(734) 214–4816; e-mail: *borushko.margaret@epa.gov.*

Correction

In the **Federal Register** of January 16, 2002, in FR Doc. 02–1109, on page 2159, in the second column, correct the **ADDRESSES** caption to read:

ADDRESSES: *Comments:* We must receive your comments by the date indicated under **DATES** above. Send paper copies of written comments (in duplicate if possible) to the contact person listed below. In your correspondence, refer to Docket A–2001–25. See Section VI.B for more information on comment procedures.

Public hearing: We will hold a public hearing on February 15, 2002 at the Washington Dulles Airport Marriott, 45020 Aviation Drive, Dulles, Virginia 20166. Phone: (703–471–9500). If you want to testify at the hearing, notify the contact person listed below at least ten days before the date of the hearing. See Section VI.B for more information on the public-hearing procedures.

Public docket: EPA's Air Docket makes materials related to this rulemaking available for review in Docket No. A–2001–25 located at U.S. Environmental Protection Agency (EPA), Air Docket (6102), Room M–1500, 401 M. Street, SW., Washington, DC 20460 (on the ground floor in Waterside Mall) from 8 a.m. to 5:30 p.m., Monday through Friday, except on government holidays. You can reach the Air Docket by telephone at (202) 260–4400. We may charge a reasonable fee for copying docket materials, as provided in 40 CFR part 2.

Dated: January 18, 2002.

Jeffrey R. Holmstead,

Assistant Administrator, Office of Air and Radiation.

[FR Doc. 02–1880 Filed 1–24–02; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Chapter IV

[CMS–9877–P]

RIN 0938–AH53

Medicare and Medicaid Programs; Terms, Definitions, and Addresses: Technical Amendments

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This technical regulation would amend CMS rules—

To simplify and rationalize the system of definitions and increase uniformity in the use of terms;

To clarify which steps of the appeals process are ''final'' and which are ''binding'';

To correct outdated addresses and organizational unit names;

To remove content that is outdated or duplicative; and

To make other editorial changes and technical corrections.

These revisions are necessary to preclude confusion regarding our regulations and to better ensure uniform understanding and application. By updating and removing content that is outdated, unnecessary, or duplicative, these changes would also shorten our rules and make them easier to use.

DATES: *Comment date:* We will consider all comments received at one of the addresses indicated below no later than 5 p.m. on March 26, 2002.

ADDRESSES: Please mail written comments (one original and three copies) to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: HCF–9877–FC, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received in the event of delivery delays.

If you prefer, you may deliver your written comments by courier (one original and three copies) to one of the following addresses:

Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or

Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Comments mailed to the above addresses indicated as appropriate for hand or courier delivery may be delayed and could be considered late.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code CMS–9877–FC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room C5–12–08 of the headquarters Centers for Medicare & Medicaid Services, 7500 Security Blvd., Baltimore, MD, on Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone: (410) 786–7197.

FOR FURTHER INFORMATION CONTACT: Margaret Teeters, (410) 786–4678.

SUPPLEMENTARY INFORMATION:

A Simplification and Rationalization of the System of Definitions

In revising the definitions system, we aim to ensure that each definition would meet the following conditions:

1. Is worded so as to preclude confusion or misinterpretation.

2. Is not duplicated.

3. Does not include requirements or prohibitions (which belong in the text of the rules); or personnel qualifications (which need to be identified as such).

4. If it is of general applicability, is located at the beginning of chapter IV.

5. If it is of limited applicability, is presented as a basic definition in that part of the regulations to which it is most pertinent or in which it is most frequently used. (When the term is used elsewhere, with the same meaning it has in the basic definition, we cite that basic definition and do not duplicate it. A separate definition of that term would be presented only if it is used with a special, different meaning (for example, in a broader or more limited sense).

We do not include definitions of terms that are not used in the text, are used in their ordinary, usual sense, or are used only once or twice. (In the latter case, the word is explained where used, not placed in a definitions section.)

We would keep all the acronyms for both programs in § 400.200.

Because of the great number of definitions in CMS's regulations, attempting to deal with all of them now would unduly delay issuance of this rule. That would not be desirable for a rule that includes content (updating and correcting) that must be made available promptly to those who implement our regulations and to the general public. We will be developing another technical rule to deal with the remaining definitions.

With respect to personnel qualifications, which have sometimes been presented as ''definitions,'' our goal has been to include in a new § 400.210, the qualifications for the practitioners whose services are most frequently used in the Medicare program. The personnel qualifications for practitioners who furnish less frequently used services would be retained in their current locations.

Qualifications that are different from the basic qualifications set forth in the new section would also be retained where they have been.

A proposed rule identified as BPD–819–P was published on March 10, 1997 at 62 FR 11005. The final rule, identified as CMS–3819–F, will revise part 484 of the CMS regulations, which

sets forth the conditions of participation for home health agencies. The revision includes changes to the personnel qualifications for speech language pathologists, physical and occupational therapists and their assistants, and social workers and social work assistants. For that reason, this rule proposes no changes in part 484, and does not include in the new § 400.210 the qualifications for the above-noted skilled professionals.

B. Effect of Appeals Decisions

Several sections in part 417 pertaining to the appeals process would be revised to clarify which steps in the process are ''binding'' but not ''final.'' The aim is to make clear that the last step in the administrative appeals process must be completed before the appellant has any right to judicial review.

C. Correction of Addresses

We would revise the following sections of the regulations to reflect CMS's new address and any applicable name changes that result from the reorganization of CMS: 401.128, 401.148, 412.63, 412.210, 430.62, 483.102, 485.623.

D. Conforming Amendments

We would correct or remove cross-references to reflect removal or transfer of definitions and personnel qualifications, and outdated or duplicative rules.

E. Clarifying Editorial Revisions

The editorial revisions would—

1. Shorten the regulations and, in order to improve clarity, make the following kinds of changes:

• Eliminate repetition and highlight the similarities and differences among rules that apply to different types of providers or practitioners. Part 456 (Utilization Control) currently includes 3 subparts that repeat all the requirements that apply equally to hospitals, mental hospitals, and intermediate care facilities for the mentally retarded (ICFs/MR).

• Shorten the content and highlight the similarities and differences by presenting the common requirements once in subpart C (''Utilization Control: All Hospitals'') and revising subparts D and F to set forth only the additional requirements that apply to mental hospitals and to ICFs/MR, respectively.

• Remove undesignated centered headings and either substitute designated subparts, or incorporate the content of the undesignated heading into the section headings. Undesignated centered headings, unlike designated subparts, cannot be used to refer to the whole group of sections they encompass. They are usually followed by incomplete section headings because the writer depends too much on the centered heading language—even when the section may appear many pages after the centered heading. This kind of change would be made in part 456 and also in part 447 (Payments for Services).

• Provide an overview of disclosure of information rules set forth in several sections. A single section lists and designates the kinds of information that must be disclosed and the entities that must make disclosure. (Part 420—Program Integrity: Medicare)

2. Make numerous minor modifications to—

• Reflect the fact that the nursing home reform amendments identify Medicaid facilities as ''nursing facilities'' (NFs) rather than ''skilled nursing facilities'' (SNFs); and

• Limit ''intermediate care facilities'' (ICFs) to those that serve persons with mental retardation and related conditions.

3. In part 498, which establishes rules for appeals from CMS determinations, we are proposing to—

• Remove references to the Office of the Inspector General (OIG) because the OIG now has its own appeals regulations in part 1005 of chapter V of this title; and

• In § 498.3(d), restore a sentence removed by a previous technical amendment. That sentence makes absolutely clear that the only administrative actions that qualify as ''initial determinations'' are those listed in paragraph (b) of the section.

4. Remove regulations that are no longer in effect.

Subpart E of part 417 would be removed because the requirements applicable to employer group health plans that include HMOs have become outdated.

Subpart I of part 456 would be removed because section 4751 of the Balanced Budget Act (BBA) of 1997 amended sections 1902(a)(26) and 1902(a)(31) of the Social Security Act to remove the requirement for States to perform Inspection of Care (IoC) reviews in institutions for mental diseases and ICFs/MR.

5. Correct cross-references that have become outdated through changes made by other regulations, as in parts 410 and 424.

F. Deferred Changes

The definitions in subpart J of part 411 and parts 435 and 436 would not be revised because those rules are undergoing extensive changes included in other **Federal Register** documents.

Other Required Information

A. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, if we proceed with a subsequent document, we will respond to the major comments in the preamble to that document.

B. Paperwork Reduction Act

This rule contains no information collection requirements subject to review by the Office of Management and Budget.

C. Regulatory Impact Statement

We have examined the impacts of this rule as required by Executive Order 12866 (Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA), Public Law 96–354. Executive Order 12866 directs agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for rules that constitute significant regulatory action, including rules that have an economic effect of $100 million or more annually (major rules). We have reviewed this rule and have determined that it is not a major rule. Therefore, we are not required to perform an assessment of the costs and savings.

The RFA requires agencies to analyze options for regulatory relief of small businesses in issuing a proposed rule and a final rule that has been preceded by a proposed rule. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $5 million or less annually. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and we certify, that this rule would not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a proposed rule or a final rule preceded by a proposed rule

may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of sections 603 and 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and we certify, that this rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandate Reform Act of 1995, Public Law 104–4, also requires that agencies assess anticipated costs and benefits before issuing any proposed rule and a final rule preceded by a proposed rule that may result in expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million or more. This rule would have no consequential effect on the governments mentioned or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this proposed rule and have determined that it would not have a substantial effect on State or local governments.

We have reviewed this rule and determined that, under the provisions of Public Law 104–121, the Contract with America Act, it is not a major rule.

In accordance with the provisions of Executive Order 12866, this rule was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 400

Grant programs—health, Health facilities, Health maintenance organizations (HMOs), Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 401

Claims, Freedom of information, Health facilities, Medicare, Privacy.

42 CFR Part 402

Administrative practice and procedure, Health facilities, Health Professions, Medicaid, Medicare, Penalties.

42 CFR Part 403

Health insurance, Hospitals, Intergovernmental relations, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 406

Health facilities, Kidney diseases, Medicare.

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Rural areas, X-ray.

42 CFR Part 411

Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney disease, Medicare, Reporting and record keeping requirements, Rural areas, X-rays.

42 CFR Part 416

Health facilities, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 417

Administrative practice and procedure, Grant programs—health, Health care, Health facilities, Health insurance, Health maintenance organizations (HMOs), Loan programs—health, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 418

Health facilities, Hospice care, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 420

Fraud, Health facilities, Health professions, Medicare.

42 CFR Part 421

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 422

Health maintenance organizations (HMO), Medicare+Choice, Provider sponsored organizations (PSO).

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare.

42 CFR Part 430

Administrative practice and procedure, Grant programs—health, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 431

Grant programs—health, Health facilities, Medicaid, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 433

Administrative practice and procedure, Child support, Claims, Grant programs—health, Medicaid, Reporting and recordkeeping requirement.

42 CFR Part 434

Grant programs—health, Health maintenance organizations (HMOs), Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 440

Grant programs—health, Medicaid.

42 CFR Part 441

Family planning, Grant programs—health, Infants and children, Medicaid, Penalties, Reporting and record keeping requirements.

42 CFR Part 442

Grant programs—health, Health facilities, Health professions, Medicaid, Nursing homes, Reporting and recordkeeping requirements.

42 CFR Part 447

Accounting, Administrative practice and procedure, Drugs, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, Rural areas.

42 CFR Part 455

Fraud, Grant programs—health, Health facilities, Health professions, Investigations, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 456

Administrative practice and procedure, Grant programs—health,

Health facilities, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 475

Grant programs—health, Health care, Health professions, Peer Review Organizations (PROs).

42 CFR Part 476

Grant programs—health, Health care, Health facilities, Health professions, Peer Review organizations (PROs), Reporting and record keeping requirements.

42 CFR Part 478

Administrative practice and procedure, Health care, Health professions, Peer Review Organizations (PROs), Reporting and record keeping requirements.

42 CFR Part 480

Health care, Health professionals, Health records, Peer Review Organizations (PROs), Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR 482

Grant programs—health, Hospitals, Medicare, Medicaid, Reporting and record keeping requirements.

42 CFR Part 483

Grant programs—health, Health facilities, Health professions, Health records, Medicaid, Medicare, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

42 CFR Part 485

Grant programs—health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 488

Health facilities, Medicare, Reporting and record keeping requirements.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 491

Grant programs—health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements, Rural areas.

42 CFR Part 493

Grant programs—health, Health facilities, Laboratories, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 498

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirement.

For the reasons set forth in the preamble, 42 CFR Chapter IV would be amended as follows:

PART 400—INTRODUCTION: DEFINITIONS; PERSONNEL QUALIFICATIONS; COLLECTIONS OF INFORMATION

A. Part 400 is amended as set forth below.

1. The heading of part 400 is revised to read as set forth above.

2. The authority citation for part 400 continues to read as follows:

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

Subpart B—Definitions and Personnel Qualifications

3. The heading of subpart B is revised to read as set forth above.

4. In § 400.200, the following changes are made:

a. The definitions of ''Area'', DAB'', ''ICF'', and ''United States'' are removed.

b. In the definition of ''FQCH'', ''means'' is revised to read ''stands for:''.

c. The following definitions are added in alphabetical order to read as follows:

§ 400.200 General definitions.

