§ 405.232 Medical and other health services; conditions, limitations, and exclusions.

In addition to the general exclusions specified in Subpart C of this part, the following conditions, limitations, and exclusions shall apply with respect to the "medical and other health services" specified in § 405.231:

* * * * *

(c) *Drugs and biologicals.* The following items and services are excluded from the term "medical and other health services":

(1) Any drug or biological that can be self-administered, whether furnished by a physician, a provider of services, or other than a provider of services.

(2) Any drug product that meets all of the following conditions:

(i) The drug product was approved by the Food and Drug Administration (FDA) before October 10, 1962.

(ii) The drug product is available only through prescription.

(iii) The drug product was the subject of a notice of opportunity for hearing issued under section 505(e) of the Federal Food, Drug, and Cosmetic Act and published in the **Federal Register** on a proposed order of FDA to withdraw its approval for the drug product because it has determined that the product is less than effective for all its labeled indications.

(iv) The drug product is presently not subject to a determination by FDA, made under its efficacy review program (see 21 CFR 310.6 for an explanation of this program), that there is a compelling justification of the drug product's medical need.

(3) Any drug product that is identical, related, or similar, as defined in 21 CFR 310.6, to a drug product that meets the conditions of paragraph (c)(2) of this section.

* * * * *

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

Part 441 is amended as set forth below:

1. The table of contents is amended to add new §§ 441.12 and 441.25 to Subpart A as follows:

* * * * *

Sec.

441.12 Inpatient hospital tests.

* * * * *

441.25 Prohibition on FFP for certain prescribed drugs.

* * * * *

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

2. Section 441.10 is amended by adding new paragraphs (f) and (g) to read as follows:

§ 441.10 Basis.

This subpart is based on the following sections of the Act which state requirements and limits on the services specified or provide Secretarial authority to prescribe regulations relating to services:

* * * * *

(f) Section 1903(i)(5) for certain prescribed drugs (§ 441.25).

(g) Section 1903(i)(6) which prohibits (except in emergency situations) FFP in expenditures for inpatient hospital tests that are not ordered by the attending physician or other licensed practitioner (§ 441.12).

3. A new § 441.12 is added to read as follows:

§ 441.12 Inpatient hospital tests.

Except in an emergency situation (see § 440.170(e)(1) of this chapter for definition), FFP is not available in expenditures for inpatient hospital tests unless the tests are specifically ordered by the attending physician or other licensed practitioner, acting within the scope of practice as defined under State law, who is responsible for the diagnosis or treatment of a particular patient's condition.

4. A new § 441.25 is added to read as follows:

§ 441.25 Prohibition on FFP for certain prescribed drugs.

(a) FFP is not available in expenditures for the purchase or administration of any drug product that meets all of the following conditions:

(1) The drug product was approved by the Food and Drug Administration (FDA) before October 10, 1962.

(2) The drug product is available only through prescription.

(3) The drug product is the subject of a notice of opportunity for hearing issued under section 505(e) of the Federal Food, Drug, and Cosmetic Act and published in the **Federal Register** on a proposed order of FDA to withdraw its approval for the drug product because it has determined that the product is less than effective for all its labeled indications.

(4) The drug product is presently not subject to a determination by FDA, made under its efficacy review program (see 21 CFR 310.6 for an explanation of this program), that there is a compelling justification of the drug product's medical need.

(b) FFP is not available in expenditures for the purchase or administration of any drug product that is identical, related, or similar, as defined in 21 CFR 310.6, to a drug product that meets the conditions of paragraph (a) of this section.

(Catalog of Federal Domestic Assistance Program No. 13.714, Medical Assistance Program and No. 13.774, Medicare—Supplementary Medical Insurance)

Dated: September 16, 1981.

Carolyne K. Davis,

Administrator, Health Care Financing Administration.

Approved: September 24, 1981.

Richard S. Schweiker,

Secretary.

[FR Doc. 81-28333 Filed 9-30-81; 8:45 am]

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Thursday
October 1, 1981

Part VIII

Department of Health and Human Services

Health Care Financing Administration

Medicaid Program; Miscellaneous Medicaid Provisions—Increased State Flexibility

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 430, 433, 435, 441, 447, and 456

Medicaid Program; Miscellaneous Medicaid Provisions—Increased State Flexibility

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: This rule amends current Medicaid regulations to implement several provisions of the Omnibus Budget Reconciliation Act of 1981 (Pub. L. 97–35). Those provisions give State agencies increased flexibility in the administration of their Medicaid programs. The following subjects and sections of the law are included in these amendments:

I. Removal of reasonable charge limits that apply to reimbursement for the services of practitioners such as physicians, and for other noninstitutional services and items such as medical supplies and laboratory services (Section 2174);

II. Removal of the requirement for collection of third party payments when the amount of reimbursement that the State expects to recover exceeds the cost of recovery (Section 2182);

III. Permitting physician assistants and nurse practitioners to recertify the need for continued inpatient care for patients in institutions and extending the period of time for recertification from 60 days to 12 months in certain facilities for the mentally retarded or persons with related conditions (section 2183).

In addition, this rule includes technical amendments that add the Northern Mariana Islands to the States and territories participating in the Medicaid program (Section 2162).

EFFECTIVE DATE: October 1, 1981. These regulations are being published in final, for reasons described in the Supplementary Information below. However, we will consider any written comments mailed by December 30, 1981 and will revise the regulations if necessary.

Section 433.139 of these regulations contains reporting requirements subject to the Paperwork Reduction Act (Pub. L. 96–511) which have not been approved by the Office of Management and Budget. The reporting is not required until the Office of Management and Budget approval has been obtained. HCFA will publish a notice in the **Federal Register** when approval has been obtained, indicating the effective date of the reporting.

ADDRESS: Address comments in writing to: Administrator, Department of Health and Human Services, Health Care Financing Administration, P.O. Box 17076, Baltimore, Maryland 21235.

If you prefer, you may deliver your comments to Room 309–G Hubert H. Humphrey Building, 200 Independence Ave., SW., Washington, D.C., or to Room 789, East High Rise Building, 6401 Security Boulevard, Baltimore, Maryland.

In commenting, please refer to BPP–174–FC. Agencies and organizations are requested to submit comments in duplicate.

Comments will be available for public inspection, beginning approximately two weeks after publication, in Room 309–G of the Department's office at 200 Independence Ave., SW., Washington, D.C. 20201, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (202–245–7890).

Because of the large number of comments we receive, we cannot acknowledge or respond to them individually. However, if as a result of comments we believe that changes are needed in these regulations, we will publish the changes in the **Federal Register** and respond to the comments in the preamble of that document.

FOR FURTHER INFORMATION CONTACT:

Paul Riesel (for Medicaid reasonable charge limits), 301–597–1843.

Kathy Rama (for flexibility in collection of payments), 301–594–8221.

Robert Wren (for recertification), 301–594–9820.

SUPPLEMENTARY INFORMATION:

I. Removal of Reasonable Charge Limits

A. Background

Before the implementation of Pub. L. 97–35, the Omnibus Budget Reconciliation Act of 1981, a Medicaid agency's reimbursement level for noninstitutional services such as physicians' services, laboratory services, and supplies and equipment (including equipment servicing) could not exceed the reasonable charges established under Medicaid and Medicare. Section 1902(a)(30) of the Social Security Act required that State plans for medical assistance must provide assurance that payments were not in excess of reasonable charges consistent with efficiency, economy, and quality of care. Section 1903(i)(1) of the Act provided that Federal financial participation (FFP) was not made under the Medicaid program to the extent that a Medicaid payment exceeded the charge that was determined to be reasonable under section 1842(b)(3) of the Act. That section addresses charges allowed under the supplementary medical insurance portion (Part B) of the Medicare program. Thus, Medicaid's upper limits for payment were tied to the Medicare reasonable charge.

Specifically, the regulations to implement the former statutory provisions imposed the following rules:

1. For services furnished under both Medicare and Medicaid by practitioners such as physicians, the Medicaid payment could not exceed the lowest of the actual charge (42 CFR 447.341(b)(1)), the applicable Medicare reasonable charge (42 CFR 447.341(b)(2) and 447.342(b)), or the Medicaid agency's own median and prevailing charge calculations (42 CFR 447.341(b)(3) and (d)). The Medicaid agency's own median and prevailing calculations also applied as limits on Medicaid payments for services furnished by practitioners (such as physicians) only under Medicaid (i.e., when there is no applicable Medicare limit).

2. For other noninstitutional services and items that are furnished under both Medicare and Medicaid, and which are subject to the lowest charge level provision under 42 CFR 405.511, the Medicaid payment could not exceed the Medicare lowest charge level limitations (42 CFR 447.351(a) and (b)). The Medicaid agencies were also required to calculate and apply their own lowest charge level limitations (42 CFR 447.351(c)) to services and items subject to the lowest charge level limitation that are furnished only under Medicaid. However, no "Medicaid only" services were designated as being subject to this limitation.

3. For services and items that were neither classified as practitioner services nor as services subject to the lowest charge level limitation, Medicaid could pay no more than (a) the Medicare reasonable charge if they were furnished under both Medicare and Medicaid (42 CFR 447.352(a)); or (b) the Medicaid agency's own customary and prevailing charge calculations if they were furnished only under Medicaid (42 CFR 447.352(b)).

