?  
- Are patients moved wheeling forward or facing elevator doors?  
- Observe staff for:  
  - Verbal cues  
  - Physical support  
  - Body mechanics | - Was there any part of your orientation when you first came to work here that addressed positioning?  
- Do you have any periodic reviews/updates on positioning? | | |
| | Specific Observation for the Ambulatory Resident (as appropriate to condition) | - Gait (steady/unsteady)  
- Appropriate devices for | | | |
| | Chair Bound Resident | Ask:  
- How often is resident repositioned/taken out of chair?  
- What is the activity at time of repositioning and/or release of the restraint?  
- What can resident do independently? | | | |
| | Ambulatory Resident | Ask:  
- Is resident encouraged to independently ambulate to and from activities and dining room (with or without personal assistance)?  
- Does resident do as much as he/she can independently?  
- What does resident do?  
- How do you know that resident is maximally independent?  
- If it is not working independently, how do | | | |
### Long Term Care Survey

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<tr>
<td>F175 (cont'd)</td>
<td>Ambulation (e.g., cane, crutches, hemi-sling), posture, appropriate staff assistance in ambulation, grab bars (bath/shower area), functionally adapted toilet area, you deal with it? - Is there something resident would like to do that he/she is not allowed to do (e.g., shave self, apply make-up, style own hair)? - What training have you had in learning to position residents and do range of motion? - What opportunity do you have for ongoing training? - Who does the actual training? Check question placement under Interviewing. May be more appropriate for resident's rights section. Observe wheelchair technique used by staff.</td>
<td></td>
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</tbody>
</table>

### Nursing Services

<table>
<thead>
<tr>
<th>G: Administration of Drugs</th>
<th>(F185=184)</th>
<th>SNF 405.1124(g)</th>
<th>ICF 442.337</th>
</tr>
</thead>
<tbody>
<tr>
<td>F185.1</td>
<td>The patient is identified prior to administration of a drug.</td>
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</tr>
</tbody>
</table>

### Ask Resident

- Do you always receive your medication on time? - If not, what is the problem? - Do you receive the correct medication? - What does it look like? - Who explained your medications to you? - What reactions do you have? - What happens if you have a question or refuse to take your medication? - Who gives you your medication? - Do your medications change in appearance?

### Review the Medication Administration record (as appropriate)

See 405.1124(g) for details of the record review.

### If the combined total of significant & non-significant errors is 55 or above, a deficiency is present. Any significant error is cause for a deficiency. See Appendix N for details.

### Physician Services

405.1124(b)(7)

442.336(d)(b)
## Long Term Care Survey

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</table>
| F187        | 2. Drugs and biologicals are administered as soon after doses are prepared. | - Do the nurses stay with you when you take your medication?  
- Do any of the medications bother you?  
- Ask staff:  
- Do you generally have available the medications you need?  
- Are there any problems in administering medications?  
- Rate drug doses refused by resident and how handled by staff. | | | |
| F188        | b. Administered by same person who prepared the doses for administration except under single unit dose packet distribution system. | | | | |
|             | Exception: LCC residents may self administer medications with their physician's permission. | | | | |
## Long Term Care Survey

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<tbody>
<tr>
<td>M. Conformance with Physician Drug Orders</td>
<td>Combine with observation of drug pass.</td>
<td>- Review the latest recap of the physicians orders</td>
<td>See Appendix N for details</td>
<td>Physician Services 405.1123(b)(1)</td>
<td></td>
</tr>
</tbody>
</table>

**Notes:**
- All residents receive medications as ordered by the attending physician.
<table>
<thead>
<tr>
<th>SURVEY AREA CROSS REFERENCE</th>
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<th>INTERVIEWING</th>
<th>RECORD REVIEW</th>
<th>EVALUATION FACTORS</th>
</tr>
</thead>
<tbody>
<tr>
<td>DIETETIC SERVICES</td>
<td>Specific Observations which might be indicative of possible nutrition problems.</td>
<td>Ask dietary manager to explain the procedure for making substitutions and recording the changes.</td>
<td>Review nutrition assessment for the following documentation:</td>
<td>Were physician diet orders followed?</td>
</tr>
<tr>
<td>(Condition of Participation)</td>
<td>Clinical - underweight/overweight - dehydration - edema - cracked lips - pallor - dull or dry hair - swollen or red tongue - bleeding gums - decubitus ulcers - infections</td>
<td>Is menu usually followed?</td>
<td>o Usual/ideal body weight/height</td>
<td>o Did nursing plan for feeding and assistance at mealtime?</td>
</tr>
<tr>
<td>F193</td>
<td>Ask Resident: 1. How are your meals? 2. Are there foods you are not allowed to have? 3. Are you on a special diet? 4. Do you receive foods that are not appropriate for your diet? 5. What time do you receive breakfast, lunch and supper? Do you always receive a meal at mealtime? If not, why? What happens then? 6. Do you like the taste of the food? 7. Is the temperature appropriate (i.e., milk chilled, coffee hot, etc.)? 8. Do you get enough to eat? What do you do if you're still hungry after a meal?</td>
<td>o Dietary allergies/sensitivities, ability to chew and swallow regular foods without difficulty.</td>
<td>o Is there rehabilitative use of assistive devices, if appropriate?</td>
<td>o Is modification of consistency of meals made if resident has a problem or change in condition?</td>
</tr>
<tr>
<td>SNF (405.1125)</td>
<td>o Physiologic factors which may affect intake: - Swallowing difficulties - Feeding - Food intolerance - Poor dentition - Sore mouth - Constipation - Diarrhea - Inability to feed self - Decreased visual and olfactory acuity - Unable to communicate - Loss of appetite</td>
<td>o Full or partial dentures - Mental and emotional condition - Physical appearance, skin condition - Appetite and food preference - Vitamin and mineral supplements - Food and fluid intake in measurable terms and frequency of meals.</td>
<td>o Are between meal and bedtime snacks provided as needed?</td>
<td>o Are between meal and bedtime snacks provided as needed?</td>
</tr>
<tr>
<td>A. Menus and Nutritional Adequacy</td>
<td>o Psychological/Social - Confusion</td>
<td>o Degree of assistance needed in eating, related mobility, vision, or other identified problems.</td>
<td>o Is socialization at meals provided?</td>
<td>o Has dietitian provided counseling of resident and family as needed (related to diet)?</td>
</tr>
<tr>
<td>F194</td>
<td>Menus are planned and followed to meet the nutritional needs of each resident in accordance with physicians orders and, to the extent medically possible, based on the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences.</td>
<td>o Medications (e.g., diuretics, insulin, antibiotics, etc.)</td>
<td>o Usual body weight is maintained/supported?</td>
<td>o Is there evidence that the plan is being carried out (e.g., documentation in the resident's chart, observation by the surveyor, and resident/staff interviews)?</td>
</tr>
<tr>
<td>SNF (405.1125(b))</td>
<td></td>
<td></td>
<td>o Related laboratory findings (e.g., fasting blood sugar, cholesterol, sodium, potassium, hemoglobin, BUN, serum albumin, transferrin or creatinine-height index if available).</td>
<td>o Is there evidence that the plan is being carried out (e.g., documentation in the resident's chart, observation by the surveyor, and resident/staff interviews)?</td>
</tr>
<tr>
<td>F194</td>
<td></td>
<td></td>
<td></td>
<td>o If the resident refuses meals or does not respond to intervention, the notes in the chart should indicate efforts to intervene or provide counseling.</td>
</tr>
<tr>
<td>ICF 442.332(a)(1)</td>
<td></td>
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</table>

Health Care Financing Administration, HHS
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>- Excessive food likes and dislikes</td>
<td>- Refusal to eat</td>
<td>- Selected biochemical changes which might indicate changes in nutritional status:</td>
<td>- Visceral protein status</td>
<td>- Food/drug interactions</td>
<td>Is there evidence that the resident's progress is regularly observed (e.g., awareness of food and fluid intake such as acceptance of foods, food consumed, and resident's appetite)?</td>
</tr>
<tr>
<td>- Nutritional status:</td>
<td>- Serum albumin</td>
<td>- Transferrin</td>
<td>- BUN</td>
<td>- Mental/emotional assessment as it relates to resident's food habits</td>
<td>o Is fluid intake for resident encouraged, Foley catheter, problem feeders monitored?</td>
</tr>
<tr>
<td>- Serum electrolytes</td>
<td></td>
<td></td>
<td></td>
<td>Review:</td>
<td>o Nursing Notes</td>
</tr>
<tr>
<td>During mealtimes observe the resident for:</td>
<td></td>
<td></td>
<td></td>
<td>Review:</td>
<td>- Physicians orders</td>
</tr>
<tr>
<td>- Adherence to food preferences</td>
<td>- Adequate space for eating</td>
<td>- Proper position for eating</td>
<td>- Notes from other professional disciplines as appropriate</td>
<td>- Progress notes</td>
<td></td>
</tr>
<tr>
<td>- Use of adaptive feeding devices</td>
<td>- Amount of food actually eaten</td>
<td>- Protection of resident's clothes</td>
<td>- Nutritional status depends on adequacy of menu planning but also whether the resident's food and how the body uses it. While the surveyor is responsible for individual nutritional assessments of residents, when specific information is needed during the survey, to make a compliance decision, the surveyor will utilize the following minimum assessment guidelines:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Amount of time resident is allowed to chew and swallow</td>
<td>- Assistance provided as needed to and from dining area</td>
<td>- All beverages are covered</td>
<td>Menu Evaluation</td>
<td>- Adequate in energy and nutrients</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- Protein</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- Calories</td>
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</table>

Ask Dietician: Describe the meal planning input you receive from residents.
### LONG TERM CARE SURVEY

<table>
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</table>
| F196(cont'd) | Assistance being provided in case of choking, incontinence, falling, or other emergencies. Nursing Staff supervision of dining areas including residents' rooms during mealtimes. | - Vitamin C
- Calcium
Selected evaluation of residents for in depth review:
A check list can be used to evaluate daily menus for basic foods:
Use standard serving portions
Daily food plan should include:
Milk GROUP
1 pt milk
MEAT GROUP
5 equivalents:* 1 equivalent equals 1 oz. of meat (edible portion) weighed after cooking (this includes eggs, dried peas, beans, nuts, and all meat, fish and poultry).
VEGETABLE AND FRUIT GROUP
5 servings or more, including a dark green or deep yellow vegetable for vitamin A value every other day and a citrus fruit or other fruit rich in Vitamin C daily. | | | |
LONG TERM CARE SURVEY

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<tbody>
<tr>
<td>F196 (cont'd)</td>
<td>Observe serving portions sizes on all menu items:</td>
<td></td>
<td></td>
<td>BREAD-CEREAL-POTATO-LEGUME-PASTA GROUP</td>
<td></td>
</tr>
<tr>
<td></td>
<td>MILK GROUP</td>
<td></td>
<td></td>
<td>7 servings</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- 1 pint daily</td>
<td></td>
<td></td>
<td>FATS AND SWEETS</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Source of: Protein</td>
<td></td>
<td></td>
<td>(Without this group the diet contains 1,415 Kcal)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Calcium</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Phosphorus</td>
<td></td>
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<tr>
<td></td>
<td>B Complex</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>MEAT GROUP</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- 5 lean meat equivalents</td>
<td></td>
<td></td>
<td>Diets should be adapted from facility's currently approved diet manual.</td>
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<tr>
<td></td>
<td>(1 meat equivalent = 1 oz meat, poultry, fish, cheese &amp; eggs; also dried peas, beans, and nuts)</td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td></td>
<td>Source of: Protein</td>
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<td></td>
<td>Iron</td>
<td></td>
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<tr>
<td></td>
<td>Vitamin B12</td>
<td></td>
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<td></td>
<td>VEGETABLE AND FRUIT GROUP</td>
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<tr>
<td></td>
<td>- 5 servings or more</td>
<td></td>
<td></td>
<td>Menus are dated and contain minimum portion sizes.</td>
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<tr>
<td></td>
<td>(1/2 cup = 1 serving)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Source of: Vitamin A, C, B6, folacin, Fiber</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>BREAD-CEREAL-POTATO-LEGUME-PASTA GROUP</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>- 2 servings</td>
<td></td>
<td></td>
<td>Are substitutions noted on the file copy?</td>
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<tr>
<td></td>
<td>(1 serving = 1 slice bread; 1/2 cup cereal; 3/4 cup flake-type cereal)</td>
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<td></td>
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<td></td>
<td>Are substitutions made within the same food group i.e., must for another source of protein in the meat group, or vegetable of similar nutritional value?</td>
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<tr>
<td>F196 (cont'd)</td>
<td>FATS AND SUGARS (to increase caloric intake) IODIZED SALT (unless contraindicated) Adequate fiber in diet</td>
<td></td>
<td>o Documentation of decision to withdraw or begin artificial feeding and hydration. Check menus for variety Are they specific (i.e., states kinds of fruit, juice, vegetables)?</td>
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**LONG TERM CARE SURVEY**

**Dietary Services**

- Selected Nutritional Requirement Record Review

N.B. The basal energy expenditure (BEE) and caloric requirement using Harris-Benedict formula recognizes the variation in energy needs for individuals.

1. **Anthropometry - Weight**

   **Height**

   NOTE: The following sample formulas and guidelines are not the only acceptable guides available. The surveyor should ask to use the assessment guidelines used by the facility before using the ones provided here.

   a. Important indicator of nutritional outcome.

   b. Disease state can have adverse effect on desired body weight.
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<thead>
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<th>LONG TERM CARE SURVEY</th>
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<table>
<thead>
<tr>
<th>SUGGESTED AREA</th>
<th>OBSERVATION</th>
<th>2. MEASUREMENTS/MEASUREMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>F &amp; B (cont'd)</td>
<td></td>
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</table>

## Calculation of Basal Energy Expenditure

### Basal Energy Expenditure

- **Females**:
  - Use the formula: 
  \[ 	ext{Basal Energy Expenditure} = (66.5 + (13.7 \	imes 	ext{Weight} \	ext{in kg}) + (5.0 \	imes 	ext{Age} \	ext{in years}) - (6.8 \	imes 	ext{Sex} \	ext{Factor}) - (11.1 \	imes 	ext{Height} \	ext{in cm}) + (8.2 \	imes 	ext{Weight} \	ext{in kg}) + (150 \	imes 	ext{Activity Level}) - 6.7 \	imes 	ext{Age} \	ext{in years}) \]
  - *Sex Factor*: 1.0 for females, 0.85 for overweight males
  - *Activity Level*: 1.0 for sedentary, 1.2 for moderate activity, 1.5 for high activity

- **Males**:
  - Use the formula: 
  \[ 	ext{Basal Energy Expenditure} = (66.5 + (13.7 \	imes 	ext{Weight} \	ext{in kg}) + (5.0 \	imes 	ext{Age} \	ext{in years}) - (6.8 \	imes 	ext{Sex} \	ext{Factor}) + (9.5 \	imes 	ext{Height} \	ext{in cm}) + (150 \	imes 	ext{Activity Level}) - 6.2 \	imes 	ext{Age} \	ext{in years}) \]
  - *Sex Factor*: 1.0 for males
  - *Activity Level*: 1.0 for sedentary, 1.2 for moderate activity, 1.5 for high activity

### Basal Energy Expenditure for Infants and Children

- **Infants**:
  - Use the formula: 
  \[ 	ext{Basal Energy Expenditure} = \left( \frac{	ext{Weight} \	ext{in kg}}{0.4} \right) \times 80 \]

- **Children**:
  - Use the formula: 
  \[ 	ext{Basal Energy Expenditure} = \left( \frac{	ext{Height} \	ext{in cm}}{100} \right) \times 2 \]
### Long Term Care Survey

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<tr>
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</thead>
<tbody>
<tr>
<td>F196 (cont'd)</td>
<td>Oral Maintenance:</td>
<td></td>
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<td></td>
<td>$1.2D \times BEE$</td>
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<td></td>
<td>(Kcals)</td>
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<td>Metric Conversions:</td>
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<td>(Approx)</td>
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<tr>
<td></td>
<td>pounds (lb.) $\times 0.45 = $ kilograms (Kg)</td>
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<td></td>
<td>inches (in.) $\times 2.5 = $ centimeters (cm)</td>
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<tr>
<td><strong>Estimating Protein Needs:</strong></td>
<td></td>
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</tr>
<tr>
<td>1. Allow 0.8 gram protein per kilogram of ideal body weight.</td>
<td></td>
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<tr>
<td>2. Increase to 1.2 - 1.5 gm/kg for patients with depleted protein stores (decubitus, draining wounds, fractures, etc.).</td>
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<tr>
<td><strong>Fluid Requirement</strong></td>
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<td>Based on actual body weight:</td>
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<td>Over 65 years with no major cardiac or renal diseases.</td>
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<tr>
<td>(NOTE: 1.0 lbs. equals 1 kg of body weight)</td>
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<tr>
<td>SURVEY AREA</td>
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<td>CROSS REFERENCE</td>
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<tr>
<td>F196 (cont'd)</td>
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<td>Example:</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>120 lbs/2.2 lbs. = 54.5 kg (55 kgs) 55 kg x 30 cc = 1,650 cc/day</td>
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<td></td>
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<td>Note: Isotonic Standard Tube Feeding: Approximately 80% water.</td>
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<td>Amputation % of Body Weight</td>
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<td></td>
<td>Leg 20%</td>
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<td></td>
<td></td>
<td>Below Knees 10%</td>
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<td></td>
<td>Arm 6%</td>
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<td>At Elbow 3.6%</td>
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<td></td>
<td>Suggested Standards for Evaluating Significance of Weight Loss</td>
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<td></td>
<td>% of body weight loss</td>
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<td>Inter- Significant Severe</td>
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<td>Val. Loss Loss</td>
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<td>1 week 1-2% 2%</td>
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<td>1 month 5% 5%</td>
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<td>3 months 7 1/2% 7 1/2%</td>
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<td></td>
<td></td>
<td>6 months 10% 10%</td>
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<tr>
<td>F76 (cont'd)</td>
<td></td>
<td></td>
<td>Lab Indices for Visceral Proteins</td>
<td>Moderate</td>
<td>Severe</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Albumin g/dL</td>
<td>Deficiency Deficiency</td>
<td>Deficiency</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3.5-3.2</td>
<td>3.2-2.0</td>
<td>2.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Total Lymphocyte Count (x10^3/mm^3)</td>
<td>1000-1500</td>
<td>1500-900</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Transferrin (if Available)</td>
<td>200-100</td>
<td>100-100</td>
</tr>
<tr>
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</tr>
<tr>
<td>B. Therapeutic Diets</td>
<td>System for the provision of diets:</td>
<td>Ask Staff:</td>
<td>Review:</td>
<td>Nursing Services [405.112] (c)</td>
<td>(g) Patient care plan (\text{179170}) Supervision of patient nutrition</td>
</tr>
<tr>
<td>F197 SNF 405.1125(c)</td>
<td>o Diietic service Kardex or file</td>
<td>o Number, type of therapeutic diets?</td>
<td>- Physician diet orders in medical record</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F198 ICF 405.1125(c) (c)</td>
<td>o Therapeutic menus</td>
<td>o Time of nutrition activity, who's responsible?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Nourishment preparation and service</td>
<td>o Nourishment provided for day of survey?</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>o Adequacy of nourishment</td>
<td><strong>SPECIAL FEEDING:</strong> The surveyor should also attempt to observe that:</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>o Individual menus or diet cards</td>
<td>- Staff use proper technique in administering feedings and medications. Check to see that staff checks the location of tube before feeding and that tubing is irrigated before and after addition of medication.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td><strong>SPECIAL FEEDING:</strong></td>
<td>- Unemed milk-based tube feeding should be discarded in a timely manner</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>F199</td>
<td>Ask Resident:</td>
<td>- Nutritional needs for resident are considered for indepth reviews.</td>
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<td></td>
<td>If the resident is able</td>
<td>- On Pureed diets:</td>
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<td></td>
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<tr>
<td></td>
<td>to be interviewed, sugges</td>
<td>o Ordered by physician</td>
<td></td>
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<tr>
<td></td>
<td>suggested questions may be:</td>
<td>o Prepared weekly for services</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1. How long have you been</td>
<td>o Some calories and/or food group as if served whole.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>fed by this tube?</td>
<td>- On Tube Feeding:</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>2. When was the last time</td>
<td>o Has the feeding been ordered by physician?</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>you tried to eat by mouth?</td>
<td>o Is tube feeding nutritionally adequate?</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>What happened?</td>
<td>o Have attempts been made to progress tube feeding if indicated?</td>
<td></td>
<td></td>
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<td></td>
<td>3. How often do you</td>
<td>o Have changes in resident condition been noted and addressed?</td>
<td></td>
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<tr>
<td></td>
<td>receive the feeding?</td>
<td>- Fluid intake records</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Is this consistent?</td>
<td>- Number of calories as recorded in medical record</td>
<td></td>
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</tbody>
</table>

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<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>F197-199 (cont'd)</td>
<td>4. Does the staff help you in feeding? Do you feel comfortable/safe with all the staff who perform the feeding? If not, what happens?</td>
<td></td>
<td></td>
<td>well as amount of additional water</td>
<td>weight loss, constipation, diarrhea, skin condition?</td>
</tr>
<tr>
<td></td>
<td>5. Are you losing or gaining weight? What is your goal?</td>
<td></td>
<td></td>
<td>- Periodic reassessment of ability to swallow</td>
<td>o Have observed problems been coordinated with other departments and resolved?</td>
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<tr>
<td></td>
<td>6. How often is the tube changed? Who does this? Do you feel comfortable/safe with all staff who perform this procedure?</td>
<td></td>
<td></td>
<td>- Record should indicate measures taken to prevent diarrhea and constipation and to treat if they have developed.</td>
<td>o Is feeding being monitored to ensure that feeding is occurring at the ordered/appropriate rate?</td>
</tr>
<tr>
<td></td>
<td>Interview staff regarding knowledge of diabetic diets.</td>
<td></td>
<td>Diabetic Diets</td>
<td>o Varied nourishments as preferences allow?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o What nourishment does the diabetic patient receive?</td>
<td></td>
<td>Review:</td>
<td>On Diabetic Diets and Other Therapeutic Diets</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o If diabetic patient refuses the meal, what is done to supplement the meal?</td>
<td></td>
<td>- Pertinent Laboratory data:</td>
<td>o Ordered by Physician</td>
<td></td>
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<tr>
<td></td>
<td>If resident is able to be interviewed, asked questions:</td>
<td></td>
<td>- urinary glucose</td>
<td>o Varied, nutritionally adequate</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1. How long have you been on your diabetic diet?</td>
<td></td>
<td>- serum glucose</td>
<td>o Individualized to suit resident</td>
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<tr>
<td></td>
<td>2. Do you know some of the foods you must avoid? What are they?</td>
<td></td>
<td>- Wt. gain/losses</td>
<td>o Re-evaluation indicates diet meets objectives. If not appropriate, documentation is provided</td>
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<td>Laboratory results support diagnosis</td>
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<td></td>
<td></td>
<td>o Between meals nourishment provided as needed and recorded in measurable amounts</td>
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</tbody>
</table>
| F197-199 (cont'd) | Observe tray/meal service:  
- Low sodium diets are palatable (taste)  
- Sugar sources on diabetic diet trays  
- Salt sources on sodium restricted diet trays. | 3. Do you receive a nourishment between meals or before going to bed? | | | |
| F198 | Therapeutic diets prescribed by the attending physician. | | | | |
| F199 | Therapeutic menus are planned in writing, prepared and served as ordered with supervision from the dietician and advice from the physician whenever necessary. | Functioning system to provide the needed nutrients:  
- Resident's general appearance  
- Meal service  
- Food acceptance  
- Adherence to food preferences  
- Food supplement  
- Type of service  
- Method of service  
- Assistance provided  
- Timely provision as ordered  
- Portion sizes  
- Conforms to physicians orders | | | |

**FOR THE RESIDENT WITH DECUBITUS ULCERS**

**Ask Staff:**
1. Regarding knowledge of dietary needs.
2. What do you do when this resident refuses milk, meats, bread, etc.?
3. What portions are provided to this resident? How often?
4. What happens when a weight loss is noticed with this resident?

**Ask Resident:**
1. Has anyone talked with you about the importance of eating your meals?
2. Do you get foods that you don't eat on your tray?
3. When do you feel hungry?
4. Do you get between meal nourishments?

A system is in place to provide the type and amount of nutritional support needed by the residents who have developed decubitus ulcers.

Food and supplementation are provided in a method to ensure intake of nutrients needed by residents with decubitus ulcers.

Nutritional intervention is assessed and reassessed to ensure appropriate intervention for acceptable health care outcomes.

Nursing Service
484.124  
(d) Patient Care Plan  
(f) Supervision of Patient Nutrition
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>F197-199 (cont'd)</td>
<td>RENAL REVIEW System in place for the correct provision of renal diets.</td>
<td>Interview Staff regarding knowledge of renal diets:</td>
<td>Renal Patient Diet Review - Pertinent Laboratory Data</td>
<td>On Renal Diets - Ordered by physician - Written menu nutritionally complete in so far as medically possible, including calories - Individualized to suit resident - Laboratory testing as needed - Coordination with dialysis unit to determine effectiveness of diet</td>
<td>Nursing Service</td>
</tr>
<tr>
<td>F199</td>
<td>- Individualized menu</td>
<td>1. What foods should be restricted when a patient has kidney problems?</td>
<td>+ Serum Sodium + Serum Potassium + Albumin + Hematocrit + Creatinine + Pertinent Medications + Vitamin/Mineral + Supplements + Weight gains/losses</td>
<td></td>
<td>405.1124</td>
</tr>
<tr>
<td>F199</td>
<td>Dietary Staff</td>
<td>2. What nourishments are given to these patients?</td>
<td></td>
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<td>(d) Patient Care Plan</td>
</tr>
<tr>
<td>F199</td>
<td>Utilize menu when serving diets.</td>
<td>3. Are fluids restricted?</td>
<td></td>
<td></td>
<td>(f) Supervision of Patient Nutrition</td>
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<tr>
<td>F199</td>
<td></td>
<td>Ask Resident:</td>
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<tr>
<td>F199</td>
<td></td>
<td>1. Are you on a special diet?</td>
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<tr>
<td>F199</td>
<td></td>
<td>2. What foods must you avoid?</td>
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<tr>
<td>F199</td>
<td></td>
<td>3. Do you feel hungry?</td>
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<tr>
<td>F199</td>
<td></td>
<td>4. Do you eat everything at mealtimes?</td>
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<tr>
<td>F199</td>
<td></td>
<td>5. Are the foods the kitchen sends you the correct ones for your diet?</td>
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<tr>
<td>F199</td>
<td></td>
<td>6. Has the dietician explained your diet to you?</td>
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</table>

Therapeutic diets prescribed by the attending physician

Therapeutic menus are planned in writing, prepared and served as ordered with supervision from the dietician and advice from the physician whenever necessary.
# Long Term Care Survey

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</table>
| C. Preparation | Observe:  
- Feeding assistance is provided or not provided by staff  
- Length of time residents sit and wait for meal service  
- Food is served soon after cooking or refrigeration  
- Trays are free of spillage of foods or liquids  
- Foods are appropriately covered and kept at a proper temperature  
- Cooking and service utensils are clean, sanitary and greaseless  
- Refrigerated foods must be covered  
- Leftover and pre-cooked foods must be dated and labeled  
- All cooked food stored above raw meats in refrigerator  
- Temperature gauge on or in refrigerator to record temperature  
- Shelving to allow air circulation  
- Food not stored in refrigerator must be stored off the floor (This is applicable to food stored in walk-in refrigerator and freezer.) | Review:  
- Plan of Care  
- Progress notes  
- Notes from other professional disciplines to determine rehabilitation potential to self feed, use of assistance devices  
- Record of food substitution to determine alternate choice provided  
- Standardized recipes | The facility has kitchen and dietary service areas adequate to meet the food service needs. These areas are properly ventilated, arranged, and equipped for sanitary refrigeration, storage, and preparation of food. Equipment and storage areas are clean, well maintained, within proper temperature ranges, and safe.  
Proper temperatures:  
- Frozen food storage -- 0 or below  
- Cold food storage -- 40-45 degrees  
- Hot food holding equipment -- 140 degrees minimum  
- Dishwasher wash cycle -- 150-250 degrees  
- Dishwasher rinse cycle -- 160-180 degrees or a color change in thermometer; or adherence to manufacturer recommendations | |
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</table>
| F207 (Cont'd) | - No rust on shelves  
- No driping or spillage on shelves and floors  
- Degree to which diet modification is commensurate with residents' tolerance and capability  
- Residents for meal satisfaction  
- Observe appearance of food color, texture, aroma, and flavor  
- Less than 75% of meal is consumed  
- Type of substitutions provided | - Progress notes  
- Diet card  
- Day's menu substitute record | Dietary personnel are clean and free of infectious disease. They practice acceptable techniques and procedures to keep foods at proper temperatures and protected against contamination.  
Is dietary information pertinent to dietary modification?  
Has resident been assessed for eating program to maintain independence?  
The food substitute is of similar nutritive value as the refused item (e.g., milk refused, alternate of calcium rich food should be provided.) | | |

To provide foods that are safe and nutritious
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<tr>
<td>D. Frequency</td>
<td>o Menus as under A on page 63</td>
<td>Interview various residents about the nourishment service: o Are nourishments offered routinely? o At what time are they offered? o By whom? o What kind of nourishments are offered?</td>
<td>Review o Menu as under A o Nourishment List</td>
<td>Three meals or their equivalent are served daily with not more than a 16-hour span between the evening meal and breakfast. The nourishment service is more difficult to evaluate: must find evidence that patients are offered nourishments on a planned basis and documented.</td>
<td></td>
</tr>
<tr>
<td>F208 SNF 405.1124(d)</td>
<td>o Who serves nourishments o Nourishment list and schedule</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>F209 ICF 442.331(a)</td>
<td></td>
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<tr>
<td>F210</td>
<td>1. At least three meals are served daily at regular hours with not more than a 16-hour span between a substantial evening meal and breakfast.</td>
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<tr>
<td>F211</td>
<td>2. To the extent medically possible, bedtime nourishments are offered to all residents.</td>
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</tbody>
</table>
## Long Term Care Survey

<table>
<thead>
<tr>
<th>Survey Area</th>
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<th>Evaluation Factors</th>
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<tbody>
<tr>
<td>E. Staffing</td>
<td>- Food service personnel are on duty for all defined dietary responsibilities: - Supervision - Food Preparation - Dishwashing - Cleaning</td>
<td>- Interview personnel to verify that they are aware of their responsibilities and job descriptions.</td>
<td></td>
<td>- From an assessment of the total dietetic service operation: + The dietetic supervisor is capable of the overall management and supervision of the dietetic service. + There are dietetic personnel on duty over a 12-hour period who demonstrate ability to perform tasks adequately. + Dietetic personnel receive appropriate orientation and training consistent with their duties and responsibilities. There is evidence that the dietetic staff are knowledgeable about food service policies and procedures and apply these accepted professional practices in their daily work.</td>
<td></td>
</tr>
<tr>
<td>F212</td>
<td>- Duty Schedules</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>SNF 405.1125 (a)</td>
<td></td>
<td></td>
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<tr>
<td>F213</td>
<td>1. Food service personnel are on duty daily over a period of 12 or more hours.</td>
<td></td>
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</tbody>
</table>

**Intent:**

Persons are providing services commensurate with their level of training; and at the level of sophistication needed by the residents.
<table>
<thead>
<tr>
<th>SURVEY AREA</th>
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<th>CROSS REFERENCE</th>
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<tbody>
<tr>
<td><strong>LONG TERM CARE SURVEY</strong></td>
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</tr>
<tr>
<td><strong>SPECIALIZED REHABILITATIVE SERVICES</strong></td>
<td><strong>OBSERVE RESIDENTS</strong></td>
<td><strong>ASK RESIDENT</strong></td>
<td><strong>REVIEW</strong></td>
<td><strong>- Are rehabilitation services integrated with restorative nursing?</strong></td>
<td><strong>Nursing Services</strong></td>
</tr>
<tr>
<td></td>
<td>As per &quot;Restorative Nursing Activities of Daily Living&quot;</td>
<td>(or ask staff, if resident has severe communication problem):</td>
<td>- Plan of care</td>
<td>405.1124</td>
<td>442.339</td>
</tr>
<tr>
<td></td>
<td>F215 SNF 405.1126(b)</td>
<td>- What kinds of therapists are working with you on your swallowing problem?</td>
<td>- Nursing assessment and progress notes</td>
<td>442.340</td>
<td></td>
</tr>
<tr>
<td></td>
<td>F216 ICF 442.343</td>
<td>- What kinds of therapists have instructed you on how to improve your swallowing?</td>
<td>- Also assignment sheets</td>
<td>442.344</td>
<td></td>
</tr>
<tr>
<td></td>
<td>A PLAN OF CARE</td>
<td>- How do the methods to improve swallowing help you?</td>
<td>- Therapy assessments/evaluations includes a minimum of:</td>
<td>442.346</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ICF 442.343(e)(1)(1)</td>
<td>- How often do you see the therapist?</td>
<td>- Name, age, date of birth</td>
<td>442.316</td>
<td></td>
</tr>
<tr>
<td></td>
<td>F217</td>
<td>- What happens if the therapist is absent for scheduled treatments?</td>
<td>- Diagnoses</td>
<td>442.316</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Where do you receive your therapy?</td>
<td>- Referring physician</td>
<td>442.316</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- How long have you been receiving therapy?</td>
<td>- and reason for referral</td>
<td>442.316</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Do other staff members assist with therapy? Who and in what way?</td>
<td>- History, precautions, limitations</td>
<td>442.316</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Are you in a comfortable environment (room temperature, privacy, etc.)?</td>
<td>- Objective documentation (e.g., tests, measurements)</td>
<td>442.316</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Do you have input into developing or revising your therapy treatments?</td>
<td>- Rehabilitation potential</td>
<td>442.316</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- What things did you do immediately before entering this facility, that you are unable to do now?</td>
<td>- Treatment plan (includes a minimum of):</td>
<td>442.316</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>ASSESS THERAPY STAFF:</strong></td>
<td>- Specific rehabilitation needs and objectives</td>
<td>442.316</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- How many days/hours per week do you provide therapy?</td>
<td>- Treatment to meet specific measurable rehabilitative goals</td>
<td>442.316</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Do you participate in the development of the resident's overall plan of care? In what way?</td>
<td>- Type, amount, frequency, duration, modalities</td>
<td>442.316</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Do you utilize P.T.</td>
<td>- Name of therapists who will provide treatment</td>
<td>442.316</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Are rehabilitation services integrated with restorative nursing?</td>
<td>- Restorative nursing - follow-up (recommendations for plan of care)</td>
<td>442.316</td>
<td></td>
</tr>
</tbody>
</table>

*Activities Program* 405.1131 442.345

*Resident Rights* 405.1121(k) 442.311

*Training* 405.1121(h) 442.311

*Infection Control* 405.1135 442.315

*Medical Records* 405.1132 442.346
### Long Term Care Survey

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<tr>
<td>F218 (cont'd)</td>
<td>Are assistive devices being provided as needed?</td>
<td>&quot;Is there an occupational therapist?&quot;</td>
<td>- Identifies modalities that will be delegated to non-skill staff</td>
<td>Physical Environment</td>
<td></td>
</tr>
<tr>
<td>C. Progress</td>
<td>Does assistive device fit well, function and are used properly (e.g., wheelchairs, crutches, braces, glasses, hearing aids, canes, artificial limbs, assistive eating devices)?</td>
<td>- How do you assure carryover of therapies?</td>
<td>- Progress notes indicate that plan of rehabilitation care has been reevaluated by the physician and therapist as necessary but at least every 30 days.</td>
<td>442.324</td>
<td></td>
</tr>
<tr>
<td>ICF 442.343(f)</td>
<td>Is staff responsive to resident expressions of discomfort?</td>
<td>- How often do you provide inservice to staff?</td>
<td>- Do you have opportunities to attend inservices?</td>
<td>Dietetic Services</td>
<td></td>
</tr>
<tr>
<td>F217</td>
<td>How are the prescribed treatments and training meeting the needs of the resident?</td>
<td>- How do you communicate patient progress/regression, etc. with physician, nursing personnel, family, other disciplines?</td>
<td>- Are there opportunities for the conduction of your therapy?</td>
<td>442.328</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Are parallel bars sturdy and well secured to floor? Are systems designed for weight lifting sturdy and well secured? If attached to wall with rigging and hand grips in good conditions?</td>
<td>- How many residents currently are receiving P.T., O.T., Speech-Language pathology and audiology therapy (SPTA)?</td>
<td>- Does equipment readily available to meet resident needs?</td>
<td>442.329</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Are nonverbal residents provided with means of communication (e.g., writing tablets and utensils, picture cards)?</td>
<td>- Do you utilize the services of a certified occupational/therapy assistant (if interviewing the registered occupational therapist)?</td>
<td>- Is there a coordinated interdisciplinary</td>
<td>442.333(c)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Are visually impaired residents provided with</td>
<td>- Are available to meet resident needs?</td>
<td></td>
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<tr>
<td>SURVEY AREA</td>
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<tr>
<td></td>
<td>magnifiers and large print books?</td>
<td>approach toward rehabilitation of the geriatric resident evident in your facility? In what way do you see this?</td>
<td></td>
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</tr>
<tr>
<td>F220</td>
<td>- Is equipment such as whirlpool cleaned between patients?</td>
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</table>

**EXCEPTION**
If resident's plan must be revised as necessary

**INTENT**
Therapy services are provided that will assist the resident to attain his/her optimal level of function.
<table>
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<tr>
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<tbody>
<tr>
<td>Pharmaceutical Services</td>
<td>- Observe residents for excess sedation or adverse effects: + drooling + shuffling gait + involuntary movements of limbs, tongue, facial muscles + loss of affect + drowsiness + postural abnormalities + pill rolling movement + observe for depression, agitation</td>
<td>Ask Resident: - Are you aware of the medications you are taking use, frequency, contraindications? - Has your physician discussed the medications you are taking, with you? - How many medications are you taking? - How do you feel the medication helps you? - How do medications bother you? (e.g., make you nauseated or dizzy) - Have you told anyone about this? Ask Staff: - How often does the pharmacist review the resident's medications? - To whom does he report any irregularities? - When the pharmacist reports irregularities, what is done about it? - To whom do you report any problems with medication? - Do you feel the residents are receiving the proper medications, amount and kind? - Is the pharmacist available to you for consultation?</td>
<td>Review medical record: - to see if pharmacist or nurse has reviewed a drug regimen on a monthly basis - for evidence that the reviewer has reported irregularities to the physician or other who has authority to correct the irregularities for evidence that the irregularities have been evaluated. - review nurses notes, progress notes, care plan, etc. for any adverse reaction to medication and indication that corrective action was taken. - screen the drug therapy of the residents included in the sample using the indicators (forms if prepared) outlined in SOM Appendix N Transmittal A174. - review pharmacists drug regimen monthly reports to determine if pharmacist has commented on potential irregularities, screened out through this process (need full year).</td>
<td>Reviews were performed in the facility. There was evidence of a review performed on every resident whose record was reviewed in depth. In records reviewed, the average prescription utilization was not substantially over 6. If it is, review for appropriateness. Apparent irregularities were identified and reported. For further information on drug regimen review.</td>
<td></td>
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<tr>
<td>Pharmacist Services</td>
<td>- ACF 405.300(b)</td>
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<tr>
<td>Pharmacist Services</td>
<td>- ACF 405.300(a)</td>
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<td>ACF 405.300(a)</td>
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<tr>
<td>The pharmacist reviews the drug regimen of each resident at least monthly &amp; reports any irregularities to the medical director and administrator.</td>
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<tr>
<td>The pharmacist may be utilized to perform this monthly review for ICF residents. Also the attending or staff physician must review medication quarterly.</td>
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**Health Care Financing Administration, HHS** 
§ 488.115

VerDate 11<SEP>98 09:26 Oct 21, 1998 Jkt 179170 PO 00000 Frm 00711 Fmt 8010 Sfmt 8006 Y:\SGML\179170T.XXX pfrm03 PsN: 179170T
### LONG TERM CARE SURVEY

<table>
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<tr>
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</thead>
<tbody>
<tr>
<td>F224 (cont'd)</td>
<td>- Where does the pharmacist perform his drug regimen review?</td>
<td></td>
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<tr>
<td>B. Labeling of Drugs and Biologicals</td>
<td>Observe labels of medications for residents observed on drug pass tour for:</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>F225</td>
<td>- name of drug</td>
<td></td>
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</tr>
<tr>
<td>F226</td>
<td>- dosage form</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>F227</td>
<td>- quantity of drug</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F228</td>
<td>- expiration date</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>F229</td>
<td>- presence of a control number</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>F230</td>
<td>- appropriate accessory or cautionary statement</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>C. Labeling of Medications</td>
<td>To ensure that residents receive medications as ordered and that they are monitored for possible side effects.</td>
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<tr>
<td><strong>Laboratory and Radiological Services</strong>&lt;br&gt;F228&lt;br&gt;SNF 485.1128&lt;br&gt;A. Provision of Services&lt;br&gt;F229&lt;br&gt;SNF 485.1128 (*)&lt;br&gt;1. All services are provided only on the orders of a physician.&lt;br&gt;F231&lt;br&gt;2. The attending physician is notified promptly of findings.</td>
<td>Observe symptoms of targeted residents, e.g., drainage, odors, jaundice, fevers, edema, etc.</td>
<td>Ask Nursing/Rehabilitative Staff: What do you do when you think a resident needs laboratory work done - blood work, cultures, etc.? How long does it take to get lab results back? What do you do with the results when they come back? Do you have any problems with your laboratory services? How are lab specimens stored? Do you have any instructions from the lab regarding collection and storage of specimens?</td>
<td>Review the physician's order sheet to see if: orders for lab services are signed that there are orders for tests that have been done. Nursing progress notes are reviewed for documentation of physician notification of lab results. Physician progress notes or other documentation indicating that the physician is aware of lab results. There are lab reports on the medical record for all tests ordered (except if just performed).</td>
<td>There must be signed physician orders for all lab/radiology services performed. Record results of all testing in the medical record. There is documentation in nursing or physician notes to indicate the results of lab tests were promptly communicated to the physician. When lab tests are performed the resident should be informed of significant findings and the possible therapeutic alternatives.</td>
<td>Nursing Services 485.1124(a)(b)(c)&lt;br&gt;Physician Services 485.1123(b)</td>
</tr>
</tbody>
</table>
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**§ 488.115**

### LONG TERM CARE SURVEY

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<tr>
<td>F232</td>
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</table>

3. Signed and dated reports of a clinical laboratory, x-ray and other diagnostic services are filled with the patient's medical record.

**INTENT**

To assure that lab tests are performed as ordered and findings are reported to physicians are made aware of symptoms that may require lab tests.
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</thead>
<tbody>
<tr>
<td><strong>Social Services</strong></td>
<td><strong>F233</strong></td>
<td><strong>SNF 405.1130</strong></td>
<td><strong>SNF 405.1130(a)</strong></td>
<td><strong>ICF 442.344(d)</strong></td>
<td>A. Plan</td>
</tr>
<tr>
<td><strong>F234</strong></td>
<td><strong>SNF 405.1130(b)</strong></td>
<td><strong>SNF 405.1130(c)</strong></td>
<td><strong>ICF 442.344(e)</strong></td>
<td></td>
<td><strong>The medicinally related social and emotional needs of the residents are identified.</strong></td>
</tr>
<tr>
<td><strong>A. Provision of Services</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>B. Provision of Services</td>
</tr>
<tr>
<td><strong>F236</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>Services are provided to meet the social and emotional needs by the facility or by referral to an appropriate social agency.</strong></td>
</tr>
</tbody>
</table>

**LONG TERM CARE SURVEY**

**Observe resident for:**
- level of alertness
- behavior exhibited (disoriented, confused, uncooperative, disruptive, aggressive, anxious, withdrawn, isolated, lonely)
- personal appearance
- apparent disabilities
- apparent vision and/or hearing problems they exhibit as you talk to them
- interaction to staff, other residents, family, visitors
- participation in group activities
- independence in activities, decision making
- Therapeutic staff intervention; constructive reaction to resident’s behavior
- resident’s participation on policy making bodies and committees of facility, e.g., resident councils.

**How long have you been in the facility?**
- Can you explain to me why you are here?
- Have you had any problem adjusting to the facility, i.e., loss of independence?
- Have you had any other problems?
- Has staff been helpful, e.g., financial?
- Do you have any family or any other visitors?
- Do they have any problems with which this facility has not been helpful?
- If exhibiting disruptive, agitated, anxious, etc., behavior I noticed that you are upset (quiet, nervous, unhappy) today. Can you tell me what has bothered you?
- Does staff respond to your suggestions regarding your own care?
- Did you participate in planning care you will get and who will give it to you?
- Do you make use of the dining, activity, community room, and/or outdoor area?

**Review medical records of residents selected for in-depth review to determine that:**
- Assessment and plan of care identifies residents medically related social and emotional needs and/or problems.
- Residents’ family and home situation, information related to medical and nursing requirements, and community resources are considered in making decisions regarding the resident’s care.
- Medical records contain current specific information and data which highlights the social and emotional needs of the resident and significant findings and actions are entered promptly in the medical record.
- Social service notes address the following, if applicable:
  - losses due to aging
  - relationship with staff and other residents
  - mental status
  - behavior problems
  - adjustment to the facility
  - illness

**The residents’ social and emotional needs are identified. The plan of care addresses those needs. The plan of care is being followed, reviewed and revised as necessary. The family’s needs and concerns are addressed if applicable. There is referral to appropriate agencies if necessary. Sufficient space is provided for private meetings and discussions.**

While it is not a program requirement, a social worker or other staff may contribute to the resident’s care plan by identifying personal strengths that can be used to build upon.

**Nursing Services**
- SNF 405.1124
- ICF 442.333

**Activities**
- SNF 405.1121
- ICF 442.345(a)(c)(d)

**Physicians Services**
- SNF 405.1122(b)
- ICF 442.346

**Patient Care Management**
- SNF 1124(d)
- ICF 442.346
### Long Term Care Survey

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<tr>
<td>F233-238 (cont'd)</td>
<td>- Can you tell me about your life here? What do you do in a usual day? - Are things like getting up, bathing, dressing, eating, done at the same time for everyone? - If you could change some things about living here, what would you change?</td>
<td>- Plan of care, social service notes, reflect the current status of the resident. - There is evidence that the resident's mental status has been considered when plan of care was developed. - Vision and hearing problems have been addressed. - Plan of care addresses residents' needs as observed by the surveyor and stated by the resident.</td>
<td>- Notes and plan indicate that needs have been re-evaluated and care plan changed as necessary. - There is evidence that the problems and needs of the family have been addressed. - There are indications that a referral has been made to the appropriate agency and a statement describing why.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. If financial assistance is indicated, arrangements are made promptly for referral to an appropriate agency.</td>
<td>Ask Social Worker/Nurse - when the social worker is readily available, delete &quot;ask the nurse&quot;. - How often is the resident seen by a social worker? - Who is responsible for identifying the resident's: + social and emotional needs + family and home situation + problem, and needs + financial needs + how are needs identified and reported? - Does resident participate in the development of his/her care plan? - Ask nursing how often the social worker sees resident. - Does the social worker discuss residents' needs/problems with nursing staff if there is a need for nursing to be involved?</td>
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</table>
### Long Term Care Survey

<table>
<thead>
<tr>
<th>Survey Area</th>
<th>Observation</th>
<th>Interviewing</th>
<th>Record Review</th>
<th>Evaluation Factors</th>
<th>Cross Reference</th>
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</thead>
<tbody>
<tr>
<td>F233-238 (cont'd)</td>
<td>- How is physician notified and involved in plan of care?</td>
<td>- The time period between date of referral and date of services is reasonable and if not, there is evidence of follow-thru by staff.</td>
<td>- There is documentation of collaboration between nursing and social work for meeting emotional needs.</td>
<td>Patient Care Management 485.112(d)</td>
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<td></td>
<td>- Ask social service staff their role, function, and what services they provide.</td>
<td>- The outside agency has documented their involvement and activities.</td>
<td>- The record reflects</td>
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<td></td>
<td>- Ask staff what referral services are available.</td>
<td>- Plan of care demonstrates awareness of behavior, articulates the reasons for it, and indicates in the plan of care an approach to the behavior.</td>
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<td></td>
<td>- If services are being provided by outside resource, are resources documented work service?</td>
<td>- Assessment should contain:</td>
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<td></td>
<td>- Ask social service staff about their background and education.</td>
<td>- a flexible approach to each resident (should be individualized);</td>
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<td></td>
<td>- If there is a consultant ask staff:</td>
<td>- awareness of a mental status evaluation;</td>
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<td></td>
<td>+ How often does the person come?</td>
<td>- resident history;</td>
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<td>+ How long do they stay?</td>
<td>+ family availability for planning, resident support, etc.</td>
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<td></td>
<td>+ What does the person do while in the facility?</td>
<td>+ identification of problems resulting from placement.</td>
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<td></td>
<td>+ What assistance, consultation is being provided?</td>
<td>+ recent social adjustment.</td>
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<td>+ Ask social service staff if adequate space is provided for them by the facility to conduct private interviews and meetings.</td>
<td>+ discharge planning.</td>
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</table>
### Section 488.115

**Long Term Care Survey**

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</thead>
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<tr>
<td>F233-238 (cont'd)</td>
<td></td>
<td></td>
<td>Social Service intervention with family and resident, i.e., grief and bereavement counseling. - Review integrated plan of care for: - Plan for concerted social services. - Plan for supportive services for adjustment. - Adjustment goals. - Interventions for specific conditions.</td>
<td>Are each resident's personal interests known? If not, what actions are being taken to identify them? Residents in facility 60 days should not be without some identified interests. Are each resident's needs identified? If not, what actions are being taken to identify them? Have medical contraindications been identified in the care plan? Needs and contraindications of residents in the facility more than 30 days should be known and/or have a plan of action.</td>
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**Activities**

- **F239**
  - SNF 405.1113
  - SNF 405.1113(b)
  - ICF 442.345

1. An ongoing program of meaningful activities is provided based on identified needs and general level of activities throughout the facility, as well as in specifically designated areas.

- How many residents are lying on their beds or sitting in chairs staring at the walls during waking hours?
- What is the level of residents' interest in activities they are doing?
- Are residents positioned correctly for activity?

- How does he/she spend the day?
- Of the activities resident has during the week, what does he/she enjoy most/least?
- If has none, why?
- Has staff asked about his/her interests?
- Suggested specific activities or people to get acquainted with in response to interests?
- What organized activities has he/she participated in this past week?
- How does resident find out about upcoming programs or happenings?

**Activities Assessment**

- Interests of the resident (past and present) are identified to resident's current capabilities and necessary adaptations to pursue their interests.

**Documentation**

- Information about social history, medical problems and limitations impacting resident's activities have been communicated to activities personnel and used in assessment and development of activities portion of care plan.
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<tr>
<th>SURVEY AREA</th>
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<tr>
<td>F242-(cont'd)</td>
<td>Are needed personal equipment (e.g., splints, glasses) and adaptations for limitations and safety (e.g., cardholder, goggles, footrests) used in activities?</td>
<td>Does resident get out of facility to activities?</td>
<td>Needs of the resident in the following areas are identified: - social interaction + creative expression + work and service opportunities + intellectual stimulation or activities + physical exercise + spiritual or religious expression - Plan of care Used all available information about: - interests + needs + indications and contraindications for activities from other assessments + physician orders and progress notes</td>
<td>Does each resident's activities promote his physical, social and mental well-being?</td>
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<td>F243</td>
<td>2. Unless contraindicated by the attending physician, all residents are encouraged to participate in activities.</td>
<td>Does resident have problems getting to activities? If so, does the staff assist? Does the staff encourage residents to go to activities? Does resident participate in Resident Council? Does resident have free choice of activities? What kind of activities do bedfast residents engage in? Ask Resident: Have you ever had difficulty in having private visits? Give examples.</td>
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<td>F244</td>
<td>3. The activities promote the physical, social and mental well being of the residents.</td>
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<td>F245</td>
<td>Is lighting adequate throughout the facility for activities in which residents are engaged? Are men and women have activities of interest to them? Do residents communicate with each other in activities? Are methods of communicating upcoming activities appropriate to the resident populations? <strong>Specific observations for physically impaired residents:</strong> Activities adapted to meet specific needs of the resident. Alert residents have activities of interest at their cognitive functional level. <strong>Specific observations for confused/disoriented, emotionally disturbed and mentally retarded residents:</strong> There are current calendars, clocks and patients.</td>
<td>Ask Nursing/Activity Staff: - Do they know the interests of residents' care? TV programs they like? Activities they want to participate in today/this week? - Do they know the personal equipment needed (e.g., glasses, hearing aids, reachers)? - Do they know the adaptive equipment used by residents for specific activities (e.g., talking books, built-up tools)? - Do they talk to residents to identify new interests and report these to &quot;dislikes&quot; to activities personnel?</td>
<td>Activities notes spell out implementation of plan, resident's reactions to specific activities, approaches, and people. Residents' participation in individual and group self-started and organized structured and unstructured activities time/pace. Evaluation of plan of care for: changes in interests; changes in precautions, changes in needs, new problems, approaches, etc. Plans are revised as needed.</td>
<td>Are equipment and supplies to meet residents' interests available and maintained in good working order? Are residents evaluated periodically with emphasis on participation levels and desire for new activities? Are plans readjusted if they do not reach desired outcomes? Residents in the facility more than 60 days should have at least two activities per month of interest to them personally.</td>
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<td>F246 (cont'd)</td>
<td>and patients names or symbols visible to all the residents.</td>
<td>- If he/she does not participate, why?</td>
<td>- Which activities appear to relax calm the resident? Excite him/her?</td>
<td>- How many residents have few activities a day of interest to them as individuals?</td>
<td>- What types of residents seem not to be interested in activities?</td>
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<td></td>
<td>Staff consistently use techniques such as reality orientation, empathy, and/or validation therapy as per each individual's needs.</td>
<td>- How does staff manage maladaptive behavior (e.g., abusive, disruptive, combative)?</td>
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<td>Resident has familiar items if available in room (e.g., family pictures, artwork, Afghan, chair from home).</td>
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<td>Residents in restraints have activities of interest geared to their abilities when restrained (e.g., table-top activity, music, radio, reading and writing materials, when out of restraints, (e.g., walks, exercise, group, talking).</td>
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<td>Small group and one-on-one involvement with staff reinforcing appropriate responses.</td>
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<td>Staff reaction to resident behavior during activities (e.g., crying, whining, demanding, non-verbal, aggression.</td>
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<td>F 246 (cont'd.)</td>
<td>Loudness.</td>
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<td>Specific observation for confused or terminally ill resident:</td>
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<td>- Appropriate items for sensory enrichment in room (e.g., TV, radio, adequate lighting)</td>
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<td>- Resident placed in supportive living environment (e.g., around people, in hall, activities room, sunshine, fresh air), when appropriate to the resident's needs and consistent with the resident's choice.</td>
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<td>Specific observation of environment for conducting activity program:</td>
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<td>- Adequate lighting.</td>
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<td>- Functional area is appropriate for activities of interest (e.g., religious services, arts and crafts, cooking, reading, TV watching, card playing, parties, discussion groups, gardening).</td>
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<td>- How do you adapt activities for needs of residents who are:</td>
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<td>- confused/disoriented</td>
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<td>- emotionally disturbed</td>
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<td>- mentally retarded</td>
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<td>- physically impaired</td>
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<td>- but alert</td>
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<td>- terminally ill?</td>
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<td>- Are community volunteers utilized in the activity program? In what way?</td>
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<td></td>
<td>- Are the residents encouraged to offer suggestions for new activities? If so, what activities have been instituted as a result?</td>
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<td></td>
<td>- How they manage maladaptive behavior (e.g., abusive, disruptive, combative)?</td>
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<td>- How do they help depressed residents (e.g., fearful, emotionally labile)?</td>
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</table>

Resident may refuse to participate in activity. However if the activities are part of a diagnostic or therapeutic program, the resident is responsible for assisting in the selection of mutually acceptable alternative activities.
<table>
<thead>
<tr>
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<th>CROSS REFERENCE</th>
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<tbody>
<tr>
<td>F246 (cont'd)</td>
<td>- Multi-purpose room use and timing of activities does not conflict. - Outdoor activity area. - Functional furniture, indoors and outdoors. - Evidence of free choice activities: - newspapers - magazines - record player - radios - games - TV's - reading - sewing - personal visits - church services - Activities, equipment and supplies are appropriate and sufficient for meeting interest of residents. - Activities equipment and supplies sufficient for conducting activities. - Activities equipment clean, safe, and in working order. - Residents have access to the total activity environment (e.g., lobby, sunroom, dayroom, porch, dining room).</td>
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## LONG TERM CARE SURVEY

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<thead>
<tr>
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<tbody>
<tr>
<td>MEDICAL RECORDS</td>
<td></td>
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<td></td>
<td>All information required is present in the record.</td>
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<td>F247</td>
<td></td>
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<td>Does the record document all observable resident needs/problems?</td>
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<tr>
<td>SNF 405.1132</td>
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<tr>
<td>Content</td>
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<td>F248</td>
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<td>SNF 405.1132(c)</td>
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<td>F249</td>
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<td>ICF 642.318(a)(c)</td>
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<tr>
<td>F250</td>
<td>1. The medical record contains sufficient information to identify the resident clearly to justify diagnoses and treatment and to document results accurately.</td>
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<td>F251</td>
<td>2. The medical record contains the following information.</td>
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<td>SURVEY AREA</td>
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<td>F251 (cont'd)</td>
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<tr>
<td>a. Identification information.</td>
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<td>F252</td>
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<td>b. Admission data including past medical social history.</td>
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<td>F253</td>
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<td>c. Transfer form, discharge summary from any transferring facility.</td>
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<td>F254</td>
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<td>F255</td>
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<td>e. Report of physical examinations.</td>
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<tr>
<td>F256</td>
<td>f. Reports of physicians' periodic evaluations and progress notes.</td>
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<td>F257</td>
<td>g. Diagnostic reports and therapeutic orders.</td>
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<td>F258</td>
<td>h. Reports of treatments.</td>
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<td>F259</td>
<td>i. Medications administered.</td>
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<td>F260</td>
<td>j. An overall plan of care setting forth goals to be accomplished through each service's designated activities, therapies, and treatments.</td>
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<td>SURVEY AREA</td>
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<td>F261</td>
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<td>k. Assessments and goals of each service's plan of care.</td>
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<td>F262</td>
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<td>1. Treatments and services rendered.</td>
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<td>F263</td>
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<td>e. Progress notes.</td>
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<td>F264</td>
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<td>n. All symptoms and other indications of illness or injury including date, time and action taken regarding each problem.</td>
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<td>F264 (cont'd)</td>
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<td>Patient Rights 488.112(b) 482.311</td>
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<td><strong>Intent</strong></td>
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<td>Brings together all resident information. Reflects the care being given to the residents and helps all care givers to make decisions on care needed.</td>
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<td><strong>Transfer Agreement</strong></td>
<td>F265</td>
<td>SNF 485.1133</td>
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<td>F266</td>
<td>SNF 485.1133(a)</td>
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<td>F267</td>
<td>ICF 442.316</td>
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<tr>
<td>F268</td>
<td>A. Whenever the physician determines that a transfer is medically appropriate between a</td>
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<td>SURVEY AREA</td>
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<td>F 268 (cont'd)</td>
<td>hospital or a facility providing more specialized care and the nursing facility, admission to the new facility shall be effected in a timely manner.</td>
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<td>Is transfer form complete with all data, with appropriate signatures? Does the medical record indicate that adequate and pertinent aspects of the discharge planning portion of the patient care plan accompany the patient on transfer?</td>
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<tr>
<td>F269</td>
<td>B. Information necessary for providing care and treatment to transferred individuals is provided.</td>
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<td>PHYSICAL ENVIRONMENT</td>
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<td>F270</td>
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<td>SNF 405.1134</td>
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### Long Term Care Survey

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<tbody>
<tr>
<td>F271 A. Nursing Unit</td>
<td>There is adequate light to prepare medications.</td>
<td>Ask Nursing Staff: - What do you use the medication room (area) for? - Where is the handwashing sink? - Do you have enough, convenient storage area for I.V. fluids and medications needing refrigeration? - Where are the keys for the medication room and on I.D. carts? - Do you feel you have adequate storage space for supplies and equipment? - If no, what problems does that cause? - Does the resident call system function properly?</td>
<td>Medication preparation and storage areas provide adequate space and light to prepare medication and to store medication and needed supplies.</td>
<td>Nursing Service 483.1114(g) 442.337 Selection Control 483.1135 Governing Body 442.325 Resident Rooms 483.1114(d) 442.325</td>
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<tr>
<td>1. Unit properly equipped for preparation and storage of drugs and biologicals.</td>
<td>There is sufficient space to prepare medications for administration in a safe and effective manner.</td>
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<tr>
<td>F273 2. Utility and storage rooms are adequate size.</td>
<td>There is sufficient space for storage of medications. Unit dose carts are protected from tampering and theft. Medications are stored in a locked area. Refrigeration facilities are available for medications. There is sufficient storage space for I.V. fluids. Handwashing facilities are readily accessible either in the medication preparation area or adjacent to it.</td>
<td>Ask Residents: - Do the hand bells in your room and in the toilets and bathing areas always work?</td>
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<td>F274 3. The unit is equipped to register resident calls with a functioning communications system from resident areas including rooms and toilets and bathing facility.</td>
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<td>F274 (cont'd)</td>
<td>Audible call system is on and working. Long cards are available for chair bound patients.</td>
<td>- If no: - How often is it that they do not work? - How long does it take to get them fixed?</td>
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<td>Health Care Financing Administration, HHS § 488.115</td>
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<tr>
<td>8. Dining and activities area</td>
<td>Area is clean and well maintained. There is sufficient space between tables to allow for safe passage of wheelchairs and residents with walkers, canes and other assistive devices.</td>
<td>Ask Residents: - Is there enough room between tables to allow you to feel safe in getting to your table? - Can you sit comfortably in your wheelchair at the table? - How is the lighting and ventilation level for you? - Are sitting preferences permitted? - Do you go to the dining room for meals?</td>
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<td>Regulations clearly set out conditions for compliance. Refer to the regulations.</td>
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<td>F275</td>
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<td>Dietetic Services 489.1125 442.331</td>
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<td>F276</td>
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<td>Patient Activities 489.1131 442.345</td>
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<td>F277</td>
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Note: The facility provides one or more clean, orderly, and appropriately furnished rooms of adequate size, designed for resident dining and resident activities.
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<tr>
<td>F278</td>
<td>2. Dining and activity rooms are well lighted and ventilated.</td>
<td>Are dining areas utilized at meal service?</td>
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<td>F279</td>
<td>3. Any multipurpose room used for dining and resident activities has sufficient space to accommodate all activities and prevent their interference with each other.</td>
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<td>F280</td>
<td>SNF 405.1134(e) Indicators (6D apply to SNFs)</td>
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<td><strong>C. Resident Rooms</strong></td>
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<td>C291</td>
<td>Observe rooms and furnishings for maintenance, cleanliness and safety.</td>
<td>Ask Residents:</td>
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<td>Look for dust/dirt on tights, high surfaces, under heating units, and in corners. Use a flashlight. Are beds, lights, plumbing all in working order? Observe for all regulatory requirements as noted to the left. Are privacy curtains present, and appropriate to maintain resident privacy?</td>
<td>- Is your room kept clean? Who cleans it? When, and how often? - Is your bed, chair, and other furniture and fixtures kept in good repair? - Do you feel you have enough privacy? - What personal belongings are you allowed to have? - Is the lighting in your room sufficient for you? - Is your chair comfortable? - When do you permit staff to clean you room? - When do you ask staff to ask to clean you room?</td>
<td>Refer to the regulations.</td>
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<tr>
<td>C298</td>
<td>1. Single rooms have at least 100 sq. ft.</td>
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<td>C293</td>
<td>2. Multiple resident rooms have no more than 4 residents and at least 80 sq. feet per resident.</td>
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<td>C294</td>
<td>3. Each room is equipped with or conveniently located near toilet and bathing facilities.</td>
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<td>F284. There is a list of maintaining physicians for the facility.</td>
<td>sufficent storage and security for their file</td>
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<tr>
<td>F285. There is a list of maintaining physicians for the facility.</td>
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<td>F286. There is a list of maintaining physicians for the facility.</td>
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## LONG TERM CARE SURVEY

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<td>F288</td>
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<td>7. The resident call system functions in resident rooms.</td>
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<td>F289</td>
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<td>8. Each room is designed and equipped for adequate nursing care and the comfort and privacy of residents.</td>
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<td>F290</td>
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<td>9. Each room is at or above grade level.</td>
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<td>F291</td>
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<tr>
<td>10. Each room has direct access to a corridor and outside exposure.</td>
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<td>Exception: Not required for ICF residents.</td>
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<tr>
<td>D. Toilet and bath facilities</td>
<td>Are there adequate numbers of toilets, baths, and showers for the residents that are accessible to, and functional for all residents? Are these conveniently located in or near resident rooms? Check for water on floors of bath and shower rooms. Is privacy provided? Are facilities clean, sanitary and free of unpleasant odors? Are bathrooms equipped with soap, toilet tissue, towels, etc.? Hot water is between 110-120 degrees or the acceptable state level.</td>
<td>Ask Residents: - When was your last bath? The one before? - What safety precautions are used for getting in and out of the bathtub? - What equipment is needed to get in and out of the tub, and how do you feel about it? - How do you get your wheelchair into the toilet or bathroom? - When, if ever, do you refuse to be bathed?</td>
<td>Bathing schedule for patients in your in depth review.</td>
<td>Privacy is maintained for residents in toilet and bathing areas. Toilet and bathing areas are clean. Water is removed from floors immediately upon completion of bathing. Hot water is within the acceptable temperature range. Soap, toilet paper and towels are available in the bathrooms. Grab bars are present and securely fastened to the wall. Ventilation and lighting systems are correctly functioning. Plumbing and other fixtures are in good condition.</td>
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<td>F292, ICT 442.326</td>
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<tr>
<td>F293</td>
<td>1. Facilities are clean, sanitary and free of odors.</td>
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<td>F294</td>
<td>2. Facilities have safe and comfortable hot water temperatures.</td>
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<td>F295</td>
<td>3. Facilities maintain privacy.</td>
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<td>F296</td>
<td>4. Facilities have grab bars and other safe guards against slipping. Bath areas are not used for storage.</td>
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<td>F297</td>
<td>5. Facilities have fixtures in good condition.</td>
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<td>F298</td>
<td>6. The resident call system functions in toilet and bath facilities.</td>
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<td>F299</td>
<td>7. Social Service Area</td>
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<td>F300</td>
<td>1. Ensures privacy for social service interviewing.</td>
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<td>F301</td>
<td>2. Adequate space for clerical and interviewing functions is provided.</td>
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<td>F302</td>
<td>3. Facilities are easily accessible to residents and staff.</td>
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Facility has appropriate arrangements for providing social services, either using:
- outside resources (contract or consultant services)
- qualified facility personnel under a clearly defined plan.

Ask Resident:
- Does the social worker see you in a private room or in your own room?
- If in your own room, do you feel that you have enough privacy?

Refer to regulations.
## Long Term Care Survey

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<tr>
<td><strong>F. Therapy areas</strong></td>
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<tr>
<td>F303</td>
<td>Therapy areas are accessible to all residents needing the facilities.</td>
<td>Ask Resident:</td>
<td>Refer to regulations.</td>
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<td></td>
<td></td>
<td>- Do you feel that the equipment you use is safe?</td>
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<td>- Do you have enough room for your treatment?</td>
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<td>F304</td>
<td>Space allows for safe maneuvering of residents and equipment and staff.</td>
<td>Ask Therapy Staff:</td>
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<td>- Is your equipment adequately maintained?</td>
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<td></td>
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<td>- Do you have enough room to safely and adequately provide treatment?</td>
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<td>F305</td>
<td>All residents are able to be observed and supervised during therapy.</td>
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<td>Equipment has labels (stickers, etc.) to indicate proper maintenance.</td>
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<td>All equipment fastened to floor and walls is secure.</td>
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<td>G. Facilities for Special Care</td>
<td>Are therapy areas properly ventilated to effectively reduce heat, moisture and odors?</td>
<td>Ask Supervisory personnel:</td>
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<td></td>
<td>Are private rooms available that meet regulatory criteria.</td>
<td>- what room(s) do you use for isolation?</td>
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<td>F307</td>
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<td>- what is your procedure if the room is already occupied when you need it for isolation?</td>
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<td>If a resident is infected and in isolation, are precautionary signs posted, and are they legible and understandable?</td>
<td>- will you show me the signs you use to identify the isolation room?</td>
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<td>Resident Rights 485.1127(a)(4) 442.311(c)(2) Infection Control 409.135(c)(a)</td>
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<td>500.1</td>
<td>STOP PROMPT</td>
<td>SUPPORTING</td>
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<td>500.2</td>
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<td>COMPLETE</td>
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<td>DECISION</td>
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<td>IMPLEMENT</td>
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<td>FOLLOW-UP</td>
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<td>H. Common Resident Areas</td>
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<td>SNF 405.1134(j)</td>
<td>Use senses - sight, hearing, olfaction when surveying common areas. Are the areas clean, sanitary and free of offensive odors?</td>
<td>Ask Residents: - Do you think that the lounges and corridors are usually clean? - Do they have any unpleasant odors? - Is the lighting level comfortable for you to read? Is it adequate for you to feel safe walking? - Do you have any difficulty with the noise level? - Is the temperature usually comfortable for you? - Do you feel there is adequate ventilation? - Are there handrails in all of the corridors? - Are they securely fastened to the wall?</td>
<td>- Floors and furniture should appear clean - free of gross contamination. - Residents should have lighting bright enough to safely negotiate corridors, lounges, etc., and in reading areas, be bright enough to read. But the brightness should be free of glare. Remember, the elderly need a higher level of lighting as their sight diminishes. - Except for times when a louder level of sound is necessary for communication, sounds should be unobtrusive and &quot;comfortable&quot;. - Room temperature comfort levels vary widely, and in general the elderly will require a higher temperature for comfort than younger people. Use information from resident interviews and your observations to determine if the temperature is &quot;comfortable&quot; for most residents. - All corridors in</td>
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<td>F312</td>
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<td>ICF 405.324</td>
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<tr>
<td>F313</td>
<td>1. All common resident areas are clean, sanitary and free of offensive odors.</td>
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<tr>
<td>F314</td>
<td>2. Provision is made for adequate and comfortable lighting levels in all areas.</td>
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<tr>
<td>F315</td>
<td>3. There is limitation of sounds at comfort levels.</td>
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</table>
## Long Term Care Survey

<table>
<thead>
<tr>
<th>Survey Area</th>
<th>Observation</th>
<th>Interviewing</th>
<th>Record Review</th>
<th>Evaluation Factors</th>
<th>Cross Reference</th>
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<tr>
<td>F316</td>
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<td>4. A comfortable room temperature is maintained.</td>
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<td>F317</td>
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<td>5. There is adequate ventilation thru windows or mechanical measures or a combination of both.</td>
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<td>F318</td>
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<tr>
<td>6. Corridors are equipped with firmly secured handrails on each side.</td>
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<tr>
<td>F319</td>
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<tr>
<td>7. Staff are aware of procedures to ensure water to all essential areas in the event of loss of normal supply.</td>
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</table>

Note: Supervisory staff are able to tell you how they will obtain water for drinking, cleaning, bathing of residents, and other essential functions if their normal water supply is interrupted.
<table>
<thead>
<tr>
<th>SURVEY AREA</th>
<th>OBSERVATION</th>
<th>INTERVIEWING</th>
<th>RECORD REVIEW</th>
<th>EVALUATION FACTORS</th>
<th>CROSS REFERENCE</th>
</tr>
</thead>
</table>
| 1. Maintenance of Building and Equipment | - Ceiling and floor tile in good condition  
- Paint in good repair  
- No holes in walls  
- Look for rat and other rodent trails outside and inside  
- Preventive maintenance program for all equipment is followed  
- Wheelchairs not stored in hallways, bathrooms, etc.  
- Window screens are in good repair  
- Check overbed tables, wheelchairs, etc., for cleanliness and operation | Ask Staff:  
- How many housekeeping staff are available?  
- How late are housekeeping staff on duty during the week?  
- How is weekend coverage different?  
Ask Resident:  
- What if any problems have you had with special equipment you need to use? | | | Physical Environment  
405.1134(d) |
<table>
<thead>
<tr>
<th>SURVEY AREA</th>
<th>LONG TERM CARE SURVEY</th>
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<tbody>
<tr>
<td></td>
<td>INTERVIEWING</td>
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<td></td>
<td>OBJECTION REVIEW</td>
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<td></td>
<td>EVALUATION FACTORS</td>
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<td>CROSST REFERENCE</td>
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</table>

4. Resident care environment to include cleanliness and safe conditions.
### 42 CFR Ch. IV (10-1-98 Edition)

#### § 488.115

<table>
<thead>
<tr>
<th>SURVEY AREA</th>
<th>OBSERVATION</th>
<th>INTERVIEWING</th>
<th>RECORD REVIEW</th>
<th>EVALUATION FACTORS</th>
<th>CROSS REFERENCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indicator 3</td>
<td>488.115(a)</td>
<td>488.115(b)</td>
<td>488.115(c)</td>
<td>488.115(d)</td>
<td>Diabetic Services</td>
</tr>
<tr>
<td>SF26</td>
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<td>405.1134(b)</td>
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<td>405.1134(h)</td>
</tr>
<tr>
<td></td>
<td>1. Kitchen and dietetic service areas are adequate to insure proper, timely service for all patients.</td>
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<td>405.1125(g)</td>
</tr>
<tr>
<td></td>
<td>2. Kitchen areas are properly ventilated, arranged, and equipped for storage and preparation of food as well as for dish and utensil cleaning, and refuse storage and removal.</td>
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<td>405.337(b)</td>
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<td>488.115(e)</td>
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<td>488.115(f)</td>
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</tbody>
</table>

#### Long Term Care Survey

**Ask Staff:**
- What have you been trained to do?
- What type of dishwasher machine do you have? How does it operate?

The proper temperature for the dishwasher wash cycle is 150-160 degrees Fahrenheit. The dishwasher rinse cycle is acceptable at temperature of 180 degrees Fahrenheit or when there is a change in the temperature-sensitive tape (thermometer). The individual manufacturers' specifications may countermand these instructions, particularly in the case of chemical sanitization.
## Long Term Care Survey

### Survey Area

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Applies to</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>K. Dietary Staff</td>
<td>NFC</td>
<td>F329 SNF 405.1125(f)</td>
</tr>
<tr>
<td>L. Dietary Sanitary Conditions</td>
<td>NFC</td>
<td>F333 SNF 405.1125(g)</td>
</tr>
</tbody>
</table>

### Observation

<table>
<thead>
<tr>
<th>Survey Area</th>
<th>Observation</th>
</tr>
</thead>
</table>
| K. Dietary Staff | Observe the following:  
- cleanliness of hands, fingernails, hair, clothing  
- use of hair restraint  
- whether employees wash hands with soap and water after using the toilet, smoking, blowing their nose, touching raw meat, poultry or eggs  
- employees using hands to mix food when utensils could be used  
- employees using the same spoon more than once for tasting food while preparing, cooking, or serving. |
| L. Dietary Sanitary Conditions | Verify that:  
- hot foods are 140 degrees or above  
- cold foods are 45 degrees or lower  
- cooked meals held longer than 72 hours are used, discarded or put in the freezer |

### Interviewing

- Ask staff:  
  - What happens when you report to work with a cold, a cut or sore on your hand?  
  - Where is handwashing sink for dietary staff?  
  - Do you use disposable plastic hand covers? If so, when?  
  - Where are your serving utensils located?  
  - What are temperatures for the refrigerators and freezers? Who is responsible for checking temperatures?  
  - Do you have thermometers to check water and food temperatures? (ask them to demonstrate how they take temperatures)
<table>
<thead>
<tr>
<th>SURVEY AREA</th>
<th>OBSERVATION</th>
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<th>RECORD REVIEW</th>
<th>EVALUATION FACTORS</th>
<th>CROSS REFERENCE</th>
</tr>
</thead>
</table>
| F333 (cont'd) | - check that the refrigerators are equipped with an accurate thermometer  
- food does not have an "off" or bad odor  
- cracked eggs are discarded  
- foods are dated and then stored as to their preparation date.  
Observe that waste is in covered containers, bagged and tied for disposal, and that dumpsters are covered. | | | | |
<table>
<thead>
<tr>
<th>SURVEY AREA</th>
<th>OBSERVATION</th>
<th>INTERVIEWING</th>
<th>RECORD REVIEW</th>
<th>EVALUATION FACTORS</th>
</tr>
</thead>
</table>
| L. Emergency Power  
F334  
SNF 405.1134(b) | Is an emergency generator available?  
Test generator under full load conditions.  
Check items of emergency power:  
- lighting  
- fire detection  
- alarms  
- extinguishing systems  
- life support systems  
Transfer time from normal power to emergency power to occur within 10 seconds.  
Check for grounded extension cords at nurses stations.  
Where are emergency outlets? | | | As per regulations and covered by the Life Safety Code surveyor |
| F335 | An emergency source of electrical power necessary to protect the health and safety of residents is available. | | | |
| F336 | Emergency power is adequate at least for lighting and all means of egress; equipment to maintain fire detection, alarm, and extinguishing systems; and life support systems. | | | |
## Long Term Care Survey

<table>
<thead>
<tr>
<th>Survey Area</th>
<th>Observation</th>
<th>Interviewing</th>
<th>Record Review</th>
<th>Evaluation Factors</th>
<th>Cross Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infection Control</td>
<td>- Observation of dressing technique to identify if infection control principles are being adhered to: - sterile technique - sterile/clean field - disposal of dressing - handwashing - use of gloves</td>
<td>Ask Staff: - What type of dressing changes are you performing? - How often are dressings changed? - Why is resident on isolation/precautions? - Do laundry/housekeeping personnel/aides know procedures?</td>
<td>Review records of residents selected for in-depth review for infection.</td>
<td>Compliance will be based mainly on your observations.</td>
<td>Nursing Services, 405.1124 442.338</td>
</tr>
<tr>
<td>A. Infection Control</td>
<td>F338</td>
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<td></td>
<td>SNF 405.1135(b)</td>
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<tr>
<td>Aseptic and isolation techniques are followed by all personnel.</td>
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<td>B. Sanitation</td>
<td>F341</td>
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<td>SNF 405.1135(c)</td>
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<tr>
<td>C. Linen</td>
<td>F343</td>
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<td></td>
<td>SNF 405.1135(d)</td>
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<tr>
<td>F342</td>
<td>The facility maintains a safe, clean, and orderly interior.</td>
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<tr>
<td>F343</td>
<td>Do aides wash hands after cleaning dirty linen?</td>
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<tr>
<td>F344</td>
<td>How do aides handle clean/dirty linen while changing beds?</td>
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</tbody>
</table>

Deficiencies will be cited if you see:
- Breaks in aseptic or isolation technique
- Clutter or unclean conditions that would cause unsafe conditions
- Inadequate supplies of linen to provide proper care and comfort for residents
- Inadequate techniques for handling clean and dirty linen
- Evidence of insect or rodent infestation
- Use flash light to check for roaches in closets, cabinets.
<table>
<thead>
<tr>
<th>SURVEY AREA</th>
<th>OBSERVATION</th>
<th>INTERVIEWING</th>
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<tbody>
<tr>
<td>F344</td>
<td>ICF 442.327</td>
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<tr>
<td>F345</td>
<td>1. The facility has available at all times a quantity of linen essential for proper care and comfort of residents.</td>
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<tr>
<td>F346</td>
<td>2. Linens are handled, stored, processed, and transported in such a manner as to prevent the spread of infection.</td>
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<tr>
<td>D. Pest Control</td>
<td>F347</td>
<td>SMF 405.1135(e)</td>
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<tr>
<td>F348</td>
<td>ICF 442.315(e)</td>
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<tr>
<td>F349</td>
<td>The facility is maintained free from insects and rodents.</td>
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</table>

Look for evidence of insect or rodent presence (mouse or rat droppings, roaches, ants, flies around trash)
- Screen doors closed
- Windows that can be opened have screens that are in good repair

Ask Staff:
- Have you seen insects (roaches, ants, flies, etc.)?
- Have you seen rodents and/or droppings?
- What foods are residents permitted to keep in their rooms?
<table>
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<tr>
<th>SURVEY AREA</th>
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<th>CROSS REFERENCE</th>
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</thead>
<tbody>
<tr>
<td>DISASTER PREPAREDNESS</td>
<td>Disaster plan is located at each nursing station.</td>
<td>Ask Residents: - Do you know what to do in case of fire? - How often do you rehearse it?</td>
<td></td>
<td>A disaster plan is available and facility staff know their roles.</td>
<td>Physical Environment 485.113(b) 442.321</td>
</tr>
<tr>
<td>F350 SNF 405.1136</td>
<td>Evacuation plans posted in each smoke compartment.</td>
<td>Ask Staff: - What are your responsibilities at a fire drill? - What is the facility's disaster plan (Specify types, e.g., fire, flood, etc.) - How you undergone disaster training? - Have you participated in a fire disaster drill? When? - How frequently are drills held? - Have you been trained or instructed in the use of fire equipment, fire containment methods? - Have you been trained in transfer or casualties and routes? - How would staff meet emotional needs of residents during/following a &quot;disaster&quot;, e.g., fire</td>
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<tr>
<td>F351 SNF 405.1136(a)</td>
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<td>F352 ICF 442.313</td>
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<tr>
<td>Indicators A and B apply to ICFs.</td>
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<tr>
<td>A. Disaster Plan</td>
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<tr>
<td>F353</td>
<td>1. Facility staff are aware of plans, procedures to be followed for fire, explosion or other disaster.</td>
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<tr>
<td>F354</td>
<td>2. Facility staff are knowledgeable about evacuation routes.</td>
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<td>SURVEY AREA</td>
<td>OBSERVATION</td>
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<tr>
<td>F355 3. Facility staff are aware of their specific responsibilities in regard to evaluation and protection of residents.</td>
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<td>F356 4. Facility staff are aware of methods of containing fire.</td>
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<tr>
<td><strong>DRILLS</strong></td>
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<tr>
<td>F357</td>
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<td>405.1136(b)</td>
</tr>
<tr>
<td>F358 1. All employees are trained as part of their employment orientation in all aspects of preparedness for any disaster.</td>
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<tr>
<td>SURVEY AREA</td>
<td>OBSERVATION</td>
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<td>F359</td>
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<tr>
<td>2. Facility staff participate in ongoing training and drills in all procedures so that each employee promptly and correctly carries out a specific role in case of a disaster.</td>
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INITIAL
To ensure a clean, safe environment for residents.
§ 488.201 Reconsideration.

(a) Right to reconsideration. (1) A national accreditation organization dissatisfied with a determination that its accreditation requirements do not provide (or do not continue to provide) reasonable assurance that the entities accredited by the accreditation organization meet the applicable long-term care requirements, conditions for coverage, conditions of certification, conditions of participation, or CLIA condition level requirements is entitled to a reconsideration as provided in this subpart.

(2) A State dissatisfied with a determination that the requirements it imposes on laboratories in that State and under the laws of that State do not provide (or do not continue to provide) reasonable assurance that laboratories licensed or approved by the State meet applicable CLIA requirements is entitled to a reconsideration as provided in this subpart.

(b) Eligibility for reconsideration. HCFA will reconsider any determination to deny, remove or not renew the approval of deeming authority to private accreditation organizations, or any determination to deny, remove or not renew the approval of a State laboratory program for the purpose of exempting the State's laboratories from CLIA requirements, if the accreditation organization or State files a written request for a reconsideration in accordance with paragraphs (c) and (d) of this section.

(c) Manner and timing of request for reconsideration. (1) A national accreditation organization or a State laboratory program described in paragraph (b), dissatisfied with a determination with respect to its deeming authority, or, in the case of a State, a determination with respect to the exemption of the laboratories in the State from CLIA requirements, may request a reconsideration of the determination by filing a request with HCFA either directly by its authorized officials or through its legal representative. The request must be filed within 60 days of the receipt of notice of an adverse determination or nonrenewal as provided in subpart A of part 488 or subpart E of part 493, as applicable.

(2) Reconsideration procedures are available after the effective date of the decision to deny, remove, or not renew the approval of an accreditation organization or State laboratory program.

(d) Content of request. The request for reconsideration must specify the findings or issues with which the accreditation organization or State disagrees and the reasons for the disagreement.

§ 488.203 Withdrawal of request for reconsideration.

A requestor may withdraw its request for reconsideration at any time before the issuance of a reconsideration determination.

§ 488.205 Right to informal hearing.

In response to a request for reconsideration, HCFA will provide the accreditation organization or the State laboratory program the opportunity for an informal hearing as described in §488.207 that will—

(a) Be conducted by a hearing officer appointed by the Administrator of HCFA; and

(b) Provide the accreditation organization or State laboratory program the opportunity to present, in writing or in person, evidence or documentation to refute the determination to deny approval, or to withdraw or not renew deeming authority or the exemption of a State's laboratories from CLIA requirements.

§ 488.207 Informal hearing procedures.

(a) HCFA will provide written notice of the time and place of the informal hearing at least 10 days before the scheduled date.

(b) The informal reconsideration hearing will be conducted in accordance with the following procedures—
§ 488.301

(1) The hearing is open to HCFA and the organization requesting the reconsideration, including—
   (i) Authorized representatives;
   (ii) Technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts); and
   (iii) Legal counsel;
(2) The hearing is conducted by the hearing officer who receives testimony and documents related to the proposed action;
(3) Testimony and other evidence may be accepted by the hearing officer even though it would be inadmissible under the usual rules of court procedures;
(4) Either party may call witnesses from among those individuals specified in paragraph (b)(1) of this section; and
(5) The hearing officer does not have the authority to compel by subpoena the production of witnesses, papers, or other evidence.

§ 488.209 Hearing officer’s findings.
(a) Within 30 days of the close of the hearing, the hearing officer will present the findings and recommendations to the accreditation organization or State laboratory program that requested the reconsideration.
(b) The written report of the hearing officer will include—
   (1) Separate numbered findings of fact; and
   (2) The legal conclusions of the hearing officer.

§ 488.211 Final reconsideration determination.
(a) The hearing officer’s decision is final unless the Administrator, within 30 days of the hearing officer’s decision, chooses to review that decision.
(b) The Administrator may accept, reject or modify the hearing officer’s findings.
(c) Should the Administrator choose to review the hearing officer’s decision, the Administrator will issue a final reconsideration determination to the accreditation organization or State laboratory program on the basis of the hearing officer’s findings and recommendations and other relevant information.
(d) The reconsideration determination of the Administrator is final.
(e) A final reconsideration determination against an accreditation organization or State laboratory program will be published by HCFA in the Federal Register.

Subpart E—Survey and Certification of Long-Term Care Facilities

SOURCE: 59 FR 56238, Nov. 10, 1994, unless otherwise noted.

§ 488.300 Statutory basis.
Sections 1819 and 1919 of the Act establish requirements for surveying SNFs and NFs to determine whether they meet the requirements for participation in the Medicare and Medicaid programs.

§ 488.301 Definitions.
As used in this subpart—
Abbreviated standard survey means a survey other than a standard survey that gathers information primarily through resident-centered techniques on facility compliance with the requirements for participation. An abbreviated standard survey may be premised on complaints received; a change of ownership, management, or director of nursing; or other indicators of specific concern.
Abuse means the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish.
Deficiency means a SNF’s or NF’s failure to meet a participation requirement specified in the Act or in part 483, subpart B of this chapter.
Dually participating facility means a facility that has a provider agreement in both the Medicare and Medicaid programs.
Extended survey means a survey that evaluates additional participation requirements subsequent to finding substandard quality of care during a standard survey.
Facility means a SNF or NF, or a distinct part SNF or NF, in accordance with §483.5 of this chapter.
§ 488.303  State plan requirement.

(a) A State plan must provide that the requirements of this subpart and subpart F of this part are met, to the extent that those requirements apply to the Medicaid program.

(b) A State may establish a program to reward, through public recognition, incentive payments, or both, nursing facilities that provide the highest quality care to Medicaid residents. For purposes of section 1903(a)(7) of the Social Security Act, proper expenses incurred by a State in carrying out such a program are considered to be expenses necessary for the proper and efficient administration of the State plan.

(c) A State must conduct periodic educational programs for the staff and residents (and their representatives) of NFs in order to present current regulations, procedures, and policies under this subpart and subpart F of this part.

(d) Required remedies for a non-State operated NF. A State must establish, in addition to termination of the provider agreement, the following remedies or an approved alternative to the following remedies for imposition against a non-State operated NF:

1. Temporary management.
2. Denial of payment for new admissions.
3. Civil money penalties.
4. Transfer of residents.
5. Closure of the facility and transfer of residents.

(e) Optional remedies for a non-State operated NF. A State may establish the following remedies for imposition against a non-State operated NF:

1. Directed plan of correction.
2. Directed in-service training.
3. Alternative or additional State remedies.

(f) Alternative or additional State remedies. If a State uses remedies that
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are in addition to those specified in paragraph (d) or (e) of this section, or alternative to those specified in paragraph (d) of this section (other than termination of participation), it must—

(1) Specify those remedies in the State plan; and

(2) Demonstrate to HCFA's satisfaction that those alternative remedies are as effective in deterring noncompliance and correcting deficiencies as the remedies listed in paragraphs (d) and (e) of this section.

[59 FR 56238, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

§ 488.305 Standard surveys.

(a) For each SNF and NF, the State survey agency must conduct standard surveys that include all of the following:

(1) A case-mix stratified sample of residents;

(2) A survey of the quality of care furnished, as measured by indicators of medical, nursing, and rehabilitative care, dietary and nutrition services, activities and social participation, and sanitation, infection control, and the physical environment;

(3) An audit of written plans of care and residents' assessments to determine the accuracy of such assessments and the adequacy of such plans of care; and

(4) A review of compliance with residents' rights requirements set forth in sections 1819(c) and 1919(c) of the Act.

(b) The State survey agency's failure to follow the procedures set forth in this section will not invalidate otherwise legitimate determinations that a facility's deficiencies exist.

§ 488.307 Unannounced surveys.

(a) Basic rule. All standard surveys must be unannounced.

