

of the date on a request by the Secretary or the Medicaid agency, full and complete information about—

(1) The ownership of any subcontractor with whom the provider has had business transactions totaling more than \$25,000 during the 12-month period ending on the date of the request; and

(2) Any significant business transactions between the provider and any wholly owned supplier, or between the provider and any subcontractor, during the 5-year period ending on the date of the request.

(c) *Denial of Federal financial participation (FFP).* (1) FFP is not available in expenditures for services furnished by providers who fail to comply with a request made by the Secretary or the Medicaid agency under paragraph (b) of this section or under § 420.205 of this chapter (Medicare requirements for disclosure).

(2) FFP will be denied in expenditures for services furnished during the period beginning on the day following the date the information was due to the Secretary or the Medicaid agency and ending on the day before the date on which the information was supplied.

§ 455.106 Disclosure by providers: Information on persons convicted of crimes.

(a) *Information that must be disclosed.* Before the Medicaid agency enters into or renews a provider agreement, or at any time upon written request by the Medicaid agency, the provider must disclose to the Medicaid agency the identity of any person who:

(1) Has ownership or control interest in the provider, or is an agent or managing employee of the provider; and

(2) Has been convicted of a criminal offense related to that person's involvement in any program under Medicare, Medicaid, or the title XX services program since the inception of those programs.

(b) *Notification to Inspector General.* (1) The Medicaid agency must notify the Inspector General of the Department of any disclosures made under paragraph (a) of this section within 20 working days from the date it receives the information.

(2) The agency must also promptly notify the Inspector General of the De-

partment of any action it takes on the provider's application for participation in the program.

(c) *Denial or termination of provider participation.* (1) The Medicaid agency may refuse to enter into or renew an agreement with a provider if any person who has an ownership or control interest in the provider, or who is an agent or managing employee of the provider, has been convicted of a criminal offense related to that person's involvement in any program established under Medicare, Medicaid or the title XX Services Program.

(2) The Medicaid agency may refuse to enter into or may terminate a provider agreement if it determines that the provider did not fully and accurately make any disclosure required under paragraph (a) of this section.

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

SOURCE: 43 FR 45266, Sept. 29, 1978, unless otherwise noted.

Subpart A—General Provisions

§ 456.1 Basis and purpose of part.

(a) This part prescribes requirements concerning control of the utilization of Medicaid services including—

(1) A statewide program of control of the utilization of all Medicaid services; and

(2) Specific requirements for the control of the utilization of Medicaid services in institutions.

(3) Specific requirements for an outpatient drug use review program.

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

(1) *Methods and procedures to safeguard against unnecessary utilization of care and services.* Section 1902(a)(30) requires that the State plan provide methods and procedures to safeguard against unnecessary utilization of care and services.

(2) *Penalty for failure to have an effective program to control utilization of institutional services.* Section 1903(g)(1) provides for a reduction in the amount of Federal Medicaid funds paid to a State for long-stay inpatient services if the State does not make a showing satisfactory to the Secretary that it has an effective program of control over utilization of those services. This penalty

provision applies to inpatient services in hospitals, mental hospitals, and intermediate care facilities (ICF's). Specific requirements are:

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

(ii) Under section 1903(g)(1)(B), services must be furnished under a plan established and periodically evaluated by a physician.

(iii) Under section 1903(g)(1)(C), the State must have in effect a continuous program of review of utilization of care and services under section 1902(a)(30) whereby each admission is reviewed or screened in accordance with criteria established by medical and other professional personnel.

(iv) Under section 1903(g)(1)(D), the State must have an effective program under sections 1902(a)(26) and (31) of review of care in intermediate care facilities and mental hospitals. This must include evaluation at least annually of the professional management of each case.

(3) *Medical review in mental hospitals.* Section 1902(a)(26)(A) requires that the plan provide for a program of medical review that includes a medical evaluation of each individual's need for care in a mental hospital, a plan of care, and, where applicable, a plan of rehabilitation.

(4) *Independent professional review in intermediate care facilities.* Section 1902(a)(31)(A) requires that the plan provide for a program of independent professional review that includes a medical evaluation of each individual's need for intermediate care and a written plan of service.

(5) *Inspection of care and services in institutions.* Sections 1902(a)(26)(B) and (C) and 1902(a)(31)(B) and (C) require that the plan provide for periodic inspections and reports, by a team of professional persons, of the care being provided to each recipient in institutions for mental diseases (IMD's), and ICF's participating in Medicaid.

(6) *Denial of FFP for failure to have specified utilization review procedures.* Section 1903(i)(4) provides that FFP is

not available in a State's expenditures for hospital or mental hospital services unless the institution has in effect a utilization review plan that meets Medicare requirements. However, the Secretary may waive this requirement if the Medicaid agency demonstrates to his satisfaction that it has utilization review procedures superior in effectiveness to the Medicare procedures.

(7) *State health agency guidance on quality and appropriateness of care and services.* Section 1902(a)(33)(A) requires that the plan provide that the State health or other appropriate medical agency establish a plan for review, by professional health personnel, of the appropriateness and quality of Medicaid services to provide guidance to the Medicaid agency and the State licensing agency in administering the Medicaid program.

(8) *Drug use review program.* Section 1927(g) of the Act provides that, for payment to be made under section 1903 of the Act for covered outpatient drugs, the State must have in operation, by not later than January 1, 1993, a drug use review (DUR) program. It also requires that each State provide, either directly or through a contract with a private organization, for the establishment of a DUR Board.

TABLE 1

[This table relates the regulations in this part to the sections of the Act on which they are based.]

Subpart A—General	1902(a)(30) 1902(a)(33)(A) 1902(a)(30)
Subpart B—Utilization Control: All Medicaid Services.	
Subpart C—Utilization Control: Hospitals	
Certification of need for care	1903(g)(1)(A)
Plan of care	1903(g)(1)(B)
Utilization review plan (including admission review).	1902(a)(30) 1903(g)(1)(C) 1903(i)(4)
Subpart D—Utilization Control: Mental Hospitals	
Certification of need for care	1903(g)(1)(A)
Medical evaluation and admission review.	1902(a)(26)(A) 1903(g)(1)(C)
Plan of care	1902(a)(26)(A) 1903(g)(1)(B)
Admission and plan of care requirements for individuals under 21.	1902(a)(26)(A) 1903(g)(1)(B), (C)
Utilization review plan	1902(a)(30) 1903(g)(1)(C) 1903(i)(4)
Subpart F—Utilization Control: Intermediate Care Facilities	
Certification of need for care	1903(g)(1)(A)
Medical evaluation and admission review.	1902(a)(31)(A) 1903(g)(1)(C)

TABLE 1—Continued

[This table relates the regulations in this part to the sections of the Act on which they are based.]

Plan of care	1902(a)(31)(A) 1903(g)(1)(B)
Utilization review plan	1902(a)(30) 1903(g)(1)(C) 1903(i)(4)
Subpart G—Inpatient Psychiatric Services for Individuals Under Age 21: Admission and Plan of Care Requirements.	1905 (a)(16) and (h)
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Subpart J—Penalty for Failure To Make a Satisfactory Showing of An Effective Institutional Utilization Control Program.	1903(g)
Subpart K—Drug Use Review (DUR) Program and Electronic Claims Management System for Outpatient Drug Claims.	1927(g) and (h)

[43 FR 45266, Sept. 29, 1978, as amended at 46 FR 48561, Oct. 1, 1981; 57 FR 49408, Nov. 2, 1992; 61 FR 38398, July 24, 1996]

§ 456.2 State plan requirements.

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

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

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

(2) Deeming of medical and utilization review requirements if the agency contracts with a PRO to perform that review, which in the case of inpatient acute care review will also serve as the initial determination for PRO medical necessity and appropriateness review for patients who are dually entitled to benefits under Medicare and Medicaid.

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

[46 FR 48566, Oct. 1, 1981, as amended at 50 FR 15327, Apr. 17, 1985; 51 FR 43198, Dec. 1, 1986]

§ 456.3 Statewide surveillance and utilization control program.

The Medicaid agency must implement a statewide surveillance and utilization control program that—

(a) Safeguards against unnecessary or inappropriate use of Medicaid services and against excess payments;

(b) Assesses the quality of those services;

(c) Provides for the control of the utilization of all services provided under the plan in accordance with subpart B of this part; and

(d) Provides for the control of the utilization of inpatient services in accordance with subparts C through I of this part.

§ 456.4 Responsibility for monitoring the utilization control program.

(a) The agency must—

(1) Monitor the statewide utilization control program;

(2) Take all necessary corrective action to ensure the effectiveness of the program;

(3) Establish methods and procedures to implement this section;

(4) Keep copies of these methods and procedures on file; and

(5) Give copies of these methods and procedures to all staff involved in carrying out the utilization control program.

§ 456.5 Evaluation criteria.

The agency must establish and use written criteria for evaluating the appropriateness and quality of Medicaid services. This section does not apply to services in hospitals and mental hospitals. For these facilities, see the following sections: §§ 456.122 and 456.132 of subpart C; and § 456.232 of subpart D.

[43 FR 45266, Sept. 29, 1978, as amended at 61 FR 38399, July 24, 1996]

§ 456.6 Review by State medical agency of appropriateness and quality of services.