4. For laboratory services performed by outside laboratories but billed by a physician, Medicaid could pay no more than the lower of (a) the laboratory's reasonable charge for the service, or (b) the amount the laboratory charged the physician, when the physician indentified both the laboratory and the amount it charged for that service. When the physician did not identify the laboratory and its charge to the

physician, Medicaid could pay no more than the lowest estimated charge at which the service could have been secured from a laboratory serving the physician's locality (42 CFR 447.342(c), published August 24, 1981, at 46 FR 42669).

Some States have informed us that these requirements created problems for them because—

1. The requirement for States to make and apply their own reasonable charge calculations and to obtain and use Medicare reasonable charge data imposed unjustified administrative costs and burdens on States;

2. Reasonable charge limits have sometimes prevented States from improving access to care by paying higher amounts for services and items that are difficult for Medicaid beneficiaries to obtain; and

3. The Medicare reasonable charges vary from physician to physician, and from locality to locality. Their use as Medicaid payment limitations has resulted in the States being unable to apply a single payment rate Statewide unless that rate is set at or below the lowest Medicare reasonable charge level in the State.

B. New Legislation

Section 2174, Pub. L. 97-35 amended section 1902(a)(30) of the Act to remove the legislative requirements that payments under Medicaid not exceed reasonable charges, and deleted paragraph (1) of section 1903(i) of the Act to remove the legislative requirement that Medicaid use the reasonable charge established by Medicare as the upper limit for reimbursing noninstitutional services.

Congress removed the Medicaid and Medicare reasonable charge levels as a ceiling on Medicaid payments because it was aware of the problems cited above, and in recognition of States' need for flexibility in their Medicaid programs. Congress expects the removal of the administrative burdens imposed on States by the prior law to improve States' administration of their Medicaid programs and to provide States with the flexibility needed to create incentives to improve the availability and utilization of physicians services under Medicaid (House Budget Committee Report, No. 97-158, page 312). With the removal of the reasonable charge limits, States can structure their payment levels to fit their specific needs.

C. Provisions of the Regulations

We are making the technical changes in the Medicaid regulations needed to remove all references to reasonable charge limits for noninstitutional services under Medicaid, except for certain laboratory services, as explained below. Therefore, we are revising 42 CFR 447.200, adding a new subpart D to 42 CFR Part 447, containing revisions to §§ 447.250, and 447.342, and deleting §§ 447.341, 447.351 and 447.352 to reflect the elimination of these limits by Pub. L. 97-35.

We are adding a new § 447.304 to clarify that when primary payment is made by Medicare for services to a beneficiary eligible under both programs, and Medicaid is responsible only for the deductible and coinsurance payments (crossover claims), Medicare upper limits will still generally apply. That is because in the crossover claim situation, most States require that a physician or other provider must accept assignment of the Medicare claim in order to receive payment from Medicaid with respect to deductibles and coinsurance. A person who accepts assignments under Medicare is prohibited from accepting more than the Medicare reasonable charge. Because Congress did not remove the reasonable charge limits on Medicare reimbursement, in this situation, the provider would not be able to accept any additional payment, even if Medicaid were willing to pay more than the Medicare limit.

We are also revising § 447.342, which contains the limits for payment of laboratory services when billed by a physician. The regulations cover two situations: one in which the laboratory services are performed by or under the supervision of a physician, and the other in which the laboratory services are performed by an outside laboratory. By virtue of amending section 1902(a)(30) of the Act to remove the limitation of Medicare reasonable charges, Congress removed that limit with respect to the first situation. However, Congress did not amend section 1902(a)(43) of the Act which specifically provides that payment to physicians for laboratory services performed by an outside laboratory may not exceed the payment authorized under section 1842(h) of the Act (Medicare). Therefore, we are retaining that limitation (see § 447.342(c)).

II. Collection of Third Party Payments

A. Background and Legislation

Under section 1902(a)(25) of the Act, States are required to take reasonable measures to determine the legal liability of third parties to pay for health care and services provided to Medicaid beneficiaries. The States are further required to treat the legal liability of a third party as a resource of the beneficiary and to seek reimbursement from the third party.

Current regulations (42 CFR 433.139) provide that States must seek reimbursement from liable third parties (defined in § 433.136 as "any individual, entity or program * * *") within 30 days after the end of the month in which the State makes a payment to a provider of health care services if the State chooses to pay the provider before seeking reimbursement from the third party. If the State learns of the existence of a liable third party after it has paid a claim, the regulations require the State to seek reimbursement from the third party within 30 days after the end of the month in which it learned of the existence of the liable third party.

In section 2182 of the Omnibus Budget Reconciliation Act of 1981, Congress amended section 1902(a)(25) of the Act to provide that third party liabilities are not to be collected by States if the amount of reimbursement a State can reasonably be expected to recover is less than the cost to the State of the recovery. The provision is intended to correct situations in which States are obligated by law to pursue claims against liable third parties even if those efforts are not cost effective. Cost-ineffective recovery attempts are also inconsistent with the general requirements for proper administration that are contained in section 1902(a)(4) of the Act.

B. Provisions of the Regulations

We are amending 42 CFR 433.139 to state that, in any case in which a State is obligated to seek reimbursement from a liable third party, it may suspend or terminate the effort if the amount it can reasonably expect to recover is less than the cost of the recovery. We are not specifying a Federal standard regarding the amount for which the State should forego collection efforts. Rather, we are leaving that to the discretion of each state. However, we are requiring that the State plan specify the threshold amount (or other guideline) the State uses for this determination, or describe the process by which the determination is made, and that the plan specify the dollar amount or time period the State uses to accumulate billings from a particular liable third party for this purpose.

III. Recertification—Physician Assistants and Nurse Practitioners

A. Background

States are required, under their Medicaid State plan, to have methods and procedures to assure the proper

utilization of care and services. (See section 1902(a)(30) of the Act.) If a State does not make a satisfactory showing to the Secretary that it has such a utilization program in operation for inpatient services in hosptials (including institutions for tuberculosis and hospitals for mental diseases), skilled nursing facilities and intermediate care facilities, Federal matching funds in expenditures for long-stay inpatient services are decreased. (See section 1903 (g)(1) and (g)(5) of the Act.)

A satisfactory showing by the State must include a physician certification of the need for inpatient services at the time of admission (or at the time the individual applies for medical assistance, if later), and recertification of that need at least every 60 days thereafter during the patient's stay. The physician certification and recertification requirement is based on the concept that the physician is a key figure in determining appropriate utilization of health services. It is a physician who decides whether an individual should be admitted for inpatient services, orders tests, drugs and treatment, and determines the length of stay in an inpatient facility.

B. New Legislation

Section 2183 of Pub. L. 97-35, amends section 1903(g)(1)(A) of the Act to allow physician assistants and nurse practitioners, under the supervision of a physician, to recertify the continued need for inpatient services. It also extends the period of time for recertification of care for patients receiving services in public institutions for the mentally retarded or persons with related conditions (ICF/MR) from once every 60 days to once every 12 months.

Although Congress agrees that it is necessary that a physician perform the initial certification to insure the most accurate diagnosis and plan of care, it finds that physician assistants and nurse practitioners, under the supervision of physicians, are well qualified to perform the recertification of the patient's need for continued inpatient care. Those professionals have the proper basic skills needed to perform the many tasks involved in recertification and can be trained in any additional skills that are required.

As to the 12-month period for recertification for a patient in a public institution for the mentally retarded (ICF/MR), Congress believes that the longer recertification period is reasonable and appropriate in view of the likelihood that the patient's condition will change slowly over an extended period of time. (H.R. Report 97-158, Vol. II, page 333) (The amendment Congress made applies only to public institutions for the mentally retarded and not to private institutions. Because the amendment refers to section 1905(d) of the Act, which pertains only to public ICF/MRs, the legislation gives us no authority to extend the recertification period with respect to private institutions. Although it is unclear why Congress chose to limit this portion of the amendment to public institutions, the latest data available for ICF/MRs indicate that, as of June 30, 1979, 97,503 patients were receiving ICF/MR care in public institutions and 18,272 were receiving such care in private institutions. Thus, relatively few ICF/MR patients would be unaffected by the change in recertification period.)

Congress emphasized that this provision in no way indicates that one year is the appropriate length of stay for a person in an ICF/MR. The appropriate length of stay for a patient in an ICF/MR is left to the judgment of the professional staff responsible for the patient's plan of care and rehabilitation. Congress considered this amendment an effective way of reducing costs while maintaining quality of care. (H.R. Report 97-158, Vol. II, Page 334)

C. Provisions of the Regulations

Section 2183 of Pub. L. 97-35 states that recertification of the need for continued inpatient services may be performed by a physician assistant or nurse practitioner under the supervision of a physician, and that the recertification period in a public institution that is an ICF/MR must at least once every 12 months.

Physician Assistant and Nurse Practitioner.—"Physician assistant" and "nurse practitioner" are currently defined in Medicaid rural health clinic regulations at 42 CFR 481.2. Those definitions have served us well in the rural health clinic setting. In addition, the use of established definitions will assure the consistency of Federal standards within the Medicaid program. Therefore, we have cross-referenced the current definitions in these regulations to the definitions of physician assistant and nurse practitioner in 42 CFR 481.2.

We are also requiring that the recertification of inpatient services by physician assistants and nurse practitioners be within the scope of their practice as defined under State law. Although the provision is not expressly stated in section 2183 of the Omnibus Budget Reconciliation Act of 1981, it is cited in both the House Report of the Committee on the budget which accompanied H.R. 3982 (a precursor to Pub. L. 97-35) and the Conference Report. (See H.R. Report 97-158, Vol. II, Report of the Committee on the Budget, page 333 and the Omnibus Budget Reconciliation Act of 1981 Conference Report, page 969) Thus, we believe this added requirement to be the intent of Congress.