(b) Review of survey agency's scheduling and surveying procedures. (1) HCFA reviews on an annual basis each State survey agency's scheduling and surveying procedures and practices to ensure that survey agencies avoid giving notice of a survey through the scheduling procedures and the conduct of the surveys.

(2) HCFA takes corrective action in accordance with the nature and complexity of the problem when survey agencies are found to have notified a SNF or NF through their scheduling or procedural policies. Sanctions for inadequate survey performance are in accordance with § 488.320.

(c) Civil money penalties. An individual who notifies a SNF or NF, or causes a SNF or NF to be notified, of the time or date on which a standard survey is scheduled to be conducted is subject to a Federal civil money penalty not to exceed $2,000.

§ 488.308 Survey frequency.

(a) Basic period. The survey agency must conduct a standard survey of each SNF and NF not later than 15 months after the last day of the previous standard survey.

(b) Statewide average interval. (1) The statewide average interval between standard surveys must be 12 months or less, computed in accordance with paragraph (d) of this section.

(2) HCFA takes corrective action in accordance with the nature of the State survey agency's failure to ensure that the 12-month statewide average interval requirement is met. HCFA's corrective action is in accordance with § 488.320.

(c) Other surveys. The survey agency may conduct a survey as frequently as necessary to—

(1) Determine whether a facility complies with the participation requirements; and

(2) Confirm that the facility has corrected deficiencies previously cited.

(d) Computation of statewide average interval. The statewide average interval is computed at the end of each Federal fiscal year by comparing the last day of the most recent standard survey for each participating facility to the last day of each facility's previous standard survey.

(e) Special surveys. (1) The survey agency may conduct a standard or an abbreviated standard survey to determine whether certain changes have caused a decline in the quality of care furnished by a SNF or a NF, within 60 days of a change in the following:

(i) Ownership;

(ii) Entity responsible for management of a facility (management firm);

(iii) Nursing home administrator; or
§ 488.310  
(iv) Director of nursing.
(2) The survey agency must review all complaint allegations and conduct a standard or an abbreviated standard survey to investigate complaints of violations of requirements by SNFs and NFs if its review of the allegation concludes that—
(i) A deficiency in one or more of the requirements may have occurred; and
(ii) Only a survey can determine whether a deficiency or deficiencies exist.
(3) The survey agency does not conduct a survey if the complaint raises issues that are outside the purview of Federal participation requirements.

§ 488.310  
Extended survey.

(a) Purpose of survey. The purpose of an extended survey is to identify the policies and procedures that caused the facility to furnish substandard quality of care.
(b) Scope of extended survey. An extended survey includes all of the following:
(1) Review of a larger sample of resident assessments than the sample used in a standard survey.
(2) Review of the staffing and inservice training.
(3) If appropriate, examination of the contracts with consultants.
(4) A review of the policies and procedures related to the requirements for which deficiencies exist.
(5) Investigation of any participation requirement at the discretion of the survey agency.
(c) Timing and basis for survey. The survey agency must conduct an extended survey not later than 14 calendar days after completion of a standard survey which found that the facility had furnished substandard quality of care.

§ 488.312  
Consistency of survey results.

HCFA does and the survey agency must implement programs to measure accuracy and improve consistency in the application of survey results and enforcement remedies.

§ 488.314  
Survey teams.

(a) Team composition. (1) Surveys must be conducted by a multidisciplinary team of professionals, which must include a registered nurse.
(2) Examples of professionals include, but are not limited to, physicians, physician assistants, nurse practitioners, physical, speech, or occupational therapists, registered professional nurses, dieticians, sanitarians, engineers, licensed practical nurses, or social workers.
(3) The State determines what constitutes a professional, subject to HCFA approval.
(4) Any of the following circumstances disqualifies a surveyor for surveying a particular facility:
(i) The surveyor currently works, or, within the past two years, has worked as an employee, as employment agency staff at the facility, or as an officer, consultant, or agent for the facility to be surveyed.
(ii) The surveyor has any financial interest or any ownership interest in the facility.
(iii) The surveyor has an immediate family member who has a relationship with a facility described in paragraphs (a)(4)(i) or paragraph (a)(4)(ii) of this section.
(iv) The surveyor has an immediate family member who is a resident in the facility to be surveyed. For purposes of this section, an immediate family member is defined at §488.301 of this part.
(b) HCFA training. HCFA provides comprehensive training to surveyors, including at least the following:
(1) Application and interpretation of regulations for SNFs and NFs.
(2) Techniques and survey procedures for conducting standard and extended surveys.
(3) Techniques for auditing resident assessments and plans of care.
(c) Required surveyor training. (1) Except as specified in paragraph (c)(3) of this section, the survey agency may not permit an individual to serve as a member of a survey team unless the individual has successfully completed a training and testing program prescribed by the Secretary.
(2) The survey agency must have a mechanism to identify and respond to in-service training needs of the surveyors.
(3) The survey agency may permit an individual who has not completed a training program to participate in a survey as a trainee if accompanied on-site by a surveyor who has successfully completed the required training and testing program.

§ 488.325 Disclosure of results of surveys and activities.

(a) Information which must be provided to public. As provided in sections 1819(g)(5) and 1919(g)(5) of the Act, the following information must be made available to the public, upon the public's request, by the State or HCFA for all surveys and certifications of SNFs and NFs:

(1) Statements of deficiencies and providers’ comments.

(2) A list of isolated deficiencies that constitute no actual harm, with the potential for minimal harm.

(3) Approved plans of correction.

(4) Statements that the facility did not submit an acceptable plan of correction or failed to comply with the conditions of imposed remedies.

§ 488.320 Sanctions for inadequate survey performance.

(a) Annual assessment of survey performance. HCFA assesses the performance of the State’s survey and certification program annually.

(b) Sanctions for inadequate survey performance. When a State demonstrates inadequate survey performance, as specified in §488.318, HCFA notifies the survey agency of the inadequacy and takes action in accordance with paragraphs (c) and (d) of this section.

(c) Medicaid facilities. (1) For a pattern of failure to identify deficiencies in Medicaid facilities, HCFA—

(i) Reduces FFP, as specified in paragraph (e) of this section, and if appropriate;

(ii) Provides for training of survey teams.

(2) For other survey inadequacies in Medicaid facilities, HCFA provides for training of survey teams.

(d) Medicare facilities. For all survey inadequacies in Medicare facilities, HCFA—

(1) Requires that the State survey agency submit a plan of correction;

(2) Provides for training of survey teams;

(3) Provides technical assistance on scheduling and procedural policies;

(4) Provides HCFA-directed scheduling;

(5) Initiates action to terminate the agreement between the Secretary and the State under section 1864 of the Act, either in whole or in part.

(e) Reduction of FFP. In reducing FFP for inadequate survey performance, HCFA uses the formula specified in section 1919(g)(3)(C) of the Act, that is 33 percent multiplied by a fraction—

(1) The numerator of which is equal to the total number of residents in the NFs that HCFA found to be noncompliant during validation surveys for that quarter; and

(2) The denominator of which is equal to the total number of residents in the NFs in which HCFA conducted validation surveys during that quarter.
§ 488.330 Certification of compliance or noncompliance.

(a) General rules—

(1) Responsibility for certification. (i) The State survey agency surveys all facilities for compliance or noncompliance with requirements for long term care facilities. The survey by the State survey agency may be followed by a Federal validation survey.

(2) Reports of adverse actions specified at §488.406 imposed on a facility.

(3) Written response by the provider.

(4) A provider’s request for an appeal and the results of any appeal.

(5) Final appeal results.

(6) Notice of termination of a facility.

(7) Medicare and Medicaid cost reports.

(8) Names of individuals with direct or indirect ownership interest in a SNF or NF, as defined in §420.201 of this chapter.

(9) Names of individuals with direct or indirect ownership interest in a SNF or NF, as defined in §420.201 of this chapter, who have been found guilty by a court of law of a criminal offense in violation of Medicare or Medicaid law.

(b) Charge to public for information. HCFA and the State may charge the public for specified services with respect to requests for information in accordance with—

(1) Section 401.140 of this chapter, for Medicare; or

(2) State procedures, for Medicaid.

(c) How public can request information. The public may request information in accordance with disclosure procedures specified in 45 CFR part 5.

(d) When information must be disclosed. The disclosing agency must make available to the public, upon the public’s request, information concerning all surveys and certifications of SNFs and NFs, including statements of deficiencies, separate listings of any isolated deficiencies that constitute no actual harm, with the potential for minimal harm, and plans of correction (which contain any provider response to the deficiency statement) within 14 calendar days after each item is made available to the facility.

(e) Procedures for responding to requests. The procedures and time periods for responding to requests are in accordance with—

(1) Section 401.136 of this chapter for documents maintained by HCFA; and

(2) State procedures for documents maintained by the State.

(f) Information that must be provided to the State’s long-term care ombudsman. The State must provide the State’s long-term care ombudsman with the following:

(1) A statement of deficiencies reflecting facility noncompliance, including a separate list of isolated deficiencies that constitute no harm with the potential for minimal harm.

(g) Information which must be provided to State by a facility with substandard quality of care. (1) To provide for the notice to physicians required under sections 1819(g)(5)(C) and 1919(g)(5)(C) of the Act, not later than 10 working days after receiving a notice of substandard quality of care, a SNF or NF must provide the State with a list of—

(i) Each resident in the facility with respect to which such finding was made; and

(ii) The name and address of his or her attending physician.

(2) Failure to disclose the information timely will result in termination of participation or imposition of alternative remedies.

(h) Information the State must provide to attending physician and State board. Not later than 20 calendar days after a SNF or NF complies with paragraph (g) of this section, the State must provide written notice of the noncompliance to—

(1) The attending physician of each resident in the facility with respect to which a finding of substandard quality of care was made; and

(2) The State board responsible for licensing the facility’s administrator.

(i) Access to information by State Medicaid fraud control unit. The State must provide access to any survey and certification information incidental to a SNF’s or NF’s participation in Medicare or Medicaid upon written request by the State Medicaid fraud control unit established under part 1007 of this title, consistent with current State laws.

[59 FR 56238, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]
(A) The State certifies the compliance or noncompliance of non-State operated NFs. Regardless of the State entity doing the certification, it is final, except in the case of a complaint or validation survey conducted by HCFA, or HCFA review of the State's findings.

(B) HCFA certifies the compliance or noncompliance of all State-operated facilities.

(C) The State survey agency certifies the compliance or noncompliance of a non-State operated SNF, subject to the approval of HCFA.

(D) The State survey agency certifies compliance or noncompliance for a dually participating SNF/NF. In the case of a disagreement between HCFA and the State survey agency, a finding of noncompliance takes precedence over that of compliance.

(ii) In the case of a validation survey, the Secretary's determination as to the facility's noncompliance is binding, and takes precedence over a certification of compliance resulting from the State survey.

(2) Basis for certification.

(i) Certification by the State is based on the survey agency findings.

(ii) Certification by HCFA is based on either the survey agency findings (in the case of State-operated facilities), or, in the case of a validation survey, on HCFA's own survey findings.

(b) Effect of certification—(1) Certification of compliance. A certification of compliance constitutes a determination that the facility is in substantial compliance and is eligible to participate in Medicaid as a NF, or in Medicare as a SNF, or in Medicare and Medicaid as a dually participating facility.

(2) Certification of noncompliance. A certification of noncompliance requires denial of participation for prospective providers and enforcement action for current providers in accordance with subpart F of this part. Enforcement action must include one of the following:

(i) Termination of any Medicare or Medicaid provider agreements that are in effect.

(ii) Application of alternative remedies instead of, or in addition to, termination procedures.

(c) Notice of certification of noncompliance and resulting action. The notice of certification of noncompliance is sent in accordance with the timeframes specified in §488.402(f), and resulting action is issued by HCFA, except when the State is taking the action for a non-State operated NF.

(d) Content of notice of certification of noncompliance. The notice of certification of noncompliance is sent in accordance with the timeframes specified in §488.402(f) and includes information on all of the following:

(1) Nature of noncompliance.

(2) Any alternative remedies to be imposed under subpart F of this part.

(3) Any termination or denial of participation action to be taken under this part.

(4) The appeal rights available to the facility under this part.

(5) Timeframes to be met by the provider and certifying agency with regard to each of the enforcement actions or appeal procedures addressed in the notice.

(e) Appeals. (1) Notwithstanding any provision of State law, the State must impose remedies promptly on any provider of services participating in the Medicaid program—

(i) After promptly notifying the facility of the deficiencies and impending remedy or remedies; and

(ii) Except for civil money penalties, during any pending hearing that may be requested by the provider of services.

(2) HCFA imposes remedies promptly on any provider of services participating in the Medicare or Medicaid program or any provider of services participating in both the Medicare and Medicaid programs—

(i) After promptly notifying the facility of the deficiencies and impending remedy or remedies; and

(ii) Except for civil money penalties, during any pending hearing that may be requested by the provider of services.

(3) The provisions of part 498 of this chapter apply when the following providers request a hearing on a denial of participation, or certification of noncompliance leading to an enforcement remedy (including termination of the provider agreement), except State monitoring:

(i) All State-operated facilities;
§ 488.331 Informal dispute resolution.

(a) Opportunity to refute survey findings. (1) For non-Federal surveys, the State must offer a facility an informal opportunity, at the facility’s request, to dispute survey findings upon the facility’s receipt of the official statement of deficiencies.

(2) For Federal surveys, HCFA offers a facility an informal opportunity, at the facility’s request, to dispute survey findings upon the facility’s receipt of the official statement of deficiencies.

(b) Failure of the State or HCFA, as appropriate, to complete informal dispute resolution timely cannot delay the effective date of any enforcement action against the facility.

(2) A facility may not seek a delay of any enforcement action against it on the grounds that informal dispute resolution has not been completed before the effective date of the enforcement action.

(c) If a provider is subsequently successful, during the informal dispute resolution process, at demonstrating that deficiencies should not have been cited, the deficiencies are removed from the statement of deficiencies and any enforcement actions imposed solely as a result of those cited deficiencies are rescinded.

(d) Notification. Upon request, HCFA does and the State must provide the facility with written notification of the informal dispute resolution process.

§ 488.332 Investigation of complaints of violations and monitoring of compliance.

(a) Investigation of complaints. (1) The State survey agency must establish procedures and maintain adequate staff to investigate complaints of violations of participation requirements.

(2) The State survey agency takes appropriate precautions to protect a complainant’s anonymity and privacy, if possible.

(3) If arrangements have been made with other State components for investigation of complaints, the State must have a means of communicating information among appropriate entities, and the State survey agency retains responsibility for the investigation process.

(4) If, after investigating a complaint, the State has reason to believe that an identifiable individual neglected or abused a resident, or misappropriated a resident’s property, the State survey agency must act on the complaint in accordance with § 488.335.

(b) On-site monitoring. The State survey agency conducts on-site monitoring on an as necessary basis when—

(1) A facility is not in substantial compliance with the requirements and is in the process of correcting deficiencies;
(2) A facility has corrected deficiencies and verification of continued substantial compliance is needed; or
(3) The survey agency has reason to question the substantial compliance of the facility with a requirement of participation.

(c) Composition of the investigative team. A State may use a specialized team, which may include an attorney, auditor and appropriate health professionals, to identify, survey, gather and preserve evidence, and administer remedies to noncompliant facilities.

§ 488.334 Educational programs.
A State must conduct periodic educational programs for the staff and residents (and their representatives) of SNFs and NFs in order to present current regulations, procedures, and policies on the survey, certification and enforcement process under this subpart and subpart F of this part.

§ 488.335 Action on complaints of resident neglect and abuse, and misappropriation of resident property.

(a) Investigation.
(1) The State must review all allegations of resident neglect and abuse, and misappropriation of resident property and follow procedures specified in § 488.332.
(2) If there is reason to believe, either through oral or written evidence that an individual used by a facility to provide services to residents could have abused or neglected a resident or misappropriated a resident’s property, the State must investigate the allegation.
(3) The State must have written procedures for the timely review and investigation of allegations of resident abuse and neglect, and misappropriation of resident property.

(b) Source of complaints. The State must review all allegations regardless of the source.

(c) Notification—(1) Individuals to be notified. If the State makes a preliminary determination, based on oral or written evidence and its investigation, that the abuse, neglect or misappropriation of property occurred, it must notify in writing—
(i) The individuals implicated in the investigation; and
(ii) The current administrator of the facility in which the incident occurred.
(2) Timing of the notice. The State must notify the individuals specified in paragraph (c)(1) of this section in writing within 10 working days of the State’s investigation.

(3) Contents of the notice. The notice must include the—
(i) Nature of the allegation(s);
(ii) Date and time of the occurrence;
(iii) Right to a hearing;
(iv) Intent to report the substantiated findings in writing, once the individual has had the opportunity for a hearing, to the nurse aide registry or appropriate licensure authority;
(v) Fact that the individual’s failure to request a hearing in writing within 30 days from the date of the notice will result in reporting the substantiated findings to the nurse aide registry or appropriate licensure authority.
(vi) Consequences of waiving the right to a hearing;
(vii) Consequences of a finding through the hearing process that the alleged resident abuse or neglect, or misappropriation of resident property did occur; and
(viii) Fact that the individual has the right to be represented by an attorney at the individual’s own expense.

(d) Conduct of hearing.
(1) The State must complete the hearing and the hearing record within 120 days from the day it receives the request for a hearing.
(2) The State must hold the hearing at a reasonable place and time convenient for the individual.

(e) Factors beyond the individual’s control. A State must not make a finding that an individual has neglected a resident if the individual demonstrates that such neglect was caused by factors beyond the control of the individual.

(f) Report of findings. If the finding is that the individual has neglected or abused a resident or misappropriated resident property or if the individual waives the right to a hearing, the State must report the findings in writing within 10 working days to—
(1) The individual;
(2) The current administrator of the facility in which the incident occurred; and
(3) The administrator of the facility that currently employs the individual,
§ 488.400 Statutory basis.

Sections 1819(h) and 1919(h) of the Act specify remedies that may be used by the Secretary or the State respectively when a SNF or a NF is not in substantial compliance with the requirements for participation in the Medicare and Medicaid programs. These sections also provide for ensuring prompt compliance and specify that these remedies are in addition to any others available under State or Federal law, and, except for civil money penalties, are imposed prior to the conduct of a hearing.

§ 488.401 Definitions.

As used in this subpart—

New admission means a resident who is admitted to the facility on or after the effective date of a denial of payment remedy and, if previously admitted, has been discharged before that effective date. Residents admitted before the effective date of the denial of payment, and taking temporary leave, are not considered new admissions, nor subject to the denial of payment.

Plan of correction means a plan developed by the facility and approved by HCFA or the survey agency that describes the actions the facility will take to correct deficiencies and specifies the date by which those deficiencies will be corrected.

§ 488.402 General provisions.

(a) Purpose of remedies. The purpose of remedies is to ensure prompt compliance with program requirements.

(b) Basis for imposition and duration of remedies. When HCFA or the State chooses to apply one or more remedies specified in § 488.406, the remedies are applied on the basis of noncompliance found during surveys conducted by HCFA or by the survey agency.

(c) Number of remedies. HCFA or the State may apply one or more remedies for each deficiency constituting noncompliance or for all deficiencies constituting noncompliance.

(d) Plan of correction requirement. (1) Except as specified in paragraph (d)(2) of this section, regardless of which remedy is applied, each facility that has deficiencies with respect to program requirements must submit a plan of correction for approval by HCFA or the survey agency.

(2) Isolated deficiencies. A facility is not required to submit a plan of correction when it has deficiencies that are isolated and have a potential for minimal harm, but no actual harm has occurred.
§ 488.406 Available remedies.

(a) General. In addition to the remedy of termination of the provider agreement, the following remedies are available:

(1) Temporary management.
(2) Denial of payment including—
   (i) Denial of payment for all individuals, imposed by HCFA, to a—
      (A) Skilled nursing facility, for Medicare;
      (B) State, for Medicaid; or
   (ii) Denial of payment for all new admissions;
(3) Civil money penalties.
(4) State monitoring.
(5) Transfer of residents.
(6) Closure of the facility and transfer of residents.
(7) Directed plan of correction.
(8) Directed in-service training.
(9) Alternative or additional State remedies approved by HCFA.
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(b) Remedies that must be established. At a minimum, and in addition to termination of the provider agreement, the State must establish the following remedies or approved alternatives to the following remedies:

(1) Temporary management.
(2) Denial of payment for new admissions.
(3) Civil money penalties.
(4) Transfer of residents.
(5) Closure of the facility and transfer of residents.
(6) State monitoring.

(c) State plan requirement. If a State wishes to use remedies for noncompliance that are either additional or alternative to those specified in paragraphs (a) or (b) of this section, it must—

(1) Specify those remedies in the State plan; and
(2) Demonstrate to HCFA's satisfaction that those remedies are as effective as the remedies listed in paragraph (a) of this section, for deterring noncompliance and correcting deficiencies.

(d) State remedies in dually participating facilities. If the State's remedy is unique to the State plan and has been approved by HCFA, then that remedy, as imposed by the State under its Medicaid authority, may be imposed by HCFA against the Medicare provider agreement of a dually participating facility.

§ 488.408 Selection of remedies.

(a) Categories of remedies. In this section, the remedies specified in §488.406(a) are grouped into categories and applied to deficiencies according to how serious the noncompliance is.

(b) Application of remedies. After considering the factors specified in §488.404, as applicable, if HCFA and the State choose to impose remedies, as provided in paragraphs (c)(1), (d)(1) and (e)(1) of this section, for facility noncompliance, instead of, or in addition to, termination of the provider agreement, HCFA does and the State must follow the criteria set forth in paragraphs (c)(2), (d)(2), and (e)(2) of this section, as applicable.

(c) Category 1. (1) Category 1 remedies include the following:

(i) Directed plan of correction.
(ii) State monitoring.
(iii) Directed in-service training.

(2) HCFA does or the State must apply one or more of the remedies in Category 1 when there—

(i) Are isolated deficiencies that constitute no actual harm with a potential for more than minimal harm but not immediate jeopardy; or
(ii) Is a pattern of deficiencies that constitutes no actual harm with a potential for more than minimal harm but not immediate jeopardy.

(3) Except when the facility is in substantial compliance, HCFA or the State may apply one or more of the remedies in Category 1 to any deficiency.

(d) Category 2. (1) Category 2 remedies include the following:

(i) Denial of payment for new admissions.
(ii) Denial of payment for all individuals imposed only by HCFA.
(iii) Civil money penalties of $50–3,000 per day.

(2) HCFA applies one or more of the remedies in Category 2, or, except for denial of payment for all individuals, the State must apply one or more of the remedies in Category 2 when there are—

(i) Widespread deficiencies that constitute no actual harm with a potential for more than minimal harm but not immediate jeopardy; or
(ii) One or more deficiencies that constitute actual harm that is not immediate jeopardy.

(3) HCFA or the State may apply one or more of the remedies in Category 2 to any deficiency except when—

(i) The facility is in substantial compliance; or
(ii) HCFA or the State imposes a civil money penalty for a deficiency that constitutes immediate jeopardy, the penalty must be in the upper range of penalty amounts, as specified in §488.438(a).

(e) Category 3. (1) Category 3 remedies include the following:

(i) Temporary management.
(ii) Immediate termination.
(iii) Civil money penalties of $3,050–$10,000 per day.
§ 488.410 Action when there is immediate jeopardy.

(a) If there is immediate jeopardy to resident health or safety, the State must (and HCFA does) either terminate the provider agreement within 23 calendar days of the last date of the survey or appoint a temporary manager to remove the immediate jeopardy. The rules for appointment of a temporary manager in an immediate jeopardy situation are as follows:

(1) HCFA does and the State must notify the facility that a temporary manager is being appointed.

(2) If the facility fails to relinquish control to the temporary manager, HCFA does and the State must terminate the provider agreement within 23 calendar days of the last day of the survey, if the immediate jeopardy is not removed. In these cases, State monitoring may be imposed pending termination.

(3) If the facility relinquishes control to the temporary manager, the State must (and HCFA does) notify the facility that, unless it removes the immediate jeopardy, its provider agreement will be terminated within 23 calendar days of the last day of the survey.

(4) HCFA does and the State must terminate the provider agreement within 23 calendar days of the last day of survey if the immediate jeopardy has not been removed.

(b) HCFA or the State may also impose other remedies, as appropriate.

(c)(1) In a NF or dually participating facility, if either HCFA or the State finds that a facility’s noncompliance poses immediate jeopardy to resident health or safety, HCFA or the State must notify the other of such a finding.

(2) HCFA or the State must do one or both of the following:

(i) Take immediate action to remove the jeopardy and correct the noncompliance through temporary management.

(ii) Terminate the facility’s participation under the State plan. If this is done, HCFA will also terminate the facility’s participation in Medicare if it is a dually participating facility.

(d) The State must provide for the safe and orderly transfer of residents when the facility is terminated.

(e) If the immediate jeopardy is also substandard quality of care, the State survey agency must notify attending physicians and the State board responsible for licensing the facility administrator of the finding of substandard quality of care, as specified in §488.325(h).

[59 FR 56243, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]
§ 488.412 Action when there is no immediate jeopardy.

(a) If a facility's deficiencies do not pose immediate jeopardy to residents' health or safety, and the facility is not in substantial compliance, HCFA or the State may terminate the facility's provider agreement or may allow the facility to continue to participate for no longer than 6 months from the last day of the survey if—

(1) The State survey agency finds that it is more appropriate to impose alternative remedies than to terminate the facility's provider agreement;

(2) The State has submitted a plan and timetable for corrective action approved by HCFA; and

(3) The facility in the case of a Medicare SNF or the State in the case of a Medicaid NF agrees to repay to the Federal government payments received after the last day of the survey that first identified the deficiencies if corrective action is not taken in accordance with the approved plan of correction.

(b) If a facility does not meet the criteria for continuation of payment under paragraph (a) of this section, HCFA will and the State must terminate the facility's provider agreement.

(c) HCFA does and the State must deny payment for new admissions when a facility is not in substantial compliance 3 months after the last day of the survey.

(d) HCFA terminates the provider agreement for SNFs and NFs, and stops FFP to a State for a NF for which participation was continued under paragraph (a) of this section, if the facility is not in substantial compliance within 6 months of the last day of the survey.

[59 FR 56243, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

§ 488.414 Action when there is repeated substandard quality of care.

(a) General. If a facility has been found to have provided substandard quality of care on the last three consecutive standard surveys, as defined in §488.305, regardless of other remedies provided—

(1) HCFA imposes denial of payment for all new admissions, as specified in §488.417; and

(2) The State must impose denial of payment for all new admissions, as specified in §488.417; and

(3) HCFA does and the State survey agency must impose State monitoring, as specified in §488.422, until the facility has demonstrated to the satisfaction of HCFA or the State, that it is in substantial compliance with all requirements and will remain in substantial compliance with all requirements.

(b) Repeated noncompliance. For purposes of this section, repeated noncompliance is based on the repeated finding of substandard quality of care and not on the basis that the substance of the deficiency or the exact tag number for the deficiency was repeated.

(c) Standard surveys to which this provision applies. Standard surveys completed by the State survey agency on or after October 1, 1990, are used to determine whether the threshold of three consecutive standard surveys is met.

(d) Program participation. (1) The determination that a certified facility has repeated instances of substandard quality of care is made without regard to any variances in the facility's program participation (that is, any standard survey completed for Medicare, Medicaid or both programs will be considered).

(2) Termination would allow the count of repeated substandard quality of care surveys to start over.

(3) Change of ownership. (i) A facility may not avoid a remedy on the basis that it underwent a change of ownership.

(ii) In a facility that has undergone a change of ownership, HCFA does not and the State may not restart the count of repeated substandard quality of care surveys unless the new owner can demonstrate to the satisfaction of HCFA or the State that the poor past performance no longer is a factor due to the change in ownership.

(e) Facility alleges corrections or achieves compliance after repeated substandard quality of care is identified. (1) If a penalty is imposed for repeated substandard quality of care, it will continue until the facility has demonstrated to the satisfaction of HCFA or the State that it is in substantial compliance with the requirements and
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§ 488.417 Denial of payment for all new admissions.

(a) Optional denial of payment. Except as specified in paragraph (b) of this section, HCFA or the State may deny payment for all new admissions when a facility is not in substantial compliance with the requirements, as defined in §488.401, as follows:

(1) Medicare facilities. In the case of Medicare facilities, HCFA may deny payment to the facility.

(2) Medicaid facilities. In the case of Medicaid facilities—

(i) The State may deny payment to the facility; and

(ii) HCFA may deny payment to the State for all new Medicaid admissions to the facility.

(b) Required denial of payment. HCFA does or the State must deny payment for all new admissions when—

(1) The facility is not in substantial compliance, as defined in §488.401, 3 months after the last day of the survey identifying the noncompliance; or

(2) The State survey agency has cited a facility with substandard quality of care on the last three consecutive standard surveys.

(c) Resumption of payments: Repeated instances of substandard quality of care. When a facility has repeated instances of substandard quality of care, payments to the facility or, under Medicaid, HCFA payments to the State on

§ 488.415 Temporary management.

(a) Definition. Temporary management means the temporary appointment by HCFA or the State of a substitute facility manager or administrator with authority to hire, terminate or reassign staff, obligate facility funds, alter facility procedures, and manage the facility to correct deficiencies identified in the facility's operation.

(b) Qualifications. The temporary manager must—

(1) Be qualified to oversee correction of deficiencies on the basis of experience and education, as determined by the State;

(2) Not have been found guilty of misconduct by any licensing board or professional society in any State;

(3) Have, or a member of his or her immediate family have, no financial ownership interest in the facility; and

(4) Not currently serve or, within the past 2 years, have served as a member of the staff of the facility.

(c) Payment of salary. The temporary manager's salary—

(1) Is paid directly by the facility while the temporary manager is assigned to that facility; and

(2) Must be at least equivalent to the sum of the following—

(i) The prevailing salary paid by providers for positions of this type in what the State considers to be the facility's geographic area;

(ii) Additional costs that would have reasonably been incurred by the provider if such person had been in an employment relationship; and

(iii) Any other costs incurred by such a person in furnishing services under such an arrangement or as otherwise set by the State.

(3) May exceed the amount specified in paragraph (c)(2) of this section if the State is otherwise unable to attract a qualified temporary manager.

(d) Failure to relinquish authority to temporary management—

(1) Termination of provider agreement. If a facility fails to relinquish authority to the temporary manager as described in this section, HCFA will or the State must terminate the provider agreement in accordance with §488.456.

(2) Failure to pay salary of temporary manager. A facility's failure to pay the salary of the temporary manager is considered a failure to relinquish authority to temporary management.

(e) Duration of temporary management. Temporary management ends when the facility meets any of the conditions specified in §488.454(c).
§ 488.418 Secretarial authority to deny all payments.

(a) HCFA option to deny all payment. If a facility has not met a requirement, in addition to the authority to deny payment for all new admissions as specified in § 488.417, HCFA may deny any further payment for all Medicare residents in the facility and to the State for all Medicaid residents in the facility.

(b) Prospective resumption of payment. Except as provided in paragraphs (d) and (e) of this section, if the facility achieves substantial compliance, HCFA resumes payment prospectively from the date that it verifies as the date that the facility achieved substantial compliance.

(c) Restriction on payment after denial of payment is imposed. If payment to the facility or to the State resumes after denial of payment for all residents, no payment is made for the period between the date that—

(1) Denial of payment was imposed; and

(2) HCFA verifies as the date that the facility achieved substantial compliance.

(d) Retroactive resumption of payment. When a facility has repeated instances of substandard quality of care, as specified in paragraph (e) of this section, when HCFA or the State finds that the facility was in substantial compliance before the date of the revisit, or before HCFA or the survey agency received credible evidence of such compliance, payment is resumed on the date that substantial compliance was achieved, as determined by HCFA.

(e) Resumption of payment—repeated instances of substandard care. When HCFA denies payment for all Medicare residents for repeated instances of substandard quality of care, payment is resumed when—

(1) The facility achieved substantial compliance, as indicated by a revisit or written credible evidence acceptable to HCFA; and

(2) HCFA believes that the facility will remain in substantial compliance.

§ 488.422 State monitoring.

(a) A State monitor—

(1) Oversees the correction of deficiencies specified by HCFA or the State survey agency at the facility site and protects the facility's residents from harm;

(2) Is an employee or a contractor of the survey agency;

(3) Is identified by the State as an appropriate professional to monitor cited deficiencies;

(4) Is not an employee of the facility;

(5) Does not function as a consultant to the facility; and
Does not have an immediate family member who is a resident of the facility to be monitored.

(b) A State monitor must be used when a survey agency has cited a facility with substandard quality of care deficiencies on the last 3 consecutive standard surveys.

(c) State monitoring is discontinued when—
   (1) The facility has demonstrated that it is in substantial compliance with the requirements, and, if imposed for repeated instances of substandard quality of care, will remain in compliance for a period of time specified by HCFA or the State; or
   (2) Termination procedures are completed.

§ 488.424 Directed plan of correction.

HCFA, the State survey agency, or the temporary manager (with HCFA or State approval) may develop a plan of correction and HCFA, the State, or the temporary manager require a facility to take action within specified timeframes.

§ 488.425 Directed inservice training.

(a) Required training. HCFA or the State agency may require the staff of a facility to attend an inservice training program if—
   (1) The facility has a pattern of deficiencies that indicate noncompliance; and
   (2) Education is likely to correct the deficiencies.

(b) Action following training. After the staff has received inservice training, if the facility has not achieved substantial compliance, HCFA or the State may impose one or more other remedies specified in §488.406.

(c) Payment. The facility pays for directed inservice training.

§ 488.426 Transfer of residents, or closure of the facility and transfer of residents.

(a) Transfer of residents. A facility must request a hearing on the determination of the noncompliance that is the basis for imposition of the civil money penalty within the time specified in one of the following sections:
   (i) Section 498.40 of this chapter for a (A) SNF;
   (B) Dually participating facility;
   (C) State-operated NF; or
   (D) Non-State operated NF against which HCFA is imposing remedies.
   (ii) Section 431.153 of this chapter for a non-State operated NF that is not subject to imposition of remedies by HCFA.

(b) Closing the facility. The facility must request a hearing on the determination of the noncompliance that is the basis for imposition of the civil money penalty within the time specified in paragraph (a)(1) of this section, HCFA or the State initiates collection of the penalty when there is a final administrative decision that upholds HCFA’s or the State’s determination of noncompliance after the facility achieves substantial compliance or is terminated.
§ 488.434 Civil money penalties: Notice of penalty.  
(a) HCFA notice of penalty.  
(1) HCFA sends a written notice of the penalty to the facility for all facilities except non-State operated NFs when the State is imposing the penalty.  
(2) Content of notice. The notice that HCFA sends includes—  
(i) The nature of the noncompliance;  
(ii) The statutory basis for the penalty;  
(iii) The amount of penalty per day of noncompliance;  
(iv) Any factors specified in §488.438(f) that were considered when determining the amount of the penalty;  
(v) The date on which the penalty begins to accrue;  
(vi) When the penalty stops accruing;  
(vii) When the penalty is collected; and  
(viii) Instructions for responding to the notice, including a statement of the facility's right to a hearing, and the implication of waiving a hearing, as provided in §488.436.  
(b) When facility does not request a hearing. If a facility does not request a hearing, in accordance with paragraph (a) of this section, HCFA or the State initiates collection of the penalty when the facility—  
(1) Achieves substantial compliance; or  
(2) Is terminated.  
(c) When facility waives a hearing. If a facility waives its right to a hearing in writing, as specified in §488.436, HCFA or the State initiates collection of the penalty when the facility—  
(1) Achieves substantial compliance; or  
(2) Is terminated.  
(d) Accrual and computation of penalties for a facility that—  
(1) Requests a hearing or does not request a hearing are specified in §488.440;  
(2) Waives its right to a hearing in writing, are specified in §§488.436(b) and 488.440.  
(e) The collection of civil money penalties is made as provided in §488.442.  

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]  

§ 488.436 Civil money penalties: Waiver of hearing, reduction of penalty amount.  
(a) Waiver of a hearing. The facility may waive the right to a hearing, in writing, within 60 days from the date of the notice imposing the civil money penalty.  
(b) Reduction of penalty amount. (1) If the facility waives its right to a hearing in accordance with the procedures specified in paragraph (a) of this section, HCFA or the State reduces the civil money penalty amount by 35 percent.  
(2) If the facility does not waive its right to a hearing in accordance with the procedures specified in paragraph (a) of this section, the civil money penalty is not reduced by 35 percent.  


§ 488.438 Civil money penalties: Amount of penalty.  
(a) Amount of penalty. The penalties are within the following ranges, set at $50 increments:  
(1) Upper range—$3,050–$10,000. Penalties in the range of $3,050–$10,000 per day are imposed for deficiencies constituting immediate jeopardy, and as specified in paragraph (d)(2) of this section.  
(2) Lower range—$50–$3,000. Penalties in the range of $50–$3,000 per day are imposed for deficiencies that do not constitute immediate jeopardy, but either caused actual harm, or caused no actual harm, but have the potential for more than minimal harm.  
(b) Basis for penalty amount. The amount of penalty is based on HCFA's or the State's assessment of factors listed in paragraph (f) of this section.
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(c) Decreased penalty amounts. Except as specified in paragraph (d)(2) of this section, if immediate jeopardy is removed, but the noncompliance continues, HCFA or the State will shift the penalty amount to the lower range.

(d) Increased penalty amounts. (1) Before the hearing, HCFA or the State may propose to increase the penalty amount for facility noncompliance which, after imposition of a lower level penalty amount, becomes sufficiently serious to pose immediate jeopardy.

(2) HCFA does and the State must increase the penalty amount for any repeated deficiencies for which a lower penalty amount was previously imposed, regardless of whether the increased penalty amount would exceed the range otherwise reserved for non-immediate jeopardy deficiencies.

(3) Repeated deficiencies are deficiencies in the same regulatory grouping of requirements found at the last survey, subsequently corrected, and found again at the next survey.

(e) Review of the penalty. When an administrative law judge or State hearing officer (or higher administrative review authority) finds that the basis for imposing a civil money penalty exists, as specified in §488.430, the administrative law judge or State hearing officer (or higher administrative review authority) may not—

(1) Set a penalty of zero or reduce a penalty to zero;

(2) Review the exercise of discretion by HCFA or the State to impose a civil money penalty; and

(3) Consider any factors in reviewing the amount of the penalty other than those specified in paragraph (f) of this section.

(f) Factors affecting the amount of penalty. In determining the amount of penalty, HCFA does or the State must take into account the following factors:

(1) The facility’s history of noncompliance, including repeated deficiencies.

(2) The facility’s financial condition.

(3) The factors specified in §488.404.

(4) The facility’s degree of culpability. Culpability for purposes of this paragraph includes, but is not limited to, neglect, indifference, or disregard for resident care, comfort or safety. The absence of culpability is not a mitigating circumstance in reducing the amount of the penalty.

§ 488.440 Civil money penalties: Effective date and duration of penalty.

(a) When penalty begins to accrue. The civil money penalty may start accruing as early as the date that the facility was first out of compliance, as determined by HCFA or the State.

(b) Duration of penalty. The civil money penalty is computed and collectible, as specified in §§ 488.432 and 488.442, for the number of days of noncompliance until the date the facility achieves substantial compliance, or, if applicable, the date of termination when—

(1) HCFA’s or the State’s decision of noncompliance is upheld after a final administrative decision;

(2) The facility waives its right to a hearing in accordance with §488.436; or

(3) The time for requesting a hearing has expired and HCFA or the State has not received a hearing request from the facility.

(c) The entire accrued penalty is due and collectible, as specified in the notice sent to the provider under paragraphs (d) and (e) of this section.

(d) When a facility achieves substantial compliance, HCFA does or the State must send a separate notice to the facility containing—

(1) The amount of penalty per day;

(2) The number of days involved;

(3) The total amount due;

(4) The due date of the penalty; and

(5) The rate of interest assessed on the unpaid balance beginning on the due date, as provided in §488.442.

(e) In the case of a terminated facility, HCFA does or the State must send this penalty information after the—

(1) Final administrative decision is made;

(2) Facility has waived its right to a hearing in accordance with §488.436; or

(3) Time for requesting a hearing has expired and HCFA or the state has not received a hearing request from the facility.

(f) Accrual of penalties when there is no immediate jeopardy. (1) In the case of noncompliance that does not pose immediate jeopardy, the daily accrual of civil money penalties is imposed for
§ 488.442 Civil money penalties: Due date for payment of penalty.

(a) When payments are due—(1) After a final administrative decision. A civil money penalty payment is due 15 days after a final administrative decision is made when—

(i) The facility achieved substantial compliance before the hearing request was due; or

(ii) The effective date of termination occurs before the hearing request was due; or

(iii) After a request to waive a hearing. A civil money penalty payment is due 15 days after receipt of the written request to waive a hearing when—

(i) The facility achieved substantial compliance before HCFA or the State received the written waiver of hearing; or

(ii) The effective date of termination occurs before HCFA or the State received the written waiver of hearing.

(4) After substantial compliance is achieved. A civil money penalty payment is due 15 days after substantial compliance is achieved when—

(i) The final administrative decision is made before the facility came into substantial compliance; or

(ii) The facility did not file a timely hearing request before it came into substantial compliance; or

(iii) The facility waived its right to a hearing before it came into substantial compliance;

(5) After the effective date of termination. A civil money penalty payment is due 15 days after the effective date of termination, if before the effective date of termination—

(i) The final administrative decision was made; or

(ii) The time for requesting a hearing has expired and the facility did not request a hearing; or

(iii) The facility waived its right to a hearing.

(6) In the cases specified in paragraph (a)(4) of this section, the period of noncompliance may not extend beyond 6 months from the last day of the survey.

(b) Deduction of penalty from amount owed. The amount of the penalty, when determined, may be deducted from any sum then or later owing by HCFA or the State to the facility.

(c) Interest—(1) Assessment. Interest is assessed on the unpaid balance of the penalty, beginning on the due date.

(2) Medicare interest. Medicare rate of interest is the higher of—
§ 488.450 Continuation of payments to a facility with deficiencies.

(a) Criteria. (1) HCFA may continue payments to a facility not in substantial compliance for the periods specified in paragraph (c) of this section if the following criteria are met:

(i) The State survey agency finds that it is more appropriate to impose alternative remedies than to terminate the facility;

(ii) The State has submitted a plan and timetable for corrective action approved by HCFA; and

(iii) The facility, in the case of a Medicare SNF, or the State, in the case of a Medicaid NF, agrees to repay the Federal government payments received under this provision if corrective action is not taken in accordance with the approved plan and timetable for corrective action.

(2) HCFA or the State may terminate the SNF or NF agreement before the end of the correction period if the criteria in paragraph (a)(1) of this section are not met or agreed to by either the facility or the State.

(b) Cessation of payments. If termination is not sought, either by itself or along with another remedy or remedies, or any of the criteria set forth in paragraph (a)(1) of this section are not met, the facility or State will receive no Medicare or Federal Medicaid payments, as applicable, from the last day of the survey.

(c) Period of continued payments. If the conditions in paragraph (a)(1) of this section are met, HCFA may continue payments to a Medicare facility or to the State for a Medicaid facility with noncompliance that does not constitute immediate jeopardy for up to 6 months from the last day of the survey.

(d) Failure to achieve substantial compliance. If the facility does not achieve substantial compliance by the end of

§ 488.444 Civil money penalties: Settlement of penalties.

(a) HCFA has authority to settle cases at any time prior to a final administrative decision for Medicare-only SNFs, State-operated facilities, or other facilities for which HCFA's enforcement action prevails, in accordance with §488.330.

(b) The State has the authority to settle cases at any time prior to the evidentiary hearing decision for all cases in which the State's enforcement action prevails.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]
the period specified in paragraph (c) of this section,

(i) HCFA will—

(1) HCFA will—

(i) Terminate the provider agreement of the Medicare SNF in accordance with §488.456; or

(ii) Discontinue Federal funding to the SNF for Medicare; and

(iii) Discontinue FFP to the State for the Medicaid NF.

(2) The State may terminate the provider agreement for the NF.

§ 488.452 State and Federal disagreements involving findings not in agreement in non-State operated NFs and dually participating facilities when there is no immediate jeopardy.

The following rules apply when HCFA and the State disagree over findings of noncompliance or application of remedies in a non-State operated NF or dually participating facility:

(a) Disagreement over whether facility has met requirements.

(1) The State's finding of noncompliance takes precedence when—

(i) HCFA finds that a NF or a dually participating facility is in substantial compliance with the participation requirements; and

(ii) The State finds that a NF or a dually participating facility has not achieved substantial compliance.

(2) HCFA's findings of noncompliance take precedence when—

(i) HCFA finds that a NF or a dually participating facility has not achieved substantial compliance; and

(ii) The State finds that a NF or a dually participating facility is in substantial compliance with the participation requirements.

(3) When HCFA's survey findings take precedence, HCFA may—

(i) Impose any of the alternative remedies specified in §488.406;

(ii) Terminate the provider agreement subject to the applicable conditions of §488.450; and

(iii) Stop FFP to the State for a NF.

(b) Disagreement over decision to terminate.

(1) HCFA's decision to terminate the participation of a facility takes precedence when—

(i) Both HCFA and the State find that the facility has not achieved substantial compliance; and

(ii) HCFA, but not the State, finds that the facility's participation should be terminated. HCFA will permit continuation of payment during the period prior to the effective date of termination not to exceed 6 months, if the applicable conditions of §488.450 are met.

(2) The State's decision to terminate a facility's participation and the procedures for appealing such termination, as specified in §431.153(c) of this chapter, takes precedence when—

(i) The State, but not HCFA, finds that a NF's participation should be terminated; and

(ii) The State's effective date for the termination of the NF's provider agreement is no later than 6 months after the last day of survey.

(c) Disagreement over timing of termination of facility. The State's timing of termination takes precedence if it does not occur later than 6 months after the last day of the survey when both HCFA and the State find that—

(1) A facility is not in substantial compliance; and

(2) The facility's participation should be terminated.

(d) Disagreement over remedies.

(1) When HCFA or the State, but not both, establishes one or more remedies, in addition to or as an alternative to termination, the additional or alternative remedies will also apply when—

(i) Both HCFA and the State find that a NF has not achieved substantial compliance; and

(ii) Both HCFA and the State find that no immediate jeopardy exists.

(2) Overlap of remedies. When HCFA and the State establish one or more remedies, in addition to or as an alternative to termination, only the HCFA remedies apply when both HCFA and the State find that a facility has not achieved substantial compliance.

(3) Regardless of whether HCFA's or the State's decision controls, only one noncompliance and enforcement decision is applied to the Medicaid agreement, and for a dually participating facility, that same decision will apply to the Medicare agreement.
§ 488.454 Duration of remedies.

(a) Except as specified in paragraph (b) of this section, alternative remedies continue until—

(1) The facility has achieved substantial compliance, as determined by HCFA or the State based upon a revisit or after an examination of credible written evidence that it can verify without an on-site visit; or

(2) HCFA or the State terminates the provider agreement.

(b) In the cases of State monitoring and denial of payment imposed for repeated substandard quality of care, remedies continue until—

(1) HCFA or the State determines that the facility has achieved substantial compliance and is capable of remaining in substantial compliance; or

(2) HCFA or the State terminates the provider agreement.

(c) In the case of temporary management, the remedy continues until—

(1) HCFA or the State determines that the facility has achieved substantial compliance and is capable of remaining in substantial compliance; or

(2) HCFA or the State terminates the provider agreement; or

(3) The facility which has not achieved substantial compliance re-assumes management control. In this case, HCFA or the State initiates termination of the provider agreement and may impose additional remedies.

(d) If the facility can supply documentation acceptable to HCFA or the State survey agency that it was in substantial compliance, and was capable of remaining in substantial compliance, if necessary, on a date preceding that of the revisit, the remedies terminate on the date that HCFA or the State can verify as the date that substantial compliance was achieved and the facility demonstrated that it could maintain substantial compliance, if necessary.

[59 FR 55243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

§ 488.456 Termination of provider agreement.

(a) Effect of termination. Termination of the provider agreement ends—

(1) Payment to the facility; and

(2) Any alternative remedy. (b) Basis for termination. (1) HCFA and the State may terminate a facility's provider agreement if a facility—

(i) Is not in substantial compliance with the requirements of participation, regardless of whether or not immediate jeopardy is present; or

(ii) Fails to submit an acceptable plan of correction within the timeframe specified by HCFA or the State.

(2) HCFA and the State terminate a facility's provider agreement if a facility—

(i) Fails to relinquish control to the temporary manager, if that remedy is imposed by HCFA or the State; or

(ii) Does not meet the eligibility criteria for continuation of payment as set forth in §488.412(a)(1).

(c) Notice of termination. Before terminating a provider agreement, HCFA does and the State must notify the facility and the public—

(1) At least 2 calendar days before the effective date of termination for a facility with immediate jeopardy deficiencies; and

(2) At least 15 calendar days before the effective date of termination for a facility with non-immediate jeopardy deficiencies that constitute noncompliance.

(d) Procedures for termination. (1) HCFA terminates the provider agreement in accordance with procedures set forth in §489.53 of this chapter; and

(2) The State must terminate the provider agreement of a NF in accordance with procedures specified in parts 431 and 442 of this chapter.

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

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Authority: Secs. 1102, 1819, 1861, 1964(m), 1966, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395i–3, 1395x, 1395aa(m), 1395cc, and 1395hh).

Source: 45 FR 22937, Apr. 4, 1980, unless otherwise noted.

Subpart A—General Provisions

§ 489.1 Statutory basis.

This part implements section 1866 of the Social Security Act. Section 1866 specifies the terms of provider agreements, the grounds for terminating a provider agreement, the circumstances under which payment for new admissions may be denied, and the circumstances under which payment may be withheld for failure to make timely utilization review. The following other sections of that Act are also pertinent.

(a) Section 1861 defines the services covered under Medicare and the providers that may be reimbursed for furnishing those services.

(b) Section 1864 provides for the use of State survey agencies to ascertain whether certain entities meet the conditions of participation.

(c) Section 1871 authorizes the Secretary to prescribe regulations for the administration of the Medicare program.

(d) Although section 1866 of the Act speaks only to providers and provider agreements, the effective date rules in this part are made applicable also to the approval of suppliers that meet the requirements specified in §489.13.
§ 489.10 Basic requirements.

(a) Any of the providers specified in § 489.2 may request participation in Medicare. In order to be accepted, it must meet the conditions of participation or requirements (for SNFs) set forth in this section and elsewhere in this chapter.

(b) The following providers are subject to the provisions of this part:

(1) Hospitals.

(2) Skilled nursing facilities (SNFs).

(3) Home health agencies (HHAs).

(4) Clinics, rehabilitation agencies, and public health agencies.

(5) Comprehensive outpatient rehabilitation facilities (CORFs).

(6) Hospices.

(7) Critical access hospital (CAHs).

(8) Community mental health centers (CMHCs).

(c)(1) Clinics, rehabilitation agencies, and public health agencies may enter into provider agreements only for furnishing outpatient physical therapy, and speech pathology services.

(2) CMHCs may enter into provider agreements only to furnish partial hospitalization services.

§ 489.11 Acceptance of a provider as a participant.

(a) Action by HCFA. If HCFA determines that the provider meets the requirements, it will send the provider—

(1) Written notice of that determination; and

(2) Two copies of the provider agreement.

(b) Action by provider. If the provider wishes to participate, it must return both copies of the agreement, duly signed by an authorized official, to HCFA, together with a written statement indicating whether it has been adjudged insolvent or bankrupt in any State or Federal court, or whether any insolvency or bankruptcy actions are pending.

(c) Notice of acceptance. If HCFA accepts the agreement, it will return one copy to the provider with a written notice that—

(1) Indicates the dates on which it was signed by the provider’s representative and accepted by HCFA; and

(2) Specifies the effective date of the agreement.

§ 489.12 Decision to deny an agreement.

(a) Bases for denial. HCFA may refuse to enter into an agreement for any of the following reasons:

(1) Principals of the prospective provider have been convicted of fraud (see §420.204 of this chapter); or

(2) The prospective provider has failed to disclose ownership and control interests in accordance with §420.206 of this chapter; or

(3) The prospective provider is unable to give satisfactory assurance of compliance with the requirements of title XVIII of the Act.

(b) [Reserved]

(c) Compliance with civil rights requirements. HCFA will not enter into a provider agreement if the provider fails to comply with civil rights requirements set forth in 45 CFR parts 80, 84, and 90, subject to the provisions of §489.10.

§ 489.13 Effective date of agreement or approval.

(a) Applicability—(1) General rule. Except as provided in paragraph (a)(2) of this section, this section applies to Medicare provider agreements with, and supplier approval of, entities that, as a basis for participation in Medicare—

(i) Are subject to survey and certification by HCFA or the State survey agency; or

(ii) Are deemed to meet Federal requirements on the basis of accreditation by an accrediting organization whose program has HCFA approval at the time of accreditation survey and accreditation decision.

(2) Exceptions. (i) For an agreement with a community mental health center (CMHC) or a Federally qualified health center (FQHC), the effective date is the date on which HCFA accepts a signed agreement which assures that the CMHC or FQHC meets all Federal requirements.

(ii) A Medicare supplier approval of a laboratory is effective only while the laboratory has in effect a valid CLIA certificate issued under part 493 of this chapter, and only for the specialty and
subspeciality tests it is authorized to perform.

(b) All Federal requirements are met on the date of survey. The agreement or approval is effective on the date the survey (including the Life Safety Code survey, if applicable) is completed, if on that date the provider or supplier meets all applicable Federal requirements as set forth in this chapter. (If the agreement or approval is time-limited, the new agreement or approval is effective on the day following expiration of the current agreement or approval.)

(c) All Federal requirements are not met on the date of survey. If on the date the survey is completed the provider or supplier fails to meet any of the requirements specified in paragraph (b) of this section, the following rules apply:

(1) For an agreement with an SNF, the effective date is the date on which—
   (i) The SNF is in substantial compliance (as defined in §488.301 of this chapter) with the requirements for participation; and
   (ii) HCFA or the State survey agency receives from the SNF, if applicable, an approvable waiver request.

(2) For an agreement with, or an approval of, any other provider or supplier, (except those specified in paragraph (a)(2) of this section), the effective date is the earlier of the following:
   (i) The date on which the provider or supplier meets all requirements.
   (ii) The date on which a provider or supplier is found to meet all conditions of participation or coverage, but has lower level deficiencies, and HCFA or the State survey agency receives an acceptable plan of correction for the lower level deficiencies, or an approvable waiver request, or both. (The date of receipt is the effective date regardless of when HCFA approves the plan of correction or the waiver request, or both.)

(d) Accredited provider or supplier requests participation in the Medicare program—(1) General rule. If the provider or supplier is currently accredited by a national accrediting organization whose program had HCFA approval at the time of accreditation survey and accreditation decision, and on the basis of accreditation, HCFA has deemed the provider or supplier to meet Federal requirements, the effective date depends on whether the provider or supplier is subject to requirements in addition to those included in the accrediting organization’s approved program.

   (i) Provider or supplier subject to additional requirements. If the provider or supplier is subject to additional requirements, the effective date of the agreement or approval is the date on which the provider or supplier meets all requirements, including the additional requirements.

   (ii) Provider or supplier not subject to additional requirements. For a provider or supplier that is not subject to additional requirements, the effective date is the date of the provider’s or supplier’s initial request for participation if on that date the provider or supplier met all Federal requirements.

§ 489.18 Change of ownership or leasing: Effect on provider agreement.

(a) What constitutes change of ownership—(1) Partnership. In the case of a partnership, the removal, addition, or substitution of a partner, unless the partners expressly agree otherwise, as permitted by applicable State law, constitutes change of ownership.

   (2) Unincorporated sole proprietorship. Transfer of title and property to another party constitutes change of ownership.

   (3) Corporation. The merger of the provider corporation into another corporation, or the consolidation of two or more corporations, resulting in the creation of a new corporation constitutes change of ownership. Transfer of corporate stock or the merger of another corporation into the provider corporation does not constitute change of ownership.
§ 489.20  Basic commitments.

The provider agrees to the following:

(a) To limit its charges to beneficiaries and to other individuals on their behalf, in accordance with provisions of subpart C of this part.

(b) To comply with the requirements of subpart D of this part for the return or other disposition of any amounts incorrectly collected from a beneficiary or any other person in his or her behalf.

(c) To comply with the requirements of §420.203 of this chapter when it hires certain former employees of intermediaries.

(d) In the case of a hospital or a CAH that furnishes services to Medicare beneficiaries, either to furnish directly or to make arrangements (as defined in §409.3 of this chapter) for all Medicare-covered services to inpatients of a hospital or a CAH except the following:

(1) Physicians’ services that meet the criteria of §415.102(a) of this chapter for payment on a reasonable charge basis.

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

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

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

(5) Services of an anesthetist, as defined in §410.69 of this chapter.

(e) In the case of a hospital or CAH that furnishes inpatient hospital services or inpatient CAH services for which payment may be made under Medicare, to maintain an agreement with a PRO for that organization to review the admissions, quality, appropriateness, and diagnostic information related to those inpatient services. The requirement of this paragraph (e) applies only if, for the area in which the hospital or CAH is located, there is a PRO that has a contract with HCFA under part B of title XI of the Act.

(f) To maintain a system that, during the admission process, identifies any primary payers other than Medicare, so that incorrect billing and Medicare overpayments can be prevented.

(g) To bill other primary payers before billing Medicare except when the primary payer is a liability insurer and except as provided in paragraph (i) of this section.

(h) If the provider receives payment for the same services from Medicare and another payer that is primary to Medicare, to reimburse Medicare any overpaid amount within 60 days.

(i) If the provider receives, from a payer that is primary to Medicare, a payment that is reduced because the provider failed to file a proper claim—

(1) To bill Medicare for an amount no greater than would have been payable as secondary payment if the primary insurer’s payment had been based on a proper claim; and
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(2) To charge the beneficiary only: (i) The amount it would have been entitled to charge if it had filed a proper claim and received payment based on such a claim; and
(ii) An amount equal to any third party payment reduction attributable to failure to file a proper claim, but only if the provider can show that—
(A) It failed to file a proper claim solely because the beneficiary, for any reason other than mental or physical incapacity, failed to give the provider the necessary information; or
(B) The beneficiary, who was responsible for filing a proper claim, failed to do so for any reason other than mental or physical incapacity.
(j) In 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, hospitals may bill liability insurers first. However, if the liability insurer does not pay “promptly”, as defined in §411.50 of this chapter, the hospital must withdraw its claim or lien and bill Medicare for covered services.
(k) In the case of home health agencies that provide home health services to Medicare beneficiaries under subpart E of part 409 and subpart C of part 410 of this chapter, to offer to furnish catheters, catheter supplies, ostomy bags, and supplies related to ostomy care to any individual who requires them as part of their furnishing of home health services.
(l) In the case of a hospital as defined in §489.24(b) to comply with §489.24.
(m) In the case of a hospital as defined in §489.24(b), to report to HCFA or the State survey agency any time it has reason to believe it may have received an individual who has been transferred in an unstable emergency medical condition from another hospital in violation of the requirements of §489.24(d).
(n) In the case of inpatient hospital services, to participate in any health plan contracted for under 10 U.S.C. 1079 or 1086 or 38 U.S.C. 613, in accordance with §489.25.
(o) In the case of inpatient hospital services, to admit veterans whose admission has been authorized under 38 U.S.C. 603, in accordance with §489.26.
(p) In the case of a hospital that participates in the Medicare program, to comply with §489.27 by giving each beneficiary a notice about his or her discharge rights at or about the time of the individual’s admission.
(q) In the case of a hospital as defined in §489.24(b)—
(1) To post conspicuously in any emergency department or in a place or places likely to be noticed by all individuals entering the emergency department, as well as those individuals waiting for examination and treatment in areas other than traditional emergency departments (that is, entrance, admitting area, waiting room, treatment area), a sign (in a form specified by the Secretary) specifying rights of individuals under Section 1867 of the Act with respect to examination and treatment for emergency medical conditions and women in labor; and
(2) To post conspicuously (in a form specified by the Secretary) information indicating whether or not the hospital or rural primary care hospital participates in the Medicaid program under a State plan approved under title XIX.
(r) In the case of a hospital as defined in §489.24(b) (including both the transferring and receiving hospitals), to maintain—
(1) Medical and other records related to individuals transferred to or from the hospital for a period of 5 years from the date of the transfer;
(2) A list of physicians who are on call for duty after the initial examination to provide treatment necessary to stabilize an individual with an emergency medical condition; and
(3) A central log on each individual who comes to the emergency department, as defined in §489.24(b), seeking assistance and whether he or she refused treatment, was refused treatment, or whether he or she was transferred, admitted and treated, stabilized and transferred, or discharged.
(s) In the case of an SNF, either to furnish directly or make arrangements (as defined in §409.3 of this chapter) for all Medicare-covered services furnished to a resident (as defined in §411.15(p)(3) of this chapter) of the SNF, except the following:
§ 489.21 Specific limitations on charges.

Except as specified in subpart C of this part, the provider agrees not to charge a beneficiary for any of the following:

(a) Services for which the beneficiary is entitled to have payment made under Medicare.

(b) Services for which the beneficiary would be entitled to have payment made if the provider—

(1) Had in its files the required certification and recertification by a physician relating to the services furnished to the beneficiary;

(2) Had furnished the information required by the intermediary in order to determine the amount due the provider on behalf of the individual for the period with respect to which payment is to be made or any prior period;

(3) Had complied with the provisions requiring timely utilization review of long stay cases so that a limitation on days of service has not been imposed under section 1866(d) of the Act (see subpart K of part 405 and part 482 of this chapter for utilization review requirements); and

(4) Had obtained, from the beneficiary or a person acting on his or her behalf, a written request for payment to be made to the provider, and had properly filed that request. (If the beneficiary or person on his or her behalf refuses to execute a written request, the provider may charge the beneficiary for all services furnished to him or her.)

(c) Inpatient hospital services furnished to a beneficiary who exhausted his or her Part A benefits, if HCFA reimburses the provider for those services.

(d) Custodial care and services not reasonable and necessary for the diagnosis or treatment of illness or injury, if—

(1) The beneficiary was without fault in incurring the expenses, and

(2) The determination that payment was incorrect was not made until after the third year following the year in which the payment notice was sent to the beneficiary.

(e) Inpatient hospital services for which a beneficiary would be entitled to have payment made under Part A of
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§ 489.24 Special responsibilities of Medicare hospitals in emergency cases.

(a) General. In the case of a hospital that has an emergency department, if any individual (whether or not eligible for Medicare benefits and regardless of ability to pay) comes by him or herself or with another person to the emergency department and a request is made on the individual’s behalf for examination or treatment of a medical condition by qualified medical personnel (as determined by the hospital in its rules and regulations), the hospital must provide for an appropriate medical screening examination within the capability of the hospital’s emergency department, including ancillary services routinely available to the emergency department, to determine whether or not an emergency medical condition exists. The examinations must be conducted by individuals determined qualified by hospital by-laws or rules and regulations and who meet the requirements of § 482.55 concerning emergency services personnel and direction.

(b) Definitions. As used in this subpart—
Capacity means the ability of the hospital to accommodate the individual requesting examination or treatment of the transferred individual. Capacity encompasses such things as numbers and availability of qualified staff, beds and equipment and the hospital's past practices of accommodating additional patients in excess of its occupancy limits.

Comes to the emergency department means, with respect to an individual requesting examination or treatment, that the individual is on the hospital property (property includes ambulances owned and operated by the hospital, even if the ambulance is not on hospital grounds). An individual in a nonhospital-owned ambulance on hospital property is considered to have come to the hospital's emergency department. An individual in a nonhospital-owned ambulance off hospital property is not considered to have come to the hospital's emergency department, even if a member of the ambulance staff contacts the hospital by telephone or telemetry communications and informs the hospital that they want to transport the individual to the hospital for examination and treatment. In such situations, the hospital may deny access if it is in "diversionary status," that is, it does not have the staff or facilities to accept any additional emergency patients. If, however, the ambulance staff disregards the hospital's instructions and transports the individual on to hospital property, the individual is considered to have come to the emergency department.

Emergency medical condition means—
(i) A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain, psychiatric disturbances and/or symptoms of substance abuse) such that the absence of immediate medical attention could reasonably be expected to result in—
(A) Placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy;
(B) Serious impairment to bodily functions; or
(C) Serious dysfunction of any bodily organ or part; or
(ii) With respect to a pregnant woman who is having contractions—
(A) That there is inadequate time to effect a safe transfer to another hospital before delivery; or
(B) That transfer may pose a threat to the health or safety of the woman or the unborn child.

Hospital includes a critical access hospital as defined in section 1861(mm)(1) of the Act.

Hospital with an emergency department means a hospital that offers services for emergency medical conditions (as defined in this paragraph) within its capability to do so.

Labor means the process of childbirth beginning with the latent or early phase of labor and continuing through the delivery of the placenta. A woman experiencing contractions is in true labor unless a physician certifies that, after a reasonable time of observation, the woman is in false labor.

Participating hospital means (i) a hospital or (ii) a critical access hospital as defined in section 1861(mm)(1) of the Act that has entered into a Medicare provider agreement under section 1866 of the Act.

Stabilized means, with respect to an "emergency medical condition" as defined in this section under paragraph (i) of that definition, that no material deterioration of the condition is likely, within reasonable medical probability, to result from or occur during the transfer of the individual from a facility or, with respect to an "emergency medical condition" as defined in this section under paragraph (ii) of that definition, that the woman has delivered the child and the placenta.

To stabilize means, with respect to an "emergency medical condition" as defined in this section under paragraph (i) of that definition, to provide such medical treatment of the condition necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the individual from a facility or that, with respect to an "emergency medical condition" as defined in this section under paragraph (ii) of that definition, the woman has delivered the child and the placenta.
Transfer means the movement (including the discharge) of an individual outside a hospital’s facilities at the direction of any person employed by (or affiliated or associated, directly or indirectly, with) the hospital, but does not include such a movement of an individual who (i) has been declared dead, or (ii) leaves the facility without the permission of any such person.

(c) Necessary stabilizing treatment for emergency medical conditions—(1) General. If any individual (whether or not eligible for Medicare benefits) comes to a hospital and the hospital determines that the individual has an emergency medical condition, the hospital must provide either—

(i) Within the capabilities of the staff and facilities available at the hospital, for further medical examination and treatment as required to stabilize the medical condition; or

(ii) For transfer of the individual to another medical facility in accordance with paragraph (d) of this section.

(2) Refusal to consent to treatment. A hospital meets the requirements of paragraph (c)(1)(i) of this section with respect to an individual if the hospital offers the individual the further medical examination and treatment described in that paragraph and informs the individual (or a person acting on the individual’s behalf) of the risks and benefits to the individual of the examination and treatment, but the individual (or a person acting on the individual’s behalf) refuses to consent to the examination and treatment. The medical record must contain a description of the examination, treatment, or both if applicable, that was refused by or on behalf of the individual. The written document must indicate that the person has been informed of the risks and benefits of the transfer and state the reasons for the individual’s refusal. The written document must indicate the person has been informed of the risks and benefits of the transfer and state the reasons for the individual’s refusal. The medical record must contain a description of the proposed transfer that was refused by or on behalf of the individual.

(d) Restricting transfer until the individual is stabilized—(1) General. If an individual at a hospital has an emergency medical condition that has not been stabilized (as defined in paragraph (b) of this section), the hospital may not transfer the individual unless—

(i) The transfer is an appropriate transfer (within the meaning of paragraph (d)(2) of this section); and

(ii)(A) The individual (or a legally responsible person acting on the individual’s behalf) requests the transfer, after being informed of the hospital’s obligations under this section and of the risk of transfer. The request must be in writing and indicate the reasons for the request as well as indicate that he or she is aware of the risks and benefits of the transfer;

(B) A physician (within the meaning of section 1861(r)(1) of the Act) has signed a certification that, based upon the information available at the time of transfer, the medical benefits reasonably expected from the provision of appropriate medical treatment at another medical facility outweigh the increased risks to the individual or, in the case of a woman in labor, to the woman or the unborn child, from being transferred. The certification must
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contain a summary of the risks and benefits upon which it is based; or  

(C) If a physician is not physically present in the emergency department at the time an individual is transferred, a qualified medical person (as determined by the hospital in its by-laws or rules and regulations) has signed a certification described in paragraph (d)(1)(iii)(B) of this section after a physician (as defined in section 1861(r)(1) of the Act) in consultation with the qualified medical person, agrees with the certification and subsequently countersigns the certification. The certification must contain a summary of the risks and benefits upon which it is based.  

(2) A transfer to another medical facility will be appropriate only in those cases in which—  

(i) The transferring hospital provides medical treatment within its capacity that minimizes the risks to the individual’s health and, in the case of a woman in labor, the health of the unborn child;  

(ii) The receiving facility—  

(A) Has available space and qualified personnel for the treatment of the individual; and  

(B) Has agreed to accept transfer of the individual and to provide appropriate medical treatment;  

(iii) The transferring hospital sends to the receiving facility all medical records (or copies thereof) related to the emergency condition which the individual has presented that are available at the time of the transfer, including available history, records related to the individual’s emergency medical condition, observations of signs or symptoms, preliminary diagnosis, results of diagnostic studies or telephone reports of the studies, treatment provided, results of any tests and the informed written consent or certification (or copy thereof) required under paragraph (d)(1)(i)(C) of this section, and the name and address of any on-call physician (described in paragraph (f) of this section) who has refused or failed to appear within a reasonable time to provide necessary stabilizing treatment. Other records (e.g., test results not yet available or historical records not readily available from the hospital’s files) must be sent as soon as practicable after transfer; and  

(iv) The transfer is effected through qualified personnel and transportation equipment, as required, including the use of necessary and medically appropriate life support measures during the transfer.  

(3) A participating hospital may not penalize or take adverse action against a physician or a qualified medical person described in paragraph (d)(1)(ii)(C) of this section because the physician or qualified medical person refuses to authorize the transfer of an individual with an emergency medical condition that has not been stabilized, or against any hospital employee because the employee reports a violation of a requirement of this section.  

(e) Recipient hospital responsibilities. A participating hospital that has specialized capabilities or facilities (including, but not limited to, facilities such as burn units, shock-trauma units, neonatal intensive care units, or (with respect to rural areas) regional referral centers) may not refuse to accept from a referring hospital within the boundaries of the United States an appropriate transfer of an individual who requires such specialized capabilities or facilities if the receiving hospital has the capacity to treat the individual.  

(f) Termination of provider agreement. If a hospital fails to meet the requirements of paragraph (a) through (e) of this section, HCFA may terminate the provider agreement in accordance with §489.53.  

(g) Consultation with Peer Review Organizations (PROs)—(1) General. Except as provided in paragraph (g)(3) of this section, in cases where a medical opinion is necessary to determine a physician’s or hospital’s liability under section 1867(d)(1) of the Act, HCFA requests the appropriate PRO (with a contract under Part B of title XI of the Act) to review the alleged section 1867(d) violation and provide a report on its findings in accordance with paragraph (g)(2)(iv) and (v) of this section. HCFA provides to the PRO all information relevant to the case and within its possession or control. HCFA, in consultation with the OIG, also provides to the PRO a list of relevant questions.
to which the PRO must respond in its report.

(2) Notice of review and opportunity for discussion and additional information. The PRO shall provide the physician and hospital reasonable notice of its review, a reasonable opportunity for discussion, and an opportunity for the physician and hospital to submit additional information before issuing its report. When a PRO receives a request for consultation under paragraph (g)(1) of this section, the following provisions apply—

(i) The PRO reviews the case before the 15th calendar day and makes its tentative findings.

(ii) Within 15 calendar days of receiving the case, the PRO gives written notice, sent by certified mail, return receipt requested, to the physician or the hospital (or both if applicable).

(iii)(A) The written notice must contain the following information:

1. The name of each individual who may have been the subject of the alleged violation.
2. The date on which each alleged violation occurred.
3. An invitation to meet, either by telephone or in person, to discuss the case with the PRO, and to submit additional information to the PRO within 30 calendar days of receipt of the notice, and a statement that these rights will be waived if the invitation is not accepted. The PRO must receive the information and hold the meeting within the 30-day period.

(B) For purposes of paragraph (g)(2)(iii)(A) of this section, the date of receipt is presumed to be 5 days after the certified mail date on the notice, unless there is a reasonable showing to the contrary.

(iv) The physician or hospital (or both where applicable) may request a meeting with the PRO. This meeting is not designed to be a formal adversarial hearing or a mechanism for discovery by the physician or hospital. The meeting is intended to afford the physician and/or the hospital a full and fair opportunity to present the views of the physician and/or hospital regarding the case. The following provisions apply to that meeting:

(A) The physician and/or hospital has the right to have legal counsel present during that meeting. However, the PRO may control the scope, extent, and manner of any questioning or any other presentation by the attorney. The PRO may also have legal counsel present.

(B) The PRO makes arrangements so that, if requested by HCFA or the OIG, a verbatim transcript of the meeting may be generated. If HCFA or OIG requests a transcript, the affected physician and/or the affected hospital may request that HCFA provide a copy of the transcript.

(C) The PRO affords the physician and/or the hospital an opportunity to present, with the assistance of counsel, expert testimony in either oral or written form on the medical issues presented. However, the PRO may reasonably limit the number of witnesses and length of such testimony if such testimony is irrelevant or repetitive. The physician and/or hospital, directly or through counsel, may disclose patient records to potential expert witnesses without violating any non-disclosure requirements set forth in part 476 of this chapter.

(D) The PRO is not obligated to consider any additional information provided by the physician and/or the hospital after the meeting, unless, before the end of the meeting, the PRO requests that the physician and/or hospital submit additional information to support the claims. The PRO then allows the physician and/or the hospital an additional period of time, not to exceed 5 calendar days from the meeting, to submit the relevant information to the PRO.

(v) Within 60 calendar days of receiving the case, the PRO must submit to HCFA a report on the PRO’s findings. HCFA provides copies to the OIG and to the affected physician and/or the affected hospital. The report must contain the name of the physician and/or the hospital, the name of the individual, and the dates and times the individual arrived at and was transferred (or discharged) from the hospital. The report provides expert medical opinion
§ 489.25 Special requirements concerning CHAMPUS and CHAMPVA programs.

For inpatient services, a hospital that participates in the Medicare program must participate in any health plan contracted under 10 U.S.C. 1079 or 1086 (Civilian Health and Medical Program of the Uniformed Services) and under 38 U.S.C. 613 (Civilian Health and Medical Program of the Veterans Administration) and accept the CHAMPUS/CHAMPVA-determined allowable amount as payment in full, less applicable deductible, patient cost-share, and noncovered items. Hospitals must meet the requirements of 32 CFR part 199 concerning program benefits under the Department of Defense. This section applies to inpatient services furnished to beneficiaries admitted on or after January 1, 1987.

§ 489.26 Special requirements concerning veterans.

For inpatient services, a hospital that participates in the Medicare program must admit any veteran whose admission is authorized by the Department of Veterans Affairs under 38 U.S.C. 603 and must meet the requirements of 38 CFR part 17 concerning admissions practices and payment methodology and amounts. This section applies to services furnished to veterans admitted on and after July 1, 1987.

§ 489.27 Beneficiary notice of discharge rights.

A hospital that participates in the Medicare program must furnish each Medicare beneficiary, or an individual acting on his or her behalf, the notice of discharge rights HCFA supplies to the hospital to implement section 1866(a)(1)(M) of the Act. The hospital must provide timely notice during the course of the hospital stay. For purposes of this paragraph, the course of the hospital stay may begin with the provision of a package of information regarding scheduled preadmission testing and registration for a planned hospital admission. The hospital must be able to demonstrate compliance with this requirement.

§ 489.28 Special capitalization requirements for HHAs.

(a) Basic rule. An HHA entering the Medicare program on or after January 1, 1998, including a new HHA as a result of the merger or acquisition of an existing HHA, must comply with the special capitalization requirements in this section.
of a change of ownership, if the change of ownership results in a new provider number being issued, must have available sufficient funds, which we term “initial reserve operating funds,” to operate the HHA for the three month period after its Medicare provider agreement becomes effective, exclusive of actual or projected accounts receivable from Medicare or other health care insurers.

(b) Standard. Initial reserve operating funds are sufficient to meet the requirement of this section if the total amount of such funds is equal to or greater than the product of the actual average cost per visit of three or more similarly situated HHAs in their first year of operation (selected by HCFA for comparative purposes) multiplied by the number of visits projected by the HHA for its first three months of operation—or 22.5 percent (one fourth of 90 percent) of the average number of visits reported by the comparison HHAs—whichever is greater.

(c) Method. HCFA, through the intermediary, will determine the amount of the initial reserve operating funds using reported cost and visit data from submitted cost reports for the first full year of operation from at least three HHAs that the intermediary serves that are comparable to the HHA that is seeking to enter the Medicare program, considering such factors as geographic location and urban/rural status, number of visits, provider-based versus free-standing, and proprietary versus non-proprietary status. The determination of the adequacy of the required initial reserve operating funds is based on the average cost per visit of the comparable HHAs; that is, by dividing the sum of total reported costs of the HHAs in their first year of operation by the sum of the HHAs’ total reported visits. The resulting average cost per visit is then multiplied by the projected visits for the first three months of operation of the HHA seeking to enter the program, but not less than 90 percent of average visits for a three month period for the HHAs used in determining the average cost per visit.

(d) Required proof of availability of initial reserve operating funds. The HHA must provide HCFA with adequate proof of the availability of initial reserve operating funds. Such proof, at a minimum, will include a copy of the statement(s) of the HHA’s savings, checking, or other account(s) that contains the funds, accompanied by an attestation from an officer of the bank or other financial institution that the funds are in the account(s) and that the funds are immediately available to the HHA. In some cases, an HHA may have all or part of the initial reserve operating funds in cash equivalents. For the purpose of this section, cash equivalents are short-term, highly liquid investments that are readily convertible to known amounts of cash and that present insignificant risk of changes in value. A cash equivalent that is not readily convertible to a known amount of cash as needed during the initial three month period for which the initial reserve operating funds are required does not qualify in meeting the initial reserve operating funds requirement. Examples of cash equivalents for the purpose of this section are Treasury bills, commercial paper, and money market funds. As with funds in a checking, savings, or other account, the HHA also must be able to document the availability of any cash equivalents. HCFA later may require the HHA to furnish another attestation from the financial institution that the funds remain available, or, if applicable, documentation from the HHA that any cash equivalents remain available, until a date when the HHA will have been surveyed by the State agency or by an approved accrediting organization. The officer of the HHA who will be certifying the accuracy of the information on the HHA’s cost report must certify what portion of the required initial reserve operating funds is non-borrowed funds, including funds invested in the business by the owner. That amount must be at least 50 percent of the required initial reserve operating funds. The remainder of the reserve operating funds may be secured through borrowing or line of credit from an unrelated lender.

(e) Borrowed funds. If borrowed funds are not in the same account(s) as the HHA’s own non-borrowed funds, the HHA also must provide proof that the borrowed funds are available for use in operating the HHA, by providing, at a
§ 489.30 Allowable charges: Deductibles and coinsurance.

(a) Part A deductible and coinsurance. The provider may charge the beneficiary or other person on his or her behalf:

(1) The amount of the inpatient hospital deductible or, if less, the actual charges for the services;

(2) The amount of inpatient hospital coinsurance applicable for each day the individual is furnished inpatient hospital services after the 60th day, during a benefit period; and

(3) The posthospital SNF care coinsurance amount.

(b) Part B deductible and coinsurance. (1) The basic allowable charges are the $75 deductible and 20 percent of the customary (insofar as reasonable) charges in excess of that deductible.

(2) For hospital outpatient services, the allowable deductible charges depend on whether the hospital can determine the beneficiary’s deductible status.

(i) If the hospital is unable to determine the deductible status, it may charge the beneficiary its full customary charges up to $75.

(ii) If the beneficiary provides official information as to deductible status, the hospital may charge only the unmet portion of the deductible.

(3) In either of the cases discussed in paragraph (b)(2) of this section, the hospital is required to file with the intermediary, on a form prescribed by HCFA, information as to the services, charges, and amounts collected.

(4) The intermediary must reimburse the beneficiary if reimbursement is authorized and credit the expenses to the beneficiary’s deductible if the deductible has not yet been met.

(5) In the case of DME furnished as a home health service under Medicare Part B, the coinsurance is 20 percent of the customary (insofar as reasonable) charge for the services, with the following 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 comparable new equipment, no coinsurance is required.


§ 489.31 Allowable charges: Blood.

(a) Limitations on charges. (1) A provider may charge the beneficiary (or other person on his or her behalf) only for the first three pints of blood or units of packed red cells furnished under Medicare Part A during a calendar year, or furnished under Medicare Part B during a calendar year.

(2) The charges may not exceed the provider’s customary charges.

(3) The provider may not charge for any whole blood or packed red cells in
any of the circumstances specified in §409.87(c)(2) of this chapter.

(b) Offset for excessive charges. If the charge exceeds the cost to the provider, that excess will be deducted from any Medicare payments due the provider.

§ 489.32 Allowable charges: Non-covered and partially covered services.

(a) Services requested by beneficiary. If services furnished at the request of a beneficiary (or his or her representative) are more expensive than, or in excess of, services covered under Medicare—

(1) A provider may charge the beneficiary an amount that does not exceed the difference between—

(i) The provider’s customary charges for the services furnished; and

(ii) The provider’s customary charges for the kinds and amounts of services that are covered under Medicare.

(2) A provider may not charge for the services unless they have been requested by the beneficiary (or his or her representative) nor require a beneficiary to request services as a condition of admission.

(3) To avoid misunderstanding and disputes, a provider must inform any beneficiary who requests a service for which a charge will be made that there will be a specified charge for that service.

(b) Services not requested by the beneficiary. For special provisions that apply when a provider customarily furnishes more expensive services, see §413.35 of this chapter.

§ 489.34 Allowable charges: Hospitals participating in State reimbursement control systems or demonstration projects.

A hospital receiving payment for a covered hospital stay under either a State reimbursement control system approved under 1886(c) of the Act or a demonstration project authorized under section 402(a) of Pub. L. 90-248 (42 U.S.C. 1395b-1) or section 222(a) of Pub. L. 92-603 (42 U.S.C. 1395b-1 (note)) and that would otherwise be subject to the prospective payment system set forth in part 412 of this chapter may charge a beneficiary for noncovered services as follows:

(a) For the custodial care and medically unnecessary services described in §412.42(c) of this chapter, after the conditions of §412.42(c)(1) through (c)(4) are met; and

(b) For all other services in accordance with the applicable rules of this subpart C.

§ 489.35 Notice to intermediary.

The provider must inform its intermediary of any amounts collected from a beneficiary or from other persons on his or her behalf.

Subpart D—Handling of Incorrect Collections

§ 489.40 Definition of incorrect collection.

(a) As used in this subpart, “incorrect collections” means any amounts collected from a beneficiary (or someone on his or her behalf) that are not authorized under subpart C of this part.

(b) A payment properly made to a provider by an individual not considered entitled to Medicare benefits will be deemed to be an “incorrect collection” when the individual is found to be retroactively entitled to benefits.

§ 489.41 Timing and methods of handling.

(a) Refund. Prompt refund to the beneficiary or other person is the preferred method of handling incorrect collections.

(b) Setting aside. If the provider cannot refund within 60 days from the date on the notice of incorrect collection, it must set aside an amount, equal to the amount incorrectly collected, in a separate account identified as to the individual to whom the payment is due. This amount incorrectly collected must be carried on the provider’s records in this manner until final disposition is made in accordance with the applicable State law.

(c) Notice to, and action by, intermediary. (1) The provider must notify
§ 489.42 Payment of offset amounts to beneficiary or other person.

(a) In order to carry out the commitment to refund amounts incorrectly collected, HCFA may determine that amounts offset in accordance with §489.41 are to be paid directly to the beneficiary or other person from whom the provider received the incorrect collection, if:

(1) HCFA finds that the provider has failed, following written request, to refund the amount of the incorrect collection to the beneficiary or other person; and

(2) The provider agreement has been terminated in accordance with the provisions of subpart E of this part.

(b) Before making a determination to make payment under paragraph (a) of this section, HCFA will give written notice to the provider (1) explaining that an incorrect collection was made and the amount; (2) requesting the provider to refund the incorrect collection to the beneficiary or other person; and

(3) Advising of HCFA’s intention to make a determination under paragraph (a) of this section.

(c) The notice will afford an authorized official of the provider an opportunity to submit, within 20 days from the date on the notice, written statement or evidence with respect to the incorrect collection and/or offset amounts. HCFA will consider any written statement or evidence in making a determination.

(d) Payment to a beneficiary or other person under the provisions of paragraph (a) of this section:

(1) Will not exceed the amount of the incorrect collection; and

(2) May be considered as payment made to the provider.

Subpart E—Termination of Agreement and Reinstatement After Termination

§ 489.52 Termination by the provider.

(a) Notice to HCFA. (1) A provider that wishes to terminate its agreement must send HCFA written notice of its intent.

(2) The notice may state the intended date of termination which must be the first day of a month.

(b) Termination date. (1) 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 provider’s notice of intent.

(2) HCFA may accept a termination date that is less than 6 months after the date on the provider’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) A cessation of business is deemed to be a termination by the provider, effective with the date on which it stopped providing services to the community.

(c) Public notice. (1) The provider must give notice to the public at least 15 days before the effective date of termination.

(2) The notice must be published in one or more local newspapers and must—

(i) Specify the termination date; and

(ii) Explain to what extent services may continue after that date, in accordance with the exceptions set forth in §489.55.

§ 489.53 Termination by HCFA.

(a) Basis for termination of agreement with any provider. HCFA may terminate the agreement with any provider if HCFA finds that any of the following failings is attributable to that provider:

(1) It is not complying with the provisions of title XVIII and the applicable regulations of this chapter or with the provisions of the agreement.
(2) It places restrictions on the persons it will accept for treatment and it fails either to exempt Medicare beneficiaries from those restrictions or to apply them to Medicare beneficiaries the same as to all other persons seeking care.

(3) It no longer meets the appropriate conditions of participation or requirements (for SNFs and NFs) set forth elsewhere in this chapter.

(4) It fails to furnish information that HCFA finds necessary for a determination as to whether payments are or were due under Medicare and the amounts due.

(5) It refuses to permit examination of its fiscal or other records by, or on behalf of HCFA, as necessary for verification of information furnished as a basis for payment under Medicare.

(6) It failed to furnish information on business transactions as required in §420.205 of this chapter.

(7) It failed at the time the agreement was entered into or renewed to disclose information on convicted individuals as required in §420.204 of this chapter.

(8) It failed to furnish ownership information as required in §420.206 of this chapter.

(9) It failed to comply with civil rights requirements set forth in 45 CFR parts 80, 84, and 90.

(10) In the case of a hospital or a critical access hospital as defined in section 1861(mm)(1) of the Act that has an emergency department, HCFA may terminate the provider agreement if—

(b) Termination of agreements with certain hospitals. In the case of a hospital or critical access hospital that has an emergency department, as defined in §489.24(b), HCFA may terminate the provider agreement if—

(1) The hospital fails to comply with the requirements of §489.24(a) through (e), which require the hospital to examine, treat, or transfer emergency medical condition cases appropriately, and require that hospitals with specialized capabilities or facilities accept an appropriate transfer; or

(2) The hospital fails to comply with §489.20(m), (q), and (r), which require the hospital to report suspected violations of §489.24(d), to post conspicuously in emergency departments or in a place or places likely to be noticed by all individuals entering the emergency departments, as well as those individuals waiting for examination and treatment in areas other than traditional emergency departments, (that is, entrance, admitting area, waiting room, treatment area), signs specifying rights of individuals under this subpart, to post conspicuously information indicating whether or not the hospital participates in the Medicaid program, and to maintain medical and other records related to transferred individuals for a period of 5 years, a list of on-call physicians for individuals with emergency medical conditions, and a central log on each individual who comes to the emergency department seeking assistance.

(c) Notice of termination—(1) Timing: Basic rule. Except as provided in paragraph (c)(2) of this section, HCFA gives the provider notice of termination at least 15 days before the effective date of termination of the provider agreement.

(2) Timing exceptions: Immediate jeopardy situations—(i) Hospital with emergency department. If HCFA finds that a
hospital with an emergency department is in violation of §489.24, paragraphs (a) through (e), and HCFA determines that the violation poses immediate jeopardy to the health or safety of individuals who present themselves to the hospital for emergency services, HCFA—

(A) Gives the hospital a preliminary notice indicating that its provider agreement will be terminated in 23 days if it does not correct the identified deficiencies or refute the finding; and

(B) Gives a final notice of termination, and concurrent notice to the public, at least 2, but not more than 4, days before the effective date of termination of the provider agreement.

(ii) Skilled nursing facilities (SNFs). For an SNF with deficiencies that pose immediate jeopardy to the health or safety of residents, HCFA gives notice at least 2 days before the effective date of termination of the provider agreement.

(3) Content of notice. The notice states the reasons for, and the effective date of, the termination, and explains the extent to which services may continue after that date, in accordance with §489.55.

(a) Basis for termination. (1) The OIG may terminate the agreement of any provider if the OIG finds that any of the following failings can be attributed to that provider.

(ii) It has knowingly and willfully made, or caused to be made, any false statement or representation of a material fact for use in an application or request for payment under Medicare.

§ 489.54 Termination by the OIG.

(a) Basis for termination. (1) The OIG may terminate the agreement of any provider if the OIG finds that any of the following failings can be attributed to that provider.

(ii) It has submitted, or caused to be submitted, requests for Medicare payment of amounts that substantially exceed the costs it incurred in furnishing the services for which payment is requested.

(iii) It has furnished services that the OIG has determined to be substantially in excess of the needs of individuals or of a quality that fails to meet professionally recognized standards of health care. The OIG will not terminate a provider agreement under paragraph (a) if HCFA has waived a disallowance with respect to the services in question on the grounds that the provider and the beneficiary could not reasonably be expected to know that payment would not be made. (The rules for determining such lack of knowledge are set forth in §§405.330 through 405.334 of this chapter.)

(b) Notice of termination. The OIG will give the provider notice of termination at least 15 days before the effective date of termination of the provider agreement.

(c) Appeal by the provider. A provider may appeal a termination of its agreement by the OIG in accordance with subpart O of part 405 of this chapter.

(d) Other applicable rules. The termination of a provider agreement by the OIG is subject to the additional procedures specified in §§1001.105 through 1001.109 of this title for notice and appeals.


§ 489.55 Exceptions to effective date of termination.