(a) The Medicaid agency must have an agreement with the State health agency or other appropriate State medical agency, under which the health or medical agency is responsible for establishing a plan for the review by professional health personnel of the appropriateness and quality of Medicaid services.

(b) The purpose of this review plan is to provide guidance to the Medicaid agency in the administration of the State plan and, where applicable, to the State licensing agency described in § 431.610.

Subpart B—Utilization Control: All Medicaid Services

§ 456.21 Scope.

This subpart prescribes utilization control requirements applicable to all services provided under a State plan.

§ 456.22 Sample basis evaluation of services.

To promote the most effective and appropriate use of available services and facilities the Medicaid agency must have procedures for the on-going evaluation, on a sample basis, of the need for and the quality and timeliness of Medicaid services.

§ 456.23 Post-payment review process.

The agency must have a post-payment review process that—

(a) Allows State personnel to develop and review—

(1) Recipient utilization profiles;

(2) Provider service profiles; and

(3) Exceptions criteria; and

(b) Identifies exceptions so that the agency can correct misutilization practices of recipients and providers.

Subpart C—Utilization Control: Hospitals

§ 456.50 Scope.

This subpart prescribes requirements for control of utilization of inpatient hospital services, including requirements concerning—

(a) Certification of need for care;

(b) Plan of care; and

(c) Utilization review plans.

§ 456.51 Definitions.

As used in this subpart:

Inpatient hospital services—

(a) Include—

(1) Services provided in an institution other than an institution for mental disease, as defined in § 440.10;

(2) [Reserved]

(3) Services provided in specialty hospitals and

(b) Exclude services provided in mental hospitals. Utilization control requirements for mental hospitals appear in subpart D.

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

Medical care criteria or *criteria* means predetermined elements against which aspects of the quality of a medical service may be compared. These criteria are developed by health professionals relying on their expertise and the professional health care literature.

[43 FR 45266, Sept. 29, 1978, as amended at 51 FR 22041, June 17, 1986]

CERTIFICATION OF NEED FOR CARE

§ 456.60 Certification and recertification of need for inpatient care.

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

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

(b) *Recertification.* (1) A physician, or physician assistant or nurse practitioner (as defined in § 491.2 of this chapter) acting within the scope of practice as defined by State law and under the supervision of a physician, must recertify for each applicant or recipient that inpatient services in a hospital are needed.

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

[46 FR 48561, Oct. 1, 1981]

PLAN OF CARE

§ 456.80 Individual written plan of care.

(a) Before admission to a hospital or before authorization for payment, a physician and other personnel involved in the care of the individual must establish a written plan of care for each applicant or recipient.

(b) The plan of care must include—

(1) Diagnoses, symptoms, complaints, and complications indicating the need for admission;

(2) A description of the functional level of the individual;

(3) Any orders for—

- (i) Medications;
- (ii) Treatments;

(iii) Restorative and rehabilitative services;

(iv) Activities;

(v) Social services;

(vi) Diet;

(4) Plans for continuing care, as appropriate; and

(5) Plans for discharge, as appropriate.

(c) Orders and activities must be developed in accordance with physician's instructions.

(d) Orders and activities must be reviewed and revised as appropriate by all personnel involved in the care of an individual.

(e) A physician and other personnel involved in the recipient's case must review each plan of care at least every 60 days.

UTILIZATION REVIEW (UR) PLAN:
GENERAL REQUIREMENT

§ 456.100 Scope.

Sections 456.101 through 456.145 of this subpart prescribe requirements for a written utilization review (UR) plan for each hospital providing Medicaid services. Sections 456.105 and 456.106 prescribe administrative requirements; §§ 456.111 through 456.113 prescribe informational requirements; §§ 456.121 through 456.129 prescribe requirements for admission review; §§ 456.131 through 456.137 prescribe requirements for continued stay review; and §§ 456.141 through 456.145 prescribe requirements for medical care evaluation studies.

§ 456.101 UR plan required for inpatient hospital services.

(a) A State plan must provide that each hospital furnishing inpatient services under the plan has in effect a written UR plan that provides for review of each recipient's need for the services that the hospital furnishes him.

(b) Each written hospital UR plan must meet the requirements under §§ 456.101 through 456.145.

UR PLAN: ADMINISTRATIVE
REQUIREMENTS

§ 456.105 UR committee required.

The UR plan must—

(a) Provide for a committee to perform UR required under this subpart;

(b) Describe the organization, composition, and functions of this committee; and

(c) Specify the frequency of meetings of the committee.

§ 456.106 Organization and composition of UR committee; disqualification from UR committee membership.

(a) For the purpose of this subpart, “UR committee” includes any group organized under paragraphs (b) and (c) of this section.

(b) The UR committee must be composed of two or more physicians, and assisted by other professional personnel.

(c) The UR committee must be constituted as—

(1) A committee of the hospital staff;

(2) A group outside the hospital staff, established by the local medical or osteopathic society and at least some of the hospitals and SNFs in the locality;

(3) A group capable of performing utilization review, established and organized in a manner approved by the Secretary.

(d) The UR committee may not include any individual who—

(1) Is directly responsible for the care of the patient whose care is being reviewed; or

(2) Has a financial interest in any hospital.

UR PLAN: INFORMATIONAL
REQUIREMENTS

§ 456.111 Recipient information required for UR.

The UR plan must provide that each recipient’s record includes information needed for the UR committee to perform UR required under this subpart. This information must include, at least, the following:

(a) Identification of the recipient.

(b) The name of the recipient’s physician.

(c) Date of admission, and dates of application for and authorization of Medicaid benefits if application is made after admission.

(d) The plan of care required under § 456.70.

(e) Initial and subsequent continued stay review dates described under §§ 456.128 and 456.133.

(f) Date of operating room reservation, if applicable.

(g) Justification of emergency admission, if applicable.

(h) Reasons and plan for continued stay, if the attending physician believes continued stay is necessary.

(i) Other supporting material that the committee believes appropriate to be included in the record.

§ 456.112 Records and reports.

The UR plan must describe—

(a) The types of records that are kept by the committee; and

(b) The type and frequency of committee reports and arrangements for their distribution to appropriate individuals.

§ 456.113 Confidentiality.

The UR plan must provide that the identities of individual recipients in all UR records and reports are kept confidential.

UR PLAN: REVIEW OF NEED FOR
ADMISSION¹

§ 456.121 Admission review required.

The UR plan must provide for a review of each recipient’s admission to the hospital to decide whether it is needed, in accordance with the requirements of §§ 456.122 through 456.129.

§ 456.122 Evaluation criteria for admission review.

The UR plan must provide that—

(a) The committee develops written medical care criteria to assess the need for admission; and

(b) The committee develops more extensive written criteria for cases that its experience shows are—

(1) Associated with high costs;

(2) Associated with the frequent furnishing of excessive services; or

¹ The Department was enjoined in 1975 in the case of American Medical Assn. et al. v. Weinberger, 395 F. Supp. 515 (N.D. Ill., 1975), aff’d., 522 F.2d 921 (7th cir., 1975) from implementing the admission review requirements contained in §§ 456.121-456.127. This case was dismissed on the condition that these requirements be revised. They are presently being revised, and will not be in force until that revision is completed.

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

§ 456.123 Admission review process.

The UR plan must provide that—

(a) Admission review is conducted by—

- (1) The UR committee;
- (2) A subgroup of the UR committee;

or

(3) A designee of the UR committee;

(b) The committee, subgroup, or designee evaluates the admission against the criteria developed under § 456.122 and applies close professional scrutiny to cases selected under § 456.129(b);

(c) If the committee, subgroup, or designee finds that the admission is needed, the committee assigns an initial continued stay review date in accordance with § 456.128;

(d) If the committee, subgroup, or designee finds that the admission does not meet the criteria, the committee or a subgroup that includes at least one physician reviews the case to decide the need for admission;

(e) If the committee or subgroup making the review under paragraph (d) of this section finds that the admission is not needed, it notifies the recipient's attending physician and gives him an opportunity to present his views before it makes a final decision on the need for the continued stay;

(f) If the attending physician does not present additional information or clarification of the need for the admission, the decision of the committee or subgroup is final; and

(g) If the attending physician presents additional information or clarification, at least two physician members of the committee review the need for the admission. If they find that the admission is not needed, their decision is final.

§ 456.124 Notification of adverse decision.

The UR plan must provide that written notice of any adverse final decision on the need for admission under § 456.123 (e) through (g) is sent to—

- (a) The hospital administrator;
- (b) The attending physician;
- (c) The Medicaid agency;
- (d) The recipient; and

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

§ 456.125 Time limits for admission review.

Except as required under § 456.127, the UR plan must provide that review of each recipient's admission to the hospital is conducted—

(a) Within one working day after admission, for an individual who is receiving Medicaid at that time; or

(b) Within one working day after the hospital is notified of the application for Medicaid, for an individual who applies while in the hospital.

§ 456.126 Time limits for final decision and notification of adverse decision.

Except as required under § 456.127, the UR plan must provide that the committee makes a final decision on a recipient's need for admission and gives notice of an adverse final decision—

(a) Within two working days after admission, for an individual who is receiving Medicaid at that time; or

(b) Within two working days after the hospital is notified of the application for Medicaid, for an individual who applies while in the hospital.

§ 456.127 Pre-admission review.