Under the Supervision of a Physician.—We do not believe that Congress intended that the physician necessarily be on the premises, or provide over-the-shoulder supervision of the physician assistant or nurse practitioner as those individuals perform the tasks involved in recertifying the need for inpatient care. That is because Congress expressed its confidence in the qualifications of those individuals in the recertification process. Therefore, our regulations do not require "direct" supervision. We believe that Congress intended the physician supervision of physician assistants and nurse practitioners involved in the recertification process to be general in nature, to free the physician to perform those procedures that require the skills of his or her profession.

In many cases, the attending physician would be the supervising physician. However, where that is not the case, and the recommendation (with regard to the need for continued care) of the physician assistant or nurse practitioner differs from that of the attending physician, we believe that it would be reasonable for States to allow the attending physician's judgment to prevail since he or she is legally responsible for the patient's condition.

Recertification in hospitals, SNFs and ICFs.—We have amended 42 CFR 456.60, 456.160, 456.260, and 456.360 to state that physician assistants and nurse practitioners may recertify the need for continued inpatient stays in these institutions.

Recertification in Public Institutions for the Mentally Retarded or Persons with Related Conditions.—We have also amended 42 CFR 456.360 to state that the recertification in these institutions must be made at least once every 12 months.

Other Technical Amendments.—We have also made technical amendments to 42 CFR 441.155, 456.1 and 456.652 to reflect the new flexibility in the law.

IV. Northern Mariana Islands

A. New Legislation

Section 2162 of Pub. L. 97-35 amends section 1101(a)(1) of the Act by adding the Northern Mariana Islands to the list of geographical areas that are included in the term "State" when used in reference to the Medicaid program.

Section 2162 also amends section 1905(b) of the Act by adding the Northern Mariana Islands to the list of the localities entitled to a designiated 50 percent Federal medical assistance percentage.

Thirdly, that section of Pub. L. 97-35 amends section 1108(c) of the Act by increasing the limits on payments under Medicaid to Puerto Rico, the Virgin Islands, and Guam, and by adding a limit on payment for the Northern Mariana Island. Section 1108(c) now specifies that the total amount certified by the Secretary under Medicaid for a fiscal year will not exceed the following amounts:

(1) Puerto Rico—$45,000,000.
(2) Virgin Islands—$1,500,000.
(3) Guam—$1,400,000.
(4) Northern Mariana Islands—$350,000.

This amendment applies to fiscal years beginning with 1982.

B. Provisions of the Regulations

The following are technical changes required to implement section 2162 of Pub. L. 97-35.

We are amending 42 CFR 430.1 by revising the definition of "State" to include the Northern Mariana Islands.

We are also making technical amendments to § 433.10 to state that the Federal medical assistance percentage is set by statute at 50 percent.

We have added a reference to the Northern Mariana Islands to the title of 42 CFR Part 435, Eligibility in the States and District of Columbia, for the following reason. Medicaid eligibility has been closely linked to eligibility for Federal Supplemental Security Income (SSI) payments since the 1972 amendments to the Social Security Act. Guam, Puerto Rico, and the Virgin Islands are ineligible for Federal SSI payments (section 1614(e) of the Act), and their Medicaid eligibility provisions differ from those of the States. Thus, Medicaid eligibility regulations for Guam, Puerto Rico, and the Virgin Islands were placed in a separate Part 436 in the Medicaid Regulations. The Northern Mariana Islands, on the other hand, are eligible for Federal SSI payments effective January 9, 1978, as specified in 20 CFR 416.120(c)(9). Therefore, Medicaid eligibility provisions for the Northern Marianas as well as for the 50 States and the District of Columbia, are those in 42 CFR Part 435.

Waiver of Proposed Rulemaking

These amendments implement the clear language of sections 2162, 2174, 2182 and 2183 of Pub. L. 97-35. Consequently, we are publishing these regulations in final form because the Congress intended to provide States with flexibility in the administration of the Medicaid program effective October 1, 1981.

In our view, publication of a notice of proposed rulemaking for these amendments is unnecessary for the immediate and proper implementation of these provisions, and would not contribute to the clarification of any issues. Moreover, the delay caused by such a notice would not serve the public interest. We therefore find good cause to waive proposed rulemaking procedures. We will however, consider any comments on these regulations that are mailed by the date specified above in the Effective Date section, and make any further changes that may be necessary.

For the reasons cited above, and in order to relieve States of administratively burdensome requirements and to provide them with the flexibility they need to tailor their programs to individual conditions and resources, we find good cause to waive a delayed effective date.

Impact Analysis

Executive Order 12291

The Secretary has determined that these final regulations do not meet the criteria for a "major rule" as defined in section 1(b) of Executive Order 12291.

These rules implement several provisions of Pub. L. 97-35, and are essentially technical in nature. The intent of Congress in enacting these sections was to remove administrative burdens.

Regulatory Flexibility Analysis (RFA)

We certify that a regulatory flexibility analysis is not required under section 604 of the Regulatory Flexibility Act (Pub. L. 96-354).

PART 430—GRANTS TO STATES FOR MEDICAL ASSISTANCE PROGRAMS

42 CFR Chapter IV, Subchapter C is amended as set forth below.

A. Part 430 is amended as follows:

1. The authority citation for Part 430 is revised to read as follows:

Authority: Secs. 1101 and 1102 of the Act (42 U.S.C. 1301 and 1302)

2. Section 430.1 is amended by revising the definition of "State" as follows:

§ 430.1 Definitions.

In this subchapter, unless the context indicates otherwise—

* * * * *

"State" means the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and the Northern Mariana Islands;

* * * * *

PART 433—STATE FISCAL ADMINISTRATION

B. Part 433 is amended as follows:

1. The authority citation for Part 433 reads as follows:

Authority: Secs. 1102, 1902(a)(4), 1902(a)(25), 1903(d)(2), 1903(o), 1903(p), and 1912 of the Social Security Act (42 U.S.C. 1302(a)(4), 1396a(a)(25), 1396b(d)(2), 1396b(o), 1396b(p), and 1396k), unless otherwise noted.

2. Section 433.10 is amended by revising paragraph (b) to read as follows:

§ 433.10 Rates of FFP for program services.

* * * * *

(b) *Federal medical assistance percentage (FMAP)*—(1) *Computation.* The FMAP is determined by the formula described in sec. 1905(b) of the Act. Under the formula, if a State's per capita income is equal to the national average per capita income, the Federal share is 55 percent. If a State's per capita income exceeds the national average, the Federal share is lower, with a statutory minimum of 50 percent. If a State's per capita income is lower than the national average, the Federal share is increased, with a statutory maximum of 83 percent. The formula used in determining the State and Federal share is as follows:

State share = (State per capita income)^2 / (National per capita income)^2 × 45 percent

Federal share = 100 percent minus the State share (with a minimum of 50 percent and a maximum of 83 percent)

The formula provides for squaring both the State and national average per capita incomes; this procedure magnifies any difference between the State's income and the national average. Consequently, Federal matching to lower income States is increased, and Federal matching to higher income States is decreased, within the statutory 50-83 percent limits. The FMAP for Puerto Rico, the Virgin Islands, Guam and the Northern Mariana Islands is set by statute at 50 percent and is subject to dollar limitations specified in section 1108 of the Act.

* * * * *

3. Section 433.139 is amended by adding a new paragraph (c) to read as follows:

§ 433.139 Payment of claims.

* * * * *

(c) An agency must suspend or terminate an effort to seek reimbursement from a liable third party if it determines that the effort would not be cost effective because the amount it reasonably expects to recover will be less than the cost of recovery. The State plan must—

(1) (i) Specify the threshold amount or other guideline that the agency uses in determining whether to seek reimbursement from a liable third party; or

(ii) Describe the process by which the agency determines that seeking reimbursement would not be cost effective; and

(2) Specify a dollar amount or period of time for which it will accumulate billings with respect to a particular liable third party, in making the decision whether to seek recovery.

PART 435—ELIGIBILITY IN THE STATES, DISTRICT OF COLUMBIA AND THE NORTHERN MARIANA ISLANDS

C. Part 435 is amended as follows:

1. The authority citation for Part 435 reads as follows:

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

2. The title of Part 435 and the introductory language of § 435.2 are amended to read as follows:

PART 435—ELIGIBILITY IN THE STATES, DISTRICT OF COLUMBIA AND THE NORTHERN MARIANA ISLANDS

* * * * *

§ 435.2 Purpose and applicability.

This part sets forth, for the 50 States, the District of Columbia and the Northern Mariana Islands—

* * * * *

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

D. Part 441 is amended as follows:

1. The authority citation for Part 441 reads as follows:

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

2. Section 441.155 is amended by revising paragraph (d)(1) to read as follows:

§ 441.155 Individual plan of care.

* * * * *

(d) The development and review of the plan of care as specified in this section satisfies the utilization control requirements for—

(1) Recertification under §§ 456.60(b), 456.160(b), 456.260(b), and 456.360(b) of this subchapter; and

* * * * *

PART 447—PAYMENT FOR SERVICES

E. Part 447 is amended as follows:

1. The table of contents for part 447 is amended by designating §§ 447.321 through 447.371 as Subpart D, removing §§ 447.341, 447.351 and 447.352, changing the center headings, and revising § 447.342.

PART 447—PAYMENTS FOR SERVICES

Subpart D—For Other Institutional and Noninstitutional Services

Sec.