* * * * *

Anesthetist means a physician anesthetist, an anesthesiologist assistant, or a certified registered nurse anesthetist.

* * * * *

CAH stands for critical access hospital.

* * * * *

Departmental Appeals Board means either of the following:

(1) A panel of members of a Board established in the office of the Secretary to provide impartial review of disputed decisions made by the operating components of the Department or by ALJs.

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

EACH stands for essential access community hospital.

* * * * *

FMAP stands for Federal medical assistance percentage.

* * * * *

HIO stands for health insuring organization.

* * * * *

Hospital means an institution that meets the requirements of section 1861(e) of the Act.

ICD–9–CM stands for International Classification of Diseases, Ninth Revision, Clinical Modification.

* * * * *

IMD stands for institution for mental diseases.

* * * * *

MCO stands for managed care organization.

* * * * *

NF stands for nursing facility.

* * * * *

PHP stands for prepaid health plan.

PHS stands for Public Health Service, and PHS Act means the Public Health Service Act.

Practitioner means a physician or any other individual who has the credentials to practice within a recognized health care discipline and who furnishes the services of that discipline to patients.

* * * * *

Qualified practitioner means a practitioner who meets the personnel qualification requirements set forth in the statute, or in this part or elsewhere in this chapter, as a condition for coverage of his or her services under Medicare or Medicaid, or both.

* * * * *

Religious nonmedical health care institution means an institution that meets the requirements of section 1861(ss)(1) of the Act.

* * * * *

RNHCI stands for religious nonmedical health care institution.

* * * * *

Significant business transaction means a business transaction or series of transactions carried out by an entity involved in the furnishing of health care services, the total of which, during any fiscal year, exceeds 5 per cent of the facility's total operating expenses or $25,000, whichever is less.

* * * * *

State means any of the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, or the Northern Mariana Islands.

State survey agency means the State health agency or other appropriate State or local agency that—

(1) Has an agreement with CMS under section 1864 of the Act, under which it performs surveys and inspections of health care facilities and recommends to CMS whether they meet the applicable requirements of section 1819, section 1832, section 1861, or subpart C of title XVIII of the Act; and

(2) Is used by the State to determine, on the basis of surveys and inspections,

whether health care facilities meet the requirements for participation in Medicaid.

* * * * *

5. In § 400.202, the following changes are made:

a. In the definition of ''Carrier'', the phrase ''payable on a charge basis'' is removed.

b. In the definition of ''Intermediary'', ''(or under any Prospective Payment System)'' is added immediately after ''payable on a cost basis''.

c. The following definitions are added in alphabetical order to read as follows:

§ 400.202 Definitions specific to Medicare.

* * * * *

Assignment means that the beneficiary transfers the right to claim payment for a service to the physician or other supplier of the service.

* * * * *

Covered services means services for which payment may be made to or on behalf of a Medicare beneficiary, subject to all requirements and limitations imposed by title XVIII of the Act and by this chapter.

* * * * *

Deductible means any of the following:

(1) The fixed amount for which the beneficiary is liable when he or she receives inpatient services in a hospital or CAH for the first time in a benefit period.

(2) The specified amount of expenses that a beneficiary must incur for covered Part B services in a calendar year before Medicare payment may be made, on his or her behalf, for additional Part B services (other than those specifically exempted under section 1833(b) of the Act and elsewhere in this chapter) furnished in that year.

(3) The expenses incurred for the first three pints of whole blood or units of packed red cells furnished to a beneficiary during a calendar year under Medicare Part A or Part B.

* * * * *

Medicare enrollee means a beneficiary who has elected to have his or her Medicare coverage provided through an HMO, CMP, HCPP, or M+C organization that participates in Medicare.

* * * * *

Physician means—

(1) A doctor of medicine or osteopathy authorized to practice medicine and surgery in the State in which he or she performs the function; and

(2) For certain specified services, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, and a chiropractor. (The specific services are set forth in subpart B of part 410 of this chapter.)

* * * * *

Skilled nursing facility (SNF) means a facility that meets the requirements of sections 1819(a) through 1819(d) of the Act.

* * * * *

6. In § 400.203, the following changes are made:

a. The definition of ''State'' is removed.

b. A definition of ''Institution for mental diseases'' is added in alphabetical order.

c. The definitions of ''FMAP'' and ''Nursing facility'' are revised to read as set forth below.

§ 400.203 Definitions specific to Medicaid.

* * * * *

Federal medical assistance percentage (FMAP) means the percentage used to calculate the amount of the Federal share of State expenditures under the Medicaid program in accordance with section 1905(b) of the Act.

* * * * *

Institution for mental diseases (IMD) means a facility that meets the requirements of section 1905(i) of the Act and the definition in § 435.1009 of this chapter.

* * * * *

Nursing facility (NF) means a facility that meets the requirements of sections 1919(a) through 1919(d) of the Act.

* * * * *

7. A new § 400.210 is added to read as follows:

§ 400.210 Personnel qualifications for Medicare.

(a) *Basis and scope.* (1) *Basis.* In order to participate in the Medicare program, providers and certain suppliers must use qualified staff. In order to be paid for the services they furnish to Medicare beneficiaries, physicians and other practitioners must meet specified qualifications.

(2) *Scope.* (i) This section sets forth the specific qualifications that must be met by those practitioners whose services are most frequently and widely used in the Medicare program.

(ii) Qualifications required of practitioners whose services are less frequently used or that are different for a particular program aspect are set forth in the subparts or sections that deal with those program aspects.

(b) *Specific requirements.* As a condition for Medicare payment to the providers and suppliers that employ them, or for the services that they furnish in independent practice, practitioners must meet the requirements for State licensing, certification, or approval, and the additional qualifications set forth in this section.

(c) An *anesthesiologist assistant* must meet the following requirements:

(1) Work under the direction of an anesthesiologist.

(2) Be in compliance with all applicable requirements of State law, including any licensure requirements the State imposes on anesthetists who are not physicians.

(3) Be a graduate of a medical school-based anesthesiologist's assistant educational program that—

(i) Is accredited by the Committee on Allied Health Education and Accreditation; and

(ii) Includes approximately 2 years of specialized basic science and clinical education in anesthesia at a level that builds on a premedical undergraduate science background.

(d) A *certified registered nurse anesthetist* must meet the following requirements:

(1) Be licensed as a registered professional nurse by the State in which he or she practices.

(2) Meet any licensure requirements the State imposes on anesthetists who are not physicians.

(3) Be a graduate of a nurse anesthesia educational program that meets the standards of the Council on Accreditation of Nurse Anesthesia Programs or any other accreditation organization that CMS designates.

(4) Meet one of the following conditions:

(i) Have passed a certification examination of the Council on Certification of Nurse Anesthetists, the Council on Recertification of Nurse Anesthetists, or any other certification organization that CMS designates.

(ii) Be a graduate of a program described in the qualification in paragraph (d)(3) of this section and, within 24 months after that graduation, meet the condition in paragraph (d)(4)(i) of this section.

(e) A *nurse-midwife* must meet the requirements in paragraphs (e)(1) and (2) of this section, and the requirement in paragraph (e)(3) or the requirement in paragraph (e)(4):

(1) Be currently licensed to practice in the State as a registered professional nurse.

(2) Be legally authorized under State law or regulations to practice as a nurse-midwife.

(3) Have completed a State-specified program of study and clinical experience for nurse-midwives.

(4) If there is no State-specified program of study and clinical experience for nurse-midwives, meet one of the following conditions:

(i) Be currently certified as a nurse-midwife by the American College of Nurse-Midwives.

(ii) Have successfully completed a formal educational program (of a least 1 academic year) that, upon completion, qualifies the nurse to take the certification examination offered by the American College of Nurse-Midwives.

(iii) Have successfully completed a formal educational program for preparing registered nurses to furnish gynecological and obstetrical care to women during pregnancy, delivery, and the post-partum period and care to normal newborns; and have practiced as a nurse-midwife for a total of 12 months during any 18-month period between August 8, 1976 and July 16, 1982.

(f) A *nurse practitioner* must meet one of the following requirements:

(1) Be a registered professional nurse who—

(i) Is authorized by the State in which he or she furnishes the services to practice as a nurse practitioner in accordance with State law; and

(ii) Is certified as a nurse practitioner by a recognized national certifying body that has established standards for nurse practitioners.

(2) Be a registered professional nurse who—

(i) Is authorized by the State in which he or she furnishes the services to practice as a nurse practitioner under State law; and

(ii) Has been granted a Medicare billing number as a nurse practitioner by December 31, 2000.

(3) Be a nurse practitioner who—

(i) On or after January 1, 2001, applies for a Medicare billing number for the first time; and

(ii) Meets the requirements specified in paragraph (f)(1) of this section

(4) Be a nurse practitioner who—

(i) On or after January 1, 2003, applies for a Medicare billing number for the first time;

(ii) Has a master's degree in nursing; and

(iii) Meets the requirements specified in paragraph (f)(1) of this section.

(g) A *physician assistant* must meet all of the following requirements:

(1) Have graduated from a physician assistant educational program that is accredited by the National Commission on Accreditation of Allied Health Education Programs;

(2) Have passed the national certification examination of the National Commission on Certification of Physician Assistants; and

(3) Be licensed by the State to practice as a physician assistant.

PART 401—GENERAL ADMINISTRATIVE REQUIREMENTS

B. Part 401 is amended as set forth below.

1. The authority citation for part 401 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1895hh). Subpart F is also issued under the authority of the Federal Claims Collection Act (31 U.S.C. 3711).

§ 401.128 [Amended]

2. In paragraph (a)(3), under ''Region IX'', ''Trust Territory of Pacific Islands'' is removed, and ''Northern Mariana Islands'' is added after ''American Samoa''.

3. In paragraph (b), the address ''Director, Office of Research, Demonstrations, and Statistics, CMS, Baltimore, Maryland 21235'' is revised to read ''Privacy Officer, CMS, 7500 Security Boulevard, Baltimore, MD 21244–1850'', and '', Office of Research, Demonstrations and Statistics'', the second time it appears, is removed.

§ 401.148 [Amended]

4. In § 401.148, the address ''CMS, 700 East High Rise Building, 6401 Security Boulevard, Baltimore, Maryland 21235,'' is revised to read ''Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850''.

PART 402—CIVIL MONEY PENALTIES, ASSESSMENTS, AND EXCLUSIONS

C. Part 402 is amended as set forth below.

1. The authority citation for part 402 continues to read as follows:

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

§ 402.113 [Amended]

2. In § 402.113, in paragraph (c), ''DAB'' is revised to read ''Departmental Appeals Board (the Board).''.

PART 403—SPECIAL PROGRAMS AND PROJECTS

D. Part 403 is amended as set forth below.

1. The authority citation for part 403 continues to read as follows:

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

§ 403.300 [Amended]

2. In § 403.300, the section heading is revised to read ''Basis and scope'' and the heading of paragraph (b) is revised to read ''Scope''.

§ 403.302 [Amended]

3. In § 403.302, the following changes are made:

a. The definition of ''Chief executive officer of a State'' is removed.

b. The definition of ''State system or system'' is amended by placing a period after ''control system'' and removing all that follows.

4. In § 403.304, the following changes are made:

a. The section heading is revised.

b. Paragraph (a) is revised.

c. Paragraph (b)(1) is revised.

The changes read as follows:

§ 403.304 Minimum requirements for approval of a State system.

(a) *Application and submission of documentation.* The State Governor or his or her designee is responsible for submitting the application for system approval and any assurances and other documentation required under this subpart.

(b) *Basis for approval: Specific requirements.* (1) CMS may approve the making of Medicare payments under a State reimbursement control system if CMS determines that the system meets the requirements of paragraphs (b) and (c) and, if applicable, paragraph (d), of this section.

(i) CMS evaluates any application for approval of a State system and gives the State notice of its determination within 60 days.

(ii) CMS may reconsider a denied application in accordance with § 403.316.

* * * * *

§§ 403.312 and 403.314 [Removed]

5. §§ 403.312 and 403.314 are removed.

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

E. Part 405 is amended as set forth below.

1. In subpart C, the authority citation is revised to read as follows:

Authority: Secs. 1102, 1870, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395gg, and 1395hh), and 31 U.S.C. 3711.

2. In § 405.400, the definition of ''Emergency care services'' is removed, and the definition of ''Emergency services'' is added to read as follows:

§ 405.400 Definitions.

* * * * *

Emergency services has the meaning given the term in § 422.113 of this chapter.

* * * * *

3. In subparts G and H, the authority citations are revised to read as follows:

Authority: Secs. 1102, 1869 and 1871 of the Social Security Act (42 U.S.C. 1302, 1395ff and 1395hh).

4. In § 405.802, the definition of ''Assignment'' is removed.

§ 405.855 [Amended]

5. In § 405.855, in paragraph (c)(1)(i), ''DAB'' is revised to read ''Departmental Appeals Board''.

§ 405.857 [Amended]

6. In § 405.857, in paragraph (a), ''DAB'', the first time it appears, is revised to read ''Departmental Appeals Board''.

§ 405.1875 [Corrected]

7. In § 405.1875, in paragraph (a)(2), ''Attorney Advisory'' is corrected to read ''Attorney Advisor''.

§ 405.1877 [Amended]

8. In § 405.1877, the following changes are made:

a. In paragraph (b) ''must file its appeal'' is revised to read ''must file the civil action''.

b. The heading of paragraph (e) is revised to read ''*Group actions.*''.

c. The heading of paragraph (f) is revised to read ''*Venue for group actions.*''.