Payment is available for up to 30 days after the effective date of termination for—

(a) Inpatient hospital services (including inpatient psychiatric hospital services) and posthospital extended care services furnished to a beneficiary who was admitted before the effective date of termination; and

(b) Home health services and hospice care furnished under a plan established
§ 489.61 Basic requirement for surety bonds.

Except as provided in §489.62, each HHA that is a Medicare participating HHA, or that seeks to become a Medicare participating HHA, must obtain a surety bond. Rider means a notice issued by a Surety that a change in the bond has occurred or will occur.

Surety bond means one or more bonds issued by one or more surety companies under 31 U.S.C. 9304 to 9308 and 31 CFR parts 223, 224, and 225, provided the bond otherwise meets the requirements of this section.

Unpaid civil money penalty or assessment means a civil money penalty or assessment imposed by HCFA on an HHA under Titles XI, XVIII, or XXI of the Social Security Act, plus accrued interest, that, after the HHA or Surety has exhausted all administrative appeals, remains unpaid (because the civil money penalty or assessment has not been paid to, or offset or compromised by, HCFA) and is not the subject of a written arrangement, acceptable to HCFA, for payment by the HHA. In the event a written arrangement for payment acceptable to HCFA, is made, an unpaid civil money penalty or assessment also means such civil money penalty or assessment, plus accrued interest, that remains due 60 days after the HHA’s default on such arrangement.

Unpaid claim means a Medicare overpayment for which the HHA is responsible, plus accrued interest, that remains due (because the overpayment has not been paid to, or recouped or compromised by, HCFA) and is not the subject of a written arrangement, acceptable to HCFA, for payment by the HHA. In the event a written arrangement for payment acceptable to HCFA, is made, an unpaid claim also means a Medicare overpayment for which the HHA is responsible, plus accrued interest, that remains due 60 days after the HHA’s default on such arrangement.

[63 FR 313, Jan. 5, 1998, as amended at 63 FR 29655, June 1, 1998]
§ 489.62 Requirement waived for Government-operated HHAs.

An HHA operated by a Federal, State, local, or tribal government agency is deemed to have provided HCFA with a comparable surety bond under State law, and HCFA therefore waives the requirements of this subpart with respect to such an HHA if, during the preceding 5 years the HHA has—

(a) Not had any unpaid claims or unpaid civil money penalties or assessments; and

(b) Not had any of its claims referred by HCFA to the Department of Justice or the General Accounting Office in accordance with part 401 of this chapter.

[63 FR 313, Jan. 5, 1998, as amended at 63 FR 29655, June 1, 1998]

§ 489.63 Parties to the bond.

The surety bond must name the HHA as Principal, HCFA as Obligee, and the surety company (and its heirs, executors, administrators, successors and assignees, jointly and severally) as Surety.

§ 489.64 Authorized Surety and exclusion of surety companies.

(a) An HHA may obtain a surety bond required under § 489.61 only from an authorized Surety.

(b) An authorized Surety is a surety company that—

(1) Has been issued a Certificate of Authority by the U.S. Department of the Treasury in accordance with 31 U.S.C. 9304 to 9308 and 31 CFR parts 223, 224, and 225 as an acceptable surety on Federal bonds and the Certificate has neither expired nor been revoked; and

(2) Has not been determined by HCFA to be an unauthorized Surety for the purpose of an HHA obtaining a surety bond under this section.

(c) HCFA determines that a surety company is an unauthorized Surety under this section—

(1) If, upon request by HCFA, the surety company fails to furnish timely confirmation of the issuance of, and the validity and accuracy of information appearing on, a surety bond an HHA presents to HCFA that shows the surety company as Surety on the bond;

(2) If, upon presentation by HCFA to the surety company of a request for payment on a surety bond and of sufficient evidence to establish the surety company’s liability on the bond, the surety company fails to timely pay HCFA in full the amount requested, up to the face amount of the bond; or

(3) For other good cause.

(d) Any determination HCFA makes under paragraph (c) of this section is effective immediately when notice of the determination is published in the Federal Register and remains in effect until a notice of reinstatement is published in the Federal Register.

(e) Any determination HCFA makes under paragraph (c) of this section does not affect the Surety’s liability under any surety bond issued by a surety company to an HHA before notice of such determination is published in accordance with paragraph (d) of this section.

(f) A determination by HCFA that a surety company is an unauthorized Surety under this section is not a debarment, suspension, or exclusion for the purposes of Executive Order No. 12549 (3 CFR, 1986 comp., p. 189).

§ 489.65 Amount of the bond.

(a) Basic rule. The amount of the surety bond must be $50,000 or 15 percent of the Medicare payments made by HCFA to the HHA in the HHA’s most recent fiscal year for which a cost report has been accepted by HCFA, whichever is greater.

(b) Computation of the 15 percent: Participating HHA.

The 15 percent is computed as follows:

(1) For the initial bond—on the basis of Medicare payments made by HCFA to the HHA in the HHA’s most recent fiscal year as shown in the HHA’s most recent cost report that has been accepted by HCFA, if the initial bond will cover less than a full fiscal year, the computation of the 15 percent will be based on the number of months of the fiscal year that the bond will cover.

(2) For subsequent bonds—on the basis of Medicare payments made by HCFA in the most recent fiscal year for
which a cost report has been accepted. However, if payments in the first six months of the current fiscal year differ from such an amount by more than 25 percent, then the amount of the bond is 15 percent of such payments projected on an annualized basis.

(c) Computation of 15 percent: An HHA that seeks to become a participating HHA by obtaining assets or ownership interest. For an HHA that seeks to become a participating HHA by purchasing the assets or the ownership interest of a participating or formerly participating HHA, the 15 percent is computed on the basis of Medicare payments made by HCFA to the participating or formerly participating HHA in the most recent fiscal year that a cost report has been accepted.

(d) Change of ownership. For an HHA that undergoes a change of ownership the 15 percent is computed on the basis of Medicare payments made by HCFA to the HHA for the most recently accepted cost report.

(e) An HHA that seeks to become a participating HHA without obtaining assets or ownership interest. For an HHA that seeks to become a participating HHA without purchasing the assets or the ownership interest of a participating or formerly participating HHA, the 15 percent computation does not apply.

(f) Exception to the basic rule. If an HHA's overpayment in the most recently accepted cost report exceeds 15 percent of annual payments, HCFA may require the HHA to secure a bond in an amount up to or equal to the amount of overpayment, provided the amount of the bond is not less than $50,000.

(g) Expiration of the 15 percent provision. For an annual surety bond, or for a rider on a continuous surety bond, that is required to be submitted on or after June 1, 2005, notwithstanding any reference in this subpart to 15 percent as a basis for determining the amount of the bond, the amount of the bond or rider, as applicable, must be $50,000 or such amount as HCFA specifies in accordance with paragraph (f) of this section, whichever amount is greater.

§ 489.66 Additional requirements of the surety bond.

The surety bond that an HHA obtains under this subpart must meet the following additional requirements:

(a) The bond must guarantee that within 30 days of receiving written notice from HCFA of an unpaid claim or unpaid civil money penalty or assessment, which notice contains sufficient evidence to establish the Surety’s liability under the bond, the Surety will pay HCFA, up to the stated amount of the bond—

(1) The full amount of any unpaid claim, plus accrued interest, for which the HHA is responsible; and

(2) The full amount of any unpaid civil money penalty or assessment imposed by HCFA on the HHA, plus accrued interest.

(b) The bond must provide the following:

(1) The Surety is liable for unpaid claims, unpaid civil money penalties, and unpaid assessments that are discovered when the surety bond is in effect, regardless of when the payment, overpayment, or other event giving rise to the claim, civil money penalty, or assessment occurred, provided HCFA makes a written demand for payment from the Surety during, or within 90 days after, the term of the bond.

(2) If the HHA fails to furnish a bond meeting the requirements of this subpart F for the year following expiration of the term of an annual bond, or if the HHA fails to submit a rider when a rider is required to be submitted under this subpart, or if the HHA’s provider agreement is terminated, the last bond or rider, as applicable, submitted by the HHA to HCFA, which bond or applicable rider meets the requirements of this subpart, remains effective and the Surety remains liable for unpaid claims, civil money penalties, and assessments that—

(i) HCFA determines or imposes on or asserts against the HHA based on overpayments or other events that took place during or prior to the term of the last bond or rider; and

(ii) Were determined or imposed during the 2 years following the date the
§ 489.67 Term and type of bond.

(a) Each participating HHA that does not meet the criteria for waiver under §489.62 must submit to HCFA in a form as HCFA may specify, a surety bond for a term beginning January 1, 1998. If an annual bond is submitted for the initial term, it must be effective through the end of the HHA’s current fiscal year.

(b) Type of bond. The type of bond required to be submitted by an HHA under this subpart may be either—

(1) An annual bond (that is, a bond that specifies an effective annual period corresponding to the HHA’s fiscal year); or

(2) A continuous bond (that is, a bond that remains in full force and effect from term to term unless it is terminated or canceled as provided for in the bond or as otherwise provided by law) that is updated by the Surety, via the issuance of a rider, for a particular fiscal year for which the bond amount has changed or will change.

(c) HHA that seeks to become a participating HHA.

(1) An HHA that seeks to become a participating HHA must submit a surety bond with its enrollment application (Form HCFA-855, OMB number 0938-0685). The term of the initial surety bond must be effective from the effective date of provider agreement as specified in §489.13 of this part. However, if the effective date of the provider agreement is less than 30 days before the end of the HHA’s current fiscal year, the HHA may obtain a bond effective through the end of the next fiscal year, provided the amount of the bond is the greater of $75,000 or 20 percent of the amount determined from the computation specified in §489.65(c) as applicable.

(2) An HHA that seeks to become a participating HHA through the purchase or transfer of assets or ownership of an HHA or by HCFA or by HCFA’s fiscal intermediaries.

(e) The bond must provide the Surety’s name, street address or post office box number, city, state, and zipcode to which the HCFA notice provided for in paragraph (a) of this section is to be sent.

[63 FR 313, Jan. 5, 1998, as amended at 63 FR 29055, June 1, 1998]

§ 489.67 Term and type of bond.

(a) Each participating HHA that does not meet the criteria for waiver under §489.62 must submit to HCFA in a form as HCFA may specify, a surety bond for a term beginning January 1, 1998. If an annual bond is submitted for the initial term, it must be effective through the end of the HHA’s current fiscal year.

(b) Type of bond. The type of bond required to be submitted by an HHA under this subpart may be either—

(1) An annual bond (that is, a bond that specifies an effective annual period corresponding to the HHA’s fiscal year); or

(2) A continuous bond (that is, a bond that remains in full force and effect from term to term unless it is terminated or canceled as provided for in the bond or as otherwise provided by law) that is updated by the Surety, via the issuance of a rider, for a particular fiscal year for which the bond amount has changed or will change.

(c) HHA that seeks to become a participating HHA.

(1) An HHA that seeks to become a participating HHA must submit a surety bond with its enrollment application (Form HCFA-855, OMB number 0938-0685). The term of the initial surety bond must be effective from the effective date of provider agreement as specified in §489.13 of this part. However, if the effective date of the provider agreement is less than 30 days before the end of the HHA’s current fiscal year, the HHA may obtain a bond effective through the end of the next fiscal year, provided the amount of the bond is the greater of $75,000 or 20 percent of the amount determined from the computation specified in §489.65(c) as applicable.

(2) An HHA that seeks to become a participating HHA through the purchase or transfer of assets or ownership of an HHA or by HCFA or by HCFA’s fiscal intermediaries.

(e) The bond must provide the Surety’s name, street address or post office box number, city, state, and zipcode to which the HCFA notice provided for in paragraph (a) of this section is to be sent.
§ 489.72 Effect of review reversing determination.

In the event a Surety has paid HCFA on the basis of liability incurred under a bond obtained by an HHA under this subpart F, and to the extent the HHA that obtained such bond (or the Surety under § 489.71) is subsequently successful in appealing the determination that was the basis of the unpaid claim or

(a) The failure of a participating HHA to obtain, file timely, and maintain a surety bond in accordance with this subpart F and HCFA’s instructions is sufficient under § 489.53(a)(1) for HCFA to terminate the HHA’s provider agreement.

(b) The failure of an HHA seeking to become a participating HHA to obtain and file timely a surety bond in accordance with this subpart F and HCFA’s instructions is sufficient under § 489.12(a)(3) for HCFA to refuse to enter into a provider agreement with the HHA.

§ 489.69 Evidence of compliance.

(a) HCFA may at any time require an HHA to make a specific showing of being in compliance with the requirements of this Subpart F and may require the HHA to submit such additional evidence as HCFA considers sufficient to demonstrate the HHA’s compliance.

(b) If requested by HCFA to do so, the failure of an HHA to timely furnish sufficient evidence to HCFA to demonstrate compliance with the requirements of this Subpart F is sufficient for HCFA to terminate the HHA’s provider agreement under § 489.53(a)(1) or to refuse to enter into a provider agreement with the HHA under § 489.12(a)(3), as applicable.

§ 489.70 Effect of payment by the Surety.

A Surety’s payment to HCFA under a bond for an unpaid claim or an unpaid civil money penalty or assessment, constitutes—

(a) Collection of the unpaid claim or unpaid civil money penalty or assessment (to the extent the Surety’s payment on the bond covers such unpaid claim, civil money penalty, or assessment); and

(b) A basis for termination of the HHA’s provider agreement under § 489.53(a)(1).

§ 489.71 Surety’s standing to appeal Medicare determinations.

A Surety has standing to appeal any matter that the HHA could appeal, provided the Surety satisfies all jurisdictional and procedural requirements that would otherwise have applied to the HHA, and provided the HHA is not, itself, actively pursuing its appeal rights under this chapter, and provided further that, with respect to unpaid claims, the Surety has paid HCFA all amounts owed to HCFA by the HHA on such unpaid claims, up to the amount of the bond.

§ 489.72 Effect of review reversing determination.

In the event a Surety has paid HCFA on the basis of liability incurred under a bond obtained by an HHA under this subpart F, and to the extent the HHA that obtained such bond (or the Surety under § 489.71) is subsequently successful in appealing the determination that was the basis of the unpaid claim or

(a) The failure of a participating HHA to obtain, file timely, and maintain a surety bond in accordance with this subpart F and HCFA’s instructions is sufficient under § 489.53(a)(1) for HCFA to terminate the HHA’s provider agreement.

(b) The failure of an HHA seeking to become a participating HHA to obtain and file timely a surety bond in accordance with this subpart F and HCFA’s instructions is sufficient under § 489.12(a)(3) for HCFA to refuse to enter into a provider agreement with the HHA.

§ 489.69 Evidence of compliance.

(a) HCFA may at any time require an HHA to make a specific showing of being in compliance with the requirements of this Subpart F and may re-
unpaid civil money penalty or assessment that caused the Surety to pay HCFA under the bond, HCFA will refund to the Surety the amount the Surety paid to HCFA to the extent such amount relates to the matter that was successfully appealed by the HHA (or by the Surety), provided all review, including judicial review, has been completed on such matter. Any additional amounts owing as a result of the appeal will be paid to the HHA.

§ 489.73 Effect of conditions of payment.

If a Surety has paid an amount to HCFA on the basis of liability incurred under a bond obtained by an HHA under this subpart F, and HCFA subsequently collects from the HHA, in whole or in part, on such unpaid claim, civil money penalty, or assessment that was the basis for the Surety’s liability, HCFA reimburses the Surety such amount as HCFA collected from the HHA, up to the amount paid by the Surety to HCFA, provided the Surety has no other liability to HCFA under the bond.

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

[63 FR 29656, June 1, 1998]

§ 489.74 Incorporation into existing provider agreements.

The requirements of this subpart F are deemed to be incorporated into existing HHA provider agreements effective January 1, 1998.

[63 FR 315, Jan. 5, 1998. Redesignated at 63 FR 29656, June 1, 1998]

Subparts G–H [Reserved]

Subpart I—Advance Directives

SOURCE: 57 FR 8203, Mar. 6, 1992, unless otherwise noted.

§ 489.100 Definition.

For purposes of this part, advance directive means a written instruction, such as a living will or durable power of attorney for health care, recognized under State law (whether statutory or as recognized by the courts of the State), relating to the provision of health care when the individual is incapacitated.

§ 489.102 Requirements for providers.

(a) Hospitals, critical access hospitals, skilled nursing facilities, nursing facilities, home health agencies, providers of home health care (and for Medicaid purposes, providers of personal care services), and hospices must maintain written policies and procedures concerning advance directives with respect to all adult individuals receiving medical care by or through the provider and are required to:

(1) Provide written information to such individuals concerning—

(i) An individual’s rights under State law (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. Providers are to update and disseminate amended information as soon as possible, but no later than 90 days from the effective date of the changes to State law; and

(ii) The written policies of the provider or organization respecting the implementation of such rights, including a clear and precise statement of limitation if the provider cannot implement an advance directive on the basis of conscience. At a minimum, a provider’s statement of limitation should:

(A) Clarify any differences between institution-wide conscience objections and those that may be raised by individual physicians;

(B) Identify the state legal authority permitting such objection; and

(C) Describe the range of medical conditions or procedures affected by the conscience objection.

(2) Document in the individual’s medical record whether or not the individual has executed an advance directive;

(3) Not condition the provision of care or otherwise discriminate against an individual based on whether or not
the individual has executed an advance directive;
(4) Ensure compliance with requirements of State law (whether statutory or recognized by the courts of the State) regarding advance directives. The provider must inform individuals that complaints concerning the advance directive requirements may be filed with the State survey and certification agency;
(5) Provide for education of staff concerning its policies and procedures on advance directives; and
(6) Provide for community education regarding issues concerning advance directives that may include material required in paragraph (a)(1) of this section, either directly or in concert with other providers and organizations. Separate community education materials may be developed and used, at the discretion of providers. The same written materials do not have to be provided in 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. A provider must be able to document its community education efforts.

(b) The information specified in paragraph (a) of this section is furnished:
(1) In the case of a hospital, at the time of the individual’s admission as an inpatient.
(2) In the case of a skilled nursing facility at the time of the individual’s admission as a resident.
(3)(i) In the case of a home health agency, in advance of the individual coming under the care of the agency. The HHA may furnish advance directives information to a patient at the time of the first home visit, as long as the information is furnished before care is provided.
(ii) In the case of personal care services, in advance of the individual coming under the care of the personal care services provider. The personal care provider may furnish advance directives information to a patient at the time of the first home visit, as long as the information is furnished before care is provided.
(4) In the case of a hospice program, at the time of initial receipt of hospice care by the individual from the program.
(c) The providers listed in paragraph (a) of this section—
(1) Are not required to provide care that conflicts with an advance directive.
(2) Are not required to implement an advance directive if, as a matter of conscience, the provider cannot implement an advance directive and State law allows any health care provider or any agent of such provider to conscientiously object.
(d) Prepaid or eligible organizations (as specified in sections 1833(a)(1)(A) and 1876(b) of the Act) must meet the requirements specified in §417.436 of this chapter.
(e) If an adult individual is incapacitated at the time of admission or at the start of care and is unable to receive information (due to the incapacitating conditions or a mental disorder) or articulate whether or not he or she has executed an advance directive, then the provider may give advance directive information to the individual’s family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated individual or to a surrogate or other concerned persons in accordance with State law. The provider is not relieved of its obligation to provide this information to the individual once he or she is no longer incapacitated or unable to receive such information. Follow-up procedures must be in place to provide the information to the individual directly at the appropriate time.
PART 491—CERTIFICATION OF CERTAIN HEALTH FACILITIES

Subpart A—Rural Health Clinics: Conditions for Certification; and FQHCs Conditions for Coverage

§ 491.1 Purpose and scope.

This subpart sets forth the conditions that rural health clinics or FQHCs must meet in order to qualify for reimbursement under Medicare (title XVIII of the Social Security Act) and that rural health clinics must meet in order to qualify for reimbursement under Medicaid (title XIX of the Act).

[57 FR 24982, June 12, 1992]

§ 491.2 Definitions.

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

Direct services means services provided by the clinic’s staff.

FQHC means an entity as defined in § 405.2401(b).

Nurse practitioner means a registered professional nurse who is currently licensed to practice in the State, who meets the State’s requirements governing the qualifications of nurse practitioners, and who meets one of the following conditions:

(1) Is currently certified as a primary care nurse practitioner by the American Nurses’ Association or by the National Board of Pediatric Nurse Practitioners and Associates; or

(2) Has satisfactorily completed a formal 1 academic year educational program that:

(i) Prepares registered nurses to perform an expanded role in the delivery of primary care;

(ii) Includes at least 4 months (in the aggregate) of classroom instruction and a component of supervised clinical practice; and

(iii) Awards a degree, diploma, or certificate to persons who successfully complete the program; or

(3) Has successfully completed a formal educational program (for preparing registered nurses to perform an expanded role in the delivery of primary care) that does not meet the requirements of paragraph (b)(2) of this section, and has been performing an expanded role in the delivery of primary care for a total of 12 months during the 18-month period immediately preceding the effective date of this subpart.

Physician means a doctor of medicine or osteopathy legally authorized to practice medicine or surgery in the State.

Physician assistant means a person who meets the applicable State requirements governing the qualifications for assistants to primary care physicians, and who meets at least one of the following conditions:

(1) Is currently certified by the National Commission on Certification of Physician Assistants to assist primary care physicians; or

(2) Has satisfactorily completed a program for preparing physician’s assistants that:

(i) Was at least 1 academic year in length;

(ii) Consisted of supervised clinical practice and at least 4 months (in the aggregate) of classroom instruction directed toward preparing students to deliver health care; and

(iii) Was accredited by the American Medical Association’s Committee on Allied Health Education and Accreditation; or

(3) Has satisfactorily completed a formal educational program (for preparing physician assistants) that does
not meet the requirements of paragraph (d)(2) of this section and assisted primary care physicians for a total of 12 months during the 18-month period that ended on December 31, 1986.

Rural area means an area that is not delineated as an urbanized area by the Bureau of the Census.

Rural health clinic or clinic means a clinic that is located in a rural area designated as a shortage area, is not a rehabilitation agency or a facility primarily for the care and treatment of mental diseases, and meets all other requirements of this subpart.

Shortage area means a defined geographic area designated by the Department as having either a shortage of personal health services (under section 1302(7) of the Public Health Service Act) or a shortage of primary medical care manpower (under section 332 of that Act).

Secretary means the Secretary of Health and Human Services, or any official to whom he has delegated the pertinent authority.

§ 491.5 Location of clinic.

(a) Basic requirements. (1) An RHC is located in a rural area that is designated as a shortage area.

(2) An FQHC is located in a rural or urban area that is designated as either a shortage area or an area that has a medically underserved population.

(b) Exceptions. (1) HCFA does not disqualify an RHC approved under this subpart if the area in which it is located subsequently fails to meet the definition of a rural, shortage area.

(2) A private, nonprofit facility that meets all other conditions of this subpart except for location in a shortage area will be certified if, on July 1, 1977, it was operating in a rural area that is determined by the Secretary (on the basis of the ratio of primary care physicians to the general population) to have an insufficient supply of physicians to meet the needs of the area served.

(c) Determinations on these exceptions will be made by the Secretary upon application by the facility.

§ 491.4 Compliance with Federal, State and local laws.

The rural health clinic or FQHC and its staff are in compliance with applicable Federal, State and local laws and regulations.

(a) Licensure of clinic or center. The clinic or center is licensed pursuant to applicable State and local law.

(b) Licensure, certification or registration of personnel. Staff of the clinic or center are licensed, certified or registered in accordance with applicable State and local laws.

[57 FR 24982, June 12, 1992]
§ 491.6 Physical plant and environment.

(a) Construction. The clinic or center is constructed, arranged, and maintained to assure access to and safety of patients, and provides adequate space for the provision of direct services.

(b) Maintenance. The clinic or center has a preventive maintenance program to ensure that:
   (1) All essential mechanical, electrical and patient-care equipment is maintained in safe operating condition;
   (2) Drugs and biologicals are appropriately stored; and
   (3) The premises are clean and orderly.

(c) Emergency procedures. The clinic or center assures the safety of patients in case of non-medical emergencies by:
   (1) Training staff in handling emergencies;
   (2) Placing exit signs in appropriate locations; and
   (3) Taking other appropriate measures that are consistent with the particular conditions of the area in which the clinic or center is located.

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§ 491.7 Organizational structure.

(a) Basic requirements. (1) The clinic or center is under the medical direction of a physician, and has a health care staff that meets the requirements of § 491.8.

(b) Disclosure. The clinic or center discloses the names and addresses of:
   (1) Its owners, in accordance with section 1124 of the Social Security Act (42 U.S.C. 132 A-3);
§ 491.8 Staffing and staff responsibilities.

(a) Staffing. (1) The clinic or center has a health care staff that includes one or more physicians. Rural health clinic staffs must also include one or more physician’s assistants or nurse practitioners.

(2) The physician member of the staff may be the owner of the rural health clinic, an employee of the clinic or center, or under agreement with the clinic or center to carry out the responsibilities required under this section.

(3) The physician assistant, nurse practitioner, nurse-midwife, clinical social worker, or clinical psychologist member of the staff may be the owner or an employee of the clinic or center, or may furnish services under contract to the center.

(4) The staff may also include ancillary personnel who are supervised by the professional staff.

(5) The staff is sufficient to provide the services essential to the operation of the clinic or center.

(6) A physician, nurse practitioner, physician assistant, nurse-midwife, clinical social worker, or clinical psychologist is available to furnish patient care services at all times the clinic or center operates. In addition, for rural health clinics, a nurse practitioner or a physician assistant is available to furnish patient care services at least 60 percent of the time the clinic operates.

(b) Physician responsibilities. (1) The physician:

(i) Except for services furnished by a clinical psychologist in an FQHC, which State law permits to be provided without physician supervision, provides medical direction for the clinic’s or center’s health care activities and consultation for, and medical supervision of, the health care staff.

(ii) In conjunction with the physician’s assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the clinic’s or center’s written policies and the services provided to Federal program patients; and

(iii) Periodically reviews the clinic’s or center’s patient records, provides medical orders, and provides medical care services to the patients of the clinic or center.

(2) A physician is present for sufficient periods of time, at least once in every 2 week period (except in extraordinary circumstances), to provide the medical direction, medical care services, consultation and supervision described in paragraph (b)(1) of this section and is available through direct telecommunication for consultation, assistance with medical emergencies, or patient referral. The extraordinary circumstances are documented in the records of the clinic or center.

(c) Physician assistant and nurse practitioner responsibilities. (1) The physician assistant and the nurse practitioner members of the clinic’s or center’s staff:

(i) Participate in the development, execution and periodic review of the written policies governing the services the clinic or center furnishes;

(ii) Participate with a physician in a periodic review of the patients’ health records.

(ii) The physician assistant or nurse practitioner performs the following functions, to the extent they are not being performed by a physician:

(i) Provides services in accordance with the clinic’s or center’s policies;

(ii) Arranges for, or refers patients to, needed services that cannot be provided at the clinic or center; and

(iii) Assures that adequate patient health records are maintained and transferred as required when patients are referred.

§ 491.9 Provision of services.

(a) Basic requirements. (1) All services offered by the clinic or center are furnished in accordance with applicable Federal, State, and local laws; and

(2) The clinic or center is primarily engaged in providing outpatient health services and meets all other conditions of this subpart.
§ 491.10 Patient health records.

(a) Records system. (1) The clinic or center maintains a clinical record system in accordance with written policies and procedures.

(2) A designated member of the professional staff is responsible for maintaining the records and for insuring that they are completely and accurately documented, readily accessible, and systematically organized.

(3) For each patient receiving health care services, the clinic or center maintains a record that includes:

(i) A description of the services the clinic or center furnishes directly and those furnished through agreement or arrangement.

(ii) Guidelines for the medical management of health problems which include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the clinic or center.

(iii) Rules for the storage, handling, and administration of drugs and biologicals.

(4) These policies are reviewed at least annually by the group of professional personnel required under paragraph (b)(2) of this section and reviewed as necessary by the clinic or center.

(c) Direct services. (1) General. The clinic or center staff furnishes those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at the entry point into the health care delivery system. These include medical history, physical examination, assessment of health status, and treatment for a variety of medical conditions.

(2) Laboratory. These requirements apply to RHCs but not to FQHCs. The RHC provides laboratory services in accordance with part 493 of this chapter, which implements the provisions of section 353 of the Public Health Service Act. The RHC provides basic laboratory services essential to the immediate diagnosis and treatment of the patient, including:

(i) Chemical examinations of urine by stick or tablet method or both (including urine ketones);

(ii) Hemoglobin or hematocrit;

(iii) Blood glucose;

(iv) Examination of stool specimens for occult blood;

(v) Pregnancy tests; and

(vi) Primary culturing for transmittal to a certified laboratory.

(3) Emergency. The clinic or center provides medical emergency procedures as a first response to common life-threatening injuries and acute illness and has available the drugs and biologicals commonly used in life-saving procedures, such as analgesics, anesthetics (local), antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids.

(d) Services provided through agreements or arrangements. (1) The clinic or center has agreements or arrangements with one or more providers or suppliers participating under Medicare or Medicaid to furnish other services to its patients, including:

(i) Inpatient hospital care;

(ii) Physician(s) services (whether furnished in the hospital, the office, the patient's home, a skilled nursing facility, or elsewhere); and

(iii) Additional and specialized diagnostic and laboratory services that are not available at the clinic or center.

(2) If the agreements are not in writing, there is evidence that patients referred by the clinic or center are being accepted and treated.

(i) Identification and social data, evidence of consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient;

(ii) Reports of physical examinations, diagnostic and laboratory test results, and consultative findings;

(iii) All physician’s orders, reports of treatments and medications, and other pertinent information necessary to monitor the patient’s progress;

(iv) Signatures of the physician or other health care professional.

(b) Protection of record information. (1) The clinic or center maintains the confidentiality of record information and provides safeguards against loss, destruction or unauthorized use.

(2) Written policies and procedures govern the use and removal of records from the clinic or center and the conditions for release of information.

(3) The patient’s written consent is required for release of information not authorized to be released without such consent.

(c) Retention of records. The records are retained for at least 6 years from date of last entry, and longer if required by State statute.

(Secs. 1102, 1833 and 1902(a)(13), Social Security Act; 49 Stat. 647, 91 Stat. 1485 (42 U.S.C. 1302, 13951 and 1396a(a)(13))


§ 491.11 Program evaluation.

(a) The clinic or center carries out, or arranges for, an annual evaluation of its total program.

(b) The evaluation includes review of:

(1) The utilization of clinic or center services, including at least the number of patients served and the volume of services;

(2) A representative sample of both active and closed clinical records; and

(3) The clinic’s or center’s health care policies.

(c) The purpose of the evaluation is to determine whether:

(1) The utilization of services was appropriate;

(2) The established policies were followed; and

(3) Any changes are needed.

(d) The clinic or center staff considers the findings of the evaluation and takes corrective action if necessary.

[57 FR 24984, June 12, 1992]

PART 493—LABORATORY REQUIREMENTS

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493.1243 Condition: Chemistry.
493.1245 Condition: Routine chemistry.
493.1247 Condition: Endocrinology.
493.1249 Condition: Toxicology.
493.1251 Condition: Hematology.
493.1253 Condition: Pathology.
493.1255 Condition: Cytology.
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Laboratories Performing High Complexity Testing

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493.1487 Condition: Laboratories performing high complexity testing; testing personnel.
493.1489 Standard; Testing personnel qualifications.
493.1491 Technologist qualifications on or before February 28, 1992.
493.1495 Standard; Testing personnel responsibilities.

Subparts N-O—[Reserved]

Subpart P—Quality Assurance for Moderate Complexity (Including the Subcategory) or High Complexity Testing, or Any Combination of These Tests

493.1701 Condition: Quality assurance; moderate complexity (including the subcategory) or high complexity testing, or any combination of these tests.
493.1703 Standard; Patient test management assessment.
493.1705 Standard; Quality control assessment.
493.1707 Standard; Proficiency testing assessment.
493.1709 Standard; Comparison of test results.
493.1711 Standard; Relationship of patient information to patient test results.
493.1713 Standard; Personnel assessment.
493.1715 Standard; Communications.
493.1717 Standard; Complaint investigations.
493.1719 Standard; Quality assurance review with staff.
493.1721 Standard; Quality assurance records.

Subpart Q—Inspection

493.1771 Condition: Inspection requirements applicable to all CLIA-certified and CLIA-exempt laboratories.
493.1773 Standard; Basic inspection requirements for all laboratories issued a CLIA certificate and CLIA-exempt laboratories.
493.1775 Standard; Inspection of laboratories issued a certificate of waiver.
§ 493.2 Definitions.

As used in this part, unless the context indicates otherwise—

Accredited institution means a school or program which—

(a) Admits as regular student only persons having a certificate of graduation from a school providing secondary education, or the recognized equivalent of such certificate;

(b) Is legally authorized within the State to provide a program of education beyond secondary education;

(c) Provides an educational program for which it awards a bachelor's degree or provides not less than a 2-year program which is acceptable toward such a degree, or provides an educational program for which it awards a master's or doctoral degree;

(d) Is accredited by a nationally recognized accrediting agency or association.

This definition includes any foreign institution of higher education that HHS or its designee determines meets substantially equivalent requirements.

Accredited laboratory means a laboratory that has voluntarily applied for and been accredited by a private, nonprofit accreditation organization approved by HCFA in accordance with this part;
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Adverse action means the imposition of a principal or alternative sanction by HCFA.

ALJ stands for Administrative Law Judge.

Alternative sanctions means sanctions that may be imposed in lieu of or in addition to principal sanctions. The term is synonymous with “intermediate sanctions” as used in section 1846 of the Act.

Analyte means a substance or constituent for which the laboratory conducts testing.

Approved accreditation organization for laboratories means a private, nonprofit accreditation organization that has formally applied for and received HCFA’s approval based on the organization’s compliance with this part.

Approved State laboratory program means a licensure or other regulatory program for laboratories in a State, the requirements of which are imposed under State law, and the State laboratory program has received HCFA approval based on the State’s compliance with this part.

Authorized person means an individual authorized under State law to order tests or receive test results, or both.

Challenge means, for quantitative tests, an assessment of the amount of substance or analyte present or measured in a sample. For qualitative tests, a challenge means the determination of the presence or the absence of an analyte, organism, or substance in a sample.

CLIA means the Clinical Laboratory Improvement Amendments of 1988.

CLIA certificate means any of the following types of certificates issued by HCFA or its agent:

1. Certificate of compliance means a certificate issued to a laboratory after an inspection that finds the laboratory to be in compliance with all applicable condition level requirements, or reissued before the expiration date, pending an appeal, in accordance with §493.49, when an inspection has found the laboratory to be out of compliance with one or more condition level requirements.

2. Certificate for provider-performed microscopy (PPM) procedures means a certificate issued or reissued before the expiration date, pending an appeal, in accordance with §493.47, to a laboratory in which a physician, midlevel practitioner or dentist performs no tests other than PPM procedures and, if desired, waived tests listed in §493.15(c).

3. Certificate of accreditation means a certificate issued on the basis of the laboratory’s accreditation by an accreditation organization approved by HCFA (indicating that the laboratory is deemed to meet applicable CLIA requirements) or reissued before the expiration date, pending an appeal, in accordance with §493.63, when a validation or complaint survey has found the laboratory to be noncompliant with one or more CLIA conditions.

4. Certificate of registration or registration certificate means a certificate issued or reissued before the expiration date, pending an appeal, in accordance with §493.45, that enables the entity to conduct moderate or high complexity laboratory testing or both until the entity is determined to be in compliance through a survey by HCFA or its agent; or in accordance with §493.57 to an entity that is accredited by an approved accreditation organization.

5. Certificate of waiver means a certificate issued or reissued before the expiration date, pending an appeal, in accordance with §493.37, to a laboratory to perform only the waived tests listed at §493.15(c).

CLIA-exempt laboratory means a laboratory that has been licensed or approved by a State where HCFA has determined that the State has enacted laws relating to laboratory requirements that are equal to or more stringent than CLIA requirements and the State licensure program has been approved by HCFA in accordance with subpart E of this part.

Condition level deficiency means noncompliance with one or more condition level requirements.

Condition level requirements means any of the requirements identified as “conditions” in subparts G through Q of this part.

Credible allegation of compliance means a statement or documentation that—

1. Is made by a representative of a laboratory that has a history of having
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maintained a commitment to compliance and of taking corrective action when required;

(2) Is realistic in terms of its being possible to accomplish the required corrective action between the date of the exit conference and the date of the allegation; and

(3) Indicates that the problem has been resolved.

Dentist means a doctor of dental medicine or doctor of dental surgery licensed by the State to practice dentistry within the State in which the laboratory is located.

Equivalency means that an accreditation organization’s or a State laboratory program’s requirements, taken as a whole, are equal to or more stringent than the CLIA requirements established by HCFA, taken as whole. It is acceptable for an accreditation organization’s or State laboratory program’s requirements to be organized differently or otherwise vary from the CLIA requirements, as long as (1) all of the requirements taken as a whole would provide at least the same protection as the CLIA requirements taken as a whole; and (2) a finding of noncompliance with respect to CLIA requirements taken as a whole would be matched by a finding of noncompliance with the accreditation or State requirements taken as a whole.

HCFA agent means an entity with which HCFA arranges to inspect laboratories and assess laboratory activities against CLIA requirements and may be a State survey agency, a private, nonprofit organization other than an approved accreditation organization, a component of HHS, or any other governmental component HCFA approves for this purpose. In those instances where all of the laboratories in a State are exempt from CLIA requirements, based on the approval of a State’s exemption request, the State survey agency is not the HCFA agent.

HHS means the Department of Health and Human Services, or its designee.

Immediate jeopardy means a situation in which immediate corrective action is necessary because the laboratory’s noncompliance with one or more condition level requirements has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health or safety of the general public. This term is synonymous with imminent and serious risk to human health and significant hazard to the public health.

Intentional violation means knowing and willful noncompliance with any CLIA condition.

Kit means all components of a test that are packaged together.

Laboratory means a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, 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. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories.

Midlevel practitioner means a nurse midwife, nurse practitioner, or physician assistant, licensed by the State within which the individual practices, if such licensing is required in the State in which the laboratory is located.

Operator means the individual or group of individuals who oversee all facets of the operation of a laboratory and who bear primary responsibility for the safety and reliability of the results of all specimen testing performed in that laboratory. The term includes—

(1) A director of the laboratory if he or she meets the stated criteria; and

(2) The members of the board of directors and the officers of a laboratory that is a small corporation under subchapter S of the Internal Revenue Code.

Owner means any person who owns any interest in a laboratory except for an interest in a laboratory whose stock and/or securities are publicly traded. (That is e.g., the purchase of shares of stock or securities on the New York
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Stock Exchange in a corporation owning a laboratory would not make a person an owner for the purpose of this regulation.

Party means a laboratory affected by any of the enforcement procedures set forth in this subpart, by HCFA or the OIG, as appropriate.

Performance characteristic means a property of a test that is used to describe its quality, e.g., accuracy, precision, analytical sensitivity, analytical specificity, reportable range, reference range, etc.

Performance specification means a value or range of values for a performance characteristic, established or verified by the laboratory, that is used to describe the quality of patient test results.

Physician means an individual with a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine degree who is licensed by the State to practice medicine, osteopathy, or podiatry within the State in which the laboratory is located.

Principal sanction means the suspension, limitation, or revocation of any type of CLIA certificate or the cancellation of the laboratory’s approval to receive Medicare payment for its services.

Prospective laboratory means a laboratory that is operating under a registration certificate or is seeking any of the three other types of CLIA certificates.

Rate of disparity means the percentage of sample validation inspections for a specific accreditation organization or State where HCFA, the State survey agency or other HCFA agent finds noncompliance with one or more condition level requirements but no comparable deficiencies were cited by the accreditation organization or the State, and it is reasonable to conclude that the deficiencies were present at the time of the most recent accreditation organization or State licensure inspection.

Example: Assume the State survey agency, HCFA or other HCFA agent performs 200 sample validation inspections for laboratories accredited by a single accreditation organization or licensed in an exempt State during a validation review period and finds that 60 of the 200 laboratories had one or more condition level requirements out of compliance. HCFA reviews the validation and accreditation organization’s or State’s inspections of the validated laboratories and determines that the State or accreditation organization found comparable deficiencies in 22 of the 60 laboratories and it is reasonable to conclude that deficiencies were present in the remaining 38 laboratories at the time of the accreditation organization’s or State’s inspection. Thirty-eight divided by 200 equals a 19 percent rate of disparity.

Referee laboratory means a laboratory currently in compliance with applicable CLIA requirements, that has had a record of satisfactory proficiency testing performance for all testing events for at least one year for a specific test, analyte, subspecialty, or specialty and has been designated by an HHS approved proficiency testing program as a referee laboratory for analyzing proficiency testing specimens for the purpose of determining the correct response for the specimens in a testing event for that specific test, analyte, subspecialty, or specialty.

Reference range means the range of test values expected for a designated population of individuals, e.g., 95 percent of individuals that are presumed to be healthy (or normal).

Sample in proficiency testing means the material contained in a vial, on a slide, or other unit that contains material to be tested by proficiency testing program participants. When possible, samples are of human origin.

State includes, for purposes of this part, each of the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands and a political subdivision of a State where the State, acting pursuant to State law, has expressly delegated powers to the political subdivision sufficient to authorize the political subdivision to act for the State in enforcing requirements equal to or more stringent than CLIA requirements.

State licensure means the issuance of a license to, or the approval of, a laboratory by a State laboratory program as meeting standards for licensing or approval established under State law.

State licensure program means a State laboratory licensure or approval program.

State survey agency means the State health agency or other appropriate State or local agency that has an
agreement under section 1864 of the Social Security Act and is used by HCFA to perform surveys and inspections.

Substantial allegation of noncompliance means a complaint from any of a variety of sources (including complaints submitted in person, by telephone, through written correspondence, or in newspaper or magazine articles) that, if substantiated, would have an impact on the health and safety of the general public or of individuals served by a laboratory and raises doubts as to a laboratory's compliance with any condition level requirement.

Target value for quantitative tests means either the mean of all participant responses after removal of outliers (those responses greater than 3 standard deviations from the original mean) or the mean established by definitive or reference methods acceptable for use in the National Reference System for the Clinical Laboratory (NRSCL) by the National Committee for the Clinical Laboratory Standards (NCCLS). In instances where definitive or reference methods are not available or a specific method's results demonstrate bias that is not observed with actual patient specimens, as determined by a defensible scientific protocol, a comparative method or a method group ("peer" group) may be used. If the method group is less than 10 participants, "target value" means the overall mean after outlier removal (as defined above) unless acceptable scientific reasons are available to indicate that such an evaluation is not appropriate.

Unsatisfactory proficiency testing performance means failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for two consecutive or two of three consecutive testing events.

Validation review period means the one year time period during which HCFA conducts validation inspections and evaluates the results of the most recent surveys performed by an accreditation organization or State laboratory program.

§ 493.3 Applicability.

(a) Basic rule. Except as specified in paragraph (b) of this section, a laboratory will be cited as out of compliance with section 353 of the Public Health Service Act unless it—

(1) Has a current, unrevoked or unsuspended certificate of waiver, registration certificate, certificate of compliance, certificate for PPM procedures, or certificate of accreditation issued by HHS applicable to the category of examinations or procedures performed by the laboratory; or

(2) Is CLIA-exempt.

(b) Exception. These rules do not apply to components or functions of—

(1) Any facility or component of a facility that only performs testing for forensic purposes;

(2) Research laboratories that test human specimens but do not report patient specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of individual patients; or

(3) Laboratories certified by the National Institutes on Drug Abuse (NIDA), in which drug testing is performed which meets NIDA guidelines and regulations. However, all other...
§ 493.5 Categories of tests by complexity.

(a) Laboratory tests are categorized as one of the following:
   (1) Waived tests.
   (2) Tests of moderate complexity, including the subcategory of PPM procedures.
   (3) Tests of high complexity.
   (b) A laboratory may perform only waived tests, only tests of moderate complexity, only PPM procedures, only tests of high complexity or any combination of these tests.
   (c) Each laboratory must be either CLIA-exempt or possess one of the following CLIA certificates, as defined in §493.2:
      (1) Certificate of registration or registration certificate.
      (2) Certificate of waiver.
      (3) Certificate for PPM procedures.
      (4) Certificate of compliance.
      (5) Certificate of accreditation.

§ 493.15 Laboratories performing waived tests.

(a) Requirement. Tests for certificate of waiver must meet the descriptive criteria specified in paragraph (b) of this section.
   (b) Criteria. Test systems are simple laboratory examinations and procedures which—
      (1) Are cleared by FDA for home use;
      (2) Employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or
      (3) Pose no reasonable risk of harm to the patient if the test is performed incorrectly.
   (c) Certificate of waiver tests. A laboratory may qualify for a certificate of waiver under section 353 of the PHS Act if it restricts the tests it performs to one or more of the following tests or examinations (or additional tests added to this list as provided under paragraph (d) of this section) and no others:
      (1) Dipstick or Tablet Reagent Urinalysis (non-automated) for the following:
         (i) Bilirubin;
         (ii) Glucose;
         (iii) Hemoglobin;
         (iv) Ketone;
         (v) Leukocytes;
         (vi) Nitrite;
         (vii) pH;
         (viii) Protein;
         (ix) Specific gravity; and
         (x) Urobilinogen.
      (2) Fecal occult blood;
      (3) Ovulation tests—visual color comparison tests for human luteinizing hormone;
      (4) Urine pregnancy tests—visual color comparison tests;
      (5) Erythrocyte sedimentation rate—non-automated;
      (6) Hemoglobin—copper sulfate—non-automated;
      (7) Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use;
      (8) Spun microhematocrit; and
      (9) Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout.
   (d) Revisions to criteria for test categorization and the list of waived tests. HHS will determine whether a laboratory test meets the criteria listed under paragraph (b) of this section for a waived test. Revisions to the list of waived tests approved by HHS will be published in the Federal Register in a notice with opportunity for comment.
   (e) Laboratories eligible for a certificate of waiver must—
      (1) Follow manufacturers’ instructions for performing the test; and
      (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.

§ 493.17 Test categorization.

(a) Categorization by criteria. Notices will be published in the Federal Register which list each specific test system, assay, and examination categorized by complexity. Using the seven criteria specified in this paragraph for categorizing tests of moderate or high complexity, each specific laboratory test system, assay, and examination will be graded for level of complexity by assigning scores of 1, 2, or 3 within each criteria. The score of “1” indicates the lowest level of complexity, and the score of “3” indicates the highest level. These scores will be totaled. Test systems, assays or examinations receiving scores of 12 or less will be categorized as moderate complexity, while those receiving scores above 12 will be categorized as high complexity.

NOTE: A score of “2” will be assigned to a criteria heading when the characteristics for a particular test are intermediate between the descriptions listed for scores of “1” and “3.”

(1) Knowledge.

(i) Score 1. (A) Minimal scientific and technical knowledge is required to perform the test; and

(B) Knowledge required to perform the test may be obtained through on-the-job instruction.

(ii) Score 3. Specialized scientific and technical knowledge is essential to perform preanalytic, analytic or postanalytic phases of the testing.

(2) Training and experience.

(i) Score 1. (A) Minimal training is required for preanalytic, analytic and postanalytic phases of the testing process; and

(B) Limited experience is required to perform the test.

(ii) Score 3. (A) Specialized training is essential to perform preanalytic, analytic or postanalytic testing process; or

(B) Substantial experience may be necessary for analytic test performance.

(3) Reagents and materials preparation.

(i) Score 1. (A) Reagents and materials are generally stable and reliable; and

(B) Reagents and materials are pre-packaged, or premeasured, or require no special handling, precautions or storage conditions.

(ii) Score 3. (A) Reagents and materials may be labile and may require special handling to assure reliability; or

(B) Reagents and materials preparation may include manual steps such as gravimetric or volumetric measurements.

(4) Characteristics of operational steps.

(i) Score 1. Operational steps are either automatically executed (such as pipetting, temperature monitoring, or timing of steps), or are easily controlled.

(ii) Score 3. Operational steps in the testing process require close monitoring or control, and may require special specimen preparation, precise temperature control or timing of procedural steps, accurate pipetting, or extensive calculations.

(5) Calibration, quality control, and proficiency testing materials.

(i) Score 1. (A) Calibration materials are stable and readily available;

(B) Quality control materials are stable and readily available; and

(C) External proficiency testing materials, when available, are stable.

(ii) Score 3. (A) Calibration materials, if available, may be labile;

(B) Quality control materials may be labile, or not available; or

(C) External proficiency testing materials, if available, may be labile.

(6) Test system troubleshooting and equipment maintenance.

(i) Score 1. (A) Test system troubleshooting is automatic or self-correcting, or clearly described or requires minimal judgment; and

(B) Equipment maintenance is provided by the manufacturer, is seldom needed, or can easily be performed.

(ii) Score 3. (A) Troubleshooting is not automatic and requires decision-making and direct intervention to resolve most problems; or

(B) Maintenance requires special knowledge, skills, and abilities.

(7) Interpretation and judgment.

(i) Score 1. (A) Minimal interpretation and judgment are required to perform preanalytic, analytic and postanalytic processes; and
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(B) Resolution of problems requires limited independent interpretation and judgment; and

(ii) Score 3. (A) Extensive independent interpretation and judgment are required to perform the preanalytic, analytic or postanalytic processes; and

(b) Revisions to the criteria for categorization. The Clinical Laboratory Improvement Advisory Committee, as defined in subpart T of this part, will conduct a review upon request of HHS and recommend to HHS revisions to the criteria for categorization of tests.

(c) Process for device/test categorization utilizing the scoring system under §493.17(a). (3)(i) For new commercial test systems, assays, or examinations, the manufacturer, as part of its 510(k) and PMA application to FDA, will submit supporting data for device/test categorization. FDA will determine the complexity category, notify the manufacturer directly, and will simultaneously inform both HCFA and CDC of the device/test category. FDA will consult with CDC concerning test categorization in the following three situations:

(A) When categorizing previously uncategorized new technology;

(B) When FDA determines it to be necessary in cases involving a request for a change in categorization; and

(C) If a manufacturer requests review of a categorization decision by FDA in accordance with 21 CFR 10.75.

(ii) Test categorization will be effective as of the notification to the applicant.

(2) For test systems, assays, or examinations not commercially available, a laboratory or professional group may submit a written request for categorization to PHS. These requests will be forwarded to CDC for evaluation; CDC will determine complexity category and notify the applicant, HCFA, and FDA of the categorization decision. In the case of request for a change of category or for previously uncategorized new technology, PHS will receive the request application and forward it to CDC for categorization.

(3) A request for recategorization will be accepted for review if it is based on new information not previously submitted in a request for categorization or recategorization by the same applicant and will not be considered more frequently than once per year.

(4) If a laboratory test system, assay or examination does not appear on the list of tests in the FEDERAL REGISTER notices, it is considered to be a test of high complexity until PHS, upon request, reviews the matter and notifies the applicant of its decision. Test categorization is effective as of the notification to the applicant.

(5) PHS will publish revisions periodically to the list of moderate and high complexity tests in the FEDERAL REGISTER in a notice with opportunity for comment.


§ 493.19 Provider-performed microcopy (PPM) procedures.

(a) Requirement. To be categorized as a PPM procedure, the procedure must meet the criteria specified in paragraph (b) of this section.

(b) Criteria. Procedures must meet the following specifications:

(1) The examination must be personally performed by one of the following practitioners:

(i) A physician during the patient’s visit on a specimen obtained from his or her own patient or from a patient of a group medical practice of which the physician is a member or an employee.

(ii) A midlevel practitioner, under the supervision of a physician or in independent practice only if authorized by the State, during the patient’s visit on a specimen obtained from his or her own patient or from a patient of a clinic, group medical practice, or other health care provider of which the midlevel practitioner is a member or an employee.

(iii) A dentist during the patient’s visit on a specimen obtained from his or her own patient or from a patient of a group dental practice of which the dentist is a member or an employee.

(2) The procedure must be categorized as moderately complex.

(3) The primary instrument for performing the test is the microscope, limited to bright-field or phase-contrast microscopy.
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(a) Laboratories performing tests of moderate complexity.

(1) All direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements.

(2) All potassium hydroxide (KOH) preparations.

(3) Pinworm examinations.

(4) Fern tests.

(5) Post-coital direct, qualitative examinations of vaginal or cervical mucus.

(6) Urine sediment examinations.

(7) Nasal smears for granulocytes.

(8) Fecal leukocyte examinations.

(9) Qualitative semen analysis (limited to the presence or absence of sperm and detection of motility).

(b) Revisions to criteria and the list of PPM procedures.

(1) The CLIAAC conducts reviews upon HHS’ request and recommends to HHS revisions to the criteria for categorization of procedures.

(2) HHS determines whether a laboratory procedure meets the criteria listed under paragraph (b) of this section for a PPM procedure. Revisions to the list of PPM procedures proposed by HHS are published in the FEDERAL REGISTER as a notice with an opportunity for public comment.

(c) Laboratory requirements. Laboratories eligible to perform PPM examinations must—

(1) Meet the applicable requirements in subpart C or subpart D, and subparts F, H, J, K, M, and P of this part.

(2) Be subject to inspection as specified under subpart Q of this part.

[60 FR 20044, Apr. 24, 1995]

§ 493.25 Laboratories performing tests of high complexity.

(a) A laboratory must obtain a certificate for tests of high complexity if it performs one or more tests that meet the criteria for tests of high complexity as specified in §493.17(a).

(b) A laboratory performing one or more tests of high complexity must meet the applicable requirements of subpart C or subpart D, and subparts F, H, J, K, M, P, and Q of this part. Under a registration certificate or certificate of compliance, PPM procedures must meet the inspection requirements at §493.1777.

(c) If the laboratory also performs tests of moderate complexity, the applicable requirements of subparts H, J, K, M, and P of this part must be met. Under a registration certificate or certificate of compliance, PPM procedures must meet the inspection requirements at §493.1777.

(d) If the laboratory also performs waived tests, the requirements of subparts H, J, K, M, and P are not applicable to the waived tests. However, the laboratory must comply with the requirements in §§493.15(e) and 493.1775.

[57 FR 7139, Feb. 28, 1992, as amended at 60 FR 20044, Apr. 24, 1995]
§ 493.35 Application for a certificate of waiver.

(a) Filing of application. Except as specified in paragraph (b) of this section, a laboratory performing only one or more waived tests listed in § 493.15 must file a separate application for each laboratory location.

(b) Exceptions.

(1) Laboratories that are not at a fixed location, that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the certificate of the designated primary site or home base, using its address.

(2) Not-for-profit or Federal, State, or local government laboratories that engage in limited (not more than a combination of 15 moderately complex or waived tests per certificate) public health testing may file a single application.

(3) Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction may file a single application or multiple applications for the laboratory sites within the same physical location or street address.

(c) Application format and contents. The application must—

(1) Be made to HHS or its designee on a form or forms prescribed by HHS;

(2) Be signed by an owner, or by an authorized representative of the laboratory who attests that the laboratory will be operated in accordance with requirements established by the Secretary under section 353 of the PHS Act; and

(3) Describe the characteristics of the laboratory operation and the examinations and other test procedures performed by the laboratory including—

(i) The name and the total number of test procedures and examinations performed annually (excluding tests the laboratory may run for quality control, quality assurance or proficiency testing purposes; (ii) The methodologies for each laboratory test procedure or examination performed, or both; and

(iii) The qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and test procedures.

(d) Access requirements. Laboratories that perform one or more waived tests listed in § 493.15(c) and no other tests must meet the following conditions:

(1) Make records available and submit reports to HHS as HHS may reasonably require to determine compliance with this section and § 493.15(e);

(2) Agree to permit announced and unannounced inspections by HHS in accordance with subpart Q of this part under the following circumstances:

(i) When HHS has substantive reason to believe that the laboratory is being operated in a manner that constitutes an imminent and serious risk to human health.

(ii) To evaluate complaints from the public.

(iii) On a random basis to determine whether the laboratory is performing tests not listed in § 493.15.

(iv) To collect information regarding the appropriateness of waiver of tests listed in § 493.15.

(e) Denial of application. If HHS determines that the application for a certificate of waiver is to be denied, HHS will—

(1) Provide the laboratory with a written statement of the grounds on which the denial is based and an opportunity for appeal, in accordance with the procedures set forth in subpart R of this part;

(2) Notify a laboratory that has its application for a certificate of waiver denied that it cannot operate as a laboratory under the PHS Act unless the denial is overturned at the conclusion of the administrative appeals process provided by subpart R; and

(3) Notify the laboratory that it is not eligible for payment under the Medicare and Medicaid programs.

§ 493.37 Requirements for a certificate of waiver.

(a) HHS will issue a certificate of waiver to a laboratory only if the laboratory meets the requirements of § 493.35.

(b) Laboratories issued a certificate of waiver—

(1) Are subject to the requirements of this subpart and § 493.15(e) of subpart A of this part; and

(2) Must permit announced or unannounced inspections by HHS in accordance with subpart Q of this part.

(c) Laboratories must remit the certificate of waiver fee specified in subpart F of this part.

(d) In accordance with subpart R of this part, HHS will suspend or revoke or limit a laboratory’s certificate of waiver for failure to comply with the requirements of this subpart. In addition, failure to meet the requirements of this subpart will result in suspension or denial of payments under Medicare and Medicaid in accordance with subpart Q of this part.

(e)(1) A certificate of waiver issued under this subpart is valid for no more than 2 years. In the event of a non-compliance determination resulting in HHS action to revoke, suspend, or limit the laboratory’s certificate of waiver, HHS will provide the laboratory with a statement of grounds on which the determination of non-compliance is based and offer an opportunity for appeal as provided in subpart R of this part.

(2) If the laboratory requests a hearing within the time specified by HHS, it retains its certificate of waiver or reissued certificate of waiver until a decision is made by an administrative law judge, as specified in subpart R of this part, except when HHS finds that conditions at the laboratory pose an imminent and serious risk to human health.

(f) For laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of a non-compliance determination even if there has been no appeals decision issued.

(1) Complete the renewal application prescribed by HHS and return it to HHS not less than 9 months nor more than 1 year before the expiration of the certificate; and

(2) Meet the requirements of §§ 493.35 and 493.37.

(g) A laboratory with a certificate of waiver that wishes to perform examinations or tests not listed in the waiver test category must meet the requirements set forth in subpart C or subpart D of this part, as applicable.


§ 493.39 Notification requirements for laboratories issued a certificate of waiver.

Laboratories performing one or more tests listed in § 493.15 and no others must notify HHS or its designee—

(a) Before performing and reporting results for any test or examination that is not specified under § 493.15 for which the laboratory does not have the appropriate certificate as required in subpart C or subpart D of this part, as applicable; and

(b) Within 30 days of any change(s) in—

(1) Ownership;

(2) Name;

(3) Location; or

(4) Director.

[57 FR 7142, Feb. 28, 1992, as amended at 60 FR 20045, Apr. 24, 1995]

Subpart C—Registration Certificate, Certificate for Provider-performed Microscopy Procedures, and Certificate of Compliance

SOURCE: 57 FR 7143, Feb. 28, 1992, unless otherwise noted.

§ 493.43 Application for registration certificate, certificate for provider-performed microscopy (PPM) procedures, and certificate of compliance.

(a) Filing of application. Except as specified in paragraph (b) of this section, all laboratories performing tests of moderate complexity (including the subcategory) or high complexity, or
§ 493.45 Requirements for a registration certificate.

Laboratories performing only waived tests, PPM procedures, or any combination of these tests, are not required to obtain a registration certificate.

(a) A registration certificate is required—

(1) Initially for all laboratories performing test procedures of moderate complexity (other than the subcategory of PPM procedures) or high complexity, or both; and

(2) For all laboratories that have been issued a certificate of waiver or certificate for PPM procedures that intend to perform tests of moderate or high complexity, or both, in addition to those tests listed in §493.15(c) or specified as PPM procedures.

(b) HHS will issue a registration certificate if the laboratory—

(1) Complies with the requirements of §493.43;

(2) Agrees to notify HHS or its designee within 30 days of any changes in ownership, name, location, director or technical supervisor (laboratories performing high complexity testing only);

(3) Agrees to treat proficiency testing samples in the same manner as it treats patient specimens; and

(4) Remits the fee for the registration certificate, as specified in subpart F of this part.

(c) Prior to the expiration of the registration certificate, a laboratory must—

(1) Remit the certificate fee specified in subpart F of this part;

(2) Be inspected by HHS as specified in subpart Q of this part; and

(3) Demonstrate compliance with the applicable requirements of this subpart and subparts H, J, K, M, P, and Q of this part.

(d) In accordance with subpart R of this part, HHS will initiate suspension or revocation of a laboratory's registration certificate and will deny the laboratory's application for a certificate of compliance for failure to comply with the requirements set forth in

any combination of these tests, must file a separate application for each laboratory location.

(b) Exceptions. (1) Laboratories that are not at a fixed location, that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the certificate of the designated primary site or home base, using its address.

(2) Not-for-profit or Federal, State, or local government laboratories that engage in limited (not more than a combination of 15 moderately complex or waived tests per certificate) public health testing may file a single application.

(3) Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction may file a single application or multiple applications for the laboratory sites within the same physical location or street address.

(c) Application format and contents. The application must—

(1) Be made to HHS or its designee on a form or forms prescribed by HHS;

(2) Be signed by an owner, or by an authorized representative of the laboratory who attests that the laboratory will be operated in accordance with the requirements established by the Secretary under section 353 of the Public Health Service Act; and

(3) Describe the characteristics of the laboratory operation and the examinations and other test procedures performed by the laboratory including—

(i) The name and total number of test procedures and examinations performed annually (excluding waived tests or tests for quality control, quality assurance or proficiency testing purposes);

(ii) The methodologies for each laboratory test procedure or examination performed, or both;

(iii) The qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the examinations and test procedures.

(d) Access and reporting requirements. All laboratories must make records available and submit reports to HHS as HHS may reasonably require to determine compliance with this section.

§ 493.49 Requirements for a certificate of compliance.

A certificate of compliance may include any combination of tests categorized as high complexity or moderate complexity or listed in §493.15(c) as waived tests. Moderate complexity tests may include those specified as PPM procedures.

(a) HHS will issue a certificate of compliance to a laboratory only if the laboratory—

(1) Meets the requirements of §§493.43 and 493.45;

(2) Remits the certificate fee specified in subpart F of this part; and

(3) Meets the applicable requirements of this subpart and subparts H, J, K, M, P, and Q of this part.
§ 493.51

(b) Laboratories issued a certificate of compliance—

(1) Are subject to the notification requirements of §493.51; and

(2) Must permit announced or unannounced inspections by HHS in accordance with subpart Q of this part—

(i) To determine compliance with the applicable requirements of this part;

(ii) To evaluate complaints;

(iii) When HHS has substantive reason to believe that tests are being performed, or the laboratory is being operated in a manner that constitutes an imminent and serious risk to human health; and

(iv) To collect information regarding the appropriateness of tests listed in §493.15 or tests categorized as moderate complexity (including the subcategory) or high complexity.

(c) Failure to comply with the requirements of this subpart will result in—

(1) Suspension, revocation or limitation of a laboratory’s certificate of compliance in accordance with subpart R of this part; and

(2) Suspension or denial of payments under Medicare and Medicaid in accordance with subpart R of this part.

(d) A certificate of compliance issued under this subpart is valid for no more than 2 years.

(e) In the event of a noncompliance determination resulting in an HHS action to revoke, suspend or limit the laboratory’s certificate of compliance, HHS will—

(1) Provide the laboratory with a statement of grounds on which the determination of noncompliance is based; and

(2) Offer an opportunity for appeal as provided in subpart R of this part. If the laboratory requests a hearing within the time period specified by HHS, the laboratory retains its certificate of compliance or reissued certificate of compliance until a decision is made by an ALJ as provided in subpart R, except when HHS finds that conditions at the laboratory pose an imminent and serious risk to human health.

(f) For laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of a noncompliance determination even if there has been no appeals decision issued.

(g) A laboratory seeking to renew its certificate of compliance must—

(1) Complete and return the renewal application to HHS 9 to 12 months prior to the expiration of the certificate of compliance; and

(2) Meet the requirements of §493.43 and paragraphs (a)(2) and (b)(2) of this section.

(h) If HHS determines that the application for the renewal of a certificate of compliance must be denied or limited, HHS will notify the laboratory in writing of the—

(1) Basis for denial of the application; and

(2) Opportunity for appeal as provided in subpart R of this part.

(i) If the laboratory requests a hearing within the time period specified by HHS, the laboratory retains its certificate of compliance or reissued certificate of compliance pending an appeal.

(j) For laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of nonrenewal of the certificate of compliance even if there has been no appeals decision issued.

[60 FR 20045, Apr. 24, 1995]

§ 493.51 Notification requirements for laboratories issued a certificate of compliance.

Laboratories issued a certificate of compliance must meet the following conditions:

(a) Notify HHS or its designee within 30 days of any change in—

(1) Ownership;

(2) Name;

(3) Location;

(4) Director; or

(5) Technical supervisor (laboratories performing high complexity only).

(b) Notify HHS no later than 6 months after performing any test or
§ 493.53 Notification requirements for laboratories issued a certificate for provider-performed microscopy (PPM) procedures.

Laboratories issued a certificate for PPM procedures must notify HHS or its designee—

(a) Before performing and reporting results for any test of moderate or high complexity, or both, in addition to tests specified as PPM procedures or any test or examination that is not specified under §493.15(c), for which it does not have a registration certificate as required in subpart C or subpart D, as applicable, of this part; and

(b) Within 30 days of any change in—
   (1) Ownership;
   (2) Name;
   (3) Location; or
   (4) Director.

§ 493.55 Application for registration certificate and certificate of accreditation.

(a) Filing of application. A laboratory may be issued a certificate of accreditation in lieu of the applicable certificate specified in subpart B or subpart C of this part provided the laboratory—
   (1) Meets the standards of a private non-profit accreditation program approved by HHS in accordance with subpart E; and
   (2) Files a separate application for each location, except as specified in paragraph (b) of this section.

(b) Exceptions. (1) Laboratories that are not at fixed locations, that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the certificate of the designated primary site or home base, using its address.

   (2) Not-for-profit or Federal, State, or local government laboratories that engage in limited (not more than a combination of 15 moderately complex or waived tests per certificate) public health testing may file a single application.

   (3) Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction may file a single application or multiple applications for the laboratory sites within the same physical location or street address.

(c) Application format and contents. The application must—(1) Be made to HHS on a form or forms prescribed by HHS;
   (2) Be signed by an owner or authorized representative of the laboratory who attests that the laboratory will be operated in accordance with the requirements established by the Secretary under section 353 of the Public Health Service Act; and
   (3) Describe the characteristics of the laboratory operation and the examinations and other test procedures performed by the laboratory including—
      (i) The name and total number of tests and examinations performed annually (excluding waived tests and tests for quality control, quality assurance or proficiency testing purposes);
      (ii) The methodologies for each laboratory test procedure or examination performed, or both; and
      (iii) The qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and test procedures.

(d) Access and reporting requirements. All laboratories must make records available and submit reports to HHS as
§ 493.57 Requirements for a registration certificate.

A registration certificate is required for all laboratories seeking a certificate of accreditation, unless the laboratory holds a valid certificate of compliance issued by HHS.

(a) HHS will issue a registration certificate if the laboratory—

(1) Complies with the requirements of §493.55;

(2) Agrees to notify HHS within 30 days of any changes in ownership, name, location, director, or supervisor (laboratories performing high complexity testing only);

(3) Agrees to treat proficiency testing samples in the same manner as it treats patient specimens; and

(4) Remits the fee for the registration certificate specified in subpart F of this part.

(b)(1) The laboratory must provide HHS with proof of accreditation by an approved accreditation program—

(i) Within 11 months of issuance of the registration certificate; or

(ii) Prior to the expiration of the certificate of compliance.

(2) If such proof of accreditation is not supplied within this timeframe, the laboratory must meet, or continue to meet, the requirements of §493.49.

(c) In accordance with subpart R of this part, HHS will initiate suspension, revocation, or limitation of a laboratory’s registration certificate and will deny the laboratory’s application for a certificate of accreditation for failure to comply with the requirements set forth in this subpart. In addition, failure to meet the requirements of this subpart will result in suspension or denial of payments under Medicare and Medicaid as specified in subpart R of this part.

(d) A registration certificate is valid for a period of no more than 2 years. However, it may be reissued if the laboratory is subject to subpart C of this part, as specified in §493.57(b)(2) and compliance has not been determined by HHS before the expiration date of the registration certificate.

(e) In the event that the laboratory does not meet the requirements of this subpart, HHS will—

(1) Deny a laboratory’s request for certificate of accreditation;

(2) Notify the laboratory if it must meet the requirements for a certificate as defined in subpart C of this part;

(3) Provide the laboratory with a statement of grounds on which the application denial is based;

(4) Offer an opportunity for appeal on the application denial as provided in subpart R of this part.

(5) For those laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of denial of the request even if there has been no appeals decision issued.

§ 493.61 Requirements for a certificate of accreditation.

(a) HHS will issue a certificate of accreditation to a laboratory if the laboratory—

(1) Meets the requirements of §493.57 or, if applicable, §493.49 of subpart C of this part; and

(2) Remits the certificate of accreditation fee specified in subpart F of this part.

(b) Laboratories issued a certificate of accreditation must—

(1) Treat proficiency testing samples in the same manner as patient samples;

(2) Meet the requirements of §493.63;

(3) Comply with the requirements of the approved accreditation program;

(4) Permit random sample validation and complaint inspections as required in subpart Q of this part;

(5) Permit HHS to monitor the correction of any deficiencies found
through the inspections specified in paragraph (b)(4) of this section:
(6) Authorize the accreditation program to release to HHS the laboratory’s inspection findings whenever HHS conducts random sample or complaint inspections; and
(7) Authorize its accreditation program to submit to HHS the results of the laboratory’s proficiency testing.
(c) A laboratory failing to meet the requirements of this section—
(1) Will no longer meet the requirements of this part by virtue of its accreditation in an approved accreditation program;
(2) Will be subject to full determination of compliance by HHS;
(3) May be subject to suspension, revocation or limitation of the laboratory’s certificate of accreditation or certain alternative sanctions; and
(4) May be subject to suspension of payments under Medicare and Medicaid as specified in subpart R.
(d) A certificate of accreditation issued under this subpart is valid for no more than 2 years. In the event of a non-compliance determination as a result of a random sample validation or complaint inspection, a laboratory will be subject to a full review by HHS in accordance with §488.11 of this chapter.
(e) Failure to meet the applicable requirements of part 493, will result in an action by HHS to suspend, revoke or limit the certificate of accreditation. HHS will—
(1) Provide the laboratory with a statement of grounds on which the determination of noncompliance is based;
(2) Notify the laboratory if it is eligible to apply for a certificate as defined in subpart C of this part; and
(3) Offer an opportunity for appeal as provided in subpart R of this part.
(f) If the laboratory requests a hearing within the time frame specified by HHS—
(1) It retains its certificate of accreditation or reissued certificate of accreditation until a decision is made by an administrative law judge as provided in subpart R of this part, unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health; and
(2) For those laboratories receiving payments from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory even if there has been no appeals decision issued.
(g) In the event the accreditation organization’s approval is removed by HHS, the laboratory will be subject to the applicable requirements of subpart C of this part or §493.57.
(h) A laboratory seeking to renew its certificate of accreditation must—
(1) Complete and return the renewal application to HHS 9 to 12 months prior to the expiration of the certificate of accreditation;
(2) Meet the requirements of this subpart; and
(3) Submit the certificate of accreditation fee specified in subpart F of this part.
(i) If HHS determines that the renewal application for a certificate of accreditation is to be denied or limited, HHS will notify the laboratory in writing of—
(1) The basis for denial of the application;
(2) Whether the laboratory is eligible for a certificate as defined in subpart C of this part;
(3) The opportunity for appeal on HHS’s action to deny the renewal application for certificate of accreditation as provided in subpart R of this part. If the laboratory requests a hearing within the time frame specified by HHS, it retains its certificate of accreditation or reissued certificate of accreditation until a decision is made by an administrative law judge as provided in subpart R of this part, unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health; and
(4) Suspension of payments under Medicare or Medicaid for those laboratories receiving payments under the Medicare or Medicaid programs.
§ 493.63 Notification requirements for laboratories issued a certificate of accreditation.
Laboratories issued a certificate of accreditation must:
§ 493.551 General requirements for laboratories.

(a) Applicability. HCFA may deem a laboratory to meet all applicable CLIA program requirements through accreditation by a private nonprofit accreditation program (that is, grant deemed status), or may exempt from CLIA program requirements all State licensed or approved laboratories in a State that has a State licensure program established by law, if the following conditions are met:

(1) The requirements of the accreditation organization or State licensure program are equal to, or more stringent than, the CLIA condition-level requirements specified in this part, and the laboratory would meet the condition-level requirements if it were inspected against these requirements.

(2) The accreditation program or the State licensure program meets the requirements of this subpart and is approved by HCFA.

(b) The laboratory authorizes the approved accreditation organization or State licensure program to release to HCFA all records and information required and permits inspections as outlined in this part.

(c) The laboratory authorizes the approved accreditation organization to release to HCFA or a HCFA agent the laboratory’s PT results that constitute unsuccessful participation in an approved PT program, in accordance with the definition of “unsuccessful participation in an approved PT program,” as specified in §493.2 of this part, when the laboratory has failed to achieve successful participation in an approved PT program.

(d) The laboratory authorizes the approved accreditation organization to release to HCFA a notification of the actions taken by the organization as a result of the unsuccessful participation in a PT program within 30 days of the initiation of the action. Based on this notification, HCFA may
take an adverse action against a laboratory that fails to participate successfully in an approved PT program.

(c) Withdrawal of laboratory accreditation. After an accreditation organization has withdrawn or revoked its accreditation of a laboratory, the laboratory retains its certificate of accreditation for 45 days after the laboratory receives notice of the withdrawal or revocation of the accreditation, or the effective date of any action taken by HCFA, whichever is earlier.

§ 493.553 Approval process (application and reapplication) for accreditation organizations and State licensure programs.

(a) Information required. An accreditation organization that applies or reaps to HCFA for deeming authority, or a State licensure program that applies or reaps to HCFA for exemption from CLIA program requirements of licensed or approved laboratories within the State, must provide the following information:

1. A detailed comparison of the individual accreditation, or licensure or approval requirements with the comparable condition-level requirements; that is, a crosswalk.

2. A detailed description of the inspection process, including the following:

   (i) Frequency of inspections.
   (ii) Copies of inspection forms.
   (iii) Instructions and guidelines.
   (iv) A description of the review and decision-making process of inspections.
   (v) A statement concerning whether inspections are announced or unannounced.

   (vi) A description of the steps taken to monitor the correction of deficiencies.

3. A description of the process for monitoring PT performance, including action to be taken in response to unsuccessful participation in a HCFA-approved PT program.

4. Procedures for responding to and for the investigation of complaints against its laboratories.

5. A list of all its current laboratories and the expiration date of their accreditation or licensure, as applicable.

6. Procedures for making PT information available (under State confidentiality and disclosure requirements, if applicable) including explanatory information required to interpret PT results, on a reasonable basis, upon request of any person.

(b) HCFA action on an application or reapplication. If HCFA receives an application or reapplication from an accreditation organization, or State licensure program, HCFA takes the following actions:

1. HCFA determines if additional information is necessary to make a determination for approval or denial of the application and notifies the accreditation organization or State to afford it an opportunity to provide the additional information.

2. HCFA may visit the accreditation organization or State licensure program offices to review and verify the policies and procedures represented in its application and other information, including, but not limited to, review and examination of documents and interviews with staff.

3. HCFA notifies the accreditation organization or State licensure program indicating whether HCFA approves or denies the request for deeming authority or exemption, respectively, and the rationale for any denial.

(c) Duration of approval. HCFA approval may not exceed 6 years.

(d) Withdrawal of application. The accreditation organization or State licensure program may withdraw its application at any time before official notification, specified at §493.553(b)(3).

§ 493.555 Federal review of laboratory requirements.

HCFA's review of an accreditation organization or State licensure program includes, but is not limited to, an evaluation of the following:

(a) Whether the organization's or State's requirements for laboratories are equal to, or more stringent than, the condition-level requirements for laboratories.

(b) The organization's or State's inspection process to determine the comparability of the full inspection and complaint inspection procedures and requirements to those of HCFA, including, but not limited to, inspection frequency and the ability to investigate
and respond to complaints against its laboratories.

(c) The organization's or State's agreement with HCFA that requires it to do the following:

(1) Notify HCFA within 30 days of the action taken, of any laboratory that has—

(i) Had its accreditation or licensure suspended, withdrawn, revoked, or limited;
(ii) In any way been sanctioned; or
(iii) Had any adverse action taken against it.

(2) Notify HCFA within 10 days of any deficiency identified in an accredited or CLIA-exempt laboratory if the deficiency poses an immediate jeopardy to the laboratory's patients or a hazard to the general public.

(3) Notify HCFA, within 30 days, of all newly—

(i) Accredited laboratories (or laboratories whose areas of specialty/subspecialty testing have changed); or
(ii) Licensed laboratories, including the specialty/subspecialty areas of testing.

(4) Notify each accredited or licensed laboratory within 10 days of HCFA's withdrawal of the organization's deeming authority or State's exemption.

(5) Provide HCFA with inspection schedules, as requested, for validation purposes.

§ 493.557 Additional submission requirements.

(a) Specific requirements for accreditation organizations. In addition to the information specified in §§493.553 and 493.555, as part of the approval and review process, an accreditation organization applying or reapplying for deeming authority must also provide the following:

(1) The specialty or subspecialty areas for which the organization is requesting deeming authority and its mechanism for monitoring compliance with all requirements equivalent to condition-level requirements within the scope of the specialty or subspecialty areas.

(2) A description of the organization's data management and analysis system with respect to its inspection and accreditation decisions, including the kinds of routine reports and tables generated by the systems.

(3) Detailed information concerning the inspection process, including, but not limited to the following:

(i) The size and composition of individual accreditation inspection teams.

(ii) Qualifications, education, and experience requirements that inspectors must meet.

(iii) The content and frequency of training provided to inspection personnel, including the ability of the organization to provide continuing education and training to inspectors.

(4) Procedures for removal or withdrawal of accreditation status for laboratories that fail to meet the organization's standards.

(5) A proposed agreement between HCFA and the accreditation organization with respect to the notification requirements specified in §493.555(c).

(6) Procedures for monitoring laboratories found to be out of compliance with its requirements. (These monitoring procedures must be used only when the accreditation organization identifies noncompliance. If noncompliance is identified through validation inspections, HCFA or a HCFA agent monitors corrections, as authorized at §493.565(d)).

(7) A demonstration of its ability to provide HCFA with electronic data and reports in compatible code, including the crosswalk specified in §493.553(a)(1), that are necessary for effective validation and assessment of the organization's inspection process.

(8) A demonstration of its ability to provide HCFA with electronic data, in compatible code, related to the adverse actions resulting from PT results constituting unsuccessful participation in PT programs as well as data related to the PT failures, within 30 days of the initiation of adverse action.

(9) A demonstration of its ability to provide HCFA with electronic data, in compatible code, for all accredited laboratories, including the area of specialty or subspecialty.

(10) Information defining the adequacy of numbers of staff and other resources.

(11) Information defining the organization's ability to provide adequate
funding for performing required inspections.

(12) Any facility-specific data, upon request by HCFA, which includes, but is not limited to, the following:

(i) PT results that constitute unsuccessful participation in a HCFA-approved PT program.

(ii) Notification of the adverse actions or corrective actions imposed by the accreditation organization as a result of unsuccessful PT participation.

(13) An agreement to provide written notification to HCFA at least 30 days in advance of the effective date of any proposed change in its requirements.

(14) An agreement to disclose any laboratory’s PT results upon reasonable request by any person.

(b) Specific requirements for a State licensure program. In addition to requirements in §§ 493.553 and 493.555, as part of the approval and review process, when a State licensure program applies or reapplies for exemption from the CLIA program, the State must do the following:

(1) Demonstrate to HCFA that it has enforcement authority and administrative structures and resources adequate to enforce its laboratory requirements.

(2) Permit HCFA or a HCFA agent to inspect laboratories in the State.

(3) Require laboratories in the State to submit to inspections by HCFA or a HCFA agent as a condition of licensure or approval.

(4) Agree to pay the cost of the validation program administered in that State as specified in §§ 493.645(a) and 493.646(b).

(5) Take appropriate enforcement action against laboratories found by HCFA not to be in compliance with requirements equivalent to CLIA requirements.

(6) Submit for Medicare and Medicaid payment purposes, a list of the specialties and subspecialties of tests performed by each laboratory.

(7) Submit a written presentation that demonstrates the agency’s ability to furnish HCFA with electronic data in compatible code, including the crosswalk specified in § 493.553(a)(1).

(8) Submit a statement acknowledging that the State will notify HCFA through electronic transmission of the following:

(i) Any laboratory that has had its licensure or approval revoked or withdrawn or has been in any way sanctioned by the State within 30 days of taking the action.

(ii) Changes in licensure or inspection requirements.

(iii) Changes in specialties or subspecialties under which any licensed laboratory in the State performs testing.

(9) Provide information for the review of the State’s enforcement procedures for laboratories found to be out of compliance with the State’s requirements.

(10) Submit information that demonstrates the ability of the State to provide HCFA with the following:

(i) Electronic data and reports in compatible code with the adverse or corrective actions resulting from PT results that constitute unsuccessful participation in PT programs.

(ii) Other data that HCFA determines are necessary for validation and assessment of the State’s inspection process requirements.

(11) Agree to provide HCFA with written notification of any changes in its licensure/approval and inspection requirements.

(12) Agree to disclose any laboratory’s PT results to HCFA at least 30 days in advance of the effective date of any proposed change in its requirements.

(13) Agree to disclose any laboratory’s PT results to HCFA at least 30 days in advance of the effective date of any proposed change in its requirements.

(14) If approved, reapply to HCFA every 2 years to renew its exempt status and to renew its agreement to pay the cost of the HCFA-administered validation program in that State.

§ 493.559 Publication of approval of deeming authority or CLIA exemption.

(a) Notice of deeming authority or exemption. HCFA publishes a notice in the Federal Register when it grants deeming authority to an accreditation organization or exemption to a State licensure program.

(b) Contents of notice. The notice includes the following:
§ 493.561 Denial of application or reapplication.

(a) Reconsideration of denial. (1) If HCFA denies a request for approval, an accreditation organization or State licensure program may request, within 60 days of the notification of denial, that HCFA reconsider its original application or application for renewal, in accordance with part 488, subpart D.

(2) If the accreditation organization or State licensure program requests a reconsideration of HCFA’s determination to deny its request for approval or reapproval, it may not submit a new application until HCFA issues a final reconsideration determination.

(b) Resubmittal of a request for approval—accreditation organization. An accreditation organization may resubmit a request for approval if a final reconsideration determination is not pending and the accreditation program meets the following conditions:

(1) It has revised its accreditation program to address the rationale for denial of its previous request.

(2) It demonstrates that it can provide reasonable assurance that its accredited facilities meet condition-level requirements.

(3) It resubmits the application in its entirety.

(c) Resubmittal of request for approval—State licensure program. The State licensure program may resubmit a request for approval if a final reconsideration determination is not pending and it has taken the necessary action to address the rationale for any previous denial.

§ 493.563 Validation inspections—Basis and focus.

(a) Basis for validation inspection—(1) Laboratory with a certificate of accreditation. HCFA or a HCFA agent may conduct an inspection of an accredited laboratory that has been issued a certificate of accreditation on a representative sample basis or in response to a substantial allegation of noncompliance.

(2) Laboratory in a State with an approved State licensure program. HCFA or a HCFA agent may conduct an inspection of any laboratory in a State with an approved State licensure program on a representative sample basis or in response to a substantial allegation of noncompliance.

(b) Validation inspection conducted on a representative sample basis. (1) HCFA or a HCFA agent conducts a validation inspection on a representative sample basis, the inspection is comprehensive, addressing all condition-level requirements, or it may be focused on a specific condition-level requirement.

(2) The number of laboratories sampled is sufficient to allow a reasonable estimate of the performance of the accreditation organization or State.

(c) Validation inspection conducted in response to a substantial allegation of noncompliance. (1) If HCFA or a HCFA agent conducts a validation inspection in response to a substantial allegation of noncompliance, the inspection focuses on any condition-level requirement that HCFA determines to be related to the allegation.

(2) HCFA or a HCFA agent substantiates a deficiency and determines that
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the laboratory is out of compliance with any condition-level requirement, HCFA or a HCFA agent conducts a full CLIA inspection.

(d) Inspection of operations and offices. As part of the validation review process, HCFA may conduct an onsite inspection of the operations and offices to verify the following:

(1) The accreditation organization's representations and to assess the accreditation organization's compliance with its own policies and procedures.

(2) The State's representations and to assess the State's compliance with its own policies and procedures, including verification of State enforcement actions taken on the basis of validation inspections performed by HCFA or a HCFA agent.

(e) Onsite inspection of an accreditation organization. An onsite inspection of an accreditation organization may include, but is not limited to, the following:

(1) A review of documents.

(2) An audit of meetings concerning the accreditation process.

(3) Evaluation of accreditation inspection results and the accreditation decision-making process.

(4) Interviews with the accreditation organization's staff.

(f) Onsite inspection of a State licensure program. An onsite inspection of a State licensure program office may include, but is not limited to, the following:

(1) A review of documents.

(2) An audit of meetings concerning the licensure or approval process.

(3) Evaluation of State inspection results and the licensure or approval decision-making process.

(4) Interviews with State employees.

§ 493.565 Selection for validation inspection—laboratory responsibilities.

A laboratory selected for a validation inspection must do the following:

(a) Authorize its accreditation organization or State licensure program, as applicable, to release to HCFA or a HCFA agent, on a confidential basis, a copy of the laboratory's most recent full, and any subsequent partial inspection. 

(b) Authorize HCFA or a HCFA agent to conduct a validation inspection.

(c) Provide HCFA or a HCFA agent with access to all facilities, equipment, materials, records, and information that HCFA or a HCFA agent determines have a bearing on whether the laboratory is being operated in accordance with the requirements of this part, and permit HCFA or a HCFA agent to copy material or require the laboratory to submit material.

(d) If the laboratory possesses a valid certificate of accreditation, authorize HCFA or a HCFA agent to monitor the correction of any deficiencies found through the validation inspection.

§ 493.567 Refusal to cooperate with validation inspection.

(a) Laboratory with a certificate of accreditation. (1) A laboratory with a certificate of accreditation that refuses to cooperate with a validation inspection by failing to comply with the requirements in § 493.565—

(i) is subject to full review by HCFA or a HCFA agent, in accordance with this part; and

(ii) may be subject to suspension, revocation, or limitation of its certificate of accreditation under this part.

(2) A laboratory with a certificate of accreditation is again deemed to meet the condition-level requirements by virtue of its accreditation when the following conditions exist:

(i) The laboratory withdraws any prior refusal to authorize its accreditation organization to release a copy of the laboratory's current accreditation inspection, PT results, or notification of any adverse actions resulting from PT failure.

(ii) The laboratory withdraws any prior refusal to allow a validation inspection.

(iii) HCFA finds that the laboratory meets all the condition-level requirements.

(b) CLIA-exempt laboratory. If a CLIA-exempt laboratory fails to comply with the requirements specified in § 493.565, HCFA notifies the State of the laboratory's failure to meet the requirements.
§ 493.569 Consequences of a finding of noncompliance as a result of a validation inspection.

(a) Laboratory with a certificate of accreditation. If a validation inspection results in a finding that the accredited laboratory is out of compliance with one or more condition-level requirements, the laboratory is subject to—

(1) The same requirements and survey and enforcement processes applied to laboratories that are not accredited and that are found out of compliance following an inspection under this part; and

(2) Full review by HCFA, in accordance with this part; that is, the laboratory is subject to the principal and alternative sanctions in §493.1806.

(b) CLIA-exempt laboratory. If a validation inspection results in a finding that a CLIA-exempt laboratory is out of compliance with one or more condition-level requirements, HCFA directs the State to take appropriate enforcement action.

§ 493.571 Disclosure of accreditation, State and HCFA validation inspection results.

(a) Accreditation organization inspection results. HCFA may disclose accreditation organization inspection results to the public only if the results are related to an enforcement action taken by the Secretary.

(b) State inspection results. Disclosure of State inspection results is the responsibility of the approved State licensure program, in accordance with State law.

(c) HCFA validation inspection results. HCFA may disclose the results of all validation inspections conducted by HCFA or its agent.

§ 493.573 Continuing Federal oversight of private nonprofit accreditation organizations and approved State licensure programs.

(a) Comparability review. In addition to the initial review for determining equivalency of specified organization or State requirements to the comparable condition-level requirements, HCFA reviews the equivalency of requirements in the following cases:

(1) When HCFA promulgates new condition-level requirements.

(2) When HCFA identifies an accreditation organization or a State licensure program whose requirements are no longer equal to, or more stringent than, condition-level requirements.

(3) When an accreditation organization or State licensure program adopts new requirements.

(4) When an accreditation organization or State licensure program adopts changes to its inspection process, as required by §493.575(b)(1), as applicable.

(5) Every 6 years, or sooner if HCFA determines an earlier review is required.

(b) Validation review. Following the end of a validation review period, HCFA evaluates the validation inspection results for each approved accreditation organization and State licensure program.

(c) Reapplication procedures. (1) Every 6 years, or sooner, as determined by HCFA, an approved accreditation organization must reapply for continued approval of deeming authority and a State licensure program must reapply for continued approval of a CLIA exemption. HCFA provides notice of the materials that must be submitted as part of the reapplication procedure.

(2) An accreditation organization or State licensure program that does not meet the requirements of this subpart, as determined through a comparability or validation review, must furnish HCFA, upon request, with the reapplication materials HCFA requests. HCFA establishes a deadline by which the materials must be submitted.

(d) Notice. (1) HCFA provides written notice, as appropriate, to the following:

(i) An accreditation organization indicating that its approval may be in jeopardy if a comparability or validation review reveals that it is not meeting the requirements of this subpart and HCFA is initiating a review of the accreditation organization’s deeming authority.