447.300 Basis and purpose.
447.302 State plan requirements.
447.304 Adherence to upper limits FFP.

Outpatient Hospital and Clinic Services

447.321 Outpatient hospital services and clinic services: Upper limits of payment.

Other Inpatient and Outpatient Facilities

447.325 Other inpatient and outpatient facility services: Upper limits of payment.

Drugs

447.331 Drugs: Upper limits of payment.
447.332 Cost of drugs.
447.333 Dispensing fee.
447.334 Upper limits for drugs furnished as part of services.

Clinical Laboratory Services

447.342 Physician billing for clinical laboratory services.

Prepaid Capitation Plans

447.361 Prepaid capitation plans: Upper limits of payment.

Rural Health Clinic Services

447.371 Services furnished by rural health clinics.

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

2. Section § 447.200 is revised to read as follows:

§ 447.200 Basis and purpose.

This subpart prescribes State plan requirements for setting payment rates to implement, in part, section 1902(a)(30) of the Act, which requires that payments for services be consistent with efficiency, economy, and quality of care.

3. Sections 477.321, 447.325, 447.331 through 447.334, 447.342, 447.361 and 447.371 are designated as Subpart D. Sections 447.300, 447.302 and 447.304 are added to Subpart D, the heading and paragraph (a) of § 447.342 are revised and § 447.342(b) is removed and reserved, §§ 447.341, 447.351, and 447.352 are removed as follows:

Subpart D—Payment Methods for Other Institutional and Noninstitutional Services

§ 447.300 Basis and purpose.

In this subpart, §§ 447.302 through 447.334 and 447.361 implement section 1902(a)(30) of the Act, which requires that payments be consistent with efficiency, economy and quality of care.

Section 447.342 of this subpart implements section 1902(a)(43) of the Act, which permits the State plan to provide for payment to a physician for laboratory services which the physician did not personally perform or supervise. Section 447.371 implements section 1902(a)(13)(F) of the Act, which requires that the State plan provide for payment for rural health clinic services in accordance with regulations prescribed by the Secretary.

§ 447.302 State plan requirements.

A State plan must provide that the requirements of this subpart are met.

§ 447.304 Adherence to upper limits; FFP.

(a) The Medicaid agency must not pay more than the upper limits described in this subpart.

(b) In the case of payments made under the plan for deductibles and coinsurance payable on an assigned Medicare claim for noninstitutional services, those payments may be made only up to the reasonable charge under Medicare.

(c) FFP is available in expenditures for payments for services that do not exceed the upper limits.

Note.—The Secretary may waive any limitation on reimbursement imposed by Subpart D of this part for experiments conducted under section 402 of Pub. L. 90-428, Incentives for Economy Experimentation, as amended by section 222(b) of Pub. L. 92-603, and under section 222(a) of Pub. L. 92-603.

* * * * *

Clinical Laboratory Services

§ 447.342 Physician billing for clinical laboratory services.

(a) This section applies when a State plan provides for payments to physicians for clinical laboratory services.

(b) [Reserved]

(c) A state plan may provide for payment to a physician who bills for clinical laboratory services performed by an outside laboratory. Under these circumstances, the plan must provide that the agency will not pay the physician more than the amount that would be authorized under Medicare in

accordance with § 405.515 (b), (c), and (d) of this chapter.

PART 456—UTILIZATION CONTROL

F. Part 456 is amended as follows.

1. The table of contents is amended by revising the headings for §§ 456.60, 456.160, 456.260, and 456.360 as follows:

PART 456—UTILIZATION CONTROL

* * * * *

Sec.

456.60 Certification and recertification of need for inpatient care.

456.160 Certification and recertification of need for inpatient care.

456.260 Certification and recertification of need for inpatient care.

456.360 Certification and recertification of need for inpatient care.

Authority: Sec. 1102 of the Social Security Act, 49 Stat. 647 (42 U.S.C. 1302).

2. Section 456.1 is amended by revising paragraph (b)(2)(i) to read as follows:

§ 456.1 Basis and purpose of part.

* * * * *

(b) The requirements in this part are based on the following sections of the Act. Table 1 shows the relationship between these sections of the Act and the requirements in this part.

* * * * *

(2) *Penalty for failure to have an effective program to control utilization of institutional services.* * * *

(i) Under section 1903(g)(1)(A), a physician must certify at admission, and a physician (or physician assistant or nurse practitioner under the supervision of a physician) must periodically recertify, the individual's need for inpatient care.

* * * * *

3. Section 456.60 is revised to read as follows:

§ 456.60 Certification and recertification of need for inpatient care.

(a) *Certification.*

(1) A physician must certify for each applicant or recipient that inpatient services in a hospital are or were needed.

(2) The certification must be made at the time of admission or, if an individual applies for assistance while in a hospital, before the Medicaid agency authorizes payment.

(b) *Recertification.*

(1) A physician, or physician assistant or nurse practitioner (as defined in § 481.2 of this chapter) acting within the scope of practice as defined by State law and under the supervision of a physician, must recertify for each applicant or recipient that inpatient services in a hospital are needed.

(2) Recertifications must be made at least every 60 days after certification.

4. Section 456.160 is revised to read as follows:

§ 456.160 Certification and recertification of need for inpatient care.

(a) *Certification.*

(1) A physician must certify for each applicant or recipient that inpatient services in a mental hospital are or were needed.

(2) The certification must be made at the time of admission or, if an individual applies for assistance while in a mental hospital, before the Medicaid agency authorizes payment.

(b) *Recertification.*

(1) A physician, or physician assistant or nurse practitioner (as defined in § 481.2 of this chapter) acting within the scope of practice as defined by State law and under the supervision of a physician, must recertify for each applicant or recipient that inpatient services in a mental hospital are needed.

(2) Recertification must be made at least every 60 days after certification.

5. Section 456.260 is revised to read as follows:

§ 456.260 Certification and recertification of need for inpatient care.

(a) *Certification.*

(1) A physician must certify and recertify for each applicant or recipient that SNF services are or were needed.

(2) The certification must be made at the time of admission or, if an individual applies for assistance while in a SNF, before the Medicaid agency authorizes payment.

(b) *Recertification.*

(1) A physician, or physician assistant or nurse practitioner (as defined in § 481.2 of this chapter) acting within the scope of practice as defined by State law and under the supervision of a physician, must recertify for each applicant or recipient that SNF services are needed.

(2) Recertification must be made at least every 60 days after certification.

6. Section 456.360 is revised to read as follows:

§ 456.360 Certification and recertification of need for inpatient care.

(a) *Certification.*

(1) A physician must certify for each applicant or recipient that ICF services are or were needed.

(2) The certification must be made at the time of admission or, if an individual applies for assistance while in an ICF, before the Medicaid agency authorizes payment.

(b) *Recertification.*

(1) A physician, or physician assistant or nurse practitioner (as defined in § 481.2 of this chapter) acting within the scope of practice as defined by State law and under the supervision of a physician, must recertify for each applicant or recipient that ICF services are needed.

(2) Recertification must be made at least—

(i) Every 12 months after certification in a public institution for the mentally retarded or persons with related conditions; and

(ii) Every 60 days after certification in an ICF other than a public institution for the mentally retarded or persons with related conditions.

7. Section 456.652 is amended by revising paragraph (a)(1) to read as follows:

§ 456.652 Requirements for an effective utilization control program.

(a) *General requirements.* In order to avoid a reduction in FFP, the Medicaid agency must make a satisfactory showing to the Administrator, in each quarter, that it has met the following requirements for each recipient:

(1) Certification and recertification of the need for inpatient care, as specified in §§ 456.60, 456.160, 456.260, 456.360 and 456.481.

* * * * *

(Catalog of Federal Assistance Program No. 13.714, Medical Assistance Program)

Dated: September 15, 1981.

Carolyne K. Davis,

Administrator, Health Care Financing Administration.

Approved: September 22, 1981.

Richard S. Schweiker,

Secretary.

[FR Doc. 81-28334 Filed 9-30-81; 8:45 am]

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Thursday
October 1, 1981

Part IX

Department of Health and Human Services

Health Care Financing Administration

Professional Standards Review Organizations

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Health Care Financing Administration

42 CFR Parts 431, 432, 433, 456, 462, 463, 466, 473, 478, and 480

Professional Standards Review; Professional Standards Review Organizations (PSRO)

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Interim final regulation with a comment period.

SUMMARY: This interim final rule is required to conform current regulations to certain provisions of the Omnibus Reconciliation Act of 1980 (Pub. L. 96–499) and the Omnibus Budget Reconciliation Act of 1981 (Pub. L. 97–35). To conform with current statutory authority, this rule makes technical changes to Parts 431, 432, 433, 456, 462, 463, 466, 473, 478, and 480 of Chapter 42 of the Code of Federal Regulations.

The Omnibus Reconciliation Act of 1980 (Pub. L. 96–499) made several adjustments to the PSRO program. In conformance with that Act, this rule changes PSRO membership and advisory group requirements.

The Omnibus Budget Reconciliation Act of 1981 (Pub. L. 97–35) has further modified the PSRO program. In conformance with that Act, this rule changes the agreement requirements between HCFA and each PSRO. Accordingly, such agreements may be for any period not to exceed 12 months (42 CFR 462.11(a)(2)), and the procedures for termination or non-renewal of the agreement are modified.