Subpart U [Amended]

9. In subpart U, the authority citation is revised to read as follows:

Authority: Secs. 1102, 1871, and 1881 of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395qq).

10. In § 405.2401, the definitions of ''Act'', ''Beneficiary'', ''Carrier'', ''CMS'', ''Covered services'', ''Deductible'', ''Nurse-midwife'', ''Nurse practitioner and physician assistant'', ''Reporting period'', and ''Secretary'' are removed, and the definition of ''Physician'' is revised to read as follows:

§ 405.2401 Scope and definitions.

* * * * *

Physician includes residents who meet the definition of § 415.152 of this chapter and meet the requirements of § 415.206(b) of this chapter for payment under the physician fee schedule.

* * * * *

PART 406—HOSPITAL INSURANCE ELIGIBILITY AND ENTITLEMENT

F. Part 406 is amended as set forth below.

1. The authority citation for part 406 continues to read as follows:

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

2. In § 406.21, paragraph (f)(1) is revised to read as follows:

§ 406.21 Individual enrollment.

* * * * *

(f) *Transfer enrollment period for HMO and CMP enrollees.* (1) *Applicability.* This paragraph applies to an enrollee of an HMO or CMP that has a contract with CMS under subpart L of part 417 of this chapter.

* * * * *

PART 409—HOSPITAL INSURANCE BENEFITS

G. Part 409 is amended as set forth below.

1. The authority citation for part 409 continues to read as follows:

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

§ 409.3 [Amended]

2. In § 409.3, the definition of ''Covered'' is removed.

§ 409.60 [Amended]

3. In § 409.60, in paragraph (c), ''405.330'', wherever it appears, is revised to read ''§ 411.400''.

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

H. Part 410 is amended as set forth below.

1. The authority citation for part 410 continues to read as follows:

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

§ 410.1 [Amended]

2. In § 410.1, paragraph (b), ''copayment'' is revised to read ''coinsurance'', and ''subpart C of part 405'' is revised to read ''part 411''.

3. In § 410.2, the definition of ''nominal charge provider'' is revised to read as follows:

§ 410.2 Definitions.

* * * * *

Nominal charge provider has the meaning given the term in § 409.3 of this chapter.

* * * * *

§ 410.32 [Amended]

4. In § 410.32, in paragraph (d)(1), ''RPCH'' is revised to read ''CAH''.

§ 410.50 [Amended]

5. In § 410.50, in paragraph (b), the word ''independent'' is removed and ''subpart M of part 405 of this chapter.'' is revised to read ''part 493 of this chapter.''.

§ 410.58 [Amended]

6. In § 410.58, the following changes are made:

a. In paragraph (a)(1), ''as defined in § 491.2 of this chapter,'' is removed.

b. In paragraph (a)(2), ''as defined in § 417.416'' is revised to read ''who has the qualifications specified in § 417.416(d)(2)''.

7. In § 410.62, the following changes are made:

a. Paragraph (a)(2)(i) is revised to read as set forth below.

b. In paragraph (a)(2)(iii), ''§ 410.63'' is revised to read ''§ 424.24''.

§ 410.62 Outpatient speech pathology services: Conditions and exclusions.

(a) * * *

(2) * * *

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

* * * * *

8. Section 410.69 is revised to read as follows:

§ 410.69 Services of a certified registered nurse anesthetist or an anesthesiologist assistant.

Medicare Part B pays for anesthesia services and related care furnished by a certified registered nurse anesthetist or an anesthesiologist assistant who—

(a) Is legally authorized to perform the services by the State in which he or she performs them; and

(b) Meets the qualifications specified in § 400.210 of this chapter.

§ 410.74 [Amended]

9. In § 410.74, the following changes are made:

a. In paragraph (a)(2)(i), ''paragraph (c) of this section'' is revised to read ''§ 400.210 of this chapter''.

b. Paragraph (c) is removed and reserved.

10. In § 410.75, paragraph (b) is revised to read as follows:

§ 410.75 Nurse practitioner's services.

* * * * *

(b) *Qualifications.* For Medicare Part B coverage of his or her services, a nurse practitioner must meet one of the requirements specified in § 400.210(f) of this chapter.

* * * * *

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

I. Part 411 is amended as set forth below.

1. The authority citation for part 411 continues to read as follows:

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

§ 411.6 [Amended]

2. In § 411.6, in paragraph (b)(4), ''(as defined in § 409.3 of this chapter)'' is removed.

§ 411.15 [Amended]

3. In § 411.15, the following changes are made:

a. In paragraph (m)(1), ''(as defined in § 409.3 of this chapter)'' is removed.

b. Paragraph (m)(3)(vi) is revised to read ''Services of a certified registered nurse anesthetist or of an anesthesiologist's assistant.''.

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

J. Part 412 is amended as set forth below.

1. The authority citation for part 412 continues to read as follows:

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

§ 412.50 [Amended]

2. In § 412.50, in paragraph (c), ''(as defined in § 409.3 of this chapter)'' is removed.

§§ 412.63 and 412.210 [Amended]

3. In § 412.63(b)(3) and § 412.210(b)(2), the address ''CMS, East High Rise Building, Room 132, 6325 Security Boulevard, Baltimore, Maryland, 21207'' is revised to read ''Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850''.

§ 412.108 [Amended]

4. In § 412.108, paragraph (a)(1)(i), ''as defined in'' is revised to read ''as determined under''.

5. In § 412.113, in paragraph (c)(2)(i)(B), the first sentence is revised to read as follows:

§ 412.113 Other payments.

* * * * *

(c) * * *

(2) * * *

(i) * * *

(B) The hospital must, as of January 1, 1988, have employed or contracted with a certified registered nurse anesthetist or an anesthesiologist's assistant to perform anesthesia services in that hospital.

* * * * *

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

K. Part 413 is amended as set forth below.

1. The authority citation for part 413 continues to read as follows:

Authority: Secs. 1102, 1861(v)(1)(A), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395x(v)(1)(A), and 1395hh).

§ 413.20 [Amended]

2. In § 413.20, in paragraph (c) introductory text, ''provider of services (as defined in § 400.202 of this chapter)'' is revised to read ''provider''.

§ 413.53 [Amended]

3. In § 413.53, in the table for Hospital K, ''ICF-type'', wherever it appears, is revised to read ''NF-type''.

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

L. Part 414 is amended as set forth below.

1. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(1) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(1)).

§ 414.2 [Amended]

2. In § 414.2, the following changes are made:

a. The definitions for *CY* and *FY* are removed.

b. In paragraph (3) of the definition of ''Physician services'', remove ''of services as defined in § 400.202 of this chapter''.

PART 416—AMBULATORY SURGICAL SERVICES

M. Part 416 is amended as set forth below.

1. The authority citation for part 416 continues to read as follows:

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

§ 416.42 [Amended]

2. In § 416.42, in paragraph(b)(2), ''as defined in § 410.68(b) of this chapter'' is removed.

§ 416.61 [Amended]

3. In § 416.61, in paragraph (b), ''include items and services'' is revised to read ''include services'', and ''of part 405'' is removed.

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

N. Part 417 is amended as set forth below.

1. The authority citation for part 417 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), secs. 1301, 1306, and 1310 of the Public Health Service Act (42 U.S.C. 300e, 300e-5, and 300e-9); and 31 U.S.C. 9701.

§ 417.1 [Amended]

2. In § 417.1, the following changes are made:

a. The definitions of ''Secretary'' and ''Significant business transaction'' are removed.

b. In the definition of ''Furnished'', ''maid'' is corrected to read ''made'', and ''dierctly'' is corrected to read ''directly''.

§ 417.101 [Amended]

3. In § 417.101, in paragraph (c), ''§§ 417.168 and 417.169,'' is revised to read

''§ 417.142(g) and (h),''.

4. In § 417.126, the following changes are made:

a. In paragraph (b)(1), ''(as defined in paragraph (c) of this section)'' is revised to read ''(as defined in § 400.200 of this chapter)''.

b. Paragraph (c) is revised to read as set forth below.

c. Paragraphs (d) and (e), the first time they appear, are removed.

§ 417.126 Recordkeeping and reporting requirements.

* * * * *

(c) *Business transaction defined.* As used in paragraph (b) of this section, a business transaction is any of the following kinds of transactions:

(1) Sale, exchange, or lease of property.

(2) Goods, services, or facilities furnished for a monetary consideration, including management services but not including—

(i) Salaries paid to employees for services performed in the normal course of their employment; or

(ii) Health services furnished to the HMO's enrollees by hospitals and other providers and by HMO staff, medical groups, IPAs, or any combination of these entities.

* * * * *

§ 417.143 [Amended]

5. In § 417.143, in paragraph (b)(2), ''417.168 and 427.169 of subpart F.'' is revised to read ''§ 417.142(g) and (h).''.

Subpart E [Removed]

6. Subpart E, consisting of §§ 417.150 through 417.159, is removed and reserved.

§ 417.404 [Amended]

7. In § 417.404, in paragraph (a)(1), ''§ 117.142'' is revised to read ''§ 417.142''.

§ 417.416 [Amended]

8. In § 417.416, in paragraph (d)(1),''(as defined in § 491.2 of this chapter)'' is removed.

§ 417.602 [Removed]

9. § 417.602 is removed.

§ 417.604 [Amended]

10. In § 417.604, in paragraph (b)(3), the parenthesis preceding ''§ 427.440(b)(2)'' is moved to precede ''under''.

§§ 417.646, 417.658, and 417.690 [Amended]

11. in § 417.646 introductory text, § 417.658, and § 417.690(c), ''final and binding'' is revised to read ''binding''.

§ 417.800 [Amended]

12. In § 417.800, the definition of ''Medicare enrollee'' is removed.

PART 418—HOSPICE CARE

O. Part 418 is amended as set forth below.

1. The authority citation for part 418 continues to read as follows:

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

§ 418.3 [Amended]

2. In § 418.3, the definition of ''Physician'' is removed.

§ 418.98 [Amended]

3. In 418.98(b)(2), ''An ICF'' is revised to read ''An NF''.

§ 418.202 [Amended]

4. In § 418.202, in paragraph (c), ''as defined in § 410.20 of this chapter'' is removed.

PART 420—PROGRAM INTEGRITY: MEDICARE

P. Part 420 is amended as set forth below.

1. The authority citation for part 420 continues to read as follows:

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

2. § 420.200 is revised to read as follows:

§ 420.200 Basis, scope, and applicability.

(a) *Basis and scope.* This subpart is based on sections 1124, 1124A, 1126, and 1861(v)(1)(I) of the Act. It sets forth requirements for providers, Part B suppliers, health maintenance organizations, and intermediaries and carriers to disclose information about the following matters and persons.

(1) The hiring of an intermediary's former employees by a provider.

(2) Any person who—

(i) Has an ownership or control interest in the provider or supplier or serves as the agent or managing employee of the provider or supplier;

(ii) Has been convicted of a criminal offense, subjected to a civil money penalty, or excluded from the program, as a result of any activities related to involvement in Medicare, Medicaid, the Maternal and Child Health program under title V of the Act, or the Social Services program under title XX of the Act, at any time since the inception of these programs; or

(iii) Has an ownership or control interest in, or is the agent or managing employee of, an entity that has been sanctioned as described in paragraph (a)(2)(ii) of this section.

(3) Significant business transactions between the provider or supplier and any subcontractor or wholly owned supplier.

(b) *Applicability.* The following are subject to the requirements of this subpart as disclosing entities:

(1) A provider of services as defined in section 1861(u) of the Act or a Part B supplier.

(2) A clinical laboratory.

(3) A renal disease facility.

(4) A rural health clinic.

(5) A Federally qualified health center.

(6) A health maintenance organization as defined in section 1301(a) of the PHS Act.

(7) A Medicare intermediary or carrier.

(8) A Medicare+Choice organization, as defined in section 1859 of the Act.

(9) A managed care entity as defined in section 1932 of the Act.

3. In § 420.201, the following changes are made:

a. The definition of ''Significant business transaction'' is removed.

b. The definitions of ''Disclosing entity'', ''Other disclosing entity'', ''Indirect ownership interest'' and ''Ownership interest'' are revised and the newly revised definition of *Other disclosing entity* is transferred to proper alphabetical order, to read as follows:

§ 420.201 Definitions.

* * * * *

Disclosing entity means any of the entities specified in § 420.200(b).

Indirect ownership interest means an ownership interest in an entity that has a direct or indirect ownership interest in a disclosing entity.

* * * * *

Other disclosing entity means any entity (other than an individual practitioner or group of practitioners) that—

(1) Is not listed in § 420.200 (b) and does not participate in Medicare; but

(2) Is required to disclose ownership and control information because it furnishes health-related services under any of the programs established under title V, XIX, or XX of the Act, or serves as a Medicaid fiscal agent.

* * * * *

Ownership interest means the possession of equity in the capital, the stock, or the profits of a disclosing entity.

* * * * *

§ 420.301 [Amended]

4. In § 420.301, the definition of ''Provider'' is removed.

PART 421—INTERMEDIARIES AND CARRIERS

Q. Part 421 is amended as set forth below.

1. The authority citation for part 421 continues to read as follows:

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

§§ 421.1 and 421.3 [Revised]

2. §§ 421.1 and 421.3 are revised to read as follows:

§ 421.1 Basis and scope.