(ii) A State licensure program indicating that its CLIA exemption may be in jeopardy if a comparability or validation review reveals that it is not meeting the requirements of this subpart and that a review is being initiated of the CLIA exemption of the State’s laboratories.
(2) The notice contains the following information:
   (i) A statement of the discrepancies that were found as well as other related documentation.
   (ii) An explanation of HCFA's review process on which the final determination is based and a description of the possible actions, as specified in §493.575, that HCFA may impose based on the findings from the comparability or validation review.
   (iii) A description of the procedures available if the accreditation organization or State licensure program, as applicable, desires an opportunity to explain or justify the findings made during the comparability or validation review.
   (iv) The reaplication materials that the accreditation organization or State licensure program must submit and the deadline for that submission.

§ 493.575 Removal of deeming authority or CLIA exemption and final determination review.

(a) HCFA review. HCFA conducts a review of the following:
   (1) A deeming authority review of an accreditation organization's program if the comparability or validation review produces findings, as described at §493.573. HCFA reviews, as appropriate, the criteria described in §§493.555 and 493.557(a) to reevaluate whether the accreditation organization continues to meet all these criteria.
   (2) An exemption review of a State's licensure program if the comparability or validation review produces findings, as described at §493.573. HCFA reviews, as appropriate, the criteria described in §§493.555 and 493.557(b) to reevaluate whether the licensure program continues to meet all these criteria.
   (3) A review of an accreditation organization or State licensure program, at HCFA's discretion, if validation review findings, irrespective of the rate of disparity, indicate widespread or systematic problems in the organization's accreditation or State's licensure process that provide evidence that the requirements, taken as a whole, are no longer equivalent to CLIA requirements, taken as a whole.
   (4) A review of the accreditation organization or State licensure program whenever validation inspection results indicate a rate of disparity of 20 percent or more between the findings of the organization or State and those of HCFA or a HCFA agent for the following periods:
      (i) One year for accreditation organizations.
      (ii) Two years for State licensure programs.

(b) HCFA action after review. Following the review, HCFA may take the following action:
   (1) If HCFA determines that the accreditation organization or State has failed to adopt requirements equal to, or more stringent than, CLIA requirements, HCFA may give a conditional approval for a probationary period of its deeming authority to an organization 30 days following the date of HCFA's determination, or exempt status to a State within 30 days of HCFA's determination, both not to exceed 1 year, to afford the organization or State an opportunity to adopt equal or more stringent requirements.
   (2) If HCFA determines that there are widespread or systematic problems in the organization's or State's inspection process, HCFA may give conditional approval during a probationary period, not to exceed 1 year, effective 30 days following the date of the determination.

(c) Final determination. HCFA makes a final determination as to whether the organization or State continues to meet the criteria described in this subpart and issues a notice that includes the reasons for the determination to the organization or State within 60 days after the end of any probationary period. This determination is based on an evaluation of any of the following:
   (1) The most recent validation inspection and review findings. To continue to be approved, the organization or State must meet the criteria of this subpart.
   (2) Facility-specific data, as well as other related information.
   (3) The organization's or State's inspection procedures, surveyors' qualifications, ongoing education, training, and composition of inspection teams.
   (4) The organization's accreditation requirements, or the State's licensure or approval requirements.
(d) Date of withdrawal of approval. HCFA may withdraw its approval of the accreditation organization or State licensure program, effective 30 days from the date of written notice to the organization or State of this proposed action, if improvements acceptable to HCFA have not been made during the probationary period.

(e) Continuation of validation inspections. The existence of any validation review, probationary status, or any other action, such as a deeming authority review, by HCFA does not affect or limit the conduct of any validation inspection.

(f) Federal Register notice. HCFA publishes a notice in the FEDERAL REGISTER containing a justification for removing the deeming authority from an accreditation organization, or the CLIA-exempt status of a State licensure program.

(g) Withdrawal of approval—effect on laboratory status—(1) Accredited laboratory. After HCFA withdraws approval of an accreditation organization’s deeming authority, the certificate of accreditation of each affected laboratory continues in effect for 60 days after it receives notification of the withdrawal of approval.

(2) CLIA-exempt laboratory. After HCFA withdraws approval of a State licensure program, the exempt status of each licensed or approved laboratory in the State continues in effect for 60 days after a laboratory receives notification from the State of the withdrawal of HCFA’s approval of the program.

(3) Extension. After HCFA withdraws approval of an accreditation organization or State licensure program, HCFA may extend the period for an additional 60 days for a laboratory if it determines that the laboratory submitted an application for accreditation to an approved accreditation organization or an application for the appropriate certificate to HCFA or a HCFA agent before the initial 60-day period ends.

(h) Immediate jeopardy to patients. (1) If at any time HCFA determines that the continued approval of deeming authority of any accreditation organization poses immediate jeopardy to the patients of the laboratories accredited by the organization, or continued approval otherwise constitutes a significant hazard to the public health, HCFA may immediately withdraw the approval of deeming authority for that accreditation organization.

(2) If at any time HCFA determines that the continued approval of a State licensure program poses immediate jeopardy to the patients of the laboratories in that State, or continued approval otherwise constitutes a significant hazard to the public health, HCFA may immediately withdraw the approval of that State licensure program.

(i) Failure to pay fees. HCFA withdraws the approval of a State licensure program if the State fails to pay the applicable fees, as specified in §§493.645(a) and 493.646(b).

(j) State refusal to take enforcement action. (1) HCFA may withdraw approval of a State licensure program if the State refuses to take enforcement action against a laboratory in that State when HCFA determines it to be necessary.

(2) A laboratory that is in a State in which HCFA has withdrawn program approval is subject to the same requirements and survey and enforcement processes that are applied to a laboratory that is not exempt from CLIA requirements.

(k) Request for reconsideration. Any accreditation organization or State that is dissatisfied with a determination to withdraw approval of its deeming authority or remove approval of its State licensure program, as applicable, may request that HCFA reconsider the determination, in accordance with subpart D of part 488.

Subpart F—General Administration

SOURCE: 57 FR 7138 and 7213, Feb. 28, 1992, unless otherwise noted.

§ 493.602 Scope of subpart.

This subpart sets forth the methodology for determining the amount of the fees for issuing the appropriate certificate, and for determining compliance with the applicable standards of the Public Health Service Act (the PHS
§ 493.639 Fee for revised certificate.

(a) If, after a laboratory is issued a registration certificate, it changes its name or location, the laboratory must pay a fee to cover the cost of issuing a revised registration certificate. The fee for the revised registration certificate is based on the cost to issue the revised certificate to the laboratory.

(b) A laboratory must pay a fee to cover the cost of issuing a revised certificate in any of the following circumstances:

(1) The fee for issuing an appropriate revised certificate is based on the cost to issue the revised certificate to the laboratory as follows:

(i) If a laboratory with a certificate of waiver wishes to perform tests in addition to those listed in §493.15(c) as waived tests, it must, as set forth in §493.638, pay an additional fee for the appropriate certificate to cover the additional testing.

(ii) If a laboratory with a certificate for PPM procedures wishes to perform tests in addition to those specified as PPM procedures or listed in §493.15(c)
as waived tests, it must, as set forth in §493.638, pay an additional fee for the appropriate certificate to cover the additional testing.

(2) A laboratory must pay a fee to cover the cost of issuing a revised certificate when—

(i) A laboratory changes its name, location, or its director; or

(ii) A laboratory deletes services or wishes to add services and requests that its certificate be changed. (An additional fee is also required under §493.643(d) if it is necessary to determine compliance with additional requirements.)

[57 FR 7213, Feb. 28, 1992, as amended at 60 FR 20047, Apr. 24, 1995]

§ 493.643 Fee for determination of program compliance.

(a) Fee requirement. In addition to the fee required under §493.638, a laboratory subject to routine inspections must pay a fee to cover the cost of determining program compliance. Laboratories issued a certificate for PPM procedures, certificate of waiver, or a certificate of accreditation are not subject to this fee for routine inspections.

(b) Costs included in the fee. Included in the fee for determining program compliance is the cost of evaluating qualifications of personnel; monitoring proficiency testing; conducting onsite inspections; documenting deficiencies; evaluating laboratories’ plans to correct deficiencies; and necessary administrative costs. HHS sets the fee amounts annually on a calendar year basis. Laboratories are inspected biennially; therefore, fees are assessed and payable biennially. If additional expenses are incurred to conduct follow up visits to verify correction of deficiencies, to impose sanctions, and/or for surveyor preparation for and attendance at ALJ hearings, HHS assesses an additional fee to include these costs. The additional fee is based on the actual resources and time necessary to perform the activities.

(c) Classification of laboratories that require inspection for purpose of determining amount of fee. (1) There are ten classifications (schedules) of laboratories for the purpose of determining the fee amount a laboratory is assessed. Each laboratory is placed into one of the ten following schedules based on the laboratory’s scope and volume of testing (excluding tests performed for quality control, quality assurance, and proficiency testing purposes).

(i) (A) Schedule A Low Volume. The laboratory performs not more than 2,000 laboratory tests annually. 

(B) Schedule A. The laboratory performs tests in no more than 3 specialties of service with a total annual volume of more than 2,000 but not more than 10,000 laboratory tests.

(ii) Schedule B. The laboratory performs tests in at least 4 specialties of service with a total annual volume of not more than 10,000 laboratory tests.

(iii) Schedule C. The laboratory performs tests in no more than 3 specialties of service with a total annual volume of more than 10,000 but not more than 25,000 laboratory tests.

(iv) Schedule D. The laboratory performs tests in at least 4 specialties with a total annual volume of more than 10,000 but not more than 25,000 laboratory tests.

(v) Schedule E. The laboratory performs more than 25,000 but not more than 50,000 laboratory tests annually.

(vi) Schedule F. The laboratory performs more than 50,000 but not more than 75,000 laboratory tests annually.

(vii) Schedule G. The laboratory performs more than 75,000 but not more than 100,000 laboratory tests annually.

(viii) Schedule H. The laboratory performs more than 100,000 but not more than 500,000 laboratory tests annually.

(ix) Schedule I. The laboratory performs more than 500,000 but not more than 1,000,000 laboratory tests annually.

(x) Schedule J. The laboratory performs more than 1,000,000 laboratory tests annually.

(2) For purposes of determining a laboratory’s classification under this section, a test is a procedure or examination for a single analyte. (Tests performed for quality control, quality assurance, and proficiency testing are excluded from the laboratory’s total annual volume). Each profile (that is, group of tests) is counted as the number of separate procedures or examinations; for example, a chemistry profile consisting of 18 tests is counted as 18 separate procedures or tests.
(3) For purposes of determining a laboratory’s classification under this section, the specialties and subspecialties of service for inclusion are:

(i) The specialty of Microbiology, which includes one or more of the following subspecialties:
   (A) Bacteriology.
   (B) Mycobacteriology.
   (C) Mycology.
   (D) Parasitology.
   (E) Virology.

(ii) The specialty of Serology, which includes one or more of the following subspecialties:
   (A) Syphilis Serology.
   (B) General immunology

(iii) The specialty of Chemistry, which includes one or more of the following subspecialties:
   (A) Routine chemistry.
   (B) Endocrinology.
   (C) Toxicology.
   (D) Urinalysis.

(iv) The specialty of Hematology.
(v) The specialty of Immunohematology, which includes one or more of the following subspecialties:
   (A) ABO grouping and Rh typing.
   (B) Unexpected antibody detection.
   (C) Compatibility testing.
   (D) Unexpected antibody identification.

(vi) The specialty of Pathology, which includes the following subspecialties:
   (A) Cytology.
   (B) Histopathology.
   (C) Oral pathology.

(vii) The specialty of Radiobioassay.
(viii) The specialty of Histocompatibility.

(ix) The specialty of Cytogenetics.

(d) Additional fees. (1) If after a certificate of compliance is issued, a laboratory adds services and requests that its certificate be upgraded, the laboratory must pay an additional fee if, in order to determine compliance with additional requirements, it is necessary to conduct an inspection, evaluate personnel, or monitor proficiency testing performance. The additional fee is based on the actual resources and time necessary to perform the activities. HHS revokes the laboratory’s certificate for failure to pay the compliance determination fee.

(2) If it is necessary to conduct a complaint investigation, impose sanctions, or conduct a hearing, HHS assesses the laboratory holding a certificate of compliance a fee to cover the cost of these activities. If a complaint investigation results in a complaint being unsubstantiated, or if an HHS adverse action is overturned at the conclusion of the administrative appeals process, the government’s costs of these activities are not imposed upon the laboratory. Costs for these activities are based on the actual resources and time necessary to perform the activities and are not assessed until after the laboratory concedes the existence of deficiencies or an ALJ rules in favor of HHS. HHS revokes the laboratory’s certificate of compliance for failure to pay the assessed costs.

§ 493.645 Additional fee(s) applicable to approved State laboratory programs and laboratories issued a certificate of accreditation, certificate of waiver, or certificate for PPM procedures.

(a) Approved State laboratory programs. State laboratory programs approved by HHS are assessed a fee for the following:
   (1) Costs of Federal inspections of laboratories in that State (that is, CLIA-exempt laboratories) to verify that standards are being enforced in an appropriate manner.
   (2) Costs incurred for investigations of complaints against the State's CLIA-exempt laboratories if the complaint is substantiated.

(3) Costs of the State's prorata share of general overhead to develop and implement CLIA.

(b) Accredited laboratories. (1) In addition to the certificate fee, a laboratory that is issued a certificate of accreditation is also assessed a fee to cover the cost of evaluating individual laboratories to determine overall whether an accreditation organization's standards and inspection policies are equivalent to the Federal program. All accredited laboratories share in the cost of these inspections. These costs are the same as those that are incurred when inspecting nonaccredited laboratories.
§ 493.646 Payment of fees.

(a) Except for CLIA-exempt laboratories, all laboratories are notified in writing by HHS or its designee of the appropriate fee(s) and instructions for submitting the fee(s), including the due date for payment and where to make payment. The appropriate certificate is not issued until the applicable fees have been paid.

(b) For State-exempt laboratories, HHS estimates the cost of conducting validation surveys within the State for a 2-year period. HHS or its designee notifies the State by mail of the appropriate fees, including the due date for payment and the address of the United States Department of Treasury designated commercial bank to which payment must be made. In addition, if complaint investigations are conducted in laboratory(s) within these States and are substantiated, HHS bills the State(s) the costs of the complaint investigations.

[57 FR 7138 and 7213, Feb. 28, 1992, as amended at 60 FR 20048, Apr. 24, 1995]

§ 493.649 Methodology for determining fee amount.

(a) General rule. The amount of the fee in each schedule for compliance determination inspections is based on the average hourly rate (which includes the costs to perform the required activities and necessary administration costs) multiplied by the average number of hours required or, if activities are performed by more than one of the entities listed in paragraph (b) of this section, the sum of the products of the applicable hourly rates multiplied by the average number of hours required by the entity to perform the activity. The fee for issuance of the registration certificate or certificate of compliance is based on the laboratory’s scope and volume of testing.

(b) Determining average hourly rates used in fee schedules. Three different entities perform activities related to the issuance or reissuance of any certificate. HHS determines the average hourly rates for the activities of each of these entities.

(1) State survey agencies. The following costs are included in determining an average hourly rate for the activities performed by State survey agencies:

(i) The costs incurred by the State survey agencies in evaluating personnel qualifications and monitoring each laboratory’s participation in an approved proficiency testing program. The cost of onsite inspections and monitoring activities is the hourly rate derived as a result of an annual budget negotiation process with each State. The hourly rate encompasses salary costs (as determined by each State’s civil service pay scale) and fringe benefit costs to support the required number of State inspectors, management and direct support staff.

(ii) Travel costs necessary to comply with each State’s administrative requirements and other direct costs such as equipment, printing, and supplies. These costs are established based on historical State requirements.
Health Care Financing Administration, HHS

§ 493.801 Condition: Enrollment and testing of samples.

Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients’ specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.

(a) Standard; Enrollment. The laboratory must—

(1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart.

(2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by HCFA; and

(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with §493.1709.

(3) For each specialty, subspecialty and analyte or test, participate in one approved proficiency testing program...

Subpart H—Participation in Proficiency Testing for Laboratories Performing Tests of Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests

§ 493.801 Condition: Enrollment and testing of samples.

Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients’ specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.

(a) Standard; Enrollment. The laboratory must—

(1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart.

(2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by HCFA; and

(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with §493.1709.

(3) For each specialty, subspecialty and analyte or test, participate in one approved proficiency testing program...

Subpart G—[Reserved]
§ 493.803  Condition: Successful participation.

(a) Each laboratory performing tests of moderate complexity (including the subcategory) and/or high complexity must successfully participate in a proficiency testing program approved by HCFA, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA.

(b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, HCFA imposes sanctions, as specified in subpart R of this part.

(c) If a laboratory fails to perform successfully in a HCFA-approved proficiency testing program, for the initial unsuccessful performance, HCFA may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather
than imposing alternative or principle sanctions except when one or more of the following conditions exists:

1. There is immediate jeopardy to patient health and safety.
2. The laboratory fails to provide HCFA or a HCFA agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance.
3. The laboratory has a poor compliance history.

§ 493.807 Condition: Reinstatement of laboratories performing tests of moderate complexity (including the subcategory), high complexity, or any combination of these tests, after failure to participate successfully.

(a) If a laboratory's certificate is suspended or limited or its Medicare or Medicaid approval is cancelled or its Medicare or Medicaid payments are suspended because it fails to participate successfully in proficiency testing for one or more specialties, subspecialties, analyte or test, or voluntarily withdraws its certification under CLIA for the failed specialty, subspecialty, or analyte, the laboratory must then demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be on site, before HCFA will consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, subspecialty, analyte or test.

(b) The cancellation period for Medicare and Medicaid approval or period for suspension of Medicare or Medicaid payments or suspension or limitation of certification under CLIA for the failed specialty, subspecialty, or analyte or test is for a period of not less than six months from the date of cancellation, limitation or suspension of the CLIA certificate.

§ 493.821 Condition: Microbiology.

The specialty of microbiology includes, for purposes of proficiency testing, the subspecialties of bacteriology, mycobacteriology, mycology, parasitology and virology.

§ 493.823 Standard; Bacteriology.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if:

1. Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;
2. The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and
3. The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.
§ 493.820 Standard; Bacteriology.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

1. Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

2. The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

3. The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

2. Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.822 Standard; Mycobacteriology.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

1. Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

2. The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

3. The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

2. Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.824 Standard; Mycology.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

1. Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

2. The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

3. The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

2. Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.826 Standard; Parasitology.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given
§ 493.835 Standard; Syphilis serology.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unsatisfactory testing events, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.833 Condition: Diagnostic immunology.

The specialty of diagnostic immunology includes for purposes of proficiency testing the subspecialties of syphilis serology and general immunology.

§ 493.835 Standard; Syphilis serology.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unsatisfactory testing events, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.
§ 493.837 Standard; General immunology.

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.839 Condition: Chemistry.

The specialty of chemistry includes for the purposes of proficiency testing the subspecialties of routine chemistry, endocrinology, and toxicology.

§ 493.841 Standard; Routine chemistry.

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—
§ 493.845 Standard; Toxicology.

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.843 Standard; Endocrinology.

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.
§ 493.849  Condition: Hematology.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—
(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;
(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and
(3) The laboratory participated in the previous two proficiency testing events.

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.
(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events is unsuccessful performance.

§ 493.851  Standard; Hematology.

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—
(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;
(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and
(3) The laboratory participated in the previous two proficiency testing events.

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.
(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events is unsuccessful performance.
§ 493.855 Standard; Cytology: gynecologic examinations.

To participate successfully in a cytology proficiency testing program for gynecologic examinations (Pap smears), the laboratory must meet the requirements of paragraphs (a) through (c) of this section.

(a) The laboratory must ensure that each individual engaged in the examination of gynecologic preparations is enrolled in a proficiency testing program approved by HCFA by January 1, 1995, if available in the State in which he or she is employed. The laboratory must ensure that each individual is tested at least once per year and obtains a passing score. To ensure this annual testing of individuals, an announced or unannounced testing event will be conducted on-site in each laboratory at least once each year. Laboratories will be notified of the time of each announced on-site testing event at least 30 days prior to each event. Additional testing events will be conducted as necessary in each State or region for the purpose of testing individuals who miss the on-site testing event and for retesting individuals as described in paragraph (b) of this section.

(b) The laboratory must ensure that each individual participates in an annual testing event that involves the examination of a 10-slide test set as described in § 493.945. Individuals who fail this testing event are retested with another 10-slide test set as described in paragraphs (b)(1) and (b)(2) of this section. Individuals who fail this second test are subsequently retested with a 20-slide test set as described in paragraphs (b)(2) and (b)(3) of this section. Individuals are given not more than 2 hours to complete a 10-slide test and not more than 4 hours to complete a 20-slide test. Unexcused failure to appear by an individual for a retest will result in test failure with resulting remediation and limitations on slide examinations as specified in (b)(1), (b)(2), and (b)(3) of this section.

(1) An individual is determined to have failed the annual testing event if he or she scores less than 90 percent on a 10-slide test set. For an individual who fails an annual proficiency testing event, the laboratory must schedule a retesting event which must take place not more than 45 days after receipt of the notification of failure.

(2) An individual is determined to have failed the second testing event if he or she scores less than 90 percent on a 10-slide test set. For an individual who fails a second testing event, the laboratory must provide him or her with documented remedial training and education in the area of failure, and must assure that all gynecologic slides evaluated subsequent to the notice of failure are reexamined until the individual is again retested with a 20-slide test set and scores at least 90 percent. Reexamination of slides must be documented.

(3) An individual is determined to have failed the third testing event if he or she scores less than 90 percent on a 20-slide test set. An individual who fails the third testing event must cease examining gynecologic slide preparations immediately upon notification of test failure and may not resume examining gynecologic slides until the laboratory assures that the individual obtains at least 35 hours of documented, formally structured, continuing education in diagnostic cytopathology that focuses on the examination of gynecologic preparations, and until he or she is retested with a 20-slide test set and scores at least 90 percent.

(c) If a laboratory fails to ensure that individuals are tested or those who fail a testing event are retested, or fails to take required remedial actions as described in paragraphs (b)(1), (b)(2) or (b)(3) of this section, HCFA will initiate intermediate sanctions or limit the laboratory's certificate to exclude gynecologic cytology testing under CLIA, and, if applicable, suspend the laboratory's Medicare and Medicaid payments for gynecologic cytology.
§ 493.857 Condition: Immunohematology.

The specialty of immunohematology includes four subspecialties for the purposes of proficiency testing: ABO group and D (Rho) typing; unexpected antibody detection; compatibility testing; and antibody identification.

§ 493.859 Standard; ABO group and D (Rho) typing.

(a) Failure to attain a score of at least 100 percent of acceptable responses for each analyte or test in each testing event is unsatisfactory analyte performance for the testing event.

(b) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(2) For any unacceptable analyte or unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analyte in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

(g) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.861 Standard; Unexpected antibody detection.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.
$493.863$ Standard; Compatibility testing.

(a) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§493.865 Standard; Antibody identification.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to identify the same antibody in two consecutive or two out of three consecutive testing events is unsuccessful performance.

(f) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.
Subpart I—Proficiency Testing Programs for Tests of Moderate Complexity (including the Subcategory), High Complexity, or Any Combination of These Tests

SOURCE: 57 FR 7151, Feb. 28, 1992, unless otherwise noted.

§ 493.901 Approval of proficiency testing programs.

In order for a proficiency testing program to receive HHS approval, the program must be offered by a private non-profit organization or a Federal or State agency, or entity acting as a designated agent for the State. An organization, Federal, or State program seeking approval or reapproval for its program for the next calendar year must submit an application providing the required information by July 1 of the current year. The organization, Federal, or State program must provide technical assistance to laboratories seeking to qualify under the program, and must, for each specialty, subspecialty, and analyte or test for which it provides testing—

(a) Assure the quality of test samples, appropriately evaluate and score the testing results, and identify performance problems in a timely manner;
(b) Demonstrate to HHS that it has—
   (1) The technical ability required to—
      (i) Prepare or purchase samples from manufacturers who prepare the samples in conformance with the appropriate good manufacturing practices required in 21 CFR parts 606, 640, and 820; and
      (ii) Distribute the samples, using rigorous quality control to assure that samples mimic actual patient specimens when possible and that samples are homogeneous, except for specific subspecialties such as cytology, and will be stable within the time frame for analysis by proficiency testing participants;
   (2) A scientifically defensible process for determining the correct result for each challenge offered by the program;
   (3) A program of sufficient annual challenge and with the frequency specified in §§ 493.909 through 493.959 to establish that a laboratory has met minimum performance requirements;
   (4) The resources needed to provide Statewide or nationwide reports to regulatory agencies on individual’s performance for gynecologic cytology and on individual laboratory performance on testing events, cumulative reports and scores for each laboratory or individual, and reports of specific laboratory failures using grading criteria acceptable to HHS. These reports must be provided to HHS on a timely basis when requested;
   (5) Provisions to include on each proficiency testing program report form used by the laboratory to record testing event results, an attestation statement that proficiency testing samples were tested in the same manner as patient specimens with a signature block to be completed by the individual performing the test as well as by the laboratory director;
   (6) A mechanism for notifying participants of the PT shipping schedule and for participants to notify the proficiency testing program within three days of the expected date of receipt of the shipment that samples have not arrived or are unacceptable for testing. The program must have provisions for replacement of samples that are lost in transit or are received in a condition that is unacceptable for testing; and
   (7) A process to resolve technical, administrative, and scientific problems about program operations;
(c) Meet the specific criteria for proficiency testing programs listed by specialty, subspecialty, and analyte or test contained in §§ 493.901 through 493.959 for initial approval and thereafter provide HHS, on an annual basis, with the information necessary to assure that the proficiency testing program meets the criteria required for approval; and
(d) Comply with all applicable packaging, shipment, and notification requirements of 42 CFR part 72.


§ 493.903 Administrative responsibilities.

The proficiency testing program must—
§ 493.911 Bacteriology.

(a) Types of services offered by laboratories. In bacteriology, for proficiency testing purposes, there are five types of laboratories:

(1) Those that interpret Gram stains or perform primary inoculation, or both; and refer cultures to another laboratory appropriately certified for the subspecialty of bacteriology for identification;

(2) Those that use direct antigen techniques to detect an organism and may also interpret Gram stains or perform primary inoculation, or perform any combination of these;

(3) Those that, in addition to interpreting Gram stains, performing primary inoculations, and using direct antigen tests, also isolate and identify aerobic bacteria from throat, urine, cervical, or urethral discharge specimens to the genus level and may also perform antimicrobial susceptibility tests on selected isolated microorganisms;

(4) Those that perform the services in paragraph (a)(3) of this section and also identify aerobic bacteria from any source to the species level and may also perform antimicrobial susceptibility tests; and

(5) Those that perform the services in paragraph (a)(4) of this section and also isolate and identify anaerobic bacteria from any source.

(b) Program content and frequency of challenge. To be approved for proficiency testing for bacteriology, the

§ 493.905 Nonapproved proficiency testing programs.

If a proficiency testing program is determined by HHS to fail to meet any criteria contained in §§ 493.901 through 493.959 for approval of the proficiency testing program, HCFA will notify the program and the program must notify all laboratories enrolled of the non-approval and the reasons for non-approval within 30 days of the notification.

§ 493.909 Microbiology.

The subspecialties under the specialty of microbiology for which a program may offer proficiency testing are bacteriology, mycobacteriology, mycology, parasitology and virology. Specific criteria for these subspecialties are found at §§ 493.911 through 493.919.
§ 493.911 42 CFR Ch. IV (10-1-98 Edition)

annual program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The samples may be provided to the laboratory through mailed shipments or, at HHS’ option, may be provided to HHS or its designee for onsite testing. For the types of laboratories specified in paragraph (a) of this section, an annual program must include samples that contain organisms that are representative of the six major groups of bacteria: anaerobes, Enterobacteriaceae, gram-positive bacilli, gram-positive cocci, gram-negative cocci, and miscellaneous gram-negative bacteria, as appropriate. The specific organisms included in the samples may vary from year to year. The annual program must include samples for bacterial antigen detection, bacterial isolation and identification, Gram stain, and antimicrobial susceptibility testing.

(1) An approved program must furnish HHS with a description of samples that it plans to include in its annual program no later than six months before each calendar year. At least 50 percent of the samples must be mixtures of the principal organism and appropriate normal flora. The program must include other important emerging pathogens (as determined by HHS) and either pathogens commonly occurring in patient specimens or opportunistic pathogens. The program must include the following two types of samples; each type of sample must meet the 50 percent mixed culture criterion:

(i) Samples that require laboratories to report only organisms that the testing laboratory considers to be a principal pathogen that is clearly responsible for a described illness (excluding immuno-compromised patients). The program determines the reportable isolates, including antimicrobial susceptibility for any designated isolate; and

(ii) Samples that require laboratories to report all organisms present. Samples must contain multiple organisms frequently found in specimens such as urine, blood, abscesses, and aspirates where multiple isolates are clearly significant or where specimens are derived from immuno-compromised patients. The program determines the reportable isolates.

(2) An approved program may vary over time. For example, the types of organisms that might be included in an approved program over time are—

Anaerobes:
- Bacteroides fragilis group
- Clostridium perfringens
- Peptostreptococcus anaerobius
- Enterobacteriaceae
- Citrobacter freundii
- Enterobacter aerogenes
- Escherichia coli
- Klebsiella pneumoniae
- Proteus mirabilis
- Salmonella typhimurium
- Serratia marcescens
- Shigella sonnei
- Yersinia enterocolitica

Gram-positive bacilli:
- Listeria monocytogenes
- Corynebacterium species CDC Group J/K

Gram-positive cocci:
- Staphylococcus aureus
- Streptococcus Group A
- Streptococcus Group B
- Staphylococcus Group F (S. bovis and enterococcus)
- Streptococcus pneumoniae

Gram-negative cocci:
- Branhamella catarrhalis
- Neisseria gonorrhoeae
- Neisseria meningitidis

Miscellaneous Gram-negative bacteria:
- Campylobacter jejuni
- Haemophilus influenzae, Type B
- Pseudomonas aeruginosa

(3) For antimicrobial susceptibility testing, the program must provide at least one sample per testing event that includes gram-positive or gram-negative strains that have a predetermined pattern of sensitivity or resistance to the common antimicrobial agents.

(c) Evaluation of a laboratory’s performance. HHS approves only those programs that assess the accuracy of a laboratory’s responses in accordance with paragraphs (c) (1) through (7) of this section.

(1) The program determines staining characteristics to be interpreted by Gram stain. The program determines the reportable bacteria to be detected by direct antigen techniques or isolation. To determine the accuracy of a laboratory’s response for Gram stain interpretation, direct antigen detection, identification, or antimicrobial susceptibility testing, the program
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must compare the laboratory’s response for each sample with the response which reflects agreement of either 90 percent of ten or more referee laboratories or 90 percent or more of all participating laboratories.

(2) To evaluate a laboratory’s response for a particular sample, the program must determine a laboratory’s type of service in accordance with paragraph (a) of this section. A laboratory must isolate and identify the organisms to the same extent it performs these procedures on patient specimens. A laboratory’s performance will be evaluated on the basis of its final answer, for example, a laboratory specified in paragraph (a)(3) of this section will be evaluated on the basis of the average of its scores for paragraphs (c)(3) through (c)(6) as determined in paragraph (c)(7) of this section.

(3) Since laboratories may incorrectly report the presence of organisms in addition to the correctly identified principal organism(s), the grading system must provide a means of deducting credit for additional erroneous organisms that are reported. Therefore, the total number of correct responses for organism isolation and identification submitted by the laboratory divided by the number of organisms present plus the number of incorrect organisms reported by the laboratory must be multiplied by 100 to establish a score for each sample in each testing event. For example, if a sample contained one principal organism and the laboratory reported it correctly but reported the presence of an additional organism, which was not considered reportable, the sample grade would be 1/(1+1)×100=50 percent.

(4) For antimicrobial susceptibility testing, a laboratory must indicate which drugs are routinely included in its test panel when testing patient samples. A laboratory’s performance will be evaluated for only those antibiotics for which service is offered. A correct response for each antibiotic will be determined as described in §§493.911(c) (1) using criteria such as the guidelines established by the National Committee for Clinical Laboratory Standards. Grading is based on the actual number of correct susceptibility responses determined by the program, multiplied by 100. For example, if a laboratory offers susceptibility testing for Enterobacteriaceae using amikacin, cephalothin, and tobramycin, and the organism in the proficiency testing sample is an Enterobacteriaceae, and the laboratory reports correct responses for two of three antimicrobial agents, the laboratory’s grade would be 2/3×100=67 percent.

(5) The performance criterion for qualitative antigen tests is the presence or absence of the bacterial antigen. The score for antigen tests is the number of correct responses divided by the number of samples to be tested for the antigen, multiplied by 100.

(6) The performance criteria for Gram stain is staining reaction, i.e., gram positive or gram negative. The score for Gram stain is the number of correct responses divided by the number of challenges to be tested, multiplied by 100.

(7) The score for a testing event in bacteriology is the average of the scores determined under paragraphs (c)(3) through (c)(6) of this section based on the type of service offered by the laboratory.


§ 493.913 Mycobacteriology.

(a) Types of services offered by laboratories. In mycobacteriology, there are five types of laboratories for proficiency testing purposes:

(1) Those that interpret acid-fast stains and refer specimen to another laboratory appropriately certified in the subspecialty of mycobacteriology;

(2) Those that interpret acid-fast stains, perform primary inoculation, and refer cultures to another laboratory appropriately certified in the subspecialty of mycobacteriology for identification;

(3) Those that interpret acid-fast stains, isolate and perform identification and/or antimycobacterial susceptibility of Mycobacterium tuberculosis, but refer other mycobacteria species to another laboratory appropriately certified in the subspecialty of
mycobacteriology for identification and/or susceptibility tests;
(4) Those that interpret acid-fast stains, isolate and identify all mycobacteria to the extent required for correct clinical diagnosis, but refer antimycobacterial susceptibility tests to another laboratory appropriately certified in the subspecialty of mycobacteriology; and
(5) Those that interpret acid-fast stains, isolate and identify all mycobacteria to the extent required for correct clinical diagnosis, and perform antimycobacterial susceptibility tests on the organisms isolated.

(b) Program content and frequency of challenge. To be approved for proficiency testing for mycobacteriology, the annual program must provide a minimum of five samples per testing event. There must be at least two testing events per year. The samples may be provided through mailed shipments or, at HHS' option, provided to HHS or its designee for on-site testing events. For types of laboratories specified in paragraphs (a)(1) and (a)(3) through (5) of this section, an annual program must include samples that contain species that are representative of the 5 major groups (complexes) of mycobacteria encountered in human specimens. The specific mycobacteria included in the samples may vary from year to year.

(1) An approved program must furnish HHS and its agents with a description of samples that it plans to include in its annual program no later than six months before each calendar year. At least 50 percent of the samples must be mixtures of the principal mycobacteria and appropriate normal flora. The program must include mycobacteria commonly occurring in patient specimens and other important emerging mycobacteria (as determined by HHS). The program determines the reportable mycobacteria to be detected by acid-fast stain, for isolation and identification, and for antimycobacterial susceptibility. To determine the accuracy of a laboratory's response, the program must compare the laboratory's response for each sample with the response that reflects agreement of either 90 percent of ten or more referee laboratories or 90 percent or more of all participating laboratories.

(2) To evaluate a laboratory's response for a particular sample, the program must determine a laboratory's type of service in accordance with paragraph (a) of this section. A laboratory must interpret acid-fast stains and isolate and identify the organisms to the same extent it performs these procedures on patient specimens. A laboratory's performance will be evaluated on the basis of the average of its scores as determined in paragraph (c)(6) of this section.

(3) Since laboratories may incorrectly report the presence of organisms in addition to the correctly identified principal organism(s), the grading system must provide a means of deducting...
credit for additional erroneous organisms reported. Therefore, the total number of correct responses submitted by the laboratory divided by the number of organisms present plus the number of incorrect organisms reported by the laboratory must be multiplied by 100 to establish a score for each sample in each testing event. For example, if a sample contained one principal organism and the laboratory reported it correctly but reported the presence of an additional organism, which was not present, the sample grade would be $\frac{1}{1+1} \times 100 = 50\%$.

For antimycobacterial susceptibility testing, a laboratory must indicate which drugs are routinely included in its test panel when testing patient samples. A laboratory's performance will be evaluated for only those antibiotics for which susceptibility testing is routinely performed on patient specimens. A correct response for each antibiotic will be determined as described in §493.913(c)(1). Grading is based on the number of correct susceptibility responses reported by the laboratory divided by the actual number of correct susceptibility responses as determined by the program, multiplied by 100. For example, if a laboratory offers susceptibility testing using three antimycobacterial agents and the laboratory reports correct response for two of the three antimycobacterial agents, the laboratory's grade would be $\frac{2}{3} \times 100 = 67\%$.

The performance criterion for qualitative tests is the presence or absence of acid-fast organisms. The score for acid-fast organism detection is the number of correct responses divided by the number of samples to be tested, multiplied by 100.

The score for a testing event in mycobacteriology is the average of the scores determined under paragraphs (c)(3) through (c)(5) of this section based on the type of service offered by the laboratory.


§ 493.915 Mycology.

(a) Types of services offered by laboratories. In mycology, there are four types of laboratories for proficiency testing purposes that may perform different levels of service for yeasts, dimorphic fungi, dermatophytes, and aerobic actinomycetes:

1. Those that isolate and identify only yeasts and/or dermatophytes to the genus level;
2. Those that isolate and identify yeasts and/or dermatophytes to the species level;
3. Those that isolate and perform identification of all organisms to the genus level; and
4. Those that isolate and perform identification of all organisms to the species level.

(b) Program content and frequency of challenge. To be approved for proficiency testing for mycology, the annual program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The samples may be provided through mailed shipments or, at HHS’s option, may be provided to HHS or its designee for on-site testing. An annual program must include samples that contain organisms that are representative of five major groups of fungi: Yeast or yeast-like fungi; dimorphic fungi; dematiaceous fungi; dermatophytes; and saprophytes, including opportunistic fungi. The specific fungi included in the samples may vary from year to year.

1. An approved program must, before each calendar year, furnish HHS with a description of samples that it plans to include in its annual program no later than six months before each calendar year. At least 50 percent of the samples must be mixtures of the principal organism and appropriate normal background flora. Other important emerging pathogens (as determined by HHS) and organisms commonly occurring in patient specimens must be included periodically in the program.

2. An approved program may vary over time. As an example, the types of organisms that might be included in an approved program over time are—

Candida albicans
Candida (other species)
Cryptococcus neoformans
Sporothrix schenckii
Exophiala jeanselmei
Fonsecaea pedrosii
Microsporum sp.
Acremonium sp.
§ 493.917 Parasitology.

(a) Types of services offered by laboratories. In parasitology there are two types of laboratories for proficiency testing purposes—

(1) Those that determine the presence or absence of parasites by direct observation (wet mount) and/or pinworm preparations and, if necessary, refer specimens to another laboratory appropriately certified in the subspecialty of parasitology for identification;

(2) Those that identify parasites using concentration preparations and/or permanent stains.

(b) Program content and frequency of challenge. To be approved for proficiency testing in parasitology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The samples may be provided through mailed shipments or, at HHS’s option, may be provided to HHS or its designee for on-site testing. An annual program must include samples that contain parasites that are commonly encountered in the United States as well as those recently introduced into the United States. Other important emerging pathogens (as determined by HHS) and parasites commonly occurring in patient specimens must be included periodically in the program.

(1) An approved program must, before each calendar year furnish HHS with a description of samples that it plans to include in its annual program no later than six months before each calendar year. Samples must include both formalinized specimens and PVA (polyvinyl alcohol) fixed specimens as well as blood smears, as appropriate for a particular parasite and stage of the parasite. The majority of samples must contain protozoa or helminths or a combination of parasites. Some samples must be devoid of parasites.

(2) An approved program may vary over time. As an example, the types of parasites that might be included in an approved program over time are—
Enterobius vermicularis
Entamoeba histolytica
Entamoeba coli
Giardia lamblia
Endolimax nana
Dientamoeba fragilis
Iodamoeba butschli
Chilomastix mesnili
Hookworm
Ascaris lumbricoides
Strongyloides stercoralis
Trichuris trichiura
Diphyllobothrium latum
Cryptosporidium sp.
Plasmodium falciparum

(3) For laboratories specified in paragraph (a)(1) of this section, the program must provide at least five samples per testing event that include challenges which contain parasites and challenges that are devoid of parasites.

(c) Evaluation of a laboratory’s performance. HHS approves only those programs that assess the accuracy of a laboratory’s responses in accordance with paragraphs (c)(1) through (6) of this section.

(1) The program must determine the reportable parasites. It may elect to establish a minimum number of parasites to be identified in samples before they are reported. Parasites found in rare numbers by referee laboratories are not considered in scoring a laboratory’s performance; such findings are neutral. To determine the accuracy of a laboratory’s response, the program must compare the laboratory’s response with the response that reflects agreement of either 90 percent of ten or more referee laboratories or 90 percent or more of all participating laboratories.

(2) To evaluate a laboratory’s response for a particular sample, the program must determine a laboratory’s type of service in accordance with paragraph (a) of this section. A laboratory must determine the presence or absence of a parasite(s) or concentrate and identify the parasites to the same extent it performs these procedures on patient specimens.

(3) Since laboratories may incorrectly report the presence of parasites in addition to the correctly identified principal parasite(s), the grading system must deduct credit for these additional erroneous parasites reported and not found in rare numbers by the program’s referencing process. Therefore, the total number of correct responses submitted by the laboratory divided by the number of parasites present plus the number of incorrect parasites reported by the laboratory must be multiplied by 100 to establish a score for each sample in each testing event. For example, if a sample contained one principal parasite and the laboratory reported it correctly but reported the presence of an additional parasite, which was not present, the sample grade would be

\[
\frac{1}{1+1} \times 100 = 50\%.
\]

(4) The criterion for acceptable performance for qualitative parasitology examinations is presence or absence of a parasite(s).

(5) The score for parasitology is the number of correct responses divided by the number of samples to be tested, multiplied by 100.

(6) The score for a testing event is the average of the sample scores as determined under paragraphs (c)(3) through (c)(5) of this section.

§ 493.919 Virology.

(a) Types of services offered by laboratories. In virology, there are two types of laboratories for proficiency testing purposes—

(1) Those that only perform tests that directly detect viral antigens or structures, either in cells derived from infected tissues or free in fluid specimens; and

(2) Those that are able to isolate and identify viruses and use direct antigen techniques.

(b) Program content and frequency of challenge. To be approved for proficiency testing in virology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The samples may be provided to the laboratory through mailed shipments or, at HHS’s option, may be provided to HHS or its designee for on-site testing. An annual program must include viral species that are the more commonly identified viruses. The specific organisms found in the samples may vary from year to year. The annual program must include samples for viral antigen detection and viral isolation and identification.
(1) An approved program must furnish HHS with a description of samples that it plans to include in its annual program no later than six months before each calendar year. The program must include other important emerging viruses (as determined by HHS) and viruses commonly occurring in patient specimens.

(2) An approved program may vary over time. For example, the types of viruses that might be included in an approved program over time are the more commonly identified viruses such as Herpes simplex, respiratory syncytial virus, adenoviruses, enteroviruses, and cytomegaloviruses.

c) Evaluation of laboratory's performance. HHS approves only those programs that assess the accuracy of a laboratory's response in accordance with paragraphs (c)(1) through (5) of this section.

(1) The program determines the reportable viruses to be detected by direct antigen techniques or isolated by laboratories that perform viral isolation procedures. To determine the accuracy of a laboratory's response, the program must compare the laboratory's response for each sample with the response that reflects agreement of either 90 percent of ten or more referee laboratories or 90 percent or more of all participating laboratories.

(2) To evaluate a laboratory's response for a particular sample, the program must determine a laboratory's type of service in accordance with paragraph (a) of this section. A laboratory must isolate and identify the viruses to the same extent it performs these procedures on patient specimens.

(3) Since laboratories may incorrectly report the presence of viruses in addition to the correctly identified principal virus, the grading system must provide a means of deducting credit for additional erroneous viruses reported. Therefore, the total number of incorrect responses determined by virus culture techniques submitted by the laboratory divided by the number of viruses present plus the number of incorrect viruses reported by the laboratory must be multiplied by 100 to establish a score for each sample in each testing event. For example, if a sample contained one principal virus and the laboratory reported it correctly but reported the presence of an additional virus, which was not present, the sample grade would be 1/ (1+1)×100=50 percent.

(4) The performance criterion for qualitative antigen tests is presence or absence of the viral antigen. The score for the antigen tests is the number of correct responses divided by the number of samples to be tested for the antigen, multiplied by 100.

(5) The score for a testing event is the average of the sample scores as determined under paragraph (c)(3) and (c)(4) of this section.

§ 493.921 Diagnostic immunology.

The subspecialties under the specialty of immunology for which a program may offer proficiency testing are syphilis serology and general immunology. Specific criteria for these subspecialties are found at §§ 493.923 and 493.927.

§ 493.923 Syphilis serology.

(a) Program content and frequency of challenge. To be approved for proficiency testing in syphilis serology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing. An annual program must include samples that cover the full range of reactivity from highly reactive to non-reactive.

(b) Evaluation of test performance. HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (b)(1) through (4) of this section.

(1) To determine the accuracy of a laboratory's response for qualitative and quantitative syphilis tests, the program must compare the laboratory's response with the response that reflects agreement of either 90 percent of ten or more referee laboratories or 90 percent or more of all participating laboratories. The proficiency testing program must indicate the minimum concentration, by method, that will be
considered as indicating a positive response. The score for a sample in syphilis serology is the average of scores determined under paragraphs (b)(2) and (b)(3) of this section.

(2) For quantitative syphilis tests, the program must determine the correct response for each method by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using fixed criteria. The criterion for acceptable performance for quantitative syphilis serology tests is the target value ± 1 dilution.

(3) The criterion for acceptable performance for qualitative syphilis serology tests is reactive or nonreactive.

(4) To determine the overall testing event score, the number of correct responses must be averaged using the following formula:

\[
\text{Number of acceptable responses for all challenges} \times \frac{100}{\text{Total number of all challenges}} = \text{Testing event score}
\]


§ 493.927 General immunology.

(a) Program content and frequency of challenge. To be approved for proficiency testing for immunology, the annual program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the full range of reactivity from highly reactive to nonreactive. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing.

(b) Challenges per testing event. The minimum number of challenges per testing event the program must provide for each analyte or test procedure is five. Analytes or tests for which laboratory performance is to be evaluated include:

- Alpha-1 antitrypsin
- Alpha-fetoprotein (tumor marker)
- Antinuclear antibody
- Antistreptolysin O
- Anti-human immunodeficiency virus (HIV)
- Complement C3
- Complement C4
- Hepatitis markers (HBsAg, anti-HBc, HBeAg)
- IgA
- IgG
- IgE
- IgM
- Infectious mononucleosis
- Rheumatoid factor
- Rubella

(c) Evaluation of a laboratory's analyte or test performance. HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c)(1) through (5) of this section.

(1) To determine the accuracy of a laboratory's response for quantitative and qualitative immunology tests or analytes, the program must compare the laboratory's response for each analyte with the response that reflects agreement of either 90 percent of ten or more referee laboratories or 90 percent or more of all participating laboratories. The proficiency testing program must indicate the minimum concentration that will be considered as indicating a positive response. The score for a sample in general immunology is either the score determined under paragraph (c)(2) or (3) of this section.

(2) For quantitative immunology analytes or tests, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using either fixed criteria or the number of standard deviations (SDs) the response differs from the target value.

Criteria for Acceptable Performance

The criteria for acceptable performance are—

<table>
<thead>
<tr>
<th>Analyte or test</th>
<th>Criteria for acceptable performance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alpha-1 antitrypsin</td>
<td>Target value ±3 SD.</td>
</tr>
<tr>
<td>Alpha-fetoprotein (tumor marker)</td>
<td>Target value ±3 SD.</td>
</tr>
</tbody>
</table>
§ 493.929 Chemistry.

The subspecialties under the specialty of chemistry for which a proficiency testing program may offer proficiency testing are routine chemistry, endocrinology, and toxicology. Specific criteria for these subspecialties are listed in §§493.931 through 493.939.

§ 493.931 Routine chemistry.

(a) Program content and frequency of challenge. To be approved for proficiency testing for routine chemistry, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the clinically relevant range of values that would be expected in patient specimens. The specimens may be provided through mailed shipments or, at HHS’ option, may be provided to HHS or its designee for on-site testing.

(b) Challenges per testing event. The minimum number of challenges per testing event a program must provide for each analyte or test procedure listed below is five serum, plasma or blood samples.

Analyte or Test Procedure

- Alanine aminotransferase (ALT/SGPT)
- Albumin
- Alkaline phosphatase
- Amylase
- Aspartate aminotransferase (AST/SGOT)
- Bilirubin, total
- Blood gas (pH, pO2, and pCO2)
- Calcium, total
- Chloride
- Cholesterol, total
- Cholesterol, high density lipoprotein
- Creatine kinase
- Creatine kinase, isoenzymes
- Creatinine
- Glucose (Excluding measurements on devices cleared by FDA for home use)
- Iron, total
- Lactate dehydrogenase (LDH)
- LDH isoenzymes
- Magnesium
- Potassium
- Sodium
- Total Protein
- Triglycerides
- Urea Nitrogen
- Uric Acid

(c) Evaluation of a laboratory’s analyte or test performance. HHS approves only those programs that assess the accuracy of a laboratory’s responses in accordance with paragraphs (c)(1) through (5) of this section.

(1) To determine the accuracy of a laboratory’s response for qualitative and quantitative chemistry tests or analytes, the program must compare the laboratory’s response for each
analyte with the response that reflects agreement of either 90 percent of ten or more referee laboratories or 90 percent or more of all participating laboratories. The score for a sample in routine chemistry is either the score determined under paragraph (c)(2) or (3) of this section.

(2) For quantitative chemistry tests or analytes, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using either fixed criteria based on the percentage difference from the target value or the number of standard deviations (SDs) the response differs from the target value.

Criteria for Acceptable Performance

The criteria for acceptable performance are—

<table>
<thead>
<tr>
<th>Analyte or test</th>
<th>Criteria for acceptable performance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alanine aminotransferase (ALT/SGPT)</td>
<td>Target value ±120%</td>
</tr>
<tr>
<td>Albumin</td>
<td>Target value ±10%</td>
</tr>
<tr>
<td>Alkaline phosphatase</td>
<td>Target value ±10%</td>
</tr>
<tr>
<td>Amylase</td>
<td>Target value ±10%</td>
</tr>
<tr>
<td>Aspartate aminotransferase (AST/SGOT)</td>
<td>Target value ±10%</td>
</tr>
<tr>
<td>Bilirubin, total</td>
<td>Target value ±30%</td>
</tr>
<tr>
<td>Blood gas pO2</td>
<td>Target value ±4.4 mg/dL or ±20% (greater)</td>
</tr>
<tr>
<td>pCO2</td>
<td>Target value ±3 SD.</td>
</tr>
<tr>
<td>pH</td>
<td>Target value ±0.04.</td>
</tr>
<tr>
<td>Calcium, total</td>
<td>Target value ±1.0 mg/dL.</td>
</tr>
<tr>
<td>Cholesterol, total</td>
<td>Target value ±10%.</td>
</tr>
<tr>
<td>Cholesterol, high density lipoprotein</td>
<td>Target value ±30%</td>
</tr>
<tr>
<td>Creatine kinase</td>
<td>Target value ±30%</td>
</tr>
<tr>
<td>Creatine kinase isoenzymes</td>
<td>MB elevated (presence or absence) or Target value ±3 SD.</td>
</tr>
<tr>
<td>Creatinine</td>
<td>Target value ±6 mg/dL or ±15% (greater).</td>
</tr>
<tr>
<td>Glucose (excluding glucose</td>
<td>Target value ±20%</td>
</tr>
<tr>
<td>performed on monitoring devices cleared by FDA for home use)</td>
<td></td>
</tr>
<tr>
<td>Iron, total</td>
<td>Target value ±20%</td>
</tr>
<tr>
<td>Lactate dehydrogenase (LDH)</td>
<td>Target value ±20%</td>
</tr>
<tr>
<td>LDH isoenzymes</td>
<td>LDH1/LDH2 (+ or −) or Target value ±30%</td>
</tr>
<tr>
<td>Magnesium</td>
<td>Target value ±5 mmol/L.</td>
</tr>
<tr>
<td>Potassium</td>
<td>Target value ±20%</td>
</tr>
<tr>
<td>Sodium</td>
<td>Target value ±10%</td>
</tr>
<tr>
<td>Total Protein</td>
<td>Target value ±20%</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>Target value ±25%</td>
</tr>
<tr>
<td>Urea nitrogen</td>
<td>Target value ±2 mg/dL or ±9% (greater).</td>
</tr>
</tbody>
</table>

(3) The criterion for acceptable performance for qualitative routine chemistry tests is positive or negative.

(4) To determine the analyte testing event score, the number of acceptable analyte responses must be averaged using the following formula:

\[
\text{Analyte score for the analyze} = \frac{\text{Number of acceptable responses for the analyze}}{\text{Total number of challenges for the analyze}} \times 100
\]

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

\[
\text{Testing event score} = \frac{\text{Total number of all challenges}}{\text{Total number of all challenges}} \times 100
\]

§ 493.933 Endocrinology.

(a) Program content and frequency of challenge. To be approved for proficiency testing for endocrinology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the clinically relevant range of values that would be expected in patient specimens. The samples may be provided through mailed shipments or, at HHS’ option, may be provided to HHS or its designee for on-site testing.

(b) Challenges per testing event. The minimum number of challenges per testing event a program must provide for each analyte or test procedure is five serum, plasma, blood, or urine samples.

Analyte or Test

Cortisol

Free Thyroxine

Human Chorionic gonadotropin (excluding urine pregnancy tests done by visual color comparison categorized as waived tests)

T3 Uptake

Triiodothyronine
§ 493.937 Thyroid-stimulating hormone

Thyroxine

(c) Evaluation of a laboratory's analytic or test performance. HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c)(1) through (5) of this section.

(1) To determine the accuracy of a laboratory's response for qualitative and quantitative endocrinology tests or analytes, a program must compare the laboratory's response for each analyte with the response that reflects agreement of either 90 percent of ten or more referee laboratories or 90 percent or more of all participating laboratories. The score for a sample in endocrinology is either the score determined under paragraph (c)(2) or (c)(3) of this section.

(2) For quantitative endocrinology tests or analytes, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using either fixed criteria based on the percentage difference from the target value or the number of standard deviations (SDs) the response differs from the target value.

Criteria for Acceptable Performance

The criteria for acceptable performance are—

<table>
<thead>
<tr>
<th>Analyte or test</th>
<th>Criteria for acceptable performance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cortisol</td>
<td>Target value $\pm$ +25%.</td>
</tr>
<tr>
<td>Free Thyroxine</td>
<td>Target value $\pm$ +3 SD.</td>
</tr>
<tr>
<td>Gonadotropin (excluding urine pregnancy tests done by visual color comparison categorized as waived tests)</td>
<td>Target value $\pm$ +3 SD positive or negative.</td>
</tr>
<tr>
<td>T3 Uptake</td>
<td>Target value $\pm$ +3 SD.</td>
</tr>
<tr>
<td>Triiodothyronine</td>
<td>Target value $\pm$ +3 SD.</td>
</tr>
<tr>
<td>Thyroid-stimulating hormone</td>
<td>Target value $\pm$ +20% or 1.0 mcg/dL (greater).</td>
</tr>
<tr>
<td>Thyroxine</td>
<td>Target value $\pm$ +20% or 1.0 mcg/dL (greater).</td>
</tr>
</tbody>
</table>

(3) The criterion for acceptable performance for qualitative endocrinology tests is positive or negative.

(4) To determine the analyte testing event score, the number of acceptable analytic responses must be averaged using the following formula:

\[
\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of challenges for the analyte}} \times 100 = \text{Analyte score for the testing event}
\]

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

\[
\frac{\text{Number of acceptable responses for all challenges}}{\text{Total number of all challenges}} \times 100 = \text{Testing event score}
\]

(c) Evaluation of a laboratory’s analyte or test performance. HHS approves only those programs that assess the accuracy of a laboratory’s responses in accordance with paragraphs (c)(1) through (4) of this section.

(1) To determine the accuracy of a laboratory’s responses for quantitative toxicology tests or analytes, the program must compare the laboratory’s response for each analyte with the response that reflects agreement of either 90 percent of ten or more referee laboratories or 90 percent or more of all participating laboratories. The score for a sample in toxicology is the score determined under paragraph (c)(2) of this section.

(2) For quantitative toxicology tests or analytes, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using fixed criteria based on the percentage difference from the target value.

Criteria for Acceptable Performance

The criteria for acceptable performance are:

<table>
<thead>
<tr>
<th>Analyte or test</th>
<th>Criteria for acceptable performance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol, blood</td>
<td>Target Value ± 25%</td>
</tr>
<tr>
<td>Blood lead</td>
<td>Target Value ±10% or 4 mcg/dL (greater)</td>
</tr>
<tr>
<td>Carbamazepine</td>
<td>Target Value ± 25%</td>
</tr>
<tr>
<td>Digoxin</td>
<td>Target Value ± 20% or ± 0.2 ng/mL (greater)</td>
</tr>
<tr>
<td>Ethisuximide</td>
<td>Target Value ± 20%</td>
</tr>
<tr>
<td>Gentamycin</td>
<td>Target Value ± 25%</td>
</tr>
<tr>
<td>Lithium</td>
<td>Target Value ± 0.3 mmol/L or ± 20% (greater)</td>
</tr>
<tr>
<td>Phenobarbital</td>
<td>Target Value ± 20%</td>
</tr>
<tr>
<td>Phenytoin</td>
<td>Target Value ± 25%</td>
</tr>
<tr>
<td>Primidone</td>
<td>Target Value ± 25%</td>
</tr>
<tr>
<td>Procainamide (and metabo-</td>
<td>Target Value ± 25%</td>
</tr>
<tr>
<td>lite)</td>
<td></td>
</tr>
<tr>
<td>Quinidine</td>
<td>Target Value ± 25%</td>
</tr>
<tr>
<td>Tobramycin</td>
<td>Target Value ± 25%</td>
</tr>
<tr>
<td>Theophylline</td>
<td>Target Value ± 25%</td>
</tr>
<tr>
<td>Valproic Acid</td>
<td>Target Value ± 25%</td>
</tr>
</tbody>
</table>

(3) To determine the analyte testing event score, the number of acceptable analyte responses must be averaged using the following formula:

\[
\frac{\text{Number of acceptable responses for the analyte} \times 100}{\text{Total number of challenges for the analyte}} = \text{Analyte score for the testing event}
\]

(4) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

\[
\frac{\text{Number of acceptable responses for all challenges} \times 100}{\text{Total number of all challenges}} = \text{Testing event score}
\]


§ 493.941  Hematology (including routine hematology and coagulation).

(a) Program content and frequency of challenge. To be approved for proficiency testing for hematology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the full range of values that would be expected in patient specimens. The samples may be provided through mailed shipments or, at HHS’ option, may be provided to HHS and/or its designee for on-site testing.

(b) Challenges per testing event. The minimum number of challenges per testing event a program must provide for each analyte or test procedure is five.

Analyte or Test Procedure

Cell identification or white blood cell differential
Erythrocyte count
Hemacrit (excluding spun microhemacrit)
Hemoglobin
Leukocyte count
Platelet count
Fibrinogen
Partial thromboplastin time
Prothrombin time

(1) An approved program for cell identification may vary over time. The types of cells that might be included in an approved program over time are—
§ 493.945 Cytology; gynecologic examinations.

(a) Program content and frequency of challenge. (1) To be approved for proficiency testing for gynecologic examinations (Pap smears) in cytology, a program must provide test sets composed of 10- and 20-glass slides. Proficiency testing programs may obtain slides for test sets from cytology laboratories, provided the slides have been retained by the laboratory for the required period specified in §493.1257. If slide preparations are still subject to retention by the laboratory, they may be loaned to a proficiency testing program if the program provides the laboratory with documentation of the loan of the slides and ensures that slides loaned to it are retrievable upon request. Each test set must include at least one slide representing each of the

(b) Criteria for acceptable performance.

The criteria for acceptable performance are:

<table>
<thead>
<tr>
<th>Analyte or test</th>
<th>Criteria for acceptable performance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cell identification</td>
<td>90% or greater consensus on identification. Target ± 3SD based on the percentage of different types of white blood cells in the samples.</td>
</tr>
<tr>
<td>White blood cell differential</td>
<td>Target ± 6%.</td>
</tr>
<tr>
<td>Erythrocyte count</td>
<td>Target ± 6%.</td>
</tr>
<tr>
<td>Hematocrit (Excluding spun hematocrit)</td>
<td>Target ± 7%.</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>Target ± 15%.</td>
</tr>
<tr>
<td>Leukocyte count</td>
<td>Target ± 15%.</td>
</tr>
<tr>
<td>Platelet count</td>
<td>Target ± 25%.</td>
</tr>
</tbody>
</table>
response categories described in paragraph (b)(3)(ii)(A) of this section, and test sets should be comparable so that equitable testing is achieved within and between proficiency testing providers.

(2) To be approved for proficiency testing in gynecologic cytology, a program must provide announced and unannounced on-site testing for each individual at least once per year and must provide an initial retesting event for each individual within 45 days after notification of test failure and subsequent retesting events within 45 days after completion of remedial action described in §493.855.

(b) Evaluation of an individual’s performance. HHS approves only those programs that assess the accuracy of each individual’s responses on both 10- and 20-slide test sets in which the slides have been referenced as specified in paragraph (b)(1) of this section.

(1) To determine the accuracy of an individual’s response on a particular challenge (slide), the program must compare the individual’s response for each slide preparation with the response that reflects the predetermined consensus agreement or confirmation on the diagnostic category, as described in the table in paragraph (b)(3)(ii)(A) of this section. For all slide preparations, a 100% consensus agreement among a minimum of three physicians certified in anatomic pathology is required. In addition, for premalignant and malignant slide preparations, confirmation by tissue biopsy is required either by comparison of the reported biopsy results or reevaluation of biopsy slide material by a physician certified in anatomic pathology.

(2) An individual qualified as a technical supervisor under §493.1449 (b) or (k) who routinely interprets gynecologic slide preparations only after they have been examined by a cytotechnologist can either be tested using a test set that has not been previously screened.

(3) The criteria for acceptable performance are determined by using the scoring system in paragraphs (b)(3)(i) and (ii) of this section.

(i) Each slide set must contain 10 or 20 slides with point values established for each slide preparation based on the significance of the relationship of the interpretation of the slide to a clinical condition and whether the participant in the testing event is a cytotechnologist, qualified under §§493.1469 or 493.1483 or functioning as a technical supervisor in cytology qualified under §493.1449 (b) or (k) of this part.

(ii) The scoring system rewards or penalizes the participants in proportion to the distance of their answers from the correct response or target diagnosis and the penalty or reward is weighted in proportion to the severity of the lesion.

(A) The four response categories for reporting proficiency testing results and their descriptions are as follows:

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A ..........</td>
<td>Unsatisfactory for diagnosis due to:</td>
</tr>
<tr>
<td></td>
<td>(1) Scant cellularity.</td>
</tr>
<tr>
<td></td>
<td>(2) Air drying.</td>
</tr>
<tr>
<td></td>
<td>(3) Obscuring material (blood, inflammatory cells, or lubricant).</td>
</tr>
<tr>
<td>B ..........</td>
<td>Normal or Benign Changes—includes:</td>
</tr>
<tr>
<td></td>
<td>(1) Normal, negative or within normal limits.</td>
</tr>
<tr>
<td></td>
<td>(2) Infection other than Human Papillomavirus (HPV) (e.g., Trichomonas vaginalis, changes or morphology consistent with Candida spp., Actinomyces spp., or Herpes simplex virus).</td>
</tr>
<tr>
<td>C ..........</td>
<td>Low Grade Squamous Intraepithelial Lesion—includes:</td>
</tr>
<tr>
<td></td>
<td>(1) Cellular changes associated with HPV.</td>
</tr>
<tr>
<td></td>
<td>(2) Mild dysplasia/CIN-1.</td>
</tr>
<tr>
<td>D ..........</td>
<td>High Grade Lesion and Carcinoma—includes:</td>
</tr>
<tr>
<td></td>
<td>(1) High grade squamous intraepithelial lesions which include moderate dysplasia/CIN-2 and severe dysplasia/carcinoma in-situ/CIN-3.</td>
</tr>
<tr>
<td></td>
<td>(2) Squamous cell carcinoma.</td>
</tr>
<tr>
<td></td>
<td>(3) Adenocarcinoma and other malignant neoplasms.</td>
</tr>
</tbody>
</table>
§ 493.959  Immunohematology.

(a) Types of services offered by laboratories. In immunohematology, there are four types of laboratories for proficiency testing purposes—

(1) Those that perform ABO group and/or D (Rho) typing;

(2) Those that perform ABO group and/or D (Rho) typing, and unexpected antibody detection;

(3) Those that in addition to paragraph (a)(1) of this section perform compatibility testing; and

(4) Those that in addition to paragraph (a)(2) of this section perform antibody identification.

(b) Program content and frequency of challenge. To be approved for proficiency testing for immunohematology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the full range of interpretation that would be expected in patient specimens. The samples may be provided through mailed shipments or, at
Health Care Financing Administration, HHS

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HHS’ option, may be provided to HHS or its designee for on-site testing.

(c) Challenges per testing event. The minimum number of challenges per testing event a program must provide for each analyte or test procedure is five.

Analyte or Test Procedure

<table>
<thead>
<tr>
<th>Analyte or Test</th>
<th>Criteria for acceptable performance</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABO group (excluding subgroups)</td>
<td>100% accuracy.</td>
</tr>
<tr>
<td>D (Rh) typing</td>
<td>100% accuracy.</td>
</tr>
<tr>
<td>Unexpected antibody detection</td>
<td>80% accuracy.</td>
</tr>
<tr>
<td>Compatibility testing</td>
<td>100% accuracy.</td>
</tr>
<tr>
<td>Antibody identification</td>
<td>80% accuracy.</td>
</tr>
</tbody>
</table>

(d) Evaluation of a laboratory’s analyte or test performance. HHS approves only those programs that assess the accuracy of a laboratory’s response in accordance with paragraphs (d)(1) through (5) of this section.

(1) To determine the accuracy of a laboratory’s response, a program must compare the laboratory’s response for each analyte with the response that reflects agreement of either 100 percent of ten or more referee laboratories or 95 percent or more of all participating laboratories except for unexpected antibody detection and antibody identification. To determine the accuracy of a laboratory’s response for unexpected antibody detection and antibody identification, a program must compare the laboratory’s response for each analyte with the response that reflects agreement of either 95 percent of ten or more referee laboratories or 95 percent or more of all participating laboratories. The score for a sample in immunohematology is either the score determined under paragraph (d)(2) or (3) of this section.

(2) Criteria for acceptable performance. The criteria for acceptable performance are—

- ABO group: 100% accuracy.
- D (Rh) typing: 100% accuracy.
- Unexpected antibody detection: 80% accuracy.
- Compatibility testing: 100% accuracy.
- Antibody identification: 80% accuracy.

(3) The criterion for acceptable performance for qualitative immunohematology tests is positive or negative.

(4) To determine the analyte testing event score, the number of acceptable analyte responses must be averaged using the following formula:

\[
\text{Analyte score for the testing event} = \frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of challenges for the analyte}} \times 100
\]

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

\[
\text{Testing event score} = \frac{\text{Number of acceptable responses for all challenges}}{\text{Total number of all challenges}} \times 100
\]

Subpart J—Patient Test Management for Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests

SOURCE: 57 FR 7162, Feb. 28, 1992, unless otherwise noted.

§ 493.1101

Condition: Patient test management; moderate complexity (including the subcategory), high complexity testing, or any combination of these tests.

Each laboratory performing moderate complexity (including the subcategory) or high complexity testing, or any combination of these tests, must employ and maintain a system that provides for proper patient preparation; proper specimen collection, identification, preservation, transportation, and processing; and accurate result reporting. This system must assure optimum patient specimen integrity and positive identification throughout the preanalytic (pre-testing), analytic (testing), and postanalytic (post-testing) processes and must meet the standards as they apply to the testing performed.

[60 FR 20048, Apr. 24, 1995]

§ 493.1103

Standard; Procedures for specimen submission and handling.

(a) The laboratory must have available and follow written policies and procedures for each of the following, if
§ 493.1105 Standard; Test requisition.

The laboratory must perform tests only at the written or electronic request of an authorized person. Oral requests for laboratory tests are permitted only if the laboratory subsequently requests written authorization for testing within 30 days. The laboratory must maintain the written authorization or documentation of efforts made to obtain a written authorization. Records of test requisitions or test authorizations must be retained for a minimum of two years. The patient's chart or medical record, if used as the test requisition, must be retained for at least two years. Immunohematology records and transfusion records must be retained for no less than five years in accordance with 21 CFR part 606, subpart I. In addition, records of blood and blood product testing must be maintained for a period not less than five years after processing records have been completed, or six months after the latest expiration date, whichever is the later date, in accordance with 21 CFR 606.160(d). The record system must provide documentation of information specified in § 493.1105 (a) through (f) and include—

(a) The patient's name or other unique identifier;
(b) The name and address of other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for utilizing the test results or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminent life threatening laboratory results or panic values;
(c) The test(s) to be performed;
(d) The date of specimen collection;
(e) For Pap smears, the patient's last menstrual period, age or date of birth, and indication of whether the patient had a previous abnormal report, treatment or biopsy; and
(f) Any additional information relevant and necessary to a specific test to assure accurate and timely testing and reporting of results.

§ 493.1107 Standard; Test records.

The laboratory must maintain a record system to ensure reliable identification of patient specimens as they are processed and tested to assure that accurate test results are reported. These records must identify the personnel performing the testing procedure. Records of patient testing, including, if applicable, instrument printouts, must be retained for at least two years. Immunohematology records and transfusion records must be retained for no less than five years in accordance with 21 CFR part 606, subpart I. In addition, records of blood and blood product testing must be maintained for a period not less than five years after processing records have been completed, or six months after the latest expiration date, whichever is the later date, in accordance with 21 CFR 606.160(d). The record system must provide documentation of information specified in § 493.1105 (a) through (f) and include—

(a) The patient identification number, accession number, or other unique identification of the specimen;
(b) The date and time of specimen receipt into the laboratory;
(c) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability; and
(d) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s), which are necessary to assure
§ 493.1109 Standard; Test report.

The laboratory report must be sent promptly to the authorized person, the individual responsible for using the test results or laboratory that initially requested the test. The original report or an exact duplicate of each test report, including final and preliminary report, must be retained by the testing laboratory for a period of at least two years after the date of reporting. Immunohematology reports and transfusion records must be retained by the laboratory for a period of no less than five years in accordance with 21 CFR part 606, subpart I. In addition, records of blood and blood product testing must be maintained for a period not less than five years after processing records have been completed, or six months after the latest expiration date, whichever is the later date, in accordance with 21 CFR 606.160(d). For pathology, test reports must be retained for a period of at least ten years after the date of reporting. This information may be maintained as part of the patient’s chart or medical record which must be readily available to the laboratory and to HHS upon request.

(a) The laboratory must have adequate systems in place to report results in a timely, accurate, reliable and confidential manner, and, ensure patient confidentiality throughout those parts of the total testing process that are under the laboratory’s control.

(b) The test report must indicate the name and address of the laboratory location at which the test was performed, the test performed, the test result and, if applicable, the units of measurement.

(c) The laboratory must indicate on the test report any information regarding the condition and disposition of specimens that do not meet the laboratory’s criteria for acceptability.

(d) Pertinent “reference” or “normal” ranges, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests or the individual responsible for utilizing the test results.

(e) The results or transcripts of laboratory tests or examinations must be released only to authorized persons or the individual responsible for utilizing the test results.

(f) The laboratory must develop and follow written procedures for reporting imminent life-threatening laboratory results or panic values. In addition, the laboratory must immediately alert the individual or entity requesting the test or the individual responsible for utilizing the test results when any test result indicates an imminent life-threatening condition.

(g) The laboratory must, upon request, make available to clients a list of test methods employed by the laboratory and, in accordance with §493.1213, as applicable, the performance specifications of each method used to test patient specimens. In addition, information that may affect the interpretation of test results, such as test interferences, must be provided upon request. Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results.

(h) The original report or exact duplicates of test reports must be maintained by the laboratory in a manner that permits ready identification and timely accessibility.


§ 493.1111 Standard; Referral of specimens.

A laboratory must refer specimens for testing only to a laboratory possessing a valid certificate authorizing the performance of testing in the specialty or subspecialty of service for the level of complexity in which the referred test is categorized.

(a) The referring laboratory must not revise results or information directly related to the interpretation of results provided by the testing laboratory.

(b) The referring laboratory may permit each testing laboratory to send the test result directly to the authorized person who initially requested the test. The referring laboratory must retain or be able to produce an exact duplicate of each testing laboratory’s report.

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(c) The authorized person who orders a test or procedure must be notified by the referring laboratory of the name and address of each laboratory location at which a test was performed.

Subpart K—Quality Control for Tests of Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests

SOURCE: 57 FR 7163, Feb. 28, 1992, unless otherwise noted.

§ 493.1201 Condition: General quality control; moderate complexity (including the subcategory) or high complexity testing, or any combination of these tests.

(a) Applicability of subpart K of this part. Subpart K is divided into two sections, general quality control and quality control for specialties and subspecialties. The quality control requirements are specified in §§ 493.1201 through 493.1285 unless—

(1) An alternative procedure specified in the manufacturer's protocol has been cleared by the Food and Drug Administration (FDA) as meeting certain CLIA requirements for general quality control and specialty/subspecialty quality control, and the manufacturer's instructions contain the following statement,

Unless this device is modified by a laboratory, the laboratory's compliance with these quality control instructions will satisfy the applicable requirements of 42 CFR 493.1203(b).

or

(2) HHS approves an equivalent procedure that is specified in Appendix C of the State Operations Manual (HCFA Pub. 7).

(b) The laboratory must establish and follow written quality control procedures for monitoring and evaluating the quality of the analytical testing process of each method to assure the accuracy and reliability of patient test results and reports. The laboratory must meet the applicable standards in §§ 493.1202 through 493.1221 of this subpart, unless an alternative procedure specified in the manufacturer's protocol has been cleared by the Food and Drug Administration (FDA) as meeting certain CLIA requirements for quality control or HHS approves an equivalent procedure specified in Appendix C of the State Operations Manual (HCFA Pub. 7). HCFA Pub. 7 is available from the Technical Information Service, U.S. Department of Commerce, 5825 Port Royal Road, Springfield, VA 22161, telephone number (703) 487-4630.

[58 FR 5230, Jan. 19, 1993, as amended at 60 FR 20048, Apr. 24, 1995]

§ 493.1202 Standard; Moderate or high complexity testing, or both: Effective from September 1, 1992 to July 31, 1998.

(a) For each test of high complexity performed, the laboratory must meet all applicable standards of this subpart.

(b) For each test of moderate complexity performed using a standardized method, or method developed in-house, a device not subject to clearance by the FDA (including any commercially distributed instrument, kit or test system subject to the Food, Drug and Cosmetic Act marketed prior to the Medical Device Amendments, Public Law 94-295, enacted on May 28, 1976, and those identified in 21 CFR parts 862, 864, and 866 as exempt from FDA premarket review), or using an instrument, kit or test system cleared by the FDA through the premarket notification (510(k)) or premarket approval (PMA) process for in-vitro diagnostic use but modified by the laboratory, the laboratory must meet all applicable standards of this subpart.

(c) For all other tests of moderate complexity performed using an instrument, kit or test system cleared by the FDA through the premarket notification (510(k)) or premarket approval (PMA) process for in-vitro diagnostic use, the laboratory must—

(1) Follow the manufacturer's instructions for instrument or test system operation and test performance;

(2) Have a procedure manual describing the processes for testing and reporting patient test results;

(3) Perform and document calibration procedures or check calibration at least once every six months;

(4) Perform and document control procedures using at least two levels of control materials each day of testing.
§ 493.1205 Standard; Facilities.

The laboratory must provide the space and environmental conditions necessary for conducting the services offered.

(a) The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of testing, including the preanalytic (pre-testing), analytic (testing), and postanalytic (post-testing), as appropriate.

(b) Safety precautions must be established, posted, and observed to ensure protection from physical, chemical, biochemical and electrical hazards and biohazardous materials.

§ 493.1206 Standard; Test methods, equipment, instrumentation, reagents, materials, and supplies.

The laboratory must utilize test methods, equipment, instrumentation, reagents, materials, and supplies that provide accurate and reliable test results and test reports.

(a) Test methodologies and equipment must be selected and testing performed in a manner that provides test results within the laboratory’s stated performance specifications for each test method as determined under §493.1213.

(b) The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing performed and for the maintenance of quality during the preanalytic, analytic, and postanalytic phases of testing.

(c) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, and accurate and reliable test system operation and test result reporting.

(i) Water quality;
(ii) Temperature;
(iii) Humidity; and
(iv) Protection of equipment and instrumentation from fluctuations and interruptions in electrical current that
§ 493.1211 Standard; Procedure manual.

(a) A written procedure manual for the performance of all analytical methods used by the laboratory must be readily available and followed by laboratory personnel. Textbooks may be used as supplements to these written descriptions but may not be used in lieu of the laboratory's written procedures for testing or examining specimens. The procedure manual must include, when applicable to the test procedure:

1. Requirements for specimen collection and processing, and criteria for specimen rejection;
2. Procedures for microscopic examinations, including the detection of inadequately prepared slides;
3. Step-by-step performance of the procedure, including test calculations and interpretation of results;
4. Preparation of slides, solutions, calibrators, controls, reagents, stains and other materials used in testing;
5. Calibration and calibration verification procedures;
6. The reportable range for patient test results as established or verified in §493.1213;
7. Control procedures;
8. Remedial action to be taken when calibration or control results fail to meet the laboratory's criteria for acceptability;
9. Limitations in methodologies, including interfering substances;
10. Reference range (normal values);
11. Imminent life-threatening laboratory results or "panic values";
12. Pertinent literature references;
13. Appropriate criteria for specimen storage and preservation to ensure specimen integrity until testing is completed;
14. The laboratory's system for reporting patient results including, when appropriate, the protocol for reporting panic values;
15. Description of the course of action to be taken in the event that a test system becomes inoperable; and
16. Criteria for the referral of specimens including procedures for specimen submission and handling as described in §493.1103.

(b) The procedure manual must include, when applicable to the test procedure:

1. Requirements for specimen collection and processing, and criteria for specimen rejection;
2. Procedures for microscopic examinations, including the detection of inadequately prepared slides;
3. Step-by-step performance of the procedure, including test calculations and interpretation of results;
4. Preparation of slides, solutions, calibrators, controls, reagents, stains and other materials used in testing;
5. Calibration and calibration verification procedures;
6. The reportable range for patient test results as established or verified in §493.1213;
7. Control procedures;
8. Remedial action to be taken when calibration or control results fail to meet the laboratory's criteria for acceptability;
9. Limitations in methodologies, including interfering substances;
10. Reference range (normal values);
11. Imminent life-threatening laboratory results or "panic values";
12. Pertinent literature references;
13. Appropriate criteria for specimen storage and preservation to ensure specimen integrity until testing is completed;
14. The laboratory's system for reporting patient results including, when appropriate, the protocol for reporting panic values;
15. Description of the course of action to be taken in the event that a test system becomes inoperable; and
16. Criteria for the referral of specimens including procedures for specimen submission and handling as described in §493.1103.

(c) Manufacturers' package inserts or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(13) of this section. Any of the items under paragraphs (b)(1) through (b)(13) of this section not provided by the manufacturer must be provided by the laboratory.

(d) Procedures must be approved, signed, and dated by the director.
(e) Procedures must be re-approved, signed and dated if the directorship of the laboratory changes.

(f) Each change in a procedure must be approved, signed, and dated by the current director of the laboratory.

(g) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance. These records must be retained for two years after a procedure has been discontinued.

§ 493.1213 Standard; Establishment and verification of method performance specifications.

Prior to reporting patient test results, the laboratory must verify or establish, for each method, the performance specifications for the following performance characteristics: accuracy; precision; analytical sensitivity and specificity, if applicable; the reportable range of patient test results; the reference range(s) (normal values); and any other applicable performance characteristic.

(a) The provisions of this section are not retroactive. Laboratories are not required to verify or establish performance specifications for any test method of moderate or high complexity in use prior to September 1, 1992.

(b)(1) Each laboratory that introduces a new procedure for patient testing using a device (instrument, kit, or test system) cleared by the FDA as meeting certain CLIA requirements for quality control, must demonstrate that, prior to reporting patient test results, it can obtain the performance specifications for accuracy, precision, and reportable range of patient test results, comparable to those established by the manufacturer. The laboratory must also verify that the manufacturer’s reference range is appropriate for the laboratory’s patient population.

(2) Each laboratory that introduces a new method or device as specified in either § 493.1202(a) or (b), or § 493.1203(a), must, prior to reporting patient test results—

(i) Verify or establish for each method the performance specifications for the following performance characteristics, as applicable:

(A) Accuracy;
(B) Precision; (C) Analytical sensitivity;
(D) Analytical specificity to include interfering substances;
(E) Reportable range of patient test results;
(F) Reference range(s); and
(G) Any other performance characteristic required for test performance.

(ii) Based upon the performance specifications verified or established in accordance with paragraph (b)(2)(i) of this section, establish calibration and control procedures for patient testing as required under §§493.1217 and 493.1218.

(c) The laboratory must have documentation of the verification or establishment of all applicable test performance specifications.


§ 493.1215 Standard; Equipment maintenance and function checks.

The laboratory must perform equipment maintenance and function checks that include electronic, mechanical and operational checks necessary for the proper test performance and test result reporting of equipment, instruments and test systems, to assure accurate and reliable test results and reports.

(a) Maintenance of equipment, instruments, and test systems. (1) For manufacturers’ equipment, instruments or test systems cleared by the FDA as meeting certain CLIA requirements for quality control, the laboratory must—

(i) Perform maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer; and

(ii) Document all maintenance performed.

(2) For methods or devices, as specified in either § 493.1202(a) or (b) or §493.1203(a), the laboratory must—

(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance necessary for accurate and reliable test results and test result reporting;

(ii) Perform maintenance with at least the frequency specified in paragraph (a)(2)(i) of this section; and

(iii) Document all maintenance performed.
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(b) Function checks of equipment, instruments, and test systems. (1) For manufacturers' equipment, instruments, or test systems cleared by the FDA as meeting certain CLIA requirements for quality control, the laboratory must—

(i) Perform function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer; and

(ii) Document all function checks performed.

(2) For methods or devices, as specified in either § 493.1202 (a) or (b) or § 493.1203(a), the laboratory must—

(i) Define a function check protocol that ensures equipment, instrument, and test system performance necessary for accurate and reliable test results and test result reporting;

(ii) Perform function checks including background or baseline checks specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted; and

(iii) Document all function checks performed.


§ 493.1217 Standard; Calibration and calibration verification procedures.

Calibration and calibration verification procedures are required to substantiate the continued accuracy of the test method throughout the laboratory's reportable range for patient test results. Calibration is the process of testing and adjusting an instrument, kit, or test system to provide a known relationship between the measurement response and the value of the substance that is being measured by the test procedure. Calibration verification is the assaying of calibration materials in the same manner as patient samples to confirm that the calibration of the instrument, kit, or test system has remained stable throughout the laboratory's reportable range for patient test results. The reportable range of patient test results is the range of test result values over which the laboratory can establish or verify the accuracy of the instrument, kit or test system measurement response. Calibration and calibration verification must be performed and documented as required in this section unless otherwise specified in §§ 493.1223 through 493.1285.

(a) For laboratory test procedures that are performed using instruments, kits, or test systems that have been cleared by the FDA as meeting certain CLIA requirements for quality control, the laboratory must, at a minimum, follow the manufacturer's instructions for calibration and calibration verification procedures using calibration materials specified by the manufacturer.

(b) For each method or device, as specified in either § 493.1202 (a) or (b) or § 493.1203(a), the laboratory must—

(1) Perform calibration procedures—

(i) At a minimum, in accordance with manufacturer's instructions, if provided, using calibration materials provided or specified, as appropriate, and with at least the frequency recommended by the manufacturer; and

(ii) In accordance with criteria established by the laboratory, as required under § 493.1213(b)(2)(i)—

(A) Including the number, type, and concentration of calibration materials, acceptable limits for calibration, and the frequency of calibration; and

(B) Using calibration materials appropriate for the methodology and, if possible, traceable to a reference method or reference material of known value; and

(iii) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification; and

(2) Perform calibration verification procedures—

(i) In accordance with the manufacturer's calibration verification instructions when they meet or exceed the requirements specified in paragraph (b)(2)(ii) of this section; or

(ii) In accordance with criteria established by the laboratory—

(A) Including the number, type, and concentration of calibration materials, acceptable limits for calibration verification and frequency of calibration verification;

(B) Using calibration materials appropriate for—

(1) The methodology and, if possible, traceable to a reference method or reference material of known value; and
(2) Verifying the laboratory’s established reportable range of patient test results, which must include at least a minimal (or zero) value, a mid-point value, and a maximum value at the upper limit of that range; and

(C) At least once every six months and whenever any of the following occur:

(1) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes;

NOTE: If reagents are obtained from a manufacturer and all of the reagents for a test are packaged together, the laboratory is not required to perform calibration verification for each package of reagents, provided the packages of reagents are received in the same shipment and contain the same lot number.

(2) There is major preventive maintenance or replacement of critical parts that may influence test performance;

(3) Controls reflect an unusual trend or shift or are outside of the laboratory’s acceptable limits and other means of assessing and correcting unacceptable control values have failed to identify and correct the problem; or

(4) The laboratory’s established schedule for verifying the reportable range for patient test results requires more frequent calibration verification than specified in paragraphs (b)(2)(ii)(C) (1), (2), or (3) of this section; and

(3) Document all calibration and calibration verification procedures performed.

[58 FR 5231, Jan. 19, 1993]

§ 493.1218 Standard; Control procedures.

Control procedures are performed on a routine basis to monitor the stability of the method or test system; control and calibration materials provide a means to indirectly assess the accuracy and precision of patient test results. Control procedures must be performed as defined in this section unless otherwise specified in §§493.1223 through 493.1286 of this subpart.

(a) For each device cleared by the FDA as meeting certain CLIA requirements for quality control, the laboratory must, at a minimum, follow the manufacturer’s instructions for control procedures. In addition, the laboratory must meet the requirements under paragraphs (c) through (e) of this section and, as applicable, paragraph (f) of this section.

(b) For each device, as specified in either §493.1202 (a) or (b) or §493.1203(a), the laboratory must evaluate instrument and reagent stability and operator variance in determining the number, type, and frequency of testing calibration or control materials and establish criteria for acceptability used to monitor test performance during a run of patient specimen(s). A run is an interval within which the accuracy and precision of a testing system is expected to be stable, but cannot be greater than 24 hours or less than the frequency recommended by the manufacturer. For each procedure, the laboratory must monitor test performance using calibration materials or control materials or a combination thereof.

(1) For qualitative tests, the laboratory must include a positive and negative control with each run of patient specimens.

(2) For quantitative tests, the laboratory must include at least two samples of different concentrations of either calibration materials, control materials, or a combination thereof with the frequency determined in §493.1218(b), but not less frequently than once each run of patient specimens.

(3) For electrophoretic determinations—

(i) At least one control sample must be used in each electrophoretic cell; and

(ii) The control sample must contain fractions representative of those routinely reported in patient specimens.

(4) Each day of use, the laboratory must evaluate the detection phase of direct antigen systems using an appropriate positive and negative control material (organism or antigen extract). When direct antigen systems include an extraction phase, the system must be checked each day of use using a positive organism.
§ 493.1219 Standard; Remedial actions.

Remedial action policies and procedures must be established by the laboratory and applied as necessary to maintain the laboratory's operation for testing patient specimens in a manner that assures accurate and reliable patient test results and reports. The laboratory must document all remedial actions taken when—

(a) Test systems do not meet the laboratory's established performance specifications, as determined in §493.1213 of this section, which include but are not limited to—

(1) Equipment or methodologies that perform outside of established operating parameters or performance specifications;

(2) Patient test values that are outside of the laboratory's reportable range of patient test results; and

(3) The determination that the laboratory's reference range for a test procedure is inappropriate for the laboratory's patient population.

(b) Results of control and calibration materials fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run or since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected and the

NOTE: A batch of media (solid, semi-solid, or liquid) consists of all tubes, plates, or containers of the same medium prepared at the same time and in the same laboratory; or, if received from an outside source or commercial supplier, consists of all of the plates, tubes or containers of the same medium that have the same lot numbers and are received in a single shipment.

§ 493.1219 Standard; Remedial actions.

Remedial action policies and procedures must be established by the laboratory and applied as necessary to maintain the laboratory’s operation for testing patient specimens in a manner that assures accurate and reliable patient test results and reports. The laboratory must document all remedial actions taken when—

(a) Test systems do not meet the laboratory’s established performance specifications, as determined in §493.1213 of this section, which include but are not limited to—

(1) Equipment or methodologies that perform outside of established operating parameters or performance specifications;

(2) Patient test values that are outside of the laboratory’s reportable range of patient test results; and

(3) The determination that the laboratory’s reference range for a test procedure is inappropriate for the laboratory’s patient population.

(b) Results of control and calibration materials fail to meet the laboratory’s established criteria for acceptability. All patient test results obtained in the unacceptable test run or since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected and the
§ 493.1221 Standard; Quality control records.

The laboratory must document and maintain records of all quality control activities specified in §§ 493.1202 through 493.1285 of this subpart and retain records for at least two years. Immunohematology quality control records must be maintained for a period of no less than five years. In addition, quality control records for blood and blood products must be maintained for a period not less than five years after processing records have been completed, or six months after the latest expiration date, whichever is the later date, in accordance with 21 CFR 606.160(d).

§ 493.1222 Condition: Quality control—specialties and subspecialties for tests of moderate or high complexity, or both.

The laboratory must establish and follow written quality control procedures for monitoring and evaluating the quality of the analytical testing process of each method to assure the accuracy and reliability of patient test results and reports. Except as specified in § 493.1202(c), the laboratory must meet the applicable general requirements specified in §§ 493.1201 through 493.1221. In addition, the laboratory must meet the applicable requirements of §§ 493.1225 through 493.1285 unless an alternative procedure specified in the manufacturer’s protocol has been cleared by the Food and Drug Administration (FDA) as meeting certain CLIA requirements for quality control or HCFA approves an equivalent procedure specified in appendix C of the State Operations Manual (HCFA Pub. 7). Failure to meet any of the applicable conditions in §§ 493.1225 through 493.1285 will result in intermediate sanctions, loss of Medicare or Medicaid approval, and/or revocation of CLIA certification for the entire specialty or subspecialty to which the condition applies, in accordance with subpart R of this part.