The Act (Pub. L. 97–35) also changed the scope and responsibility of the PSRO program. PSROs are no longer required to review care paid for by the Medicaid and Maternal and Child Health and Crippled Children's Services programs (Titles XIX and V of the Social Security Act), but may conduct such review at the option of the individual States. These changes apply to PSROs entering into or renewing their agreement on or after October 1, 1981. A PSRO with a current agreement which was entered into before October 1, 1981 will continue to have responsibility for the review of health care services provided to recipients of the Medicaid or Maternal and Child Health and Crippled Children's Services programs (Titles XIX and V of the Social Security Act) until the next renewal of that agreement or in accordance with instructions in the current grants.

DATES: These regulations are effective on October 1, 1981. Although we are issuing this as an interim final rule for reasons stated in the Supplementary Information, we will consider any comments mailed by November 30, 1981.

Section 431.630 of this regulation contains reporting or recordkeeping requirements which have not been approved by OMB. The reporting and/or recordkeeping referenced in these sections is not required until OMB approval has been obtained. HCFA will publish a further notice in the **Federal Register** when OMB approves or disapproves these requirements.

ADDRESSES: Address comments in writing to: Administrator, Department of Health and Human Services, Health Care Financing Administration, P.O. Box 17082, Baltimore, Maryland 21235.

If you prefer, you may deliver your comments to Room 309–G Hubert H. Humphrey Building, 200 Independence Ave., SW., Washington, D.C., or to Room 789, East High Rise Building, 6401 Security Boulevard, Baltimore, Maryland, 21235. In commenting, please refer to HSQ–105–FC. Agencies and organizations are requested to submit comments in duplicate.

Comments will be available for public inspection, beginning approximately two weeks after publication, in Room 309–G of the Department's office at 200 Independence Ave., SW., Washington, D.C., 20201 on Monday through Friday of each week from 8:30 a.m. to 5:00 p.m., (202) 245–7890.

Because of the large number of comments we receive, we cannot acknowledge or respond to them individually. However, if as a result of comments, we believe that changes are needed in these regulations, we will publish the changes in the **Federal Register** and respond to public comments in that document.

FOR FURTHER INFORMATION CONTACT:

Geraldine L. Ellis (301) 594–1432
David McNally (for Part 433) (301) 597–1397

SUPPLEMENTARY INFORMATION:

Establishment of Professional Standards Review Organizations (PSROs) was mandated by Congress in the 1972 Amendments to the Social Security Act (Pub. L. 92–603). The purpose of the PSRO program was to assure that health care services and items for which payment may be made in whole or in part under the Medicare, Medicaid, and Maternal and Child Health and Crippled Children's Services program (Titles XVIII, XIX, and V of the Act) are medically necessary; conform to appropriate professional standards; and are delivered in the most effective, efficient, and economical manner consistent with quality care.

The Omnibus Reconciliation Act of 1980 (Pub. L. 96–499) made several adjustments to the PSRO program. In conformance with that Act, this rule deletes the requirement that PSROs have formal advisory groups (42 CFR Part 480), allows PSROs to accept as members health care practitioners, other than physicians, who have independent hospital admitting privileges (42 CFR 462.4), and requires advisory groups to Statewide Professional Standard Review Councils to include a registered nurse and a doctor of dental surgery or dental medicine (42 CFR 478.102).

Although the basic purpose of the PSRO program is unchanged, the scope of its review authority has been altered by Section 2113 of the Omnibus Budget Reconciliation Act of 1981 (Pub. L. 97–35). As a result, PSROs are no longer required to perform review of services furnished to Medicaid recipients. States now have the option of contracting with PSROs for the performance of medical or utilization review functions. This allows the individual States the flexibility of determining whether it is to their benefit to contract with a local PSRO for these services or to utilize another method to accomplish the utilization control required by Title XIX. If a State elects to contract with a PSRO, the PSRO is obligated to agree to perform review as long as it is not inconsistent with the PSRO's responsibilities to perform Medicare review. In addition, any State contracting with a PSRO is eligible for Federal Financial Participation (FFP) at the rate of 75 percent for all funds expended by the PSRO for these purposes (42 CFR 433.15), as required by section 1903(a)(3)(C) of the Act (added by section 2113(n)(2) of Pub. L. 97–35). States contracting with review organizations not designated as PSROs under Part B of Title XI of the Act are eligible for FFP at the rate of 50 percent.

To effect these changes, all references to the Medicaid and the Maternal and Child Health and Crippled Children's Services programs (Titles XIX and V of the Social Security Act) as a mandatory review responsibility of the PSRO have been deleted. Similarly, since the PSRO does not have mandatory responsibility for Medicaid review, the requirement for State assessment or State approval of an individual PSRO's plan or performance has been deleted. These changes apply to agreements between HCFA and a PSRO entered into on or after October 1, 1981. A PSRO with a current agreement which was entered into before October 1, 1981 will continue to have responsibility and authority to review health care services provided or

proposed to be provided to recipients of the Medicaid and Maternal and Child Health and Crippled Children's Services programs until the next renewal date of that agreement or in accordance with instructions in the current grant.

In addition, the regulations have been amended to require a State, electing to contract with a PSRO, to submit a written amendment to the State plan. This requirement is based on section 1902(a)(4) of the Act, which requires State plans to provide such methods of administration as are found by the Secretary to be necessay for the proper and efficient operation of the plan. Requiring a State plan amendment is necessary to enable HCFA and the State to determine the degree to which the State will be relieved of medical and utilization review responsibility, pursuant to new section 1902(d) of the Act (Section 2113(m) of Pub. L. 97–35), and to enable HCFA and the State to schedule audits of the PSROs. The amendment must specify the specific time period covered by the contract and the services and providers subject to PSRO review. It must also specify that the State agency or HHS will be permitted to audit and inspect PSRO records relative to the contract. These records must be retained by the PSRO in accordance with 45 CFR Part 74. The plan must also specify that the State will monitor and evaluate PSRO performance, in a manner sufficient to assure that the PSRO is adequately fufilling its obligations under the contract. The State plan must identify specifically the types of services being reviewed by the PSRO; that is, hospital services, services in a skilled or intermediate care facility, or other services agreed upon. The State plan should also indicate if the review will be conclusive for payment purposes.

The review to be performed by the PSRO must not be inconsistent with the review conducted by the PSRO of Title XVIII services under its agreement with HCFA and must be sufficient in scope to satisfy the intention of the utilization control provision of the Act, consistent with section 1155(a)(1) of the Act, as amended by section 2113(d)(2) of Pub. L. 97–35. A State may be deemed to have satisfied requirements for utilization control specified in 42 CFR Part 456 with respect to those services or providers the PSRO contracts with the State to review pursuant to section 1902(d) of the Act.

Additionally, section 2111 of Pub. L. 97–35, amending section 1155(e) of the Act, modified the PSRO program regarding delegation of review. In conformance with that Act, this rule allows the PSRO the option of delegating review functions to a hospital review committee but does not require delegation (42 CFR 466.1(a)(2)). Section 2112 of Pub. L. 97–35 also eliminated certain distinctions between conditional and fully designated PSROs with respect to their agreements with HCFA. The regulations concerning the duration, renewal, and termination of agreements and grants, as well as the regulations involving the reevaluation of a PSRO's capability, have been changed to indicate that PSROs will be assessed periodically, that an agreement between the Secretary and a PSRO may not exceed 12 months, and that the agreement can be terminated upon 90 days' notice by the Secretary to the organization. Additionally, the regulations have been amended to indicate that when HCFA determines that a PSRO agreement should be terminated or not renewed, the PSRO, either conditionally or fully designated, will not be entitled to a formal hearing but will be entitled to an informal meeting in accordance with 42 CFR 462.12. If the agreement to be terminated was entered into before August 13, 1981, the date of enactment of Pub. L. 97–35, and involves a fully designated PSRO, the PSRO is entitled to a formal hearing in accordance with current procedures. In all cases, in accordance with section 2112(a)(2)(B) of Pub. L. 97–35, the decision of the Secretary is final and is not subject to judicial review.

42 CFR 432.50 and 433.15 have been revised to delete references to a special rate of FFP for the salary and training of State surveyors. This special rate expired by the terms of the statute and regulations on September 30, 1980.

Waiver of Notice of Proposed Rulemaking

We have determined that good cause exists for publication of this rule without a prior notice and comment period. These changes are necessary to bring 42 CFR, Subchapter D, into conformance with the Social Security Act, and they are nondiscretionary. Since the Omnibus Reconciliation Act of 1980 (Pub. L. 96–499) and the Omnibus Budget Reconciliation Act of 1981 (Pub. L. 97–35) mandate the changes, we find good cause to waive the NPRM.

Executive Order Certification

The Secretary has determined, in accordance with Executive Order 12291, that the final rule does not constitute a "major rule" because it will not have an annual economic effect of $100 million or more; result in a major increase in costs or prices for consumers, industries, any governmental agencies, or any geographic regions; or have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. The major expected effects of this rule are that States will have more flexibility in choosing review methods and that Federal costs will be reduced as inefficent and ineffective PSROs are identified.

Regulatory Flexibility Act

The Secretary certifies, pursuant to Section 605(b) of the Regulatory Flexibility Act, that the regulation in this notice will not have a significant economic impact on a substantial number of small entities including: 1) small businesses as defined under section 3 of the Small Business Act; 2) not-for-profit enterprises independently owned and operated and not dominant in their fields; or 3) governmental jurisdictions serving less than 50,000 persons. The reason for the negative certification is that PSROs are not considered subject to the provisions of the Regulatory Flexibility Act.

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

42 CFR Part 431 is amended as follows:

Section 431.630 is revised as follows:

§ 431.630 Coordination of Medicaid with Professional Standards Review Organizations.

The State plan must provide that the Medicaid agency will comply with provisions of Part 463 of this chapter, relating to the activities of PSROs.