(a) *Basis.* (1) This part is based on the indicated provisions of the following sections of the Act:

1124—Requirements for disclosure of certain information.

1816 and 1842—Use of organizations and agencies to make Medicare payments to providers and suppliers of covered services.

(2) Section 421.118 is also based on 42 U.S.C. 1395b-1(a)(1)(F), which authorizes demonstration projects involving intermediary agreements and carrier contracts.

(b) *Scope.* This part sets forth—

(1) The procedures for selecting intermediaries and carriers;

(2) The requirements for approval of intermediary agreements and carrier contracts;

(3) The functions that intermediaries and carriers are required to perform;

(4) The criteria for—

(i) Evaluating intermediary and carrier performance;

(ii) Designating intermediaries and carriers to serve a class of providers on a regional or national basis; and

(iii) Assigning and reassigning providers or suppliers to particular intermediaries.

(5) CMS's authority to perform certain functions directly or by contract; and

(6) The appeal rights of intermediaries and carriers dissatisfied with specified adverse actions.

§ 421.3 Definition.

For purposes of designation of intermediaries (§ 421.117) and application of performance criteria and standards (§§ 421.120 and 421.122) ''intermediary'' includes a Blue Cross plan that has entered into a CMS-approved subcontract with the Blue Cross and Blue Shield Association to perform intermediary functions.

PART 422—MEDICARE+CHOICE PROGRAM

R. Part 422 is amended as set forth below.

1. The authority citation for part 422 continues to read as follows:

Authority: Secs.1102, 1851 through 1857, 1859, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395w–21 through 1395w–27, and 1395hh).

§ 422.500 [Amended]

2. In § 422.500, the definition of ''Significant business transaction'' is removed.

§ 422.562 [Amended]

3. In paragraph (b)(3)(v), ''DAB'' is revised to read ''Departmental Appeals Board''.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

S. Part 424 is amended as set forth below.

1. The authority citation for part 424 continues to read as follows:

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

§ 424.3 [Amended]

2. In § 424.3, the definition of ''ICD–9-CM'' is removed.

§ 424.20 [Amended]

3. In § 424.20(e)(2), ''neither of whom has'' is revised to read ''who does not have''.

PART 430—GRANTS TO STATES FOR MEDICAL ASSISTANCE PROGRAMS

Part 430 is amended as set forth below.

1. The authority citation for part 430 continues to read as follows:

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

§ 430.25 [Amended]

2. In § 430.25(c)(2), ''SNF, ICF, or ICF/MR'' is revised to read ''NF or ICF/MR''.

§ 430.30 [Amended]

3. In § 430.30(e), the language following ''under this subpart:'' is revised to read as follows:

§ 430.30 Grants procedures.

* * * * *

(e) * * *

§ 74.12—Forms for applying for HHS financial assistance.

§ 74.23—Cost sharing or matching.

§ 74.25—Revision of budget and program plans.

§ 74.52—Financial reporting.

§ 430.62 [Amended]

4. In § 430.62, the name and address ''Docket Clerk, Hearing Staff, Bureau of Eligibility, Reimbursement, and Coverage, 300 East High Rise, 6325 Security Boulevard, Baltimore, Maryland 21207. Telephone: (301) 594–8261'' is revised to read ''Centers for Medicare & Medicaid Services, Office of Hearings, 7500 Security Boulevard, Baltimore, MD 21244–1850''.

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

U. Part 431 is amended as set forth below.

1. The authority citation for part 431 continues to read as follows:

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

2. Throughout this subpart E, all references to ''skilled nursing facility'' are removed.

§ 431.57 [Amended]

3. In § 431.57, the following changes are made:

a. In paragraphs (b) and (c),''subchapter'' is revised to read ''chapter''.

b. In paragraph (e), ''of this part'' is removed.

§ 431.200 [Amended]

4. In § 431.200, remove ''skilled nursing facilities and''.

§ 431.201 [Amended]

5. In § 431.201:

a. In the definition of ''Action'', remove ''skilled nursing facilities and''.

b. The definition of ''Date of action'' is removed.

§ 431.206 [Amended]

6. In § 431.206, in paragraph (c)(3), remove ''a skilled nusring facility or''.

§ 431.210 [Amended]

7. In § 431.210, in paragraph (a), remove ''State, skilled nursing facility, or nursing facility'' and add in its place ''State or nursing facility''.

8. Section 431.211 is revised to read as follows:

§ 431.211 Advance notice.

Except as permitted under §§ 431.213 and 431.214, the State or local agency must mail the notice required under § 431.206(c)(2) through (c)(4) at least 10 days before the intended effective date of the action.

9. In § 431.213, the following changes are made:

a. The introductory text and paragraph (h) are revised to read as set forth below.

b. Remove the semicolons at the end of paragraphs (a) through (g) and add periods in their place, and remove the ''or'' after paragraph (g).

§ 431.213 Exceptions to advance notice requirements.

The agency may mail the notice no later than the effective date of the action or the date of the determination, as applicable, under any of the following circumstances:

* * * * *

(h) The discharge or transfer of the recipient will be effective in less that 10 days and the timing exception of § 483.12(a)(5)(ii) of this chapter applies.

10. In § 431.214, the introductory text is revised to read as follows:

§ 431.214 Notice in cases of probable fraud.

The agency may shorten the period of advance notice to 5 days before the effective date of the action or the date of the determination, as applicable, if—

* * * * *

§ 431.220 [Amended]

11. In § 431.220, in paragraph (a)(3), remove ''skilled nursing facility or''.

§ 431.241 [Amended]

12. In § 431.241, in paragraph (c), remove ''skilled nursing facility or''.

§ 431.242 [Amended]

13. In § 431.242, in paragraph (a)(2), remove ''skilled nursing facility''.

14. In § 431.610, the following changes are made:

a. In paragraph (g)(1), ''subchapter'' is revised to read ''chapter''.

b. Paragraph (g)(3) is revised to read as follows:

§ 431.610 Relations with standard-setting and survey agencies.

* * * * *

(g) * * *

(3) Have qualified personnel perform on-site inspections at least once during each certification period, or more often if there is a compliance question.

* * * * *

15. In § 431.620, paragraph (b) is revised to read as follows:

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

* * * * *

(b) *Definition. Institution for mental diseases (IMD)* has the meaning given the term in § 400.203 of this chapter.

* * * * *

§ 431.701 [Amended]

16. In § 431.701, the following changes are made:

a. Under the definition of ''Nursing home'', paragraphs (a) and (b) are redesignated as paragraphs (1) and (2).

b. In newly designated paragraph (2), ''subchapter'' is revised to read ''chapter''.

17. In § 431.804, the definitions of ''active case'' and ''administrative period'' are revised to read as follows:

§ 431.804 Definitions.

* * * * *

Active case means an individual or family that the State agency has determined to be currently eligible for Medicaid.

Administrative period means the 2-month period (review month and preceding month) during which a case error is not cited for the State agency's failure to take any action required by a change in case circumstances.

* * * * *

PART 433—STATE FISCAL ADMINISTRATION

V. Part 433 is amended as set forth below.

1. The authority citation for part 433 is revised to read as follows:

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

§ 433.1 [Removed]

2. § 433.1 is removed.

3. In subpart A, a new § 433.5 is added, to read as follows:

§ 433.5 Basis and scope.

(a) *Basis.* Most of the sections in this subpart identify the statutory provisions on which the rules are based. Certain portions of section 1902(a) of the Act are the basis for general administrative requirements such as those for accounting systems, cost allocation, reporting, and the handling of checks that are uncashed or canceled.

(b) *Scope.* This subpart sets forth the conditions for, and the rates of, FFP and the general administrative requirements related to the State's fiscal activities.

4. Section 433.111 is amended to revise the section heading and paragraph (b) to read as follows:

§ 433.111 Terminology.

* * * * *

(b) *Mechanized claims processing and information retrieval system* or *system* means the system of hardware and software used to process Medicaid claims and to produce and retrieve services utilization and management information required by the Medicaid single State agency and the Federal Government for program administration and auditing.

(1) The claims are from providers of medical care and services furnished to recipients under the Medicaid program.

(2) The system consists of the following:

(i) Required subsystems specified in the State Medicaid Manual.

(ii) Required changes to the required system or subsystem, published in accordance with § 433.123, and specified in the State Medicaid Manual.

(iii) System enhancements approved by CMS.

(3) Eligibility determination systems are not part of the claims processing and information retrieval system or enhancements to that system.

5. In § 433.304, the following changes are made:

a. The definitions of ''Provider'' and ''Recoupment'' are removed.

b. The definitions of ''Abuse'', ''Fraud'', ''Overpayment'', and ''Third party'' are revised; and a definition of ''Sixty-day period'' is added to read as set forth below.

§ 433.304 Definitions.

Abuse has the meaning given the term in § 455.2 of this chapter.

* * * * *

Fraud has the meaning given the term in § 455.2 of this chapter.

Overpayment means the portion of a Medicaid payment to a provider—

(1) That is in excess of the amount allowable for the services under section 1902 of the Act and implementing regulations; and

(2) That must be refunded to CMS by the State under section 1903 of the Act and this subpart.

* * * * *

Sixty-day period means the 60 calendar days immediately following discovery of an overpayment, allowed for the State agency to recover or seek to recover the overpayment.

Third party has the meaning given the term in § 433.136.

PART 434—CONTRACTS

W. Part 434 is amended as set forth below.

1. The authority citation for part 434 continues to read as follows:

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

§ 434.2 [Corrected]

2. In § 434.2, the definition of ''Prepaid health plan'', ''Medical agency'' is corrected to read ''Medicaid agency''.

§ 434.6 [Amended]

3. In § 434.6(a)(1), ''appendix G;'' is revised to read ''appendix A;''.

§ 434.21 [Amended]

4. In § 434.21(b)(3), ''Skilled nursing facility (SNF) services'' is revised to read ''Nursing facility services''.

PART 440—SERVICES: GENERAL PROVISIONS

X. Part 440 is amended as set forth below.

1. The authority citation for part 440 continues to read as follows:

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

§ 440.10 [Amended]

2. In § 440.10(b), ''SNF and ICF services'' is revised to read ''NF services''.

3. In § 440.20, the following changes are made:

a. The introductory text of paragraph (b) and paragraph (b)(1) are revised to read as set forth below.

b. In paragraph (b)(2), ''(as defined in §§ 405.2401 and 491.2 of this chapter)'' is removed.

c. In paragraph (c), second sentence, ''furnishd'' is corrected to read ''furnished''.

§ 440.20 Outpatient hospital services and rural health clinic services.

* * * * *

(b) *Rural health clinic services* means the following services when they are furnished by a rural health clinic that has been certified in accordance with part 491 of this chapter, and by practitioners who are acting within the scope of their practice under State law and who meet the conditions specified in this paragraph:

(1) Services furnished by a physician in the clinic and services furnished away from the clinic if the physician's contract with the clinic so provides.

4. In § 440.40, paragraph (a) is revised to read as follows:

§ 440.40 Nursing facility services for individuals age 21 or older (other than services in institutions for mental diseases), 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 inpatient care that meets the requirements of paragraphs (a)(2) and (a)(3) of this section and includes the following:

(i) Skilled nursing care and related services for residents who require medical or nursing care.

(ii) Rehabilitation services for the rehabilitation of injured, disabled, or sick persons.

(iii) Health related care and services for individuals who, because of their mental or physical condition, require, on a regular basis, services that—

(A) Are above the level of room and board; and

(B) Must be made available on an inpatient basis.

(2) The services must be ordered by, and furnished under the direction of, a physician.

(3) The services must be provided by one of the following:

(i) A facility or distinct part of a facility that is certified as meeting the requirements for participation that are set forth in subpart B of part 483 of this chapter.

(ii) If specified in the State plan, a swing-bed hospital that has CMS approval to furnish SNF services under Medicare.

(iii) Any facility located on an Indian reservation if the facility is certified by the Secretary as meeting the requirements of subpart B of part 483 of this chapter.

* * * * *

§ 440.50 [Amended]

5. In paragraph (a) introductory text, ''skilled'' and ''by a physician'' are removed.

6. In § 440.70. paragraph (c) is revised to read as follows:

§ 440.70 Home health services.

* * * * *

(c) Services furnished to a recipient whose place of residence is a hospital or a nursing facility are not ''home health services''. However, home health services may be furnished to residents of an ICF/MR if they are services other than those required under subpart I of part 483 of this chapter. For example, a registered nurse may provide short-term care for a recipient in an ICF/MR to avoid having to transfer the recipient to a nursing facility.

* * * * *

§ 440.80 [Amended]

7. In § 440.80(c)(3), ''A skilled nursing facility'' is revised to read ''A nursing facility''.

8. In § 440.140, the following changes are made:

a. The section heading is revised to read as follows: ''§ 440.140 Inpatient hospital services and nursing facility services for individuals age 65 or older in institutions for mental diseases.''

b. In paragraph (a), introductory text, ''(b), (c), and (e)'' is removed.

c. In paragraph (a)(2), ''subpart H of'' is removed.

§ 440.165 [Amended]

9. Section 440.165 is amended by revising paragraph (b) to read as follows:

§ 440.165 Nurse-midwife service.

* * * * *

(b) ''Nurse-midwife'' means a registered professional nurse who meets the applicable qualifications set forth in § 400.210(b) of this chapter.