The UR plan must provide for review and final decision prior to admission for certain providers or categories of admissions that the UR committee designates under § 456.142(b) (4)(iii) to receive pre-admission review.

§ 456.128 Initial continued stay review date.

The UR plan must provide that—

(a) When a recipient is admitted to the hospital under the admission review requirements of this subpart, the committee assigns a specified date by which the need for his continued stay will be reviewed;

(b) The committee bases its assignment of the initial continued stay review date on—

- (1) The methods and criteria required to be described under § 456.129;
- (2) The individual's condition; and
- (3) The individual's projected discharge date;

(c)(1) The committee uses any available appropriate regional medical care appraisal norms, such as those developed by abstracting services or third party payors, to assign the initial continued stay review date;

(2) These regional norms are based on current and statistically valid data on duration of stay in hospitals for patients whose characteristics, such as age and diagnosis, are similar to those of the individual whose case is being reviewed;

(3) If the committee uses norms to assign the initial continued stay review date, the number of days between the individual's admission and the initial continued stay review date is no greater than the number of days reflected in the 50th percentile of the norms. However, the committee may assign a later review date if it documents that the later date is more appropriate; and

(d) The committee ensures that the initial continued stay review date is recorded in the individual's record.

§ 456.129 Description of methods and criteria: Initial continued stay review date; close professional scrutiny; length of stay modification.

The UR plan must describe—

(a) The methods and criteria, including norms if used, that the committee uses to assign the initial continued stay review date under § 456.128.

(b) The methods that the committee uses to select categories of admission to receive close professional scrutiny under § 456.123(b); and

(c) The methods that the committee uses to modify an approved length of stay when the recipient's condition or treatment schedule changes.

UR PLAN: REVIEW OF NEED FOR CONTINUED STAY

§ 456.131 Continued stay review required.

The UR plan must provide for a review of each recipient's continued stay in the hospital to decide whether it is needed, in accordance with the requirements of §§ 456.132 through 456.137.

§ 456.132 Evaluation criteria for continued stay.

The UR plan must provide that—

(a) The committee develops written medical care criteria to assess the need for continued stay.

(b) The committee develops more extensive written criteria for cases that its experience shows are—

(1) Associated with high costs;

(2) Associated with the frequent furnishing of excessive services; or

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

§ 456.133 Subsequent continued stay review dates.

The UR plan must provide that—

(a) The committee assigns subsequent continued stay review dates in accordance with §§ 456.128 and 456.134(a);

(b) The committee assigns a subsequent review date each time it decides under § 456.135 that the continued stay is needed; and

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

§ 456.134 Description of methods and criteria: Subsequent continued stay review dates; length of stay modification.

The UR plan must describe—

(a) The methods and criteria, including norms if used, that the committee uses to assign subsequent continued stay review dates under § 456.133; and

(b) The methods that the committee uses to modify an approved length of stay when the recipient's condition or treatment schedule changes.

§ 456.135 Continued stay review process.

The UR plan must provide that—

(a) Review of continued stay cases is conducted by—

(1) The UR committee;

(2) A subgroup of the UR committee;

or

(3) A designee of the UR committee;

(b) The committee, subgroup or designee reviews a recipient's continued stay on or before the expiration of each assigned continued stay review date;

(c) For each continued stay of a recipient in the hospital, the committee, subgroup or designee reviews and evaluates the documentation described under § 456.111 against the criteria developed under § 456.132 and applies close

professional scrutiny to cases selected under § 456.129(b);

(d) If the committee, subgroup, or designee finds that a recipient's continued stay in the hospital is needed, the committee assigns a new continued stay review date in accordance with § 456.133;

(e) If the committee, subgroup, or designee finds that a continued stay case does not meet the criteria, the committee or a subgroup that includes at least one physician reviews the case to decide the need for continued stay;

(f) If the committee or subgroup making the review under paragraph (e) of this section finds that a continued stay is not needed, it notifies the recipient's attending physician and gives him an opportunity to present his reviews before it makes a final decision on the need for the continued stay;

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

(h) If the attending physician presents additional information or clarification, at least two physician members of the committee review the need for the continued stay. If they find that the recipient no longer needs inpatient hospital services, their decision is final.

§ 456.136 Notification of adverse decision.

The UR plan must provide that written notice of any adverse final decision on the need for continued stay under § 456.135 (f) through (h) is sent to—

- (a) The hospital administrator;
- (b) The attending physician;
- (c) The Medicaid agency;
- (d) The recipient; and
- (e) If possible, the next of kin or sponsor.

§ 456.137 Time limits for final decision and notification of adverse decision.

The UR plan must provide that—

(a) The committee makes a final decision on a recipient's need for continued stay and gives notice under § 456.136 of an adverse final decision within 2 working days after the assigned continued stay review dates, except as re-

quired under paragraph (b) of this section.

(b) If the committee makes an adverse final decision on a recipient's need for continued stay before the assigned review date, the committee gives notice under § 456.136 within 2 working days after the date of the final decision.

UR PLAN: MEDICAL CARE EVALUATION STUDIES

§ 456.141 Purpose and general description.

(a) The purpose of medical care evaluation studies is to promote the most effective and efficient use of available health facilities and services consistent with patient needs and professionally recognized standards of health care.

(b) Medical care evaluation studies—

- (1) Emphasize identification and analysis of patterns of patient care; and
- (2) Suggest appropriate changes needed to maintain consistently high quality patient care and effective and efficient use of services.

§ 456.142 UR plan requirements for medical care evaluation studies.

(a) The UR plan must describe the methods that the committee uses to select and conduct medical care evaluation studies under paragraph (b)(1) of this section.

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

- (1) Determines the methods to be used in selecting and conducting medical care evaluation studies in the hospital;
- (2) Documents for each study—
 - (i) Its results; and
 - (ii) How the results have been used to make changes to improve the quality of care and promote more effective and efficient use of facilities and services;
- (3) Analyzes its findings for each study; and
- (4) Takes action as needed to—
 - (i) Correct or investigate further any deficiencies or problems in the review process for admissions or continued stay cases;
 - (ii) Recommend more effective and efficient hospital care procedures; or

(iii) Designate certain providers or categories of admissions for review prior to admission.

§ 456.143 Content of medical care evaluation studies.

Each medical care evaluation study must—

(a) Identify and analyze medical or administrative factors related to the hospital's patient care;

(b) Include analysis of at least the following:

(1) Admissions;

(2) Durations of stay;

(3) Ancillary services furnished, including drugs and biologicals;

(4) Professional services performed in the hospital; and

(c) If indicated, contain recommendations for changes beneficial to patients, staff, the hospital, and the community.

§ 456.144 Data sources for studies.

Data that the committee uses to perform studies must be obtained from one or more of the following sources:

(a) Medical records or other appropriate hospital data;

(b) External organizations that compile statistics, design profiles, and produce other comparative data;

(c) Cooperative endeavors with—

(1) PROs;

(2) Fiscal agents;

(3) Other service providers; or

(4) Other appropriate agencies.

[43 FR 45266, Sept. 29, 1978, as amended at 51 FR 43198, Dec. 1, 1986]

§ 456.145 Number of studies required to be performed.

The hospital must, at least, have one study in progress at any time and complete one study each calendar year.

**Subpart D—Utilization Control:
Mental Hospitals**

§ 456.150 Scope.

This subpart prescribes requirements for control of utilization of inpatient services in mental hospitals, including requirements concerning—

(a) Certification of need for care;

(b) Medical evaluation and admission review;

(c) Plan of care; and

(d) Utilization review plans.

§ 456.151 Definitions.

As used in this subpart:

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

Medical care criteria or *criteria* means predetermined elements against which aspects of the quality of a medical service may be compared. These criteria are developed by health professionals relying on their expertise and the professional health care literature.

CERTIFICATION OF NEED FOR CARE

§ 456.160 Certification and recertification of need for inpatient care.

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

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

(b) *Recertification.* (1) A physician, or physician assistant or nurse practitioner (as defined in § 491.2 of this chapter) acting within the scope of practice as defined by State law and under the supervision of a physician, must recertify for each applicant or recipient that inpatient services in a mental hospital are needed.

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

[46 FR 48561, Oct. 1, 1981]

**MEDICAL, PSYCHIATRIC, AND SOCIAL
EVALUATIONS AND ADMISSION REVIEW**

§ 456.170 Medical, psychiatric, and social evaluations.

(a) Before admission to a mental hospital or before authorization for payment, the attending physician or staff physician must make a medical evaluation of each applicant's or recipient's need for care in the hospital; and appropriate professional personnel must make a psychiatric and social evaluation.

(b) Each medical evaluation must include—

(1) Diagnoses;

(2) Summary of present medical findings;

(3) Medical history;

§ 456.171

- (4) Mental and physical functional capacity;
- (5) Prognoses; and
- (6) A recommendation by a physician concerning—
 - (i) Admission to the mental hospital; or
 - (ii) Continued care in the mental hospital for individuals who apply for Medicaid while in the mental hospital.

§ 456.171 Medicaid agency review of need for admission.

Medical and other professional personnel of the Medicaid agency or its designees must evaluate each applicant's or recipient's need for admission by reviewing and assessing the evaluations required by § 456.170.

PLAN OF CARE

§ 456.180 Individual written plan of care.