[58 FR 5232, Jan. 19, 1993]

§ 493.1225 Condition: Microbiology.

The laboratory must meet the applicable quality control requirements in §§ 493.1201 through 493.1221 and in §§ 493.1227 through 493.1235 of this subpart for the subspecialties for which it is certified under the specialty of microbiology.

§ 493.1227 Condition: Bacteriology.

To meet the quality control requirements for bacteriology, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 and paragraphs (a) through (c) of this section. All quality control activities must be documented.

(a) The laboratory must check positive and negative reactivity with control organisms—

(1) Each day of use for catalase, coagulase, beta-lactamase, and oxidase reagents and DNA probes;

(2) Each week of use for Gram and acid-fast stains, bacitracin, optochin, ONPG, X, and V discs or strips; and

(3) Each month of use for antisera.

(b) Each week of use, the laboratory must check XV discs or strips with a positive control organism.

(c) For antimicrobial susceptibility tests, the laboratory must check each new batch of media and each lot of antimicrobial discs before, or concurrent with, initial use, using approved reference organisms.

(1) The laboratory’s zone sizes or minimum inhibitory concentration for

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§ 493.1229 Condition: Mycobacteriology.

To meet the quality control requirements for mycobacteriology, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 of this subpart and with paragraphs (a) through (d) of this section. All quality control activities must be documented.

(a) Each day of use, the laboratory must check the iron uptake test with at least one acid-fast organism that produces a positive reaction and with an organism that produces a negative reaction and check all other reagents or test procedures used for mycobacteria identification with at least one acid-fast organism that produces a positive reaction.

(b) The laboratory must check fluorochrome acid-fast stains for positive and negative reactivity each week of use.

(c) The laboratory must check acid-fast stains each week of use with an acid-fast organism that produces a positive reaction.

(d) For susceptibility tests performed on Mycobacterium tuberculosis isolates, the laboratory must check the procedure each week of use with a strain of Mycobacterium tuberculosis susceptible to all antimycobacterial agents tested.

§ 493.1231 Condition: Mycology.

To meet the quality control requirements for mycology, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 of this subpart and with paragraphs (a) through (d) of this section. All quality control activities must be documented.

(a) Each day of use, the laboratory must check the iron uptake test with the auxanographic medium for nitrate assimilation must check the nitrate reagent with a peptone control.

(b) Each week of use, the laboratory must check all reagents used with biochemical tests and other test procedures for mycological identification with an organism that produces a positive reaction.

(c) Each week of use, the laboratory must check acid-fast stains for positive and negative reactivity.

(d) For susceptibility tests, the laboratory must test each drug each day of use with at least one control strain that is susceptible to the drug. The laboratory must establish control limits. Criteria for acceptable control results must be met prior to reporting patient results.

§ 493.1233 Condition: Parasitology.

To meet the quality control requirements for parasitology, the laboratory must comply with the applicable requirements of §§ 493.1201 through 493.1221 of this subpart and with paragraphs (a) through (c) of this section. All quality control activities must be documented.

(a) The laboratory must have available a reference collection of slides or photographs, and, if available, gross specimens for identification of parasites and use these references in the laboratory for appropriate comparison with diagnostic specimens.

(b) The laboratory must calibrate and use the calibrated ocular micrometer for determining the size of ova and parasites, if size is a critical parameter.

(c) Each month of use, the laboratory must check permanent stains using a fecal sample control that will demonstrate staining characteristics.

§ 493.1235 Condition: Virology.

To meet the quality control requirements for virology, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 of this subpart and with paragraphs (a) through (c) of this section. All quality control activities must be documented.

(a) The laboratory must have available host systems for the isolation of viruses and test methods for the identification of viruses that cover the entire range of viruses that are etiologically related to clinical diseases for which services are offered.
(b) The laboratory must maintain records that reflect the systems used and the reactions observed.
(c) In tests for the identification of viruses, the laboratory must simultaneously culture uninoculated cells or cell substrate controls as a negative control to detect erroneous identification results.

§ 493.1237 Condition: Diagnostic immunology.

The laboratory must meet the applicable quality control requirements in §§493.1201 through 493.1221 and §§493.1239 through 493.1241 of this subpart for the subspecialties for which it is certified under the specialty of diagnostic immunology.

§ 493.1239 Condition: Syphilis serology.

To meet the quality control requirements for syphilis serology, the laboratory must comply with the applicable requirements in §§493.1201 through 493.1221 of this subpart and with paragraphs (a) through (e) of this section. All quality control activities must be documented.

(a) For laboratories performing syphilis testing, the equipment, glassware, reagents, controls, and techniques for tests for syphilis must conform to manufacturers’ specifications.

(b) The laboratory must run serologic tests on patient specimens concurrently with a positive serum control of known titer or controls of graded reactivity plus a negative control.

(c) The laboratory must employ positive and negative controls that evaluate all phases of the test system to ensure reactivity and uniform dosages.

(d) The laboratory may not report test results unless the predetermined reactivity pattern of the controls is observed.

(e) All facilities manufacturing blood and blood products for transfusion or serving as referral laboratories for these facilities must meet—

1. The HIV testing requirements of 21 CFR 610.45; and
2. Hepatitis testing requirements of 21 CFR 610.40.

§ 493.1241 Condition: General immunology.

To meet the quality control requirements for general immunology, the laboratory must comply with the applicable requirements in §§493.1201 through 493.1221 of this subpart and with paragraphs (a) through (d) of this section. All quality control activities must be documented.

(a) The laboratory must run serologic tests on patient specimens concurrently with a positive serum control of known titer or controls of graded reactivity, if applicable, plus a negative control.

(b) The laboratory must employ controls that evaluate all phases of the test system (antigens, complement, erythrocyte indicator systems, etc.) to ensure reactivity and uniform dosages when positive and negative controls alone are not sufficient.

(c) The laboratory may not report test results unless the predetermined reactivity pattern of the controls is observed.

(d) All facilities manufacturing blood and blood products for transfusion or serving as referral laboratories for these facilities must meet—

1. The HIV testing requirements of 21 CFR 610.45; and
2. Hepatitis testing requirements of 21 CFR 610.40.

§ 493.1243 Condition: Chemistry.

The laboratory must meet the applicable quality control requirements in §§493.1201 through 493.1221 and §§493.1245 through 493.1249 of this subpart for the subspecialties for which it is certified under the specialty of chemistry.

§ 493.1245 Condition: Routine chemistry.

To meet the quality control requirements for routine chemistry, the laboratory must comply with the applicable requirements in §§493.1201 through 493.1221. All quality control activities must be documented. In addition, for blood gas analyses, the laboratory must—

(a) Calibrate or verify calibration according to the manufacturer’s specifications and with at least the frequency recommended by the manufacturer;

(b) Test one sample of control material each eight hours of testing;

(c) Use a combination of calibrators and control materials that include
§ 493.1247

both low and high values on each day of testing; and

(d) Include one sample of calibration material or control material each time patients are tested unless automated instrumentation internally verifies calibration at least every thirty minutes.

§ 493.1247 Condition: Endocrinology.

To meet the quality control requirements for endocrinology, the laboratory must comply with the applicable requirements contained in §§ 493.1201 through 493.1221 of this subpart. All quality control activities must be documented.

§ 493.1249 Condition: Toxicology.

To meet the quality control requirements for toxicology, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 of this subpart. All quality control activities must be documented. In addition, for drug abuse screening using thin layer chromatography—

(a) Each plate must be spotted with at least one sample of calibration material containing all drug groups identified by thin layer chromatography which the laboratory reports; and

(b) At least one control sample must be included in each chamber, and the control sample must be processed through each step of patient testing, including extraction procedures.

§ 493.1251 Condition: Urinalysis.

Except for those tests categorized as waived, to meet the quality control requirements for urinalysis, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221.

[58 FR 5232, Jan. 19, 1993]

§ 493.1255 Condition: Pathology.

The laboratory must meet the applicable quality control requirements in §§ 493.1201 through 493.1221 and §§ 493.1257 through 493.1261 of this subpart for the subspecialties for which it is certified under the specialty of pathology. All quality control activities must be documented.

§ 493.1257 Condition: Cytology.

To meet the quality control requirements for cytology, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 of this subpart and paragraphs (a) through (g) of this section.

(a) The laboratory must assure that—

(1) All gynecologic smears are stained using a Papanicolaou or modified Papanicolaou staining method;

(2) Effective measures are taken to prevent cross-contamination between gynecologic and nongynecologic specimens during the staining process;

(3) Nongynecologic specimens that have a high potential for cross-contamination are stained separately from other nongynecologic specimens, and the stains are filtered or changed following staining;

(4) Diagnostic interpretations are not reported on unsatisfactory smears; and

(5) All cytology slide preparations are evaluated on the premises of a laboratory certified to conduct testing in the subspecialty of cytology.

(b) The laboratory is responsible for ensuring that—

(1) Each individual engaged in the evaluation of cytology preparations by nonautomated microscopic technique examines no more than 100 slides (one patient per slide, gynecologic or nongynecologic, or both) in a 24 hour period, irrespective of the site or laboratory. This limit represents an absolute maximum number of slides and is not to be employed as a performance target for each individual. Previously examined negative, reactive, reparative, atypical, premalignant or malignant gynecologic cases as defined in paragraph (c)(1) of this section, previously examined nongynecologic cytology preparations, and tissues patholoty slides examined by a technical supervisor qualified under §493.1449 (b) or (k) are not included in the 100 slide limit. (For this section, all references to technical supervisor refer to individuals qualified under §§ 493.1449 (b) and (k));

(2) For purposes of workload calculations, each slide preparation (gynecologic and nongynecologic) made using automated, semi-automated, or other liquid-based slide preparatory techniques which result in cell dispersion over one-half or less of the total available slide area and which is examined by nonautomated microscopic technique counts as one-half slide.

(3) Records are maintained of the total number of slides examined by each individual during each 24 hour period, and the number of hours each individual spends examining slides in the 24 hour period;

(i) The maximum number of 100 slides described in paragraph (b)(1) of this section is examined in no less than an 8 hour workday;

(ii) For the purposes of establishing workload limits for individuals examining slides by nonautomated microscopic technique on other than an 8 hour workday basis (includes full-time employees with duties other than slide examination and part-time employees), a period of 8 hours must be used to pro-rate the number of slides that may be examined. Use the formula—

\[
\text{No. of hours examining slides} \times \frac{100}{8}
\]

to determine maximum slide volume to be examined.

(3) The individual qualified under §§493.1449 (b) or (k) who provides technical supervision of cytology must ensure that—

(1) All gynecologic smears interpreted to be showing reactive or reparative changes, atypical squamous or glandular cells of undetermined significance, or to be in the premalignant (dysplasia, cervical intraepithelial neoplasia or all squamous intraepithelial lesions including human papillomavirus-associated changes) or malignant category are confirmed by a technical supervisor in cytology. The report must be signed to reflect the review or, if a computer report is generated with signature, it must reflect an electronic signature authorized by the technical supervisor in cytology;

(2) All nongynecologic cytologic preparations are reviewed by the technical supervisor in cytology. The report must be signed to reflect technical supervisory review or, if a computer report is generated with signature, it must reflect an electronic signature authorized by the technical supervisor;

(3) The slide examination performance of each cytotecnologist is evaluated and documented, including performance evaluation through the re-examination of normal and negative cases and feedback on the reactive, reparative, atypical, malignant or premalignant cases as defined in paragraph (c)(1) of this section; and

(4) A maximum number of slides, not to exceed the maximum workload limit described in paragraph (b) of this section is established by the technical supervisor for each individual examining slide preparations by nonautomated microscopic technique.

(i) The actual workload limit must be documented for each individual and established in accordance with the individual's capability based on the performance evaluation as described in paragraph (c)(3) of this section.

(ii) Records are available to document that each individual's workload
limit is reassessed at least every 6 months and adjusted when necessary.

d) The laboratory must establish and follow a program designed to detect errors in the performance of cytologic examinations and the reporting of results.

(1) The laboratory must establish a program that includes a review of slides from at least 10 percent of the gynecologic cases interpreted to be negative for reactive, reparative, atypical, premalignant or malignant conditions as defined in paragraph (c)(1) of this section that are examined by each individual not qualified under §§493.1449 (b) or (k). This review must be done by a technical supervisor in cytology, a cytology general supervisor qualified under §493.1469, or a cytotechnologist qualified under §493.1483 who has the experience specified in §493.1469(b)(2).

(i) The review must include negative cases selected at random from the total caseload and from patients or groups of patients that are identified as having a high probability of developing cervical cancer, based on available patient information;

(ii) Records of initial examinations and rescreening results must be available; and

(iii) The review must be completed before reporting patient results on those cases selected.

(2) The laboratory must compare clinical information, when available, with cytology reports and must compare all malignant and premalignant (as defined in paragraph (c)(1) of this section) gynecology reports with the histopathology report, if available in the laboratory (either on-site or in storage), and determine the causes of any discrepancies.

(3) For each patient with a current high grade intraepithelial lesion or above (moderate dysplasia or CIN-2 or above), the laboratory must review all normal or negative gynecologic specimens received within the previous five years, if available in the laboratory (either on-site or in storage). If significant discrepancies are found that would affect patient care, the laboratory must notify the patient's physician and issue an amended report.

(4) The laboratory must establish and document an annual statistical evaluation of the number of cytology cases examined, number of specimens processed by specimen type, volume of patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation), number of gynecologic cases where cytology and available histology are discrepant, the number of gynecologic cases where any rescreen of a normal or negative specimen results in recategorization as malignant or premalignant, as defined in paragraph (c)(1) of the section, and the number of gynecologic cases for which histology results were unavailable to compare with malignant or premalignant cytology cases as defined in paragraph (c)(1) of this section.

(5) The laboratory must evaluate the case reviews of each individual examining slides against the laboratory's overall statistical values, document any discrepancies, including reasons for the deviation, and document corrective action, if appropriate.

e) The laboratory report must—

(1) Clearly distinguish specimens or smears, or both, that are unsatisfactory for diagnostic interpretation; and

(2) Contain narrative descriptive nomenclature for all results.

f) Corrected reports issued by the laboratory must indicate the basis for correction.

g) The laboratory must retain all slide preparations for five years from the date of examination, or slides may be loaned to proficiency testing programs, in lieu of maintaining them for this time period, provided the laboratory receives written acknowledgment of the receipt of slides by the proficiency testing program and maintains the acknowledgment to document the loan of such slides. Documentation for slides loaned or referred for purposes other than proficiency testing must also be maintained. All slides must be retrievable upon request.

§ 493.1259 Condition: Histopathology.

To meet the quality control requirements for histopathology, a laboratory
must comply with the applicable requirements in §§493.1201 through 493.1221 of this subpart and paragraphs (a) through (e) of this section. All quality control activities must be documented. 

(a) A control slide of known reactivity must be included with each slide or group of slides for differential or special stains. Reaction(s) of the control slide with each special stain must be documented. 

(b) The laboratory must retain stained slides at least ten years from the date of examination and retain specimen blocks at least two years from the date of examination. 

(c) The laboratory must retain remnants of tissue specimens in a manner that assures proper preservation of the tissue specimens until the portions submitted for microscopic examination have been examined and a diagnosis made by an individual qualified under §§493.1449(b) or 493.1449(l)(1) of this part. In addition, an individual who meets the requirements of §§493.1449(b), 493.1449(l)(1) or 493.1449(l)(2), may examine and provide reports for specimens for skin pathology; an individual meeting the requirements of §§493.1449(b) or 493.1449(l)(3) may examine and provide reports for ophthalmic pathology; an individual meeting the requirements of §§493.1449(b) or 493.1449(m) may examine and provide reports for oral pathology specimens. 

(d) All tissue pathology reports must be signed by an individual qualified as specified in paragraph (c) of the section. If a computer report is generated with an electronic signature, it must be authorized by the individual qualified as specified in paragraph (c) of this section. 

(e) The laboratory must utilize acceptable terminology of a recognized system of disease nomenclature in reporting results. 

§ 493.1263 Condition: Radiobioassay. 
To meet quality control requirements for radiobioassay, the laboratory must comply with the applicable requirements of §§493.1201 through 493.1221 of this subpart. All quality control activities must be documented. 

§ 493.1265 Condition: Histocompatibility. 
In addition to meeting the applicable requirements for general quality control in §§493.1201 through 493.1221, for quality control for general immunology in §493.1241 of this subpart and for immunohematology in §493.1269 of this subpart, the laboratory must comply with the applicable requirements in paragraphs (a) through (d) of this section. All quality control activities must be documented. 

(a) For renal allotransplantation, the laboratory must meet the following requirements: 

(i) Selecting appropriate patient serum samples for crossmatching; 

(ii) The technique used in crossmatching; 

(iii) Preparation of donor lymphocytes for crossmatching; and 

(iv) Reporting crossmatch results; 

(b) The laboratory must— 

(i) Have available results of final crossmatches before an organ or tissue is transplanted; and 

(ii) Make a reasonable attempt and document efforts to have available serum specimens for all potential transplant recipients at initial typing, for periodic screening, for pre-transplantation crossmatch and following sensitizing events, such as transfusion and transplant loss; 

(c) The laboratory's storage and maintenance of both recipient sera and reagents must— 

(i) Be at an acceptable temperature range for sera and components; 

(ii) Use a temperature alarm system and have an emergency plan for alternate storage; and 

(iii) Ensure that all specimens are properly identified and easily retrievable; 

(d) The laboratory's reagent typing sera inventory (applicable only to locally constructed trays) must indicate
source, bleeding date and identification number, and volume remaining;

(5) The laboratory must properly label and store cells, complement, buffer, dyes, etc.;

(6) The laboratory must—
(i) HLA type all potential transplant recipients;
(ii) Type cells from organ donors referred to the laboratory; and
(iii) Have available and follow a policy that establishes when antigen redefinition and retyping are required;
(7) The laboratory must have available and follow criteria for—
(i) The preparation of lymphocytes for HLA-A, B and DR typing;
(ii) Selecting typing reagents, whether locally or commercially prepared;
(iii) The assignment of HLA antigens; and
(iv) Assuring that reagents used for typing recipients and donors are adequate to define all major and International Workshop HLA-A, B and DR specificities and common splits;

(b) If the laboratory performs histocompatibility testing for—
(1) Transfusions and other non-renal transplantation, excluding bone marrow and living transplants, all the requirements specified in this section, as applicable, except for the performance of mixed lymphocyte cultures, must be met;
(2) Bone marrow transplantation, all the requirements specified in this section, including the performance of mixed lymphocyte cultures or other augmented testing to evaluate class II compatibility, must be met; and
(3) Non-renal solid organ transplantation, the results of final crossmatches must be available before transplantation when the recipient has demonstrated presensitization by prior serum screening except for emergency situations. The laboratory must document the circumstances, if known, under which emergency transplants are
performed, and records must reflect any information concerning the transplant provided to the laboratory by the patient's physician.  

(c) Laboratories performing HLA typing for disease-associated studies must meet all the requirements specified in this section except for the performance of mixed lymphocyte cultures, antibody screening and crossmatching.  

(d) For laboratories performing organ donor HIV testing the requirements of §493.1241 of this subpart for the transfusion of blood and blood products must be met.

§ 493.1267 Condition: Clinical cyto genetics.

To meet the quality control requirements for clinical cytogenetics, the laboratory must comply with the applicable requirements of §§493.1201 through 493.1221 of this subpart and with paragraphs (a) through (d) of this section. All quality control activities must be documented.

(a) When determination of sex is performed by X and Y chromatin counts, these counts must be based on an examination of an adequate number of cells. Confirmatory testing such as full chromosome analysis must be performed for all atypical results.

(b) The laboratory must have records that reflect the media used and document the reactions observed, number of cells counted, the number of cells karyotyped, the number of chromosomes counted for each metaphase spread, and the quality of the banding; that the resolution is sufficient to support the reported results; and that an adequate number of karyotypes are prepared for each patient.

(c) The laboratory also must have policies and procedures for assuring an accurate and reliable patient sample identification during the process of accessioning, cell preparation, photographing or other image reproduction technique, and photographic printing, and storage and reporting of results or photographs.

(d) The laboratory report must include the summary and interpretation of the observations and number of cells counted and analyzed and the use of appropriate nomenclature.

§ 493.1269 Condition: Immunohematology.

To meet the quality control requirements for immunohematology, the laboratory must comply with the applicable requirements in §§493.1201 through 493.1221 of this subpart and with paragraphs (a) through (d) of this section. All quality control activities must be documented.

(a) The laboratory must perform ABO group and D(Rho) typing, unexpected antibody detection, antibody identification and compatibility testing in accordance with manufacturer's instructions, if provided, and as applicable, with 21 CFR part 606 (with the exception of 21 CFR 606.20a, Personnel) and 21 CFR part 640 et seq.

(b) The laboratory must perform ABO group by concurrently testing unknown red cells with anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells.

(c) The laboratory must determine the D(Rho) type by testing unknown red cells with anti-D (anti-Rho) blood grouping reagent.

(d) If required in the manufacturer's package insert for anti-D reagents, the laboratory must employ a control system capable of detecting false positive D(Rho) test results.

§ 493.1271 Condition: Transfusion services and bloodbanking.

If a facility provides services for the transfusion of blood and blood products, the facility must be under the adequate control and technical supervision of the pathologist or other doctor of medicine or osteopathy meeting the qualifications in subpart M for technical supervision in immunohematology. The facility must ensure that there are facilities for procurement, safekeeping and transfusion of blood and blood products and that blood and blood products must be available to meet the needs of the physicians responsible for the diagnosis,
management, and treatment of patients. The facility meets this condition by complying with the standards in §§493.1273 through 493.1285.

[58 FR 5233, Jan. 19, 1993]

§ 493.1273 Standard; Immunohematological collection, processing, dating periods, labeling and distribution of blood and blood products.

In addition to the requirements in paragraphs (a) through (d) of this section, the facility must also meet the applicable quality control requirements in §§493.1201 through 493.1221 of this part.

(a) Blood and blood product collection, processing and distribution must comply with 21 CFR part 640 and 21 CFR part 606, and the testing laboratory must meet the applicable requirements of part 493.

(b) Dating periods for blood and blood products must conform to 21 CFR 610.53.

(c) Labeling of blood and blood products must conform to 21 CFR part 606, subpart G.

(d) Policies to ensure positive identification of a blood or blood product recipient must be established, documented, and followed.

§ 493.1275 Standard; Blood and blood products storage facilities.

(a) The blood and blood products must be stored under appropriate conditions, which include an adequate temperature alarm system that is regularly inspected.

(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period; and

(2) Inspections of the alarm system must be documented.

(b) If blood is stored or maintained for transfusion outside of a monitored refrigerator, the facility must ensure and document that storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product.

§ 493.1277 Standard; Arrangement for services.

In the case of services provided outside the blood bank, the facility must have an agreement reviewed and approved by the director that governs the procurement, transfer and availability of blood and blood products.

§ 493.1279 Standard; Provision of testing.

There must be provision for prompt ABO blood group, D(Rho) type, unexpected antibody detection and compatibility testing in accordance with §493.1269 of this subpart and for laboratory investigation of transfusion reactions, either through the facility or under arrangement with an approved facility on a continuous basis, under the supervision of a pathologist or other doctor of medicine or osteopathy meeting the qualifications of §§493.1449(b) or 493.1449(q).

§ 493.1283 Standard; Retention of samples of transfused blood.

According to the facility's established procedures, samples of each unit of transfused blood must be retained for further testing in the event of reactions. The facility must promptly dispose of blood not retained for further testing that has passed its expiration date.

§ 493.1285 Standard; Investigation of transfusion reactions.

The facility, according to its established procedures, must promptly investigate all transfusion reactions occurring in all facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. The facility must document that all necessary remedial actions are taken to prevent future recurrences of transfusion reactions and that all policies and procedures are reviewed to assure that they are adequate to ensure the safety of individuals being transfused within the facility.

Subpart L—[Reserved]
Subpart M—Personnel for Moderate Complexity (Including the Subcategory) and High Complexity Testing

§ 493.1351 General.
This subpart consists of the personnel requirements that must be met by laboratories performing moderate complexity testing, PPM procedures, high complexity testing, or any combination of these tests.

§ 493.1353 Scope.
In accordance with §493.19(b), the moderate complexity procedures specified as PPM procedures are considered such only when personally performed by a health care provider during a patient visit in the context of a physical examination. PPM procedures are subject to the personnel requirements in §§493.1355 through 493.1365.

§ 493.1355 Condition: Laboratories performing PPM procedures; laboratory director.
The laboratory must have a director who meets the qualification requirements of §493.1357 and provides overall management and direction in accordance with §493.1359.

§ 493.1357 Standard: Laboratory director qualifications.
The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of PPM procedures as specified in §493.19(c) and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part.

(a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if the licensing is required.

(b) The laboratory director must meet one of the following requirements:

(1) Be a physician, as defined in §493.2.

(2) Be a midlevel practitioner, as defined in §493.2, authorized by a State to practice independently in the State in which the laboratory is located.

(3) Be a dentist, as defined in §493.2.

§ 493.1359 Standard: PPM laboratory director responsibilities.
The laboratory director is responsible for the overall operation and administration of the laboratory, including the prompt, accurate, and proficient reporting of test results. The laboratory director must—

(a) Direct no more than five laboratories; and

(b) Ensure that any procedure listed under §493.19(c)—

(1) Is personally performed by an individual who meets the qualification requirements in §493.1363; and

(2) Is performed in accordance with applicable requirements in subparts H, J, K, M, and P of this part.

§ 493.1361 Condition: Laboratories performing PPM procedures; testing personnel.
The laboratory must have a sufficient number of individuals who meet the qualification requirements of §493.1363 to perform the functions specified in §493.1365 for the volume and complexity of testing performed.

§ 493.1363 Standard: PPM testing personnel qualifications.
Each individual performing PPM procedures must—

(a) Possess a current license issued by the State in which the laboratory is located if the licensing is required; and

(b) Meet one of the following requirements:

(1) Be a physician, as defined in §493.2.

(2) Be a midlevel practitioner, as defined in §493.2, under the supervision of a physician or in independent practice if authorized by the State in which the laboratory is located.
§ 493.1365 Standard; PPM testing personnel responsibilities.

The testing personnel are responsible for specimen processing, test performance, and for reporting test results. Any PPM procedure must be—
(a) Personally performed by one of the following practitioners:
(1) A physician during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group medical practice of which the physician is a member or employee;
(2) A midlevel practitioner, under the supervision of a physician or in independent practice if authorized by the State in which the laboratory is located, during the patient's visit on a specimen obtained from his or her own patient or from the patient of a clinic, group medical practice, or other health care provider, in which the midlevel practitioner is a member or an employee;
(3) A dentist during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group dental practice of which the dentist is a member or employee;
(b) Performed using a microscope limited to a brightfield or a phase/contrast microscope.

§ 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director.

The laboratory must have a director who meets the qualification requirements of §493.1405 of this subpart and provides overall management and direction in accordance with §493.1407 of this subpart.

§ 493.1405 Standard; Laboratory director qualifications.

The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part.

(a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and
(b) The laboratory director must—
(1) (i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and
(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or
(2) (i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and
(ii) Have had laboratory training or experience consisting of:
(A) At least one year directing or supervising non-waived laboratory testing; or
(B) Beginning September 1, 1993, have at least 20 continuing medical education credit hours in laboratory practice commensurate with the director responsibilities defined in §493.1407; or
(C) Laboratory training equivalent to paragraph (b)(2)(ii)(B) of this section obtained during medical residency. (For example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or
(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; and
(i) Be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or the American Board of Medical Laboratory Immunology; or
(ii) Have had at least one year experience directing or supervising non-waived laboratory testing;
(4) (i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution;
(ii) Have at least one year of laboratory training or experience, or both in non-waived testing; and
(ii) In addition, have at least one year of supervisory laboratory experience in non-waived testing; or
(iii) Have earned a bachelor’s degree in a chemical, physical, or biological science or medical technology from an accredited institution;
(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing; and
(iii) In addition, have at least 2 years of supervisory laboratory experience in non-waived testing;
(6) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under §493.1406;
(7) On or before February 28, 1992, qualified under State law to direct a laboratory in the State in which the laboratory is located.
§493.1406 Standard; Laboratory director qualifications on or before February 28, 1992.
The laboratory director must be qualified to manage and direct the laboratory personnel and test performance.
(a) The laboratory director must possess a current license as a laboratory director issued by the State, if such licensing exists; and
(b) The laboratory director must:
(1) Be a physician certified in anatomical or clinical pathology (or both) by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification;
(2) Be a physician who:
(i) Is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties; or
(ii) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties;
(iii) Held a bachelor’s degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties;
(iv) Achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S.
§ 493.1407 Standard; Laboratory director responsibilities.

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurately, and proficiently and for assuring compliance with the applicable regulations.

(a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of § 493.1409, 493.1415, and 493.1421, respectively.

(b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

(c) The laboratory director must be accessible to the laboratory to provide on-site, telephone or electronic consultation as needed.

(d) Each individual may direct no more than five laboratories.

(e) The laboratory director must—

(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment in which employees are protected from physical, chemical, and biological hazards;

(3) Ensure that—

(i) The test methodologies selected have the capability of providing the quality of results required for patient care;

(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;

(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that—

(i) The proficiency testing samples are tested as required under subpart H of this part;

(ii) The results are returned within the timeframes established by the proficiency testing program;

(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; and

(iv) An approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory;

(5) Ensure that the quality control and quality assurance programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, and that patient test results are reported only when the system is functioning properly;

(8) Ensure that reports of test results include pertinent information required for interpretation;

[58 FR 5233, Jan. 19, 1993]
(9) Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions;

(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and

(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

§ 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant.

The laboratory must have a technical consultant who meets the qualification requirements of § 493.1411 of this subpart and provides technical oversight in accordance with § 493.1413 of this subpart.

§ 493.1411 Standard; Technical consultant qualifications.

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.

(a) The technical consultant must possess a current license issued by the State in which the laboratory is located, if such licensing is required.

(b) The technical consultant must—

(1) (i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification;

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or

(iii) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or

(iii) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(iii) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or

(iii) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and
non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or

(4)(i) Have earned a bachelor’s degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible.

NOTE: The technical consultant requirements for “laboratory training or experience, or both” in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor’s degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

§ 493.1413 Standard; Technical consultant responsibilities.

The technical consultant is responsible for the technical and scientific oversight of the laboratory. The technical consultant is not required to be onsite at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation, as specified in paragraph (a) of this section.

(a) The technical consultant must be accessible to the laboratory to provide on-site, telephone, or electronic consultation; and

(b) The technical consultant is responsible for—

(1) Selection of test methodology appropriate for the clinical use of the test results;

(2) Verification of the test procedures performed and the establishment of the laboratory’s test performance characteristics, including the precision and accuracy of each test and test system;

(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered;

(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory’s established performance specifications;

(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly;

(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to—

(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;

(ii) Monitoring the recording and reporting of test results;

(iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;

(iv) Direct observation of performance of instrument maintenance and function checks;

(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and

(vi) Assessment of problem solving skills; and

(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first
year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual’s performance must be reevaluated to include the use of the new test methodology or instrumentation.

§ 493.1415 Condition: Laboratories performing moderate complexity testing; clinical consultant.

The laboratory must have a clinical consultant who meets the qualification requirements of §493.1417 of this part and provides clinical consultation in accordance with §493.1419 of this part.

§ 493.1417 Standard; Clinical consultant qualifications.

The clinical consultant must be qualified to consult with and render opinions to the laboratory’s clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must—

(a) Be qualified as a laboratory director under §493.1405(b) (1), (2), or (3)(i); or

(b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located.

§ 493.1419 Standard; Clinical consultant responsibilities.

The clinical consultant provides consultation regarding the appropriate-ness of the testing ordered and interpretation of test results. The clinical consultant must—

(a) Be available to provide clinical consultation to the laboratory’s clients;

(b) Be available to assist the laboratory’s clients in ensuring that appropriate tests are ordered to meet the clinical expectations;

(c) Ensure that reports of test results include pertinent information required for specific patient interpretation; and

(d) Ensure that consultation is available and communicated to the laboratory’s clients on matters related to the quality of the test results reported and their interpretation concerning specific patient conditions.

§ 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel.

The laboratory must have a sufficient number of individuals who meet the qualification requirements of §493.1423, to perform the functions specified in §493.1425 for the volume and complexity of tests performed.

§ 493.1423 Standard; Testing personnel qualifications.

Each individual performing moderate complexity testing must—

(a) Possess a current license issued by the State in which the laboratory is located, if such licensing is required; and

(b) Meet one of the following requirements:

(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master’s, or bachelor’s degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or

(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or

(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or

(4)(i) Have earned a high school diploma or equivalent; and

(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. Such training must ensure that the individual has—

(A) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens;
§ 493.1425

(B) The skills required for implementing all standard laboratory procedures;
(C) The skills required for performing each test method and for proper instrument use;
(D) The skills required for performing preventive maintenance, troubleshooting and calibration procedures related to each test performed;
(E) A working knowledge of reagent stability and storage;
(F) The skills required to implement the quality control policies and procedures of the laboratory;
(G) An awareness of the factors that influence test results; and
(H) The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results.


§ 493.1425 Standard; Testing personnel responsibilities.

The testing personnel are responsible for specimen processing, test performance, and for reporting test results.

(a) Each individual performs only those moderate complexity tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities.

(b) Each individual performing moderate complexity testing must—

(1) Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results;

(2) Maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient samples;

(3) Adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed;

(4) Follow the laboratory's established corrective action policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance;

(5) Be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director; and

(6) Document all corrective actions taken when test systems deviate from the laboratory's established performance specifications.

LABORATORIES PERFORMING HIGH COMPLEXITY TESTING

§ 493.1441 Condition: Laboratories performing high complexity testing; laboratory director.

The laboratory must have a director who meets the qualification requirements of §493.1443 of this subpart and provides overall management and direction in accordance with §493.1445 of this subpart.

§ 493.1443 Standard; Laboratory director qualifications.

The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R.

(a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and

(b) The laboratory director must—

(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and

(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and
§ 493.1445 Standard; Laboratory director responsibilities.

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations.

(a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under §§493.1447, 493.1453, 493.1459, and 493.1487, respectively.

(b) If the laboratory director reappor-  
tions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

(c) The laboratory director must be  
accessible to the laboratory to provide onsite, telephone or electronic consultation as needed.

(d) Each individual may direct no  
more than five laboratories.

(e) The laboratory director must—  
(1) Ensure that testing systems de-  
volved and used for each of the tests  
performed in the laboratory provide  
quality laboratory services for all as-  
pects of test performance, which in-  
cludes the preanalytic, analytic, and  
postanalytic phases of testing;

(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe envi-  
rnonment in which employees are pro-  
tected from physical, chemical, and bi-  
ological hazards;

(3) Ensure that—  
(i) The test methodologies selected  
have the capability of providing the  
quality of results required for patient  
care;

(ii) Verification procedures used are  
adequate to determine the accuracy,  
precision, and other pertinent perform-  
ance characteristics of the method; and

(iii) Laboratory personnel are per-  
foming the test methods as required  
for accurate and reliable results;

(4) Ensure that the laboratory is en-  
rolled in an HHS-approved proficiency  
testing program for the testing per-  
fomed and that—  
(i) The proficiency testing samples  
are tested as required under subpart H  
of this part;

(ii) The results are returned within  
the timeframes established by the prof-  
ciency testing program;
(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; and

(iv) An approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory;

(5) Ensure that the quality control and quality assurance programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified, and that patient test results are reported only when the system is functioning properly;

(8) Ensure that reports of test results include pertinent information required for interpretation;

(9) Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions;

(10) Ensure that a general supervisor provides on-site supervision of high complexity test performance by testing personnel qualified under § 493.1489(b)(4);

(11) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

(12) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and

(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

§ 493.1447 Condition: Laboratories performing high complexity testing; technical supervisor.

The laboratory must have a technical supervisor who meets the qualification requirements of § 493.1449 of this subpart and provides technical supervision in accordance with § 493.1451 of this subpart.

§ 493.1449 Standard; Technical supervisor qualifications.

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical supervision for each of the specialties and sub-specialties of service in which the laboratory performs high complexity tests or procedures. The director of a laboratory performing high complexity testing may function as the technical supervisor provided he or she meets the qualifications specified in this section.

(a) The technical supervisor must possess a current license issued by the
State in which the laboratory is located, if such licensing is required; and

(b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor—

(1) Is a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(2) Is certified in both anatomic and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications that are equivalent to those required for such certification.

(c) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of bacteriology, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the subspecialty of bacteriology; or

(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the subspecialty of bacteriology; or

(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or

(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology.

(d) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycobacteriology, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or

(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the subspecialty of mycobacteriology; or

(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or

(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology.
complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or

(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or

(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology.

(e) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycology, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of pediatric medicine licensed to practice medicine, osteopathy, or pediatrics in the State in which the laboratory is located; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or

(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or

(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or

(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology.

(f) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of parasitology, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of pediatric medicine licensed to practice medicine, osteopathy, or pediatrics in the State in which the laboratory is located; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or

(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or

(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or

(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology.
of 6 months experience in high complexity testing within the subspecialty of parasitology;

(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or

(4)(i) Have earned a master’s degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or

(5)(i) Have earned a bachelor’s degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology.

(g) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of virology, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or

(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or

(4)(i) Have earned a master’s degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or

(5)(i) Have earned a bachelor’s degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology.

(h) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of diagnostic immunology, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or
(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and
(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or
(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and
(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of diagnostic immunology; or
(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and
(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of diagnostic immunology; or
(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and
(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology.

(3) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of chemistry, the individual functioning as the technical supervisor must—

(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and
(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or
(3)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and
(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or

(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and
(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or
(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and
(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry.

(j) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of hematology, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and
(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or
(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and
(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of hematology (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or
(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

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(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of hematology; or

(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology; or

(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology.

(k)(1) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of cytology, the individual functioning as the technical supervisor must—

(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Meet one of the following requirements—

(A) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(B) Be certified by the American Society of Cytology to practice cytopathology or possess qualifications that are equivalent to those required for such certification; or

(2) An individual qualified under §493.1449(b) or paragraph (k)(1) of this section may delegate some of the cytology technical supervisor responsibilities to an individual who is in the final year of full-time training leading to certification specified in paragraphs (b) or (k)(1)(ii)(A) of this section provided the technical supervisor qualified under §493.1449(b) or paragraph (k)(1) of this section remains ultimately responsible for ensuring that all of the responsibilities of the cytology technical supervisor are met.

(l) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of histopathology, the individual functioning as the technical supervisor must—

(1) Meet one of the following requirements:

(i) (A) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(B) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification;

(ii) An individual qualified under §493.1449(b) or paragraph (l)(1) of this section may delegate to an individual who is in the final year of full-time training leading to certification specified in paragraph (b) or (l)(1)(ii)(B) of this section, the responsibility for examination and interpretation of histopathology specimens.

(2) For tests in dermatopathology, meet one of the following requirements:

(i) (A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and—

(B) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(B) Be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(B) Be certified in dermatopathology by the American Board of Dermatology or possess qualifications that are equivalent to those required for such certification; or

(ii) An individual qualified under §493.1449(b) or paragraph (l)(2)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (l)(2)(ii) of this section. Provided the technical supervisor qualified under §493.1449 or paragraph (l)(1) of this section remains ultimately responsible for ensuring that all of the responsibilities of the dermatopathology technical supervisor are met.
paragraphs (b) or (l)(2)(i)(B) of this section, the responsibility for examination and interpretation of dermatopathology specimens.

(3) For tests in ophthalmic pathology, meet one of the following requirements:

(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and—

(B) Must meet one of the following requirements:

(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2) Be certified by the American Board of Ophthalmology or possess qualifications that are equivalent to those required for such certification and have successfully completed at least 1 year of formal post-residency fellowship training in ophthalmic pathology; or

(ii) An individual qualified under §493.1449(b) or paragraph (l)(3)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (l)(1) or (2) of this section, the responsibility for examination and interpretation of oral pathology specimens.

(m) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of oral pathology, the individual functioning as the technical supervisor must—

(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(3) An individual qualified under §493.1449(b) or paragraph (m)(1) or (2) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (m)(1) or (2) of this section, the responsibility for examination and interpretation of oral pathology specimens.

(n) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of radiobioassay, the individual functioning as the technical supervisor must—

(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or

(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of radiobioassay; or

(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or

(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in
high complexity testing for the specialty of radiobioassay.

(o) If the laboratory performs tests in the specialty of histocompatibility, the individual functioning as the technical supervisor must either—

(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have training or experience that meets one of the following requirements:

(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or

(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and

(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility; or

(2)(i) Have an earned doctoral degree in a biological or clinical laboratory science from an accredited institution; and

(ii) Have training or experience that meets one of the following requirements:

(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or

(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and

(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility.

(p) If the laboratory performs tests in the specialty of clinical cytogenetics, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics; or

(2)(i) Hold an earned doctoral degree in a biological science, including biochemistry, or clinical laboratory science from an accredited institution; and

(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics.

(q) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of immunohematology, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of immunohematology.

NOTE: The technical supervisor requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service. For example, an individual, who has a doctoral degree in chemistry and additionally has documentation of 1 year of laboratory experience working concurrently in high complexity testing in the specialties of microbiology and chemistry and 6 months of that work experience included high complexity testing in bacteriology, mycology, and mycobacteriology, would qualify as the technical supervisor for the specialty of chemistry and the subspecialties of bacteriology, mycology, and mycobacteriology.


The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section.

(a) The technical supervisor must be accessible to the laboratory to provide
on-site, telephone, or electronic consultation; and
(b) The technical supervisor is responsible for—
(1) Selection of the test methodology that is appropriate for the clinical use of the test results;
(2) Verification of the test procedures performed and establishment of the laboratory’s test performance characteristics, including the precision and accuracy of each test and test system;
(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered;
(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;
(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory’s established performance specifications;
(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly;
(7) Identifying training needs and ensuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;
(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to—
(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;
(ii) Monitoring the recording and reporting of test results;
(iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;
(iv) Direct observation of performance of instrument maintenance and function checks;
(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and
(vi) Assessment of problem solving skills; and
(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual’s performance must be reevaluated to include the use of the new test methodology or instrumentation.
(c) In cytology, the technical supervisor or the individual qualified under §493.1449(k)(2)—
(1) May perform the duties of the cytology general supervisor and the cytotechnologist, as specified in §§493.1471 and 493.1485, respectively;
(2) Must establish the workload limit for each individual examining slides;
(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary;
(4) Must perform the functions specified in §493.1257(c);
(5) Must ensure that each individual examining gynecologic preparations participates in an HHS approved cytology proficiency testing program, as specified in §493.945 and achieves a passing score, as specified in §493.855; and
(6) If responsible for screening cytology slide preparations, must document the number of cytology slides screened in 24 hours and the number of hours devoted during each 24-hour period to screening cytology slides.
§ 493.1453 Condition: Laboratories performing high complexity testing; clinical consultant.

The laboratory must have a clinical consultant who meets the requirements of §493.1455 of this subpart and provides clinical consultation in accordance with §493.1457 of this subpart.

§ 493.1455 Standard; Clinical consultant qualifications.

The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must—

(a) Be qualified as a laboratory director under §493.1443(b)(1), (2), or (3)(i) or, for the subspecialty of oral pathology, §493.1443(b)(6); or

(b) Be a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located.


§ 493.1457 Standard; Clinical consultant responsibilities.

The clinical consultant provides consultation regarding the appropriateness of the testing ordered and interpretation of test results. The clinical consultant must—

(a) Be available to provide consultation to the laboratory's clients;

(b) Be available to assist the laboratory's clients in ensuring that appropriate tests are ordered to meet the clinical expectations;

(c) Ensure that reports of test results include pertinent information required for specific patient interpretation; and

(d) Ensure that consultation is available and communicated to the laboratory's clients on matters related to the quality of the test results reported and their interpretation concerning specific patient conditions.

§ 493.1459 Condition: Laboratories performing high complexity testing; general supervisor.

The laboratory must have one or more general supervisors who are qualified under §493.1461 of this subpart to provide general supervision in accordance with §493.1463 of this subpart.

§ 493.1461 Standard: General supervisor qualifications.

The laboratory must have one or more general supervisors who, under the direction of the laboratory director and supervision of the technical supervisor, provides day-to-day supervision of testing personnel and reporting of test results. In the absence of the director and technical supervisor, the general supervisor must be responsible for the proper performance of all laboratory procedures and reporting of test results.

(a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and

(b) The general supervisor must be qualified as a—

(1) Laboratory director under §493.1443; or

(2) Technical supervisor under §493.1449.

(c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must—

(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or

(2)(i) Qualify as testing personnel under §493.1489(b)(2); and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or

(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under §493.1462 on or before February 28, 1992.

(ii) Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets...
the requirements of §493.1462 on or before January 1, 1994.’”

(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995—

(i) Meet one of the following requirements:

(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS.

(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician).

(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or

(5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and—

(i) Be a high school graduate or equivalent; and

(ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992.

(d) For blood gas analysis, the individual providing general supervision must—

(1) Be qualified under §§493.1461(b)(1) or (2), or 493.1461(c); or

(2)(i) Have earned a bachelor’s degree in respiratory therapy or cardiovascular technology from an accredited institution; and

(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or

(3)(i) Have earned an associate degree related to pulmonary function from an accredited institution; and

(ii) Have at least two years of training or experience, or both in blood gas analysis.

(e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed:

(1) In histopathology, by an individual who is qualified as a technical supervisor under §§493.1449(b) or 493.1449(1)(1); (2) In dermatopathology, by an individual who is qualified as a technical supervisor under §§493.1449(b) or 493.1449(1) or (2); (3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under §§493.1449(b) or 493.1449(1)(3); and

(4) In oral pathology, by an individual who is qualified as a technical supervisor under §§493.1449(b) or 493.1449(n).
§ 493.1463 Standard: General supervisor responsibilities.

The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.

(a) The general supervisor—(1) Must be accessible to testing personnel at all times testing is performed to provide on-site, telephone or electronic consultation to resolve technical problems in accordance with policies and procedures established either by the laboratory director or technical supervisor;

(2) Is responsible for providing day-to-day supervision of high complexity test performance by a testing personnel qualified under § 493.1489;

(3) Except as specified in paragraph (c) of this section, must be on-site to provide direct supervision when high complexity testing is performed by any individuals qualified under § 493.1489;

(4) Is responsible for monitoring test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained.

(b) The director or technical supervisor may delegate to the general supervisor the responsibility for—

(1) Assuring that all remedial actions are taken whenever test systems deviate from the laboratory’s established performance specifications;

(2) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is properly functioning;

(3) Providing orientation to all testing personnel; and

(4) Annually evaluating and documenting the performance of all testing personnel.

(c) Exception. For individuals qualified under § 493.1489(b)(5), who were performing high complexity testing on or before January 19, 1993, the requirements of paragraph (a)(3) of this section are not effective, provided that all high complexity testing performed by the individual in the absence of a general supervisor is reviewed within 24 hours by a general supervisor qualified under § 493.1461.

§ 493.1467 Condition: Laboratories performing high complexity testing; cytology general supervisor.

For the subspecialty of cytology, the laboratory must have a general supervisor who meets the qualification requirements of § 493.1469 of this subpart, and provides supervision in accordance with § 493.1471 of this subpart.

§ 493.1469 Standard: Cytology general supervisor qualifications.

The cytology general supervisor must be qualified to supervise cytology services. The general supervisor in cytology must possess a current license issued by the State in which the laboratory is located, if such licensing is required, and must—

(a) Be qualified as a technical supervisor under § 493.1449 (b) or (k); or

(b)(1) Be qualified as a cytotechnologist under § 493.1483; and

(2) Have at least 3 years of full-time (2,000 hours per year) experience as a cytotechnologist within the preceding 10 years.

§ 493.1471 Standard: Cytology general supervisor responsibilities.

The technical supervisor of cytology may perform the duties of the cytology general supervisor or delegate the responsibilities to an individual qualified under § 493.1469.
§ 493.1481 Condition: Laboratories performing high complexity testing; cytotechnologist.

For the subspecialty of cytology, the laboratory must have a sufficient number of cytotechnologists who meet the qualifications specified in § 493.1483 to perform the functions specified in § 493.1485.

§ 493.1483 Standard: Cytotechnologist qualifications.

Each person examining cytology slide preparations must meet the qualifications of § 493.1449 (b) or (k), or—

(a) Possess a current license as a cytotechnologist issued by the State in which the laboratory is located, if such licensing is required; and

(b) Meet one of the following requirements:

(1) Have successfully completed 2 years in an accredited institution with at least 12 semester hours in science, 8 hours of which are in biology; and

(A) Have had 12 months of training in a school of cytotechnology accredited by an accrediting agency approved by HHS; or

(B) Have received 6 months of formal training in a school of cytotechnology accredited by an accrediting agency approved by HHS and 6 months of full-time experience in cytotechnology in a laboratory acceptable to the pathologist who directed the formal 6 months of training; or

(ii) Have achieved a satisfactory grade to qualify as a cytotechnologist in a proficiency examination approved by HHS and designed to qualify persons as cytotechnologists; or

(4) Before September 1, 1994, have full-time experience of at least 2 years or equivalent within the preceding 5 years examining slide preparations under the supervision of a physician qualified under § 493.1449(b) or (k)(1), and before January 1, 1969, must have—

(i) Graduated from high school;

(ii) Completed 6 months of training in cytotechnology in a laboratory directed by a pathologist or other physician providing cytology services; and

(iii) Completed 2 years of full-time supervised experience in cytotechnology; or

(5)(i) On or before September 1, 1994, have full-time experience of at least 2 years or equivalent examining cytology slide preparations within the preceding 5 years in the United States under the supervision of a physician qualified under § 493.1449(b) or (k)(1); and

(ii) On or before September 1, 1995, have met the requirements in either paragraph (b)(1) or (2) of this section.

[57 FR 7172, Feb. 28, 1992, as amended at 59 FR 685, Jan. 6, 1994]

§ 493.1485 Standard; Cytotechnologist responsibilities.

The cytotechnologist is responsible for documenting—

(a) The slide interpretation results of each gynecologic and nongynecologic cytology case he or she examined or reviewed (as specified in § 493.1257(d)).
Health Care Financing Administration, HHS § 493.1489

(b) For each 24-hour period, the total number of slides examined or reviewed in the laboratory as well as the total number of slides examined or reviewed in any other laboratory or for any other employer; and
(c) The number of hours spent examining slides in each 24-hour period.

§ 493.1487 Condition: Laboratories performing high complexity testing; testing personnel.

The laboratory has a sufficient number of individuals who meet the qualification requirements of § 493.1489 of this subpart to perform the functions specified in § 493.1495 of this subpart for the volume and complexity of testing performed.

§ 493.1489 Standard; Testing personnel qualifications.

Each individual performing high complexity testing must—
(a) Possess a current license issued by the State in which the laboratory is located, if such licensing is required; and
(b) Meet one of the following requirements:
(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution;
(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or—
(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes—
(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either—
(1) 24 semester hours of medical laboratory technology courses; or
(2) 24 semester hours of science courses that include—
(i) Six semester hours of chemistry; and
(ii) Six semester hours of biology; and
(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and
(B) Have laboratory training that includes either of the following:
(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS.
(This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.)
(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing.
(3) Have previously qualified or could have qualified as a technologist under § 493.1491 on or before February 28, 1992;
(4) On or before April 24, 1995 be a high school graduate or equivalent and have either—
(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or
(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician);
(5)(i) Until September 1, 1997—
(A) Have earned a high school diploma or equivalent; and
(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has—
(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens;
(2) The skills required for implementing all standard laboratory procedures;
(3) The skills required for performing each test method and for proper instrument use;
(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed;
(5) A working knowledge of reagent stability and storage;
(6) The skills required to implement the quality control policies and procedures of the laboratory;
(7) An awareness of the factors that influence test results; and
(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and
(ii) As of September 1, 1997, be qualified under § 493.1489(b)(1), (b)(2), (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995;
(6) For blood gas analysis—
(i) Be qualified under § 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5);
(ii) Have earned a bachelor’s degree in respiratory therapy or cardiovascular technology from an accredited institution; or
(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or
(7) For histopathology, meet the qualifications of § 493.1449 (b) or (l) to perform tissue examinations.

§ 493.1491 Technologist qualifications on or before February 28, 1992.

In order to qualify as high complexity testing personnel under § 493.1489(b)(3), the individual must have met or could have met the following qualifications for technologist as they were in effect on or before February 28, 1992. Each technologist must
(a) Possess a current license as a laboratory technologist issued by the State, if such licensing exists; and
(b)(1) Have earned a bachelor’s degree in medical technology from an accredited university; or
(2) Have successfully completed 3 years of academic study (a minimum of 90 semester hours or equivalent) in an accredited college or university, which met the specific requirements for entrance into a school of medical technology accredited by an accrediting agency approved by the Secretary, and has successfully completed a course of training of at least 12 months in such a school; or
(3) Have earned a bachelor’s degree in one of the chemical, physical, or biological sciences and, in addition, has at least 1 year of pertinent full-time laboratory experience or training, or both, in the specialty or subspecialty in which the individual performs tests; or
(4)(i) Have successfully completed 3 years (90 semester hours or equivalent) in an accredited college or university with the following distribution of courses—
(A) For those whose training was completed before September 15, 1963. At least 24 semester hours in chemistry and biology courses of which—
(1) At least 6 semester hours were in inorganic chemistry and at least 3 semester hours were in other chemistry courses; and
(2) At least 12 semester hours in biology courses pertinent to the medical sciences; or
(B) For those whose training was completed after September 14, 1963.
(1) 16 semester hours in chemistry courses that included at least 6 semester hours in inorganic chemistry and that are acceptable toward a major in chemistry;
(2) 16 semester hours in biology courses that are pertinent to the medical sciences and are acceptable toward a major in the biological sciences; and
(3) 3 semester hours of mathematics; and
(ii) Has experience, training, or both, covering several fields of medical laboratory work of at least 1 year and of such quality as to provide him or her with education and training in medical technology equivalent to that described in paragraphs (b)(1) and (2) of this section; or
(5) With respect to individuals first qualifying before July 1, 1971, the technologist—
(i) Was performing the duties of a laboratory technologist at any time between July 1, 1961, and January 1, 1968, and
(ii) Has had at least 10 years of pertinent laboratory experience prior to January 1, 1968. (This required experience may be met by the substitution of education for experience); or
§ 493.1495 Standard; Testing personnel responsibilities.

The testing personnel are responsible for specimen processing, test performance and for reporting test results.

(a) Each individual performs only those high complexity tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities.

(b) Each individual performing high complexity testing must—

(1) Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results;

(2) Maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient specimens;

(3) Adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed;

(4) Follow the laboratory's established policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance;

(5) Be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the general supervisor, technical supervisor, clinical consultant, or director;

(6) Document all corrective actions taken when test systems deviate from the laboratory's established performance specifications; and

(7) Except as specified in paragraph (c) of this section, if qualified under §493.1489(b)(5), perform high complexity testing only under the onsite, direct supervision of a general supervisor qualified under §493.1461.

(c) Exception. For individuals qualified under §493.1489(b)(5), who were performing high complexity testing on or before January 19, 1993, the requirements of paragraph (b)(7) of this section are not effective, provided that all high complexity testing performed by the individual in the absence of a general supervisor is reviewed within 24 hours by a general supervisor qualified under §493.1461.

§ 493.1701 Condition: Quality assurance; moderate complexity (including the subcategory) or high complexity testing, or any combination of these tests.

Each laboratory performing moderate complexity (including the subcategory) or high complexity testing, or any combination of these tests, must establish and follow written policies and procedures for a comprehensive quality assurance program that is designed to monitor and evaluate the ongoing and overall quality of the total testing process (preanalytic, analytic, postanalytic). The laboratory's quality assurance program must evaluate the effectiveness of its policies and procedures; identify and correct problems; assure the accuracy, reliable and prompt reporting of test results; and assure the adequacy and competency of the staff. As necessary, the laboratory must revise policies and procedures based upon the results of those evaluations. The laboratory must meet the standards as they apply to the services offered, complexity of testing performed and test results reported, and the unique practices of each testing entity. All quality assurance activities must be documented.

[57 FR 7183, Feb. 28, 1992, unless otherwise noted.]
§ 493.1703 Standard; Patient test management assessment.

The laboratory must have an ongoing mechanism for monitoring and evaluating the systems required under subpart J, Patient Test Management. The laboratory must monitor, evaluate, and revise, if necessary, based on the results of its evaluations, the following:

(a) The criteria established for patient preparation, specimen collection, labeling, preservation and transportation;

(b) The information solicited and obtained on the laboratory's test requisition for its completeness, relevance, and necessity for the testing of patient specimens;

(c) The use and appropriateness of the criteria established for specimen rejection;

(d) The completeness, usefulness, and accuracy of the test report information necessary for the interpretation or utilization of test results;

(e) The timely reporting of test results based on testing priorities (STAT, routine, etc.); and

(f) The accuracy and reliability of test reporting systems, appropriate storage of records and retrieval of test results.

§ 493.1705 Standard; Quality control assessment.

The laboratory must have an ongoing mechanism to evaluate the corrective actions taken under §493.1219, Remedial actions. Ineffective policies and procedures must be revised based on the outcome of the evaluation. The mechanism must evaluate and review the effectiveness of corrective actions taken for—

(a) Problems identified during the evaluation of calibration and control data for each test method;

(b) Problems identified during the evaluation of patient test values for the purpose of verifying the reference range of a test method; and

(c) Errors detected in reported results.

§ 493.1707 Standard; Proficiency testing assessment.

Under subpart H of this part, Proficiency Testing, the corrective actions taken for any unacceptable, unsatisfactory, or unsuccessful proficiency testing result(s) must be evaluated for effectiveness.

§ 493.1709 Standard; Comparison of test results.

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

(b) If a laboratory performs tests that are not included under subpart I of this part, Proficiency Testing Programs, the laboratory must have a system for verifying the accuracy of its test results at least twice a year.

[58 FR 5236, Jan. 19, 1993]

§ 493.1711 Standard; Relationship of patient information to patient test results.

For internal quality assurance, the laboratory must have a mechanism to identify and evaluate patient test results that appear inconsistent with relevant criteria such as—

(a) Patient age;

(b) Sex;

(c) Diagnosis or pertinent clinical data, when provided;

(d) Distribution of patient test results when available; and

(e) Relationship with other test parameters, when available within the laboratory.

§ 493.1713 Standard; Personnel assessment.

The laboratory must have an ongoing mechanism to evaluate the effectiveness of its policies and procedures for assuring employee competence and, if applicable, consultant competence.

§ 493.1715 Standard; Communications.

The laboratory must have a system in place to document problems that occur as a result of breakdowns in communication between the laboratory and the authorized individual who orders or receives the results of test procedures or examinations. Corrective actions must be taken, as necessary, to resolve
the problems and minimize communication breakdowns.

[58 FR 5296, Jan. 19, 1993]

§ 493.1717 Standard; Complaint investigations.

The laboratory must have a system in place to assure that all complaints and problems reported to the laboratory are documented. Investigations of complaints must be made, when appropriate, and, as necessary, corrective actions are instituted.

§ 493.1719 Standard; Quality assurance review with staff.

The laboratory must have a mechanism for documenting and assessing problems identified during quality assurance reviews and discussing them with the staff. The laboratory must take corrective actions that are necessary to prevent recurrences.

§ 493.1721 Standard; Quality assurance records.

The laboratory must maintain documentation of all quality assurance activities including problems identified and corrective actions taken. All quality assurance records must be available to HHS and maintained for a period of 2 years.

[58 FR 5296, Jan. 19, 1993]

Subpart Q—Inspection

SOURCE: 57 FR 7184, Feb. 28, 1992, unless otherwise noted.

§ 493.1771 Condition: Inspection requirements applicable to all CLIA-certified and CLIA-exempt laboratories.

(a) Each laboratory issued a CLIA certificate must meet the requirements in § 493.1773 and the specific requirements for its certificate type, as specified in §§ 493.1775 through 493.1780.

(b) All CLIA-exempt laboratories must comply with the inspection requirements in §§ 493.1773 and 493.1780, when applicable.

[63 FR 26737, May 14, 1998]

§ 493.1773 Standard: Basic inspection requirements for all laboratories issued a CLIA certificate and CLIA-exempt laboratories.

(a) A laboratory issued a certificate must permit HCFA or a HCFA agent to conduct an inspection to assess the laboratory's compliance with the requirements of this part. A CLIA-exempt laboratory and a laboratory that requests, or is issued a certificate of accreditation, must permit HCFA or a HCFA agent to conduct validation and complaint inspections.

(b) General requirements. As part of the inspection process, HCFA or a HCFA agent may require the laboratory to do the following:

(1) Test samples, including proficiency testing samples, or perform procedures.

(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part.

(3) Permit laboratory personnel to be observed performing all phases of the total testing process (preanalytic, analytic, and postanalytic).

(4) Permit HCFA or a HCFA agent access to all areas encompassed under the certificate including, but not limited to, the following:

(i) Specimen procurement and processing areas.

(ii) Storage facilities for specimens, reagents, supplies, records, and reports.

(iii) Testing and reporting areas.

(5) Provide HCFA or a HCFA agent with copies or exact duplicates of all records and data it requires.

(c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection.

(d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by HCFA or a HCFA agent to make a determination of the laboratory's compliance with the applicable requirements of this part.

(e) Reinspection. HCFA or a HCFA agent may reinspect a laboratory at any time to evaluate the ability of the laboratory to provide accurate and reliable test results.
§ 493.1775 Standard: Inspection of laboratories issued a certificate of waiver or a certificate for provider-performed microscopy procedures.

(a) A laboratory that has been issued a certificate of waiver or a certificate for provider-performed microscopy procedures is not subject to biennial inspections.

(b) If necessary, HCFA or a HCFA agent may conduct an inspection of a laboratory issued a certificate of waiver or a certificate for provider-performed microscopy procedures at any time during the laboratory’s hours of operation to do the following:

(1) Determine if the laboratory is operated and testing is performed in a manner that does not constitute an imminent and serious risk to public health.

(2) Evaluate a complaint from the public.

(3) Determine whether the laboratory is performing tests beyond the scope of the certificate held by the laboratory.

(4) Collect information regarding the appropriateness of tests specified as waived tests or provider-performed microscopy procedures.

(c) The laboratory must comply with the basic inspection requirements of § 493.1773.

§ 493.1777 Standard: Inspection of laboratories that have requested or have been issued a certificate of accreditation.

(a) Initial inspection. (1) A laboratory issued a registration certificate must permit an initial inspection to assess the laboratory’s compliance with the requirements of this part before HCFA issues a certificate of compliance.

(2) The inspection may occur at any time during the laboratory’s hours of operation.

(b) Subsequent inspections. (1) HCFA or a HCFA agent may conduct subsequent inspections on a biennial basis or with such other frequency as HCFA determines to be necessary to ensure compliance with the requirements of this part.

(2) HCFA bases the nature of subsequent inspections on the laboratory’s compliance history.

(c) Provider-performed microscopy procedures. The inspection sample for review may include testing in the subcategory of provider-performed microscopy procedures.

(d) Compliance with basic inspection requirements. The laboratory must comply with the basic inspection requirements of § 493.1773.

§ 493.1780 Standard: Inspection of CLIA-exempt laboratories or laboratories requesting or issued a certificate of accreditation.

(a) Validation inspection. HCFA or a HCFA agent may conduct a validation inspection of any accredited or CLIA-exempt laboratory at any time during its hours of operation.

(b) Complaint inspection. HCFA or a HCFA agent may conduct a complaint inspection of a CLIA-exempt laboratory or a laboratory requesting or issued a certificate of accreditation at any time during its hours of operation upon receiving a complaint applicable to the requirements of this part.

(c) Noncompliance determination. If a validation or complaint inspection results in a finding that the laboratory is not in compliance with one or more condition-level requirements, the following actions occur:

(1) A laboratory issued a certificate of accreditation is subject to a full review by HCFA, in accordance with subpart E of this part and § 488.11 of this chapter.
§ 493.1800 Basis and scope.

(a) Statutory basis. (1) Section 1846 of the Act—
   (i) Provides for intermediate sanctions that may be imposed on laboratories that perform clinical diagnostic tests on human specimens when those laboratories are found to be out of compliance with one or more of the conditions for Medicare coverage of their services; and
   (ii) Requires the Secretary to develop and implement a range of such sanctions, including four that are specified in the statute.
(2) The Clinical Laboratories Improvement Act of 1967 (section 353 of the Public Health Service Act) as amended by CLIA ‘88—
   (i) Establishes requirements for all laboratories that perform clinical diagnostic tests on human specimens;
   (ii) Requires a Federal certification scheme to be applied to all such laboratories; and
   (iii) Grants the Secretary broad enforcement authority, including—
      (A) Use of intermediate sanctions;
      (B) Suspension, limitation, or revocation of the certificate of a laboratory that is out of compliance with one or more requirements for a certificate; and
      (C) Civil suit to enjoin any laboratory activity that constitutes a significant hazard to the public health.
(3) Section 353 also—
   (i) Provides for imprisonment or fine for any person convicted of intentional violation of CLIA requirements;
   (ii) Specifies the administrative hearing and judicial review rights of a laboratory that is sanctioned under CLIA; and
   (iii) Requires the Secretary to publish annually a list of all laboratories that have been sanctioned during the preceding year.
(b) Scope and applicability. This subpart sets forth—
   (1) The policies and procedures that HCFA follows to enforce the requirements applicable to laboratories under CLIA and under section 1846 of the Act; and
   (2) The appeal rights of laboratories on which HCFA imposes sanctions.

§ 493.1804 General considerations.

(a) Purpose. The enforcement mechanisms set forth in this subpart have the following purposes:
   (1) To protect all individuals served by laboratories against substandard testing of specimens.
   (2) To safeguard the general public against health and safety hazards that might result from laboratory activities.
   (3) To motivate laboratories to comply with CLIA requirements so that they can provide accurate and reliable test results.
(b) Basis for decision to impose sanctions. (1) HCFA’s decision to impose sanctions is based on one or more of the following:
   (i) Deficiencies found by HCFA or its agents in the conduct of inspections to certify or validate compliance with Federal requirements, or through review of materials submitted by the laboratory (e.g., personnel qualifications).
   (ii) Unsuccessful participation in proficiency testing.
   (2) HCFA imposes one or more of the alternative or principal sanctions specified in §§ 493.1806 and 493.1807 when HCFA or HCFA’s agent finds that a laboratory has condition-level deficiencies.
(c) Imposition of alternative sanctions. (1) HCFA may impose alternative sanctions in lieu of, or in addition to principal sanctions, (HCFA does not impose alternative sanctions on laboratories
§ 493.1806 Available sanctions: All laboratories.

(a) Applicability. HCFA may impose one or more of the sanctions specified in this section on a laboratory that is out of compliance with one or more CLIA conditions.

(b) Principal sanction. HCFA may impose any of the three principal CLIA sanctions, which are suspension, limitation, or revocation of any type of CLIA certificate.

(c) Alternative sanctions. HCFA may impose one or more of the following alternative sanctions in lieu of or in addition to imposing a principal sanction, except on a laboratory that has a certificate of waiver.

(1) Directed plan of correction, as set forth at §493.1832.

(2) State onsite monitoring as set forth at §493.1836.

(3) Civil money penalty, as set forth at §493.1834.

(d) Civil suit. HCFA may bring suit in the appropriate U.S. District Court to enjoin continuation of any activity of any laboratory (including a CLIA-exempt laboratory that has been found with deficiencies during a validation survey), if HCFA has reason to believe that continuation of the activity would constitute a significant hazard to the public health.

(e) Criminal sanctions. Under section 353(1) of the PHS Act, an individual who is convicted of intentionally violating any CLIA requirement may be imprisoned or fined.

§ 493.1807 Additional sanctions: Laboratories that participate in Medicare.

The following additional sanctions are available for laboratories that are out of compliance with one or more CLIA conditions and that have approval to receive Medicare payment for their services.

(a) Principal sanction. Cancellation of the laboratory’s approval to receive Medicare payment for its services.
(b) Alternative sanctions. (1) Suspension of payment for tests in one or more specific specialties or subspecialties, performed on or after the effective date of sanction.

(2) Suspension of payment for all tests in all specialties and subspecialties performed on or after the effective date of sanction.

§ 493.1808 Adverse action on any type of CLIA certificate: Effect on Medicare approval.

(a) Suspension or revocation of any type of CLIA certificate. When HCFA suspends or revokes any type of CLIA certificate, HCFA concurrently cancels the laboratory’s approval to receive Medicare payment for its services.

(b) Limitation of any type of CLIA certificate. When HCFA limits any type of CLIA certificate, HCFA concurrently limits Medicare approval to only those specialties or subspecialties that are authorized by the laboratory’s limited certificate.

§ 493.1809 Limitation on Medicaid payment.

As provided in section 1902(a)(9)(C) of the Act, payment for laboratory services may be made under the State plan only if those services are furnished by a laboratory that has a CLIA certificate or is licensed by a State whose licensure program has been approved by the Secretary under this part.

[57 FR 7237, Feb. 28, 1992; 57 FR 35761, Aug. 11, 1992]

§ 493.1810 Imposition and lifting of alternative sanctions.

(a) Notice of noncompliance and of proposed sanction: Content. If HCFA or its agency identifies condition level noncompliance in a laboratory, HCFA or its agent gives the laboratory written notice of the following:

(1) The condition level noncompliance that it has identified.

(2) The sanction or sanctions that HCFA or its agent proposes to impose against the laboratory.

(3) The rationale for the proposed sanction or sanctions.

(4) The projected effective date and duration of the proposed sanction or sanctions.

(5) The authority for the proposed sanction or sanctions.

(b) Opportunity to respond. During the period specified in paragraph (a)(6) of this section, the laboratory may submit to HCFA or its agent written evidence or other information against the imposition of the proposed sanction or sanctions.

(c) Notice of imposition of sanction—(1) Content. HCFA gives the laboratory written notice that acknowledges any evidence or information received from the laboratory and specifies the following:

(i) The sanction or sanctions to be imposed against the laboratory.

(ii) The authority and rationale for the imposing sanction or sanctions.

(iii) The effective date and duration of sanction.

(2) Timing. (i) If HCFA or its agent determines that the deficiencies pose immediate jeopardy, HCFA provides notice at least 5 days before the effective date of sanction.

(ii) If HCFA or its agent determines that the deficiencies do not pose immediate jeopardy, HCFA provides notice at least 15 days before the effective date of the sanction.

(d) Duration of alternative sanctions. An alternative sanction continues until the earlier of the following occurs:

(1) The laboratory corrects all condition level deficiencies.

(2) HCFA’s suspension, limitation, or revocation of the laboratory’s CLIA certificate becomes effective.

(e) Lifting of alternative sanctions—(1) General rule. Alternative sanctions are not lifted until a laboratory’s compliance with all condition level requirements is verified.

(2) Credible allegation of compliance. When a sanctioned laboratory submits a credible allegation of compliance, HCFA’s agent determines whether—

(i) It can certify compliance on the basis of the evidence presented by the laboratory in its allegation; or

(ii) It must revisit to verify whether the laboratory has, in fact, achieved compliance.
§ 493.1812 Action when deficiencies pose immediate jeopardy.

If a laboratory’s deficiencies pose immediate jeopardy, the following rules apply:

(a) HCFA requires the laboratory to take immediate action to remove the jeopardy and may impose one or more alternative sanctions to help bring the laboratory into compliance.

(b) If the findings of a revisit indicate that a laboratory has not eliminated the jeopardy, HCFA suspends or limits the laboratory’s CLIA certificate no earlier than 5 days after the date of notice of suspension or limitation. HCFA may later revoke the certificate.

(c) In addition, if HCFA has reason to believe that the continuation of any activity by any laboratory (either the entire laboratory operation or any specialty or subspecialty of testing) would constitute a significant hazard to the public health, HCFA may bring suit and seek a temporary injunction or restraining order against continuation of that activity by the laboratory, regardless of the type of CLIA certificate the laboratory has and of whether it is State-exempt.

§ 493.1814 Action when deficiencies are at the condition level but do not pose immediate jeopardy.

If a laboratory has condition level deficiencies that do not pose immediate jeopardy, the following rules apply:

(a) Initial action. (1) HCFA may cancel the laboratory’s approval to receive Medicare payment for its services.

(2) HCFA may suspend, limit, or revoke the laboratory’s CLIA certificate.

(3) If HCFA does not impose a principal sanction under paragraph (a)(1) or (a)(2) of this section, it imposes one or more alternative sanctions. In the case of unsuccessful participation in proficiency testing, HCFA may impose the training and technical assistance requirement set forth at § 493.1838 in lieu of, or in addition to, one or more alternative sanctions.

(b) Failure to correct condition level deficiencies. If HCFA imposes alternative sanctions for condition level deficiencies that do not pose immediate jeopardy, and the laboratory does not correct the condition level deficiencies within 12 months after the last day of inspection, HCFA—

(1) Cancels the laboratory’s approval to receive Medicare payment for its services, and discontinues the Medicare payment sanctions as of the day cancellation is effective.

(2) Following a revisit which indicates that the laboratory has not corrected its condition level deficiencies, notifies the laboratory that it proposes to suspend, limit, or revoke the certificate, as specified in § 493.1816(b), and the laboratory’s right to hearing; and

(3) May impose (or continue, if already imposed) any alternative sanctions that do not pertain to Medicare payments. (Sanctions imposed under the authority of section 353 of the PHS Act may continue for more than 12 months from the last date of inspection, while a hearing on the proposed suspension, limitation, or revocation of the certificate of compliance, registration certificate, certificate of accreditation, or certificate for PPM procedures is pending.)

(c) Action after hearing. If a hearing decision upholds a proposed suspension, limitation, or revocation of a laboratory’s CLIA certificate, HCFA discontinues any alternative sanctions as of the day it makes the suspension, limitation, or revocation effective.

[57 FR 7237, Feb. 28, 1992, as amended at 60 FR 20051, Apr. 24, 1995]

§ 493.1816 Action when deficiencies are not at the condition level.

If a laboratory has deficiencies, that are not at the condition level, the following rules apply:

(a) Initial action. The laboratory must submit a plan of correction that is acceptable to HCFA in content and time frames.

(b) Failure to correct deficiencies. If, on revisit, it is found that the laboratory has not corrected the deficiencies within 12 months after the last day of inspection, the following rules apply:
§ 493.1828 Suspension of all Medicare payments.

(a) Application. (1) HCFA may suspend payment for all Medicare-approved laboratory services when the laboratory has condition level deficiencies.

(2) HCFA suspends payment for all Medicare covered laboratory services when the following conditions are met:

(i) Either—

(A) The laboratory has not corrected its condition level deficiencies included in the plan of correction within 3 months from the last date of inspection; or

(B) The laboratory has been found to have the same condition level deficiencies during three consecutive inspections; and

(ii) The laboratory has chosen (in return for not having its Medicare approval immediately cancelled), to not charge Medicare beneficiaries or their private insurance carriers for services for which Medicare payment is suspended.

(b) Procedures. Before imposing this sanction, HCFA provides notice of sanction and opportunity to respond in accordance with §493.1810.

(c) Duration and effect of sanction. This sanction continues until the laboratory corrects the condition level deficiencies or HCFA cancels the laboratory’s approval to receive Medicare payment for its services, but in no event longer than 12 months.

(1) If the laboratory corrects all condition level deficiencies, HCFA resumes Medicare payment effective for all services furnished on or after the date the deficiencies are corrected.

(2) [Reserved]

[57 FR 7237, Feb. 28, 1992; 57 FR 35761, Aug. 11, 1992]
§ 493.1832 Duration and effect of sanction.

(c) Duration and effect of sanction. (1) Suspension of payment continues until all condition level deficiencies are corrected, but never beyond twelve months.

(2) If all the deficiencies are not corrected by the end of the 12 month period, HCFA cancels the laboratory's approval to receive Medicare payment for its services.

§ 493.1832 Directed plan of correction and directed portion of a plan of correction.

(a) Application. HCFA may impose a directed plan of correction as an alternative sanction for any laboratory that has condition level deficiencies. If HCFA does not impose a directed plan of correction as an alternative sanction for a laboratory that has condition level deficiencies, it at least imposes a directed portion of a plan of correction when it imposes any of the following alternative sanctions:

(1) State onsite monitoring.

(2) Civil money penalty.

(3) Suspension of all or part of Medicare payments.

(b) Procedures—(1) Directed plan of correction. When imposing this sanction, HCFA—

(i) Gives the laboratory prior notice of the sanction and opportunity to respond in accordance with §493.1810;

(ii) Directs the laboratory to take specific corrective action within specific time frames in order to achieve compliance; and

(iii) May direct the laboratory to submit the names of laboratory clients for notification purposes, as specified in paragraph (b)(3) of this section.

(2) Directed portion of a plan of correction. HCFA may decide to notify clients of a sanctioned laboratory, because of the seriousness of the noncompliance (e.g., the existence of immediate jeopardy) or for other reasons. When imposing this sanction, HCFA takes the following steps—

(i) Directs the laboratory to submit to HCFA, the State survey agency, or other HCFA agent, within 10 calendar days after the notice of the alternative sanction, a list of names and addresses of all physicians, providers, suppliers, and other clients who have used some or all of the services of the laboratory since the last certification inspection or within any other timeframe specified by HCFA.

(ii) Within 30 calendar days of receipt of the information, may send to each laboratory client, via the State survey agency, a notice containing the name and address of the laboratory, the nature of the laboratory's noncompliance, and the kind and effective date of the alternative sanction.

(iii) Sends to each laboratory client, via the State survey agency, notice of the recission of an adverse action within 30 days of the rescission.

(3) Notice of imposition of a principal sanction following the imposition of an alternative sanction. If HCFA imposes a principal sanction following the imposition of an alternative sanction, and for which HCFA has already obtained a list of laboratory clients, HCFA may use that list to notify the clients of the imposition of the principal sanction.

(c) Duration of a directed plan of correction. If HCFA imposes a directed plan of correction, and on revisit it is found that the laboratory has not corrected the deficiencies within 12 months from the last day of inspection, the following rules apply:

(1) HCFA cancels the laboratory's approval for Medicare payment of its services, and notifies the laboratory of HCFA's intent to suspend, limit, or revoke the laboratory's CLIA certificate.

(2) The directed plan of correction continues in effect until the day suspension, limitation, or revocation of the laboratory's CLIA certificate.

§ 493.1834 Civil money penalty.

(a) Statutory basis. Sections 1846 of the Act and 353(h)(2)(B) of the PHS Act authorize the Secretary to impose civil money penalties on laboratories. Section 1846(b)(3) of the Act specifically provides that incrementally more severe fines may be imposed for repeated or uncorrected deficiencies.

(b) Scope. This section sets forth the procedures that HCFA follows to impose a civil money penalty in lieu of, or in addition to, suspending, limiting, or revoking the certificate of compliance, registration certificate, certificate of accreditation, or certificate for PPM procedures of a laboratory that is
found to have condition level deficiencies.

(c) Basis for imposing a civil money penalty. HCFA may impose a civil money penalty against any laboratory determined to have condition level deficiencies regardless of whether those deficiencies pose immediate jeopardy.

(d) Amount of penalty—(1) Factors considered. In determining the amount of the penalty, HCFA takes into account the following factors:

(i) The nature, scope, severity, and duration of the noncompliance.

(ii) Whether the same condition level deficiencies have been identified during three consecutive inspections.

(iii) The laboratory’s overall compliance history including but not limited to any period of noncompliance that occurred between certifications of compliance.

(iv) The laboratory’s intent or reason for noncompliance.

(v) The accuracy and extent of laboratory records and their availability to HCFA, the State survey agency, or other HCFA agent.

(2) Range of penalty amount.

(i) For a condition level deficiency that poses immediate jeopardy, the range is $3,050-$10,000 per day of noncompliance or per violation.

(ii) For a condition level deficiency that does not pose immediate jeopardy, the range is $50-$3,000 per day of noncompliance or per violation.

(3) Decreased penalty amounts. If the immediate jeopardy is removed, but the deficiency continues, HCFA shifts the penalty amount to the lower range.

(4) Increased penalty amounts. HCFA may, before the hearing, propose to increase the penalty amount for a laboratory that has deficiencies which, after imposition of a lower level penalty amount, become sufficiently serious to pose immediate jeopardy.

(e) Procedures for imposition of civil money penalty—(1) Notice of intent. (i) HCFA sends the laboratory written notice of HCFA’s intent to impose a civil money penalty.

(ii) The notice includes the following information:

(A) The statutory basis for the penalty.

(B) The proposed daily or per violation amount of the penalty.

(C) The factors (as described in paragraph (d)(1) of this section) that HCFA considered.

(D) The opportunity for responding to the notice in accordance with §493.1810(c).

(E) A specific statement regarding the laboratory’s appeal rights.

(2) Appeal rights. (i) The laboratory has 60 days from the date of receipt of the notice of intent to impose a civil money penalty to request a hearing in accordance with §493.1844(g).

(ii) If the laboratory requests a hearing, all other pertinent provisions of §493.1844 apply.

(iii) If the laboratory does not request a hearing, HCFA may reduce the proposed penalty amount by 35 percent.

(f) Accrual and duration of penalty—(1) Accrual of penalty. The civil money penalty begins accruing as follows:

(i) 5 days after notice of intent if there is immediate jeopardy.

(ii) 15 days after notice of intent if there is not immediate jeopardy.

(ii) 15 days after notice of intent if there is not immediate jeopardy.

(2) Duration of penalty. The civil money penalty continues to accrue until the earliest of the following occurs:

(i) The laboratory’s compliance with condition level requirements is verified on the basis of the evidence presented by the laboratory in its credible allegation of compliance or at the time or revisit.

(ii) Based on credible evidence presented by the laboratory at the time of revisit, HCFA determines that compliance was achieved before the revisit. (In this situation, the money penalty stops accruing as of the date of compliance.)

(iii) HCFA suspends, limits, or revokes the laboratory’s certificate of compliance, registration certificate, certificate of accreditation, or certificate for PPM procedures.

(g) Computation and notice of total penalty amount—(1) Computation. HCFA computes the total penalty amount after the laboratory’s compliance is verified or HCFA suspends, limits, or revokes the laboratory’s CLIA certificate but in no event before—

(i) The 60 day period for requesting a hearing has expired without a request or the laboratory has explicitly waived its right to a hearing; or
§ 493.1836 State onsite monitoring.

(a) Application. (1) HCFA may require continuous or intermittent monitoring of a plan of correction by the State survey agency to ensure that the laboratory makes the improvements necessary to bring it into compliance with the condition level requirements. (The State monitor does not have management authority, that is, cannot hire or fire staff, obligate funds, or otherwise dictate how the laboratory operates. The monitor’s responsibility is to oversee whether corrections are made.)

(2) The laboratory must pay the costs of onsite monitoring by the State survey agency.

(i) Following a hearing requested by the laboratory, the ALJ issues a decision that upholds imposition of the penalty.

(2) Notice of penalty amount and due date of penalty. The notice includes the following information:

(i) Daily or per violation penalty amount.

(ii) Number of days or violations for which the penalty is imposed.

(iii) Total penalty amount.

(iv) Due date for payment of the penalty.

(h) Due date for payment of penalty. (1) Payment of a civil money penalty is due 15 days from the date of the notice specified in paragraph (g)(2) of this section.

(2) HCFA may approve a plan for a laboratory to pay a civil money penalty, plus interest, over a period of up to one year from the original due date.

(i) Collection and settlement—(1) Collection of penalty amounts. (i) The determined penalty amount may be deducted from any sums then or later owing by the United States to the laboratory subject to the penalty.

(ii) Interest accrues on the unpaid balance of the penalty, beginning on the due date. Interest is computed at the rate specified in §405.378(d) of this chapter.

(2) Settlement. HCFA has authority to settle any case at any time before the ALJ issues a hearing decision.


§ 493.1838 Training and technical assistance for unsuccessful participation in proficiency testing.

If a laboratory’s participation in proficiency testing is unsuccessful, HCFA may require the laboratory to undertake training of its personnel, or to obtain necessary technical assistance, or both, in order to meet the requirements of the proficiency testing program. This requirement is separate from the principal and alternative sanctions set forth in §§493.1806 and 493.1807.
§ 493.1840 Suspension, limitation, or revocation of any type of CLIA certificate.

(a) Adverse action based on actions of the laboratory's owner, operator or employees. HCFA may initiate adverse action to suspend, limit or revoke any CLIA certificate if HCFA finds that a laboratory's owner or operator or one of its employees has—
   (1) Been guilty of misrepresentation in obtaining a CLIA certificate;
   (2) Performed, or represented the laboratory as entitled to perform, a laboratory examination or other procedure that is not within a category of laboratory examinations or other procedures authorized by its CLIA certificate;
   (3) Failed to comply with the certificate requirements and performance standards;
   (4) Failed to comply with reasonable requests by HCFA for any information or work on materials that HCFA concludes is necessary to determine the laboratory's continued eligibility for its CLIA certificate or continued compliance with performance standards set by HCFA;
   (5) Refused a reasonable request by HCFA or its agent for permission to inspect the laboratory and its operation and pertinent records during the hours that the laboratory is in operation;
   (6) Violated or aided and abetted in the violation of any provisions of CLIA and its implementing regulations;
   (7) Failed to comply with an alternative sanction imposed under this subpart; or
   (8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked. (This provision applies only to the owner or operator, not to all of the laboratory's employees.)

(b) Adverse action based on improper referrals in proficiency testing. If HCFA determines that a laboratory has intentionally referred its proficiency testing samples to another laboratory for analysis, HCFA revokes the laboratory's CLIA certificate for at least one year, and may also impose a civil money penalty.

(c) Adverse action based on exclusion from Medicare. If the OIG excludes a laboratory from participation in Medicare, HCFA suspends the laboratory's CLIA certificate for the period during which the laboratory is excluded.

(d) Procedures for suspension or limitation—(1) Basic rule. Except as provided in paragraph (d)(2) of this section, HCFA does not suspend or limit a CLIA certificate until after an ALJ hearing decision (as provided in §493.1844) that upholds suspension or limitation.

(2) Exceptions. HCFA may suspend or limit a CLIA certificate before the ALJ hearing in any of the following circumstances:
   (i) The laboratory's deficiencies pose immediate jeopardy.
   (ii) The laboratory has refused a reasonable request for information or work on materials.
   (iii) The laboratory has refused permission for HCFA or a HCFA agent to inspect the laboratory or its operation.

(e) Procedures for revocation. (1) HCFA does not revoke any type of CLIA certificate until after an ALJ hearing that upholds revocation.

(2) HCFA may revoke a CLIA certificate after the hearing decision even if it had not previously suspended or limited that certificate.

(f) Notice to the OIG. HCFA notifies the OIG of any violations under paragraphs (a)(1), (a)(2), (a)(6), and (b) of this section within 30 days of the determination of the violation.

§ 493.1842 Cancellation of Medicare approval.

(a) Basis for cancellation. (1) HCFA always cancels a laboratory's approval to receive Medicare payment for its services if HCFA suspends or revokes the laboratory's CLIA certificate.

(2) HCFA may cancel the laboratory's approval under any of the following circumstances:
   (i) The laboratory is out of compliance with a condition level requirement.
   (ii) The laboratory fails to submit a plan of correction satisfactory to HCFA.
   (iii) The laboratory fails to correct all its deficiencies within the time frames specified in the plan of correction.

(b) Notice and opportunity to respond. Before canceling a laboratory's approval to receive Medicare payment for
its services, HCFA gives the laboratory—
(1) Written notice of the rationale for, effective date, and effect of, cancellation;
(2) Opportunity to submit written evidence or other information against cancellation of the laboratory’s approval.
This sanction may be imposed before the hearing that may be requested by a laboratory, in accordance with the appeals procedures set forth in §493.1844.
(c) Effect of cancellation. Cancellation of Medicare approval terminates any Medicare payment sanctions regardless of the time frames originally specified.

§ 493.1844 Appeals procedures.
(a) General rules. (1) The provisions of this section apply to all laboratories and prospective laboratories that are dissatisfied with any initial determination under paragraph (b) of this section.
(2) Hearings are conducted in accordance with procedures set forth in subpart D of part 498 of this chapter, except that the authority to conduct hearings and issue decisions may be exercised by ALJs assigned to, or detailed to, the Departmental Appeals Board.
(3) Any party dissatisfied with a hearing decision is entitled to request review of the decision as specified in subpart E of part 498 of this chapter, except that the authority to review the decision may be exercised by the Departmental Appeals Board.
(4) When more than one of the actions specified in paragraph (b) of this section are carried out concurrently, the laboratory has a right to only one hearing on all matters at issue.
(b) Actions that are initial determinations. The following actions are initial determinations and therefore are subject to appeal in accordance with this section:
(1) The suspension, limitation, or revocation of the laboratory’s CLIA certificate by HCFA because of noncompliance with CLIA requirements.
(2) The denial of a CLIA certificate.
(3) The imposition of alternative sanctions under this subpart (but not the determination as to which alternative sanction or sanctions to impose).
(4) The denial or cancellation of the laboratory’s approval to receive Medicare payment for its services.
(c) Actions that are not initial determinations. Actions that are not listed in paragraph (b) of this section are not initial determinations and therefore are not subject to appeal under this section. They include, but are not necessarily limited to, the following:
(1) The finding that a laboratory accredited by a HCFA-approved accreditation organization is no longer deemed to meet the conditions set forth in subparts H, J, K, M, P, and Q of this part. However, the suspension, limitation or revocation of a certificate of accreditation is an initial determination and is appealable.
(2) The finding that a laboratory determined to be in compliance with condition-level requirements but has deficiencies that are not at the condition level.
(3) The determination not to reinstate a suspended CLIA certificate because the reason for the suspension has not been removed or there is insufficient assurance that the reason will not recur.
(4) The determination as to which alternative sanction or sanctions to impose, including the amount of a civil money penalty to impose per day or per violation.
(5) The denial of approval for Medicare payment for the services of a laboratory that does not have in effect a valid CLIA certificate.
(6) The determination that a laboratory’s deficiencies pose immediate jeopardy.
(7) The amount of the civil money penalty assessed per day or for each violation of Federal requirements.
(d) Effect of pending appeals—(1) Alternative sanctions. The effective date of an alternative sanction (other than a civil money penalty) is not delayed because the laboratory has appealed and the hearing or the hearing decision is pending.
(2) Suspension, limitation, or revocation of a laboratory’s CLIA certificate—(i) General rule. Except as provided in paragraph (d)(2)(ii) of this section, suspension, limitation, or revocation of a
CLIA certificate is not effective until after a hearing decision by an ALJ is issued.