§ 440.166 [Amended]

10. In § 440.166, in paragraph (d), ''this subchapter.'' is revised to read ''this chapter.''.

§ 440.220 [Amended]

11. In § 440.220, in paragraph (a)(3), ''skilled'' is removed.

§ 440.250 [Amended]

12. In § 440.250, the following changes are made:

a. In paragraph (a), ''skilled nursing facility services'' is revised to read ''nursing facility services''.

b. In paragraph (m), ''(as defined in § 440.255)'' is removed.

13. Paragraph (b)(1) is revised to read as follows:

§ 440.255 Limited services available to certain aliens.

* * * * *

(b) * * *

(1) Emergency services as defined in § 447.53(b) of this chapter.

* * * * *

PART 441—SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES

Y. Part 441 is amended as set forth below.

1. The authority citation for part 441 continues to read as follows:

Authority: Section 1102 of the Social Security Act (42 U.S.C. 1302).

§ 441.1 [Amended]

2. In § 441.1, the following changes are made:

a. The word ''subchapter'', wherever it appears, is revised to read ''chapter''.

b. Revise ''intermediate care facility services for the mentally retarded'' to read ''nursing facilities and intermediate care facilities for persons with mental retardation''.

§ 441.15 [Amended]

3. In § 441.15, the following changes are made:

a. In the introductory text, the word ''subchapter'' is revised to read ''chapter''.

b. In paragraph (b)(2), ''skilled'' and ''individuals;'' are removed.

c. In paragraph (b)(3), ''skilled nursing facility'' is revised to read ''nursing facility''.

4. Section 441.17 is revised to read as follows:

§ 441.17 Laboratory services.

(a) The plan must provide for payment for laboratory services as defined in § 440.30 of this chapter, if they are furnished by entities that meet the following additional requirements, as appropriate:

(1) For hospital-based laboratories, the requirements of § 482.27 of this chapter.

(2) For services furnished by rural health clinics, the requirements of § 491.9(c)(2) of this chapter.

(3) For NF-based laboratories, the requirements of § 483.75(j) of this chapter

(b) Laboratory records must contain the name (or other identifier approved by the Medicaid agency) of the person from whom the specimen was taken.

§ 441.100 [Amended]

5. In § 441.100, '', skilled nursing services, and intermediate care facility services'' is revised to read ''and nursing facility services''.

§ 441.150 [Amended]

6. In § 441.150, ''subchapter'' is revised to read ''chapter''.

§ 441.152 [Amended]

7. In § 441.152, the following changes are made:

a. The designation ''(a)'' is removed and ''§ 441.154'' is revised to read''§ 441.153''.

b. The designations ''(1)'', ''(2)'', and ''(3)'' are revised to read ''(a)'', ''(b)'', and ''(c)'', respectively.

c. Paragraph (b) is removed.

§ 441.155 [Amended]

8. In § 441.155, the following changes are made:

a. In paragraph (a), ''to the extent that'' is revised to read ''to the point at which''.

b. Paragraph (d) is removed.

§ 441.181 [Amended]

9. In paragraph (a)(2), the parenthetical statement at the end is removed.

§ 441.302 [Amended]

10. In § 441.302, the following changes are made:

a. Throughout § 441.302, ''a NF'' is revised to read ''an NF''.

b. In § 441.302(d), ''an SNF, ICF, or ICF/MR'' is revised to read ''an NF or ICF/MR''.

§ 441.354 [Amended]

11. In § 441.354, the following changes are made:

a. In paragraph (b)(1), ''an SNF or ICF'' is revised to read ''an NF'', and ''(NF effective October 1, 1990)'' is removed.

b. In paragraph (c), in the ''P'' and ''Q'' factors of the formula, ''for SNF and ICF'' is revised to read ''for NF'', and ''(NF effective October 1, 1990)'' is removed.

PART 442—STANDARDS FOR PAYMENT TO NURSING FACILITIES AND INTERMEDIATE CARE FACILITIES FOR THE MENTALLY RETARDED

Z. Part 442 is amended as set forth below.

1. The authority citation for part 442 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302), unless otherwise noted.

§ 442.2 [Amended]

2. In § 442.2, the definition of ''Immediate jeopardy'' is revised to read as follows:

§ 442.2 Terms.

* * * * *

Immediate jeopardy has the meaning given that term in § 488.1 of this chapter.

* * * * *

PART 447—PAYMENT FOR SERVICES

AA. Part 447 is amended as set forth below.

1. The authority citation for part 447 continues to read as follows:

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

2. Subparts B and C are redesignated as subparts C and D, respectively.

3. The undesignated centered heading ''Cost Sharing'' is removed and the following is added in its place:

* * * * *

Subpart B—Cost Sharing

* * * * *

§ 447.50 [Amended]

4. In § 447.50, the following changes are made:

a. The heading of § 447.50 is revised to read ''Basis and purpose.''.

b. The designation ''(a)'' is removed.

c. ''§§ 447.51 through 447.59 prescribe '' is revised to read ''this subpart prescribes''.

5. The undesignated centered heading immediately preceding § 447.51 is removed.

§ 447.51 [Amended]

6. In § 447.51, the following changes are made:

a. The heading of § 447.51 is revised to read ''Enrollment fees and premiums or similar charges: Requirements and options.''.

b. In paragraph (a), ''subchapter'' is revised to read ''chapter''.

§ 447.52 [Amended]

7. In § 447.52, the heading is revised to read ''Enrollment fees and premiums or similar charges: Minimum and maximum income-related charges.''.

8. The undesignated centered heading immediately preceding § 447.53 is removed.

9. In § 447.53, the following changes are made:

a. The heading of § 447.53 is revised to read as set forth below.

b. The heading for paragraph (a) is revised to read ''Basic rule.''.

c. Paragraphs (b) and (c) are revised to read as follows:

§ 447.53 Deductibles, coinsurance, and copayment, or similar charges: General rules.

* * * * *

(b) *Exceptions.* The plan may not provide for imposition of a deductible, coinsurance, copayment, or similar charge for the following services furnished to categorically needy or medically needy individuals:

(1) *Services to children.* This means services to individuals under 18 years of age or (at State option) to individuals under 21, 20, or 19 years of age, or any reasonable category of individuals 18 years of age or over but under 21.

(2) *Services related to pregnancy.* This means services furnished to pregnant women if the services are related to the pregnancy or to any other condition that may complicate the pregnancy. These services include the following:

(i) Routine prenatal care.

(ii) Labor and delivery.

(iii) Routine postpartum care.

(iv) Family planning services.

(v) Services for complications likely to affect pregnancy or delivery, such as hypertension, diabetes, or urinary tract infection.

(vi) Services furnished during the postpartum period for conditions or complications related to the pregnancy.(The postpartum period begins on the last day of the pregnancy and ends on the last day of the month in which the subsequent 60-day period ends.)

(3) *Services to individuals in institutions.* This means services furnished to any individual who—

(i) Is an inpatient of a hospital, NF, other medical institution, or ICF/MR; and

(ii) Is required, as a condition for receiving services in the institution, to contribute to the medical care costs all but the minimum amount of income he or she needs for personal expenses. (Sections 435.725, 435.733, 435.832, and 436.832 of this chapter specify the groups to which this requirement applies.)

(4) *Emergency services.* This means services furnished in a hospital, clinic, office, or other facility that is equipped to furnish emergency services, that is, services that are required after the sudden onset of a medical condition manifesting itself by acute symptoms so severe (including severe pain) that failure to provide immediate medical attention could reasonably be expected to result in—

(i) Serious jeopardy to the patient's health;

(ii) Serious impairment of bodily functions; or

(iii) Serious dysfunction of any bodily organ or part.

(5) *Family planning services.* This means family planning services furnished to individuals of child-bearing age.

(6) *Hospice care.* This means hospice care as defined in section 1905(o) of the Act.

(c) *Optional exclusions.* States may, at their option—

(1) Exempt from cost sharing all services furnished to pregnant women; and

(2) Exempt from copayment charges any HMO services furnished to medically needy Medicaid enrollees.

* * * * *

§ 447.54 [Amended]

10. In § 447.54, the section heading is revised to read: ''Maximum allowable cost sharing amounts.''.

11. The undesignated center heading immediately preceding § 447.59 is removed.

12. § 447.59 is revised to read as follows:

§ 447.59 Federal financial participation (FFP): Limits related to cost sharing.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, FFP is not available for expenditures for cost sharing amounts (enrollment fees or premiums, deductibles, coinsurance, copayment, or similar charges) that a recipient should have paid.

(b) *Exception.* FFP is available for the amounts that the agency pays as bad debts of providers under § 447.57. (We note that FFP is not available for payments the agency makes on behalf of an ineligible individual even if he or she has paid any required premium or enrollment fee.)

13. The undesignated center headings immediately preceding §§ 447.251, 447.257, 447.271, and 447.280 are removed.

14. Section 447.253 is amended to revise paragraph (b)(1)(ii)(B) to read as follows:

§ 447.253 Other requirements.

* * * * *

(b) * * *

(1) * * *

(ii) * * *

(B) If a State elects to cover services furnished at an inappropriate level of care (hospital inpatient services furnished to patients who require nursing facility level of care), the State's methods and standards specify that payment for this type of care is at the lower rates appropriate for nursing facility care, consistent with section 1861(v)(1)(G) of the Act; and

* * * * *

§ 447.257 [Amended]

15. The heading of § 447.257 is revised to read ''Limits on FFP.''.

§ 447.272 [Amended]

16. In § 447.272, paragraph (c), ''§§ 447.296 through 447.299.'' is revised to read ''subpart E.''.

§ 447.280 [Amended]

17. The heading of § 447.280 is revised to read ''Special rules for swing-bed hospitals.''.

Subpart F [Amended]

18. All undesignated center headings in subpart F are removed.

§ 447.331 [Amended]

19. In § 447.331, in paragraph (a), ''set forth in paragraph (b)'' is revised to read ''set forth in paragraph (b) of this section''.

20. In § 447.332, the following changes are made:

a. In paragraph (a)(1) introductory text, ''will establish'' is revised to read ''establishes''.

b. In paragraph (a)(3), ''will identify'' is revised to read ''identifies''.

c. Paragraph (b) is revised to read as follows:

§ 447.332 Upper limits for multiple source drugs.

* * * * *

(b) *Specific upper limits.* (1) The agency's payments for multiple source drugs identified and listed in accordance with paragraph (a) of this section may not exceed, in the aggregate, payment levels determined by applying, for each drug entity—

(i) A reasonable dispensing fee established by the agency; plus

(ii) An amount established by CMS that is equal to 150 percent of the published price at which the least costly therapeutic equivalent can be purchased by pharmacists.

(2) In selecting the size of the drug entity, the agency must—

(i) For non-liquids commonly available in quantities of 100 tablets or capsules, use that size;

(ii) For non-liquids not commonly available in quantities of 100 tablets or capsules, use the commonly listed package size; and

(iii) For liquids, use the commonly listed package size.

(3) In determining the least costly equivalent, the agency must use all available national compendia.

§ 447.333 [Amended]

21. In § 447.333, in paragraphs (b)(1)(i) and (b)(1)(ii), ''this subpart'' is revised to read ''this part''.

§ 447.334 [Amended]

22. In § 447.334, the following changes are made:

a. ''skilled nursing facility services'' is revised to read ''nursing facility services''.

b. ''and intermediate care facility services'' is removed.

PART 455—PROGRAM INTEGRITY: MEDICAID

BB. Part 455 is amended as set forth below.

1. The authority citation for part 455 continues to read as follows:

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

§ 455.2 [Amended]

2. In § 455.2, the following changes are made:

a. The definitions of ''Practitioner'' and ''Suspension'' are removed.

b. The definition of ''Exclusion'' is revised to read as follows:

§ 455.2 Definitions.

* * * * *

Exclusion means denial of participation in the Medicaid program for a provider that has defrauded or abused the program, or been convicted of a program-related offense under a Federal, State, or local law.

* * * * *

3. In § 455.3, the following changes are made:

a. The introductory text is republished and paragraph (a) is revised to read as set forth below.

b. In paragraph (b), ''or suspended practitioners'' is removed.

c. In paragraph (c), ''or suspension'' is removed.

§ 455.3 Other applicable regulations.

Part 1002 of this title sets forth the following:

(a) State plan requirements for excluding providers for fraud or abuse or for conviction of program-related crimes.

* * * * *

4. Section 455.100 is revised to read as follows:

§ 455.100 Basis and scope.

(a) This subpart implements sections 1124, 1126, 1902(a)(38), and 1903(i)(2) of the Act.

(b) It sets forth State plan requirements for disclosure of information regarding—

(1) Ownership and control of providers and fiscal agents, and their subcontractors;

(2) Persons convicted of criminal offenses related to their involvement in any program under Medicare, Medicaid, or the social services program under title XX of the Act; and

(3) Business transactions between providers and their subcontractors or wholly owned suppliers.

(c) It also provides instructions for determining ownership or control percentages, and specifies the penalties for failure to furnish the required information timely.

§ 455.101 [Amended]

5. In § 455.101, the definition of ''Significant business transaction'' is removed, and the definitions of ''Indirect ownership interest'' and ''Ownership interest'' are revised to read as follows:

§ 455.101 Definitions.

* * * * *

Indirect ownership interest has the meaning given the term in § 420.201 of this chapter.