- (a) Before admission to a mental hospital or before authorization for payment, the attending physician or staff physician must establish a written plan of care for each applicant or recipient.
 - (b) The plan of care must include—
 - (1) Diagnoses, symptoms, complaints, and complications indicating the need for admission;
 - (2) A description of the functional level of the individual;
 - (3) Objectives;
 - (4) Any orders for—
 - (i) Medications;
 - (ii) Treatments;
 - (iii) Restorative and rehabilitative services;
 - (iv) Activities;
 - (v) Therapies;
 - (vi) Social services;
 - (vii) Diet; and
 - (viii) Special procedures recommended for the health and safety of the patient;
 - (5) Plans for continuing care, including review and modification to the plan of care; and
 - (6) Plans for discharge.
 - (c) The attending or staff physician and other personnel involved in the recipient's care must review each plan of care at least every 90 days.

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§ 456.181 Reports of evaluations and plans of care.

A written report of each evaluation and plan of care must be entered in the applicant's or recipient's record—

- (a) At the time of admission; or
- (b) If the individual is already in the facility, immediately upon completion of the evaluation or plan.

UTILIZATION REVIEW (UR) PLAN:
GENERAL REQUIREMENTS

§ 456.200 Scope.

Sections 456.201 through 456.245 of this subpart prescribe requirements for a written utilization review (UR) plan for each mental hospital providing Medicaid services. Sections 456.205 and 456.206 prescribe administrative requirements; §§ 456.211 through 456.213 prescribe informational requirements; §§ 456.231 through 456.238 prescribe requirements for continued stay review; and §§ 456.241 through 456.245 prescribe requirements for medical care evaluation studies.

§ 456.201 UR plan required for inpatient mental hospital services.

- (a) The State plan must provide that each mental hospital furnishing inpatient services under the plan has in effect a written UR plan that provides for review of each recipient's need for the services that the mental hospital furnishes him.
- (b) Each written mental hospital UR plan must meet the requirements under §§ 456.201 through 456.245.

UR PLAN: ADMINISTRATIVE
REQUIREMENTS

§ 456.205 UR committee required.

- The UR plan must—
- (a) Provide for a committee to perform UR required under this subpart;
 - (b) Describe the organization, composition, and functions of this committee; and
 - (c) Specify the frequency of meetings of the committee.

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

(a) For the purpose of this subpart, “UR committee” includes any group organized under paragraphs (b) and (c) of this section.

(b) The UR committee must be composed of two or more physicians, one of whom is knowledgeable in the diagnosis and treatment of mental diseases, and assisted by other professional personnel.

(c) The UR committee must be constituted as—

(1) A committee of the mental hospital staff;

(2) A group outside the mental hospital staff, established by the local medical or osteopathic society and at least some of the hospitals and SNFs in the locality; or

(3) A group capable of performing utilization review, established and organized in a manner approved by the Secretary.

(d) The UR committee may not include any individual who—

(1) Is directly responsible for the care of patients whose care is being reviewed; or

(2) Has a financial interest in any mental hospital.

UR PLAN: INFORMATIONAL
REQUIREMENTS

§ 456.211 Recipient information required for UR.

The UR plan must provide that each recipient’s record includes information needed to perform UR required under this subpart. This information must include, at least, the following:

(a) Identification of the recipient.

(b) The name of the recipient’s physician.

(c) Date of admission, and dates of application for and authorization of Medicaid benefits if application is made after admission.

(d) The plan of care required under § 456.172.

(e) Initial and subsequent continued stay review dates described under §§ 456.233 and 456.234.

(f) Reasons and plan for continued stay, if the attending physician believes continued stay is necessary.

(g) Other supporting material that the committee believes appropriate to be included in the record.

§ 456.212 Records and reports.

The UR plan must describe—

(a) The types of records that are kept by the committee; and

(b) The type and frequency of committee reports and arrangements for their distribution to appropriate individuals.

§ 456.213 Confidentiality.

The UR plan must provide that the identities of individual recipients in all UR records and reports are kept confidential.

UR PLAN: REVIEW OF NEED FOR
CONTINUED STAY

§ 456.231 Continued stay review required.

The UR plan must provide for a review of each recipient’s continued stay in the mental hospital to decide whether it is needed, in accordance with the requirements of §§ 456.232 through 456.238.

§ 456.232 Evaluation criteria for continued stay.

The UR plan must provide that—

(a) The committee develops written medical care criteria to assess the need for continued stay.

(b) The committee develops more extensive written criteria for cases that its experience shows are—

(1) Associated with high costs;

(2) Associated with the frequent furnishing of excessive services; or

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

§ 456.233 Initial continued stay review date.

The UR plan must provide that—

(a) When a recipient is admitted to the mental hospital under admission review requirements of this subpart, the committee assigns a specified date by which the need for his continued stay will be reviewed;

(b) If an individual applies for Medicaid while in the mental hospital, the committee assigns the initial continued stay review date within 1 working day after the mental hospital is notified of the application for Medicaid;

(c) The committee bases its assignment of the initial continued stay review date on—

(1) The methods and criteria required to be described under § 456.235(a);

(2) The individual's condition; and

(3) The individual's projected discharge date;

(d)(1) The committee uses any available appropriate regional medical care appraisal norms, such as those developed by abstracting services or third party payors, to assign the initial continued stay review date;

(2) These norms are based on current and statistically valid data on duration of stay in mental hospitals for patients whose characteristics, such as age and diagnosis, are similar to those of the individual whose need for continued stay is being reviewed;

(3) If the committee uses norms to assign the initial continued stay review date, the number of days between the individual's admission and the initial continued stay review date is no greater than the number of days reflected in the 50th percentile of the norms. However, the committee may assign a later review date if it documents that the later date is more appropriate;

(e) The initial continued stay review date is not in any case later than 30 days after admission of the individual or notice to the mental hospital of his application for Medicaid; and

(f) The committee insures that the initial continued stay review date is recorded in the individual's record.

§ 456.234 Subsequent continued stay review dates.

The UR plan must provide that—

(a) The committee assigns subsequent continued stay review dates in accordance with §§ 456.235(a) and 456.233;

(b) The committee assigns a subsequent continued stay review date at least every 90 days each time it decides under § 456.236 that the continued stay is needed; and

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

§ 456.235 Description of methods and criteria: Continued stay review dates; length of stay modification.

The UR plan must describe—

(a) The methods and criteria, including norms if used, that the committee uses to assign initial and subsequent continued stay review dates under §§ 456.233 and 456.234 of this subpart; and

(b) The methods that the committee uses to modify an approved length of stay when the recipient's condition or treatment schedule changes.

§ 456.236 Continued stay review process.

The UR plan must provide that—

(a) Review of continued stay cases is conducted by—

(1) The UR committee;

(2) A subgroup of the UR committee; or

(3) A designee of the UR committee;

(b) The committee, subgroup or designee reviews a recipient's continued stay on or before the expiration of each assigned continued stay review date;

(c) For each continued stay of a recipient in the mental hospital, the committee, subgroup or designee reviews and evaluates the documentation described under § 456.211 against the criteria developed under § 456.232 and applies close professional scrutiny to cases described under § 456.232(b).

(d) If the committee, subgroup or designee finds that a recipient's continued stay in the mental hospital is needed, the committee assigns a new continued stay review date in accordance with § 456.234;

(e) If the committee, subgroup or designee finds that a continued stay case does not meet the criteria, the committee or a subgroup that includes at least one physician reviews the case to decide the need for continued stay;

(f) If the committee or subgroup making the review under paragraph (e) of this section finds that a continued stay is not needed, it notifies the recipient's attending or staff physician and gives him an opportunity to present his views before it makes a

final decision on the need for the continued stay;

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

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

§ 456.237 Notification of adverse decision.

The UR plan must provide that written notice of any adverse final decision on the need for continued stay under § 456.236 (f) through (h) is sent to—

- (a) The hospital administrator;
- (b) The attending or staff physician;
- (c) The Medicaid agency;
- (d) The recipient; and
- (e) If possible, the next of kin or sponsor.

§ 456.238 Time limits for final decision and notification of adverse decision.

The UR plan must provide that—

(a) The committee makes a final decision on a recipient's need for continued stay and gives notice under § 456.237 of an adverse decision within 2 working days after the assigned continued stay review date, except as required under paragraph (b) of this section.

(b) If the committee makes an adverse final decision on a recipient's need for continued stay before the assigned review date, the committee gives notice under § 456.237 within 2 working days after the date of the final decision.

UR PLAN: MEDICAL CARE EVALUATION STUDIES

§ 456.241 Purpose and general description.

(a) The purpose of medical care evaluation studies is to promote the most effective and efficient use of available health facilities and services consistent with patient needs and profes-

sionally recognized standards of health care.

(b) Medical care evaluation studies—

(1) Emphasize identification and analysis of patterns of patient care; and

(2) Suggest appropriate changes needed to maintain consistently high quality patient care and effective and efficient use of services.

§ 456.242 UR plan requirements for medical care evaluation studies.

(a) The UR plan must describe the methods that the committee uses to select and conduct medical care evaluation studies under paragraph (b)(1) of this section.

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

(1) Determines the methods to be used in selecting and conducting medical care evaluation studies in the mental hospital;

(2) Documents for each study—

(i) Its results; and

(ii) How the results have been used to make changes to improve the quality of care and promote more effective and efficient use of facilities and services;

(3) Analyzes its findings for each study; and

(4) Takes action as needed to—

(i) Correct or investigate further any deficiencies or problems in the review process; or

(ii) Recommend more effective and efficient hospital care procedures.