(a) The State plan may provide for the review of Medicaid services by a PSRO designated under Part B of Title XI of the Act. Medicaid requirements for medical and utilization review shall be deemed to be met for those services or providers subject to such contracted review.

(b) The State plan must specify how the contract with the PSRO satisfies the requirements that:

(1) The provisions of paragraphs (a), (b), (c), (g), (h), (i), (m), and (n) of § 431.503 of this subchapter are met;

(2) A monitoring and evaluation plan is in effect by which the State will assure satisfactory performance by the PSRO;

(3) The services and providers subject to PSRO review are identified; and

(4) The review activities performed by the PSRO are not inconsistent with those activities performed for the review of Title XVIII services, including a

description of whether and to what extent PSRO determinations will be considered conclusive for payment purposes.

PART 432—STATE PERSONNEL ADMINISTRATION

42 CFR Part 432 is amended as follows:

Section 432.50(b) is amended by removing and reserving paragraph (4) as follows:

§ 432.50 FFP: Staffing and training costs.

* * * * *

(b) *Rates of FFP.* * * *

* * * * *

(4) [Reserved]

* * * * *

PART 433—STATE FISCAL ADMINISTRATION

42 CFR Part 433 is amended as follows:

Section 433.15(b) is amended by removing and reserving paragraph (b)(1), redesignating paragraph (b)(6) as (b)(7), and adding new paragraph (b)(6) as follows:

§ 433.15 Rates of FFP for administration.

* * * * *

(b) *Activities and rates* * * * (1) [Reserved]

* * * * *

(6)(i) Funds expended for the performance of medical and utilization review by a Professional Standards Review Organization under a contract entered into under Section 1902(d) of the Act; 75: percent (Section 1903(a)(3) of the Act).

(ii) If a State contracts for medical and utilization review with any individual or organization not designated under Part B of Title XI of the Act, funds expended for such review will be reimbursed as provided in paragraph (b)(7) of this section.

(7) All other activities the Secretary finds necessary for proper and efficient administration of the State plan: 50 percent. (Section 1903(a)(7).) (See also § 455.300 of this subchapter for FFP at 90 percent for State Medicaid fraud control units under section 1903(a)(6).)

PART 456—UTILIZATION CONTROL

42 CFR Part 456 is amended as follows:

Section 456.2 is revised as follows:

§ 456.2 State plan requirements

(a) A State plan must provide that the requirements of this part are met.

(b) These requirements may be met by the State by:

(1) Assuming direct responsibility for assuring that the requirements of this Part are met; or

(2) Deeming, if the State contracts with a PSRO in accordance with § 431.630 of this subchapter.

(c) In accordance with § 431.15 of this subchapter, FFP will be available for expenses incurred in meeting the requirements of this Part.

PART 462—PROFESSIONAL STANDARDS REVIEW

42 CFR Part 462 is amended as follows:

1. The table of contents to Part 462 is amended by revising the title of § 462.11; adding a new § 462.12; and redesignating §§ 462.12 through 462.15 as §§ 462.13 through 462.16 as follows:

Sec.

Authority. Secs. 1152, 1154, and 1155(f) (2) and (3), Social Security Act, 36 Stat. 1430, 1431, 1432, 1435 (42 U.S.C. 1320c–1, 1320c–3, 1320c–4(f) (2) and (3)); sec. 1102, Social Security Act, 49 Stat. 647 (42 U.S.C. 1302), unles otherwise noted.

2. Section 462.4 is amended by revising paragraphs (a)(3), (a)(5), and (c)(1) to read as follows:

§ 462.4 Requirements for designation as a priority PSRO.

To be eligible for designation as a priority PSRO, an organization must meet the following requirements:

(a) *Composition of the organization.* * * *

(3) Be composed of:

(i) Licensed physicians engaged in the active practice of medicine, surgery, or osteopathy in the PSRO area; and

(ii) If the PSRO chooses, other health care practitioners who have independent admitting privileges and are engaged in the practice of their professions in the PSRO area.

* * * * *

(5) Maintain open membership for all eligible persons who voluntarily choose to become members and so inform the PSRO in writing.

(i) All physicians engaged in the active practice of medicine, surgery or osteopathy in the PSRO area are eligible to become members.

(ii) If the PSRO chooses, other health care practitioners who have independent admitting privileges and are engaged in the practice of their professions in the PSRO area can become members.

* * * * *

(c) *Composition of the governing body.* (1) A majority of the governing body must be members but the governing body may include non-members, such as consumers, health care practitioners other than physicians, and other physicians.

* * * * *

3. Section 462.6 is amended by removing and reserving paragraph (b)(4) and revising paragraph (b)(7)(i) as follows:

§ 462.6 Application requirements for conditional designation.

* * * * *

(b) *Initial application.* An organization not previously designated as a PSRO shall include in its application:

* * * * *

(4) [Reserved]

* * * * *

(7) A plan for insuring administrative coordination of the applicant's activities with:

(i) Medicare fiscal intermediaries, carriers, and HCFA Office of Direct Reimbursement, as provided in part 463 of this chapter; and

* * * * *

4. Section 462.8 is amended by revising paragraph (b)(2) as follows:

§ 462.8 Conditional designation as a PSRO.

* * * * *

(b) HCFA's determination will be based on the following factors:

* * * * *

(2) Comments and recommendations submitted by appropriate Medicare fiscal agents in accordance with the procedures for evaluation of capability contained in § 463.2 of this chapter.

5. Section 462.11 is amended by revising paragraphs (a) and (b) (2) and adding new paragraphs (c) and (d) as follows:

§ 462.11 Duration, renewal, and voluntary termination or nonrenewal of grants.

(a) *Grant period.* The initial grant to a PSRO, whether conditional or fully designated, will be for a term not to exceed 12 months.

(b) *Renewal* * * *

(2) If HCFA determines that a conditionally designated PSRO has made satisfactory progress in carrying out its formal plan and remains qualified for conditional designation, or that a fully designated PSRO has performed in a satisfactory manner and remains qualified for full designation, it will renew the grant for an additional period not to exceed 12 months, provided it is in the best interest of the Federal government.

(c) *Voluntary termination or nonrenewal.* If a PSRO determines that it does not want to have its grant renewed, if must notify HCFA not later than 90 days before the expiration of its grant. HCFA may permit notice of less than 90 days if it determines that an earlier termination date would not unduly interrupt the system of peer review established by the PSRO nor unduly interfere with the effective and efficient administration of the PSRO program.

(d) *Transfer of records.* If a grant to a PSRO is terminated or is not renewed, the PSRO shall transfer to HCFA or a successor PSRO any information (acquired or developed in carrying out PSRO duties and functions) that is requested by HCFA.

6. Part 462 is amended by redesignating §§ 462.12 through 462.15, as §§ 462.13 through 462.16 and by adding a new § 462.12 to read as follows:

§ 462.12 Involuntary termination or nonrenewal of grants.

(a) *Reevaluation factors.* Periodically, the Secretary will reevaluate a PSRO's capability to perform review functions. He will consider:

(1) The progress of the PSRO in carrying out its formal plan;

(2) Any comments or recommendations submitted by the Medicare fiscal agents; and

(3) Other relevant factors as determined by the Secretary.

(b) *Notice of tentative determination and intended action.* If, after such reevaluation, the Secretary has reason to believe that the PSRO is not performing in a satisfactory manner the duties and functions which it was found capable of performing, he will notify the PSRO of the grounds for this belief and of the action that he proposes to take. This action may include:

(1) Placing restrictions upon the exercise of review responsibility or the performance of certain duties and functions by the PSRO, including revision of the conditional PSRO's phase-in timetable;

(2) Requiring the PSRO to take corrective action, including the acceptance of technical assistance to improve its performance;

(3) Suspending the authority of the conditional PSRO to make conclusive determinations;

(4) Terminating the agreement with the PSRO upon 90 days notice to the PSRO, pursuant to sections 1152(d) and 1154(d) of the Act;

(5) Not renewing the agreement;

(6) Any other action the Secretary may deem appropriate.

(c) *Notice to State and Medicare fiscal agencies.* The Secretary will, as soon as practicable:

(1) Notify the Medicare fiscal agents, affected health care institutions, and the Medicaid State agency (if the PSRO has a contract under Title XI Part B of the Act) of his belief and intended action under paragraph (b) of this section; and

(2) Solicit their comments on the action he proposes to take.

(d) *Informal meeting and decision.* (1) The notice to the PSRO under paragraph (b) of this section shall offer the PSRO an opportunity:

(i) To respond to any comments of the Medicare fiscal agents;

(ii) To submit written material; and

(iii) To meet informally with an official designated by the Secretary to show cause why the action proposed by the Secretary should not be taken.

(2) If the PSRO does not submit written material or request an informal meeting within 30 days after receipt of the Secretary's notice, the Secretary's tentative decision shall become final and he will so notify the PSRO, Medicare fiscal agent(s), affected health care institutions, and Medicaid State agency (if the PSRO has a contract under Title XI Part B of the Act) and state the basis for his decision.

(3) If the PSRO submits written material within 30 days, the Secretary will consider this material prior to making a final decision.

(4) If the PSRO request an informal meeting within 30 days after receipt of the Secretary's notice, a meeting will be scheduled as soon as practicable.

(5) After this meeting, the official designated by the Secretary will render promptly a recommended decision to the Secretary.

(6) The Secretary will adopt, revise or set aside the recommended decision and will notify the PSRO, appropriate agencies and affected health care institutions of his decision, the effective date, and the basis for it.