* * * * *

Ownership interest has the meaning given the term in § 420.201 of this chapter.

* * * * *

PART 456—UTILIZATION CONTROL

CC. Part 456 is amended as set forth below.

1. The authority citation for part 456 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302), unless otherwise noted.

Subpart A [Amended]

2. In subpart A, the following changes are made:

§ 456.1 [Amended]

a. In § 456.1, the following changes are made:

1. In paragraph (b)(2), in the last full sentence of the introductory text, ''and intermediate care facilities (ICF's).'' is revised to read ''and ICFs/MR.''.

2. In paragraph (b)(5), ''(IMD's)'' is revised to read ''(IMDs)'', and ''ICF's'' is revised to read ''ICFs/MR''.

b. § 456.5 is revised to read as follows:

§ 456.5 Evaluation criteria.

(a) The agency must establish and use written criteria for evaluating the quality and appropriateness of Medicaid services.

(b) The utilization review (UR) plan must provide that the UR committee—

(1) Develops written criteria for assessment of the need for admission and the need for continued stay; and

(2) Develops more extensive written criteria for cases that its experience shows are—

(i) Associated with high costs;

(ii) Associated, frequently, with the furnishing of excessive services; or

(iii) Attended by physicians whose patterns of care are frequently found to be questionable.

c. A new § 456.10 is added, to read as follows:

§ 456.10 Definitions.

As used in this part—

Medical care appraisal norms or *norms* means numerical or statistical measures of usually observed performance; and

Medical care criteria or *criteria* means predetermined elements against which aspects of the quality of a medical service may be compared.

Subpart C—Utilization Control: All Hospitals

3. In subpart C, the following changes are made:

a. The heading of subpart C is revised to read as set forth above.

b. All undesignated centered headings in subpart C are removed.

c. § 456.50 is revised to read as follows:

§ 456.50 Scope.

This subpart sets forth the requirements that all hospitals must meet for certification of need for care, plan of care, and utilization review (UR) plans.

§ 456.51 [Removed]

d. Section 456.51 is removed.

456.60 [Amended]

e. In § 456.60, in paragraph (b)(1), ''(as defined in § 491.2 of this chapter)'' is removed.

f. § 456.100 is revised to read as follows:

§ 456.100 UR plan: Basic requirement.

The State plan must provide that each hospital furnishing inpatient services under the plan has in effect a written UR plan that meets the requirements of this subpart.

§ 456.101 [Removed]

g. § 456.101 is removed.

§ 456.111 [Amended]

h. In § 456.111, the following changes are made:

1. In paragraph (d), ''§ 456.70.'' is revised to read ''§ 456.80.''.

2. In paragraph (h), ''(or, in an ICF/MR, the mental retardation professional)'' is inserted immediately before ''believes continued stay is necessary.''.

i. Section 456.133 is revised to read as follows:

§ 456.133 Subsequent continued stay review dates.

The UR plan must provide as follows:

(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 that the continued stay is needed and, for a mental hospital patient, it schedules subsequent reviews for at least every 90 days.

(c) The committee ensures that each continued stay review date it assigns is entered in the recipient's record.

j. Section 456.135 is amended to revise paragraphs (f), (g), and (h) to read as follows:

§ 456.135 Continued stay review process.

* * * * *

(f) If the committee, subgroup, or designee finds that a continued stay is not needed, it notifies the recipient's attending physician (in the case of a mental hospital patient, it may be the attending or staff physician) and provides an opportunity for the physician to present his or her views before it makes a final decision.

(g) If the attending or staff physician does not present additional information or clarification of the need for continued stay, the decision of the committee, subgroup, or designees is final.

(h) If the attending or staff physician presents additional information or clarification, at least two physician members of the committee (at least one of which is knowledgeable about mental diseases) review the need for continued stay. If they find that the patient no longer needs inpatient care, their decision is final.

k. Section 456.136 is amended to revise paragraph (b), to read as follows:

§ 456.136 Notification of adverse decision.

* * * * *

(b) The attending physician (or the attending or staff physician in a mental hospital);

* * * * *

§ 456.141 Medical care evaluation studies: Purpose and general description.

l. The section heading is revised to read as set forth above.

Subpart D—Utilization Control: Additional Requirements for Mental Hospitals

4. In subpart D, the following changes are made:

a. The subpart heading is revised to read as set forth above.

b. All undesignated center headings are removed.

c. Section 456.150 is revised to read as follows:

§ 456.150 Scope.

This subpart sets forth the utilization control requirements that mental hospitals must meet in addition to those required of all hospitals as set forth in subpart C of this part.

§§ 456.151 and 456.160 [Removed]

d. §§ 456.151 and 456.160 are removed.

e. § 456.180 is revised to read as follows:

§ 456.180 Individual written plan of care.

For mental hospital patients, the following rules apply:

(a) The plan of care required under § 456.80 must be expanded to include—

(1) Objectives;

(2) Any orders for therapies or for special procedures recommended for the patient's health and safety; and

(3) Provision for modifying the plan of care as needed.

(b) The attending or staff physician must participate in reviewing the plan at least every 90 days (rather than every 60 days as is required for all other hospitals).

§§ 456.200, 456.201, and 456.205 [Removed]

f. Sections 456.200, 456.201, and 456.205 are removed.

g. Section 456.206 is revised to read as follows:

§ 456.206 Organization of UR committee; disqualification from UR committee membership.

The rules for mental hospitals differ from those set forth in § 456.106 only in that—

(a) One of the physician members of the UR committee must be knowledgeable in the diagnosis and treatment of mental diseases; and

(b) A member is disqualified on the basis of financial interest only if it is an interest in a mental hospital.

§§ 456.211 through 456.213 [Removed]

h. Sections 456.211 through 456.213 are removed.

i. § 456.231 is revised to read as follows:

§ 456.231 Continued stay review: Basic requirement.

The UR plan must provide for a review of each recipient's continued stay in a mental hospital to decide whether it is needed, in accordance with the applicable requirements of subpart C of this part and this subpart.

§ 456.232 [Removed]

j. Section 456.232 is removed.

k. Section 456.233 is revised to read as follows:

§ 456.233 Date of initial continued stay review.

(a) For mental hospital patients, the following rules apply, in addition to those set forth in § 456.128.

(b) If an individual applies for Medicaid while a patient in a mental hospital—

(1) The committee sets the date for initial continued stay review within 1 working day after the hospital receives notice of the application; and

(2) That date may not be later than 30 days after admission of the patient or 30 days after receipt of notice of his or her application for Medicaid, whichever is earlier.

§§ 456.234 through 456.245 [Removed]

l. Sections 456.234 through 456.245 are removed.

Subpart F—Utilization Control: Intermediate Care Facilities for Persons with Mental Retardation (ICFs/MR)

5. In subpart F, the following changes are made:

a. The heading of subpart F is revised as set forth above.

b. All undesignated center headings in subpart F are removed.

c. Section 456.350 is revised to read as follows:

§ 456.350 Scope.

This subpart sets forth the requirements that ICFs/MR must meet in addition to those specified, for hospitals, in subparts C and D of this part. In applying the rules of those subparts, references to ''hospitals'' must be read as references to ''ICF/MR''.

d. § 456.351 is revised to read as follows:

§ 456.351 Definition.

ICF/MR services means services that meet the conditions specified in § 440.150 of this chapter, but exclude services furnished in a religious nonmedical health care institution as defined in § 440.170(b) of this chapter.

e. Section 456.360 is revised to read as follows:

§ 456.360 Certification and recertification of need for inpatient care.

The rules of § 456.60 apply, except that recertification is required every 12 months rather than every 60 days.

f. In § 456.370, the following changes are made:

1. Paragraphs (a) and (b) are revised to read as set forth below.

2. In paragraph (c)(8), ''ICF'', wherever it appears, is revised to read ''ICF/MR''.

§ 456.370 Medical, social, and psychological evaluations.

(a) Before admission to an ICF/MR, or before authorization of payment, an interdisciplinary team of health professionals must make a comprehensive medical and social evaluation, and if appropriate, a psychological evaluation, of each applicant's or recipient's need for care in an ICF/MR.

(b) The psychological evaluation must be made not more than 3 months before admission.

* * * * *

§ 456.371 [Amended]

g. In § 456.371, ''ICF services'' is revised to read ''ICF/MR services''.

h. § 456.380 is revised to read as follows:

§ 456.380 Individual written plan of care.

The plan of care must meet the requirements set forth in § 456.180 for a plan of care for a mental hospital patient.

i. Section 456.381 is revised to read as follows:

§ 456.381 Reports and evaluations of plans of care.

The rules for mental hospitals, as set forth in § 456.181, also apply to ICFs/MR.

j. § 456.400 is revised to read as follows:

§ 456.400 Utilization review plan: General requirements.

The State plan must—

(a) Provide that each ICF/MR has on file and implements a written UR plan that provides for review of each recipient's need for the services the ICF/MR furnishes, and meets the requirements of this subpart; and

(b) Specify the method used to perform UR, which may be any of the following:

(1) Review conducted by the facility.

(2) Direct review in the facility by individuals who are—

(i) Employed by the medical assistance unit of the Medicaid agency; or

(ii) Under contract to the Medicaid agency.

(3) Any other method.

§ 456.401 [Removed]

k. § 456.401 is removed.

l. Section 456.405 is revised to read as follows:

§ 456.405 UR plan: Administrative requirements.

The UR plan must meet the following requirements:

(a) Specify how and when UR review is performed.

(b) Provide that review is performed by a group of professional personnel that—

(1) Includes at least one physician and one mental retardation professional; and

(2) Does not include any individual who—

(i) Is responsible for the care of the individual being reviewed;

(ii) Is employed by the ICF/MR; or

(iii) Has a financial interest in any ICF/MR.

(c) Describe the UR support responsibilities of the ICF/MR's administrative staff and the procedures used by that staff to take corrective action.

§§ 456.406 and 456.407 [Removed]

m. §§ 456.406 and 456.407 are removed.

n. § 456.411 is revised to read as follows:

§ 456.411 UR plan: Information requirements.

(a) *Recipient records.* The UR plan must provide that each recipient's record contains the information specified in § 456.111 and also the name of the qualified mental retardation professional. (The qualifications for this professional are set forth in § 483.430 of this chapter.)

(b) *Other records and reports, and confidentiality.* The requirements set forth in §§ 456.112 and 456.113 apply also to ICFs/MR.

§§ 456.412 and 456.413 [Removed]

o. §§ 456.412 and 456.413 are removed.

p. In § 456.431, the following changes are made:

1. In paragraph (a), ''recipients'' is revised to read ''recipient's''.

2. The section heading and paragraphs (b) introductory text, (b)(1), and (b)(2) are revised to read as follows:

§ 456.431 Continued stay review.

* * * * *

(b) The UR plan requirement for continued stay review may be met by either of the following:

(1) Reviews that apply the criteria specified in § 456.5(b) and are performed in accordance with this subpart.

(2) Reviews that meet the onsite inspection requirements of subpart I of this part provided—

(i) The composition of the independent professional review team meets the requirements of § 456.405; and

(ii) The reviews are conducted at least every 6 months.

§ 456.432 [Removed]

q. § 456.432 is removed.

r. § 456.433 is revised to read as follows:

§ 456.433 Initial continued stay review date.

The UR plan must—

(a) Provide that, when a recipient is admitted to an ICF/MR, the UR committee assigns, for the initial continued stay review, a specific date that is—

(1) Not later than 6 months after admission; and

(2) May be earlier than 6 months after admission if indicated at the time of admission.

(b) Describe the methods and criteria that are the basis for assigning the date; and

(c) Ensure that the date is entered in the recipient's record.

§ 456.434 [Amended]

s. In § 456.434, in paragraph (a), ''§ 456.435.'' is revised to read ''the methods and criteria required to be described under § 456.433(b).''.

§ 456.435 [Removed]

t. § 456.435 is removed.

u. In § 456.436, the following changes are made:

1. In paragraph (c), ''ICF'' is revised to read ''ICF/MR'', ''§ 456.411'' is revised to read ''§ 456.411(a)'', ''§ 456.432'' is revised to read ''§ 456.5(b)(1)'', and ''§ 456.432(b)'' is revised to read ''§ 456.5(b)(2)''.

2. Paragraph (f) is revised to read as set forth below.

3. In paragraphs (g) and (h), ''attending physician or'' is removed.

4. In paragraph (i), ''ICF services'' is revised to read ''ICF/MR services''.

§ 456.436 Continued stay review process.

* * * * *

(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 qualified mental retardation professional within one working day of its decision and allows 2 working days from the date of notice for the professional to present his or her views before it makes a final decision.

* * * * *

v. § 456.437 is revised to read as follows:

§ 456.437 Notification of adverse decision.

The UR plan must provide that the UR committee gives written notice of any adverse decision on the need for continued stay—

(a) Not later than 2 days after the final decision; and

(b) To the following:

(1) The administrator of the ICF/MR.

(2) The qualified mental retardation professional.

(3) The Medicaid agency.

(4) The recipient.

(5) If possible, the next of kin or sponsor.

§ 456.438 [Removed]

w. § 456.438 is removed.

Subpart H [Amended]

6. In subpart H, the following changes are made:

a. The undesignated center heading immediately preceding § 456.505 is removed.

b. The heading of § 456.505 is revised to read as follows:

§ 456.505 Basis for waiver of UR requirements.