(ii) Exceptions. (A) If HCFA determines that conditions at a laboratory pose immediate jeopardy, the effective date of the suspension or limitation of a CLIA certificate is not delayed because the laboratory has appealed and the hearing or the hearing decision is pending.

(B) HCFA may suspend or limit a laboratory’s CLIA certificate before an ALJ hearing or hearing decision if the laboratory has refused a reasonable request for information (including but not limited to billing information), or for work on materials, or has refused permission for HCFA or a HCFA agent to inspect the laboratory or its operation.

(3) Cancellation of Medicare approval. The effective date of the cancellation of a laboratory’s approval to receive Medicare payment for its services is not delayed because the laboratory has appealed and the hearing or hearing decision is pending.

(4) Effect of ALJ decision. (i) An ALJ decision is final unless, as provided in paragraph (a)(3) of this section, one of the parties requests review by the Departmental Appeals Board within 60 days, and the Board reviews the case and issues a revised decision.

(ii) If an ALJ decision upholds a suspension imposed because of immediate jeopardy, that suspension becomes a revocation.

(e) Appeal rights for prospective laboratories—(1) Reconsideration. Any prospective laboratory dissatisfied with a denial of a CLIA certificate, or of approval for Medicare payment for its services, may initiate the appeals process by requesting reconsideration in accordance with §§ 498.22 through 498.25 of this chapter.

(2) Notice of reopening. If HCFA reopens an initial or reconsidered determination, HCFA gives notice to the laboratory, and may give notice to physicians, providers, suppliers, and other laboratory clients, according to the procedures set forth at §493.1832. In addition, HCFA notifies the general public each time one of these principal sanctions is imposed.

(3) ALJ hearing. Any prospective laboratory dissatisfied with a reconsidered determination under paragraph (e)(1) of this section, or a revised reconsidered determination under §498.30 of this chapter, is entitled to a hearing before an ALJ, as specified in paragraph (a)(2) of this section.

(4) Review of ALJ hearing decisions. Any prospective laboratory that is dissatisfied with an ALJ’s hearing decision or dismissal of a request for hearing may file a written request for review by the Departmental Appeals Board as provided in paragraph (a)(3) of this section.

(f) Appeal rights of laboratories—(1) ALJ hearing. Any laboratory dissatisfied with the suspension, limitation, or revocation of its CLIA certificate, with the imposition of an alternative sanction under this subpart, or with cancellation of the approval to receive Medicare payment for its services, is entitled to a hearing before an ALJ as specified in paragraph (a)(2) of this section and has 60 days from the notice of sanction to request a hearing.

(2) Review of ALJ hearing decisions. Any laboratory that is dissatisfied with an ALJ’s hearing decision or dismissal of a request for hearing may file a written request for review by the Departmental Appeals Board, as provided in paragraph (a)(3) of this section.

(3) Judicial review. Any laboratory dissatisfied with the decision to impose a civil money penalty or to suspend, limit, or revoke its CLIA certificate may, within 60 days after the decision becomes final, file with the U.S. Court of Appeals of the circuit in which the laboratory has its principal place of business, a petition for judicial review.

(g) Notice of adverse action. (1) If HCFA suspends, limits, or revokes a laboratory’s CLIA certificate or cancels the approval to receive Medicare payment for its services, HCFA gives notice to the laboratory, and may give notice to physicians, providers, suppliers, and other laboratory clients, according to the procedures set forth at §493.1832. In addition, HCFA notifies the general public each time one of these principal sanctions is imposed.

(2) The notice to the laboratory—

(i) Sets forth the reasons for the adverse action, the effective date and effect of that action, and the appeal rights if any; and

(ii) When the certificate is limited, specifies the specialties or subspecialties of tests that the laboratory is no
§ 493.1846

longer authorized to perform, and that are no longer covered under Medicare.
(3) The notice to other entities includes the same information except the information about the laboratory’s appeal rights.

(h) Effective date of adverse action. (1) When the laboratory’s deficiencies pose immediate jeopardy, the effective date of the adverse action is at least 5 days after the date of the notice.
(2) When HCFA determines that the laboratory’s deficiencies do not pose immediate jeopardy, the effective date of the adverse action is at least 15 days after the date of the notice.

(57 FR 7237, Feb. 28, 1992; 57 FR 35761, Aug. 11, 1992)

§ 493.1846 Civil action.

If HCFA has reason to believe that continuation of the activities of any laboratory, including a State-exempt laboratory, would constitute a significant hazard to the public health, HCFA may bring suit in a U.S. District Court to enjoin continuation of the specific activity that is causing the hazard or to enjoin the continued operation of the laboratory if HCFA deems it necessary. Upon proper showing, the court shall issue a temporary injunction or restraining order without bond against continuation of the activity.

§ 493.1850 Laboratory registry.

(a) Once a year HCFA makes available to physicians and to the general public specific information (including information provided to HCFA by the OIG) that is useful in evaluating the performance of laboratories, including the following:
(1) A list of laboratories that have been convicted, under Federal or State laws relating to fraud and abuse, false billing, or kickbacks.
(2) A list of laboratories that have had their CLIA certificates suspended, limited, or revoked, and the reason for the adverse actions.
(3) A list of persons who have been convicted of violating CLIA requirements, as specified in section 353(1) of the PHS Act, together with the circumstances of each case and the penalties imposed.
(4) A list of laboratories on which alternative sanctions have been imposed, showing—
(i) The effective date of the sanctions;
(ii) The reasons for imposing them;
(iii) Any corrective action taken by the laboratory; and
(iv) If the laboratory has achieved compliance, the verified date of compliance.
(5) A list of laboratories whose accreditation has been withdrawn or revoked and the reasons for the withdrawal or revocation.
(6) All appeals and hearing decisions.
(7) A list of laboratories against which HCFA has brought suit under §493.1846 and the reasons for those actions.
(8) A list of laboratories that have been excluded from participation in Medicare or Medicaid and the reasons for the exclusion.

(b) The laboratory registry is compiled for the calendar year preceding the date the information is made available and includes appropriate explanatory information to aid in the interpretation of the data. It also contains corrections of any erroneous statements or information that appeared in the previous registry.

Subpart S—[Reserved]

Subpart T—Consultations

SOURCE: 57 FR 7185, Feb. 28, 1992, unless otherwise noted.

§ 493.2001 Establishment and function of the Clinical Laboratory Improvement Advisory Committee.

(a) HHS will establish a Clinical Laboratory Improvement Advisory Committee to advise and make recommendations on technical and scientific aspects of the provisions of this part 493.
(b) The Clinical Laboratory Improvement Advisory Committee will be comprised of individuals involved in the provision of laboratory services, utilization of laboratory services, development of laboratory testing or methodology, and others as approved by HHS.
(c) HHS will designate specialized subcommittees as necessary.
(d) The Clinical Laboratory Improvement Advisory Committee or any designated subcommittees will meet as needed, but not less than once each year.
(e) The Clinical Laboratory Improvement Advisory Committee or subcommittee, at the request of HHS, will review and make recommendations concerning:
   (1) Criteria for categorizing tests and examinations of moderate complexity (including the subcategory) and high complexity;
   (2) Determination of waived tests;
   (3) Personnel standards;
   (4) Patient test management, quality control, quality assurance standards;
   (5) Proficiency testing standards;
   (6) Applicability to the standards of new technology; and
   (7) Other issues relevant to part 493, if requested by HHS.
(f) HHS will be responsible for providing the data and information, as necessary, to the members of the Clinical Laboratory Improvement Advisory Committee.


PART 494 [RESERVED]
§ 498.1 Statutory basis.

(a) Section 1866(h) of the Act provides for a hearing and for judicial review of the hearing for any institution or agency dissatisfied with a determination that it is not a provider, or with any determination described in section 1866(b)(2) of the Act.

(b) Section 1866(b)(2) of the Act lists determinations that serve as a basis for termination of a provider agreement.

(c) Sections 1128(a) and (b) of the Act provide for exclusion of certain individuals or entities because of conviction of crimes related to their participation in Medicare and section 1128(f) provides for hearing and judicial review for exclusions.

(d) Section 1156 of the Act establishes certain obligations for practitioners and providers of health care services, and provides sanctions and penalties for those that fail to meet those obligations.

(e)-(f) [Reserved]

(g) Although § 1866(h) of the Act is silent regarding appeal rights for suppliers and practitioners, the rules in this part include procedures for review of determinations that affect those two groups.

(h) Section 1128A(c)(2) of the Act provides that the Secretary may not collect a civil money penalty until the affected entity has had notice and opportunity for a hearing.

(i) Section 1819(h) of the Act—

(1) Provides that, for SNFs found to be out of compliance with the requirements for participation, specified remedies may be imposed instead of, or in addition to, termination of the facility's Medicare provider agreement; and

(2) Makes certain provisions of section 1128A of the Act applicable to civil money penalties imposed on SNFs.

(j) Section 1891(e) of the Act provides that, for home health agencies (HHAs) found to be out of compliance with the conditions of participation, specified remedies may be imposed instead of, or in addition to, termination of the HHA's Medicare provider agreement.

(k) Section 1891(f) of the Act—

(1) Requires the Secretary to develop a range of such remedies; and

(2) Makes certain provisions of section 1128A of the Act applicable to civil money penalties imposed on HHAs.


§ 498.2 Definitions.

As used in this part—

Affected party means a provider, prospective provider, supplier, prospective supplier, or practitioner that is affected by an initial determination or by any subsequent determination or decision issued under this part, and “party” means the affected party or HCFA (or the OIG), as appropriate.

ALJ stands for Administrative Law Judge.

Departmental Appeals Board means a Board established in the Office of the Secretary to provide impartial review of disputed decisions made by the operating components of the Department.

OHA stands for the Social Security Administration's Office of Hearings and Appeals.

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

Provider means a hospital, critical access hospital (CAH), skilled nursing facility (SNF), comprehensive outpatient rehabilitation facility (CORF), home
§ 498.3 Scope and applicability.

(a) Scope. This part sets forth procedures for reviewing initial determinations that HCFA makes with respect to the matters specified in paragraph (b) of this section, and that the OIG makes with respect to the matters specified in paragraph (c) of this section. It also specifies, in paragraph (d) of this section, administrative actions that are not subject to appeal under this part.

(b) Initial determinations by HCFA. HCFA makes initial determinations with respect to the following matters:

(1) Whether a prospective provider qualifies as a provider.

(2) Whether an institution is a hospital qualified to elect to claim payment for all emergency hospital services furnished in a calendar year.

(3) Whether an institution continues to remain in compliance with the qualifications for claiming reimbursement for all emergency services furnished in a calendar year.

(4) Whether a prospective supplier meets the conditions for coverage of its services as those conditions are set forth elsewhere in this chapter.

(5) Whether the services of a supplier continue to meet the conditions for coverage.

(6) Whether a physical therapist in independent practice or a chiropractor meets the requirements for coverage of his or her services as set forth in subpart D of part 486 of this chapter and § 410.22 of this chapter, respectively.

(7) The termination of a provider agreement in accordance with § 489.53 of this chapter, or the termination of a rural health clinic agreement in accordance with § 405.2404 of this chapter, or the termination of a Federally qualified health center agreement in accordance with § 405.2436 of this chapter.

(8) HCFA’s cancellation, under section 1910(b) of the Act, of an ICF/MR’s approval to participate in Medicaid.

(9) Whether, for purposes of rate setting and reimbursement, an ESRD treatment facility is considered to be hospital-based or independent.

(10) Whether to deny payment under § 409.19 or § 409.64 of this chapter, pertaining to cardiac pacemakers and the pacemaker registry.

(11) Whether a hospital, skilled nursing facility, home health agency, or hospice program meets or continues to meet the advance directives requirements specified in subpart I of part 489 of this chapter.

(12) With respect to an SNF or NF, a finding of noncompliance that results in the imposition of a remedy specified in § 488.406 of this chapter, except the State monitoring remedy, and the loss of the approval for a nurse-aide training program.

(13) The level of noncompliance found by HCFA in an SNF or NF but only if a successful challenge on this issue would affect the range of civil money penalty amounts that HCFA could collect. (The scope of review during a hearing on imposition of a civil money penalty is set forth in § 488.438(e) of this chapter.)
§ 498.3

(14) The effective date of a Medicare provider agreement or supplier approval.

(c) Initial determinations by the OIG. The OIG makes initial determinations with respect to the following matters:

(1) The termination of a provider agreement in accordance with part 1001, subpart C of this title.

(2) The suspension, or exclusion from coverage and the denial of reimbursement for services furnished by a provider, practitioner, or supplier, because of fraud or abuse, or conviction of crimes related to participation in the program, in accordance with part 1001, subpart B of this title.

(3) The imposition of sanctions in accordance with part 1004 of this title.

(d) Administrative actions that are not initial determinations. Administrative actions that are not initial determination (and therefore not subject to appeal under this part) include but are not limited to the following:

(1) The finding that a provider or supplier determined to be in compliance with the conditions or requirements for participation or for coverage has deficiencies.

(2) The finding that a prospective provider does not meet the conditions of participation set forth elsewhere in this chapter, if the prospective provider is, nevertheless, approved for participation in Medicare on the basis of special access certification, as provided in subpart B of part 488 of this chapter.

(3) The refusal to enter into a provider agreement because the prospective provider is unable to give satisfactory assurance of compliance with the requirements of title XVIII of the Act.

(4) The finding that an entity that had its provider agreement terminated may not file another agreement because the reasons for terminating the previous agreement have not been removed or there is insufficient assurance that the reasons for the exclusion will not recur.

(5) The determination not to reinstate a suspended or excluded practitioner, provider, or supplier because the reason for the suspension or exclusion has not been removed, or there is insufficient assurance that the reason will not recur.

(6) The finding that the services of a laboratory are covered as hospital services or as physician’s services, rather than as services of an independent laboratory, because the laboratory is not independent of the hospital or of the physician’s office.

(7) The refusal to accept for filing an election to claim payment for all emergency hospital services furnished in a calendar year because the institution—

(i) Had previously charged an individual or other person for services furnished during that calendar year;

(ii) Submitted the election after the close of that calendar year; or

(iii) Had previously been notified of its failure to continue to comply.

(8) The finding that the reason for the revocation of a supplier’s right to accept assignment has not been removed or there is insufficient assurance that the reason will not recur.

(9) The finding that a hospital accredited by the Joint Commission on Accreditation of Hospitals or the American Osteopathic Association is not in compliance with a condition of participation, and a finding that that hospital is no longer deemed to meet the conditions of participation.

(10) With respect to an SNF or NF—

(i) The finding that the SNF’s or NF’s deficiencies pose immediate jeopardy to the health or safety of its residents;

(ii) Except as provided in paragraph (b)(13) of this section, a determination by HCFA as to the facility’s level of noncompliance; and

(iii) The imposition of State monitoring or the loss of the approval for a nurse-aide training program.

(11) The choice of alternative sanction or remedy to be imposed on a provider or supplier.

(12) The determination that the accreditation requirements of a national accreditation organization do not provide (or do not continue to provide) reasonable assurance that the entities accredited by the accreditation organization meet the applicable long-term care requirements, conditions for coverage, conditions of certification, conditions of participation, or CLIA condition level requirements.

(13) The determination that requirements imposed on a State’s laboratories under the laws of that State do
§ 498.4 NFs subject to appeals process in part 498.

A NF is considered a provider for purposes of this part when it has in effect an agreement to participate in Medicaid, including an agreement to participate in both Medicaid and Medicare and it is a—

(a) State-operated NF; or

(b) Non State-operated NF that is subject to compliance action as a result of—

(1) A validation survey by HCFA; or

(2) HCFA's review of the State's survey findings.

§ 498.5 Appeal rights.

(a) Appeal rights of prospective providers. (1) Any prospective provider dissatisfied with an initial determination or revised initial determination that it does not qualify as a provider may request reconsideration in accordance with §498.22(a).

(2) Any prospective provider dissatisfied with a reconsidered determination under paragraph (a)(1) of this section, or a revised reconsidered determination under §498.30, is entitled to a hearing before an ALJ.

(b) Appeal rights of providers. Any provider dissatisfied with an initial determination to terminate its provider agreement is entitled to a hearing before an ALJ.

(c) Appeal rights of providers and prospective providers. Any provider or prospective provider dissatisfied with a hearing decision may request Departmental Appeals Board review, and has a right to seek judicial review of the Board's decision.

(d) Appeal rights of prospective suppliers. (1) Any prospective supplier dissatisfied with an initial determination or a revised initial determination that its services do not meet the conditions for coverage may request reconsideration in accordance with §498.22(a).

(2) Any prospective supplier dissatisfied with a reconsidered determination under paragraph (d)(1) of this section, or a revised reconsidered determination under §498.30, is entitled to a hearing before an ALJ.

(e) Appeal rights of suppliers. Any supplier dissatisfied with an initial determination that the services subject to the determination no longer meet the conditions for coverage, is entitled to a hearing before an ALJ.

(f) Appeal rights of suppliers and prospective suppliers. (1) Any supplier or prospective supplier dissatisfied with the hearing decision may request Departmental Appeals Board review of the ALJ's decision.

(2) Suppliers and prospective suppliers do not have a right to judicial review except as provided in paragraph (i) of this section.

(g) Appeal rights for certain practitioners. A physical therapist in independent practice or a chiropractor dissatisfied with a determination that he or she does not meet the requirements for coverage of his or her services has the same appeal rights as suppliers have under paragraphs (d), (e) and (f) of this section.

(h) Appeal rights for nonparticipating hospitals that furnish emergency services. A nonparticipating hospital dissatisfied with a determination or decision that it does not qualify to elect to claim payment for all emergency services furnished during a calendar year...
§ 498.10 Appointment of representatives.

(a) An affected party may appoint as its representative anyone not disqualified or suspended from acting as a representative in proceedings before the Secretary or otherwise prohibited by law.

(b) If the representative appointed is not an attorney, the party must file written notice of the appointment with HCFA, the ALJ, or the Departmental Appeals Board.

(c) If the representative appointed is an attorney, the attorney’s statement that he or she has the authority to represent the party is sufficient.

§ 498.11 Authority of representatives.

(a) A representative appointed and qualified in accordance with § 498.10 may, on behalf of the represented party—

(1) Give and accept any notice or request pertinent to the proceedings set forth in this part;

(2) Present evidence and allegations as to facts and law in any proceedings affecting that party to the same extent as the party; and

(3) Obtain information to the same extent as the party.

(b) A notice or request may be sent to the affected party, to the party’s representative, or to both. A notice or request sent to the representative has the same force and effect as if it had been sent to the party.

§ 498.13 Fees for services of representatives.

Fees for any services performed on behalf of an affected party by an attorney appointed and qualified in accordance with § 498.10 are not subject to the provisions of section 206 of Title II of the Act, which authorizes the Secretary to specify or limit those fees.

§ 498.15 Charge for transcripts.

A party that requests a transcript of prehearing or hearing proceedings or Board review must pay the actual or estimated cost of preparing the transcript unless, for good cause shown by that party, the payment is waived by the ALJ or the Departmental Appeals Board, as appropriate.

§ 498.17 Filing of briefs with the ALJ or Departmental Appeals Board, and opportunity for rebuttal.

(a) Filing of briefs and related documents. If a party files a brief or related document such as a written argument, contention, suggested finding of fact, conclusion of law, or any other written statement, it must submit an original and one copy to the ALJ or the Departmental Appeals Board, as appropriate. The material may be filed by mail or in person and must include a statement certifying that a copy has been furnished to the other party.

(b) Opportunity for rebuttal. (1) The other party will have 20 days from the date of mailing or personal service to submit any rebuttal statement or additional evidence. If a party submits a rebuttal statement or additional evidence, it must file an original and one copy with the ALJ or the Board and furnish a copy to the other party.

(2) The ALJ or the Board will grant an opportunity to reply to the rebuttal statement only if the party shows good cause.

Subpart B—Initial, Reconsidered, and Revised Determinations

§ 498.20 Notice and effect of initial determinations.

(a) Notice of initial determination—(1) General rule. HCFA or the OIG, as appropriate, mails notice of an initial determination to the affected party, setting forth the basis or reasons for the determination, the effect of the determination, and the party's right to reconsideration, if applicable, or to a hearing.

(2) Special rules: Independent laboratories and suppliers of portable x-ray services. If HCFA determines that an independent laboratory or a supplier of portable x-ray services no longer meets the conditions for coverage of some or all of its services, the notice—

(i) Specifies an effective date of termination of coverage that is at least 15 days after the date of the notice;

(ii) Is also sent to physicians, hospitals, and other parties that might use the services of the laboratory or supplier; and

(iii) In the case of laboratories, specifies the categories of laboratory tests that are no longer covered.

(3) Special rules: Nonparticipating hospitals that elect to claim payment for emergency services. If HCFA determines that a nonparticipating hospital no longer qualifies to elect to claim payment for all emergency services furnished in a calendar year, the notice—

(i) States the calendar year to which the determination applies;

(ii) Specifies an effective date that is at least 5 days after the date of the notice; and

(iii) Specifies that the determination applies to services furnished, in the specified calendar year, to patients accepted (as inpatients or outpatients) on or after the effective date of the determination.

(4) Other special rules. Additional rules pertaining, for example, to content and timing of notice, notice to the public and to other entities, and time allowed for submission of additional information, are set forth elsewhere in this chapter, as follows:

Part 405 Subpart X—for rural health clinics.
Part 416—for ambulatory surgical centers.
Part 489—for providers, when their provider agreements have been terminated.
Part 1001, Subpart B—for excluded or suspended providers, suppliers, physicians, or practitioners.
Part 1001, Subpart C—for providers, when their provider agreements are terminated by the OIG.
Part 1004—for sanctioned providers and practitioners.

(2) Effect of initial determination. An initial determination is binding unless it is—

(1) Reconsidered in accordance with § 498.24;

(2) Reversed or modified by a hearing decision in accordance with § 498.78; or

(3) Revised in accordance with § 498.32 or § 498.100.

§ 498.22 Reconsideration.

(a) Right to reconsideration. HCFA reconsiders any initial determination that affects a prospective provider or supplier, or a hospital seeking to qualify to claim payment for all emergency hospital services furnished in a calendar year, if the affected party files a written request in accordance with paragraphs (b) and (c) of this section.
(None of the determinations made by the OIG are subject to reconsideration.)

(b) Request for reconsideration: Manner and timing. The affected party specified in paragraph (a) of this section, if dissatisfied with the initial determination may request reconsideration by filing the request—
(1) With HCFA or with the State survey agency;
(2) Directly or through its legal representative or other authorized official; and
(3) Within 60 days from receipt of the notice of initial determination, unless the time is extended in accordance with paragraph (d) of this section. The date of receipt will be presumed to be 5 days after the date on the notice unless there is a showing that it was, in fact, received earlier or later.

(c) Content of request. The request for reconsideration must state the issues, or the findings of fact with which the affected party disagrees, and the reasons for disagreement.

(d) Extension of time to file a request for reconsideration. (1) If the affected party is unable to file the request within the 60 days specified in paragraph (b) of this section, it may file a written request with HCFA, stating the reasons why the request was not filed timely.
(2) HCFA will extend the time for filing a request for reconsideration if the affected party shows good cause for missing the deadline.

§ 498.23 Withdrawal of request for reconsideration.

A request for reconsideration is considered withdrawn if the requestor files a written withdrawal request before HCFA mails the notice of reconsidered determination, and HCFA approves the withdrawal request.

§ 498.24 Reconsidered determination.

When a request for reconsideration has been properly filed in accordance with §498.22, HCFA—
(a) Receives written evidence and statements that are relevant and material to the matters at issue and are submitted within a reasonable time after the request for reconsideration;
(b) Considers the initial determination, the findings on which the initial determination was based, the evidence considered in making the initial determination, and any other written evidence submitted under paragraph (a) of this section, taking into account facts relating to the status of the prospective provider or supplier subsequent to the initial determination; and
(c) Makes a reconsidered determination, affirming or modifying the initial determination and the findings on which it was based.

§ 498.25 Notice and effect of reconsidered determination.

(a) Notice. (1) HCFA mails notice of a reconsidered determination to the affected party.
(2) The notice gives the reasons for the determination.
(3) If the determination is adverse, the notice specifies the conditions or requirements of law or regulations that the affected party fails to meet, and informs the party of its right to a hearing.

(b) Effect. A reconsidered determination is binding unless—
(1) HCFA or the OIG, as appropriate, further revises the revised determination; or
(2) The revised determination is reversed or modified by a hearing decision.

Subpart C—Reopening of Initial or Reconsidered Determinations

§ 498.30 Limitation on reopening.

An initial or reconsidered determination that a prospective provider is a provider or that a hospital qualifies to elect to claim payment for all emergency services furnished in a calendar year may not be reopened. HCFA or the OIG, as appropriate, may on its own initiative, reopen any other initial or reconsidered determination, within 12 months after the date of notice of the initial determination.

§ 498.32 Notice and effect of reopening and revision.

(a) Notice. (1) HCFA or the OIG, as appropriate, gives the affected party notice of reopening and of any revision of the reopened determination.
(2) The notice of revised determination states the basis or reason for the revised determination.

(3) If the determination is that a supplier or prospective supplier does not meet the conditions for coverage of its services, the notice specifies the conditions with respect to which the affected party fails to meet the requirements of law and regulations, and informs the party of its right to a hearing.

(b) Effect. A revised determination is binding unless:

(1) The affected party requests a hearing before an ALJ; or

(2) HCFA or the OIG further revises the revised determination.

Subpart D—Hearings
§ 498.42 Parties to the hearing.

The parties to the hearing are the affected party and HCFA or the OIG, as appropriate.

§ 498.44 Designation of hearing official.

(a) The Associate Commissioner for Hearings and Appeals, or his or her delegate designates an ALJ or a member or members of the Departmental Appeals Board to conduct the hearing.

(b) If appropriate, the Associate Commissioner or the delegate may substitute another ALJ or another member or other members of the Departmental Appeals Board to conduct the hearing.

(c) As used in this part, “ALJ” includes a member or members of the Departmental Appeals Board who are designated to conduct a hearing.

§ 498.45 Disqualification of Administrative Law Judge.

(a) An ALJ may not conduct a hearing in a case in which he or she is prejudiced or partial to the affected party or has any interest in the matter pending for decision.

(b) A party that objects to the ALJ designated to conduct the hearing must give notice of its objections at the earliest opportunity.

(c) The ALJ will consider the objections and decide whether to withdraw or proceed with the hearing.

(1) If the ALJ withdraws, another will be designated to conduct the hearing.

(2) If the ALJ does not withdraw, the objecting party may, after the hearing, present its objections to the Departmental Appeals Board as reasons for changing, modifying, or reversing the ALJ’s decision or providing a new hearing before another ALJ.

§ 498.47 Prehearing conference.

(a) At any time before the hearing, the ALJ may call a prehearing conference for the purpose of delineating the issues in controversy, identifying the evidence and witnesses to be presented at the hearing, and obtaining stipulations accordingly.

(b) On the request of either party or on his or her own motion, the ALJ may
§ 498.48 Notice of prehearing conference.
(a) Timing of notice. The ALJ will fix a time and place for the prehearing conference and mail written notice to the parties at least 10 days before the scheduled date.
(b) Content of notice. The notice will inform the parties of the purpose of the conference and specify what issues are sought to be resolved, agreed to, or excluded.
(c) Additional issues. Issues other than those set forth in the notice of determination or the request for hearing may be considered at the prehearing conference if—
(1) Either party gives timely notice to that effect to the ALJ and the other party; or
(2) The ALJ raises the issues in the notice of prehearing conference or at the conference.

§ 498.49 Conduct of prehearing conference.
(a) The prehearing conference is open to the affected party or its representative, to the HCFA or OIG representatives and their technical advisors, and to any other persons whose presence the ALJ considers necessary or proper.
(b) The ALJ may accept the agreement of the parties as to the following:
(1) Facts that are not in controversy.
(2) Questions that have been resolved favorably to the affected party after the determination in dispute.
(3) Remaining issues to be resolved.
(c) The ALJ may request the parties to indicate the following:
(1) The witnesses that will be present to testify at the hearing.
(2) The qualifications of those witnesses.
(3) The nature of other evidence to be submitted.

§ 498.50 Record, order, and effect of prehearing conference.
(a) Record of prehearing conference. (1) A record is made of all agreements and stipulations entered into at the prehearing conference.
(2) The record may be transcribed at the request of either party or the ALJ.
(b) Order and opportunity to object. (1) The ALJ issues an order setting forth the results of the prehearing conference, including the agreements made by the parties as to facts not in controversy, the matters to be considered at the hearing, and the issues to be resolved.
(2) Copies of the order are sent to all parties and the parties have 10 days to file objections to the order.
(3) After the 10 days have elapsed, the ALJ settles the order.
(c) Effect of prehearing conference. The agreements and stipulations entered into at the prehearing conference are binding on all parties, unless a party presents facts that, in the opinion of the ALJ, would make an agreement unreasonable or inequitable.

§ 498.52 Time and place of hearing.
(a) The ALJ fixes a time and place for the hearing and gives the parties written notice at least 10 days before the scheduled date.
(b) The notice informs the parties of the general and specific issues to be resolved at the hearing.

§ 498.53 Change in time and place of hearing.
(a) The ALJ may change the time and place for the hearing either on his or her own initiative or at the request of a party for good cause shown, or may adjourn or postpone the hearing.
(b) The ALJ may reopen the hearing for receipt of new evidence at any time before mailing the notice of hearing decision.
(c) The ALJ gives the parties reasonable notice of any change in time or place or any adjournment or reopening of the hearing.

§ 498.54 Joint hearings.
When two or more affected parties have requested hearings and the same or substantially similar matters are at issue, the ALJ may, if all parties agree, fix a single time and place for the prehearing conference or hearing and conduct all proceedings jointly. If joint hearings are held, a single record of the proceedings is made and a separate decision issued with respect to each affected party.
§ 498.56 Hearing on new issues.

(a) Basic rules. (1) Within the time limits specified in paragraph (b) of this section, the ALJ may, at the request of either party, or on his or her own motion, provide a hearing on new issues that impinge on the rights of the affected party.

(2) The ALJ may consider new issues even if HCFA or the OIG has not made initial or reconsidered determinations on them, and even if they arose after the request for hearing was filed or after a prehearing conference.

(3) The ALJ may give notice of hearing on new issues at any time after the hearing request is filed and before the hearing record is closed.

(b) Time limits. The ALJ will not consider any issue that arose on or after any of the following dates:

(1) The effective date of the termination of a provider agreement.

(2) The date on which it is determined that a supplier no longer meets the conditions for coverage of its services.

(3) The effective date of the notice to a hospital of its failure to remain in compliance with the qualifications for claiming reimbursement for all emergency services furnished to Medicare beneficiaries during the calendar year.

(4) The effective date of the suspension, or of the exclusion from coverage of services furnished by a suspended or excluded practitioner, provider, or supplier.

(5) With respect to Medicaid SNFs or ICFs surveyed under section 1910(c) of the Act—

(i) The completion date of the survey or resurvey that is the basis for a proposed cancellation of approval; or

(ii) If approval was cancelled before the hearings, because of immediate and serious threat to patient health and safety, the effective date of cancellation.

(c) Notice and conduct of hearing on new issues. (1) Unless the affected party waives its right to appear and present evidence, notice of the time and place of hearing on any new issue will be given to the parties in accordance with § 498.52.

(2) After giving notice, the ALJ will, except as provided in paragraph (d) of this section, proceed to hearing on new issues in the same manner as on an issue raised in the request for hearing.

(d) Remand to HCFA or the OIG. At the request of either party, or on his or her own motion, in lieu of a hearing under paragraph (c) of this section, the ALJ may remand the case to HCFA or the OIG for consideration of the new issue and, if appropriate, a determination. If necessary, the ALJ may direct HCFA or the OIG to return the case to the ALJ for further proceedings.

§ 498.58 Subpoenas.

(a) Basis for issuance. The ALJ, upon his or her own motion or at the request of a party, may issue subpoenas if they are reasonably necessary for the full presentation of a case.

(b) Timing of request by a party. The party must file a written request for a subpoena with the ALJ at least 5 days before the date set for the hearing.

(c) Content of request. The request must:

(1) Identify the witnesses or documents to be produced;

(2) Describe their addresses or location with sufficient particularity to permit them to be found; and

(3) Specify the pertinent facts the party expects to establish by the witnesses or documents, and indicate why those facts could not be established without use of a subpoena.

(d) Method of issuance. Subpoenas are issued in the name of the Secretary, who pays the cost of issuance and the fees and mileage of any subpoenaed witnesses.

§ 498.60 Conduct of hearing.

(a) Participants in the hearing. The hearing is open to the parties and their representatives and technical advisors, and to any other persons whose presence the ALJ considers necessary or proper.

(b) Hearing procedures. (1) The ALJ inquires fully into all of the matters at issue, and receives in evidence the testimony of witnesses and any documents that are relevant and material.

(2) If the ALJ believes that there is relevant and material evidence available which has not been presented at
§ 498.61 Evidence.

Evidence may be received at the hearing even though inadmissible under the rules of evidence applicable to court procedure. The ALJ rules on the admissibility of evidence.

[59 FR 56252, Nov. 10, 1994, as amended at 61 FR 32350, June 24, 1996]

§ 498.62 Witnesses.

Witnesses at the hearing testify under oath or affirmation. The representative of each party is permitted to examine his or her own witnesses subject to interrogation by the representative of the other party. The ALJ may ask any questions that he or she deems necessary. The ALJ rules upon any objection made by either party as to the propriety of any question.

§ 498.63 Oral and written summation.

The parties to a hearing are allowed a reasonable time to present oral summation and to file briefs or other written statements of proposed findings of fact and conclusions of law. Copies of any briefs or other written statements must be sent in accordance with § 498.17.

§ 498.64 Record of hearing.

A complete record of the proceedings at the hearing is made and transcribed in all cases.

§ 498.66 Waiver of right to appear and present evidence.

(a) Waiver procedures. (1) If an affected party wishes to waive its right to appear and present evidence at the hearing, it must file a written waiver with the ALJ.

(2) If the affected party wishes to withdraw a waiver, it may do so, for good cause, at any time before the ALJ mails notice of the hearing decision.

(b) Effect of waiver. If the affected party waives the right to appear and present evidence, the ALJ need not conduct an oral hearing except in one of the following circumstances:

(1) The ALJ believes that the testimony of the affected party or its representatives or other witnesses is necessary to clarify the facts at issue.

(2) HCFA or the OIG shows good cause for requiring the presentation of oral evidence.

(c) Dismissal for failure to appear. If, despite the waiver, the ALJ sends notice of hearing and the affected party fails to appear, or to show good cause for the failure, the ALJ will dismiss the appeal in accordance with § 498.69.

(d) Hearing without oral testimony. When there is no oral testimony, the ALJ will—

(1) Make a record of the relevant written evidence that was considered in making the determination being appealed, and of any additional evidence submitted by the parties;

(2) Furnish to each party copies of the additional evidence submitted by the other party; and

(3) Give both parties a reasonable opportunity for rebuttal.

(e) Handling of briefs and related statements. If the parties submit briefs or other written statements of evidence or proposed findings of facts or conclusions of law, those documents will be handled in accordance with § 498.17.

§ 498.68 Dismissal of request for hearing.

(a) The ALJ may, at any time before mailing the notice of the decision, dismiss a hearing request if a party withdraws its request for a hearing or the affected party asks that its request be dismissed.
(b) An affected party may request a dismissal by filing a written notice with the ALJ.

§ 498.69 Dismissal for abandonment.

(a) The ALJ may dismiss a request for hearing if it is abandoned by the party that requested it.

(b) The ALJ may consider a request for hearing to be abandoned if the party or its representative—

(1) Fails to appear at the prehearing conference or hearing without having previously shown good cause for not appearing; and

(2) Fails to respond, within 10 days after the ALJ sends a “show cause” notice, with a showing of good cause.

§ 498.70 Dismissal for cause.

On his or her own motion, or on the motion of a party to the hearing, the ALJ may dismiss a hearing request either entirely or as to any stated issue, under any of the following circumstances:

(a) Res judicata. There has been a previous determination or decision with respect to the rights of the same affected party on the same facts and law pertinent to the same issue or issues which has become final either by judicial affirmance or, without judicial consideration, because the affected party did not timely request reconsideration, hearing, or review, or commence a civil action with respect to that determination or decision.

(b) No right to hearing. The party requesting a hearing is not a proper party or does not otherwise have a right to a hearing.

(c) Hearing request not timely filed. The affected party did not file a hearing request timely and the time for filing has not been extended.

§ 498.71 Notice and effect of dismissal and right to request review.

(a) Notice of the ALJ’s dismissal action is mailed to the parties. The notice advises the affected party of its right to request that the dismissal be vacated as provided in §498.72.

(b) The dismissal of a request for hearing is binding unless it is vacated by the ALJ or the Departmental Appeals Board.

§ 498.72 Vacating a dismissal of request for hearing.

An ALJ may vacate any dismissal of a request for hearing if a party files a request to that effect within 60 days from receipt of the notice of dismissal and shows good cause for vacating the dismissal. (Date of receipt is determined in accordance with §498.22(b)(3).)

§ 498.74 Administrative Law Judge’s decision.

(a) Timing, basis and content. As soon as practical after the close of the hearing, the ALJ issues a written decision in the case. The decision is based on the evidence of record and contains separate numbered findings of fact and conclusions of law.

(b) Notice and effect. A copy of the decision is mailed to the parties and is binding on them unless—

(1) A party requests review by the Departmental Appeals Board within the time period specified in §498.82, and the Board reviews the case;

(2) The Departmental Appeals Board denies the request for review and the party seeks judicial review by filing an action in a United States District Court or, in the case of a civil money penalty, in a United States Court of Appeals;

(3) The decision is revised by an ALJ or the Departmental Appeals Board; or

(4) The decision is a recommended decision directed to the Board.

[52 FR 22446, June 12, 1987, as amended at 61 FR 32351, June 24, 1996]

§ 498.76 Removal of hearing to Departmental Appeals Board.

(a) At any time before the ALJ receives oral testimony, the Board may remove to itself any pending request for a hearing.

(b) Notice of removal is mailed to each party.

(c) The Board conducts the hearing in accordance with the rules that apply to ALJ hearings under this subpart.

§ 498.78 Remand by the Administrative Law Judge.

(a) If HCFA or the OIG requests remand, and the affected party concurs in writing or on the record, the ALJ may remand any case properly before him or her to HCFA or the OIG for a
§ 498.80 Right to request Departmental Appeals Board review of Administrative Law Judge's decision or dismissal.

Either of the parties has a right to request Departmental Appeals Board review of the ALJ's decision or dismissal order, and the parties are so informed in the notice of the ALJ's action.

§ 498.82 Request for Departmental Appeals Board review.

(a) Manner and time of filing. (1) Any party that is dissatisfied with an ALJ's decision or dismissal of a hearing request, may file a written request for review by the Departmental Appeals Board. (2) The requesting party or its representative or other authorized official must file the request with the OHA within 60 days from receipt of the notice of decision or dismissal, unless the Board, for good cause shown by the requesting party, extends the time for filing. The rules set forth in §498.40(c) apply to extension of time for requesting Departmental Appeals Board review. (The date of receipt of notice is determined in accordance with §498.22(c)(3).)

(b) Content of request for review. A request for review of an ALJ decision or dismissal must specify the issues, the findings of fact or conclusions of law with which the party disagrees, and the basis for contending that the findings and conclusions are incorrect.

§ 498.83 Departmental Appeals Board action on request for review.

(a) Request by HCFA or the OIG. The Departmental Appeals Board may dismiss, deny, or grant a request made by HCFA or the OIG for review of an ALJ decision or dismissal.

(b) Request by the affected party. The Board will grant the affected party's request for review unless it dismisses the request for one of the following reasons: (1) The affected party requests dismissal of its request for review. (2) The affected party did not file timely or show good cause for late filing. (3) The affected party does not have a right to review. (4) A previous determination or decision, based on the same facts and law, and regarding the same issue, has become final through judicial affirmance or because the affected party failed to timely request reconsideration, hearing, Board review, or judicial review, as appropriate.

(c) Effect of dismissal. The dismissal of a request for Departmental Appeals Board review is binding and not subject to further review.

(d) Review panel. If the Board grants a request for review of the ALJ's decision, the review will be conducted by a panel of at least two members of the Board, designated by the Chairperson or Deputy Chairperson, and one individual designated by the Secretary from the U.S Public Health Service.

§ 498.85 Procedures before the Departmental Appeals Board on review.

The parties are given, upon request, a reasonable opportunity to file briefs or other written statements as to fact and law, and to appear before the Departmental Appeals Board to present evidence or oral arguments. Copies of any brief or other written statement must be sent in accordance with §498.17.

§ 498.86 Evidence admissible on review.

(a) The Departmental Appeals Board may admit evidence into the record in addition to the evidence introduced at the ALJ hearing, (or the documents considered by the ALJ if the hearing was waived), if the Board considers that the additional evidence is relevant and material to an issue before it.

(b) If it appears to the Board that additional relevant evidence is available, the Board will require that it be produced.

(c) Before additional evidence is admitted into the record—
§ 498.95 Extension of time for seeking judicial review.

(a) Any affected party that is dissatisfied with an Departmental Appeals Board decision and is entitled to judicial review must commence civil action within 60 days from receipt of the notice of the Board's decision (as determined under §498.22(c)(3)), unless the Board extends the time in accordance with paragraph (c) of this section.

(b) The request for extension must be filed in writing with the Board before the 60-day period ends.

(c) For good cause shown, the Board may extend the time for commencing civil action.

§ 498.90 Effect of Departmental Appeals Board decision.

(a) General rule. The Board's decision is binding unless—

(1) The affected party has a right to judicial review and timely files a civil action in a United States District Court or, in the case of a civil money penalty, in a United States Court of Appeals; or

(2) The Board reopens and revises its decision in accordance with §498.102.

(b) Right to judicial review. Section 498.5 specifies the circumstances under which an affected party has a right to seek judicial review.

(c) Special rules: Civil money penalty.

(1) Finality of Board's decision. When HCFA imposes a civil money penalty, notice of the Board's decision (or denial of review) is the final administrative action that initiates the 60-day period for seeking judicial review.

(2) Timing for collection of civil money penalty. For SNFs and NFs, the rules that apply are those set forth in subpart F of part 488 of this chapter.

[61 FR 32351, June 24, 1996]
§ 498.100 Basis, timing, and authority for reopening an ALJ or Board decision.

(a) Basis and timing for reopening. An ALJ of Departmental Appeals Board decision may be reopened, within 60 days from the date of the notice of decision, upon the motion of the ALJ or the Board or upon the petition of either party to the hearing.

(b) Authority to reopen. (1) A decision of the Departmental Appeals Board may be reopened only by the Departmental Appeals Board.

(2) A decision of an ALJ may be reopened by that ALJ, by another ALJ if that one is not available, or by the Departmental Appeals Board. For purposes of this paragraph, an ALJ is considered to be unavailable if the ALJ has died, terminated employment, or been transferred to another duty station, is on leave of absence, or is unable to conduct a hearing because of illness.

§ 498.102 Revision of reopened decision.

(a) Revision based on new evidence. If a reopened decision is to be revised on the basis of new evidence that was not included in the record of that decision, the ALJ or the Departmental Appeals Board—

(1) Notifies the parties of the proposed revision; and

(2) Unless the parties waive their right to hearing or appearance—

(i) Grants a hearing in the case of an ALJ revision; and

(ii) Grants opportunity to appear in the case of a Board revision.

(b) Basis for revised decision and right to review. (1) If a revised decision is necessary, the ALJ or the Departmental Appeals Board, as appropriate, renders it on the basis of the entire record.

(2) If the decision is revised by an ALJ, the Departmental Appeals Board may review that revised decision at the request of either party or on its own motion.

§ 498.103 Notice and effect of revised decision.

(a) Notice. The notice mailed to the parties states the basis or reason for the revised decision and informs them of their right to Departmental Appeals Board review of an ALJ revised decision, or to judicial review of a Board reviewed decision.

(b) Effect—(1) ALJ revised decision. An ALJ revised decision is binding unless it is reviewed by the Departmental Appeals Board.

(2) Departmental Appeals Board revised decision. A Board revised decision is binding unless a party files a civil action in a district court of the United States within the time frames specified in § 498.95.
CHAPTER V—OFFICE OF INSPECTOR GENERAL—HEALTH CARE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUBCHAPTER A—GENERAL PROVISIONS

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PART 1000—INTRODUCTION; GENERAL DEFINITIONS

Subpart A [Reserved]

Subpart B—Definitions

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1000.10 General definitions.
1000.20 Definitions specific to Medicare.
1000.30 Definitions specific to Medicaid.

AUTHORITY: 42 U.S.C. 1320 and 1395hh.

SOURCE: 51 FR 34766, Sept. 30, 1986, unless otherwise noted.

Subpart A [Reserved]

Subpart B—Definitions

§ 1000.10 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.

Beneficiary means any individual eligible to have benefits paid to him or her, or on his or her behalf, under Medicare or any State health care program.


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

Directly, as used in the definition of “furnished” in this section, means the provision of items and services by individuals or entities (including items and services provided by them, but manufactured, ordered or prescribed by another individual or entity) who submit claims to Medicare, Medicaid or other Federal health care programs.

ESRD stands for end-stage renal disease.

FR stands for Federal Register.

Furnished refers to items or services provided or supplied, directly or indirectly, by any individual or entity. This includes items and services manufactured, distributed or otherwise provided by individuals or entities that do not directly submit claims to Medicare, Medicaid or other Federal health care programs, but that supply items or services to providers, practitioners or suppliers who submit claims to these programs for such items or services.

HCFA stands for Health Care Financing Administration.

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.

Indirectly, as used in the definition of “furnished” in this section, means the provision of items and services manufactured, distributed or otherwise supplied by individuals or entities who do not directly submit claims to Medicare, Medicaid or other Federal health care programs, but that provide items and services to providers, practitioners or suppliers who submit claims to these programs for such items and services. This term does not include individuals and entities that submit claims directly to these programs for items and services ordered or prescribed by another individual or entity.


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.

OIG means the Office of Inspector General within HHS.

PRO stands for Utilization and Quality Control Peer Review Organization.

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.
§ 1000.20

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.


Effective Date Note: At 63 FR 46685, Sept. 2, 1998, § 1000.10 was amended by republishing the introductory paragraph; by revising the definition for the term Furnished; and by adding, alphabetically, definitions for the terms Directly and Indirectly, effective Oct. 2, 1998. For the convenience of the user, the superseded text is set forth as follows:

§ 1000.10 General definitions.

* * * * *

Furnished refers to items and services provided directly by, or under the direct supervision of, or ordered by, a practitioner or other individual, or ordered or prescribed by a physician, (either as an employee or in his or her own capacity), a provider, or other supplier of services.

* * * * *

§ 1000.20 Definitions specific to Medicare.

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

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.

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.

Provider means a hospital, a skilled nursing facility, a comprehensive outpatient rehabilitation facility, a home health agency, or effective November 1, 1983 through September 30, 1986, 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 a similar agreement but only to furnish outpatient physical therapy or speech pathology services.


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 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.


§ 1000.30 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.

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 sections 1905(a)(1) through (18) of the Act.

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.
SUBCHAPTER B—OIG AUTHORITIES

PART 1001—PROGRAM INTEGRITY—MEDICARE AND STATE HEALTH CARE PROGRAMS

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AUTHORITY: 42 U.S.C. 1302, 1320a-7, 1320a-7b, 1395u(j), 1395u(k), 1395y(d), 1395y(e), 1395cc(b)(2) (D), (E) and (F), and 1395hh; and sec. 2455, Pub.L. 103-355, 108 Stat. 3327 (31 U.S.C. 6101 note).

SOURCE: 57 FR 3330, Jan. 29, 1992, unless otherwise noted.

Subpart A—General Provisions

§ 1001.1 Scope and purpose.

(a) The regulations in this part specify certain bases upon which individuals and entities may, or in some cases must, be excluded from participation in the Medicare and certain State health care programs. They also state the effect of exclusion, the factors that will be considered in determining the length of any exclusion, the provisions governing noticed of exclusions, and the process by which an excluded individual or entity may seek reinstatement into the programs.

(b) The regulations in this part are applicable to and binding on the Office of Inspector General (OIG) in imposing and proposing exclusions, as well as to Administrative Law Judges (ALJs), the Departmental Appeals Board (DAB), and federal courts in reviewing the imposition of exclusions by the OIG (and, where applicable, in imposing exclusions proposed by the OIG).

§ 1001.2 Definitions.

Controlled substance means a drug or other substance, or immediate precursor:

(a) Included in schedules I, II, III, IV or V of part B of subchapter I in 21 U.S.C. chapter 13, or
(b) That is deemed a controlled substance by the law of any State.

Convicted means that—

(a) A judgment of conviction has been entered against an individual or entity by a Federal, State or local court, regardless of whether:
   (1) There is a post-trial motion or an appeal pending, or
   (2) The judgment of conviction or other record relating to the criminal conduct has been expunged or otherwise removed;
(b) A Federal, State or local court has made a finding of guilt against an individual or entity;
(c) A Federal, State or local court has accepted a plea of guilty or nolo contendere by an individual or entity; or
(d) An individual or entity has entered into participation in a first offender, deferred adjudication or other program or arrangement where judgment of conviction has been withheld.

Exclusion means that items and services furnished, ordered or prescribed by a specified individual or entity will not be reimbursed under Medicare, Medicaid and all other Federal health care programs until the individual or entity is reinstated by the OIG.

HHS means Department of Health and Human Services.

Incarceration means imprisonment or any type of confinement with or without supervised release, including, but not limited to, community confinement, house arrest and home detention.


Patient means any individual who is receiving health care items or services, including any item or service provided to meet his or her physical, mental or emotional needs or well-being (including a resident receiving care in a facility as described in part 483 of this chapter), whether or not reimbursed under Medicare, Medicaid and any other Federal health care program and regardless of the location in which such item or service is provided.


Professionally recognized standards of health care are Statewide or national standards of care, whether in writing or otherwise. That professional peers of the individual or entity whose provision of care is an issue, recognize as applying to those peers practicing or providing care within a State. When the Department has declared a treatment modality not to be safe and effective, practitioners who employ such a treatment modality will be deemed not to meet professionally recognized standards of health care. This definition will not be construed to mean that all other treatments meet professionally recognized standards.

Sole community physician means a physician who is the only physician who provides primary care services to Federal or State health care program beneficiaries within a defined service area.

Sole source of essential specialized services in the community means that an individual or entity—

(1) Is the only practitioner, supplier or provider furnishing specialized services in an area designated by the Health Resources Services Administration as a health professional shortage area for that medical specialty, as listed in 42 part 5, appendices B-F;
(2) Is a sole community hospital, as defined in §412.92 of this title; or
(3) Is the only source of specialized services in a reasonably defined service area where services by a non-specialist could not be substituted for the source without jeopardizing the health or safety of beneficiaries.

State health care program means:

(a) A State plan approved under title XIX of the Act (Medicaid),
(b) Any program receiving funds under title V of the Act or from an allotment to a State under such title (Maternal and Child Health Services Block Grant program), or
(c) Any program receiving funds under title XX of the Act or from any
§ 1001.101

allotment to a State under such title (Block Grants to States for Social Services).

State Medicaid Fraud Control Unit means a unit certified by the Secretary as meeting the criteria of 42 U.S.C. 1396b(q) and §1002.305 of this chapter.


EFFECTIVE DATE NOTE: At 63 FR 46686, Sept. 2, 1998, §1001.2 is amended by revising the definitions for the terms Exclusion, Professionally recognized standards of health care, and Sole source of essential specialized services in the community; and by adding definitions for the terms Incarceration and Patient, effective Oct. 2, 1998. For the convenience of the user, the superseded text is set forth as follows:

§ 1001.2 Definitions.

* * * * *

Exclusion means that items and services furnished by a specified individual or entity will not be reimbursed under Medicare or the State health care programs.

* * * * *

Professionally recognized standards of health care are Statewide or national standards of care, whether in writing or not, that professional peers of the individual or entity whose provision of care is an issue, recognize as applying to those peers practicing or providing care within a State. Where the Food and Drug Administration (FDA), the Health Care Financing Administration (HCFA) or the Public Health Service (PHS) has declared a treatment modality not to be safe and effective, practitioners who employ such a treatment modality will be deemed not to meet professionally recognized standards of health care. This definition shall not be construed to mean that all other treatments meet professionally recognized standards.

* * * * *

Sole source of essential specialized services in the community means that an individual or entity—

(a) Is the only practitioner, supplier or provider furnishing specialized services in an area designated by the Public Health Service as a health manpower shortage area for that medical specialty, as listed in 42 CFR part 5, appendices B-F;

(b) Is a sole community hospital, as defined in §412.92 of this title; or

(c) Is the only source for specialized services in a defined service area where services by a non-specialist could not be substituted for the source without jeopardizing the health or safety of beneficiaries.

* * * * *

Subpart B—Mandatory Exclusions

§ 1001.101 Basis for liability.

The OIG will exclude any individual or entity that—

(a) Has been convicted of a criminal offense related to the delivery of an item or service under Medicare or a State health care program, including the performance of management or administrative services relating to the delivery of items or services under any such program;

(b) Has been convicted, under Federal or State law, of a criminal offense related to the neglect or abuse of a patient, in connection with the delivery of a health care item or service, including any offense that the OIG concludes entailed, or resulted in, neglect or abuse of patients (the delivery of a health care item or service includes the provision of any item or service to an individual to meet his or her physical, mental or emotional needs or well-being, whether or not reimbursed under Medicare, Medicaid or any Federal health care program);

(c) Has been convicted, under Federal or State law, of a felony that occurred after August 21, 1996 relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other misconduct—

(1) In connection with the delivery of a health care item or service, including the performance of management or administrative services relating to the delivery of such items or services; or

(2) With respect to any act or omission in a health care program (other than Medicare and a State health care program) operated by, or financed in whole or in part, by any Federal, State or local government agency; or

(d) Has been convicted, under Federal or State law, of a felony that occurred after August 21, 1996 relating to the unlawful manufacture, distribution, prescription or dispensing of a controlled substance, as defined under Federal or State law. This applies to any individual or entity that—
(1) Is, or has ever been, a health care practitioner, provider or supplier;
(2) Holds, or has held, a direct or indirect ownership or control interest (as defined in section 1124(a)(3) of the Act) in an entity that is a health care provider or supplier, or is, or has ever been, an officer, director, agent or managing employee (as defined in section 1126(b) of the Act) of such an entity; or
(3) Is, or has ever been, employed in any capacity in the health care industry.

[63 FR 46686, Sept. 2, 1998]

EFFECTIVE DATE NOTE: At 63 FR 46686, Sept. 2, 1998, §1001.101 was revised, effective Oct. 2, 1998. For the convenience of the user, the superseded text is set forth as follows:

§ 1001.101 Basis for liability.

The OIG will exclude any individual or entity that—
(a) Has been convicted of a criminal offense related to the delivery of an item or service under Medicare or a State health care program, including the performance of management or administrative services relating to the delivery of items or services under any such program, or
(b) Has been convicted, under Federal or State law, of a criminal offense related to the neglect or abuse of a patient, in connection with the delivery of a health care item or service, including any offense that the OIG concludes entailed, or resulted in, neglect or abuse of patients. The conviction need not relate to a patient who is a program beneficiary.

§ 1001.102 Length of exclusion.

(a) No exclusion imposed in accordance with §1001.101 will be for less than 5 years.

(b) Any of the following factors may be considered to be aggravating and a basis for lengthening the period of exclusion—

(1) The acts resulting in the conviction, or similar acts, resulted in financial loss to a government program or to one or more entities of $1,500 or more. (The entire amount of financial loss to such programs or entities, including any amounts resulting from similar acts not adjudicated, will be considered regardless of whether full or partial restitution has been made);
(2) The acts that resulted in the conviction, or similar acts, were committed over a period of one year or more;
(3) The acts that resulted in the conviction, or similar acts, had a significant adverse physical, mental or financial impact on one or more program beneficiaries or other individuals;
(4) In convictions involving patient abuse or neglect, the action that resulted in the conviction was premeditated, was part of a continuing pattern or behavior, or consisted of non-consensual sexual acts;
(5) The sentence imposed by the court included incarceration;
(6) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing;
(7) The individual or entity has at any time been overpaid a total of $1,500 or more by Medicare, Medicaid and all other Federal health care programs, or other third-party payers, as a result of improper billings; or
(8) Whether the individual or entity was convicted of other offenses besides those which formed the basis for the exclusion, or has been the subject of any other adverse action by any Federal, State or local government agency or board, if the adverse action is based on the same set of circumstances that serves as the basis for imposition of the exclusion.

(c) Only if any of the aggravating factors set forth in paragraph (b) of this section justifies an exclusion longer than 5 years, may mitigating factors be considered as a basis for reducing the period of exclusion to no less than 5 years. Only the following factors may be considered mitigating—

(1) The individual or entity was convicted of 3 or fewer misdemeanor offenses, and the entire amount of financial loss to Medicare and the State health care programs due to the acts that resulted in the conviction, and similar acts, is less than $1,500;
(2) The record in the criminal proceedings, including sentencing documents, demonstrates that the court determined that the individual had a mental, emotional or physical condition before or during the commission of the offense that reduced the individual’s culpability; or
(3) The individual’s or entity’s cooperation with Federal or State officials resulted in—
(i) Others being convicted or excluded from Medicare, Medicaid and all other Federal health care programs,
(ii) Additional cases being investigated or reports being issued by the appropriate law enforcement agency identifying program vulnerabilities or weaknesses, or
(iii) The imposition against anyone of a civil money penalty or assessment under part 1003 of this chapter.


EFFECTIVE DATE NOTE: At 63 FR 46686, Sept. 2, 1998, §1001.102 was amended by revising paragraph (b); republishing introductory paragraph (c); and revising paragraph (c)(3), effective Oct. 2, 1998. For the convenience of the user, the superseded text is set forth as follows:

§1001.102 Length of exclusion.

(b) Any of the following factors may be considered to be aggravating and a basis for lengthening the period of exclusion—

(1) The acts resulting in the conviction, or similar acts, resulted in financial loss to Medicare and the State health care programs of $1,500 or more. (The entire amount of financial loss to such programs will be considered, including any amounts resulting from similar acts not adjudicated, regardless of whether full or partial restitution has been made to the programs);

(2) The acts that resulted in the conviction, or similar acts, were committed over a period of one year or more;

(3) The acts that resulted in the conviction, or similar acts, had a significant adverse physical, mental or financial impact on one or more program beneficiaries or other individuals;

(4) The sentence imposed by the court included incarceration;

(5) The convicted individual or entity has a prior criminal, civil or administrative sanction record; or

(6) The individual or entity has at any time been overpaid a total of $1,500 or more by Medicare or State health care programs as a result of improper billings.

(c) * * *

(3) The individual's or entity's cooperation with Federal or State officials resulted in—

(i) Others being convicted or excluded from Medicare or any of the State health care programs, or

(ii) The imposition against anyone of a civil money penalty or assessment under part 1003 of this chapter.

42 CFR Ch. V (10-1-98 Edition)

§1001.201 Conviction relating to fraud.

(a) Circumstance for exclusion. The OIG may exclude an individual or entity convicted under Federal or State law of—

(1) A misdemeanor relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct—

(i) In connection with the delivery of any health care item or service, including the performance of management or administrative services relating to the delivery of such items or services, or

(ii) With respect to any act or omission in a health care program, other than Medicare and a State health care program, operated by, or financed in whole or in part by, any Federal, State or local government agency; or

(2) Fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct with respect to any act or omission in a program, other than a health care program, operated by or financed in whole or in part by any Federal, State or local government agency.

(b) Length of exclusion. (1) An exclusion imposed in accordance with this section will be for a period of 3 years, unless aggravating or mitigating factors listed in paragraphs (b)(2) and (b)(3) of this section form a basis for lengthening or shortening that period.

(2) Any of the following factors may be considered to be aggravating and a basis for lengthening the period of exclusion—

(i) The acts resulting in the conviction, or similar acts, resulted in financial loss of $1,500 or more to a government program or to one or more other entities, or had a significant financial impact on program beneficiaries or other individuals. (The total amount of financial loss will be considered, including any amounts resulting from similar acts not adjudicated, regardless of whether full or partial restitution has been made);

(ii) The acts that resulted in the conviction, or similar acts, were committed over a period of one year or more;
§ 1001.301 Conviction relating to obstruction of an investigation.

(a) Circumstance for exclusion. The OIG may exclude an individual or entity that has been convicted under Federal or State law of a criminal offense relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct

(1) In connection with the interference with or obstruction of any investigation into any

(iii) The individual's or entity's cooperation with Federal or State officials resulted in—

(A) Others being convicted or excluded from Medicare, Medicaid and all other Federal health care programs,

(B) Additional cases being investigated or reports being issued by the appropriate law enforcement agency identifying program vulnerabilities or weaknesses, or

(C) The imposition of a civil money penalty against others; or

(iv) Alternative sources of the type of health care items or services furnished by the individual or entity are not available.

§ 1001.201 Conviction relating to program or health care fraud.

(a) Circumstance for exclusion. The OIG may exclude an individual or entity convicted under Federal or State law of a criminal offense relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct—

(1) In connection with the delivery of any health care item or service, including the performance of management or administrative services relating to the delivery of such items or services, or

(2) With respect to any act or omission in a program operated by, or financed in whole or in part by, any Federal, State or local government agency.

(b) * * *

(ii) The record in the criminal proceedings, including sentencing documents, demonstrates that the court determined that the individual had a mental, emotional or physical condition, before or during the commission of the offense, that reduced the individual's culpability;

(iii) The individual's or entity's cooperation with Federal or State officials resulted in—

(A) Others being convicted or excluded from Medicare or any of the State health care programs, or

(B) Additional cases being investigated or reports being issued by the appropriate law enforcement agency identifying program vulnerabilities or weaknesses, or

(C) The imposition of a civil money penalty against others; or

(iv) Alternative sources of the type of health care items or services furnished by the individual or entity are not available.

(2) * * *

(iii) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing; or

(iv) Whether the individual or entity was convicted of other offenses besides those which formed the basis for the exclusion, or has been the subject of any other adverse action by any Federal, State or local government agency or board, if the adverse action is based on the same set of circumstances that serves as the basis for the imposition of the exclusion.

Only the following factors may be considered as mitigating and a basis for reducing the period of exclusion—

(i) The individual or entity was convicted of 3 or fewer offenses, and the entire amount of financial loss to a government program or to other individuals or entities due to the acts that resulted in the conviction and similar acts is less than $1,500;

(ii) The record in the criminal proceedings, including sentencing documents, demonstrates that the court determined that the individual had a mental, emotional or physical condition, before or during the commission of the offense, that reduced the individual's culpability;

(iii) The individual's or entity's cooperation with Federal or State officials resulted in—

(A) Others being convicted or excluded from Medicare or any of the State health care programs, or

(B) Additional cases being investigated or reports being issued by the appropriate law enforcement agency identifying program vulnerabilities or weaknesses, or

(C) The imposition of a civil money penalty against others; or
§ 1001.401

(criminal offense described in §§ 1001.101 or 1001.201.

(b) Length of exclusion. (1) An exclusion imposed in accordance with this section will be for a period of 3 years, unless aggravating or mitigating factors listed in paragraphs (b)(2) and (b)(3) of this section form the basis for lengthening or shortening that period.

(2) Any of the following factors may be considered to be aggravating and a basis for lengthening the period of exclusion—

(i) The interference with, or obstruction of, the investigation caused the expenditure of significant additional time or resources;

(ii) The interference or obstruction had a significant adverse mental, physical or financial impact on program beneficiaries or other individuals or on the Medicare or State health care programs;

(iii) The interference or obstruction also affected a civil or administrative investigation;

(iv) The sentence imposed by the court included incarceration;

(v) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing; or

(vi) Whether the individual or entity was convicted of other offenses besides those which formed the basis for the exclusion, or has been the subject of any other adverse action by any Federal, State or local government agency or board, if the adverse action is based on the same set of circumstances that serves as the basis for the imposition of the exclusion.

(3) Only the following factors may be considered as mitigating and a basis for reducing the period of exclusion—

(i) The record of the criminal proceedings, including sentencing documents, demonstrates that the court determined that the individual had a mental, emotional or physical condition, before or during the commission of the offense, that reduced the individual's culpability;

(ii) The individual's or entity's cooperation with Federal or State officials resulted in—

(A) Others being convicted or excluded from Medicare, Medicaid and all other Federal health care programs,

(B) Additional cases being investigated or reports being issued by the appropriate law enforcement agency identifying program vulnerabilities or weaknesses, or

(C) The imposition of a civil money penalty against others; or

(iii) Alternative sources of the type of health care items or services furnished by the individual or entity are not available.


EFFECTIVE DATE NOTE: At 63 FR 46687, Sept. 2, 1998, §1001.301 was amended by republishing introductory paragraph (b)(2); revising paragraphs (b)(2)(iv) and (v); by adding a new paragraph (b)(2)(vi); by republishing introductory paragraph (b)(3); and by revising paragraph (b)(3)(ii), effective Oct. 2, 1998. For the convenience of the user, the superseded text is set forth as follows:

§ 1001.301 Conviction relating to obstruction of an investigation.

* * * * *

(b) * * *

(2) * * *

* * * * *

(iv) The sentence imposed by the court included incarceration; or

(v) The convicted individual or entity has a prior criminal, civil or administrative sanction record.

(3) * * *

(ii) The individual's or entity's cooperation with Federal or State officials resulted in—

(A) Others being convicted or excluded from Medicare or any of the State health care programs, or

(B) The imposition of a civil money penalty against others; or

* * * * *

§ 1001.401 Misdemeanor conviction relating to controlled substances.

(a) Circumstance for exclusion. The OIG may exclude an individual or entity convicted under Federal or State law of a misdemeanor relating to the unlawful manufacture, distribution, prescription or dispensing of a controlled substance, as defined under Federal or State law. This section applies to any individual or entity that—

(1) Is, or has ever been, a health care practitioner, provider or supplier;

* * * * *
(2) Holds or has held a direct or indirect ownership or control interest, as defined in section 1124(a)(3) of the Act, in an entity that is a health care provider or supplier, or is or has been an officer, director, agent or managing employee, as defined in section 1126(b) of the Act, of such an entity; or
(3) Is, or has ever been, employed in any capacity in the health care industry.
(b) For purposes of this section, the definition of controlled substance will be the definition that applies to the law forming the basis for the conviction.
(c) Length of exclusion. (1) An exclusion imposed in accordance with this section will be for a period of 3 years, unless aggravating or mitigating factors listed in paragraphs (b)(2) and (b)(3) of this section form a basis for lengthening or shortening that period.
(2) Any of the following factors may be considered to be aggravating and a basis for lengthening the period of exclusion—
(i) The acts that resulted in the conviction or similar acts were committed over a period of one year or more;
(ii) The acts that resulted in the conviction or similar acts had a significant adverse physical, mental or financial impact on program beneficiaries or other individuals or the Medicare or State health care programs;
(iii) The sentence imposed by the court included incarceration;
(iv) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing; or
(v) Whether the individual or entity was convicted of other offenses besides those which formed the basis for the exclusion, or has been the subject of any other adverse action by any other Federal, State or local government agency or board, if the adverse action is based on the same set of circumstances that serves as the basis for the imposition of the exclusion.
(3) Only the following factors may be considered as mitigating and a basis for shortening the period of exclusion—
(i) The individual’s or entity’s cooperation with Federal or State officials resulted in—
(A) Others being convicted or excluded from Medicare, Medicaid and all other Federal health care programs,
(B) Additional cases being investigated or reports being issued by the appropriate law enforcement agency identifying program vulnerabilities or weaknesses, or
(C) The imposition of a civil money penalty against others; or
(ii) Alternative sources of the type of health care items or services furnished by the individual or entity are not available.


EFFECTIVE DATE NOTE: At 63 FR 46687, Sept. 2, 1998, § 1001.401 was amended by revising the section heading; revising paragraph (a); by republishing introductory paragraph (c)(2); by revising paragraphs (c)(2)(iii) and (iv); by adding a new paragraph (c)(2)(v); by republishing introductory paragraph (c)(3); and by revising paragraph (c)(3)(i), effective Oct. 2, 1998. For the convenience of the user, the superseded text is set forth as follows:

§ 1001.401 Conviction relating to controlled substances.
(a) Circumstance for exclusion. The OIG may exclude an individual or entity convicted under Federal or State law of a criminal offense relating to the unlawful manufacture, distribution, prescription or dispensing of a controlled substance, as defined under Federal or State law.

* * * * *
(c) * * *
(2) * * *
(iii) The sentence imposed by the court included incarceration; or
(iv) The convicted individual or entity has a prior criminal, civil or administrative sanction record.
(3) * * *
(i) The individual’s or entity’s cooperation with Federal or State officials resulted in—
(A) Others being convicted or excluded from Medicare or any of the State health care programs, or
(B) The imposition of a civil money penalty against others; or

* * * * *

§ 1001.501 License revocation or suspension.
(a) Circumstance for exclusion. The OIG may exclude an individual or entity that has—
(1) Had a license to provide health care revoked or suspended by any State licensing authority, or has otherwise lost such a license (including the right
to apply for or renew such a license, for reasons bearing on the individual's or entity's professional competence, professional performance or financial integrity; or

(2) Has surrendered such a license while a formal disciplinary proceeding concerning the individual’s or entity’s professional competence, professional performance or financial integrity was pending before a State licensing authority.

(b) Length of exclusion. (1) An exclusion imposed in accordance with this section will not be for a period of time less than the period during which an individual’s or entity’s license is revoked, suspended or otherwise not in effect as a result of, or in connection with, a State licensing agency action.

(2) Any of the following factors may be considered aggravating and a basis for lengthening the period of exclusion—

(i) The acts that resulted in the revocation, suspension or loss of the individual’s or entity’s license to provide health care had or could have had a significant adverse physical, emotional or financial impact on one or more program beneficiaries or other individuals;

(ii) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing;

(iii) The acts, or similar acts, had or could have had a significant adverse impact on the financial integrity of the programs; or

(iv) The individual or entity has been the subject of any other adverse action by any other Federal, State or local government agency or board, if the adverse action is based on the same set of circumstances that serves as the basis for the imposition of the exclusion.

(3) Only if any of the aggravating factors listed in paragraph (b)(2) of this section justifies a longer exclusion may mitigating factors be considered as a basis for reducing the period of exclusion to a period not less than that set forth in paragraph (b)(1) of this section. Only the following factors may be considered mitigating—

(i) The individual’s or entity’s cooperation with a State licensing authority resulted in—

(A) The sanctioning of other individuals or entities, or

(B) Additional cases being investigated or reports being issued by the appropriate law enforcement agency identifying program vulnerabilities or weaknesses; or

(ii) Alternative sources of the type of health care items or services furnished by the individual or entity are not available.

(4) When an individual or entity has been excluded under this section, the OIG will consider a request for reinstatement in accordance with §1001.3003 if the individual or entity obtains a valid license in the State where the license was originally revoked, suspended, surrendered or otherwise lost.

(c) Exceptions—(1) Length of exclusion. If, prior to the notice of exclusion by the OIG, the licensing authority of a State (other than the one in which the individual's or entity's license had been revoked, suspended, surrendered or otherwise lost), being fully apprised of all of the circumstances surrounding the prior action by the licensing board of the first State, grants the individual or entity a license or takes no significant adverse action as to a currently held license, an exclusion imposed in accordance with this section may be for a period of time less than that prescribed by paragraph (b)(1) of this section.

(2) Consideration of early reinstatement. If an individual or entity that has been excluded in accordance with this section fully and accurately discloses the circumstances surrounding this action to a licensing authority of a different State, and that State grants the individual or entity a new license or takes no significant adverse action as to a currently held license, the OIG will consider a request for early reinstatement.
§ 1001.501 License revocation or suspension.

* * * * *

(b) * * * (1) Except as provided in paragraph (c) of this section, an exclusion imposed in accordance with this section will never be for a period of time less than the period during which an individual's or entity's license is revoked, suspended or otherwise not in effect as a result of, or in connection with, a State licensing agency action.

(2) * * *

(ii) The individual or entity has a prior criminal, civil or administrative sanction record; or

(iii) The acts (or similar acts) had or could have had a significant adverse impact on the financial integrity of the programs.

(3) * * *

(i) The individual's or entity's cooperation with a State licensing authority resulted in the sanctioning of other individuals or entities; or

* * * * *

§ 1001.601 Exclusion or suspension under a Federal or State health care program.

(a) Circumstance for exclusion. (1) The OIG may exclude an individual or entity suspended or excluded from participation, or otherwise sanctioned, under—

(i) Any Federal program involving the provision of health care, or

(ii) A State health care program, for reasons bearing on the individual's or entity's professional competence, professional performance or financial integrity.

(2) The term "or otherwise sanctioned" in paragraph (a)(1) of this section is intended to cover all actions that limit the ability of a person to participate in the program at issue regardless of what such an action is called, and includes situations where an individual or entity voluntarily withdraws from a program to avoid a formal sanction.

(b) Length of exclusion. (1) An exclusion imposed in accordance with this section will not be for a period of time less than the period during which the individual or entity is excluded or suspended from a Federal or State health care program.

(2) Any of the following factors may be considered aggravating and a basis for lengthening the period of exclusion—

(i) The acts that resulted in the exclusion, suspension or other sanction under Medicare, Medicaid and all other Federal health care programs had, or could have had, a significant adverse impact on Federal or State health care programs or the beneficiaries of those programs or other individuals;

(ii) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing; or

(iii) The individual or entity has been the subject of any other adverse action by any Federal, State or local government agency or board, if the adverse action is based on the same set of circumstances that serves as the basis for the imposition of the exclusion.

(3) Only if any of the aggravating factors set forth in paragraph (b)(2) of this section justifies a longer exclusion may mitigating factors be considered as a basis for reducing the period of exclusion to a period not less than that set forth in paragraph (b)(1) of this section. Only the following factors may be considered mitigating—

(i) The individual's or entity's cooperation with Federal or State officials resulted in—

(A) The sanctioning of other individuals or entities, or

(B) Additional cases being investigated or reports being issued by the appropriate law enforcement agency identifying program vulnerabilities or weaknesses; or

(ii) Alternative sources of the types of health care items or services furnished by the individual or entity are not available.

(4) If the individual or entity is eligible to apply for reinstatement in accordance with § 1001.3001 of this part, and the sole reason for the State denying reinstatement is the existing Medicare exclusion imposed by the OIG as a result of the original State action, the OIG will consider a request for reinstatement.


Effective Date Note: At 63 FR 46688, Sept. 2, 1998, §1001.601 was amended by revising paragraph (b), effective Oct. 2, 1998. For the convenience of the user, the superseded text is set forth as follows:
§ 1001.601 Exclusion or suspension under a Federal or State health care program.

* * * * *

(b) Length of exclusion. (1) An exclusion imposed in accordance with this section will be for a period of 3 years, unless aggravating or mitigating factors set forth in paragraphs (b)(2) and (b)(3) of this section form the basis for lengthening or shortening that period.

(2) Any of the following factors may be considered aggravating and a basis for lengthening the period of exclusion—

(i) The acts that resulted in the exclusion, suspension or other sanction under the Federal or State health care program had, or could have had, a significant adverse impact on Federal or State health care programs or the beneficiaries of those programs or other individuals;

(ii) The period of exclusion, suspension or other sanction imposed under the Federal or State health care program is greater than 3 years; or

(iii) The individual or entity has a prior criminal, civil or administrative record.

(3) Only the following factors may be considered mitigating and a basis for shortening the period of exclusion—

(i) The period of exclusion, suspension or other sanction imposed under the Federal or State health care program is less than 3 years;

(ii) The individual's or entity's cooperation with Federal or State officials resulted in the sanctioning of other individuals or entities; or

(iii) Alternative sources of the types of health care items or services furnished by the individual or entity are not available.

The OIG will normally not consider a request for reinstatement in accordance with §1001.3001 until the period of exclusion imposed by the OIG has expired.

* * * * *

§ 1001.701 Excessive claims or furnishing of unnecessary or substandard items and services.

(a) Circumstance for exclusion. The OIG may exclude an individual or entity that has—

(1) Submitted, or caused to be submitted, bills or requests for payments under Medicare or any of the State health care programs containing charges or costs for items or services furnished that are substantially in excess of such individual's or entity's usual charges or costs for such items or services; or

(2) Furnished, or caused to be furnished, to patients (whether or not covered by Medicare or any of the State health care programs) any items or services substantially in excess of the patient's needs, or of a quality that fails to meet professionally recognized standards of health care.

(b) The OIG's determination under paragraph (a)(2) of this section—that the items or services furnished were excessive or of unacceptable quality—will be made on the basis of information, including sanction reports, from the following sources:

(1) The PRO for the area served by the individual or entity;

(2) State or local licensing or certification authorities;

(3) Fiscal agents or contractors, or private insurance companies;

(4) State or local professional societies; or

(5) Any other sources deemed appropriate by the OIG.

(c) Exceptions. An individual or entity will not be excluded for—

(1) Submitting, or causing to be submitted, bills or requests for payment that contain charges or costs substantially in excess of usual charges or costs when such charges or costs are due to unusual circumstances or medical complications requiring additional time, effort, expense or other good cause; or

(2) Furnishing, or causing to be furnished, items or services in excess of the needs of patients, when the items or services were ordered by a physician or other authorized individual, and the individual or entity furnishing the items or services was not in a position to determine medical necessity or to refuse to comply with the order of the physician or other authorized individual.

(d) Length of exclusion. (1) An exclusion imposed in accordance with this section will be for a period of 3 years, unless aggravating or mitigating factors set forth in paragraphs (d)(2) and (d)(3) of this section form a basis for lengthening or shortening the period. In no case may the period be shorter than 1 year for any exclusion taken in accordance with paragraph (a)(2) of this section.
(2) Any of the following factors may be considered aggravating and a basis for lengthening the period of exclusion—
   (i) The violations were serious in nature, and occurred over a period of one year or more;
   (ii) The violations had a significant adverse physical, mental or financial impact on program beneficiaries or other individuals;
   (iii) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing;
   (iv) The violation resulted in financial loss to Medicare, Medicaid and all other Federal health care programs of $1,500 or more; or
   (v) The individual or entity has been the subject of any other adverse action by any Federal, State or local government agency or board, if the adverse action is based on the same set of circumstances that serves as the basis for the imposition of the exclusion.

(3) Only the following factors may be considered mitigating and a basis for reducing the period of exclusion—
   (i) There were few violations and they occurred over a short period of time; or
   (ii) Alternative sources of the type of health care items or services furnished by the individual or entity are not available.

§ 1001.901 False or improper claims.

(a) Circumstance for exclusion. The OIG may exclude any individual or entity that it determines has committed an act described in section 1128A of the Act. The imposition of a civil money penalty or assessment is not a prerequisite for an exclusion under this section.

(b) Length of exclusion. In determining the length of an exclusion imposed in accordance with this section, the OIG will consider the following factors—

(1) The nature and circumstances surrounding the actions that are the basis for liability, including the period of time over which the acts occurred, the number of acts, whether there is evidence of a pattern and the amount claimed;

(2) The degree of culpability;

(3) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing (The lack of any prior record is to be considered neutral);

(4) The individual or entity has been the subject of any other adverse action by any Federal, State or local government agency or board, if the adverse action is based on the same set of circumstances that serves as the basis for the imposition of the exclusion;

(5) Other matters as justice may require.
§ 1001.952 Exceptions.

The following payment practices shall not be treated as a criminal offense under section 1128B of the Act and shall not serve as the basis for an exclusion:

(a) Investment Interests. As used in section 1128B of the Act, “remuneration” does not include any payment that is a return on an investment interest, such as a dividend or interest income, made to an investor as long as all of the applicable standards are met within one of the following two categories of entities:

(1) If, within the previous fiscal year or previous 12 month period, the entity possesses more than $50,000,000 in undepreciated net tangible assets...
(based on the net acquisition cost of purchasing such assets from an unrelated entity) related to the furnishing of items and services, all of the following five applicable standards must be met—

(i) With respect to an investment interest that is an equity security, the equity security must be registered with the Securities and Exchange Commission under 15 U.S.C. 78l(b) or (g).

(ii) The investment interest of an investor in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must be obtained on terms equally available to the public through trading on a registered national securities exchange, such as the New York Stock Exchange or the American Stock Exchange, or on the National Association of Securities Dealers Automated Quotation System.

(iii) The entity or any investor must not market or furnish the entity's items or services (or those of another entity as part of a cross referral agreement) to passive investors differently than to non-investors.

(iv) The entity must not loan funds to or guarantee a loan for an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity if the investor uses any part of such loan to obtain the investment interest.

(v) The amount of payment to an investor in return for the investment interest must be directly proportional to the amount of the capital investment of that investor.

(2) If the entity possesses investment interests that are held by either active or passive investors, all of the following eight applicable standards must be met—

(i) No more than 40 percent of the value of the investment interests of each class of investments may be held in the previous fiscal year or previous 12 month period by investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity.

(ii) The terms on which an investment interest is offered to a passive investor, if any, who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must be no different from the terms offered to other passive investors.

(iii) The terms on which an investment interest is offered to an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must not be related to the previous or expected volume of referrals, items or services furnished, or the amount of business otherwise generated from that investor to the entity.

(iv) There is no requirement that a passive investor, if any, make referrals to, be in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity as a condition for remaining as an investor.

(v) The entity or any investor must not market or furnish the entity's items or services (or those of another entity as part of a cross referral agreement) to passive investors differently than to non-investors.

(vi) No more than 40 percent of the gross revenue of the entity in the previous fiscal year or previous 12 month period may come from referrals, items or services furnished, or business otherwise generated from investors.

(vii) The entity must not loan funds to or guarantee a loan for an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity if the investor uses any part of such loan to obtain the investment interest.

(viii) The amount of payment to an investor in return for the investment interest must be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.

For purposes of paragraph (a) of this section, the following terms apply. Active investor means an investor either who is responsible for the day-to-day management of the entity and is a bona fide general partner in a partnership under the Uniform Partnership Act or who agrees in writing to undertake liability for the actions of the entity’s agents acting within the scope of
their agency. Investment interest means a security issued by an entity, and may include the following classes of investments: shares in a corporation, interests or units of a partnership, bonds, debentures, notes, or other debt instruments. Investor means an individual or entity either who directly holds an investment interest in an entity, or who holds such investment interest indirectly by, including but not limited to, such means as having a family member hold such investment interest or holding a legal or beneficial interest in another entity (such as a trust or holding company) that holds such investment interest. Passive investor means an investor who is not an active investor, such as a limited partner in a partnership under the Uniform Partnership Act, a shareholder in a corporation, or a holder of a debt security.

(b) Space Rental. As used in section 1128B of the Act, “remuneration” does not include any payment made by a lessee to a lessor for the use of premises, as long as all of the following five standards are met—

1. The lease agreement is set out in writing and signed by the parties.
2. The lease specifies the premises covered by the lease.
3. If the lease is intended to provide the lessee with access to the premises for periodic intervals of time, rather than on a full-time basis for the term of the lease, the lease specifies exactly the schedule of such intervals, their precise length, and the exact rent for such intervals.
4. The term of the lease is for not less than one year.
5. The aggregate rental charge is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare or a State health care program.

For purposes of paragraph (c) of this section, the term fair market value means the value of the rental property when obtained from a manufacturer or professional distributor, but shall not be adjusted to reflect the additional value that one party (either the prospective lessee or lessor) would attribute to the property as a result of its proximity or convenience to sources of referrals or business otherwise generated for which payment may be made in whole or in part under Medicare or a State health care program.

(c) Equipment rental. As used in section 1128B of the Act, “remuneration” does not include any payment made by a lessee of equipment to the lessor of the equipment for the use of the equipment, as long as all of the following five standards are met—

1. The lease agreement is set out in writing and signed by the parties.
2. The lease specifies the equipment covered by the lease.
3. If the lease is intended to provide the lessee with use of the equipment for periodic intervals of time, rather than on a full-time basis for the term of the lease, the lease specifies exactly the schedule of such intervals, their precise length, and the exact rent for such interval.
4. The term of the lease is for not less than one year.
5. The aggregate rental charge is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare or a State health care program.

For purposes of paragraph (c) of this section, the term fair market value means the value of the equipment when obtained from a manufacturer or professional distributor, but shall not be adjusted to reflect the additional value that one party (either the prospective lessee or lessor) would attribute to the equipment as a result of its proximity or convenience to sources of referrals or business otherwise generated for which payment may be made in whole or in part under Medicare or a State health care program.

(d) Personal services and management contracts. As used in section 1128B of the Act, “remuneration” does not include any payment made by a principal to an agent as compensation for the services of the agent, as long as all of the following six standards are met—
§ 1001.952

(1) The agency agreement is set out in writing and signed by the parties.

(2) The agency agreement specifies the services to be provided by the agent.

(3) If the agency agreement is intended to provide for the services of the agent on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals.

(4) The term of the agreement is for not less than one year.

(5) The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare or a State health care program.

(6) The services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.

For purposes of paragraph (d) of this section, an agent of a principal is any person, other than a bona fide employee of the principal, who has an agreement to perform services for, or on behalf of, the principal.

(e) Sale of practice. As used in section 1128B of the Act, “remuneration” does not include any payment made to a practitioner by another practitioner where the former practitioner is selling his or her practice to the latter practitioner, as long as both of the following two standards are met—

(1) The period from the date of the first agreement pertaining to the sale to the completion of the sale is not more than one year.

(2) The practitioner who is selling his or her practice will not be in a professional position to make referrals to, or otherwise generate business for, the purchasing practitioner for which payment may be made in whole or in part under Medicare or a State health care program after one year from the date of the first agreement pertaining to the sale.

(f) Referral services. As used in section 1128B of the Act, “remuneration” does not include any payment or exchange of anything of value between an individual or entity (“participant”) and another entity serving as a referral service (“referral service”), as long as all of the following four standards are met—

(1) The referral service does not exclude as a participant in the referral service any individual or entity who meets the qualifications for participation.

(2) Any payment the participant makes to the referral service is assessed equally against and collected equally from all participants, and is only based on the cost of operating the referral service, and not on the volume or value of any referrals or business otherwise generated by the participants for the referral service for which payment may be made in whole or in part under Medicare or a State health care program.

(3) The referral service imposes no requirements on the manner in which the participant provides services to a referred person, except that the referral service may require that the participant charge the person referred at the same rate as it charges other persons not referred by the referral service, or that these services be furnished free of charge or at reduced charge.

(4) The referral service makes the following five disclosures to each person seeking a referral, with each such disclosure maintained by the referral service in a written record certifying such disclosure and signed by either such person seeking a referral or by the individual making the disclosure on behalf of the referral service—

(i) The manner in which it selects the group of participants in the referral service to which it could make a referral;

(ii) Whether the participant has paid a fee to the referral service;

(iii) The manner in which it selects a particular participant from this group for that person;

(iv) The nature of the relationship between the referral service and the
group of participants to whom it could make the referral; and

(v) The nature of any restrictions that would exclude such an individual or entity from continuing as a participant.

(g) Warranties. As used in section 1128B of the Act, “remuneration” does not include any payment or exchange of anything of value under a warranty provided by a manufacturer or supplier of an item to the buyer (such as a health care provider or beneficiary) of the item, as long as the buyer complies with all of the following standards in paragraphs (g)(1) and (g)(2) of this section and the manufacturer or supplier complies with all of the following standards in paragraphs (g)(3) and (g)(4) of this section—

(1) The buyer must fully and accurately report any price reduction of the item (including a free item), which was obtained as part of the warranty, in the applicable cost reporting mechanism or claim for payment filed with the Department or a State agency.

(2) The buyer must provide, upon request by the Secretary or a State agency, information provided by the manufacturer or supplier as specified in paragraph (g)(3) of this section.

(3) The manufacturer or supplier must comply with either of the following two standards—

(i) The manufacturer or supplier must fully and accurately report the price reduction of the item (including a free item), which was obtained as part of the warranty, on the invoice or statement submitted to the buyer, and inform the buyer of its obligations under paragraphs (a)(1) and (a)(2) of this section.

(ii) Where the amount of the price reduction is not known at the time of sale, the manufacturer or supplier must fully and accurately report the existence of a warranty on the invoice or statement, inform the buyer of its obligations under paragraphs (g)(1) and (g)(2) of this section, and, when the price reduction becomes known, provide the buyer with documentation of the calculation of the price reduction resulting from the warranty.

(h) Discounts. As used in section 1128B of the Act, “remuneration” does not include a discount, as defined in paragraph (h)(3) of this section, on a good or service received by a buyer, which submits a claim or request for payment for the good or service for which payment may be made in whole or in part under Medicare or a State health care program, from a seller as long as the buyer complies with the applicable standards of paragraph (h)(1) of this section and the seller complies with the applicable standards of paragraph (h)(2) of this section:

(1) With respect to the following three categories of buyers, the buyer must comply with all of the applicable standards within each category—

(i) If the buyer is an entity which reports its costs on a cost report required by the Department or a State agency, it must comply with all of the following four standards—

(A) The discount must be earned based on purchases of that same good or service bought within a single fiscal year of the buyer;

(B) The buyer must claim the benefit of the discount in the fiscal year in which the discount is earned or the following year;

(C) The buyer must fully and accurately report the discount in the applicable cost report; and

(D) The buyer must provide, upon request by the Secretary or a State agency, information provided by the seller as specified in paragraph (h)(2)(ii) of this section.

(ii) If the buyer is an entity which is a health maintenance organization or competitive medical plan acting in accordance with a risk contract under
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section 1876(g) or 1903(m) of the Act, or under another State health care program, it need not report the discount except as otherwise may be required under the risk contract.

(iii) If the buyer is not an entity described in paragraphs (h)(1)(i) or (h)(1)(ii) of this section, it must comply with all of the following three standards—

(A) The discount must be made at the time of the original sale of the good or service;

(B) Where an item or service is separately claimed for payment with the Department or a State agency, the buyer must fully and accurately report the discount on that item or service; and

(C) The buyer must provide, upon request by the Secretary or a State agency, information provided by the seller as specified in paragraph (h)(2)(ii)(A) of this section.