(e) *Effect of decision of the Secretary.* The decision of the Secretary is final and is not subject to judicial review.

Part 463—Review Responsibility and Authority of Professional Standards Review Organizations (PSRO's)

42 CFR Part 463 is amended as follows:

1. The table of contents to Part 463 is amended by removing § 463.11 from Subpart A, by removing and reserving § 463.27 from Subpart C, and removing and reserving Subpart D.

§ 463.1 [Amended]

Section 463.1 is amended by removing the definitions for "Combined facility," "Intermediate care facility (ICF)," "Intermediate care facility for the mentally retarded (ICF–MR)," "Medicaid State agency," and "Title V State agency."

* * * * *

3. Section 463.2 is amended by removing paragraphs (a) (2), (3), (4), (e) (3) and (4); by removing and reserving paragraphs (b)(2), (c), (d), and (e)(1)(ii); and by revising paragraphs (a) and (e)(2) as follows:

§ 463.2 Evaluation of capability.

(a) *Formal plan.* An organization wishing to be designated as a conditional PSRO shall submit to the Secretary a formal plan detailing the necessary tasks and a phase-in timetable for the orderly assumption and implementation of review responsibility.

* * * * *

(b) *Evaluation by the Secretary.* The Secretary will evaluate the capability of the organization to exercise review responsibility and determine whether to designate it as a conditional PSRO, on the basis of the following factors:

(1) The formal plan, and any modification or amendments submitted by the organization;

(2) [Reserved]

(c) [Reserved]

(d) [Reserved]

(e) *Extension of PSRO review activities.* (1) Once designated, the conditional PSRO shall submit to the Secretary, at least once a year, any modification to the formal plan; and any amendments to extend the PSRO's review activities to:

(i) Skilled nursing facilities, as defined in section 1861(j) of the Act;

(ii) [Reserved]

(iii) Ambulatory care services.

(2) Paragraphs (a) and (b) of this section (relating to the Secretary's evaluation of an organization's capability to be designated as a conditional PSRO) apply to any amendments to extend a PSRO's review activities to these facilities and services.

4. Section 463.3 is amended by revising paragraphs (b)(2) and (c) to read as follows:

§ 463.3 Notification of designation and capability.

* * * * *

(b) *Review not conclusive for claims payment.* (1) The notification under paragraph (a)(2) of this section may include a time limited authorization for the PSRO to perform review which is not conclusive for purposes of claims payment.

(2) During this time, the Title XVIII requirements regarding utilization review, physician certifications, and State agency surveys and certifications shall be deemed to be satisfied.

(c) *Notice to fiscal and survey agencies.* (1) The Secretary will notify the appropriate State survey agency and the Medicare fiscal agents of the PSRO's approved phase-in timetable at the time of designation.

* * * * *

5. Section 463.4 is amended by revising paragraph (c)(1) to read as follows:

§ 463.4 General requirements

* * * * *

(c) *Public access.* The PSRO shall maintain and make available for public inspection, at its principal business office:

(1) A copy of each MOU (or other administrative procedures) with Medicare fiscal agents; and

(2) A copy of its current approved phase-in timetable.

* * * * *

6. Section 463.5 is revised as follows:

§ 463.5 Coordination with Medicare fiscal agents.

(a) *Procedures for MOUs.* If a Medicaid or Title V State agency or Medicare fiscal agent notifies the PSRO that it wishes a written memorandum of understanding incorporating their administrative procedures:

(1) The SPRO and the fiscal agent shall negotiate in good faith in an effort to reach written agreement.

(2) If they cannot reach agreement, the Secretary will assist them in resolving matters in dispute.

(3) The PSRO is required to incorporate its procedures into an MOU approved by the Secretary, before it may make conclusive determinations for the Medicare program, unless the Secretary finds that the agency or agent has:

(i) Refused to negotiate in good faith or in a timely manner; or

(ii) Insisted on including the MOU provisions which are not consistent with the provisions of the Act.

(4) The MOU shall include procedures for:

(i) Informing Medicare fiscal agents of PSRO approval or disapproval of health care services and items;

(ii) Exchanging data or information;

(iii) Modifying the procedures when additional PSRO review responsibility is authorized by the Secretary; and

(iv) Dealing with any other matters that are necessary for coordination.

(5) [Reserved]

(6) [Reserved]

(b) [Reserved]

(c) *Action by the Secretary.* (1) At least 30 days prior to the timetable date for initial assumption of review responsibility, the PSRO shall submit to the Secretary for approval its MOUs or administrative procedures, including any comments by the agencies or agents.

(2) If the Secretary approves the MOUs or procedures, the PSRO shall follow them.

(3) If the Secretary disapproves the MOUs or procedures, he will:

(i) Notify in writing the PSRO and the appropriate agencies and agents, stating the reasons for disapproval; and

(ii) Require the PSRO to revise its MOUs or procedures and, if necessary, modify its timetable.

(d) *Modification of MOUs.* the MOUs or procedures may be modified, with the Secretary's approval:

(1) Through a revised MOU with the agent(s); or

(2) In the case of procedures, by the PSRO, after providing opportunity for comment by the agencies and agents.

7. Section 463.8 is amended by revising paragraph (c)(1) as follows:

§ 463.8 Notices regarding assumption of responsibility.

* * * * *

(c) *Effect of delay in PSRO's assumption of responsibility.* (1) The activities required under title XVIII of the Act, as specified in Subpart C of this part, shall continue in effect in the institution until the PSRO is able to assume responsibility.

* * * * *

8. Section 463.10 is amended by revising paragraph (a)(1), removing and reserving paragraphs (a)(2) and (b), and removing paragraphs (d), (e), and (f) as follows:

§ 463.10 Monitoring.

(a) *Use of appropriate agencies and agents.* (1) The Secretary will periodically evaluate the review performance of conditional PSRO's. He may arrange to have Medicare fiscal agents or State agencies assist him in monitoring the activities of a conditional PSRO.

(2) [Reserved]

(3) If monitoring is authorized, the PSRO shall take all necessary and appropriate actions to facilitate monitoring activities.

(b) [Reserved]

(c) *Meetings.* (1) If a monitoring agency considers that PSRO performance is not effective, it shall

(i) Notify the PSRO and meet with it to discuss methods for improving effectiveness; and

(ii) Promptly notify the Secretary of any serious problems and of the results of its meeting with the PSRO.

(2) The Secretary may decide to reevaluate the PSRO's capability or take other appropriate action.

§ 463.11 [Removed]

9. Section 463.11 is removed.

10. Section 463.15 is revised to read as follows:

§ 463.15 Basic requirement.

No Federal funds appropriated under Title XVIII of the Act shall be used (directly or indirectly) for the payment of any claim for services or items provided in a health care institution where a PSRO is exercising review responsibility for those services unless the conditions of this subpart are met.

11. Section 463.16 is amended by revising paragraph (c) to read as follows:

§ 463.16 Effect of PSRO action.

* * * * *

(c) *Conclusive effect on payment agencies.* Unless services or items have been disapproved by the PSRO or disapproved under section 1159 of the Act, payment shall not be denied by a Medicare fiscal agent on the grounds that the services:

(1) Were not medically necessary; or

(2) Were not of a quality which meets professionally recognized standards of health care; or

(3) Were provided inappropriately on an inpatient health care facility of a different type.

12. Section 463.17 is revised to read as follows:

§ 463.17 Duration of payment after PSRO disapproval.

In any case in which a PSRO disapproves institutional care provided or proposed to be provided to a Medicare beneficiary:

(a) Payment may be made for the services furnished before the second day after the day on which the provider received notice of the disapproval; or

(b) If the PSRO determines that more time is required in order to arrange post discharge care, payment may be made for the services furnished before the fourth day after the day on which the provider received the notice.

13. Section 463.18 is revised to read as follows:

§ 463.18 Coverage determinations.

Nothing in this part shall be construed as precluding the Secretary, Medicare fiscal agent, in the proper exercise of its duties and functions, from reviewing claims to determine whether they meet the coverage requirements of Title XVIII. (See § 463.26 (b) and (c).)

Subpart C—Correlation of Title XI Functions With Functions Required Under Title XVIII of the Act.

14. Part 463, Subpart C is amended by revising the title as set forth above.

15. Section 463.27 is removed and reserved as follows:

§ 463.27 [Reserved]

PART 463, SUBPART D [REMOVED]

16. Part 463, Subpart D is removed in its entirety.

PART 466—PSRO HOSPITAL REVIEW

42 CFR Part 466 is amended as follows:

1. Section 466.1 is amended by revising paragraph (a) as follows:

§ 466.1 Statutory provisions and applicability.

(a) *Statutory provisions.* (1) Section 1155(a) of the Social Security Act requires that each PSRO assume, at the earliest date practicable after designation of a PSRO by HCFA, responsibility for the review of the professional activities of institutional and non-institutional providers and physicians and other health care practitioners in the provision of health care services under the Medicare program. The purpose of PSRO review is to determine whether:

(i) The services and items are or were medically necessary;

(ii) The quality of the services meets professionally recognized standards of health care; and

(iii) Those services and items proposed to be provided on an inpatient basis could, consistent with the provision of appropriate medical care, be effectively provided on an outpatient basis or more economically in an inpatient health care facility of a different type.

* * * * *

(2) Section 1155(e) of the Act allows PSROs to use the services, and accept the findings, of hospital review committees that demonstrate their capacity to carry out review functions in a timely and effective manner and provides that the Secretary may, for good cause, disapprove such acceptance.