§ 456.243 Content of medical care evaluation studies.

Each medical care evaluation study must—

(a) Identify and analyze medical or administrative factors related to the mental hospital's patient care;

(b) Include analysis of at least the following:

(1) Admissions.

(2) Durations of stay.

(3) Ancillary services furnished, including drugs and biologicals.

(4) Professional services performed in the hospital; and

(c) If indicated, contain recommendations for change beneficial to patients, staff, the hospital, and the community.

§ 456.244 Data sources for studies.

Data that the committee uses to perform studies must be obtained from one or more of the following sources:

- (a) Medical records or other appropriate hospital data.
- (b) External organizations that compile statistics, design profiles, and produce other comparative data.
- (c) Cooperative endeavors with—
 - (1) PROs;
 - (2) Fiscal agents;
 - (3) Other service providers; or
 - (4) Other appropriate agencies.

[43 FR 45266, Sept. 29, 1978, as amended at 51 FR 43198, Dec. 1, 1986]

§ 456.245 Number of studies required to be performed.

The mental hospital must, at least, have one study in progress at any time and complete one study each calendar year.

Subpart E—[Reserved]

Subpart F—Utilization Control: Intermediate Care Facilities

§ 456.350 Scope.

This subpart prescribes requirements for control of utilization of intermediate care facility (ICF) services including requirements concerning—

- (a) Certification of need for care;
- (b) Medical evaluation and admission review;
- (c) Plan of care; and
- (d) Utilization review plans.

§ 456.351 Definition.

As used in this subpart:

Intermediate care facility services means those items and services furnished in an intermediate care facility as defined in §§ 440.140 and 440.150 of this subchapter, but excludes those services if they are provided in Christian Science sanatoria.

CERTIFICATION OF NEED FOR CARE

§ 456.360 Certification and recertification of need for inpatient care.

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

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

(b) *Recertification.* (1) A physician, or physician assistant or nurse practitioner (as defined in § 491.2 of this chapter) acting within the scope of practice as defined by State law and under the supervision of a physician, must recertify for each applicant or recipient that ICF services are needed.

(2) Recertification must be made at least—

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

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

[46 FR 48561, Oct. 1, 1981, as amended at 50 FR 33034, Aug. 16, 1985]

MEDICAL, PSYCHOLOGICAL, AND SOCIAL EVALUATIONS AND ADMISSION REVIEW

§ 456.370 Medical, psychological, and social evaluations.

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

(b) In an institution for the mentally retarded or persons with related conditions, the team must also make a psychological evaluation of need for care. The psychological evaluation must be made before admission or authorization of payment, but not more than three months before admission.

(c) Each evaluation must include—

- (1) Diagnoses;
- (2) Summary of present medical, social, and where appropriate, developmental findings;
- (3) Medical and social family history;
- (4) Mental and physical functional capacity;
- (5) Prognoses;
- (6) Kinds of services needed;

(7) Evaluation by an agency worker of the resources available in the home, family and community; and

(8) A recommendation concerning—

(i) Admission to the ICF; or

(ii) Continued care in the ICF for individuals who apply for Medicaid while in the ICF.

§ 456.371 Exploration of alternative services.

If the comprehensive evaluation recommends ICF services for an applicant or recipient whose needs could be met by alternative services that are currently unavailable, the facility must enter this fact in the recipient's record and begin to look for alternative services.

§ 456.372 Medicaid agency review of need for admission.

Medical and other professional personnel of the Medicaid agency or its designees must evaluate each applicant's or recipient's need for admission by reviewing and assessing the evaluations required by § 456.370.

PLAN OF CARE

§ 456.380 Individual written plan of care.

(a) Before admission to an ICF or before authorization for payment, a physician must establish a written plan of care for each applicant or recipient.

(b) The plan of care must include—

(1) Diagnoses, symptoms, complaints, and complications indicating the need for admission;

(2) A description of the functional level of the individual;

(3) Objectives;

(4) Any orders for—

(i) Medications;

(ii) Treatments;

(iii) Restorative and rehabilitative services;

(iv) Activities;

(v) Therapies;

(vi) Social services;

(vii) Diet; and

(viii) Special procedures designed to meet the objectives of the plan of care;

(5) Plans for continuing care, including review and modification of the plan of care; and

(6) Plans for discharge.

(c) The team must review each plan of care at least every 90 days.

§ 456.381 Reports of evaluations and plans of care.

A written report of each evaluation and plan of care must be entered in the applicant's or recipient's record—

(a) At the time of admission; or

(b) If the individual is already in the ICF, immediately upon completion of the evaluation or plan.

UTILIZATION REVIEW (UR) PLAN:

GENERAL REQUIREMENT

§ 456.400 Scope.

Sections 456.401 through 456.438 of this subpart prescribe requirements for a written utilization review (UR) plan for each ICF providing Medicaid services. Sections 456.405 through 456.407 prescribe administrative requirements; §§ 456.411 through 456.413 prescribe informational requirements; and §§ 456.431 through 456.438 prescribe requirements for continued stay review.

§ 456.401 State plan UR requirements and options; UR plan required for intermediate care facility services.

(a) The State plan must provide that—

(1) UR is performed for each ICF that furnishes inpatient services under the plan;

(2) Each ICF has on file a written UR plan that provides for review of each recipient's need for the services that the ICF furnishes him; and

(3) Each written ICF UR plan meets requirements under §§ 456.401 through 456.438.

(b) The State plan must specify the method used to perform UR, which may be—

(1) Review conducted by the facility;

(2) Direct review in the facility by individuals—

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

(ii) Under contract to the Medicaid agency; or

(3) Any other method.

UR PLAN: ADMINISTRATIVE
REQUIREMENTS

§ 456.405 Description of UR review function: How and when.

The UR plan must include a written description of—

- (a) How UR is performed in the ICF; and
- (b) When UR is performed.

§ 456.406 Description of UR review function: Who performs UR; disqualification from performing UR.

(a) The UR plan must include a written description of who performs UR in the ICF.

(b) UR must be performed using a method specified under § 456.401(b) by a group of professional personnel that includes—

- (1) At least one physician;
- (2) In an ICF that cares primarily for mental patients, at least one individual knowledgeable in the treatment of mental diseases; and
- (3) In an institution for the mentally retarded, a least one individual knowledgeable in the treatment of mental retardation.

(c) The group performing UR may not include any individual who—

- (1) Is directly responsible for the care of the recipient whose care is being reviewed;
- (2) Is employed by the ICF; or
- (3) Has a financial interest in any ICF.

§ 456.407 UR responsibilities of administrative staff.

The UR plan must describe—

- (a) The UR support responsibilities of the ICF's administrative staff; and
- (b) Procedures used by the staff for taking needed corrective action.

UR PLAN: INFORMATIONAL
REQUIREMENTS

§ 456.411 Recipient information required for UR.

The UR plan must provide that each recipient's record include information needed to perform UR required under this subpart. This information must include, at least, the following:

- (a) Identification of the recipient.
- (b) The name of the recipient's physician.

(c) The name of the qualified mental retardation professional (as defined under § 442.401 of this subchapter), if applicable.

(d) Date of admission, and dates of application for and authorization of Medicaid benefits if application is made after admission.

(e) The plan of care required under § 456.372;

(f) Initial and subsequent continued stay review dates described under §§ 456.433 and 456.434.

(g) Reasons and plan for continued stay, if the attending physician or qualified mental retardation professional believes continued stay is necessary.

(h) Other supporting material that the UR group believes appropriate to be included in the record.

§ 456.412 Records and reports.

The UR plan must describe—

- (a) The types of records that are kept by the group performing UR; and
- (b) The type and frequency of reports made by the UR group, and arrangements for distribution of the reports to appropriate individuals.

§ 456.413 Confidentiality.

The UR plan must provide that the identities of individual recipients in all UR records and reports are kept confidential.

UR PLAN: REVIEW OF NEED FOR
CONTINUED STAY

§ 456.431 Continued stay review required.

(a) The UR plan must provide for a review of each recipients continued stay in the ICF at least every 6 months to decide whether it is needed.

(b) The UR plan requirement for continued stay review may be met by—

(1) Reviews that are performed in accordance with the requirements of §§ 456.432 through 456.437; or

(2) Reviews that meet on-site inspection requirements under subpart I if—

- (i) The composition of the independent professional review team under subpart I meets the requirements of § 456.406; and

(ii) Reviews are conducted as frequently as required under §§ 456.433 and 456.434.

§ 456.432 Evaluation criteria for continued stay.

The UR plan must provide that—

(a) The group performing UR develops written criteria to assess the need for continued stay.

(b) The group develops more extensive written criteria for cases that its experience shows are—

- (1) Associated with high costs;
- (2) Associated with the frequent furnishing of excessive services; or
- (3) Attended by physicians whose patterns of care are frequently found to be questionable.

§ 456.433 Initial continued stay review date.