(2) With respect to either of the following two categories of buyers, the seller must comply with all of the applicable standards within each category—

(i) If the buyer is an entity described in paragraph (h)(1)(ii) of this section, the seller need not report the discount to the buyer for purposes of this provision.

(ii) If the buyer is any other individual or entity, the seller must comply with either of the following two standards—

(A) Where a discount is required to be reported to the Department or a State agency under paragraph (h)(1) of this section, the seller must fully and accurately report such discount on the invoice or statement submitted to the buyer, and inform the buyer of its obligations to report such discount; or

(B) Where the value of the discount is not known at the time of sale, the seller must fully and accurately report the existence of a discount program on the invoice or statement submitted to the buyer, inform the buyer of its obligations under paragraph (h)(1) of this section and, when the value of the discount becomes known, provide the buyer with documentation of the calculation of the discount identifying the specific goods or services purchased to which the discount will be applied.

(3) For purposes of this paragraph, the term discount means a reduction in the amount a seller charges a buyer (who buys either directly or through a wholesaler or a group purchasing organization) for a good or service based on an arms length transaction. The term discount may include a rebate check, credit or coupon directly redeemable from the seller only to the extent that such reductions in price are attributable to the original good or service that was purchased or furnished. The term discount does not include—

(i) Cash payment;

(ii) Furnishing one good or service without charge or at a reduced charge in exchange for any agreement to buy a different good or service;

(iii) A reduction in price applicable to one payor but not to Medicare or a State health care program;

(iv) A reduction in price offered to a beneficiary (such as a routine reduction or waiver of any coinsurance or deductible amount owed by a program beneficiary);

(v) Warranties;

(vi) Services provided in accordance with a personal or management services contract; or

(vii) Other remuneration in cash or in kind not explicitly described in this paragraph.

(i) Employees. As used in section 1128B of the Act, “remuneration” does not include any amount paid by an employer to an employee, who has a bona fide employment relationship with the employer, for employment in the furnishing of any item or service for which payment may be made in whole or in part under Medicare or a State health care program. For purposes of paragraph (i) of this section, the term employee has the same meaning as it does for purposes of 26 U.S.C. 3121(d)(2).

(j) Group purchasing organizations. As used in section 1128B of the Act, “remuneration” does not include any payment by a vendor of goods or services to a group purchasing organization (GPO), as part of an agreement to furnish such goods or services to an individual or entity as long as both of the following two standards are met—

(1) The GPO must have a written agreement with each individual or entity, for which items or services are...
furnished, that provides for either of the following—

(i) The agreement states that participating vendors from which the individual or entity will purchase goods or services will pay a fee to the GPO of 3 percent or less of the purchase price of the goods or services provided by that vendor.

(ii) In the event the fee paid to the GPO is not fixed at 3 percent or less of the purchase price of the goods or services, the agreement specifies the amount (or if not known, the maximum amount) the GPO will be paid by each vendor (where such amount may be a fixed sum or a fixed percentage of the value of purchases made from the vendor by the members of the group under the contract between the vendor and the GPO).

(2) Where the entity which receives the goods or service from the vendor is a health care provider of services, the GPO must disclose in writing to the entity at least annually, and to the Secretary upon request, the amount received from each vendor with respect to purchases made by or on behalf of the entity.

For purposes of paragraph (j) of this section, the term group purchasing organization (GPO) means an entity authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services for which payment may be made in whole or in part under Medicare or a State health care program, and who are neither wholly-owned by the GPO nor subsidiaries of a parent corporation that wholly owns the GPO (either directly or through another wholly-owned entity).

(b) Waiver of beneficiary coinsurance and deductible amounts. As used in section 1128B of the Act, “remuneration” does not include any reduction or waiver of a Medicare or a State health care program beneficiary’s obligation to pay coinsurance or deductible amounts as long as all of the standards are met within either of the following two categories of health care providers:

(1) If the coinsurance or deductible amounts are owed to a hospital for inpatient hospital services for which Medicare pays under the prospective payment system, the hospital must comply with all of the following three standards—

(i) The hospital must not later claim the amount reduced or waived as a bad debt for payment purposes under Medicare or otherwise shift the burden of the reduction or waiver onto Medicare, a State health care program, other payers, or individuals.

(ii) The hospital must offer to reduce or waive the coinsurance or deductible amounts without regard to the reason for admission, the length of stay of the beneficiary, or the diagnostic related group for which the claim for Medicare reimbursement is filed.

(iii) The hospital’s offer to reduce or waive the coinsurance or deductible amounts must not be made as part of a price reduction agreement between a hospital and a third-party payer (including a health plan as defined in paragraph (l)(2) of this section), unless the agreement is part of a contract for the furnishing of items or services to a beneficiary of a Medicare supplemental policy issued under the terms of section 1882(t)(1) of the Act.

(2) If the coinsurance or deductible amounts are owed by an individual who qualifies for subsidized services under a provision of the Public Health Services Act or under titles V or XIX of the Act to a federally qualified health care center or other health care facility under any Public Health Services Act grant program or under title V of the Act, the health care center or facility may reduce or waive the coinsurance or deductible amounts for items or services for which payment may be made in whole or in part under part B of Medicare or a State health care program.

(l) Increased coverage, reduced cost-sharing amounts, or reduced premium amounts offered by health plans. As used in section 1128B of the Act, “remuneration” does not include the additional coverage of any item or service offered by a health plan to an enrollee or the reduction of some or all of the enrollee’s obligation to pay the health plan or a contract health care provider for cost-sharing amounts (such as coinsurance, deductible, or copayment amounts) or for premium amounts attributable to items or services covered by the health plan, the Medicare program, or a State health care program,
as long as the health plan complies with all of the standards within one of the following two categories of health plans:

(i) If the health plan is a risk-based health maintenance organization, competitive medical plan, prepaid health plan, or other health plan under contract with HCFA or a State health care program and operating in accordance with section 1876(g) or 1903(m) of the Act, under a Federal statutory demonstration authority, or under other Federal statutory or regulatory authority, it must offer the same increased coverage or reduced cost-sharing or premium amounts to all Medicare or State health care program enrollees covered by the contract unless otherwise approved by HCFA or by a State health care program.

(ii) If the health plan is a health maintenance organization, competitive medical plan, health care prepayment plan, prepaid health plan or other health plan that has executed a contract or agreement with HCFA or with a State health care program to receive payment for enrollees on a reasonable cost or similar basis, it must comply with both of the following two standards—

(A) The health plan must offer the same increased coverage or reduced cost-sharing or premium amounts to all Medicare or State health care program enrollees covered by the contract or agreement unless otherwise approved by HCFA or by a State health care program; and

(B) The health plan must not claim the costs of the increased coverage or the reduced cost-sharing or premium amounts as a bad debt for payment purposes under Medicare or a State health care program or otherwise shift the burden of the increased coverage or reduced cost-sharing or premium amounts to the extent that increased payments are claimed from Medicare or a State health care program.

(ii) For purposes of paragraph (l) of this section, the terms—

Contract health care provider means an individual or entity under contract with a health plan to furnish items or services to enrollees who are covered by the health plan, Medicare, or a State health care program.

Enrollee means an individual who has entered into a contractual relationship with a health plan (or on whose behalf an employer, or other private or governmental entity has entered into such a relationship) under which the individual is entitled to receive specified health care items and services, or insurance coverage for such items and services, in return for payment of a premium or a fee.

Health plan means an entity that furnishes or arranges under agreement with contract health care providers for the furnishing of items or services to enrollees, or furnishes insurance coverage for the provision of such items and services, in exchange for a premium or a fee, where such entity:

(i) Operates in accordance with a contract, agreement or statutory demonstration authority approved by HCFA or a State health care program;

(ii) Charges a premium and its premium structure is regulated under a State insurance statute or a State enabling statute governing health maintenance organizations or preferred provider organizations;

(iii) Is an employer, if the enrollees of the plan are current or retired employees, or is a union welfare fund, if the enrollees of the plan are union members; or

(iv) Is licensed in the State, is under contract with an employer, union welfare fund, or a company furnishing health insurance coverage as described in conditions (ii) and (iii) of this definition, and is paid a fee for the administration of the plan which reflects the fair market value of those services.

(m) Price reductions offered to health plans. (1) As used in section 1128B of the Act, “remuneration” does not include a reduction in price a contract health care provider offers to a health plan in accordance with the terms of a written agreement between the contract health care provider and the health plan for the sole purpose of furnishing to enrollees items or services that are covered by the health plan, Medicare, or a State health care program, as long as both the health plan and contract health care provider comply with all of the applicable standards within one of the following four categories of health plans:
(i) If the health plan is a risk-based health maintenance organization, competitive medical plan, or prepaid health plan under contract with HCFA or a State agency and operating in accordance with section 1876(g) or 1903(m) of the Act, under a Federal statutory demonstration authority, or under other Federal statutory or regulatory authority, the contract health care provider must not claim payment in any form from the Department or the State agency for items or services furnished in accordance with the agreement except as approved by HCFA or the State health care program, or otherwise shift the burden of such an agreement to the extent that increased payments are claimed from Medicare or a State health care program.

(ii) If the health plan is a health maintenance organization, competitive medical plan, health care prepayment plan, prepaid health plan, or other health plan that has executed a contract or agreement with HCFA or a State health care program to receive payment for enrollees on a reasonable cost or similar basis, the health plan and contract health care provider must comply with all of the following four standards—

(A) The term of the agreement between the health plan and the contract health care provider must be for not less than one year;

(B) The agreement between the health plan and the contract health care provider must specify in advance the covered items and services to be furnished to enrollees, which party is to file claims or requests for payment with Medicare or the State health care program for such items and services, and the schedule of fees the contract health care provider will charge for furnishing such items and services to enrollees;

(C) The fee schedule contained in the agreement between the health plan and the contract health care provider must remain in effect throughout the term of the agreement, unless a fee increase results directly from a payment update authorized by Medicare or the State health care program;

(D) The party submitting claims or requests for payment from Medicare or the State health care program for items and services furnished in accordance with the agreement must not claim or request payment for amounts in excess of the fee schedule;

(E) The contract health care provider and the health plan must fully and accurately report on any cost report filed with Medicare or a State health care program the fee schedule amounts charged in accordance with the agreement and, upon request, will report to the Medicare or a State health care program the terms of the agreement and the amounts paid in accordance with the agreement; and

(F) The party to the agreement, which does not have the responsibility under the agreement for filing claims or requests for payment, must not claim or request payment in any form.
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from the Department or the State health care program for items or services furnished in accordance with the agreement, or otherwise shift the burden of such an agreement to the extent that increased payments are claimed from Medicare or a State health care program.

(iv) If the health plan is not described in paragraphs (m)(1)(i) or (m)(1)(ii) of this section, and the contract health care provider is paid on an at-risk, capitated basis, both the health plan and contract health care provider must comply with all of the following five standards—

(A) The term of the agreement between the health plan and the contract health provider must be for not less than one year;

(B) The agreement between the health plan and the contract health care provider must specify in advance the covered items and services to be furnished to enrollees and the total amount per enrollee (which may be expressed in a per month or other time period basis) the contract health care provider will be paid by the health plan for furnishing such items and services to enrollees and must set forth any copayments, if any, to be paid by enrollees to the contract health care provider for covered services;

(C) The payment amount contained in the agreement between the health care plan and the contract health care provider must remain in effect throughout the term of the agreement;

(D) The contract health care provider and the health plan must fully and accurately report to the Medicare and State health care program upon request, the terms of the agreement and the amounts paid in accordance with the agreement; and

(E) The contract health care provider must not claim or request payment in any form from the Department, a State health care program or an enrollee (other than copayment amounts described in paragraph (m)(2)(iv)(B) of this section) and the health plan must not pay the contract care provider in excess of the amounts described in paragraph (m)(2)(iv)(B) of this section for items and services covered by the agreement.

(2) For purposes of this paragraph, the terms contract health care provider, enrollee, and health plan have the same meaning as in paragraph (l)(2) of this section.


§ 1001.953 OIG report on compliance with investment interest safe harbor.

Within 180 days of the effective date of this subpart, the OIG will report to the Secretary on the compliance with §§1001.952(a)(2)(i) and 1001.952(a)(2)(vi).


§ 1001.1001 Exclusion of entities owned or controlled by a sanctioned person.

(a) Circumstance for exclusion. (1) The OIG may exclude an entity if:

(i) A person with a relationship with such entity—

(A) Has been convicted of a criminal offense as described in sections 1128(a) and 1128(b) (1), (2) or (3) of the Act;

(B) Has had civil money penalties or assessments imposed under section 1128A of the Act; or

(C) Has been excluded from participation in Medicare or any of the State health care programs, and

(ii) Such a person—

(A) Has a direct or indirect ownership interest (or any combination thereof) of 5 percent or more in the entity;

(B) Is the owner of a whole or part interest in any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the entity or any of the property or assets thereof, in which whole or part interest is equal to or exceeds 5 percent of the total property and assets of the entity;

(C) Is an officer or director of the entity, if the entity is organized as a corporation;

(D) Is a partner in the entity, if the entity is organized as a partnership;

(E) Is an agent of the entity; or

(F) Is a managing employee, that is, an individual (including a general manager, business manager, administrator or director) who exercises operational or managerial control over the entity

or part thereof, or directly or indirectly conducts the day-to-day operations of the entity or part thereof.

(2) For purposes of this section, the term:
   Agent means any person who has express or implied authority to obligate or act on behalf of an entity.

   Indirect ownership interest includes an ownership interest through any other entities that ultimately have an ownership interest in the entity in issue. (For example, an individual has a 10 percent ownership interest in the entity at issue if he or she has a 20 percent ownership interest in a corporation that wholly owns a subsidiary that is a 50 percent owner of the entity in issue.)

   Ownership interest means an interest in:
   (i) The capital, the stock or the profits of the entity, or
   (ii) Any mortgage, deed, trust or note, or other obligation secured in whole or in part by the property or assets of the entity.

(b) Length of exclusion.

(1) Except as provided in §1001.3002(c), exclusions under this section will be for the same period as that of the individual whose relationship with the entity is the basis for this exclusion, if the individual has been or is being excluded.

(2) If the individual was not excluded, the length of the entity's exclusion will be determined by considering the factors that would have been considered if the individual had been excluded.

(3) An entity excluded under this section may apply for reinstatement at any time in accordance with the procedures set forth in §1001.3001.

[63 FR 46689, Sept. 2, 1998]


§1001.1051 Failure to disclose certain information.

(a) Circumstance for exclusion. The OIG may exclude any entity that did not fully and accurately, or completely, make disclosures as required by section 1124, 1124A or 1126 of the Act, and by part 455, subpart B and part 420, subpart C of this title.

(b) Length of exclusion. The following factors will be considered in determining the length of an exclusion under this section—

(1) The number of instances where full and accurate, or complete, disclosure was not made;

(2) The significance of the undisclosed information;

(3) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing (The lack of any prior record is to be considered neutral);

(4) Any other facts that bear on the nature or seriousness of the conduct;

(5) The availability of alternative sources of the type of health care services provided by the entity; and

§1001.1051 Exclusion of individuals with ownership or control interest in sanctioned entities.

(a) Circumstance for exclusion. The OIG may exclude any individual who—

(1) Has a direct or indirect ownership or control interest in a sanctioned entity, and who knows or should know (as defined in section 1128A(i)(6) of the Act) of the action constituting the basis for the conviction or exclusion set forth in paragraph (b) of this section; or

(2) Is an officer or managing employee (as defined in section 1128(b) of the Act) of such an entity.

(b) For purposes of paragraph (a) of this section, the term "sanctioned entity" means an entity that—

(1) Has been convicted of any offense described in §§1001.101 through 1001.401 of this part; or

(2) Has been terminated or excluded from participation in Medicare, Medicaid and all other Federal health care programs.

(c) Length of exclusion.

(1) If the entity has been excluded, the length of the individual's exclusion will be for the same period as that of the sanctioned entity with which the individual has the prohibited relationship.

(2) If the entity was not excluded, the length of the individual's exclusion will be determined by considering the factors that would have been considered if the entity had been excluded.

(3) An individual excluded under this section may apply for reinstatement in accordance with the procedures set forth in §1001.3001.
§ 1001.1201 Failure to provide payment information.

(a) Circumstance for exclusion. The OIG may exclude any individual or entity that furnishes items or services for which payment may be made under Medicare or any of the State health care programs and that:

(1) Fails to provide such information as is necessary to determine whether such payments are or were due and the amounts thereof, or

(2) Has refused to permit such examination and duplication of its records as may be necessary to verify such information.

(b) Length of exclusion. The following factors will be considered in determining the length of an exclusion under this section—

(1) The number of instances where information was not provided;

(2) The circumstances under which such information was not provided;

(3) The amount of the payments at issue;

(4) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing (The lack of any prior record is to be considered neutral); and

(5) The availability of alternative sources of the type of health care items or services provided by the individual or entity.


§ 1001.1301 Failure to grant immediate access.

(a) Circumstance for exclusion. (1) The OIG may exclude any individual or entity that fails to grant immediate access upon reasonable request to—

(i) The Secretary, a State survey agency or other authorized entity for the purpose of determining, in accordance with section 1864(a) of the Act, whether—

(A) An institution is a hospital or skilled nursing facility;

(B) An agency is a home health agency;

(C) An agency is a hospice program;

(D) A facility is a rural health clinic as defined in section 1861(aa)(2) of the Act, or a comprehensive outpatient rehabilitation facility as defined in section 1861(cc)(2) of the Act;

(E) A laboratory is meeting the requirements of section 1861(s)(15) and (16) of the Act, and section 353(f) of the Public Health Service Act;

(F) A clinic, rehabilitation agency or public health agency is meeting the requirements of section 1861(p)(4) (A) or (B) of the Act;

(G) An ambulatory surgical center is meeting the standards specified under section 1832(a)(2)(F) of the Act;

(H) A portable x-ray unit is meeting the requirements of section 1861(s)(3) of the Act;

(I) A screening mammography service is meeting the requirements of section 1834(c)(3) of the Act;

(J) An end-stage renal disease facility is meeting the requirements of section 1881(b) of the Act;

§ 1001.1101 Failure to disclose certain information.

(b) * * *

(3) The entity’s prior criminal, civil and administrative sanction record (The lack of any prior record is to be considered neutral);
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(K) A physical therapist in independent practice is meeting the requirements of section 1861(p) of the Act;

(L) An occupational therapist in independent practice is meeting the requirements of section 1861(g) of the Act;

(M) An organ procurement organization meets the requirements of section 1138(b) of the Act; or.

(N) A rural primary care hospital meets the requirements of section 1820(i)(2) of the Act;

(ii) The Secretary, a State survey agency or other authorized entity to perform the reviews and surveys required under State plans in accordance with sections 1902(a)(26) (relating to inpatient mental hospital services), 1902(a)(31) (relating to intermediate care facilities for the mentally retarded), 1919(g) (relating to nursing facilities), 1929(i) (relating to providers of home and community care and community care settings), 1902(a)(33) and 1903(g) of the Act;

(iii) The OIG for the purposes of reviewing records, documents and other data necessary to the performance of the Inspector General's statutory functions; or

(iv) A State Medicaid fraud control unit for the purpose of conducting its activities.

(2) For purposes of paragraphs (a)(1)(i) and (a)(1)(ii) of this section, the term—

Failure to grant immediate access means:

(i) Except where the OIG or State Medicaid fraud control unit reasonably believes that requested documents are about to be altered or destroyed, the failure to produce or make available for inspection and copying requested records upon reasonable request, or to provide a compelling reason why they cannot be produced, within 24 hours of such request;

(ii) Where the OIG or State Medicaid fraud control unit has reason to believe that requested documents are about to be altered or destroyed, the failure to provide access to requested records at the time the request is made.

Reasonable request means a written request for documents, signed by a designated representative of the OIG or the State Medicaid fraud control unit, and made by a properly identified agent of the OIG or a State Medicaid fraud control unit to perform the reviews and surveys required under State plans in accordance with titles V, XI, XVIII, XIX or XX of the Act. The request will include a statement of the authority for the request, the rights of the individual or entity in responding to the request, the definition of reasonable request and immediate access, and the effective date, length, and scope and effect of the exclusion that would be imposed for failure to comply with the request, and the earliest date that a request for reinstatement would be considered.

(4) Nothing in this section shall in any way limit access otherwise authorized under State or Federal law.

(b) Length of exclusion. (1) An exclusion of an individual under this section may be for a period equal to the sum of:

(i) The length of the period during which the immediate access was not granted, and

(ii) An additional period of up to 90 days.

(2) The exclusion of an entity may be for a longer period than the period in which immediate access was not granted based on consideration of the following factors—
§ 1001.1401 Violations of PPS corrective action.

(a) Circumstance for exclusion. The OIG may exclude any hospital that HCFCA determines has failed substantially to comply with a corrective action plan required by HCFCA under section 1886(f)(2)(B) of the Act.

(b) Length of exclusion. The following factors will be considered in determining the length of exclusion under this section—

(1) The impact of the hospital’s failure to comply on Medicare or any of the State health care programs, program beneficiaries or other individuals;

(2) The circumstances under which the failure occurred;

(3) The nature of the failure to comply;

(4) The impact of the failure on Medicare or any of the State health care programs, program beneficiaries or the public; and

(5) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing (The lack of any prior record is to be considered neutral).

(3) For purposes of paragraphs (b)(1) and (b)(2) of this section, the length of the period in which immediate access was not granted will be measured from the time the request is made, or from the time by which access was required to be granted, whichever is later.

(c) The exclusion will be effective as of the date immediate access was not granted.


Effective Date Note: At 63 FR 46689, Sept. 2, 1998, §1001.1401 was amended by revising paragraph (b)(5), effective Oct. 2, 1998. For the convenience of the user, the superseded text is set forth as follows:

§ 1001.1401 Violations of PPS corrective action.

* * * * *

(b) * * *

(iv) The entity’s prior criminal, civil or administrative sanction record (The lack of any prior record is to be considered neutral).

* * * * *

§ 1001.1501 Default of health education loan or scholarship obligations.

(a) Circumstance for exclusion. Except as provided in paragraph (a)(4) of this section, the OIG may exclude any individual that the Public Health Service (PHS) determines is in default on repayments of scholarship obligations or loans in connection with health professions education made or secured in whole or in part by the Secretary.

(b) Before imposing an exclusion in accordance with paragraph (a)(1) of this section, the OIG must determine—

(1) The impact of the failure to comply on Medicare or any of the State health care programs, program beneficiaries or other individuals;

(2) The circumstances under which the failure occurred;

(3) The nature of the failure to comply;

(4) The impact of the failure on Medicare or any of the State health care programs, program beneficiaries or the public; and

(5) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing (The lack of any prior record is to be considered neutral).


Effective Date Note: At 63 FR 46689, Sept. 2, 1998, §1001.1501 was amended by revising paragraph (b)(5), effective Oct. 2, 1998. For the convenience of the user, the superseded text is set forth as follows:

§ 1001.1501 Default of health education loan or scholarship obligations.

(b) * * *

(iv) The entity’s prior criminal, civil or administrative sanction record (The lack of any prior record is to be considered neutral).
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billing for services of as-

section 1842(j) of the Act;

(ii) The number of beneficiaries for whom services were billed in excess of the maximum allowable charges;

(iii) The amount of the charges that were in excess of the maximum allowable charges;

(iv) Whether the physician has a documented history of criminal, civil or administrative wrongdoing (The lack of any prior record is to be considered neutral); and

(v) The availability of alternative sources of the type of health care items or services furnished by the physician.

(2) The period of exclusion may not exceed 5 years.

§ 1001.1601 Violations of the limitations on physician charges.

(a) Circumstance for exclusion. (1) The OIG may exclude a physician whom it determines—

(i) Is a non-participating physician under section 1842(j) of the Act;

(ii) Furnished services to a beneficiary;

(iii) Knowingly and willfully billed—

(A) On a repeated basis for such services charges in excess of the maximum allowable actual charge determined in accordance with section 1842(j)(1)(C) of the Act for the period January 1, 1987 through December 31, 1990, or

(B) Individuals enrolled under part B of title XVIII of the Act during the statutory freeze for actual charges in excess of such physician's actual charges determined in accordance with section 1842(j)(1)(A) of the Act for the period July 1, 1984 to December 31, 1986; and

(iv) Is not the sole community physician or sole source of essential specialized services in the community.

(2) The OIG will take into account access of beneficiaries to physicians' services for which Medicare payment may be made in determining whether to impose an exclusion.

(b) Length of exclusion. (1) In determining the length of an exclusion in accordance with this section, the OIG will consider the following factors—

(i) The number of services for which the physician billed in excess of the maximum allowable charges;
(3) Is not the sole community physician or sole source of essential specialized services in the community.

(b) The OIG will take into account access of beneficiaries to physicians’ services for which Medicare payment may be made in determining whether to impose an exclusion.

(c) Length of exclusion. (1) In determining the length of an exclusion in accordance with this section, the OIG will consider the following factors—
   (i) The number of instances for which claims were submitted or beneficiaries were billed for unapproved use of assistants during cataract operations;
   (ii) The amount of the claims or bills presented;
   (iii) The circumstances under which the claims or bills were made, including whether the services were medically necessary;
   (iv) Whether approval for the use of an assistant was requested from the PRO or carrier;
   (v) Whether the physician has a documented history of criminal, civil or administrative wrongdoing (The lack of any prior record is to be considered neutral); and
   (vi) The availability of alternative sources of the type of health care items or services furnished by the physician.

(2) The period of exclusion may not exceed 5 years.


Effect Date Note: At 63 FR 46690, Sept. 2, 1998, § 1001.1701 was amended by revising paragraph (c)(1)(v), effective Oct. 2, 1998. For the convenience of the user, the superceded text is set forth as follows:

§ 1001.1701 Billing for services of assistant at surgery during cataract operations.

(a) The OIG has the authority to grant or deny a request from a State health care program that an exclusion from that program be waived with respect to an individual or entity, except that no waiver may be granted with respect to an exclusion under § 1001.101(b). The request must be in writing and from an individual directly responsible for administering the State health care program.

(b) With respect to exclusions under § 1001.101(a), a request from a State health care program for a waiver of the exclusion will only be considered if the individual or entity is the sole community physician or the sole source of essential specialized services in a community.

(c) With respect to exclusions imposed under subpart C of this part, a request for waiver will only be granted if the OIG determines that imposition of the exclusion would not be in the public interest.

(d) If the basis for the waiver ceases to exist, the waiver will be rescinded, and the individual or entity will be excluded for the period remaining on the exclusion, measured from the time the exclusion would have been imposed if the waiver had not been granted.

(e) In the event a waiver is granted, it is applicable only to the program(s) for which waiver is requested.

(f) The decision to grant, deny or rescind a request for a waiver is not subject to administrative or judicial review.

(g) The Inspector General may waive the exclusion of an individual or entity from participation in the Medicare program in conjunction with granting a waiver requested by a State health care program. If a State program waiver is rescinded, the derivative waiver of the exclusion from Medicare is automatically rescinded.

§ 1001.1801 Scope and effect of exclusion.

(a) Scope of exclusion. Exclusions of individuals and entities under this title will be from Medicare, State health care programs, and all other Executive
Branch procurement and nonprocurement programs and activities. The OIG will exclude the individual or entity from the Medicare program and direct State agency administering a State health care program to exclude the individual or entity for the same period. In the case of an individual or entity not eligible to participate in Medicare, the exclusion will still be effective on the date, and for the period, established by the OIG.

(b) Effect of exclusion on excluded individuals and entities. (1) Unless and until an individual or entity is reinstated into the Medicare program in accordance with subpart F of this part, no payment will be made by Medicare, Medicaid and all other Federal health care programs for any item or service furnished, on or after the effective date specified in the notice period, by an excluded individual or entity, or at the medical direction or on the prescription of a physician or other authorized individual who is excluded when the individual or entity furnishing such item or service knew, or had reason to know, of the exclusion. This section applies regardless of whether an individual or entity has obtained a program provider number or equivalent, either as an individual or as a member of a group, prior to being reinstated.

(2) An excluded individual or entity may not take assignment of an enrollee’s claim on or after the effective date of exclusion.

(3) An excluded individual or entity that submits, or causes to be submitted, claims for items or services furnished during the exclusion period is subject to civil money penalty liability under section 1128A(a)(1)(D) of the Act, and criminal liability under section 1128B(a)(1) of the Act and other provisions. In addition, submitting claims, or causing claims to be submitted or payments to be made for items or services furnished, ordered or prescribed, including administrative and management services or salary, may serve as the basis for denying reinstatement to the programs.

(c) Exceptions to paragraph (b)(1) of this section. (1) If an enrollee of Part B of Medicare submits an otherwise payable claim for items or services furnished by an excluded individual or entity, or under the medical direction of or on the prescription of an excluded physician or other authorized individual after the effective date of exclusion, HCFA will pay the first claim submitted by the enrollee and immediately notify the enrollee of the exclusion. (2) HCFA will not pay an enrollee for items or services furnished by an excluded individual or entity, or under the medical direction or on the prescription of an excluded physician or other authorized individual more than 15 days after the date on the notice to the enrollee, or after the effective date of the exclusion, whichever is later.

(3) Unless the Secretary determines that the health and safety of beneficiaries receiving services under Medicare or a State health care program warrants the exclusion taking effect earlier, payment may be made under such program for up to 30 days after the effective date of the exclusion for—

(i) Inpatient institutional services furnished for an individual who was admitted to an excluded institution before the date of the exclusion,

(ii) Home health services and hospice care furnished to an individual under a plan of care established before the effective date of the exclusion, and

(iii) Any health care items that are ordered by a practitioner, provider or supplier from an excluded manufacturer before the effective date of the exclusion and delivered within 30 days of the effective date of such exclusion. (For the period October 2, 1998, to October 4, 1999, payment may be made under Medicare or a State health care program for up to 60 days after the effective date of the exclusion for any health care items that are ordered by a practitioner, provider or supplier from an excluded manufacturer before the effective date of such exclusion and delivered within 60 days of the effective date of the exclusion.)

(4) HCFA will not pay any claims submitted by, or for items or services ordered or prescribed by, an excluded provider for dates of service 15 days or more after the notice of the provider’s exclusion was mailed to the supplier.

(5)(i) Notwithstanding the other provisions of this section, payment may be made under Medicare or a State health care program for certain emergency
§ 1001.2001 Notice of intent to exclude.

(a) Except as provided in paragraph (b) of this section, if the OIG proposes to exclude an individual or entity in accordance with subpart C of this part, or in accordance with subpart B of this part where the exclusion is for a period exceeding 5 years, it will send written notice of its intent, the basis for the proposed exclusion and the potential effect of an exclusion. Within 30 days of receipt of notice, which will be deemed to be 5 days after the date on the notice, the individual or entity may submit documentary evidence and written argument concerning whether the exclusion is warranted and any related issues. In conjunction with this submission, an individual or entity may request an opportunity to present oral argument to an OIG official.
(b) Exception. If the OIG proposes to exclude an individual or entity under the provisions of §§1001.1301, 1001.1401 or 1001.1501 of this part, paragraph (a) of this section will not apply.

(c) If an entity has a provider agreement under section 1866 of the Act, and the OIG proposes to terminate that agreement in accordance with section 1866(b)(2)(C) of the Act, the notice provided for in paragraph (a) of this section will so state.

[63 FR 46690, Sept. 2, 1998]

**EFFECTIVE DATE NOTE:** At 63 FR 46690, Sept. 2, 1998, §1001.2001 was revised, effective Oct. 2, 1998. For the convenience of the user, the superseded text is set forth as follows:

§ 1001.2001 Notice of intent to exclude.

(a) Except as provided in paragraph (c) of this section, if the OIG proposes to exclude an individual or entity in accordance with subpart C of this part or in accordance with subpart B of this part where the exclusion is for a period exceeding 5 years, it will send written notice of its intent, the basis for the proposed exclusion, and the potential effect of an exclusion. Within 30 days of receipt of notice, which will be deemed to be 5 days after the date on the notice, the individual or entity may submit documentary evidence and written argument concerning whether the exclusion is warranted and any related issues.

(b) If the OIG proposes to exclude an individual or entity in accordance with §§1001.701 or 1001.801, the individual or entity may submit, in addition to the information described in paragraph (a) of this section, a written request to present evidence or argument orally to an OIG official.

(c) Exception. If the OIG proposes to exclude an individual or entity under the provisions of §§1001.1301, 1001.1401 or 1001.1501, paragraph (a) of this section will not apply.

(d) If an entity has a provider agreement under section 1866 of the Act, and the OIG proposes to terminate that agreement in accordance with section 1866(b)(2)(C) of the Act, the notice provided for in paragraphs (a) and (b) of this section will so state.

§ 1001.2002 Notice of exclusion.

(a) Except as provided in §1001.2003, if the OIG determines that exclusion is warranted, it will send a written notice of this decision to the affected individual or entity.

(b) The exclusion will be effective 20 days from the date of the notice.

(c) The written notice will state—

1. The basis for the exclusion;
2. The length of the exclusion and, where applicable, the factors considered in setting the length;
3. The effect of the exclusion;
4. The earliest date on which the OIG will consider a request for reinstatement;
5. The requirements and procedures for reinstatement; and
6. The appeal rights available to the excluded individual or entity.

(d) Paragraph (b) of this section does not apply to exclusions imposed in accordance with §1001.1301.

(e) No later than 15 days prior to the final exhibit exchanges required under §1005.8 of this chapter, the OIG may amend its notice letter if information comes to light that justifies the imposition of a different period of exclusion other than the one proposed in the original notice letter.


**EFFECTIVE DATE NOTE:** At 63 FR 46690, Sept. 2, 1998, §1001.2002 was amended by adding a new paragraph (e), effective Oct. 2, 1998.

§ 1001.2003 Notice of proposal to exclude.

(a) Except as provided in paragraph (c) of this section, if the OIG proposes to exclude an individual or entity in accordance with §§1001.901, 1001.951, 1001.1601 or 1001.1701, it will send written notice of this decision to the affected individual or entity. The written notice will provide the same information set forth in §1001.2002(c). If an entity has a provider agreement under section 1866 of the Act, and the OIG also proposes to terminate that agreement in accordance with section 1866(b)(2)(C) of the Act, the notice will so indicate. The exclusion will be effective 60 days after the receipt of the notice (as defined in §1005.2 of this chapter) unless, within that period, the individual or entity files a written request for a hearing in accordance with part 1005 of this chapter. Such request must set forth—

1. The specific issues or statements in the notice with which the individual or entity disagrees;
2. The basis for that disagreement;
3. The defenses on which reliance is intended;
§ 1001.2004 Notice of proposal to exclude.

(4) Any reasons why the proposed length of exclusion should be modified; and

(5) Reasons why the health or safety of individuals receiving services under Medicare or any of the State health care programs does not warrant the exclusion going into effect prior to the completion of an administrative law judge (ALJ) proceeding in accordance with part 1005 of this chapter.

(b)(1) If the individual or entity does not make a written request for a hearing as provided for in paragraph (a) of this section, the OIG will send a notice of exclusion as described in §1001.2002.

(2) If the individual or entity makes a timely written request for a hearing and the OIG determines that the health or safety of individuals receiving services under Medicare or any of the State health care programs does not warrant an immediate exclusion, an exclusion will not go into effect unless an ALJ upholds the decision to exclude.

(c) If, prior to issuing a notice of proposal to exclude under paragraph (a) of this section, the OIG determines that the health or safety of individuals receiving services under Medicare or any of the State health care programs warrants the exclusion taking place prior to the completion of an ALJ proceeding in accordance with part 1005 of this chapter, the OIG will proceed under §§1001.2001 and 1001.2002.


EFFECTIVE DATE NOTE: At 63 FR 46690, Sept. 2, 1998, §1001.2003 was amended by revising introductory paragraph (a), effective Oct. 2, 1998. For the convenience of the user, the superseded text is set forth as follows:

§ 1001.2003 Notice of proposal to exclude.

(a) Except as provided in paragraph (c) of this section, if the OIG proposes to exclude an individual or entity in accordance with §§1001.901, 1001.951, 1001.1601 or 1001.1701, it will send written notice of this decision to the affected individual or entity. The written notice will provide the same information set forth in §1001.2002(c). If an entity has a provider agreement under section 1866 of the Act, and the OIG also proposes to terminate that agreement in accordance with section 1866(b)(2)(C) of the Act, the notice will so indicate. The exclusion will be effective 60 days after the date of the notice unless, within that period, the individual or entity files a written request for a hearing in accordance with part 1005 of this chapter. Such request must set forth—

* * * * * *

§ 1001.2004 Notice to State agencies.

HHS will promptly notify each appropriate State agency administering or supervising the administration of each State health care program of:

(a) The facts and circumstances of each exclusion, and

(b) The period for which the State agency is being directed to exclude the individual or entity.

§ 1001.2005 Notice to State licensing agencies.

(a) HHS will promptly notify the appropriate State(s) or local agencies or authorities having responsibility for the licensing or certification of an individual or entity excluded (or directed to be excluded) from participation of the facts and circumstances of the exclusion.

(b) HHS will request that appropriate investigations be made and sanctions invoked in accordance with applicable State law and policy, and will request that the State or local agency or authority keep the Secretary and the OIG fully and currently informed with respect to any actions taken in response to the request.

§ 1001.2006 Notice to others regarding exclusion.

(a) HHS will give notice of the exclusion and the effective date to the public, to beneficiaries (in accordance with §1001.1901(c)), and, as appropriate, to—

(1) Any entity in which the excluded individual is known to be serving as an employee, administrator, operator, or in which the individual is serving in any other capacity and is receiving payment for providing services (The lack of this notice will not affect HCFA’s ability to deny payment for services);

(2) State Medicaid Fraud Control Units;

(3) Utilization and Quality Control Peer Review Organizations;

(4) Hospitals, skilled nursing facilities, home health agencies and health maintenance organizations;
(5) Medical societies and other professional organizations;
(6) Contractors, health care prepayment plans, private insurance companies and other affected agencies and organizations;
(7) The State and Area Agencies on Aging established under title III of the Older Americans Act;
(8) The National Practitioner Data Bank.
(9) Other Departmental operating divisions, Federal agencies, and other agencies or organizations, as appropriate.

(b) In the case of an exclusion under § 1001.101 of this chapter, if section 304(a)(5) of the Controlled Substances Act (21 U.S.C. 824(a)(5)) applies, HHS will give notice to the Attorney General of the United States of the facts and circumstances of the exclusion and the length of the exclusion.


Effective Date Note: At 63 FR 46690, Sept. 2, 1998, § 1001.2006 was amended by republishing introductory paragraph (a); revising paragraphs (a)(1) and (a)(7); redesignating existing paragraph (a)(8) as (a)(9); and by adding a new paragraph (a)(10), effective Oct. 2, 1998. For the convenience of the user, the superseded text is set forth as follows:

§ 1001.2006 Notice to others regarding exclusion.
(a) * * *
(1) Any entity in which the excluded individual or entity is known to be serving as an employee, administrator, operator, or in which the individual or entity is serving in any other capacity and is receiving payment for providing services (The lack of this notice will not affect HCFA’s ability to deny payment for services);

* * * * *
(7) The State and Area Agencies on Aging established under title III of the Older Americans Act; and
(8) Other Departmental operating divisions, Federal agencies, and other agencies or organizations, as appropriate.

§ 1001.2007 Appeal of exclusions.
(a)(1) Except as provided in § 1001.2003, an individual or entity excluded under this Part may file a request for a hearing before an ALJ only on the issues of whether:

(i) The basis for the imposition of the sanction exists, and
(ii) The length of exclusion is unreasonable.
(2) When the OIG imposes an exclusion under subpart B of this part for a period of 5 years, paragraph (a)(1)(ii) of this section will not apply.
(3) The request for a hearing should contain the information set forth in § 1005.2(d) of this chapter.
(b) The excluded individual or entity has 60 days from the receipt of notice of exclusion provided for in § 1001.2002 to file a request for such a hearing.
(c) The standard of proof at a hearing is preponderance of the evidence.
(d) When the exclusion is based on the existence of a conviction, a determination by another government agency or any other prior determination, the basis for the underlying determination is not reviewable and the individual or entity may not collaterally attack the underlying determination, either on substantive or procedural grounds, in this appeal.
(e) The procedures in part 1005 of this chapter will apply to the appeal.

Subpart F—Reinstatement into the Programs

§ 1001.3001 Timing and method of request for reinstatement.
(a)(1) Except as provided in paragraphs (a)(2) and (a)(3) of this section or in § 1001.501(b)(4) of this Part, an excluded individual or entity (other than those excluded in accordance with §§ 1001.1001 and 1001.1501) may submit a written request for reinstatement to the OIG only after the date specified in the notice of exclusion. Submitting a program provider number or equivalent does not reinstate eligibility.

(2) An entity under § 1001.1001 may apply for reinstatement prior to the date specified in the notice of exclusion by submitting a written request for reinstatement that includes documentation demonstrating that the OIG must be met.
(3) Upon receipt of a written request, the OIG will require the requestor to furnish specific information and authorization to obtain information from private health insurers, peer review bodies, probation officers, professional
§ 1001.3002 Basis for reinstatement.

(a)(1) The OIG will authorize reinstatement if it determines that—
(i) The period of exclusion has expired;
(ii) There are reasonable assurances that the types of actions that formed the basis for the original exclusion have not recurred and will not recur; and
(iii) There is no additional basis under sections 1128(a) or (b) or 1128A of the Act for continuation of the exclusion.

(2) Submitting claims or causing claims to be submitted or payments to be made by the programs for items or services furnished, ordered or prescribed, including administrative and management services or salary, may serve as the basis for denying reinstatement. This section applies regardless of whether an individual or entity has obtained a program provider number or equivalent, either as an individual or as a member of a group, prior to being reinstated.

(b) In making the reinstatement determination, the OIG will consider—
(1) Conduct of the individual or entity occurring prior to the date of the notice of exclusion, if not known to the OIG at the time of the exclusion;
(2) Conduct of the individual or entity after the date of the notice of exclusion;
(3) Whether all fines, and all debts due and owing (including overpayments) to any Federal, State or local government that relate to Medicare, Medicaid and all other Federal health care programs, have been paid or satisfactory arrangements have been made to fulfill these obligations; and
(4) Whether HCFA has determined that the individual or entity complies with, or has made satisfactory arrangements to fulfill, all of the applicable conditions of participation or supplier conditions for coverage under the statutes and regulations.

(c) If the OIG determines that the criteria in paragraphs (a)(1)(ii) and (iii) of this section have been met, an entity excluded in accordance with §1001.1001 will be reinstated upon a determination by the OIG that the individual whose conviction, exclusion or civil money penalty was the basis for the entity's exclusion—
(1) Has reduced his or her ownership or control interest in the entity below 5 percent;
(2) Is no longer an officer, director, agent or managing employee of the entity; or
(3) Has been reinstated in accordance with paragraph (a) of this section or §1001.3005.

(d) Reinstatement will not be effective until the OIG grants the request and provides notice under §1001.3003(a) of this part. Reinstatement will be effective as provided in the notice.

(e) A determination with respect to reinstatement is not appealable or reviewable except as provided in §1001.3004.
(f) An ALJ may not require reinstatement of an individual or entity in accordance with this chapter.


EFFECTIVE DATE NOTE: At 63 FR 46691, Sept. 2, 1998, §1001.3002 is amended by revising paragraph (a); republishing introductory paragraph (b), revising paragraphs (b)(3) and (4) and deleting paragraph (b)(5); and by revising introductory paragraph (c) and paragraph (d), effective Oct. 2, 1998. For the convenience of the user, the superseded text is set forth as follows:

§ 1001.3002 Basis for reinstatement.

(a) The OIG will authorize reinstatement if it determines that—

(1) The period of exclusion has expired;

(2) There are reasonable assurances that the types of actions that formed the basis for the original exclusion have not recurred and will not recur; and

(3) There is no additional basis under sections 1128 (a) or (b) or 1128A of the Act for continuation of the exclusion.

(b) * * *

(3) Whether all fines, and all debts due and owing (including overpayments) to any Federal, State or local government that relate to Medicare or any of the State health care programs, have been paid or satisfactory arrangements have been made to fulfill these obligations;

(4) Whether HCFA has determined that the individual or entity complies with, or has made satisfactory arrangements to fulfill, all of the applicable conditions of participation or supplier conditions for coverage under the statutes and regulations; and

(c) If the OIG determines that the criteria in paragraphs (a)(2) and (a)(3) of this section have been met, an entity excluded in accordance with §1001.1001 will be reinstated upon a determination by the OIG that the individual whose conviction, exclusion or civil money penalty was the basis for the entity’s exclusion—

* * * * *

(d) Reinstatement will not be effective until OIG grants the request and provides notice under §1001.3003(a)(1). Reinstatement will be effective as provided in the notice.

* * * * *

§ 1001.3003 Approval of request for reinstatement.

(a) If the OIG grants a request for reinstatement, the OIG will—

(1) Notify HCFA of the date of the individual’s or entity’s reinstatement in the Medicare program;

(2) Give written notice to the excluded individual or entity specifying the date when Medicare participation may resume;

(3) Notify State agencies that administer the State health care programs that the individual or entity has been reinstated into the Medicare program; and

(4) To the extent applicable, give notice to those agencies, groups, individuals and others that were originally notified of the exclusion.

(b) If the OIG makes a determination to reinstate an individual or entity under Medicare, the State health care program upon notification from the OIG must automatically reinstate the individual or entity under such program, effective on the date of reinstatement under Medicare, unless—

(1) Reinstatement is not available to such excluded party under State law, or

(2) A longer exclusion period was established in accordance with the State’s own authorities and procedures.

§ 1001.3004 Denial of request for reinstatement.

(a) If a request for reinstatement is denied, OIG will give written notice to the requesting individual or entity. Within 30 days of the date on the notice, the excluded individual or entity may submit:

(1) Documentary evidence and written argument against the continued exclusion,

(2) A written request to present written evidence and oral argument to an OIG official, or

(3) Both documentary evidence and a written request.

(b) After evaluating any additional evidence submitted by the excluded individual or entity (or at the end of the 30-day period, if none is submitted), the OIG will send written notice either confirming the denial, and indicating that a subsequent request for reinstatement will not be considered until
§ 1001.3005 Reversed or vacated decisions.
(a) An individual or entity will be reinstated into the Medicare program retroactive to the effective date of the exclusion when such exclusion is based on—
(1) A conviction that is reversed or vacated on appeal; or
(2) An action by another agency, such as a State agency or licensing board, that is reversed or vacated on appeal.
(b) If an individual or entity is reinstated in accordance with paragraph (a) of this section, HCFA will make payment for services covered under Medicare that were furnished or performed during the period of exclusion.
(c) The OIG will give notice of a reinstatement under this section in accordance with §1001.3003(a).
(d) An action taken by OIG under this section will not require any State health care program to reinstate the individual or entity if it has imposed an exclusion under its own authority.

Subpart A—General Provisions

§ 1002.1 Scope and purpose.

The regulations in this part specify certain bases upon which individuals and entities may, or in some cases must, be excluded from participation in the Medicaid program. These regulations specifically address the authority of State agencies to exclude on their own initiative, regardless of whether the OIG has excluded an individual or entity under part 1001 of this chapter. These regulations also delineate the States’ obligation to inform the OIG of certain Medicaid-related convictions.

PART 1002—PROGRAM INTEGRITY—STATE-INITIATED EXCLUSIONS FROM MEDICAID

Subpart A—General Provisions

Sec.
1002.1 Scope and purpose.
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1002.3 Disclosure by providers and State Medicaid agencies.
1002.100 State plan requirement.

Subpart B—Mandatory Exclusion

1002.203 Mandatory exclusion.

Subpart C—Permissive Exclusions

1002.210 Permissive exclusions; general authority.
1002.211 Effect of exclusion.
1002.212 State agency notifications.
1002.213 Appeals of exclusions.
1002.214 Basis for reinstatement after State agency-initiated exclusion.

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1002.215 Action on request for reinstatement.

Subpart D—Notification to OIG of State or Local Convictions of Crimes Against Medicaid

1002.220 Notification of State or local convictions of crimes against Medicaid.

Authority: 42 U.S.C. 1320a-3, 1320a-5, 1320a-7, 1396(a)(4)(A), 1396(p)(1), 1396a(30), 1396a(39), 1396d(a)(6), 1396d(b)(3), 1396b(i)(2) and 1396b(q).

Source: 57 FR 3343, Jan. 29, 1992, unless otherwise noted.

Subpart A—General Provisions

§ 1002.1 Scope and purpose.

The regulations in this part specify certain bases upon which individuals and entities may, or in some cases must, be excluded from participation in the Medicaid program. These regulations specifically address the authority of State agencies to exclude on their own initiative, regardless of whether the OIG has excluded an individual or entity under part 1001 of this chapter. These regulations also delineate the States’ obligation to inform the OIG of certain Medicaid-related convictions.

§ 1002.2 General authority.

(a) In addition to any other authority it may have, a State may exclude an individual or entity from participation in the Medicaid program for any reason for which the Secretary could exclude that individual or entity from participation in the Medicare program under sections 1128, 1128A or 1866(b)(2) of the Social Security Act.

(b) Nothing contained in this part should be construed to limit a State’s own authority to exclude an individual or entity from Medicaid for any reason or period authorized by State law.

§ 1002.3 Disclosure by providers and State Medicaid agencies.

(a) Information that must be disclosed. Before the Medicaid agency enters into or renews a provider agreement, or at any time upon written request by the Medicaid agency, the provider must disclose to the Medicaid agency the identity of any person described in §1001.1001(a)(1) of this chapter.
(b) Notification to Inspector General. (1) The Medicaid agency must notify the Inspector General of any disclosures made under paragraph (a) of this section within 20 working days from the date it receives the information.

(2) The agency must promptly notify the Inspector General of any action it takes on the provider’s application for participation in the program.

(3) The agency must also promptly notify the Inspector General of any action it takes to limit the ability of an individual or entity to participate in its program, regardless of what such an action is called. This includes, but is not limited to, suspension actions, settlement agreements and situations where an individual or entity voluntarily withdraws from the program to avoid a formal sanction.

(c) Denial or termination of provider participation. (1) The Medicaid agency may refuse to enter into or renew an agreement with a provider if any person who has ownership or control interest in the provider, or who is an agent or managing employee of the provider, has been convicted of a criminal offense related to that person’s involvement in any program established under Medicare, Medicaid or the title XX Services program.

(2) The Medicaid agency may refuse to enter into, or terminate, a provider agreement if it determines that the provider did not fully and accurately make any disclosure required under paragraph (a) of this section.

[57 FR 3343, Jan. 29, 1992, as amended at 63 FR 46691, Sept. 2, 1998]

Effective Date Note: At 63 FR 46691, Sept. 2, 1998, §1002.3 was amended by revising the section heading and paragraph (b)(2), and by adding a new paragraph (b)(3), effective Oct. 2, 1998. For the convenience of the user, the superseded text is set forth as follows:

§1002.3 Disclosure by providers: information on persons convicted of crimes.

| * | * | * | * | * | *

(b) * * *

(2) The agency must also promptly notify the Inspector General of any action it takes on the provider’s application for participation in the program.

§1002.100 State plan requirement.

The plan must provide that the requirements of this subpart are met. However, the provisions of these regulations are minimum requirements. The agency may impose broader sanctions if it has the authority to do so under State law.

Subpart B—Mandatory Exclusion

§1002.203 Mandatory exclusion.

(a) The State agency, in order to receive Federal financial participation (FFP), must provide that it will exclude from participation any HMO, or entity furnishing services under a waiver approved under section 1915(b)(1) of the Act, if such organization or entity—

(1) Could be excluded under §1001.1001 or §1001.1051 of this chapter, or

(2) Has, directly or indirectly, a substantial contractual relationship with an individual or entity that could be excluded under §1001.1001 or §1001.1051 of this chapter.

(b) As used in this section, the term—Exclude includes the refusal to enter into or renew a participation agreement or the termination of such an agreement.

Substantial contractual relationship is one in which the sanctioned individual described in §1001.1001 of this chapter has direct or indirect business transactions with the organization or entity that, in any fiscal year, amount to more than $25,000 or 5 percent of the organization’s or entity’s total operating expenses, whichever is less. Business transactions include, but are not limited to, contracts, agreements, purchase orders, or leases to obtain services, supplies, equipment, space or salaried employment.

[57 FR 3343, Jan. 29, 1992, as amended at 63 FR 46691, Sept. 2, 1998]

Effective Date Note: At 63 FR 46691, Sept. 2, 1998, §1002.203 was amended by revising paragraph (a), effective Oct. 2, 1998. For the convenience of the user, the superseded text is set forth as follows:

§1002.203 Mandatory exclusion.

(a) The State agency, in order to receive Federal financial participation (FFP), must provide that it will exclude from participation any HMO, or entity furnishing services
§ 1002.210

under a Waiver approved under section 1915(b)(1) of the Act, if such organization or entity—

(1) Could be excluded under §1001.1001 of this chapter, or

(2) Has, directly or indirectly, a substantial contractual relationship with an individual or entity that could be excluded under §1001.1001 of this chapter.

* * * * *

Subpart C—Permissive Exclusions

§ 1002.210 Permissive exclusions; general authority.

The State agency must have administrative procedures in place that enable it to exclude an individual or entity for any reason for which the Secretary could exclude such individual or entity under parts 1001 or 1003 of this chapter. The period of such exclusion is at the discretion of the State agency.

§ 1002.211 Effect of exclusion.

(a) Denial of payment. Except as provided for in §1001.1901(c)(3), (c)(4), and (c)(5)(i) of this chapter, no payment may be made by the State agency for any item or service furnished on or after the effective date specified in the notice by an excluded individual or entity, or at the medical direction or on the prescription of a physician who is excluded when a person furnishing such item or service knew, or had reason to know, of the exclusion.

(b) Denial of FFP. FFP is not available where the State agency is required to deny payment under paragraph (a) of this section. FFP will be reinstated at such time as the excluded individual or entity is reinstated in the Medicaid program.

[57 FR 3343, Jan. 29, 1992, as amended at 63 FR 46691, Sept. 2, 1998]

Effective Date Note: At 63 FR 46691, Sept. 2, 1998, §1002.211 was amended by revising paragraph (a), effective Oct. 2, 1998. For the convenience of the user, the superseded text is set forth as follows:

§ 1002.211 Effect of exclusion.

(a) Denial of payment. Except as provided for in §1001.1901(c)(3) and (c)(4)(i) of this chapter, no payment may be made by the State agency for any item or service furnished on or after the effective date specified in the notice by an excluded individual or entity, or at the medical direction or on the prescription of a physician who is excluded when a person furnishing such item or service knew, or had reason to know, of the exclusion.

* * * * *

§ 1002.212 State agency notifications.

When the State agency initiates an exclusion under §1002.210, it must provide to the individual or entity subject to the exclusion notification consistent with that required in subpart E of part 1001 of this chapter, and must notify other State agencies, the State medical licensing board (where applicable), the public, beneficiaries, and others as provided in §§1001.2005 and 1001.2006 of this chapter.

§ 1002.213 Appeals of exclusions.

Before imposing an exclusion under §1002.210, the State agency must give the individual or entity the opportunity to submit documents and written argument against the exclusion. The individual or entity must also be given any additional appeals rights that would otherwise be available under procedures established by the State.

§ 1002.214 Basis for reinstatement after State agency-initiated exclusion.

(a) The provisions of this section and §1002.215 apply to the reinstatement in the Medicaid program of all individuals or entities excluded in accordance with §1002.210, if a State affords reinstatement opportunity to those excluded parties.

(b) An individual or entity who has been excluded from Medicaid may be reinstated only by the Medicaid agency that imposed the exclusion.

(c) An individual or entity may submit to the State agency a request for reinstatement at any time after the date specified in the notice of exclusion.

§ 1002.215 Action on request for reinstatement.

(a) The State agency may grant reinstatement only if it is reasonably certain that the types of actions that
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formed the basis for the original exclusion have not recurred and will not recur. In making this determination, the agency will consider, in addition to any factors set forth in State law—

(1) The conduct of the individual or entity occurring prior to the date of the notice of exclusion, if not known to the agency at the time of the exclusion;

(2) The conduct of the individual or entity after the date of the notice of exclusion; and

(3) Whether all fines, and all debts due and owing (including overpayments) to any Federal, State or local government that relate to Medicare or any of the State health care programs, have been paid, or satisfactory arrangements have been made, that fulfill these obligations.

(b) Notice of action on request for reinstatement. (1) If the State agency approves the request for reinstatement, it must give written notice to the excluded party, and to all others who were informed of the exclusion in accordance with §1002.212, specifying the date on which Medicaid program participation may resume.

(2) If the State agency does not approve the request for reinstatement, it will notify the excluded party, and all others who were informed of the exclusion in accordance with §1002.212, of the case, it must send notice within 15 days after the conviction.

(c) If the State agency was not so involved, it must give notice within 15 days after it learns of the conviction.

PART 1003—CIVIL MONEY PENALTIES, ASSESSMENTS AND EXCLUSIONS

Sec. 1003.100 Basis and purpose.

1003.101 Definitions.

1003.102 Basis for civil money penalties and assessments.

1003.103 Amount of penalty.

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1003.129 Notice to other agencies.

1003.132 Limitations.

1003.133 Statistical sampling.

1003.134 Effect of exclusion.

1003.135 Reinstatement.

AUTHORITY: 42 U.S.C. 1320±7, 1320±7a, 1320±7(c), 1320b±10, 1395m, 1395n(g), 1395ss(d), 1396b(m), 11131(c) and 11137(b)(2).

SOURCE: 51 FR 34777, Sept. 30, 1986, unless otherwise noted.

§ 1003.100 Basis and purpose.

(a) Basis. This part implements sections 1128(c), 1128A, 1140, 1842(j), 1842(k), 1876(i)(6), 1877(g), 1882(d) and 1903(m)(5) of the Social Security Act, and sections 421(c) and 427(b)(2) of Pub. L. 99±660 (42 U.S.C. 1320±7, 1320±7a, 1320±7(c), 1330b(10), 1395m, 1395n(g), 1395ss(d), 1395u(j), 1395u(k), 1396b(m), 11131(c) and 11137(b)(2)).

(b) Purpose. This part—

(1) Provides for the imposition of civil money penalties and, as applicable, assessments against persons who—

(i) Have submitted certain prohibited claims under the Medicare, Medicaid,
or the Maternal and Child Health Services or Social Services Block Grant programs;

(ii) Seek payment in violation of the terms of an assignment agreement or a limitation on charges or payments under the Medicare program, or a requirement not to charge in excess of the amount permitted under the Medicaid program;

(iii) Give false or misleading information that might affect the decision to discharge a Medicare patient from the hospital;

(iv) Fail to report information concerning medical malpractice payments or who improperly disclose, use or permit access to information reported under part B of title IV of Public Law 99–660, and regulations specified in 45 CFR part 60;

(v) Misuse certain Departmental and Medicare and Medicaid program words, letters, symbols or emblems;

(vi) Violate a requirement of section 1867 of the Act or § 489.24 of this title;

(vii) Substantially fail to provide an enrollee with required medically necessary items and services, or who engage in certain marketing, enrollment, reporting, claims payment, employment or contracting abuses, or that do not meet the requirements for physician incentive plans for Medicare specified in §§ 417.479 (d) through (i) of this title;

(viii) Have submitted certain prohibited claims under the Medicare program;

(ix) Present or cause to be presented a bill or claim for designated health service (as defined in § 411.351 of this title) that they know, or should know, were furnished in accordance with a referral prohibited under § 411.353 of this title;

(x) Have collected amounts that they know or should know were billed in violation of § 411.353 of this title and have not refunded the amounts collected on a timely basis; or

(xi) Are physicians or entities that enter into an arrangement or scheme that they know or should know has as a principal purpose the assuring of referrals by the physician to a particular entity which, if made directly, would violate the provisions of § 411.353 of this title.

(2) Provides for the exclusion of persons from the Medicare or State health care programs against whom a civil money penalty or assessment has been imposed, and the basis for reinstatement of persons who have been excluded; and

(3) Sets forth the appeal rights of persons subject to a penalty, assessment and exclusion.


§ 1003.101 Definitions.

For purposes of this part:

Act means the Social Security Act.

Adverse effect means medical care has not been provided and the failure to provide such necessary medical care has presented an imminent danger to the health, safety, or well-being of the patient or has placed the patient unnecessarily in a high-risk situation.

ALJ means an Administrative Law Judge.

Assessment means the amount described in § 1003.104, and includes the plural of that term.

Claim means an application for payment for an item or service for which payment may be made under Medicare, Medicaid, or a State plan for medical assistance, or

(a) An item or service for which payment may be made under Medicaid, or

(b) An item or service for which medical assistance is provided under a State plan for medical assistance, or

(c) An item or service for which payment may be made under the Maternal and Child Health Services Block Grant program.

Contracting organization means a public or private entity, including of a health maintenance organization (HMO), competitive medical plan, or health insuring organization (HIO) which meets the requirements of section 1876(b) of the Act or is subject to the requirements in sections 1903(m)(2)(A) of the Act and which has contracted with the Department or a State to furnish services to Medicare beneficiaries or Medicaid recipients.

Department means the Department of Health and Human Services.
Enrollee means an individual who is eligible for Medicare or Medicaid and who enters into an agreement to receive services from a contracting organization that contracts with the Department under title XVIII or title XIX of the Act.

Exclusion means the temporary or permanent barring of a person from participation in the Medicare program or in a State health care program, and that items or services furnished or ordered by such person are not reimbursed under such programs.

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

HCFA means the Health Care Financing Administration.

Inspector General means the Inspector General of the Department or his or her designees.

Item or service includes (a) any item, device, medical supply or service claimed to have been provided to a patient and listed in an itemized claim for program payment or a request for payment, and (b) in the case of a claim based on costs, any entry or omission in a cost report, books of account or other documents supporting the claim.

Maternal and Child Health Services Block Grant program means the program authorized under Title V of the Act.

Medicaid means the program of grants to the States for medical assistance authorized under title XIX of the Act.

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

Participating hospital means (1) a hospital or (2) a rural primary care hospital as defined in section 1861(mm)(1) of the Act that has entered into a Medicare provider agreement under section 1866 of the Act.

Penalty means the amount described in §1003.103 and includes the plural of that term.

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

Physician incentive plan means any compensation arrangement between a contracting organization and a physician group that may directly or indirectly have the effect of reducing or limiting services provided with respect to enrollees in the organization.

Program means the Medicare, Medicaid, Maternal and Child Health Services Block Grant, and Social Services Block Grant programs.

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

Respondent means the person upon whom the Department has imposed, or proposes to impose, a penalty, assessment or exclusion.

Responsible physician means a physician who is responsible for the examination, treatment, or transfer of an individual who comes to a participating hospital’s emergency department seeking assistance and includes a physician on call for the care of such individual.

Secretary means the Secretary of the Department or his or her designees.

Social Services Block Grant program means the program authorized under title XX of the Social Security Act.

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

State health care program means a State plan approved under title XIX of the Act, any program receiving funds under title V of the Act or from an allotment to a State under such title, or any program receiving funds under title XX of the Act or from an allotment to a State under such title.

Timely basis means, in accordance with §1003.102(b)(9) of this part, the 60-
§ 1003.102 Basis for civil money penalties and assessments.

(a) The OIG may impose a penalty and assessment against any person whom it determines in accordance with this part has presented, or caused to be presented, a claim which is for—

1. An item or service that the person knew, or should have known, was not provided as claimed;

2. An item or service for which the person knew, or should have known, that the claim was false or fraudulent;

3. An item or service furnished during a period in which the person was excluded from participation in the program to which the claim was made in accordance with a determination made under sections 1128 (42 U.S.C. 1320a-7), 1128A (42 U.S.C. 1320a-7a), 1156 (42 U.S.C. 1320c-5), 1160 (42 U.S.C. 1320c-9(b)) as in effect on September 2, 1982 (42 U.S.C. 1320c-9(b)), 1842(j)(2) (42 U.S.C. 1395u(j)), 1862(d) as in effect on August 18, 1987 (42 U.S.C. 1395y(d)), or 1866(b) (42 U.S.C. 1395cc(b));

4. A physician's services (or an item or service) for which the person knew, or should have known, that the individual who furnished (or supervised the furnishing of) the service—

1. Was not licensed as a physician;

2. Was licensed as a physician, but such license had been obtained through a misrepresentation of material fact (including cheating on an examination required for licensing); or

3. Represented to the patient at the time the service was furnished that the physician was certified in a medical specialty board when he or she was not so certified; or

4. A payment that such person knows, or should know, may not be made under §411.353 of this title.

(b) The OIG may impose a penalty, and where authorized, an assessment against any person (including an insurance company in the case of paragraphs (b)(5) and (b)(6) of this section) whom it determines in accordance with this part—

1. Has presented or caused to be presented a request for payment in violation of the terms of—

(i) An agreement to accept payments on the basis of an assignment under section 1842(b)(3)(B)(ii) of the Act;

(ii) An agreement with a State agency or other requirement of a State Medicaid plan not to charge a person for an item or service in excess of the amount permitted to be charged;

(iii) An agreement to be a participating physician or supplier under section 1842(h)(1); or

(iv) An agreement in accordance with section 1866(a)(1)(G) of the Act not to charge any person for inpatient hospital services for which payment had been denied or reduced under section 1866(f)(2) of the Act.

2. Is a non-participating physician under section 1842(j) of the Act and has knowingly and willfully billed—

1. On a repeated basis for such services actual charges in excess of the maximum allowable actual charge determined in accordance with section 1842(j)(1)(C) of the Act for the period January 1, 1987 through December 31, 1990; or

2. Individuals enrolled under part B of title XVIII of the Act during the statutory freeze for actual charges in excess of such physician's actual charges determined in accordance with section 1842(j)(1)(A) of the Act for the period July 1, 1984 to December 31, 1986.

3. Is a physician who has knowingly and willfully—

1. Billed for services as an assistant at surgery during a routine cataract operation, or

2. Included in his or her bill the services of an assistant at surgery during a routine cataract operation, and has not received prior approval from the appropriate Peer Review Organization or Medicare carrier for such services based on the existence of a complicating medical condition; or

4. Has given to any person, in the case of inpatient hospital services subject to the provisions of section 1886 of the Act, information that he or she knew, or should have known, was false or misleading and that could reasonably have been expected to influence
the decision when to discharge such person or another person from the hospital.

(5) Fails to report information concerning a payment made under an insurance policy, self-insurance or otherwise, for the benefit of a physician, dentist or other health care practitioner in settlement of, or in satisfaction in whole or in part of, a medical malpractice claim or action or a judgment against such a physician, dentist or other health care practitioner in accordance with section 421 of Pub. L. 99-660 (42 U.S.C. 11131) and as required by regulations at 45 CFR part 60.

(6) Improperly discloses, uses or permits access to information reported in accordance with part B of title IV of Pub. L. 99-660, in violation of section 427 of Pub. L. 99-660 (42 U.S.C. 11137) or regulations at 45 CFR part 60. (The disclosure of information reported in accordance with part B of title IV in response to a subpoena or a discovery request is considered to be an improper disclosure in violation of section 427 of Pub. L. 99-660. However, disclosure or release by an entity of original documents or underlying records from which the reported information is obtained or derived is not considered to be an improper disclosure in violation of section 427 of Pub. L. 99-660.)

(7) Has made use of the words, letters, symbols or emblems as defined in paragraph (b)(7)(i) of this section in such a manner that such person knew or should have known would convey, or in a manner which reasonably could be interpreted or construed as conveying, the false impression that an advertisement, solicitation or other item was authorized, approved or endorsed by the Department or HCFA, or that such person or organization has some connection with or authorization from the Department or HCFA. Civil money penalties—

(i) May be imposed, regardless of the use of a disclaimer of affiliation with the United States Government, the Department or its programs, for misuse of—

(A) The words “Department of Health and Human Services,” “Health and Human Services,” “Health Care Financing Administration,” “Medicare,” or “Medicaid,” or any other combination or variation of such words;

(B) The letters “DHHS,” “HHS,” or “HCFA,” or any other combination or variation of such letters; or

(C) A symbol or emblem of the Department or HCFA (including the design of, or a reasonable facsimile of the design of, the Medicare card, the check used for payment of benefits under title II, or envelopes or other stationery used by the Department or HCFA) or any other combination or variation of such symbols or emblems; and

(ii) Will not be imposed against any agency or instrumentality of a State, or political subdivision of the State, that makes use of any symbol or emblem, or any words or letters which specifically identifies that agency or instrumentality of the State or political subdivision.

(8) Is a contracting organization that HCFA determines has committed an act or failed to comply with the requirements set forth in §417.500(a) or §434.67(a) of this title or failed to comply with the requirement set forth in §434.80(c) of this title.

(9) Has not refunded on a timely basis, as defined in §1003.101 of this part, amounts collected as the result of billing an individual, third party payer or other entity for a designated health service that was provided in accordance with a prohibited referral as described in §411.353 of this title;

(10) Is a physician or entity that enters into—

(i) A cross referral arrangement, for example, whereby the physician owners of entity “X” refer to entity “Y,” and the physician owners of entity “Y” refer to entity “X” in violation of §411.353 of this title, or

(ii) Any other arrangement or scheme that the physician or entity knows, or should know, has a principal purpose of circumventing the prohibitions of §411.353 of this title.

(c)(1) The Office of the Inspector General (OIG) may impose a penalty for violations of section 1867 of the Act or §489.24 of this title against—

(i) Any participating hospital with an emergency department that—

(A) Knowingly violates the statute on or after August 1, 1986 or;
§ 1003.103

(B) Negligently violates the statute on or after May 1, 1991; and
(ii) Any responsible physician who—
(A) Knowingly violates the statute on or after August 1, 1986;
(B) Negligently violates the statute on or after May 1, 1991;
(C) Signs a certification under section 1867(c)(1)(A) of the Act if the physician knew or should have known that the benefits of transfer to another facility did not outweigh the risks of such a transfer; or
(D) Misrepresents an individual’s condition or other information, including a hospital’s obligations under this section.

(2) For purposes of this section, a responsible physician or hospital “knowingly” violates section 1867 of the Act if the responsible physician or hospital recklessly disregards, or deliberately ignores a material fact.

(d)(1) In any case in which it is determined that more than one person was responsible for presenting or causing to be presented a claim as described in paragraph (a) of this section, each such person may be held liable for the penalty prescribed by this part, and an assessment may be imposed against any one such person or jointly and severally against two or more such persons, but the aggregate amount of the assessments collected may not exceed the amount that could be assessed if only one person was responsible.

(2) In any case in which it is determined that more than one person was responsible for presenting or causing to be presented a request for payment or for giving false or misleading information as described in paragraph (b) of this section, each such person may be held liable for the penalty prescribed by this part.

(3) In any case in which it is determined that more than one person was responsible for failing to report information that is required to be reported on a medical malpractice payment, or for improperly disclosing, using, or permitting access to information, as described in paragraphs (b)(5) and (b)(6) of this section, each such person may be held liable for the penalty prescribed by this part.

(4) In any case in which it is determined that more than one responsible physician violated the provisions of section 1867 of the Act or of § 489.24 of this title, a penalty may be imposed against each responsible physician.

(5) Under this section, a principal is liable for penalties and assessments for the actions of his or her agent acting within the scope of the agency.

§ 1003.103 Amount of penalty.

(a) Except as provided in paragraphs (b), (c) and (d) of this section, the OIG may impose a penalty of not more than $2,000 for each item or service that is subject to a determination under § 1003.102.

(b) The OIG may impose a penalty of not more than $15,000 for each person with respect to whom a determination was made that false or misleading information was given under § 1003.102(b)(4), or for each item and service that is subject to a determination under § 1003.102(a)(5) or § 1003.102(b)(9) of this part. The OIG may impose a penalty of not more than $100,000 for each arrangement or scheme that is subject to a determination under § 1003.102(b)(10) of this part.

(c) The OIG may impose a penalty of not more than $11,000 for each payment for which there was a failure to report required information in accordance with § 1003.102(b)(5), or for each improper disclosure, use or access to information that is subject to a determination under § 1003.102(b)(6).

(d)(1) The OIG may impose a penalty of not more than $5,000 for each violation resulting from the misuse of Departmental, HCFA, Medicare or Medicaid program words, letters, symbols or emblems as described in § 1003.102(b)(7) relating to printed media, and a penalty of not more than $25,000 in the case of such misuse related to a broadcast or telecast, that is related to a determination under § 1003.102(b)(7).

(2) For purposes of this paragraph, a violation is defined as—

(i) In the case of a direct mailing solicitation or advertisement, each separate piece of mail which contains one or more words, letters, symbols or emblems related to a determination under §1003.102(b)(7);

(ii) In the case of a printed solicitation or advertisement, each reproduction, reprinting or distribution of such item related to a determination under §1003.102(b)(7); and

(iii) In the case of a broadcast or teletext, each airing of a single commercial or solicitation related to a determination under §1003.102(b)(7).

(e) For violations of section 1867 of the Act or §489.24 of this title, the OIG may impose—

(1) Against each participating hospital with an emergency department, a penalty of not more than—

(i) $25,000 for each knowing violation occurring on or after August 1, 1986 and before December 22, 1987;

(ii) $50,000 for each knowing violation occurring on or after December 22, 1987; and

(iii) $50,000 for each negligent violation occurring on or after May 1, 1991, except that if the participating hospital has fewer than 100 State-licensed, Medicare-certified beds on the date the penalty is imposed, the penalty will not exceed $25,000 and

(2) Against each responsible physician, a penalty of not more than—

(i) $25,000 for each knowing violation occurring on or after August 1, 1986 and before December 22, 1987;

(ii) $50,000 for each knowing violation occurring on or after December 22, 1987; and

(iii) $50,000 for each negligent violation occurring on or after May 1, 1991.

(f)(1) The OIG may, in addition to or in lieu of other remedies available under law, impose a penalty of up to $25,000 for each determination by HCFA that a contracting organization has—

(i) Failed substantially to provide an enrollee with required medically necessary items and services and the failure adversely affects (or has the likelihood of adversely affecting) the enrollee;

(ii) Misrepresented or falsified information furnished to an individual or any other entity under section 1876 or section 1903(m) of the Act;

(v) Failed to comply with the requirements of section 1876(g)(6)(A) of the Act, regarding prompt payment of claims; or

(vi) Failed to comply with the requirements of §§417.479 (d) through (i) of this title for Medicare, and §§417.479 (d) through (g) and (i) of this title for Medicaid, regarding certain prohibited incentive payments to physicians.

(2) The OIG may, in addition to or in lieu of other remedies available under law, impose a penalty of up to $25,000 for each determination by HCFA that a contracting organization with a contract under section 1876 of the Act—

(i) Employs or contracts with individuals or entities excluded, under section 1128 or section 1128A of the Act, from participation in Medicare 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 services (directly or indirectly) through an excluded individual or entity.

(3) The OIG may, in addition to or in lieu of other remedies available under law, impose a penalty of up to $100,000 for each determination that a contracting organization has—

(i) Misrepresented or falsified information to the Secretary under section 1876 of the Act or to the State under section 1903(m) of the Act; or

(ii) Acted to expel or to refuse to reenroll a Medicaid recipient because of the individual’s health status or requirements for health care services, or engaged in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by section 1876 or section 1903(m) of the Act) with
§ 1003.104  Amount of assessment.

A person subject to a penalty determined under §1003.102(a) may be subject, in addition, to an assessment of not more than twice the amount claimed for each item or service which was a basis for the penalty. The assessment is in lieu of damages sustained by the Department or a State agency because of that claim.

§ 1003.105  Exclusion from participation in Medicare and State health care programs.

(a)(1) Except as set forth in paragraph (b) of this section, the following persons may be subject, in lieu of or in addition to any penalty or assessment, to an exclusion from participation in Medicare for a period of time determined under §1003.107. The OIG will also direct each appropriate State agency to exclude the person from each health care program for the same period of time—

(i) Any person who is subject to a penalty or assessment under §1003.102 (a) or (b)(1) through (b)(4).

(ii) Any responsible physician who—

(A) Knowingly violates section 1867 of the Act or §489.24 of this title on or after December 22, 1967, but before July 1, 1990;

(B) Knowingly and willfully, or negligently, violates section 1867 of the Act or §489.24 of this title on or after July 1, 1990 but before May 1, 1991; or

(C) Commits a gross and flagrant, or repeated, violation of section 1867 of the Act or §489.24 of this title on or after May 1, 1991. For purposes of this section, a gross and flagrant violation is one that presents an imminent danger to the health, safety or well-being of the individual who seeks emergency examination and treatment or places that individual unnecessarily in a high-risk situation.

(b)(1) With respect to determinations under §1003.102(b)(2) or (b)(3), or with respect to violations occurring on or after December 22, 1967 and before July 1, 1990 under §1003.105(a)(1)(ii), a physician may not be excluded if the OIG determines that he or she is the sole community physician or the sole source of essential specialized services in a community.

(2)(i) With respect to any exclusion based on liability for a penalty or assessment under §1003.102 (a), (b)(1), or (b)(4), the OIG will consider an application from a State agency for a waiver if the person is the sole community physician or the sole source of essential specialized services in a community. With respect to any exclusion imposed under §1003.105(a)(1)(ii), the OIG will consider an application from a State agency for a waiver if the physician's exclusion from the State health care program would deny beneficiaries access to medical care or would otherwise cause hardship to beneficiaries.

(ii) If a waiver is granted, it is applicable only to the State health care program for which the State requested the waiver.

(iii) If the OIG subsequently obtains information that the basis for a waiver...
§ 1003.106 Determinations regarding the amount of the penalty and assessment.

(a) Amount of penalty. (1) In determining the amount of any penalty or assessment in accordance with §1003.102 (a), (b)(2), (b)(4), (b)(9), and (b)(10), the Department will take into account—
(i) The nature of the claim, request for payment or information given, and the circumstances under which it was presented or given;
(ii) The degree of culpability of the person submitting the claim or request for payment, or giving the information;
(iii) The history of prior offenses of the person submitting the claim or request for payment, or giving the information;
(iv) The financial condition of the person presenting the claim or request for payment, or giving the information;
(v) The completeness and timeliness of the refund with respect to §1003.102(b)(9);
(vi) The amount of financial interest involved with respect to §1003.102(b)(10); and
(vii) Such other matters as justice may require.
(2) In determining the amount of any penalty in accordance with §§1003.102 (b)(5) and (b)(6), the Department will take into account—
(i) The nature and circumstances resulting in the failure to report medical malpractice payments or the improper disclosure of information;
(ii) The degree of culpability of the person in failing to provide timely and complete malpractice payment data or in improperly disclosing, using or permitting access to information;
(iii) The materiality, or significance of omission, of the information to be reported with regard to medical malpractice judgments or settlements, or the materiality of the improper disclosure of, or use of, or access to information;
(iv) Any prior history of the person with respect to violations of these provisions; and
(v) Such other matters as justice may require.
(3)(i) In determining the amount of any penalty in accordance with §1003.102(b)(7), the OIG will take into account—
(A) The nature and objective of the advertisement, solicitation or other communication, and the degree to which it has the capacity to deceive members of the public;
(B) The degree of culpability of the individual, organization or entity in the use of the prohibited words, letters, symbols or emblems;
(C) The frequency and scope of the violation, and whether a specific segment of the population was targeted;
(D) The prior history of the individual, organization or entity in its willingness or refusal to comply with informal requests to correct violations;
(E) The history of prior offenses of the individual, organization or entity in its misuse of Departmental and program words, letters, symbols and emblems;
(F) The financial condition of the individual, organization or entity involved with the violation; and
(G) Such other matters as justice may require.
(ii) The use of a disclaimer of affiliation with the United States Government, the Department or its programs will not be considered as a mitigating factor in determining the amount of penalty in accordance with §1003.102(b)(7).

(4) In determining the amount of any penalty in accordance with §1003.102(c), the OIG takes into account:
   (i) The degree of culpability of the respondent;
   (ii) The seriousness of the condition of the individual seeking emergency medical treatment;
   (iii) The prior history of offenses of the respondent in failing to provide appropriate emergency medical screening, stabilization and treatment of individuals coming to a hospital's emergency department or to effect an appropriate transfer;
   (iv) The respondent's financial condition;
   (v) The nature and circumstances of the violation; and
   (vi) Such other matters as justice may require.

(5) In determining the appropriate amount of any penalty in accordance with §1003.103(f), the OIG will consider as appropriate:
   (i) The nature and scope of the required medically necessary item or service not provided and the circumstances under which it was not provided;
   (ii) The degree of culpability of the contracting organization;
   (iii) The seriousness of the adverse effect that resulted or could have resulted from the failure to provide required medically necessary care;
   (iv) The harm which resulted or could have resulted from the provision of care by a person that the contracting organization is expressly prohibited, under section 1876(i)(6) or section 1903(p)(2) of the Act, from contracting with or employing;
   (v) The harm which resulted or could have resulted from the contracting organization's expulsion or refusal to reenroll a Medicare beneficiary or Medicaid recipient;
   (vi) The nature of the misrepresentation or fallacious information furnished by the contracting organization to the Secretary, State, enrollee or other entity under section 1876 or section 1903(m) of the Act;
   (vii) The extent to which the failure to provide medically necessary services could be attributed to a prohibited inducement to reduce or limit services under a physician incentive plan and the harm to the enrollee which resulted or could have resulted from such failure. It would be considered an aggravating factor if the contracting organization knowingly or routinely engaged in any prohibited practice which acted as an inducement to reduce or limit medically necessary services provided with respect to a specific enrollee in the organization;
   (viii) The history of prior offenses by the contracting organization or principals of the contracting organization, including whether, at any time prior to determination of the current violation or violations, the contracting organization or any of its principals were convicted of a criminal charge or were held liable for civil or administrative sanctions in connection with a program covered by this part or any other public or private program of payment for medical services; and
   (ix) Such other matters as justice may require.

(b) Determining the amount of the penalty or assessment. As guidelines for taking into account the factors listed in paragraph (a)(1) of this section, the following circumstances are to be considered:

(1) Nature and circumstances of the incident. It should be considered a mitigating circumstance if all the items or services or incidents subject to a determination under §1003.102 included in the action brought under this part were of the same type and occurred within a short period of time, there were few such items or services or incidents, and the total amount claimed or requested for such items or services was less than $1,000. It should be considered an aggravating circumstance if—
   (i) Such items or services or incidents were of several types, occurred over a lengthy period of time;
   (ii) There were many such items or services or incidents (or the nature and circumstances indicate a pattern of claims or requests for payment for
such items or services or a pattern of incidents;

(iii) The amount claimed or requested for such items or services was substantial; or

(iv) The false or misleading information given resulted in harm to the patient, a premature discharge or a need for additional services or subsequent hospital admission.

(2) Degree of culpability. It should be considered a mitigating circumstance if the claim or request for payment for the item or service was the result of an unintentional and unrecognized error in the process respondent followed in presenting claims or requesting payment, and corrective steps were taken promptly after the error was discovered. It should be considered an aggravating circumstance if—

(i) The respondent knew the item or service was not provided as claimed or if the respondent knew that the claim was false or fraudulent;

(ii) The respondent knew that the items or services were furnished during a period that he or she had been excluded from participation and that no payment could be made as specified in §1003.102(a)(3) or because payment would violate the terms of an assignment or an agreement with a State agency or other agreement or limitation on payment under §1003.102(b);

(iii) The respondent knew that the information could reasonably be expected to influence the decision of when to discharge a patient from a hospital.

(3) Prior offenses. It should be considered an aggravating circumstance if at any time prior to the incident or presentation of any claim or request for payment which included an item or service subject to a determination under §1003.102, the respondent was held liable for criminal, civil or administrative sanctions in connection with a program covered by this part or any other public or private program of reimbursement for medical services.

(4) Other wrongful conduct. It should be considered an aggravating circumstance if there is proof that a respondent engaged in wrongful conduct, other than the specific conduct upon which liability is based, relating to government programs or in connection with the delivery of a health care item or service. The statute of limitations governing civil money penalty proceedings will not apply to proof of other wrongful conduct as an aggravating circumstance.

(5) Financial condition. It should be considered a mitigating circumstance if imposition of the penalty or assessment without reduction will jeopardize the ability of the respondent to continue as a health care provider. In all cases, the resources available to the respondent will be considered when determining the amount of the penalty and assessment.

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

(c) In determining the amount of the penalty and assessment to be imposed for every item or service or incident subject to a determination under §§1003.102(a) and (b)(1) through (b)(4)—

(1) If there are substantial or several mitigating circumstances, the aggregate amount of the penalty and assessment should be set at an amount sufficiently below the maximum permitted by §§1003.103(a) and 1003.104, to reflect that fact.

(2) If there are substantial or several aggravating circumstances, the aggregate amount of the penalty and assessment should be set at an amount sufficiently close or at the maximum permitted by §§1003.103(a) and 1003.104, to reflect that fact.

(3) Unless there are extraordinary mitigating circumstances, the aggregate amount of the penalty and assessment should never be less than double the approximate amount of damages and costs (as defined in paragraph (d) of this section) sustained by the United States, or any State, as a result of claims or incidents subject to a determination under §§1003.102(a) and (b)(1) through (b)(4).

(d) In considering the factors listed in paragraph (a)(4) of this section, for violations subject to a determination

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under §1003.103(e), the following circumstances are to be considered, as appropriate, in determining the amount of any penalty—

(1) Nature and circumstances of the incident. It would be considered a mitigating circumstance if, where more than one violation exists, the appropriate items or services not provided were:
   (i) Few in number, or
   (ii) Of the same type and occurred within a short period of time.

   It would be considered an aggravating circumstance if such items or services were of several types and occurred over a lengthy period of time, or if there were many such items or services (or the nature and circumstances indicate a pattern of such items or services not being provided).

(2) Degree of culpability. It would be considered a mitigating circumstance if the violation was the result of an unintentional, unrecognized error, and corrective action was taken promptly after discovery of the error.

(3) Failure to provide required care. It would be considered an aggravating circumstance if the failure to provide required care was attributable to an individual or entity that the contracting organization is expressly prohibited by law from contracting with or employing.

(4) Use of excluded individuals. It would be considered an aggravating factor if the contracting organization knowingly or routinely engages in the prohibited practice of contracting or employing, either directly or indirectly, individuals or entities excluded from the Medicare program under section 1128 or section 1128A of the Act.

(5) Routine practices. It would be considered an aggravating factor if the contracting organization knowingly or routinely engages in the prohibited practice of contracting or employing, either directly or indirectly, individuals or entities excluded from the Medicare program under section 1128 or section 1128A of the Act.

(6) Prior offenses. It would be considered an aggravating circumstance if at any time prior to determination of the current violation or violations, the contracting organization or any of its principals was convicted on criminal charges or held liable for civil or administrative sanctions in connection with a program covered by this part or any other public or private program of payment for medical services. The lack of prior liability for criminal, civil, or administrative sanctions by the contracting organization, or the principals of the contracting organization, would not necessarily be considered a mitigating circumstance in determining civil money penalty amounts.

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

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

(3) Nothing in this section will limit the authority of the Department to settle any issue or case as provided by §1003.126, or to compromise any penalty and assessment as provided by §1003.128.


§1003.107 Determinations regarding exclusion.

(a) In determining whether to exclude a person under this part and the duration of any exclusion, the Department considers the circumstances described in §1003.106(a).

(b) With respect to determinations to exclude a person under §§1003.102(a) or (b)(1) through (b)(4), the Department considers those circumstances described in §1003.106(b). Where there are aggravating circumstances with respect to such determinations, the person should be excluded.

(c) In determining whether to exclude a physician under §§1003.102(b)(2) or (b)(3) or, with respect to a violation occurring on or after December 22, 1987
and before July 1, 1990, under §1003.105(a)(1)(ii), the Department also considers the access of beneficiaries to physicians’ services.

(d) Except as set forth in paragraph (e), the guidelines set forth in this section are not binding. Nothing in this section limits the authority of the Department to settle any issue or case as provided by §1003.126.

(e) An exclusion based on a determination under §§1003.102(b)(2) or (b)(3) or, with respect to a violation occurring on or after December 22, 1987 and before July 1, 1990, under §1003.105(a)(1)(ii), may not exceed 5 years.

§1003.108 Penalty, assessment, and exclusion not exclusive.

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

§1003.109 Notice of proposed determination.

(a) If the Inspector General proposes a penalty and, when applicable, assessment, or proposes to exclude a respondent from participation in Medicare or any State health care program, as applicable, in accordance with this part, he or she must deliver or send by certified mail, return receipt requested, to the respondent, written notice of his or her intent to impose a penalty, assessment and exclusion, as applicable. The notice includes—

(1) Reference to the statutory basis for the penalty, assessment and exclusion;

(2) A description of the claims, requests for payment, or incidents with respect to which the penalty, assessment and exclusion are proposed (except in cases where the Inspector General is relying upon statistical sampling in accordance with §1003.133 in which case the notice shall describe those claims and requests for payment comprising the sample upon which the Inspector General is relying and will also briefly describe the statistical sampling technique utilized by the Inspector General);

(3) The reason why such claims, requests for payment or incidents subject the respondent to a penalty, assessment and exclusion; the amount of the proposed penalty, assessment and the period of proposed exclusion (where applicable);

(4) The amount of the proposed penalty, assessment and the period of proposed exclusion (where applicable);

(5) Any circumstances described in §1003.106 that were considered when determining the amount of the proposed penalty and assessment and the period of exclusion;

(6) Instructions for responding to the notice, including—

(i) A specific statement of respondent’s right to a hearing, and

(ii) A statement that failure to request a hearing within 60 days permits the imposition of the proposed penalty, assessment and exclusion without right of appeal; and

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

(b) Any person upon whom the Inspector General has proposed the imposition of a penalty, assessment or exclusion may appeal such proposed penalty, assessment or exclusion in accordance with §1005.2 of this chapter. The provisions of part 1005 of this chapter govern such appeals.

(c) If the respondent fails, within the time permitted, to exercise his or her right to a hearing under this section, any exclusion, penalty, or assessment becomes final.

§1003.110 Failure to request a hearing.

If the respondent does not request a hearing within the time prescribed by §1003.109(a), the Inspector General may impose the proposed penalty, assessment, and exclusion, or any less severe penalty, assessment, and suspension. The Inspector General shall notify the
§ 1003.114 Collateral estoppel.

(a) Where a final determination that the respondent presented or caused to be presented a claim or request for payment falling within the scope of §1003.102 has been rendered in any proceeding in which the respondent was a party and had an opportunity to be heard, the respondent shall be bound by such determination in any proceeding under this part.