* * * * *

Subpart I [Removed]

7. Subpart I, consisting of §§ 456.600 through 456.614, is removed and reserved.

§ 456.722 [Amended]

8. In § 456.722(c)(1), in the second sentence, ''subpart P and appendix G–O of OMB circular A–102'' is removed.

PART 475—PEER REVIEW ORGANIZATIONS

DD. Part 475 is amended as set forth below.

1. The authority citation for part 475 continues to read as follows:

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

§ 475.1 [Amended]

2. In § 475.1, the following changes are made:

a. The introductory text is revised to read ''As used in this subchapter—''.

b. Definitions of ''Affiliate of a payor organization'', ''Non-facility organization'', and ''PRO area'' are added, in alphabetical order.

c. The heading *Health care facility* is revised to read *Health care facility or facility.*

d. The definitions of ''Payor organization'' and ''Physician'' are revised to read as set forth below.

§ 475.1 Definitions.

* * * * *

Affiliate of a payor organization means an organization with a governing body, two or more members of which are—

(1) Governing body members, officers, partners, or 5 percent or more owners of the payor organization; or

(2) Managing employees of an HMO or CMP.

* * * * *

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 health care facility; and

(3) Is not owned by one or more health care facilities or any association of facilities in the PRO area.

Payor organization means any organization (other than a self-insured employer) that pays providers or practitioners (directly or indirectly) for services that the organization reviews,

or would review if it entered into a PRO contract.

Physician includes—

(1) An intern, resident, or Federal Government employee authorized under State or Federal law to practice medicine, surgery, or osteopathy in the PRO area; and

(2) An individual licensed to practice medicine in American Samoa or the Northern Mariana Islands.

PRO area means the geographic area designated as the area within which a designated PRO performs utilization and quality control review under its PRO contract with CMS.

§ 475.100 [Amended]

3. In § 475.100, ''Social Security'' and ''as amended by the Peer Review Improvement Act of 1982 (Pub. L. 97–248)'' are removed.

§ 475.105 [Amended]

4. In paragraph (b) of § 475.105, ''Effective November 15, 1984, the'' is removed, and ''The'' is added in its place, and ''will not apply'' is revised to read ''does not apply''.

5. Section 475.106 is revised to read as follows:

§ 475.106 Prohibition against contracting with payor organizations and affiliates of payor organizations.

Payor organizations and their affiliates are not eligible to become PROs for the area in which they make payments unless CMS determines, on the basis of lack of response to an appropriate Request for Proposal, that there is not available any eligible organization that is not a payor organization or affiliate of a payor organization.

§ 475.107 [Amended]

6. In § 475.107, the following changes are made:

a. In the introductory text, ''will take'' is revised to read ''takes''.

b. In paragraphs (a) and (b), ''Identify'' is revised to read ''Identifies''.

c. In paragraph (c), ''Assign'' is revised to read ''Assigns''.

d. In paragraph (d), ''award'' is revised to read ''awards''.

PART 476—UTILIZATION AND QUALITY CONTROL REVIEW

EE. Part 476 is amended as set forth below.

1. The authority citation for part 476 continues to read as follows:

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

§ 476.1 [Amended]

2. In § 476.1, the following changes are made:

a. The definitions of ''Five percent or more owner'', ''Health care facility or facility'', ''Health care practitioners other than physicians'', ''Hospital'', ''Non-facility organization'', ''Physician'', ''Practitioner'', ''Preadmission certification'', ''Review responsibility'' and ''Skilled nursing facility'' are removed.

b. The following definitions are revised to read as follows:

§ 476.1 Definitions.

* * * * *

Active staff privileges means authorization, on a regular, rather than an infrequent or courtesy basis—

(1) For a physician or other health care practitioner to order the admission of patients to a facility; and

(2) For a physician to perform diagnostic and treatment services in the facility.

* * * * *

Diagnosis related group (DRG) means a system for classifying inpatient hospital discharges as a basis for Medicare payment under the prospective payment system.

DRG validation means PRO validation to the effect that the DRG classification assigned to a discharge is based on the correct diagnostic and procedural information.

* * * * *

Hospital means a health care institution or distinct part of an institution as defined in section 1861(e) through (g) of the Act, including a religious nonmedical health care institution as defined in section 1861(ss)(1) of the Act.

* * * * *

Peer review means review of services by health care practitioners in the same professional field as the practitioner who ordered or furnished the services.

* * * * *

3. § 476.74 is revised to read as follows:

§ 476.74 General requirements for the assumption of review.

In assuming review responsibility, a PRO must comply with the following conditions:

(a) Assume review responsibility in accordance with the schedule, functions, and negotiated objectives specified in its contract with CMS.

(b) Notify the appropriate Medicare fiscal intermediary or carrier of its assumption of review in particular health care facilities no later than 5 working days after the day it assumes review in the facility.

(c) Maintain and make available for public inspection at its principal business office—

(1) A copy of each agreement with a Medicare intermediary or carrier;

(2) A copy of its current approved review plan, including its method for implementing review; and

(3) Copies of all subcontracts for the conduct of review.

(d) Limit subcontracts for review by health care facilities to review of quality of care. (There is no limit to the types of review that the PRO may subcontract to organizations that are not health care facilities.)

(e) If required by CMS—

(1) Compile statistics based on the criteria specified in § 411.402 of this chapter;

(2) Make limitation of liability determinations in accordance with subpart K of part 411 of this chapter; and

(3) Notify providers regarding these determinations. (Appeals from these determinations are subject to the rules set forth in part 405 of this chapter—subpart G for Part A services, and subpart H for Part B services.)

(f) Make its responsibilities under its contract with CMS primary to all its other interests and activities.

§ 476.86 [Amended]

4. In § 476.86(b), ''or SNF care'' is removed and''§§ 405.1035, 405.1042, and 405.1137 of this chapter.'' is revised to read ''§ 482.30 of this chapter.''.

PART 478—RECONSIDERATIONS AND APPEALS

FF. Part 478 is amended as set forth below.

1. The authority citation for part 478 continues to read as follows:

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

§ 478.46 [Revised]

2. Section 478.46 is revised to read as follows:

§ 478.46 Departmental Appeals Board review and judicial review.

(a) *Board review.* The circumstances under which the Departmental Appeals Board (the ''Board'') will review an ALJ hearing decision or dismissal are the same as those set forth at 20 CFR 404.970 for Appeals Council review.

(b) *Basis for seeking judicial review.* (1) The affected party may seek judicial review of the Board's decision, or of the ALJ's hearing decision if the Board denies review, if the amount in controversy is $2,000 or more.

(2) The party must file the civil action within 60 days from the date of receipt

of the notice of the Board's determination or denial of review.

PART 480—ACQUISITION, PROTECTION, AND DISCLOSURE OF PEER REVIEW INFORMATION

GG. Part 480 is amended as set forth below.

1. The authority citation for part 480 continues to read as follows:

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

Subpart B—PRO Information: General Provisions

2. The heading of subpart B is revised to read as set forth above.

3. The undesignated centered heading immediately preceding § 480.101 is removed.

§ 480.101 [Amended]

4. In § 480.101, the following changes are made:

a. The definitions of ''Health care facility or facility'', ''Non-facility organization'', and ''practitioner'' are removed.

b. The definition of *Implicitly identify (ies)* is removed and a new definition of *Implicitly identifies* is added in its place to read as follows:

§ 480.101 Scope and definitions.

* * * * *

(b) * * *

Implicitly identifies refers to data so unique, or to numbers so small, that the identity of a particular patient, practitioner, or reviewer would be obvious.

5. § 480.103 is amended to revise paragraph (b) to read as follows:

§ 480.103 Statutory bases for disclosure of information.

* * * * *

(b) Section 1160 of the Act provides that PRO information must be held in confidence and not disclosed to any person except—

(1) To the extent necessary to carry out the purposes of title XI, part B, of the Act;

(2) In cases and circumstances specified by regulation to ensure adequate protection of the rights and interests of patients, practitioners, and providers of health care; and

(3) As necessary to assist the following agencies in the performance of their duties:

(i) Federal and State agencies recognized by the Secretary as having responsibility for identifying and investigating cases or patterns of fraud or abuse.

(ii) Federal and State agencies recognized by the Secretary as having responsibility for identifying cases or patterns involving risks to the public health.

(iii) Appropriate State agencies responsible for licensing or certifying providers or practitioners.

(iv) Federal or State health planning agencies that need PROs to furnish them aggregate statistical data on a geographical, institutional, or other basis.

Subpart C—PRO Access to Information and PRO Responsibilities

6. The heading of subpart C is revised to read as set forth above.

7. The undesignated center heading immediately preceding § 480.115 is removed.

Subpart D—Disclosure of Nonconfidential Information

8. The heading of subpart D is revised to read as set forth above.

Subpart E—Disclosure of Confidential Information

9. The heading of subpart E is revised to read as set forth above.

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

HH. Part 482 is amended as set forth below.

1. The authority citation for part 482 continues to read as follows:

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

§ 482.30 [Amended]

2. In § 482.30(a)(2), ''§ 456.50 through 456.245 of this chapter.'' is revised to read ''part 456 of this chapter.''.

§ 482.52 [Amended]

3. In § 482.52, in paragraphs (a)(4) and (a)(5), '', as defined in § 410.69(b) of this chapter,'' is removed.

PART 483—REQUIREMENTS FOR STATES AND FOR LONG TERM CARE FACILITIES

II. Part 483 is amended as set forth below.

1. The authority citation for part 483 continues to read as follows:

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

§ 483.40 [Amended]

2. In § 483.40, in paragraph (e)(1)(i), ''the applicable definition in § 491.2 of this chapter'' is revised to read ''the qualifications set forth in § 400.210 of this chapter''.

§ 483.102 Applicability and evaluation criteria.

3. In § 483.102, the following changes are made:

a. The section heading is revised to read as set forth above.

b. The paragraph heading *Applicability* is inserted immediately after the designation (a).

c. The heading of paragraph (b) is revised to read *Evaluation criteria.*

d. Footnotes 1 and 2 are revised to read as set forth below.

* * * * *

[1] The Diagnostic and Statistical Manual of Mental Disorders is available for inspection at the Centers for Medicare & Medicaid Services, CMS Library, Room C2–07–13, 7500 Security Boulevard, Baltimore, MD 21244–1850, 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, 4100 K Street, NW., Washington, DC 20005.

* * * * *

[2] The American Association on Mental Retardation's Manual on Classification in Mental Retardation is available for inspection at the Centers for Medicare & Medicaid Services, CMS Library, Room C2–07–13, 7500 Security Boulevard, Baltimore, MD 21244–1850, or at the Office of the Federal Register, suite 700, 800 North Capitol St., NW., Washington, DC. Copies may be obtained from the American Association on Mental Retardation, 1719 Kalorama Rd., NW., Washington, DC 20009.

§ 483.460 [Amended]

4. In § 483.460—

a. In paragraph (b)(1), ''that specified plan of care requirements for ICFs'' is removed.

b. In paragraph (b)(2), the phrase ''physicians must participate in'' is removed.

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

JJ. Part 485 is amended as set forth below.

1. The authority citation for part 485 continues to read as follows:

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

2. Section 485.51 is revised to read as follows:

§ 485.51 Definition.

As used in this subpart, unless the context indicates otherwise, *Comprehensive outpatient rehabilitation facility, CORF,* or *facility* means a nonresidential facility that is established and operated, at a single fixed location, exclusively for the purpose of providing outpatient diagnostic, therapeutic, and restorative services that are for the rehabilitation of injured, disabled, or sick persons, and that are furnished by, or under the supervision of, a physician.

§ 485.70 [Amended]

3. In § 485.70, the following changes are made:

a. In paragraph (c), ''§ 405.1202(f) and (g) of this chapter.'' is revised to read''§ 484.4 of this chapter.''

b. In paragraph (m),''§ 485.705(f) of this chapter.'' is revised to read ''§ 484.4 of this chapter.''.

4. In § 485.604, paragraphs (b) and (c) are removed, and a new paragraph (b) is added, to read as follows:

§ 485.604 Personnel qualifications.

* * * * *

(b) A nurse practitioner and a physician assistant must meet the qualifications specified in § 400.210(f) and (g) of this chapter.

* * * * *

§ 485.639 [Amended]

5. In § 485.639, in paragraphs (c)(1)(v) and (c)(1)(vi), '', as defined in § 410.69(b) of this chapter'' is removed.

§ 485.705 [Amended]

6. In § 485.705, paragraphs (b)(2) and (c)(8) are revised to read as set forth below.

§ 485.705 Personnel qualifications.

* * * * *

(b) * * *

(2) For a speech/language pathologist, the qualifications set forth in § 484.4 of this chapter.

* * * * *

(c) * * *

(8) A nurse practitioner is a person who must meet one of the requirements specified in § 400.210(f) of this chapter.

* * * * *

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

KK. Part 488 is amended as set forth below.

1. The authority citation for part 488 continues to read as follows:

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

§ 488.1 [Amended]

2. In § 488.1, the following changes are made:

a. The definitions of ''Act'', ''Provider of services or provider'', and ''State'' are removed.

b. The following definition is added in alphabetical order:

§ 488.1 Definitions.

* * * * *

Immediate jeopardy means a situation in which the provider's noncompliance with one or more of the requirements for participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a patient or resident.