The UR plan must provide that—

(a) When a recipient is admitted to the ICF under admission review requirements of this subpart, the group performing UR assigns a specified date by which the need for his continued stay will be reviewed;

(b) The group performing UR bases its assignment of the initial continued stay review date on the methods and criteria required to be described under § 456.435(a);

(c) The initial continued stay review date is—

- (1) Not later than 6 months after admission; or
- (2) Earlier than 6 months after admission, if indicated at the time of admission; and

(d) The group performing UR insures that the initial continued stay review date is recorded in the recipient's record.

§ 456.434 Subsequent continued stay review dates.

The UR plan must provide that—

(a) The group performing UR assigns subsequent continued stay review dates in accordance with § 456.435.

(b) The group assigns a subsequent continued stay review date each time it decides under § 456.436 that the continued stay is needed—

- (1) At least every 6 months; or

(2) More frequently than every six months if indicated at the time of continued stay review; and

(c) The group insures that each continued stay review date it assigns is recorded in the recipient's record.

§ 456.435 Description of methods and criteria: Continued stay review dates.

The UR plan must describe the methods and criteria that the group performing UR uses to assign initial and subsequent continued stay review dates under §§ 456.433 and 456.434.

§ 456.436 Continued stay review process.

The UR plan must provide that—

(a) Review of continued stay cases is conducted by—

- (1) The group performing UR; or
- (2) A designee of the UR group;

(b) The group or its designee reviews a recipient's continued stay on or before the expiration of each assigned continued stay review date.

(c) For each continued stay of a recipient in the ICF, the group or its designee reviews and evaluates the documentation described under § 456.411 against the criteria developed under § 456.432 and applies close professional scrutiny to cases described under § 456.432(b);

(d) If the group or its designee finds that a recipient's continued stay in the ICF is needed, the group assigns a new continued stay review date in accordance with § 456.434;

(e) If the group or its designee finds that a continued stay case does not meet the criteria, the group or a subgroup that includes at least one physician reviews the case to decide the need for continued stay;

(f) If the group or subgroup making the review under paragraph (e) of this section finds that a continued stay is not needed, it notifies the recipient's attending physician or, in institutions for the mentally retarded, the recipient's qualified mental retardation professional, within 1 working day of its decision, and gives him 2 working days from the notification date to present his views before it makes a final decision on the need for the continued stay;

(g) If the attending physician or qualified mental retardation professional does not present additional information or clarification of the need for the continued stay, the decision of the UR group is final;

(h) If the attending physician or qualified mental retardation professional presents additional information or clarification, the need for continued stay is reviewed by—

(1) The physician member(s) of the UR group, in cases involving a medical determination; or

(2) The UR group, in cases not involving a medical determination; and

(i) If the individuals performing the review under paragraph (h) of this section find that the recipient no longer needs ICF services, their decision is final.

§ 456.437 Notification of adverse decision.

The UR plan must provide that written notice of any adverse final decision on the need for continued stay under § 456.436 (g) through (i) is sent to—

- (a) The ICF administrator;
- (b) The attending physician;
- (c) The qualified mental retardation professional, if applicable;
- (d) The Medicaid agency;
- (e) The recipient; and
- (f) If possible, the next of kin or sponsor.

§ 456.438 Time limits for notification of adverse decision.

The UR plan must provide that the group gives notice under § 456.437 of an adverse decision not later than 2 days after the date of the final decision.

Subpart G—Inpatient Psychiatric Services for Individuals Under Age 21: Admission and Plan of Care Requirements

§ 456.480 Scope.

This subpart concerns admission and plan of care requirements that apply to inpatient psychiatric services for individuals under age 21 in hospitals, mental hospitals, and intermediate care facilities.

[43 FR 45266, Sept. 29, 1978, as amended at 61 FR 38399, July 24, 1996]

§ 456.481 Admission certification and plan of care.

If a facility provides inpatient psychiatric services to a recipient under age 21—

(a) The admission certification by the review team required in § 441.152 satisfies the requirement for physician certification of need for care in §§ 456.60, 456.160, and 456.360; and

(b) The development and review of the plan of care required in § 441.154 satisfies the requirement for physician recertification of need for care in the sections cited in paragraph (a) and the requirement for establishment and periodic review of the plan of care in §§ 456.80, 456.180, and 456.380.

(c) The plan of care must be established by the team described in § 441.156.

[43 FR 45266, Sept. 29, 1978, as amended at 61 FR 38399, July 24, 1996]

§ 456.482 Medical, psychiatric, and social evaluations.

If a facility provides inpatient psychiatric services to a recipient under age 21, the medical, psychiatric, and social evaluations required by §§ 456.170, and 456.370 must be made by the team described in § 441.153.

[43 FR 45266, Sept. 29, 1978, as amended at 61 FR 38399, July 24, 1996]

Subpart H—Utilization Review Plans: FFP, Waivers, and Variances for Hospitals and Mental Hospitals

§ 456.500 Purpose.

For hospitals and mental hospitals, this subpart—

- (a) Prescribes conditions for the availability of FFP relating to UR plans;
- (b) Prescribes conditions for granting a waiver of UR plan requirements; and
- (c) Prescribes conditions for granting a variance in UR plan requirements for remote facilities.

[43 FR 45266, Sept. 29, 1978, as amended at 61 FR 38399, July 24, 1996]

§ 456.501 UR plans as a condition for FFP.

(a) Except when waived under §§ 456.505 through 456.508, FFP is not available in expenditures for Medicaid services furnished by a hospital or mental hospital unless the facility has in effect a UR plan that meets the utilization review requirements for Medicare under section 1861(k) of the Act.

(b) A facility that participates in Medicare and Medicaid must use the same UR standards and procedures and review committee for Medicaid as it uses for Medicare.

(c) A facility that does not participate in Medicare must meet the UR plan requirements in subpart C or D of this part, which are equivalent to the Medicare UR plan requirements in §§ 405.1137, 482.30, and 482.60 of this chapter.

[43 FR 45266, Sept. 29, 1978, as amended at 51 FR 22042, June 17, 1986; 61 FR 38399, July 24, 1996]

UR PLAN: WAIVER OF REQUIREMENTS

§ 456.505 Applicability of waiver.

The Administrator may waive the UR plan requirements of subparts C or D of this part, except for provisions relating to disqualification of UR committee members under § 456.106 of subpart C, and § 456.206 of subpart D, if the Medicaid agency—

(a) Applies for a waiver; and

(b) Demonstrates to the Administrator's satisfaction that it has in operation specific UR procedures that are superior in their effectiveness to the UR plan requirements under subpart C or D of this part.

[43 FR 45266, Sept. 29, 1978, as amended at 61 FR 38399, July 24, 1996]

§ 456.506 Waiver options for Medicaid agency.

(a) The agency may apply for a waiver at any time it has the procedures referred to under § 456.505(b) in operation at least—

- (1) On a demonstration basis; or
- (2) In any part of the State.

(b) Any hospital or mental hospital participating under the plan that is not covered by a waiver must continue to

meet all the UR plan requirements under subpart C or D of this part.

[43 FR 45266, Sept. 29, 1978, as amended at 61 FR 38399, July 24, 1996]

§ 456.507 Review and granting of waiver requests.

(a) When the agency applies for a waiver, the Administrator will assess the agency's UR procedures and grant the waiver if he determines that the procedures meet criteria he establishes.

(b) The Administrator will review and evaluate each waiver between 1 and 2 years after he has granted it and between 1 and 2 years periodically thereafter.

§ 456.508 Withdrawal of waiver.

(a) The Administrator will withdraw a waiver if he determines that State procedures are no longer superior in their effectiveness to the procedures required for UR plans under subpart C or D of this part.

(b) If a waiver is withdrawn by the Administrator, each hospital or mental hospital covered by the waiver must meet all the UR plan requirements under subpart C or D of this part.

[43 FR 45266, Sept. 29, 1978, as amended at 61 FR 38399, July 24, 1996]

UR PLAN: REMOTE FACILITY VARIANCES FROM TIME REQUIREMENTS

§ 456.520 Definitions.

As used in §§ 456.521 through 456.525 of this subpart:

Available physician or other professional personnel means an individual who—

(a) Is professionally qualified;

(b) Is not precluded from participating in UR under § 456.107 of subpart C; or § 456.207 of subpart D; and

(c) Is not precluded from effective participation in UR because he requires more than approximately 1 hour to travel between the remote facility and his place of work.

Remote facility means a facility located in an area that does not have enough available physicians or other professional personnel to perform UR as required under subparts C or D of this part, and for which the State requests a variance.

Variance means permission granted by the Administrator to the Medicaid agency for a specific remote facility to use time periods different from those specified for the start and completion of reviews of all cases under the following sections: §§ 456.125, 456.126, 456.136, and 456.137 of subpart C; and § 456.238 of subpart D.

[43 FR 45266, Sept. 29, 1978, as amended at 61 FR 38399, July 24, 1996]

§ 456.521 Conditions for granting variance requests.

(a) Except as described under paragraph (b) of this section, the administrator may grant a variance for a specific remote facility if the agency submits concurrently—

(1) A request for the variance that documents to his satisfaction that the facility is unable to meet the time requirements for which the variance is requested; and

(2) A revised UR plan for the facility.

(b) The Administrator will not grant a variance if the remote facility is operating under a UR plan waiver that the Secretary has granted or is considering under §§ 456.505 through 456.508.

§ 456.522 Content of request for variance.