(b) In a proceeding under this part that—

(1) is against a person who has been convicted (whether upon a verdict after trial or upon a plea of guilty or nolo contendere) of a Federal crime charging fraud or false statements, and

(2) involves the same transactions as in the criminal action, the person is estopped from denying the essential elements of the criminal offense.

[57 FR 3348, Jan. 29, 1992]

§ 1003.126 Settlement.

The Inspector General has exclusive authority to settle any issues or case, without the consent of the ALJ or the Secretary, at any time prior to a final decision by the Secretary. Thereafter, the General Counsel has such exclusive authority.

§ 1003.127 Judicial review.

Section 1128A(e) of the Act authorizes judicial review of a penalty, assessment or exclusion that has become final. Judicial review may be sought by a respondent only with respect to a penalty, assessment or exclusion with respect to which the respondent filed an exception under §1005.21(c) of this chapter unless the failure or neglect to urge such exception will be excused by the court in accordance with section 1128A(e) of the Act because of extraordinary circumstances.

[57 FR 3349, Jan. 29, 1992]

§ 1003.128 Collection of penalty and assessment.

(a) Once a determination by the Secretary has become final, collection of any penalty and assessment will be the responsibility of HCFA, except in the case of the Maternal and Child Health Services Block Grant program, where the collection will be the responsibility of the PHS, and in the case of the Social Services Block Grant program, where the collection will be the responsibility of the Office of Human Development Services.

(b) A penalty and assessment imposed under this part may be compromised by the General Counsel, after consultation with the Inspector General, and may be recovered in a civil action brought in the United States district court for the district where the claim was presented, or where the respondent resides.

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

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


§ 1003.129 Notice to other agencies.

Whenever a penalty, assessment or exclusion become final, the following organizations and entities will be notified about such action and the reasons for it—the appropriate State or local medical or professional association; the appropriate Peer Review Organization; as appropriate, the State agency responsible or the administration of each State health care program; the appropriate Medicare carrier or intermediary; the appropriate State or local...
licensing agency or organization (including the Medicare and Medicaid State survey agencies); and the long-term care ombudsman. In cases involving exclusions, notice will also be given to the public of the exclusion and its effective date.

[57 FR 3349, J an. 29, 1992]

§ 1003.132 Limitations.
No action under this part will be entertained unless commenced, in accordance with §1003.109(a) of this part, within 6 years from the date on which the claim was presented, the request for payment was made, or the incident occurred.

[57 FR 3349, J an. 29, 1992]

§ 1003.133 Statistical sampling.
(a) In meeting the burden of proof set forth in §1005.15, the Inspector General may introduce the results of a statistical sampling study as evidence of the number and amount of claims and/or requests for payment as described in §1003.102 that were presented or caused to be presented by respondent. Such a statistical sampling study, if based upon an appropriate sampling and computed by valid statistical methods, shall constitute prima facie evidence of the number and amount of claims or requests for payment as described in §1003.102.

(b) Once the Inspector General has made a prima facie case as described in paragraph (a) of this section, the burden of production shall shift to respondent to produce evidence reasonably calculated to rebut the findings of the statistical sampling study. The Inspector General will then be given the opportunity to rebut this evidence.


§ 1003.134 Effect of exclusion.
The effect of an exclusion will be as set forth in §1001.1901 of this chapter.

[57 FR 3349, J an. 29, 1992]

§ 1003.135 Reinstatement.
A person who has been excluded in accordance with this part may apply for reinstatement at the end of the period of exclusion. The OIG will consider any request for reinstatement in accordance with the provisions of §§1001.3001 through 1001.3004 of this chapter.

[57 FR 3349, J an. 29, 1992]
(1) Setting forth certain obligations imposed on practitioners and providers of services under Medicare;
(2) Establishing criteria and procedures for the reports required from peer review organizations (PROs) when there is failure to meet those obligations;
(3) Specifying the policies and procedures for making determinations on violations and imposing sanctions; and
(4) Defining the procedures for appeals by the affected party and the procedures for reinstatements.

(b) Definitions. As used in this part, unless the context indicates otherwise—

Dentist is limited to licensed doctors of dental surgery or dental medicine.
Economically means the services are provided at the least expensive, medically appropriate type of setting or level of care available.
Exclusion means that items and services furnished or ordered (or at the medical direction or on the prescription of a physician) by a specified health care practitioner, provider or other person during a specified period are not reimbursed under titles V, XVIII, XIX, or XX of the Social Security Act and all other Federal non-procurement programs.
Gross and flagrant violation means a violation of an obligation has occurred in one or more instances which presents an imminent danger to the health, safety, or well-being of a program patient or places the program patient unnecessarily in high-risk situations.
Health care service or services means services or items for which payment may be made (in whole or in part) under the Medicare or State health care programs.
Health professional shortage area (HPSA) means an area designated by the Secretary and defined in 42 CFR 5.2.
Metropolitan Statistical Area means an area as defined by the Executive Office of Management and Budget.
Obligation means any of the obligations specified at section 1156(a) of the Act.
Other person means a hospital or other health care facility, an organization or an agency that provides health care services or which payment may be made (in whole or in part) under the Medicare or State health care programs.
Pattern or care means that the care under question has been demonstrated in more than three instances, each of which involved different admissions.
Pharmacy professional is a term limited to individuals who are licensed or registered to provide pharmaceutical services.
Podiatric professional is a term limited to licensed doctors of podiatric medicine.
Practice area means the location where over 50 percent of the practitioner’s or other person’s patients are seen.
Practitioner means a physician or other health care professional licensed under State law to practice his or her profession.
Primary medical care professional is a term limited to:
(i) Licensed doctors of medicine and doctors of osteopathy providing direct patient care who practice in the fields of general or family practice, general internal medicine, pediatrics, obstetrics and gynecology, surgery, and any other specialty that is not accommodated by the remaining specialty HPSA designator, or
(ii) Those facilities where care and treatment is provided to patients with health problems other than mental disorders.
Pro area means the geographic area subject to review by a particular PRO.
Provider means a hospital or other health care facility, agency, or organization.
Psychiatric professional is a term limited to licensed doctors of medicine who limit their practice to psychiatry or to those facilities where care and treatment is limited to patients with mental disorders.
Rural means any area outside an urban area.
Rural health professional shortage area means any health professional shortage area located outside a Metropolitan Statistical Area.
Sanction means an exclusion or monetary penalty that the Secretary may impose on a practitioner or other person as a result of a recommendation from a PRO.
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Serious risk includes situations that may involve the risk of unnecessary treatment, prolonged treatment, lack of treatment, incorrect treatment, medical complication, premature discharge, physiological or anatomical impairment, disability, or death.

State health care program means a State plan approved under title XIX, any program receiving funds under title V or from an allotment to a State under such title, or any program receiving funds under title XX or from an allotment to a State under such title.

Substantial violation in a substantial number of cases means a pattern of providing care, as defined in this section, that is inappropriate, unnecessary, or does not meet recognized professional standards of care, or is not supported by the necessary documentation of care as required by the PRO.

Urban means a Metropolitan Statistical Area as defined by the Executive Office of Management and Budget.

Vision care professional is a term limited to licensed doctors of medicine who limit their practice to ophthalmology and to doctors of optometry.

Subpart B—Sanctions Under the PRO Program; General Provisions § 1004.10 Statutory obligations of practitioners and other persons.

It is the obligation of any health care practitioner or other person who furnishes or orders health care services that may be reimbursed under the Medicare or State health care programs to ensure, to the extent of his or her or its authority, that those services are—

(a) Provided economically and only when, and to the extent, medically necessary;

(b) Of a quality that meets professionally recognized standards of health care; and

(c) Supported by evidence of medical necessity and quality in the form and fashion and at such time that the reviewing PRO may reasonably require (including copies of the necessary documentation and evidence of compliance with pre-admission or pre-procedure review requirements) to ensure that the practitioner or other person is meeting the obligations imposed by section 1156(a) of the Act.

§ 1004.20 Sanctions.

In addition to any other sanction provided under the law, a practitioner or other person may be—

(a) Excluded from participating in programs under titles V, XVIII, XIX, and XX of the Social Security Act for a period of no less than 1 year; or

(b) In lieu of exclusion and as a condition for continued participation in titles V, XVIII, XIX, and XX of the Act, if the violation involved the provision or ordering of health care services (or services furnished at the medical direction or on the prescription of a physician) that were medically improper or unnecessary, required to pay an amount of up to $10,000 for each instance in which improper or unnecessary services were furnished or ordered (or prescribed, if appropriate). The practitioner or other person will be required either to pay the monetary assessment within 6 months of the date of notice or have it deducted from any sums the Federal Government owes the practitioner or other person.


Subpart C—PRO Responsibilities § 1004.30 Basic responsibilities.

(a) The PRO must use its authority or influence to enlist the support of other professional or government agencies to ensure that each practitioner or other person complies with the obligations specified in §1004.10.

(b) When the PRO identifies situations where an obligation specified in §1004.10 is violated, it will afford the practitioner or other person reasonable notice and opportunity for discussion and, if appropriate, a suggested method for correcting the situation and a time period for a corrective action in accordance with §§1004.40 and 1004.60.

(c) The PRO must submit a report to the OIG after the notice and opportunity provided under paragraph (b) of this section and, if appropriate, the opportunity to enter into and complete a corrective action plan (CAP) if the PRO finds that the practitioner or other person has—
§ 1004.40 Action on identification of a violation.

When a PRO identifies a violation, it must—
(a) Indicate whether the violation is a gross and flagrant violation or is a substantial violation in a substantial number of cases; and
(b) Send the practitioner or other person written notice of the identification of a violation containing the following information—
(1) The obligation(s) involved;
(2) The situation, circumstances or activity that resulted in a violation;
(3) The authority and responsibility of the PRO to report violations of any obligation under section 1156(a) of the Act;
(4) A suggested method for correcting the situation and a time period for corrective action, if appropriate;
(5) The sanction that the PRO could recommend to the OIG;
(6) The right of the practitioner or other person to submit to the PRO within 30 days of receipt of the notice additional information or a written request for a meeting with the PRO to review and discuss the finding, or both. The date of receipt is presumed to be 5 days after the date on the notice, unless there is a reasonable showing to the contrary. The notice will also state that if a meeting is requested—
(i) It will be held within 30 days of receipt by the PRO of the request, but may be extended for good cause;
(ii) The practitioner or other person may have an attorney present; and
(iii) The attorney, if present, will be permitted to make opening and closing remarks, ask clarifying questions at the meeting and assist the practitioner or other person in presenting the testimony of expert witnesses who may appear on the practitioner’s or other person’s behalf; and
(7) A copy of the material used by the PRO in arriving at its finding except for PRO deliberations, as set forth in §476.139 of this part.

§ 1004.50 Meeting with a practitioner or other person.

If the practitioner or other person requests a meeting with the PRO—
(a) The PRO panel that meets with the practitioner or other person must consist of a minimum of 3 physicians;
(b) No physician member of the PRO panel may be in direct economic competition with the practitioner or other person being considered for sanction;
(c) The PRO must ensure that no physician member of the PRO panel has a substantial bias for or against the practitioner or other person being considered for sanction;
(d) At least one member of the PRO panel meeting with the practitioner or other person should practice in a similar area, e.g., urban or rural, and at least one member of the panel must be in the same specialty (both requirements could be met by a single individual);
(e) If the practitioner or other person has an attorney present, that attorney will be permitted to make opening and closing remarks, ask clarifying questions and assist the practitioner or
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other person in presenting the testimony of expert witnesses who may appear on the practitioner's or other person behalf;

(f) The physician who recommends to the PRO that a practitioner or other person be sanctioned may not vote on that recommendation at the meeting;

(g) The PRO may allow the practitioner or other person 5 working days after the meeting to provide the PRO additional relevant information that may affect its finding; and

(h) A verbatim record must be made of the meeting and must be made available to the practitioner or other person promptly.

§ 1004.60 PRO finding of a violation.

(a) On the basis of any additional information received, the PRO will affirm or modify its finding. If the PRO affirms its finding, it may suggest in writing a method for correcting the situation and a time period for corrective action. This CAP could correspond with, or be a continuation of, a prior CAP or be a new proposal based on additional information received by the PRO. If the finding has been resolved to the PRO's satisfaction, the PRO may modify its initial finding or recommendation or close the case.

(b) The PRO must give written notice to the practitioner or other person of any action it takes as a result of the additional information received, as specified in §1004.70.

(c) At least one member of the PRO participating in the process which resulted in a recommendation to the OIG that a practitioner or other person be sanctioned should practice in a similar geographic area, e.g., urban or rural, and at least one member of the panel must be in the same medical specialty. Both requirements can be met by a single individual. In addition, no one at the PRO who is a participant in such a finding may be in direct economic competition with, or have a substantial bias for or against, that practitioner or other person being recommended for sanction.

§ 1004.70 PRO action on final finding of a violation.

If the finding is not resolved to the PRO's satisfaction as specified in §1004.60(a), the PRO must—

(a) Submit its report and recommendation to the OIG;

(b) Send the affected practitioner or other person a concurrent final notice, with a copy of all the material that is being forwarded to the OIG, advising that—

(1) The PRO recommendation has been submitted to the OIG;

(2) The practitioner or other person has 30 days from receipt of this final notice to submit any additional written material or documentary evidence to the OIG at its headquarters location. The date of receipt is presumed to be 5 days after the date on the notice, unless there is a reasonable showing to the contrary; and

(3) Due to the 120-day statutory requirement specified in §1004.100(e), the period for submitting additional information will not be extended and any material received by the OIG after the 30-day period will not be considered; and

(c) Provide notice to the State medical board or to other appropriate licensing boards for other practitioner types when it submits a report and recommendations to the OIG with respect to a physician or other person whom the board is responsible for licensing.

§ 1004.80 PRO report to the OIG.

(a) Manner of reporting. If the violation(s) identified by the PRO have not been resolved, it must submit a report and recommendation to the OIG at the field office with jurisdiction.

(b) Content of report. The PRO report must include the following information—

(1) Identification of the practitioner or other person and, when applicable, the name of the director, administrator or owner of the entity involved;

(2) The type of health care services involved;

(3) A description of each failure to comply with an obligation, including specific dates, places, circumstances and other relevant facts;
§ 1004.90 Basis for recommended sanction.

The PRO's specific recommendation must be based on documentation provided to the OIG showing its consideration of—

(a) The type of offense involved;
(b) The severity of the offense;
(c) The deterrent value;
(d) The practitioner's or other person's previous sanction record;
(e) The availability of alternative sources of services in the community; and
(f) Any other factors that the PRO considers relevant, such as the duration of the problem.

Subpart D—OIG Responsibilities

§ 1004.100 Acknowledgement and review of report.

(a) Acknowledgement. The OIG will inform the PRO of the date it received the PRO's report and recommendation.

(b) Review. The OIG will review the PRO report and recommendation to determine whether—

(1) The PRO has followed the regulatory requirements of this part; and
(2) A violation has occurred.

(c) Rejection of the PRO recommendation. If the OIG decides that a sanction is not warranted, it will notify the PRO that recommended the sanction, the affected practitioner or other person, and the licensing board informed by the PRO of the sanction recommendation that the recommendation is rejected.

(d) Decision to sanction. If the OIG decides that a violation of obligations has occurred, it will determine the appropriate sanction by considering—

(1) The recommendation of the PRO;
(2) The type of offense;
(3) The severity of the offense;
(4) The previous sanction record of the practitioner or other person;
(5) The availability of alternative sources of services in the community;
(6) Any prior problems the Medicare or State health care programs have had with the practitioner or other person; and
(7) Any other matters relevant to the particular case.

(e) Exclusion sanction. If the PRO submits a recommendation for exclusion to the OIG, and a determination is not made by the 120th day after actual receipt by the OIG, the exclusion sanction recommended will become effective and the OIG will provide notice in accordance with § 1004.110(f).

(f) Monetary penalty. If the PRO recommendation is to assess a monetary penalty, the 120-day provision does not
§ 1004.110 Notice of sanction.

(a) The OIG must notify the practitioner or other person of the adverse determination and of the sanction to be imposed.

(b) The sanction is effective 20 days from the date of the notice. Receipt is presumed to be 5 days after the date on the notice, unless there is a reasonable showing to the contrary.

(c) The notice must specify—
   (1) The legal and factual basis for the determination;
   (2) The sanction to be imposed;
   (3) The effective date and, if appropriate, the duration of the exclusion;
   (4) The appeal rights of the practitioner or other person;
   (5) The opportunity and the process necessary to provide alternative notification as set forth in paragraphs (d) and (e) of this section; and
   (6) In the case of exclusion, the earliest date on which the OIG will accept a request for reinstatement.

(d) Patient notification. (1)(i) The OIG will provide a sanctioned practitioner or other person an opportunity to elect to inform each of their patients of the sanction action. In order to elect this option, the sanctioned practitioner or other person must, within 30 calendar days from receipt of the OIG notice, inform both new and existing patients through written notice—based on a suggested (non-mandatory) model provided to the sanctioned individual by the OIG—of the sanction and, in the case of an exclusion, its effective date. Receipt of the OIG notice is presumed to be 5 days after the date of the notice, unless there is a reasonable showing to the contrary. Within this same period, the practitioner or other person must sign and return the certification that the OIG will provide with the notice. For purposes of this section, the term “all existing patients” includes all patients currently under active treatment with the practitioner or other person, as well as all patients who have been treated by the practitioner or other person within the last 3 years. In addition, the practitioner or other person must notify all prospective patients orally at the time such persons request an appointment.
   (ii) The certification will provide that the practitioner or other person—
      (A) Has informed each of his, her or its patients in writing that the practitioner or other person has been sanctioned, or if a hospital, has informed all physicians having privileges at the hospital that it has been sanctioned;
      (B) If excluded from Medicare and the State health care programs, has informed his, her or its existing patients in writing that the programs will not pay for items and services furnished or ordered (or at the medical direction or on the prescription of an excluded physician) by the practitioner or other person until they are reinstated, or if a hospital, has provided this information to all physicians having privileges at that hospital;
      (C) If excluded from Medicare and State health care programs, will provide prospective patients—or if a hospital, physicians requesting privileges at that hospital prior to furnishing or ordering (or in the case of an excluded physician, medically directing or prescribing) services—oral information of both the sanction and that the programs will not pay for services provided and written notification of the same at the time of the provision of services;
      (D) If excluded from Medicare and State health care programs and is an entity such as a hospital, has posted a notice in its emergency room, business office and in all affiliated entities that the programs will not pay for services provided; and
      (E) Certifies to the truthfulness and accuracy of the notification and the statements in the certification.
§ 1004.120 Effect of an exclusion on program payments and services.

The effect of an exclusion is set forth in §1001.1901 of this chapter.

§ 1004.130 Reinstatement after exclusion.

(a) A practitioner or other person who has been excluded in accordance with this part may apply for reinstatement at the end of the period of exclusion. The OIG will consider any request for reinstatement in accordance with provisions of §§1001.3001 through 1001.3005 of this chapter.

(b) The OIG may also consider a practitioner's or other person's compliance with the certification obligation in §1004.110(d) at the time of reinstatement.

Subpart F—Appeals

§ 1004.140 Appeal rights.

(a) Right to preliminary hearing. (1)(i) A practitioner or other person excluded from participation in Medicare and any

Subpart E—Effect and Duration of Exclusion

§ 1004.120 Effect of an exclusion on program payments and services.

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Subpart F—Appeals

§ 1004.140 Appeal rights.

(a) Right to preliminary hearing. (1)(i) A practitioner or other person excluded from participation in Medicare and any

(2) If the sanctioned practitioner or other person does not inform his, her or its patients and does not return the required certification within the 30-day period, or if the sanctioned practitioner or other person returns the certification within the 30-day period but the OIG obtains reliable evidence that such person nevertheless has not adequately informed new and existing patients of the sanction, the OIG—

(i) Will see that the public is notified directly of the identity of the sanctioned practitioner or other person, the finding that the obligation has been violated, and the effective date of any exclusion; and

(ii) May consider this failure to adhere to the certification obligation as an adverse factor at the time the sanctioned practitioner or other person requests reinstatement.

(3) If the sanctioned practitioner or other person is entitled to a preliminary hearing in accordance with §1004.140(a) and requests such a preliminary hearing, and if the administrative law judge (ALJ) decides that he, she or it poses a risk to program beneficiaries, the sanctioned practitioner or other person would have 30 days from the date of receipt of the ALJ's decision to provide certification to the OIG in accordance with §1004.110(d)(1). The date of receipt is presumed to be 5 days after the date of the ALJ's decision, unless there is a reasonable showing to the contrary.

(e) Notice of the sanction is also provided to the following entities as appropriate—

(1) The PRO that originated the sanction report;

(2) PROs in adjacent areas;

(3) State Medicaid fraud control units and State licensing and accreditation bodies;

(4) Appropriate program contractors and State agencies;

(5) Hospitals, including the hospital where the sanctioned individual's case originated and where the individual currently has privileges, if known; skilled nursing facilities, home health agencies, and health maintenance organizations and Federally-funded community health centers where the practitioner or other person works;

(6) Medical societies and other professional organizations; and

(7) Medicare carriers and fiscal intermediaries, health care prepayment plans and other affected agencies and organizations.

(f) If an exclusion sanction is effectuated because a decision was not made within 120 days after receipt of the PRO recommendation, notification is as follows—

(1) As soon as possible after the 120th day, the OIG will issue a notice to the practitioner or other person, in compliance with the requirements of paragraph (c) of this section, affirming the PRO recommendation based on the OIG's review of the case, and that the exclusion is effective 20 days from the date of the notice; and

(2) Notice of sanction is also provided as specified in paragraph (e) of this section.

Subpart F—Appeals

§ 1004.140 Appeal rights.

(a) Right to preliminary hearing. (1)(i) A practitioner or other person excluded from participation in Medicare and any
§ 1004.140

State health care programs under section 1156 of the Act may request a preliminary hearing if the location where services are rendered to over 50 percent of the practitioner’s or other person’s patients at the time of the exclusion notice is in a rural HPSA or in a county with a population of less than 70,000.

(ii) Unless the practitioner’s or other person’s practice meets the definition for psychiatric professional, vision care professional, dental professional, podiatric professional or pharmacy professional, the HPSA used by the OIG for determination of entitlement to a preliminary hearing will be the HPSA list for primary medical care professional.

(iii) Information on the population size of a county in order to determine entitlement to a preliminary hearing will be obtained by the OIG from the responsible officials of that county.

(2)(i) A request for a preliminary hearing must be made in writing and received by the Departmental Appeals Board (DAB) no later than the 15th day after the notice of exclusion is received by a practitioner or other person. The date of receipt of the notice of exclusion by the practitioner or other person is presumed to be 5 days after the date appearing on the notice, unless there is a reasonable showing to the contrary.

(ii) A request for a preliminary hearing will stay the effective date of the exclusion pending a decision of the ALJ at the preliminary hearing, and all the parties informed by the OIG of the exclusion will be notified of the stay.

(iii) A request for a preliminary hearing received after the 15-day period has expired will be treated as a request for a hearing before an ALJ in accordance with paragraph (b) of this section.

(iv) If the practitioner or other person exercises his, her or its right to a preliminary hearing, such a hearing must be held by the ALJ in accordance with paragraph (a)(3)(ii) of this section unless the OIG waives it in accordance with paragraph (a)(6)(i) of this section.

(v) The ALJ cannot consolidate the preliminary hearing with a full hearing without the approval of all parties to the hearing.

(3)(i) The preliminary hearing will be conducted by an ALJ of the DAB in a city that the ALJ deems equitable to all parties. The ALJ will conduct the preliminary hearing and render a decision no later than 45 days after receipt of the request for such a hearing by the DAB. Unless there is a reasonable showing to the contrary, date of receipt by the DAB is presumed to be 5 days after the date on the request for a preliminary hearing or, if undated, the date of receipt will be the date the DAB actually received the request. A reasonable extension to the 45-day period of up to 15 days may be requested by any party to the preliminary hearing and such a request may be granted upon concurrence by all parties to the preliminary hearing. Such request must be received no later than 15 days prior to the scheduled date of the preliminary hearing.

(ii) The only issue to be heard and decided on by the ALJ at the preliminary hearing, based on the preponderance of the evidence, is whether the practitioner’s or other person’s continued participation in the Medicare and State health care programs during the appeal of the exclusion before an ALJ would place program beneficiaries at serious risk. The ALJ’s decision is to be based on the preponderance of the evidence.

(iii) In the interest of time, the ALJ may issue an oral decision to be followed by a written decision.

(iv) In those cases where the ALJ has stayed an exclusion after a preliminary hearing, a full hearing must be held and a decision rendered by the ALJ within 6 months. If, for any reason, the request for a full hearing before the ALJ is withdrawn or dismissed, the practitioner or other person will be excluded effective 5 days after the notice of the withdrawal or dismissal is received in the OIG headquarters.

(4) The preliminary hearing decision is not appealable or subject to further administrative or judicial review.

(5) A practitioner or other person found at the preliminary hearing not to place program beneficiaries at serious risk, but later determined to have been properly excluded from program participation after a full hearing before an ALJ, is not entitled to have the exclusion stayed further during an appeal.
(b)(i) After notice of a timely request for a preliminary hearing, the OIG may determine that the practitioner's or other person's continued program participation during the appeal before the ALJ will not place program beneficiaries at serious risk and waive the preliminary hearing. Under these circumstances, the exclusion will be stayed pending the decision of the ALJ after a full hearing. the hearing must be held, and a decision reached, within 6 months.

(ii) If the OIG decides to waive the preliminary hearing, the request for the preliminary hearing will be considered a request for a hearing before the ALJ in accordance with paragraph (b) of this section.

(b) Right to administrative review. (1) A practitioner or other person dissatisfied with an OIG determination, or an exclusion that results from a determination not being made within 120 days, is entitled to appeal such sanction in accordance with part 1005 of this chapter.

(2) Due to the 120-day statutory requirement specified in § 1004.100(e), the following limitations apply—

(i) The period of time for submitting additional information will not be extended.

(ii) Any material received by the OIG after the 30-day period allowed will not be considered by the ALJ or the DAB.

(3) The OIG’s determination continues in effect unless reversed by a hearing.

(c) Rights to judicial review. Any practitioner or other person dissatisfied with a final decision of the Secretary may file a civil action in accordance with the provisions of section 205(g) of the Act.

PART 1005—APPEALS OF EXCLUSIONS, CIVIL MONEY PENALTIES AND ASSESSMENTS

Sec.
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1005.2 Hearing before an administrative law judge.
1005.3 Rights of parties.
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1005.20 Initial decision.
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1005.23 Harmless error.

Authority: 42 U.S.C. 405(a), 405(b), 1302, 1320a-7, 1320a-7a and 1320c-5.

Source: 57 FR 3350, Jan. 29, 1992, unless otherwise noted.

§ 1005.1 Definitions.

Civil money penalty cases refer to all proceedings arising under any of the statutory bases for which the OIG has been delegated authority to impose civil money penalties under Medicare or the State health care programs.

DAB refers to the Departmental Appeals Board or its delegatee.

Exclusion cases refer to all proceedings arising under any of the statutory bases for which the OIG has been delegated authority to impose exclusions under Medicare or the State health care programs.

§ 1005.2 Hearing before an administrative law judge.

(a) A party sanctioned under any criteria specified in parts 1001, 1003 and 1004 of this chapter may request a hearing before an ALJ.

(b) In exclusion cases, the parties to the proceeding will consist of the petitioner and the IG. In civil money penalty cases, the parties to the proceeding will consist of the respondent and the IG.

(c) The request for a hearing will be made in writing, signed by the petitioner or respondent or by his or her attorney. The request must be filed within 60 days after the notice, provided in accordance with §§ 1001.2002, 1001.2003 or 1003.109, is received by the
petitioner or respondent. For purposes of this section, the date of receipt of the notice letter will be presumed to be 5 days after the date of such notice unless there is a reasonable showing to the contrary.

(d) The request for a hearing will contain a statement as to the specific issues or findings of fact and conclusions of law in the notice letter with which the petitioner or respondent disagrees, and the basis for his or her contention that the specific issues or findings and conclusions were incorrect.

(e) The ALJ will dismiss a hearing request where—

(1) The petitioner’s or the respondent’s hearing request is not filed in a timely manner;
(2) The petitioner or respondent withdraws his or her request for a hearing;
(3) The petitioner or respondent abandons his or her request for a hearing; or
(4) The petitioner’s or respondent’s hearing request fails to raise any issue which may properly be addressed in a hearing.

§ 1005.3 Rights of parties.

(a) Except as otherwise limited by this part, all parties may—

(1) Be accompanied, represented and advised by an attorney;
(2) Participate in any conference held by the ALJ;
(3) Conduct discovery of documents as permitted by this part;
(4) Agree to stipulations of fact or law which will be made part of the record;
(5) Present evidence relevant to the issues at the hearing;
(6) Present and cross-examine witnesses;
(7) Present oral arguments at the hearing as permitted by the ALJ; and
(8) Submit written briefs and proposed findings of fact and conclusions of law after the hearing.

(b) Fees for any services performed on behalf of a party by an attorney are not subject to the provisions of section 206 of title II of the Act, which authorizes the Secretary to specify or limit these fees.

§ 1005.4 Authority of the ALJ.

(a) The ALJ will conduct a fair and impartial hearing, avoid delay, maintain order and assure that a record of the proceeding is made.

(b) The ALJ has the authority to—

(1) Set and change the date, time and place of the hearing upon reasonable notice to the parties;
(2) Continue or recess the hearing in whole or in part for a reasonable period of time;
(3) Hold conferences to identify or simplify the issues, or to consider other matters that may aid in the expeditious disposition of the proceeding;
(4) Administer oaths and affirmations;
(5) Issue subpoenas requiring the attendance of witnesses at hearings and the production of documents at or in relation to hearings;
(6) Rule on motions and other procedural matters;
(7) Regulate the scope and timing of documentary discovery as permitted by this part;
(8) Regulate the course of the hearing and the conduct of representatives, parties, and witnesses;
(9) Examine witnesses;
(10) Receive, rule on, exclude or limit evidence;
(11) Upon motion of a party, take official notice of facts;
(12) Upon motion of a party, decide cases, in whole or in part, by summary judgment where there is no disputed issue of material fact; and
(13) Conduct any conference, argument or hearing in person or, upon agreement of the parties, by telephone.

(c) The ALJ does not have the authority to—

(1) Find invalid or refuse to follow Federal statutes or regulations or secretarial delegations of authority;
(2) Enter an order in the nature of a directed verdict;
(3) Compel settlement negotiations;
(4) Enjoin any act of the Secretary;
(5) Review the exercise of discretion by the OIG to exclude an individual or entity under section 1128(b) of the Act, or determine the scope or effect of the exclusion;
(6) Set a period of exclusion at zero, or reduce a period of exclusion to zero, in any case where the ALJ finds that
§ 1005.5 Ex parte contacts.

No party or person (except employees of the ALJ's office) will communicate in any way with the ALJ on any matter at issue in a case, unless on notice and opportunity for all parties to participate. This provision does not prohibit a party or person from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures.

§ 1005.6 Prehearing conferences.

(a) The ALJ will schedule at least one prehearing conference, and may schedule additional prehearing conferences as appropriate, upon reasonable notice to the parties.

(b) The ALJ may use prehearing conferences to discuss the following—

(1) Simplification of the issues;

(2) The necessity or desirability of amendments to the pleadings, including the need for a more definite statement;

(3) Stipulations and admissions of fact or as to the contents and authenticity of documents;

(4) Whether the parties can agree to submission of the case on a stipulated record;

(5) Whether a party chooses to waive appearance at an oral hearing and to submit only documentary evidence (subject to the objection of other parties) and written argument;

(6) Limitation of the number of witnesses;

(7) Scheduling dates for the exchange of witness lists and of proposed exhibits;

(8) Discovery of documents as permitted by this part;

(9) The time and place for the hearing;

(10) Such other matters as may tend to encourage the fair, just and expeditious disposition of the proceedings; and

(11) Potential settlement of the case.

(c) The ALJ will issue an order containing the matters agreed upon by the parties or ordered by the ALJ at a prehearing conference.

§ 1005.7 Discovery.

(a) A party may make a request to another party for production of documents for inspection and copying which are relevant and material to the issues before the ALJ.

(b) For the purpose of this section, the term documents includes information, reports, answers, records, accounts, papers and other data and documentary evidence. Nothing contained in this section will be interpreted to require the creation of a document, except that requested data stored in an electronic data storage system will be produced in a form accessible to the requesting party.

(c) Requests for documents, requests for admissions, written interrogatories, depositions and any forms of discovery, other than those permitted under paragraph (a) of this section, are not authorized.

(d) This section will not be construed to require the disclosure of interview reports or statements obtained by any party, or on behalf of any party, of persons who will not be called as witnesses by that party, or analyses and summaries prepared in conjunction with the investigation or litigation of the case, or any otherwise privileged documents.

(e)(1) After a party has been served with a request for production of documents, that party may file a motion for a protective order.

(2) The ALJ may grant a motion for a protective order if he or she finds that the discovery sought—

(i) Is unduly costly or burdensome,

(ii) Will unduly delay the proceeding, or

(iii) Seeks privileged information.

(3) The burden of showing that discovery should be allowed is on the party seeking discovery.

§ 1005.8 Exchange of witness lists, witness statements and exhibits.

(a) At least 15 days before the hearing, the ALJ will order the parties to exchange witness lists, copies of prior written statements of proposed witnesses and copies of proposed hearing exhibits, including copies of any written statements that the party intends to offer in lieu of live testimony in accordance with § 1005.16.

(b) (1) If at any time a party objects to the proposed admission of evidence not exchanged in accordance with paragraph (a) of this section, the ALJ will determine whether the failure to comply with paragraph (a) of this section should result in the exclusion of such evidence.

(2) Unless the ALJ finds that extraordinary circumstances justified the failure to timely exchange the information listed under paragraph (a) of this section, the ALJ must exclude from the party’s case-in-chief:

(i) The testimony of any witness whose name does not appear on the witness list, and

(ii) Any exhibit not provided to the opposing party as specified in paragraph (a) of this section.

(3) If the ALJ finds that extraordinary circumstances existed, the ALJ must then determine whether the admission of such evidence would cause substantial prejudice to the objecting party. If the ALJ finds that there is no substantial prejudice, the evidence may be admitted. If the ALJ finds that there is substantial prejudice, the ALJ may exclude the evidence, or at his or her discretion, may postpone the hearing for such time as is necessary for the objecting party to prepare and respond to the evidence.

(c) Unless another party objects within a reasonable period of time prior to the hearing, documents exchanged in accordance with paragraph (a) of this section will be deemed to be authentic for the purpose of admissibility at the hearing.

§ 1005.9 Subpoenas for attendance at hearing.

(a) A party wishing to procure the appearance and testimony of any individual at the hearing may make a motion requesting the ALJ to issue a subpoena if the appearance and testimony are reasonably necessary for the presentation of a party’s case.

(b) A subpoena requiring the attendance of an individual may also require the individual to produce evidence at the hearing in accordance with § 1005.7.

(c) When a subpoena is served by a respondent or petitioner on a particular individual or particular office of the OIG, the OIG may comply by designating any of its representatives to appear and testify.

(d) A party seeking a subpoena will file a written motion not less than 30 days before the date fixed for the hearing, unless otherwise allowed by the ALJ for good cause shown. Such request will:

(1) Specify any evidence to be produced,

(2) Designate the witnesses, and

(3) Describe the address and location with sufficient particularity to permit such witnesses to be found.

(e) The subpoena will specify the time and place at which the witness is to appear and any evidence the witness is to produce.

(f) Within 15 days after the written motion requesting issuance of a subpoena is served, any party may file an opposition or other response.

(g) If the motion requesting issuance of a subpoena is granted, the party seeking the subpoena will serve it by delivery to the individual named, or by certified mail addressed to such individual at his or her last dwelling place or principal place of business.

(h) The individual to whom the subpoena is directed may file with the ALJ a motion to quash the subpoena.

(i) The exclusive remedy for contumacy by, or refusal to obey a subpoena duly served upon, any person is specified in section 205(e) of the Social Security Act (42 U.S.C. 405(e)).

§ 1005.10 Fees.

The party requesting a subpoena will pay the cost of the fees and mileage of any witness subpoenaed in the amounts that would be payable to a witness in a proceeding in United States District Court. A check for witness fees and mileage will accompany the subpoena.
§ 1005.11 Form, filing and service of papers.

(a) Forms. (1) Unless the ALJ directs the parties to do otherwise, documents filed with the ALJ will include an original and two copies.

(2) Every pleading and paper filed in the proceeding will contain a caption setting forth the title of the action, the case number, and a designation of the paper, such as motion to quash subpoena.

(3) Every pleading and paper will be signed by, and will contain the address and telephone number of the party or the person on whose behalf the paper was filed, or his or her representative.

(4) Papers are considered filed when they are mailed.

(b) Service. A party filing a document with the ALJ or the Secretary will, at the time of filing, serve a copy of such document on every other party. Service upon any party of any document will be made by delivering a copy, or placing a copy of the document in the United States mail, postage prepaid and addressed, or with a private delivery service, to the party’s last known address. When a party is represented by an attorney, service will be made upon such attorney in lieu of the party.

(c) Proof of service. A certificate of the individual serving the document by personal delivery or by mail, setting forth the manner of service, will be proof of service.

§ 1005.12 Computation of time.

(a) In computing any period of time under this part or in an order issued thereunder, the time begins with the day following the act, event or default, and includes the last day of the period unless it is a Saturday, Sunday or legal holiday observed by the Federal Government, in which event it includes the next business day.

(b) When the period of time allowed is less than 7 days, intermediate Saturdays, Sundays and legal holidays observed by the Federal Government will be excluded from the computation.

(c) Where a document has been served or issued by placing it in the mail, an additional 5 days will be added to the time permitted for any response. This paragraph does not apply to requests for hearing under § 1005.2.

§ 1005.13 Motions.

(a) An application to the ALJ for an order or ruling will be by motion. Motions will state the relief sought, the authority relied upon and the facts alleged, and will be filed with the ALJ and served on all other parties.

(b) Except for motions made during a prehearing conference or at the hearing, all motions will be in writing. The ALJ may require that oral motions be reduced to writing.

(c) Within 10 days after a written motion is served, or such other time as may be fixed by the ALJ, any party may file a response to such motion.

(d) The ALJ may not grant a written motion before the time for filing responses has expired, except upon consent of the parties or following a hearing on the motion, but may overrule or deny such motion without awaiting a response.

(e) The ALJ will make a reasonable effort to dispose of all outstanding motions prior to the beginning of the hearing.

§ 1005.14 Sanctions.

(a) The ALJ may sanction a person, including any party or attorney, for failing to comply with an order or procedure, for failing to defend an action or for other misconduct that interferes with the speedy, orderly or fair conduct of the hearing. Such sanctions will reasonably relate to the severity and nature of the failure or misconduct. Such sanction may include—

(1) In the case of refusal to provide or permit discovery under the terms of this part, drawing negative factual inferences or treating such refusal as an admission by deeming the matter, or certain facts, to be established;

(2) Prohibiting a party from introducing certain evidence or otherwise supporting a particular claim or defense;

(3) Striking pleadings, in whole or in part;

(4) Staying the proceedings;
(5) Dismissal of the action;
(6) Entering a decision by default; and
(7) Refusing to consider any motion or other action that is not filed in a timely manner.

(b) In civil money penalty cases commenced under section 1128A of the Act or under any provision which incorporates section 1128A(c)(4) of the Act, the ALJ may also order the party or attorney who has engaged in any of the acts described in paragraph (a) of this section to pay attorney's fees and other costs caused by the failure or misconduct.

§ 1005.15 The hearing and burden of proof.
(a) The ALJ will conduct a hearing on the record in order to determine whether the petitioner or respondent should be found liable under this part.
(b) Burden of proof in civil money penalty cases under part 1003, in Peer Review Organization exclusion cases under part 1004, and in exclusion cases under §§1001.701, 1001.901 and 1001.951 of this chapter—
(1) The respondent bears the burden of going forward and the burden of persuasion with respect to affirmative defenses and any mitigating circumstances; and
(2) The IG bears the burden of going forward and the burden of persuasion with respect to all other issues.
(c) Burden of proof in all other exclusion cases. In all exclusion cases except those governed by paragraph (b) of this section, the ALJ will allocate the burden of proof as the ALJ deems appropriate.
(d) The burden of persuasion will be judged by a preponderance of the evidence.
(e) The hearing will be open to the public unless otherwise ordered by the ALJ for good cause shown.
(f) (1) A hearing under this part is not limited to specific items and information set forth in the notice letter to the petitioner or respondent. Subject to the 15-day requirement under §1005.8, additional items and information, including aggravating or mitigating circumstances that arose or became known subsequent to the issuance of the notice letter, may be introduced by either party during its case-in-chief unless such information or items are—
(i) Privileged;
(ii) Disqualified from consideration due to untimeliness in accordance with §1004.130(a)(2)(iii); or
(iii) Deemed otherwise inadmissible under §1005.17.
(2) After both parties have presented their cases, evidence may be admitted on rebuttal even if not previously exchanged in accordance with §1005.8.

§ 1005.16 Witnesses.
(a) Except as provided in paragraph (b) of this section, testimony at the hearing will be given orally by witnesses under oath or affirmation.
(b) At the discretion of the ALJ, testimony (other than expert testimony) may be admitted in the form of a written statement. Any such written statement must be provided to all other parties along with the last known address of such witness, in a manner that allows sufficient time for other parties to subpoena such witness for cross-examination at the hearing. Prior written statements of witnesses proposed to testify at the hearing will be exchanged as provided in §1005.8.
§ 1005.17 Evidence.

(a) The ALJ will determine the admissibility of evidence.

(b) Except as provided in this part, the ALJ will not be bound by the Federal Rules of Evidence. However, the ALJ may apply the Federal Rules of Evidence where appropriate, for example, to exclude unreliable evidence.

(c) The ALJ must exclude irrelevant or immaterial evidence.

(d) Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or by considerations of undue delay or needless presentation of cumulative evidence.

(e) Although relevant, evidence must be excluded if it is privileged under Federal law.

(f) Evidence concerning offers of compromise or settlement made in this action will be inadmissible to the extent provided in Rule 408 of the Federal Rules of Evidence.

(g) Evidence of crimes, wrongs or acts other than those at issue in the instant case is admissible in order to show motive, opportunity, intent, knowledge, preparation, identity, lack of mistake, or existence of a scheme. Such evidence is admissible regardless of whether the crimes, wrongs or acts occurred during the statute of limitations period applicable to the acts which constitute the basis for liability in the case, and regardless of whether they were referenced in the IG’s notice sent in accordance with §§ 1001.2002, 1001.2003 or 1003.109.

(h) The ALJ will permit the parties to introduce rebuttal witnesses and evidence.

(i) All documents and other evidence offered or taken for the record will be open to examination by all parties, unless otherwise ordered by the ALJ for good cause shown.

(j) The ALJ may not consider evidence regarding the issue of willingness and ability to enter into and successfully complete a corrective action plan when such evidence pertains to matters occurring after the submittal of the case to the Secretary. The determination regarding the appropriateness of any corrective action plan is not reviewable.

§ 1005.18 The record.

(a) The hearing will be recorded and transcribed. Transcripts may be obtained following the hearing from the ALJ.

(b) The transcript of testimony, exhibits and other evidence admitted at the hearing, and all papers and requests filed in the proceeding constitute the record for the decision by the ALJ and the Secretary.

(c) The record may be inspected and copied (upon payment of a reasonable fee) by any person, unless otherwise ordered by the ALJ for good cause shown.

(d) For good cause, the ALJ may order appropriate redactions made to the record.

§ 1005.19 Post-hearing briefs.

The ALJ may require the parties to file post-hearing briefs. In any event, any party may file a post-hearing brief. The ALJ will fix the time for filing such briefs which are not to exceed 60 days from the date the parties receive
§ 1005.20 Initial decision.

(a) The ALJ will issue an initial decision, based only on the record, which will contain findings of fact and conclusions of law.

(b) The ALJ may affirm, increase or reduce the penalties, assessment or exclusion proposed or imposed by the IG, or reverse the imposition of the exclusion. In exclusion cases where the period of exclusion commenced prior to the hearing, any period of exclusion imposed by the ALJ will be deemed to commence on the date such exclusion originally went into effect.

(c) The ALJ will issue the initial decision to all parties within 60 days after the time for submission of post-hearing briefs and reply briefs, if permitted, has expired. The decision will be accompanied by a statement describing the right of any party to file a notice of appeal with the DAB and instructions for how to file such appeal.

(d) Except as provided in paragraph (e) of this section, unless the initial decision is appealed to the DAB, it will be final and binding on the parties 30 days after the ALJ serves the parties with a copy of the decision. If service is by mail, the date of service will be deemed to be 5 days from the date of mailing.

(e) If an extension of time within which to appeal the initial decision is granted under §1005.21(a), except as provided in §1005.22(a), the initial decision will become final and binding on the day following the end of the extension period.

§ 1005.21 Appeal to DAB.

(a) Any party may appeal the initial decision of the ALJ to the DAB by filing a notice of appeal with the DAB within 30 days of the date of service of the initial decision. The DAB may extend the initial 30 day period for a period of time not to exceed 30 days if a party files with the DAB a request for an extension within the initial 30 day period and shows good cause.

(b) If a party files a timely notice of appeal with the DAB, the ALJ will forward the record of the proceeding to the DAB.

(c) A notice of appeal will be accompanied by a written brief specifying exceptions to the initial decision and reasons supporting the exceptions. Any party may file a brief in opposition to exceptions, which may raise any relevant issue not addressed in the exceptions, within 30 days of receiving the notice of appeal and accompanying brief. The DAB may permit the parties to file reply briefs.

(d) There is no right to appear personally before the DAB, or to appeal to the DAB any interlocutory ruling by the ALJ.

(e) The DAB will not consider any issue not raised in the parties’ briefs, nor any issue in the briefs that could have been raised before the ALJ but was not.

(f) If any party demonstrates to the satisfaction of the DAB that additional evidence not presented at such hearing is relevant and material and that there were reasonable grounds for the failure to adduce such evidence at such hearing, the DAB may remand the matter to the ALJ for consideration of such additional evidence.

(g) The DAB may decline to review the case, or may affirm, increase, reduce, reverse or remand any penalty, assessment or exclusion determined by the ALJ.

(h) The standard of review on a disputed issue of fact is whether the initial decision is supported by substantial evidence on the whole record. The standard of review on a disputed issue of law is whether the initial decision is erroneous.

(i) Within 60 days after the time for submission of briefs and reply briefs, if permitted, has expired, the DAB will issue to each party to the appeal a copy of the DAB’s decision and a statement describing the right of any petitioner or respondent who is found liable to seek judicial review.

(j) Except with respect to any penalty, assessment or exclusion remanded
§ 1005.22 Stay of initial decision.

(a) In a CMP case under section 1128A of the Act, the filing of a respondent's request for review by the DAB will automatically stay the effective date of the ALJ's decision.

(b) (1) After the DAB renders a decision in a CMP case, pending judicial review, the respondent may file a request for stay of the effective date of any penalty or assessment with the ALJ. The request must be accompanied by a copy of the notice of appeal filed with the Federal court. The filing of such a request will automatically act to stay the effective date of the penalty or assessment until such time as the ALJ rules upon the request.

(2) The ALJ may not grant a respondent's request for stay of any penalty or assessment unless the respondent posts a bond or provides other adequate security.

(3) The ALJ will rule upon a respondent's request for stay within 10 days of receipt.

§ 1005.23 Harmless error.

No error in either the admission or the exclusion of evidence, and no error or defect in any ruling or order or in any act done or omitted by the ALJ or by any of the parties, including Federal representatives such as Medicare carriers and intermediaries and Peer Review Organizations, is ground for vacating, modifying or otherwise disturbing an otherwise appropriate ruling or order or act, unless refusal to take such action appears to the ALJ or the DAB inconsistent with substantial justice. The ALJ and the DAB at every stage of the proceeding will disregard any error or defect in the proceeding that does not affect the substantial rights of the parties.

PART 1006—INVESTIGATIONAL INQUIRIES

Sec. 1006.1 Scope.
1006.2 Contents of subpoena.
1006.3 Service and fees.
1006.4 Procedures for investigational inquiries.
1006.5 Enforcement of a subpoena.

Authority: 42 U.S.C. 405(d), 405(e), 1302 and 1320a-7a.
Office of Inspector General—Health Care, HHS § 1006.4

Source: 57 FR 3354, Jan. 29, 1992, unless otherwise noted.

§ 1006.1 Scope.

(a) The provisions in this part govern subpoenas issued by the Inspector General, or his or her delegates, in accordance with sections 205(d) and 1128A(j) of the Act, and require the attendance and testimony of witnesses and the production of any other evidence at an investigational inquiry.

(b) Such subpoenas may be issued in investigations under section 1128A of the Act or under any other section of the Act that incorporates the provisions of section 1128A(j).

(c) Nothing in this part is intended to apply to or limit the authority of the Inspector General, or his or her delegates, to issue subpoenas for the production of documents in accordance with 5 U.S.C. 6(a)(4), App. 3.

§ 1006.2 Contents of subpoena.

A subpoena issued under this part will—

(a) State the name of the individual or entity to whom the subpoena is addressed;

(b) State the statutory authority for the subpoena;

(c) Indicate the date, time and place that the investigational inquiry at which the witness is to testify will take place;

(d) Include a reasonably specific description of any documents or items required to be produced; and

(e) If the subpoena is addressed to an entity, describe with reasonable particularity the subject matter on which testimony is required. In such event, the named entity will designate one or more individuals who will testify on its behalf, and will state as to each individual so designated that individual’s name and address and the matters on which he or she will testify. The individual so designated will testify as to matters known or reasonably available to the entity.

§ 1006.3 Service and fees.

(a) A subpoena under this part will be served by—

(1) Delivering a copy to the individual named in the subpoena;

(2) Delivering a copy to the entity named in the subpoena at its last principal place of business; or

(3) Registered or certified mail addressed to such individual or entity at its last known dwelling place or principal place of business.

(b) A verified return by the individual serving the subpoena setting forth the manner of service or, in the case of service by registered or certified mail, the signed return post office receipt, will be proof of service.

(c) Witnesses will be entitled to the same fees and mileage as witnesses in the district courts of the United States (28 U.S.C. 1821 and 1825). Such fees need not be paid at the time the subpoena is served.

§ 1006.4 Procedures for investigational inquiries.

(a) Testimony at investigational inquiries will be taken under oath or affirmation.

(b) Investigational inquiries are nonpublic investigatory proceedings. Attendance of non-witnesses is within the discretion of the OIG, except that—

(1) A witness is entitled to be accompanied, represented and advised by an attorney; and

(2) Representatives of the OIG and the Office of the General Counsel are entitled to attend and ask questions.

(c) A witness will have an opportunity to clarify his or her answers on the record following the questions by the OIG.

(d) Any claim of privilege must be asserted by the witness on the record.

(e) Objections must be asserted on the record. Errors of any kind that might be corrected if promptly presented will be deemed to be waived unless reasonable objection is made at the investigational inquiry. Except where the objection is on the grounds of privilege, the question will be answered on the record, subject to the objection.

(f) If a witness refuses to answer any question not privileged or to produce requested documents or items, or engages in conduct likely to delay or obstruct the investigational inquiry, the OIG may seek enforcement of the subpoena under § 1006.5.
§ 1006.5

(g)(1) The proceedings will be recorded and transcribed.

(2) The witness is entitled to a copy of the transcript, upon payment of prescribed costs, except that, for good cause, the witness may be limited to inspection of the official transcript of his or her testimony.

(3)(i) The transcript will be submitted to the witness for signature.

(ii) Where the witness will be provided a copy of the transcript, the transcript will be submitted to the witness for signature. The witness may submit to the OIG written proposed corrections to the transcript, with such corrections attached to the transcript. If the witness does not return a signed copy of the transcript or proposed corrections within 30 days of its being submitted to him or her for signature, the witness will be deemed to have agreed that the transcript is true and accurate.

(iii) Where, as provided in paragraph (g)(2) of this section, the witness is limited to inspecting the transcript, the witness will have the opportunity at the time of inspection to propose corrections to the transcript, with corrections attached to the transcript. The witness will also have the opportunity to sign the transcript. If the witness does not sign the transcript or offer corrections within 30 days of receipt of notice of the opportunity to inspect the transcript, the witness will be deemed to have agreed that the transcript is true and accurate.

(iv) The OIG’s proposed corrections the record of transcript will be attached to the transcript.

(h) Testimony and other evidence obtained in an investigational inquiry may be used by the OIG or DHHS in any of its activities, and may be used or offered into evidence in any administrative or judicial proceeding.

§ 1007. Definitions.

As used in this part, unless otherwise indicated by the context:

Employ or employee, as the context requires, means full-time duty intended to last at least a year. It includes an arrangement whereby an individual is on full-time detail or assignment to the unit from another government agency, if the detail or assignment is for a period of at least 1 year and involves supervision by the unit.

Provider means an individual or entity that furnishes items or services for which payment is claimed under Medicaid.

Unit means the State Medicaid fraud control unit.

PART 1007—STATE MEDICAID FRAUD CONTROL UNITS

Sec.
1007.1 Definitions.
1007.3 Scope and purpose.
1007.5 Basic requirement.
1007.7 Organization and location requirements.
1007.9 Relationship to, and agreement with, the Medicaid agency.
1007.11 Duties and responsibilities of the unit.
1007.13 Staffing requirements.
1007.15 Applications, certification and recertification.
1007.17 Annual report.
1007.19 Federal financial participation (FFP).
1007.21 Other applicable HHS regulations.

Authority: 42 U.S.C. 1396b(a)(6), 1396b(b)(3) and 1396b(q).

Source: 57 FR 3355, Jan. 29, 1992, unless otherwise noted.

§ 1007.3 Scope and purpose.

As used in this part, unless otherwise indicated by the context:

Employ or employee, as the context requires, means full-time duty intended to last at least a year. It includes an arrangement whereby an individual is on full-time detail or assignment to the unit from another government agency, if the detail or assignment is for a period of at least 1 year and involves supervision by the unit.

Provider means an individual or entity that furnishes items or services for which payment is claimed under Medicaid.

Unit means the State Medicaid fraud control unit.

§ 1007.5 Enforcement of a subpoena.

A subpoena to appear at an investigational inquiry is enforceable through the District Court of the United States and the district where the subpoenaed person is found, resides or transacts business.
§ 1007.5 Basic requirement.
A State Medicaid fraud control unit must be a single identifiable entity of the State government certified by the Secretary as meeting the requirements of §§ 1007.7 through 1007.13 of this part.

§ 1007.7 Organization and location requirements.
Any of the following three alternatives is acceptable:
(a) The unit is located in the office of the State Attorney General or another department of State government which has Statewide authority to prosecute individuals for violations of criminal laws with respect to fraud in the provision or administration of medical assistance under a State plan implementing title XIX of the Act;
(b) If there is no State agency with Statewide authority and capability for criminal fraud prosecutions, the unit has established formal procedures that assure that the unit refers suspected cases of criminal fraud in the State Medicaid program to the appropriate State prosecuting authority or authorities, and provides assistance and coordination to such authority or authorities in the prosecution of such cases;
(c) The unit has a formal working relationship with the office of the State Attorney General and has formal procedures for referring to the Attorney General suspected criminal violations occurring in the State Medicaid program and for effective coordination of the activities of both entities relating to the detection, investigation and prosecution of those violations. Under this requirement, the office of the State Attorney General must agree to assume responsibility for prosecuting alleged criminal violations referred to it by the unit. However, if the Attorney General finds that another prosecuting authority has the demonstrated capacity, experience and willingness to prosecute an alleged violation, he or she may refer a case to that prosecuting authority, as long as the Attorney General’s Office maintains oversight responsibility for the prosecution and for coordination between the unit and the prosecuting authority.

§ 1007.9 Relationship to, and agreement with, the Medicaid agency.
(a) The unit must be separate and distinct from the Medicaid agency.
(b) No official of the Medicaid agency will have authority to review the activities of the unit or to review or overrule the referral of a suspected criminal violation to an appropriate prosecuting authority.
(c) The unit will not receive funds paid under this part either from or through the Medicaid agency.
(d) The unit will enter into an agreement with the Medicaid agency under which the Medicaid agency will agree to comply with all requirements of §455.21(a)(2) of this title.

§ 1007.11 Duties and responsibilities of the unit.
(a) The unit will conduct a Statewide program for investigating and prosecuting (or referring for prosecution) violations of all applicable State laws pertaining to fraud in the administration of the Medicaid program, the provision of medical assistance, or the activities of providers of medical assistance under the State Medicaid plan.
(b) (1) The unit will also review complaints alleging abuse or neglect of patients in health care facilities receiving payments under the State Medicaid plan and may review complaints of the misappropriation of patient’s private funds in such facilities.
(2) If the initial review indicates substantial potential for criminal prosecution, the unit will investigate the complaint or refer it to an appropriate criminal investigative or prosecutive authority.
(3) If the initial review does not indicate a substantial potential for criminal prosecution, the unit will refer the complaint to an appropriate State agency.
(c) If the unit, in carrying out its duties and responsibilities under paragraphs (a) and (b) of this section, discovers that overpayments have been made to a health care facility or other provider of medical assistance under the State Medicaid plan, the unit will either attempt to collect such overpayment or refer the matter to an appropriate State agency for collection.
\section*{§ 1007.13 Staffing requirements.}

(a) The unit will employ sufficient professional, administrative, and support staff to carry out its duties and responsibilities in an effective and efficient manner. The staff must include:

(1) One or more attorneys experienced in the investigation or prosecution of civil fraud or criminal cases, who are capable of giving informed advice on applicable law and procedures and providing effective prosecution or liaison with other prosecutors;

(2) One or more experienced auditors capable of supervising the review of financial records and advising or assisting in the investigation of alleged fraud; and

(3) A senior investigator with substantial experience in commercial or financial investigations who is capable of supervising and directing the investigative activities of the unit.

(b) The unit will employ, or have available to it, professional staff who are knowledgeable about the provision of medical assistance under title XIX and about the operation of health care providers.

\section*{§ 1007.15 Applications, certification and recertification.}

(a) Initial application. In order to receive FFP under this part, the unit must submit to the Secretary, an application approved by the Governor, containing the following information and documentation—

(1) A description of the applicant’s organization, structure, and location within State government, and an indication of whether it seeks certification under § 1007.7 (a), (b), or (c);

(2) A statement from the State Attorney General that the applicant has authority to carry out the functions and responsibilities set forth in this part. If the applicant seeks certification under § 1007.7(b), the statement must also specify either that—

(i) There is no State agency with the authority to exercise Statewide prosecutorial authority for the violations with which the unit is concerned, or

(ii) Although the State Attorney General may have common law authority for Statewide criminal prosecutions, he or she has not exercised that authority;

(3) A copy of whatever memorandum of agreement, regulation, or other document sets forth the formal procedures required under §1007.7(b), or the formal working relationship and procedures required under §1007.7(c);

(4) A copy of the agreement with the Medicaid agency required under §1007.9;

(5) A statement of the procedures to be followed in carrying out the functions and responsibilities of this part;

(6) A projection of the caseload and a proposed budget for the 12-month period for which certification is sought; and

(7) Current and projected staffing, including the names, education, and experience of all senior professional staff already employed and job descriptions, with minimum qualifications, for all professional positions.

(b) Conditions for, and notification of certification. (1) The Secretary will approve an application only if he or she has specifically approved the applicant’s formal procedures under §1007.7 (b) or (c), if either of those provisions is applicable, and has specifically certified that the applicant meets the requirements of §1007.7;
(2) The Secretary will promptly notify the applicant whether the application meets the requirements of this part and is approved. If the application is not approved, the applicant may submit an amended application at any time. Approval and certification will be for a period of 1 year.

(c) Conditions for recertification. In order to continue receiving payments under this part, a unit must submit a reapplication to the Secretary at least 60 days prior to the expiration of the 12-month certification period. A reapplication must—

(1) Advise the Secretary of any changes in the information or documentation required under paragraphs (a) (1) through (5) of this section;

(2) Provide projected caseload and proposed budget for the recertification period; and

(3) Include or reference the annual report required under §1007.17.

(d) Basis for recertification. (1) The Secretary will consider the unit’s reapplication, the reports required under §1007.17, and any other reviews or information he or she deems necessary or warranted, and will promptly notify the unit whether he or she has approved the reapplication and recertified the unit.

(2) In reviewing the reapplication, the Secretary will give special attention to whether the unit has used its resources effectively in investigating cases of possible fraud, in preparing cases for prosecution, and in prosecuting cases or cooperating with the prosecuting authorities.

(Approved by the Office of Management and Budget under control number 0990–0162)

§ 1007.17 Annual report.

At least 60 days prior to the expiration of the certification period, the unit will submit to the Secretary a report covering the last 12 months (the first 9 months of the certification period for the first annual report), and containing the following information—

(a) The number of investigations initiated and the number completed or closed, categorized by type of provider;

(b) The number of cases prosecuted or referred for prosecution; the number of cases finally resolved and their outcomes; and the number of cases investigated but not prosecuted or referred for prosecution because of insufficient evidence;

(c) The number of complaints received regarding abuse and neglect of patients in health care facilities; the number of such complaints investigated by the unit; and the number referred to other identified State agencies;

(d) The number of recovery actions initiated by the unit; the number of recovery actions referred to another agency; the total amount of overpayments identified by the unit; and the total amount of overpayments actually collected by the unit;

(e) The number of recovery actions initiated by the Medicaid agency under its agreement with the unit, and the total amount of overpayments actually collected by the Medicaid agency under this agreement;

(f) Projections for the succeeding 12 months for items listed in paragraphs (a) through (e) of this section;

(g) The costs incurred by the unit; and

(h) A narrative that evaluates the unit’s performance; describes any specific problems it has had in connection with the procedures and agreements required under this part; and discusses any other matters that have impaired its effectiveness.

(Approved by the Office of Management and Budget under control number 0990–0162)

§ 1007.19 Federal financial participation (FFP).

(a) Rate of FFP. Subject to the limitation of this section, the Secretary will reimburse each State by an amount equal to 90 percent of the costs incurred by a certified unit which are attributable to carrying out its functions and responsibilities under this part.

(b) Retroactive certification. The Secretary may grant certification retroactive to the date on which the unit first met all the requirements of the statute and of this part. For any quarter with respect to which the unit is certified, the Secretary will provide reimbursement for the entire quarter.
(c) Amount of FFP. FFP for any quarter will not exceed the higher of $125,000 or one-quarter of 1 percent of the sums expended by the Federal, State, and local governments during the previous quarter in carrying out the State Medicaid program.

(d) Costs subject to FFP. (1) FFP is available under this part for the expenditures attributable to the establishment and operation of the unit, including the cost of training personnel employed by the unit. Reimbursement will be limited to costs attributable to the specific responsibilities and functions set forth in this part in connection with the investigation and prosecution of suspected fraudulent activities and the review of complaints of alleged abuse or neglect of patients in health care facilities.

(2) (i) Establishment costs are limited to clearly identifiable costs of personnel that—
A. Devote full time to the establishment of the unit which does achieve certification; and
B. Continue as full-time employees after the unit is certified.
(ii) All establishment costs will be deemed made in the first quarter of certification.

(e) Costs not subject to FFP. FFP is not available under this part for expenditures attributable to—
(1) The investigation of cases involving program abuse or other failures to comply with applicable laws and regulations, if these cases do not involve substantial allegations or other indications of fraud;
(2) Efforts to identify situations in which a question of fraud may exist, including the screening of claims, analysis of patterns of practice, or routine verification with recipients of whether services billed by providers were actually received;
(3) The routine notification of providers that fraudulent claims may be punished under Federal or State law;
(4) The performance by a person other than a full-time employee of the unit of any management function for the unit, any audit or investigation, any professional legal function, or any criminal, civil or administrative prosecution of suspected providers;
(5) The investigation or prosecution of cases of suspected recipient fraud not involving suspected conspiracy with a provider; or
(6) Any payment, direct or indirect, from the unit to the Medicaid agency, other than payments for the salaries of employees on detail to the unit.

§ 1007.21 Other applicable HHS regulations.
Except as otherwise provided in this part, the following regulations from 45 CFR subtitle A apply to grants under this part:
P. Part 16, subpart C—Department Grant Appeals Process—Special Provisions Applicable To Reconsideration of Disallowances [Note that this applies only to disallowance determinations and not to any other determinations, e.g., over certification or recertification];
P. Part 74—Administration of Grants;
P. Part 75—Informal Grant Appeals Procedures;
P. Part 80—Nondiscrimination Under Programs Receiving Federal Assistance Through the Department of Health and Human Services, Effective Title VI of the Civil Rights Act of 1964;
P. Part 81—Practice and Procedure for Hearings Under 45 CFR part 80;
P. Part 84—Nondiscrimination on the Basis of Handicap in Programs and Activities Receiving or Benefiting From Federal Financial Assistance;
P. Part 91—Nondiscrimination on the Basis of Age in HHS Programs or Activities Receiving Federal Financial Assistance.

PART 1008—ADVISORY OPINIONS BY THE OIG

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Authority: 42 U.S.C. 1320a-7d(b).

Source: 62 FR 7357, Feb. 19, 1997, unless otherwise noted.

Subpart A—General Provisions

§ 1008.1 Basis and purpose.

(a) This part contains the specific procedures for the submission of requests by an individual or entity for advisory opinions to, and the issuance of advisory opinions by, the OIG, in consultation with the Department of Justice (DoJ), in accordance with section 1128D(b) of the Social Security Act (Act), 42 U.S.C. 1320a-7d(b). The OIG will issue such advisory opinions based on actual or proposed factual circumstances submitted by the requesting individual or entity, or by counsel on behalf of the requesting individual or entity, provided all other requirements of this part are satisfied (including the requirement that the requesting individual or entity provide the certifications required in accordance with §1008.38 of this part).

(b) An individual or entity may request an advisory opinion from the OIG regarding any of five specific subject matters described in §1008.5 of this part.

(c) The requesting party must provide a complete description of the facts as set forth in subpart B of this part, and pay the costs to the OIG of processing the request for an advisory opinion as set forth in subpart C of this part.

(d) Nothing in this part limits the investigatory or prosecutorial authority of the OIG, DoJ, or any other agency of the Government.


§ 1008.3 Effective period.

The provisions in this part are applicable to requests for advisory opinions submitted on or after February 21, 1997, and before August 21, 2000, and to any requests submitted during any other time period for which the OIG is required by law to issue advisory opinions.

§ 1008.5 Matters subject to advisory opinions.

(a) An individual or entity may request an advisory opinion from the OIG regarding—

(1) What constitutes prohibited remuneration within the meaning of section 1128B(b) of the Act;

(2) Whether an arrangement, or proposed arrangement, satisfies the criteria set forth in section 1128B(b)(3) of the Act for activities that do not result in prohibited remuneration;

(3) Whether an arrangement, or proposed arrangement, satisfies the criteria set forth in §1001.952 of this chapter for activities that do not result in prohibited remuneration;

(4) What constitutes an inducement to reduce or limit services under section 1128A(b) of the Act to Medicare or Medicaid program beneficiaries; and

(5) Whether any activity, or proposed activity, constitutes grounds for the imposition of a sanction under sections 1128, 1128A or 1128B of the Act.

(b) Exceptions. The OIG will not address through the advisory opinion process—

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(1) What the fair market value will be, or whether fair market value was paid or received, for any goods, services or property; or

(2) Whether an individual is a bona fide employee within the requirements of section 3121(d)(2) of the Internal Revenue Code of 1986.


Subpart B—Preliminary Obligations and Responsibilities of the Requesting Party

§ 1008.11 Who may submit a request.

Any individual or entity may submit a request to the OIG for an advisory opinion regarding an existing arrangement or one which the requestor in good faith specifically plans to undertake. The requestor must be a party to the arrangement, or proposed arrangement, that is the subject of the request.

§ 1008.15 Facts subject to advisory opinions.

(a) The OIG will consider requests from a requesting party for advisory opinions regarding the application of specific facts to the subject matters set forth in §1008.5(a) of this part. The facts must relate to an existing arrangement, or one which the requestor in good faith plans to undertake. The plans may be contingent upon receiving a favorable advisory opinion. The advisory opinion request should contain a complete description of the arrangement that the requestor is undertaking, or plans to undertake.

(b) Requests presenting a general question of interpretation, posing a hypothetical situation, or regarding the activities of third parties do not qualify as advisory opinion requests.

(c) Advisory opinion request will not be accepted and/or opinions will not be issued when—

(1) The request is not related to a named individual or entity;

(2) The same, or substantially the same, course of action is under investigation, or is or has been the subject of a proceeding involving the Department of Health and Human Services or another governmental agency; or

(3) An informed opinion cannot be made, or could be made only after extensive investigation, clinical study, testing, or collateral inquiry.


§ 1008.18 Preliminary questions suggested for the requesting party.

(a) The OIG may establish and maintain a set of questions corresponding to the categories of opinion subject matter as set forth in §1008.5(a) of this part as appropriate. The questions will be designed to elicit specific information relevant to the advisory opinion being sought; however, answering the questions is voluntary.

(b) Questions the OIG suggests that the requestor address may be obtained from the OIG. Requests should be made in writing, specify the subject matter, and be sent to the headquarters offices of the OIG.

(c) When submitting a request for an advisory opinion, a requestor may answer the questions corresponding to the subject matter for which the opinion is requested. The extent to which any of the questions is not fully answered may affect the content of the advisory opinion.


Subpart C—Advisory Opinion Fees

§ 1008.31 OIG fees for the cost of advisory opinions.

(a) Responsibility for fees. The requestor is responsible for paying a fee equal to the costs incurred by the Department in responding to the request for an advisory opinion.

(b) Initial payment. A request for an advisory opinion must be accompanied by a check or money order payable to the Treasury of the United States for $250. This initial payment is non-refundable.

(c) Calculation of costs: Prior to the issuance of the advisory opinion, the OIG will calculate the costs incurred by the Department in responding to the request. The calculation will include the costs of salaries and benefits payable to attorneys and others who
Agreement to pay all costs. (1) By submitting the request for an advisory opinion, the requestor agrees, except as indicated in paragraph (d)(4) of this section, to pay all costs incurred by the OIG in responding to the request for an advisory opinion. (2) In its request for an advisory opinion, the requestor may request a written estimate of the cost involved in processing the advisory opinion. Within 10 business days of receipt of the request, the OIG will notify in writing of such estimate. Such estimate will not be binding on the Department, and the actual cost to be paid may be higher or lower than estimated. The time period for issuing the advisory opinion will be tolled from the time the OIG notifies the requestor of the estimate until the OIG receives written confirmation from the requestor that the requestor wants the OIG to continue processing the request. Such notice may include a new or revised triggering dollar amount, as set forth in paragraph (d)(3) of this section. (3) In its request for an advisory opinion, the requestor may designate a triggering dollar amount. If the OIG estimates that the costs of processing the advisory opinion request have reached, or are likely to exceed, the designated triggering dollar amount, the OIG will notify the requestor. The requestor may revise its designated triggering dollar amount in writing in its response to notification of a cost estimate in accordance with paragraph (d)(2) of this section. (4) If the OIG notifies the requestor that the estimated cost of processing the request has reached or is likely to exceed the triggering dollar amount, the OIG will stop processing the request until such time as the requestor makes a written request for the OIG to continue processing the request. Any delay in the processing of the request for an advisory opinion attributable to these procedures will toll the time for issuance of an advisory opinion until the requestor asks the OIG to continue working on the request. (5) If the requestor chooses not to pay for completion of an advisory opinion, or withdraws the request, the requestor is still obligated to pay for all costs incurred and identified by the OIG attributable to processing the request for an advisory opinion up to that point. (6) If the costs incurred by the OIG in responding to the request are greater than the amount paid by the requestor, the OIG will, prior to the issuance of the advisory opinion, notify the requestor of any additional amount due. The OIG will not issue an advisory opinion until the full amount owed by the requestor has been paid. Once the requestor has paid the OIG the total amount due for the costs of processing the request, the OIG will issue the advisory opinion. The time period for issuing advisory opinions will be tolled from the time the OIG notifies the requestor of the amount owed until the time full payment is received. (e) Fees for outside experts. (1) In addition to the fees identified in this section, the requestor also must pay any required fees for expert opinions, if any, from outside sources, as described in §1008.33. (2) If the OIG determines that it is necessary to obtain expert advice to issue a requested advisory opinion, the OIG will notify the requestor of that fact and provide the identity of the appropriate expert and an estimate of the costs of the expert advice.
§ 1008.36 Submission of a request.

(a) A request for a formal advisory opinion must be submitted in writing. An original and 2 copies of the request should be addressed to the headquarters offices of the OIG.

(b) Each request for an advisory opinion must include—

1. To the extent known to the requestor, the identities, including the names and addresses, of the requestor and of all other actual and potential parties to the arrangement, that are the subject of the request for an advisory opinion;

2. The name, title, address, and daytime telephone number of a contact person who will be available to discuss the request for an advisory opinion with the OIG on behalf of the requestor;

3. A declaration of the subject category or categories as described in §1008.5 of this part for which the advisory opinion is requested. To the extent an individual or entity requests an advisory opinion in accordance with §§1008.3(a)(3) or (a)(5) of this part, the requesting individual or entity should identify the specific subsections of sections 1128, 1129A or 1128B of the Act or the specific provision of §1001.952 of this chapter about which an advisory opinion is sought;

4. A complete and specific description of all relevant information bearing on the arrangement for which an advisory opinion is requested and on the circumstances of the conduct, including—

(i) Background information,

(ii) For existing arrangements, complete copies of all operative documents,

(iii) For proposed arrangements, complete copies of all operative documents, if possible, and otherwise descriptions of proposed terms, drafts, or models of documents sufficient to permit the OIG to render an informed opinion,

(iv) Detailed statements of all collateral or oral understandings, if any, and

(v) If applicable, a designation of trade secrets or confidential commercial or financial information in the manner described in 45 CFR 5.65;

5. Signed certifications by the requestor(s), as described in §1008.37 of this part;

6. A check or money order payable to the Treasury of the United States in the amount of $250, as discussed in §1008.31(b) of this part;

7. A declaration regarding whether an advisory opinion in accordance with part 411 of this title has been or will be requested from HCFA about the arrangement that is the subject of the advisory opinion request; and

8. Each requesting party’s Taxpayer Identification Number.

(Approved by the Office of Management and Budget under control number 0990-0213)

§ 1008.37 Disclosure of ownership and related information.

Each individual or entity requesting an advisory opinion must supply full and complete information as to the identity of each entity owned or controlled by the individual or entity, and of each person with an ownership or control interest in the entity, as defined in section 1124(a)(1) of the Social Security Act (42 U.S.C. 1320a-3(a)(1)) and part 420 of this chapter.

(Approved by the Office of Management and Budget under control #0990-0213)
§ 1008.38 Signed certifications by the requestor.

(a) Every request must include the following signed certification from all requestors: “With knowledge of the penalties for false statements provided by 18 U.S.C. 1001 and with knowledge that this request for an advisory opinion is being submitted to the Department of Health and Human Services, I certify that all of the information provided is true and correct, and constitutes a complete description of the facts regarding which an advisory opinion is sought, to the best of my knowledge and belief.”

(b) If the advisory opinion relates to a proposed arrangement, the request must also include the following signed certification from all requestors: “The arrangement described in this request for an advisory opinion is one that the requestor(s) in good faith plan(s) to undertake.” This statement may be made contingent on a favorable OIG advisory opinion, in which case, the phrase “if the OIG issues a favorable advisory opinion” should be added to the certification.

(c) The certification(s) must be signed by—

(1) The requestor, if the requestor is an individual;

(2) The chief executive officer, or comparable officer, of the requestor, if the requestor is a corporation;

(3) The managing partner of the requestor, if the requestor is a partnership; or

(4) The managing member, or comparable person, if the requestor is a limited liability company.

§ 1008.39 Additional information.

(a) If the request for an advisory opinion does not contain all of the information required by §1008.36 of this part, or the OIG believes it needs more information prior to rendering an advisory opinion, the OIG may, at any time, request whatever additional information or documents it deems necessary. The time period for the issuance of an advisory opinion will be tolled from the time the OIG requests the additional information from the requestor until such time as the OIG determines that it has received the requested information.

(b) The OIG may request additional information before or after the request for an advisory opinion has been accepted.

(c) Additional information should be provided in writing and certified to be a true, correct and complete disclosure of the requested information in a manner equivalent to that described in §1008.38 of this part.

(d) In connection with any request for an advisory opinion, the OIG or DoJ may conduct whatever independent investigation they believe appropriate.

(e) Requesting parties are required to notify the OIG if they request an advisory opinion in accordance with part 411 of this title from HCFA about the arrangement that is the subject of their advisory opinion request.

(f) Where appropriate, after receipt of an advisory opinion request, the OIG may consult with the requesting parties to the extent the OIG deems necessary.

§ 1008.40 Withdrawal.

The requestor of an advisory opinion may withdraw the request prior to the issuance of a formal advisory opinion by the OIG. The withdrawal must be written and must be submitted to the same address as the submitted request, as indicated in §§1008.18(b) and 1008.36(a) of this part. Regardless of whether the request is withdrawn, the requestor must pay the costs expended by the OIG in processing the opinion, as discussed in §1008.31(d) of this part. The OIG reserves the right to retain any request for an advisory opinion, documents and information submitted to it under these procedures, and to use them for any governmental purposes.
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Subpart E—Obligations and Responsibilities of the OIG

§ 1008.41 OIG acceptance of the request.

(a) Upon receipt of a request for an advisory opinion, the OIG will promptly make an initial determination whether the submission includes all of the information the OIG will require to process the request.

(b) Within 10 working days of receipt of the request, the OIG will—

(1) Formally accept the request for an advisory opinion,

(2) Notify the requestor of what additional information is needed, or

(3) Formally decline to accept the request.

(c) If the requestor provides the additional information requested, or otherwise resubmits the request, the OIG will process the resubmission in accordance with paragraphs (a) and (b) of this section as if it was an initial request for an advisory opinion.

(d) Upon acceptance of the request, the OIG will notify the requestor by regular U.S. mail of the date that the request for the advisory opinion was formally accepted.

(e) The 60-day period for issuance of an advisory opinion set forth in §1008.43(c) of this part will not commence until the OIG has formally accepted the request for an advisory opinion.


§ 1008.43 Issuance of a formal advisory opinion.

(a) An advisory opinion will be considered issued once payment is received and it is dated, numbered, and signed by an authorized official of the OIG.

(b) An advisory opinion will contain a description of the material facts provided to the OIG with regard to the arrangement for which an advisory opinion has been requested. The advisory opinion will state the OIG’s opinion regarding the subject matter of the request based on the facts provided to the OIG. If necessary, to fully describe the arrangement, the OIG is authorized to include in the advisory opinion the material facts of the arrangement, notwithstanding that some of these facts could be considered confidential information or trade secrets within the meaning of 18 U.S.C. 1905.

(c)(1) The OIG will issue an advisory opinion, in accordance with the provisions of this part, within 60 days after the request for an advisory opinion has been formally accepted;

(2) If the 60th day falls on a Saturday, Sunday, or Federal holiday, the time period will end at the close of the next business day following the weekend or holiday;

(3) The 60 day period will be tolled from the time the OIG—

(i) Notifies the requestor that the costs have reached, or are likely to exceed, the triggering amount until the time when the OIG receives written notice from the requestor to continue processing the request;

(ii) Requests additional information from the requestor until the time the OIG receives the requested information;

(iii) Notifies the requestor of the full amount due until the time the OIG receives payment of the full amount owed; and

(iv) Notifies the requestor of the need for expert advice until the time the OIG receives the expert advice.

(d) After the OIG has notified the requestor of the full amount owed and the OIG has received full payment of that amount, the OIG will issue the advisory opinion and promptly mail it to the requestor by regular first class U.S. mail.


§ 1008.45 Rescission, termination or modification.

(a) Any advisory opinion given by the OIG is without prejudice to the right of the OIG to reconsider the questions involved and, where the public interest requires, to rescind, terminate or modify the advisory opinion. Requestors will be given a preliminary notice of the OIG’s intent to rescind, terminate or modify the opinion, and will be provided a reasonable opportunity to respond. A final notice of rescission, termination or modification will be given to the requestor so that the individual or entity may discontinue or modify.
as the case may be, the course of action taken in accordance with the OIG advisory opinion.

(b) For purposes of this part—

(1) To rescind an advisory opinion means that the advisory opinion is revoked retroactively to the original date of issuance with the result that the advisory opinion will be deemed to have been without force and effect from the original date of issuance. Recission may occur only where relevant and material facts were not fully, completely and accurately disclosed to the OIG.

(2) To terminate an advisory opinion means that the advisory opinion is revoked as of the termination date and is no longer in force and effect after the termination date. The OIG will not proceed against the requestor under this part if such action was promptly, diligently, and in good faith discontinued in accordance with reasonable time frames established by the OIG after consultation with the requestor.

(3) To modify an advisory opinion means that the advisory opinion is amended, altered, or limited, and that the advisory opinion continues in full force and effect after the termination date. The OIG will not proceed against the requestor under this part if such action was promptly, diligently, and in good faith modified in accordance with reasonable time frames established by the OIG after consultation with the requestor.

§ 1008.47 Disclosure.

(a) Advisory opinions issued and released in accordance with the provisions set forth in this part will be available to the public.

(b) Promptly after the issuance and release of an advisory opinion to the requestor, a copy of the advisory opinion will be available for public inspection between the hours of 10:00 a.m. and 3:00 p.m. on normal business days at the headquarters offices of the OIG and on the DHHS/OIG web site.

(c) Any pre-decisional document, or part of such pre-decisional document, that is prepared by the OIG, DoJ, or any other Department or agency of the United States in connection with an advisory opinion request under the procedures set forth in this part generally will be exempt from disclosure under 5 U.S.C. 552, and will not be made publicly available.

(d) Documents submitted by the requestor to the OIG in connection with a request for an advisory opinion may be available to the public in accordance with 5 U.S.C. 552 through procedures set forth in 45 CFR part 5.

(e) Nothing in this section will limit the OIG's right, in its discretion, to issue a press release or otherwise publicly disclose the identity of the requesting party or parties, and the nature of the action taken by the OIG upon the request.


Subpart F—Scope and Effect of OIG Advisory Opinions

§ 1008.51 Exclusivity of OIG advisory opinions.

The only method for obtaining a binding advisory opinion regarding any of the subject matters set forth in §1008.5(a) is through the procedures described in this part. No binding advisory opinion, oral or written, has or may be issued by the OIG regarding the specific matters set forth in §1008.5(a) except through written opinions issued in accordance with this part.

§ 1008.53 Affected parties.

An advisory opinion issued by the OIG will have no application to any individual or entity that does not join in the request for the opinion. No individual or entity other than the requestor(s) may rely on an advisory opinion.

§ 1008.55 Admissibility of evidence.

(a) The failure of a party to seek an advisory opinion may not be introduced into evidence to prove that the party intended to violate the provisions of sections 1128, 1128A or 1128B of the Act.

(b) An advisory opinion may not be introduced into evidence by a person or entity that was not the requestor of the advisory opinion to prove that the person or entity did not violate the
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provisions of sections 1128, 1128A or 1128B of the Act or any other law.


§ 1008.59 Range of the advisory opinion.

(a) An advisory opinion will state only the OIG’s opinion regarding the subject matter of the request. If the arrangement for which an advisory opinion is requested is subject to approval or regulation by any other Federal, State or local government agency, such advisory opinion may not be taken to indicate the OIG’s views on the legal or factual issues that may be raised before that agency. The OIG will not provide any legal opinion on questions or issues regarding an authority which is vested in other Federal, State or local government agencies.

(b) An advisory opinion issued under this part will not bind or obligate any agency other than the Department. It will not affect the requestor’s, or anyone else’s, obligations to any other agency, or under any statutory or regulatory provision other than that which is the specific subject matter of the advisory opinion.

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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Alphabetical List of Agencies Appearing in the CFR
Table of OMB Control Numbers
Redesignation Tables
List of CFR Sections Affected
Material Approved for Incorporation by Reference

(Revised as of October 1, 1998)

The Director of the Federal Register has approved under 5 U.S.C. 552(a) and 1 CFR Part 51 the incorporation by reference of the following publications. This list contains only those incorporations by reference effective as of the revision date of this volume. Incorporations by reference found within a regulation are effective upon the effective date of that regulation. For more information on incorporation by reference, see the preliminary pages of this volume.

42 CFR (PARTS 430-End)
HEALTH CARE FINANCING ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

American Association on Mental Retardation
1719 Kalorama Rd., N.W., Washington, DC 20009
Classification in Mental Retardation, 1983 .............................................. 483.102(b)

American National Standards Institute
11 West 42nd St., New York, NY 10036 Telephone: (212) 642-4900
ANSI A117.1-1971 Specifications for Making Buildings and Facilities Accessible to and Usable by Physically Handicapped People. 442.330(a)(2) and (b)

American Psychiatric Association
Division of Publications and Marketing, 1400 K St., N.W., Washington, DC 20005
Diagnostic and Statistical Manual of Mental Disorders, Third Edition, Revised, 1987. 483.102(b)

National Academy of Sciences
Academy Press, 2101 Constitution Ave., NW., Washington, DC 20418

National Fire Protection Association
1 Batterymarch Park, Quincy, MA 02269-9101, FAX (617) 770-3500
NFPA Life Safety Code, Chapters 12 and 13, 1985 ................................. 485.623(d)
NFPA Standard No. 220, Standard on Type of Building Construction (1979 Ed.). 442.323
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II  Office of the Federal Register (Parts 50—299)  
IV  Miscellaneous Agencies (Parts 400—500)

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XI  Armed Forces Retirement Home (Part 2100)  
XIV  Federal Labor Relations Authority, General Counsel of the Federal Labor Relations Authority and Federal Service Impasses Panel (Parts 2400—2499)  
XV  Office of Administration, Executive Office of the President (Parts 2500—2599)  
XVI  Office of Government Ethics (Parts 2600—2699)  
XXI  Department of the Treasury (Parts 3100—3199)
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XXVIII Department of Justice (Part 3801)
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XXXI Farm Credit Administration (Parts 4100–4199)
XXXIII Overseas Private Investment Corporation (Part 4301)
XXXV Office of Personnel Management (Part 4501)
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V Agricultural Research Service, Department of Agriculture (Parts 500—599)

VI Natural Resources Conservation Service, Department of Agriculture (Parts 600—699)

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VIII Grain Inspection, Packers and Stockyards Administration (Federal Grain Inspection Service), Department of Agriculture (Parts 800—899)

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### Table of OMB Control Numbers

The OMB control numbers for chapter IV of title 42 appear in §400.310. Sections 400.300 and 400.310 are reprinted below for the convenience of the user.

#### Subpart C—OMB Control Numbers for Approved Collections of Information

_Sourced from 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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Sections in 42 CFR that contain collections of information that are currently valid may be found in §400.310. OMB control numbers are identified in the following sections of 42 CFR:

- 417.436, 417.801
- 405.2112, 405.2123, 405.2134, 405.2136–405.2140, 405.2171
- 409.43
- 410.109
- 411.25, 411.32
- 411.54
- 411.165
- 411.404, 411.406
- 411.408
- 412.42
- 412.109
- 415.109
- 415.162
- 416.43
- 416.47
- 417.126
- 417.436, 417.801

Current OMB control Nos.

- 0938–0193
- 0938–0247
- 0938–0610
- 0938–0006
- 0938–0072
- 0938–0057
- 0938–0472
- 0938–0506
- 0938–0610
- 0938–0266
- 0938–0499
- 0938–0554
- 0938–0555
§ 400.310

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

At 51 FR 22042, June 17, 1986, certain sections of regulations formerly appearing in title 42, part 405, subpart J were redesignated as part 482.

For the convenience of the user, the following table shows the relationship of the redesignated sections.

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Redesignation Table II

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 1000 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.

This 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. In the case of title 45, all of the source sections were redesignated. In the case of 42 CFR chapter IV, some of the source sections were redesignated, but others were retained in chapter IV and duplicated in chapter V.

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42 CFR Chapter IV

42 CFR Chapter IV

45 CFR Subtitle A
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Redesignation Table III

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.

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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.

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At 53 FR 36571, Sept. 21, 1988, the Department of Health and Human Services revised part 430. The following derivation table identifies the sections of 45 CFR chapter IV from which 42 CFR chapter IV derives its content.

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Redesignation Table VI

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.

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| 484.48 |
| 484.52 |
| 484.38 |
Redesignation Table VII

In title 42, part 431, §§ 431.800—431.865 (subpart P), were redesignated at 55 FR 22165, May 31, 1990. The following tables show the relationship of the former sections to the current ones.

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## List of CFR Sections Affected

All changes in this volume of the Code of Federal Regulations which were made by documents published in the Federal Register since January 1, 1986, are enumerated in the following list. Entries indicate the nature of the changes effected. Page numbers refer to Federal Register pages. The user should consult the entries for chapters and parts as well as sections for revisions.


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| 1001.1701 | (c)(1)(v) revised; eff. 10-2-98 | 46690 |
| 1001.1901 | (b)(1), (3), (c)(3)(i), (ii), and (5)(ii) revised; (c)(4) redesignated as (c)(5); (c)(3)(iii) and new (4) added; eff. 10-2-98 | 46690 |
| 1001.2001 | Revised; eff. 10-2-98 | 46690 |
| 1001.2002 | (e) added; eff. 10-2-98 | 46690 |
| 1001.2003 | (a) introductory text revised; eff. 10-2-98 | 46690 |
| 1001.2006 | (a)(1) and (7) revised; (a)(8) redesignated as (a)(9); new (a)(8) added; eff. 10-2-98 | 46690 |
| 1001.3001 | (a)(1) revised; eff. 10-2-98 | 46691 |
| 1001.3002 | (a), (b)(3), (4), (c) introductory text and (d) revised; (b)(5) removed; eff. 10-2-98 | 46691 |
| 1002.203 | (a) revised; eff. 10-2-98 | 46691 |
| 1002.211 | (a) revised; eff. 10-2-98 | 46691 |
| 1005.15 | (f)(1) introductory text revised; eff. 10-2-98 | 46691 |
| 1005.21 | (k)(2) and (3) revised; eff. 10-2-98 | 46691 |
| 1008.1 | (a) and (b) revised | 38324 |
| 1008.5 | (b)(1) revised | 38324 |
| 1008.15 | (c) introductory text and (3) revised | 38324 |

### 1998

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