* * * * *

2. Section 466.2 is amended by revising the following definition and removing the definition for "Intermediate care facility (ICF)."

§ 466.2 Definitions.

* * * * *

"Federal program patient" means a patient who is or may be eligible to have payment made on his behalf under the Medicare program.

* * * * *

3. Section 466.10 is amended by revising paragraphs (b) and (d) as follows:

§ 466.10 General requirements for concurrent review.

* * * * *

(b) *Basis for determination of appropriateness.* In the case of Medicare beneficiaries, the PSRO must determine whether a particular level of care is appropriate in accordance with the level-of-care provisions in sections 1814 and 1861 of the Act, 42 CFR 405.116, 405.126–405.128a, and pertinent guidelines issued by HCFA.

* * * * *

(d) *Coverage determinations.* Nothing in §§ 466.10 through 466.16 shall be construed as precluding a Medicare intermediary or carrier in the proper exercise of its duties and functions, from:

(1) Reviewing claims to determine whether they meet the pertinent coverage requirements of Medicare; or

(2) Requesting the PSRO to make a retrospective determination regarding the medical necessity and appropriateness of specific health care services in the application of coverage requirements.

* * * * *

4. Section 466.12 is amended by revising paragraph (f)(2) to read as follows:

§ 466.12 Continued stay review.

* * * * *

(f) *PSRO responsibilities.* * * *

(2) The PSRO shall maintain, at its principal business office, and make available to HCFA, fiscal intermediaries, and other interested parties, copies of:

(i) Its physician certification requirements; and

(ii) Its procedures for informing physicians and other appropriate health care practitioners of those requirements.

5. Section 466.16 is amended by removing and reserving paragraph (c) and revising paragraph (e) as follows:

§ 466.16 Notice of adverse determination.

* * * * *

(c) [Reserved]

* * * * *

(e) *Notice to payers.* The PSRO must provide prompt written notice of an adverse determination to the Medicare intermediary of carrier.

* * * * *

6. Section 466.21 is amended by revising paragraph (a)(1) to read follows:

§ 466.21 Reviewer qualifications and participation.

(a) *Staff privileges.* (1) Each person who makes a determination about health care services provided, or proposed to be provided, must have active staff privileges in at least one of the hospitals participating in the Medicare program in the PSRO area.

* * * * *

7. Section 466.32 is amended by revising paragraph (c) to read as follows:

§ 466.32 Details of delegated review plan.

The delegated review plan must include:

* * * * *

(c) A description of the coordination procedures developed with Medicare fiscal agents including the mechanisms for notifying these agents of delegated review determinations that impact on claims payment;

* * * * *

8. Section 466.33 is amended by revising paragraph (b)(2) to read as follows:

§ 466.33 Determination and notice of hospital capability.

* * * * *

(b) *Basis for determination.* In making a determination of capability, the PSRO must use written evaluation factors which have been approved by HCFA. These evaluation factors must measure the capability of the hospital review committee to perform review activities effectively and efficiently. They must include at least:

(1) The degree to which the proposed organization for review and review mechanisms provides the capability to meet the objectives of the PSRO's approved formal plan;

(2) The adequacy of the hospital's performance in Medicare utilization review activities. In evaluating this factor the PSRO shall consider information:

(i) Obtained from the State survey agency and the appropriate Medicare intermediaries, and

(ii) Obtained through site visits to the hospital;

* * * * *

9. Section 466.38 is amended by revising paragraph (c) to read as follows:

§ 466.38 Monitoring by HCFA.

* * * * *

(c) *Disapproval by HCFA.* HCFA may disapprove a delegation for good cause, after taking into consideration any comments submitted by Medicare fiscal agents regarding:

(1) The appropriateness of delegation of review to a hospital; or

(2) The effectiveness of performance of delegated review functions by that hospital.

* * * * *

10. Section 466.62 is amended by removing paragraph (c)(3) and revising paragraph (d) as follows:

§ 466.62 Reimbursement to delegated hospitals.

* * * * *

(c) *Reimbursement.*

* * * * *

(3) [Reserved]

(d) *PSRO Monitoring.* (1) The PSRO is responsible for monitoring the total cost of delegated review and the delegated review activity to assure the hospital's conformance with the review plan. Payment of the unit cost rate per admission is contingent on the hospital executing the approved review plan. The PSRO may withdraw delegation if the hospital does not perform review consistent with the plan.

(2) The hospital must maintain records, and submit reports regarding its review activities and costs to the PSRO or to HCFA as required by HCFA. Fiscal intermediaries are responsible for audits of review costs for hospitals participating in the Medicare Program.

PART 473—HEARINGS AND APPEALS ON PSRO DETERMINATIONS

42 CFR Part 473 is amended as follows:

Section 473.2 is amended by revising paragraph (a) to read as follows:

§ 473.2 Right to reconsideration, review and hearing.

(a) Any beneficiary who is entitled to benefits under Title XVIII of the Act, or a provider or practitioner who is dissatisfied with a determination, with respect to a claim, made by a Professional Standards Review Organization in carrying out its responsibilities for the review of professional activities in accordance with paragraphs (1) and (2) of section 1155(a) of the Act shall, after being notified of such determination, be entitled to a reconsideration thereof by the Professional Standards Review Organization, and, where the Professional Standards Review Organization reaffirms such determination in a State which has established a Statewide Professional Standards Review Council, and where the matter in controversy is $100 or more, such determination shall, upon the written request of the dissatisfied party, be reviewed by professional members of such Council and, if the Council so determines, revised.

* * * * *

PART 478—STATEWIDE PROFESSIONAL STANDARDS REVIEW COUNCILS

42 CFR Part 478 is amended as follows:

1. Section 478.4 is amended by revising paragraph (f)(1) to read as follows:

§ 478.4 Qualifications and selection of Statewide Council members.

* * * * *

(f) *Qualifications of public representatives.* Each public representative shall be:

(1) Knowledgeable by education and/or experience about health care that is provided in the State under Title XVIII of the Act;

* * * * *

2. Section 478.6 is amended by revising paragraphs (c)(2) and (f) as follows:

§ 478.6 Duties and functions.

* * * * *

(c) *Data gathering procedures and operating procedures.* Each Statewide Council shall, at the request of the Secretary or the PSROs, assist in:

* * * * *

(2) Coordinating PSRO data activities in the State with other programs of the Department of Health and Human Services, including Cooperative Health Systems, Health Systems Agencies, and the programs under Title XVIII of the Act.

* * * * *

(f) *Assistance in assuring practitioner and provider compliance.* (1) Each Statewide Council shall help assure compliance with the obligations imposed by section 1160(a) of the Act on practitioners and other providers of health care services for which payment may be made under Title XVIII of the Act.

(2) In order to carry out this responsibility, the Council shall, in accordance with section 1160(c) of the Act:

(i) Use whatever authority or influence it may possess as a professional organization:

(ii) Enlist the support of other professional or governmental organizations;

(iii) Use educational and other appropriate means; and

(iv) Work cooperatively with PSROs in the State.

* * * * *

3. Section 478.102 is amended by revising paragraph (a)(3) to read as follows:

§ 478.102 Membership.

(a) *Composition, terms and qualifications.* * * *

(3) The membership of each Advisory Group shall consist of representatives of health care practitioners (other than physicians of hospitals and of other health care facilities which provide within the State health care services for which payment, in whole or in part, may be made under Title XVIII of the Act and who are knowledgeable about the types of health care services being reviewed in the State. In addition, the membership of each Advisory Group shall meet the following requirements:

(i) *Representatives of health care practitioners (other than physicians).* At least one-half of the members of each Advisory Group shall be representatives of health care practitioners (other than physicians), including at least one registered professional nurse and at least one doctor of dental surgery or dental medicine. For purposes of this subpart, health care practitioners (other than physicians) are those health professionals who do not hold a Doctor of Medicine or Doctor of Osteopathy degree, meet all applicable State or Federal requirements for practice of their profession, and are actively involved in the delivery of patient care or services which are directly or indirectly paid for under Titles V, XVIII and/or XIX of the Act. Each such

representative shall practice his or her profession in the State.

(ii) *Representatives of hospitals.* One or more members of each Advisory Group shall be representatives of hospitals. Each such representative shall be actively involved in the administration of or provision of services in a hospital which is located in the State and which has in effect arrangements for reimbursement for services under Title XVIII of the Act.

(iii) *Representatives of other health care facilities.* One or more members of each Advisory Group shall be representatives of health care facilities other than hospitals. At least one such member shall be a representative of a skilled nursing facility (as defined in section 1861(j) of the Act). Each such representative shall be actively involved in the administration of or provision of, services in a health care facility other than a hospital which is located in the State and which has in effect arrangements for reimbursement for services under Title XVIII of the Act.

PART 480—ADVISORY GROUPS TO PSRO's

42 CFR Part 480 is removed.

(Sections 1102, 1152, 1153, 1154, 1155, 1158, 1159, 1162, 1168, 1902, and 1903 of the Social Security Act (42 U.S.C. 1302, 1320c–1, 1320c–2, 1320c–3, 1320c–4, 1320c–7, 1320c–8, 1320c–11, 1320c–17, 1396a, and 1396o))

Catalog of Federal Domestic Assistance Programs No. 13.714—Medical Assistance Programs; 13.773—Medicare Hospital Insurance; 13.774—Medicare Supplementary Medical Insurance.

Dated: September 15, 1981.

Carolyne K. Davis,

Administrator, Health Care Financing Administration.

Approved: September 22, 1981.

Richard S. Schweiker,

Secretary.

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