The agency's request for a variance must include—

(a) The name, location, and type of the remote facility;

(b) The number of total patient admissions and the average daily patient census at the facility in the 6 months preceding the request;

(c) The number of Medicare and Medicaid patient admissions and the average daily Medicare and Medicaid patient census at the facility in the 6 months preceding the request;

(d) The name and location of each hospital, mental hospital, and ICF located within a 50-mile radius of the facility;

(e) The distance and average travel time between the remote facility and each facility listed in paragraph (e) of this section;

(f) Documentation by the facility of its attempts to obtain the services of available physicians or other professional personnel, or both;

(g) The names of all physicians on the active staff, and the names of all other professional personnel on the staff whose availability is relevant to the request;

(h) The practice locations of available physicians and the estimated number of available professional personnel whose availability is relevant to the request;

(i) Documentation by the facility of its inability to perform UR within the time requirements for which the variance is requested and its good faith efforts to comply with the UR plan requirements of subpart C or D of this part;

(j) An assurance by the facility that it will continue its good faith efforts to meet the UR plan requirements of subpart C or D of this part; and

(k) A statement of whether a planning or conditional PSRO exists in the area where the facility is located.

[43 FR 45266, Sept. 29, 1978, as amended at 61 FR 38399, July 24, 1996]

§ 456.523 Revised UR plan.

(a) The revised UR plan for the remote facility must specify the methods and procedures that the facility will use if a variance is granted to insure that it—

(1) Maintains effective and timely control over the utilization of services; and

(2) Conducts reviews in a way that improves the quality of care provided to patients.

(b) The revised UR plan for the remote facility is the basis for validation of UR under sec. 1903(g)(2) of the Act for the period when a variance is in effect.

§ 456.524 Notification of Administrator's action and duration of variance.

(a) The Administrator—

(1) Will notify the agency of the action he takes on its request for a variance; and

(2) Will specify the period of time, not to exceed 1 year, for which the variance may be granted.

(b) When it receives the Administrator's notification, the agency must promptly notify the remote facility of his action.

§ 456.525 Request for renewal of variance.

(a) The agency must submit a request for renewal of a variance to the Administrator at least 30 days before the variance expires.

(b) The renewal request must contain the information required under § 456.522.

(c) The renewal request must show, to the Administrator's satisfaction, that the remote facility continues to meet the requirements of §§ 456.521 through 456.523.

Subpart I—Inspections of Care in Intermediate Care Facilities and Institutions for Mental Diseases**§ 456.600 Purpose.**

This subpart prescribes requirements for periodic inspections of care and services intermediate care facilities (ICF's), and institutions for mental diseases (IMD's).

[43 FR 45266, Sept. 29, 1978, as amended at 61 FR 38399, July 24, 1996]

§ 456.601 Definitions.

For purposes of this subpart—

Facility means an institution for mental diseases, or an intermediate care facility.

Intermediate care facility includes institutions for the mentally retarded or persons with related conditions but excludes Christian Science sanatoria operated, or listed and certified, by the First Church of Christ Scientist, Boston, Mass.

Institution for mental diseases includes a mental hospital, a psychiatric facility, and an intermediate care facility that primarily cares for mental patients.

Psychiatric facility includes a facility or program that provides inpatient psychiatric services for individuals under 21, as specified in § 441.151 of this chapter, but does not include psychiatric wards in acute care hospitals.

[44 FR 56337, Oct. 1, 1979, as amended at 61 FR 38399, July 24, 1996]

§ 456.602 Inspection team.

(a) A team, as described in this section and § 456.603 must periodically inspect the care and services provided to recipients in each facility.

(b) Each team conducting periodic inspections must have a least one member who is at physician or registered nurse and other appropriate health and social service personnel.

(c) For an IMD other than an ICF, each team must have a psychiatrist or physician knowledgeable about mental institutions and other appropriate mental health and social service personnel.

(d) For an ICF that primarily cares for mental patients, each team must have at least one member who knows the problems and needs of mentally retarded individuals.

(e) For an institution for the mentally retarded or persons with related conditions, each team must have at least one member who knows the problems and needs of mentally retarded individuals.

(f) For ICFs primarily serving individuals 65 years of age or older, each team must have at least one member who knows the problems and needs of those individuals.

(g) If there is no physician on the team, the Medicaid agency must insure that a physician is available to provide consultation to the team.

(h) If a team has one or more physicians, it must be supervised by a physician.

§ 456.603 Financial interests and employment of team members.

(a) Except as provided in paragraph (b) of this section—

(1) [Reserved]

(2) No member of a team that reviews care in an ICF may have a financial interest in or be employed by any ICF.

(b) A member of a team that reviews care in an IMD or an institution for the mentally retarded or persons with related conditions—

(1) May not have a financial interest in any institution of that same type but may have a financial interest in other facilities or institutions; and

(2) May not review care in an institution where he is employed but may review care in any other facility or institution.

[43 FR 45266, Sept. 29, 1978, as amended at 61 FR 38399, July 24, 1996]

§ 456.604 Physician team member inspecting care of recipients.

No physician member of a team may inspect the care of a recipient for whom he is the attending physician.

§ 456.605 Number and location of teams.

There must be a sufficient number of teams so located within the State that onsite inspections can be made at appropriate intervals in each facility caring for recipients.

§ 456.606 Frequency of inspections.

The team and the agency must determine, based on the quality of care and services being provided in a facility and the condition of recipients in the facility, at what intervals inspections will be made. However, the team must inspect the care and services provided to each recipient in the facility at least annually.

§ 456.607 Notification before inspection.

No facility may be notified of the time of inspection more than 48 hours before the scheduled arrival of the team.

§ 456.608 Personal contact with and observation of recipients and review of records.

(a) For recipients under age 21 in psychiatric facilities and recipients in ICFs, other than those described in paragraph (b) of this section, the team's inspection must include—

(1) Personal contact with and observation of each recipient; and

(2) Review of each recipient's medical record.

(b) For recipients age 65 or older in IMDs, the team's inspection must include—

(1) Review of each recipient's medical record; and

(2) If the record does not contain complete reports of periodic assessments required by § 441.102 of this sub-

chapter or, if such reports are inadequate, personal contact with and observation of each recipient

[43 FR 45266, Sept. 29, 1978, as amended at 44 FR 17940, Mar. 23, 1979; 61 FR 38399, July 24, 1996]

§ 456.609 Determinations by team.

The team must determine in its inspection whether—

(a) The services available in the facility are adequate to—

(1) Meet the health needs of each recipient, and the rehabilitative and social needs of each recipient in an ICF; and

(2) Promote his maximum physical, mental, and psychosocial functioning.

(b) It is necessary and desirable for the recipient to remain in the facility;

(c) It is feasible to meet the recipient's health needs and, in an ICF, the recipient's rehabilitative needs, through alternative institutional or noninstitutional services; and

(d) Each recipient under age 21 in a psychiatric facility and each recipient in an institution for the mentally retarded or persons with related conditions is receiving active treatment as defined in § 441.154 of this subchapter.

§ 456.610 Basis for determinations.

In making the determinations on adequacy of services and related matters under § 456.609 for each recipient, the team may consider such items as whether—

(a) The medical evaluation, any required social and psychological evaluations, and the plan of care are complete and current; the plan of care and, where required, the plan of rehabilitation are followed; and all ordered services, including dietary orders, are provided and properly recorded;

(b) The attending physician reviews prescribed medications—

(1) At least every 30 days in psychiatric facilities, and mental hospitals; and

(2) At least quarterly in ICFs;

(c) Tests or observations of each recipient indicated by his medication regimen are made at appropriate times and properly recorded;

(d) Physician, nurse, and other professional progress notes are made as required and appear to be consistent with the observed condition of the recipient;

(e) The recipient receives adequate services, based on such observations as—

- (1) Cleanliness;
- (2) Absence of bedsores;
- (3) Absence of signs of malnutrition or dehydration; and
- (4) Apparent maintenance of maximum physical, mental, and psychosocial function;

(f) In an ICF, the recipient receives adequate rehabilitative services, as evidenced by—

(1) A planned program of activities to prevent regression; and

(2) Progress toward meeting objectives of the plan of care;

(g) The recipient needs any service that is not furnished by the facility or through arrangements with others; and

(h) The recipient needs continued placement in the facility or there is an appropriate plan to transfer the recipient to an alternate method of care.

[43 FR 45266, Sept. 29, 1978, as amended at 61 FR 38399, July 24, 1996]

§ 456.611 Reports on inspections.

(a) The team must submit a report promptly to the agency on each inspection.

(b) The report must contain the observations, conclusions, and recommendations of the team concerning—

(1) The adequacy, appropriateness, and quality of all services provided in the facility or through other arrangements, including physician services to recipients; and

(2) Specific findings about individual recipients in the facility.

(c) The report must include the dates of the inspection and the names and qualifications of the members of the team.

[43 FR 45266, Sept. 29, 1978, as amended at 44 FR 56337, Oct. 1, 1979]

§ 456.612 Copies of reports.

The agency must send a copy of each inspection report to—

- (a) The facility inspected;

(b) The facility's utilization review committee;

(c) The agency responsible for licensing, certification, or approval of the facility for purposes of Medicare and Medicaid; and

(d) Other State agencies that use the information in the reports to perform their official function, including, if inspection reports concern IMD's, the appropriate State mental health authorities.