* * * * *

c. In the definition of ''Substantial allegation of noncompliance'', ''raises doubts as to a provider's or supplier's noncompliance'' is revised to read ''raises doubts as to a provider's or supplier's compliance''.

§ 488.56 [Amended]

3. In § 488.56, in paragraph (b) introductory text and paragraph (b)(2), ''§ 488.75(i)'' is corrected to read ''§ 483.75''.

4. In § 488.64, the following changes are made:

a. Paragraph (b) is revised to read as set forth below.

b. In paragraphs (c), and (d), ''§ 405.1137 of this chapter, or § 482.30 of this chapter, as applicable.'' is revised to read ''§ 482.30 of this chapter.''.

c. In paragraph (g), ''pursuant to § 405.1137 of this chapter or § 482.30'' is revised to read ''in accordance with § 482.30 of this chapter''.

§ 488.64 Remote facility variances for utilization review requirements.

* * * * *

(b) The Secretary may grant a facility a variance from the utilization review time-frames set forth in § 482.30 of this chapter if the requesting facility can show, to CMS's satisfaction, that it has been unable to comply with those time-frames by reason of lack of sufficient professional personnel available to conduct the reviews.

* * * * *

§ 488.301 [Amended]

5. In § 488.301, the following changes are made:

a. In the definition of ''Validation survey'', ''Secretary'' is revised to read ''CMS''.

b. The definition of ''Immediate jeopardy'' is removed.

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVALS

LL. Part 489 is amended as set forth below.

1. The authority citation for part 489 is revised to read as follows:

Authority: Secs. 1102, 1819, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395i–3, and 1395hh).

§ 489.3 [Amended]

2. In § 489.3, the definition of ''Immediate jeopardy'' is revised and a definition of ''Supplier approval'' is added, in alphabetical order, to read as follows:

§ 489.3 Definitions.

Immediate jeopardy has the meaning given the term in § 488.1 of this chapter.

* * * * *

Supplier approval means approval by CMS for a supplier to receive payment for Medicare covered services it furnishes to Medicare beneficiaries.

PART 491—CERTIFICATION OF CERTAIN FACILITIES

MM. Part 491 is amended as set forth below.

1. The authority citation for part 491 is revised to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), and sec. 332 of the Public Health Service Act (42 U.S.C. 254e).

§ 491.2 [Amended]

2. In § 491.2, the following changes are made:

a. The definitions of ''Nurse practitioner'', ''Physician'', ''Physician assistant'', and ''Secretary'' are removed.

b. The definition of ''FQHC'' is removed and a new definition of *Federally qualified health center (FQHC)* is added in its place to read as follows:

§ 491.2 Definitions.

* * * * *

Federally qualified health center (FQHC) has the meaning given the term in § 405.2401(b) of this chapter.

* * * * *

§ 491.3 [Amended]

3. In § 491.3, ''subpart S of 42 CFR part 405'' is revised to read ''subparts A through C of part 488 of this chapter.''.

PART 493—LABORATORY REQUIREMENTS

NN. Part 493 is amended as set forth below.

1. The authority citation for part 493 is revised to read as follows:

Authority: Sec. 353 of the Public Health Service Act and secs. 1102 and 1871 of the

Social Security Act (42 U.S.C. 263a, 1302, and 1395hh).

§ 493.1 [Corrected]

2. In § 493.1, ''the sentence following section 1861(s)(13),'' is removed.

§ 493.2 [Amended]

3. In § 493.2, the following changes are made:

a. The statements and definitions for ''HHS'', ''Physician'', and ''State survey agency'' are removed.

b. The definition of ''immediate jeopardy'' is revised to read as set forth below.

c. In the definition of ''party'', the word ''imposed'' is inserted immediately before ''by CMS''.

d. The definitions of ''sample'', ''State'' and ''Substantial allegation of noncompliance'' are revised to read as follows:

§ 493.2 Definitions.

* * * * *

Immediate jeopardy has the meaning given that term in § 488.1 of this chapter.

* * * * *

Sample, in relation to proficiency testing, means the material that is to be tested by the participants in the proficiency testing program.

State includes any political subdivision to which the State has expressly delegated powers sufficient to enable it to enforce requirements equal to, or more stringent than, CLIA requirements.

* * * * *

Substantial allegation of noncompliance has the meaning given that term in § 488.1 of this chapter.

* * * * *

§ 493.57 [Amended]

4. In § 493.57, in paragraph (e)(2), ''as defined in subpart C of this part;'' is revised to read ''as set forth in subpart C of this part;''.

§ 493.61 [Amended]

5. In § 493.61, the following changes are made:

a. In paragraph (e)(2), ''for a certificate as defined in subpart C of this part; and'' is revised to read ''for one of the certificates specified in subpart C of this part; and''.

b. In paragraph (i)(2), ''for a certificate as defined in subpart C of this part; '' is revised to read ''for any of the certificates specified in subpart C of this part;''

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF ICFs/MR AND CERTAIN NFs IN THE MEDICAID PROGRAM

OO. Part 498 is amended as set forth below.

1. The authority citation for part 498 continues to read as follows:

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

§ 498.2 [Amended]

2. In § 498.2, the definitions of ''Departmental Appeals Board'', ''OHA'', and ''OIG'' are removed.

§ 498.3 [Amended]

3. In § 498.3:

a. Paragraph (a)(1) is revised to read as set forth below.

b. In paragraph (c), the introductory text is designated as ''(1)'', paragraph designations ''(1)'', ''(2)'', and ''(3)'' are revised to read ''(i)'', ''(ii)'', and ''(iii)'', respectively.

c. A new paragraph (c)(2) is added to read as set forth below.

d. Paragraph (d) introductory text is revised as set forth below.

§ 498.3 Scope and applicability.

(a) *Scope.* (1) This part sets forth procedures for reviewing initial determinations that CMS makes with respect to the matters specified in paragraph (b) of this section, and identifies, in paragraph (c) of this section, matters for which the OIG makes initial determinations and provides appeals procedures. It also specifies, in paragraph (d) of this section, administrative actions that are not subject to appeal under this part.

* * * * *

(c) * * *

(2) Appeals procedures for OIG determinations are set forth in part 1005 of this chapter.

* * * * *

(d) *CMS Administrative actions that are not initial determinations.* CMS administrative actions other than those specified in paragraph (b) of this section are not initial determinations and thus are not subject to appeal under this part. Administrative actions that are not initial determinations (and therefore not subject to appeal under this part) include but are not limited to the following:

* * * * *

§ 498.5 [Amended]

4. In § 498.5(j)(2)(i), ''the SNF or ICF'' is revised to read ''the ICF/MR'', and ''patients'' is revised to read ''residents''.

§ 498.22 [Amended]

5. In § 498.22, in paragraph (a), the parenthetical statement at the end of the paragraph is removed.

§ 498.40 [Amended]

6. In § 498.40, in paragraph (a)(1), ''or the OIG, as appropriate, or with OHA.'' is removed and ''or the Departmental Appeals Board.'' is added in its place.

§ 498.42 [Amended]

7. In § 498.42, insert a period after ''CMS'', and remove the remainder of the sentence.

8. Section 498.44 is revised to read as follows:

§ 498.44 Designation of hearing official.

(a) The Chair of the Departmental Appeals Board (the Board) or his or her delegate designates an ALJ or a member or members of the Board to conduct the hearing.

(b) If appropriate, the Chair or the delegate may substitute a different ALJ or member or members of the Board to conduct the hearing.

(c) As used in this part, ''ALJ'' includes a member or members of the Board who are designated to conduct a hearing.

§ 498.56 [Amended]

9. In § 498.56, in paragraph (b)(5), ''SNFs or ICFs'' is revised to read ''ICFs/MR''.

§ 498.82 [Amended]

10. In § 498.82, paragraph (a)(2), the following changes are made:

a. The term ''the OHA'' is revised to read ''the Board''.

b. ''Departmental Appeals Board'' is revised to read ''Board''.

c. ''§ 98.22(c)(3)'' is corrected to read ''§ 498.22(b)(3)''.

11. In § 498.83, paragraph (d) is revised to read as follows:

§ 498.83 Departmental Appeals Board action on request for review.

* * * * *

(d) *Review panel.* If the Board grants a request for review of the ALJ decision, the review is conducted by a panel of three members of the Board designated by the Chair or Deputy Chair.

PP. Nomenclature changes.

1. Throughout this chapter IV:

a. ''DAB'', wherever it appears, is revised to read ''Board''.

b. ''DAB's'', wherever it appears, is revised to read ''Board's''.

c. ''(DAB)'', wherever it appears, is removed.

2. Throughout this chapter IV, ''a SNF'', and ''a NF'', wherever they appear, are revised to read ''an SNF'' and ''an NF'', respectively.

3. Throughout chapter IV, ''intermediate care facility for the mentally retarded'' wherever it appears, is revised to read ''intermediate care facility for persons with mental retardation and related conditions''.

4. In the following locations, ''co-payment'' wherever it appears, is revised to read ''copayment'': §§ 447.54(a)(3) (table heading), 447.55(a) and (b), 447.56, and 447.58.

5. In § 447.54(a)(3) text, ''co-payments'' is revised to read ''copayments''.

6. In the following locations, ''the OIG, as appropriate,'' is removed: § 498.20(a)(1), § 498.25(b)(1), and § 498.32(a)(1).

7. In the following locations, ''or the OIG'' is removed:§ 498.32(b)(2), § 498.56(a)(2), § 498.56(d), heading and text, § 498.66(b)(2),§ 498.78(a), and § 498.83(a), heading and text.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; Program No. 93.774, Medicare—Supplementary Medical Insurance; Program No. 93.778, Medical Assistance)

Dated: August 8, 2001.

Ruben J. King-Shaw, Jr.,

Deputy Administrator and Chief Operating Officer, Centers for Medicare & Medicaid Services.

Dated: September 9, 2001.

Tommy G. Thompson,

Secretary.

[FR Doc. 02–1065 Filed 1–24–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 401

[CMS–6011–P]

RIN 0938–AK45

Medicare Program; Reporting and Repayment of Overpayments

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would supplement and modify the notice of proposed rulemaking that was published on March 25, 1998 (63 FR 14506). That notice proposed to amend the Medicare regulations governing liability for overpayments from the Centers for Medicare & Medicaid services (CMS) to providers, suppliers, and individuals to eliminate application of certain regulations of the Social Security Administration and to replace them with regulations more specific to circumstances involving Medicare overpayments.

This proposed regulation would supplement and modify that notice in order to establish, in regulations, the longstanding resp[onsibility of providers, suppliers, individuals and also managed care organizations contracting with us to report and return overpayments to us. This proposed would establish the timeframe and process for making the reports and returning the overpayments.

DATES: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on March 26, 2002.

ADDRESSES: Mail written comments (one original and three copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–6011–P, PO Box 8013, Baltimore, MD 21244–8013.

If you prefer, you may deliver, by courier, your written comments (one original and three copies) to one of the following addresses: Hubert H. Humphrey Building, Room 443–G, 200 Independence Avenue, SW., Washington, DC 20201, or Centers for Medicare & Medicaid Services, C5–14–03, Central Building, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Comments mailed to those addresses designated for courier delivery may be delayed and could be considered late. Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. Please refer to file code CMS–6011–P on each comment.

Comments received timely will be available for public inspection as they are received, beginning approximately 3 weeks after publication of this document, in room C5–12–08 of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland, Monday through Friday of each week from 8:30 a.m. to 5 p.m. Please call (410) 786–7197 to make an appointment to view comments.

FOR FURTHER INFORMATION CONTACT: Paul Reed (410) 786–4001.

SUPPLEMENTARY INFORMATION:

I. Background

On March 25, 1998 we published in the **Federal Register** (63 FR 14506) a notice of proposed rulemaking that would amend the Medicare regulations governing liability for overpayments to eliminate application of certain regulations of the Social Security Administration and to replace them with regulations more specific to circumstances involving Medicare overpayments.

Section 401.310 of those proposed regulations defined overpayment as those Medicare funds that a provider, supplier, or individual has received in excess of amounts payable under the Medicare statute and regulations. The notice of proposed rulemaking described the types of overpayments, and gave examples of causes of overpayments, such as payments made by Medicare for noncovered services, Medicare payments in excess of the allowable amount for an identified covered service, errors and nonreimbursable expenditures in cost reports, duplicate payments, and Medicare payment when another entity had the primary responsibility for payment (63 FR 14517). It also stated that once a determination and any adjustments in the amount of the overpayments have been made, the remaining amount is a debt owed to the United States Government. After publishing that notice of proposed rulemaking, we received several comments on their provisions. In addition, on June 26, 1998, we published the Medicare+Choice (M+C) interim final rules (63 FR 34968) in which we addressed a process for reporting to us violations of the law, including overpayments. We stated that we wanted M+C organizations to self identify when they had been overpaid. While the amount of estimated overpayments has decreased in recent years, the number and amount of overpayments continue to be a significant issue in the Medicare program.

The June 29, 2000 final M+C regulation (65 FR 40170) eliminated any requirement for self-reporting of overpayments on the basis that it was arguably unfair to impose a self-reporting requirement on M+C organizations, but not on other types of providers and suppliers participating in the Medicare program. The preamble to that regulation stated:

''While we are withdrawing all requirements for self-reporting in this rule, we believe that the required reporting of overpayments is an effective tool for promoting Medicare