§ 456.613 Action on reports.

The agency must take corrective action as needed based on the report and recommendations of the team submitted under this subpart.

§ 456.614 Inspections by utilization review committee.

A utilization review committee under subparts C through F of this part may conduct the periodic inspections required by this subpart if—

(a) The committee is not based in the facility being reviewed; and

(b) The composition of the committee meets the requirements of this subpart.

Subpart J—Penalty for Failure To Make a Satisfactory Showing of an Effective Institutional Utilization Control Program

AUTHORITY: Secs. 1102 and 1903(g) of the Social Security Act (42 U.S.C. 1302 and 1396 b(g)).

SOURCE: 44 FR 56338, Oct. 1, 1979, unless otherwise noted.

§ 456.650 Basis, purpose and scope.

(a) *Basis.* Section 1903(g) of the Act requires that FFP for long-stay inpatient services at a level of care be reduced, by a specified formula, for any quarter in which a State fails to make a satisfactory showing that it has an effective program of utilization control for that level of care.

(b) *Purpose.* This subpart specifies—

(1) What States must do to make a satisfactory showing;

(2) How the Administrator will determine whether reductions will be imposed; and

(3) How the required reductions will be implemented.

(c) *Scope.* The reductions required by this subpart do not apply to—

(1) Services provided under a contract with a health maintenance organization; or

(2) Facilities in which a PRO is performing medical and utilization reviews under contract with the Medicaid agency in accordance with § 431.630 of this chapter.

[44 FR 56338, Oct. 1, 1979, as amended at 50 FR 15327, Apr. 17, 1985; 51 FR 43198, Dec. 1, 1986]

§ 456.651 Definitions.

For purposes of this subpart—

Facility, with respect to inpatient psychiatric services for individuals under 21, includes a psychiatric program as specified in § 441.151 of this chapter.

Level of care means one of the following types of inpatient services: hospital, mental hospital, intermediate care facility, or psychiatric services for individuals under 21.

Long-stay services means services provided to a recipient after a total of 60 days of inpatient stay (90 in the case of mental hospital services) during a 12-month period beginning July 1, not counting days of stay paid for wholly or in part by Medicare.

[43 FR 45266, Sept. 29, 1978, as amended at 61 FR 38399, July 24, 1996]

§ 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, 456.360 and 456.481.

(2) A plan of care established and periodically reviewed and evaluated by a physician, as specified in §§ 456.80, 456.180, and 456.481.

(3) A continuous program of utilization review under which the admission of each recipient is reviewed or screened in accordance with section 1903(g)(1)(C) of the Act; and

(4) A regular program of reviews, including medical evaluations, and annual on-site reviews of the care of each recipient, as specified in §§ 456.170, and 456.482 and subpart I of this part.

(b) *Annual on-site review requirements.*

(1) An agency meets the quarterly on-site review requirements of paragraph (a)(4) of this section for a quarter if it completes on-site reviews of each recipient in every facility in the State, and in every State-owned facility regardless of location, by the end of the quarter in which a review is required under paragraph (b)(2) of this section.

(2) An on-site review is required in a facility by the end of a quarter if the facility entered the Medicaid program during the same calendar quarter 1 year earlier or has not been reviewed since the same calendar quarter 1 year earlier. If there is no Medicaid recipient in the facility on the day a review is scheduled, the review is not required until the next quarter in which there is a Medicaid recipient in the facility.

(3) If a facility is not reviewed in the quarter in which it is required to be reviewed under paragraph (b)(2) of this section, it will continue to require a review in each subsequent quarter until the review is performed.

(4) The requirement for an on-site review in a given quarter is not affected by the addition or deletion of a level of care in a facility's provider agreement.

(c) *Facilities without valid provider agreements.* The requirements of paragraphs (a) and (b) of this section apply with respect to recipients for whose care the agency intends to claim FFP even if the recipients receive care in a facility whose provider agreement has expired or been terminated.

[44 FR 56338, Oct. 1, 1979, as amended at 46 FR 48561, Oct. 1, 1981; 61 FR 38399, July 24, 1996]

§ 456.653 Acceptable reasons for not meeting requirements for annual on-site review.

The Administrator will find an agency's showing satisfactory, even if it failed to meet the annual review requirements of § 456.652(a)(4), if—

(a) The agency demonstrates that—

(1) It completed reviews by the end of the quarter in at least 98 percent of all facilities requiring review by the end of the quarter;

(2) It completed reviews by the end of the quarter in all facilities with 200 or more certified Medicaid beds requiring review by the end of the quarter; and

(3) With respect to all unreviewed facilities, the agency exercised good faith and due diligence by attempting to review those facilities and would have succeeded but for events beyond its control which it could not have reasonably anticipated; or

(b) The agency demonstrates that it failed to meet the standard in paragraph (a) (1) and (2) of this section by the close of the quarter for technical reasons, but met the standard within 30 days after the close of the quarter. Technical reasons are circumstances within the agency's control.

(c) Facilities that are reviewed under paragraph (b) of this section, after the quarter in which they were due for review, retain their original anniversary quarter due date for purposes of subsequent reviews.

§ 456.654 Requirements for content of showings and procedures for submittal.

(a) An agency's showing for a quarter must—

(1) Include a certification by the agency that the requirements of § 456.652(a) (1) through (4) were met during the quarter for each level of care or, if applicable, a certification of the reasons the annual on-site review requirements of § 456.652(a)(4) were not met in any facilities;

(2) For all mental hospitals, intermediate care facilities, and facilities providing inpatient psychiatric services for individuals under 21, participating in Medicaid any time during the 12-month period ending on the last day of the quarter, list each facility by level of care, name, address and provider number;

(3) For each facility entering or leaving the program during the 12-month period ending on the last day of the quarter, list the beginning or ending dates of the provider agreement and supply a copy of the provider agreement;

(4) If review has been contracted to a PRO under § 431.630 of this chapter, list the date the PRO contracted for review.

(5) List all dates of on-site reviews completed by review teams anytime during the 12-month period ending on the last day of the quarter;

(6) For all facilities in which an on-site review was required but not conducted, list the facility by name, address and provider number;

(7) For each on-site review in a mental hospital, intermediate care facility that primarily cares for mental patients, or inpatient psychiatric facility, list the name and qualifications of one team member who is a physician; and

(8) For each on-site review in an intermediate care facility that does not primarily care for mental patients, list the name and qualifications of one team member who is either a physician or registered nurse.

(b) The quarterly showing must be in the form prescribed by the Administrator.

(c) The quarterly showing must be postmarked or received within 30 days after the close of the quarter for which it is made, unless the agency demonstrates good cause for later submittal and the showing is postmarked or received within 45 days after the close of the quarter. Good cause means unanticipated circumstances beyond the agency's control.

[44 FR 56338, Oct. 1, 1979, as amended at 50 FR 15327, Apr. 17, 1985; 51 FR 43198, Dec. 1, 1986; 61 FR 38399, July 24, 1996]

§ 456.655 Validation of showings.

(a) The Administrator will periodically validate showings submitted under § 456.654. Validation procedures will include on-site sample surveys of institutions and surveys at the Medicaid agencies.

(b) The Administrator will not find an agency's showing satisfactory if the information obtained through his validation procedures demonstrates, that any of the requirements of § 456.652(a) (1) through (4) were not met during the quarter for which the showing was made.

§ 456.656 Reductions in FFP.

(a) If the Administrator determines an agency's showing does not meet each of the requirements of this subpart, he will give the agency 30 days

notice before making the required reduction.

(b) If the Administrator determines that a showing for any quarter is unsatisfactory on its face, he will make the required reduction in the grant award based on the Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program for that quarter. (This form HCFA-64 is described in § 430.30(c) of this chapter.)

(c) If the Administrator finds a showing satisfactory on its face, but after validation determines the showing to be unsatisfactory, he will notify the agency of any required reduction in FFP no later than the first day of the fourth calendar quarter following the calendar quarter for which the showing was made. Any required reduction will be made by amending or adjusting the agency's grant award.

(d) The agency may request reconsideration of a reduction in accordance with the procedures specified in 45 CFR part 16.

§ 456.657 Computation of reductions in FFP.

(a) For each level of care specified in a provider agreement, and for each quarter for which a satisfactory showing is not made, the amount of the reduction in FFP is computed as follows:

(1) For each level of care, the number of recipients who received services in facilities that did not meet the requirements of this subpart is divided by the total number of recipients who received services in facilities for which a showing was required under this subpart. If any of the requirements specified in § 456.652(a)(1) through (4) were not met for any recipient in a facility, the reduction will be computed on the total number of recipients in that facility at the level of care in question.

(2) The fraction obtained in paragraph (a)(1) of this section is multiplied by one-third.

(3) The product obtained in paragraph (a)(2) of this section is multiplied by the Federal Medical Assistance Percentage (FMAP).

(4) The product obtained in paragraph (a)(3) of this section is multiplied by the agency payments for longstay services furnished during the quarter at that level of care.

(b) If any of the data required to compute the amount of the reduction in FFP are unavailable, the Administrator will substitute an estimate. If the agency determines the exact data to the satisfaction of the Administrator, the estimate may later be adjusted. If the number of recipients in individual facilities is not available, the fraction specified in paragraph (a)(1) of this section will be estimated, for each level of care, by dividing the number of facilities in which the requirements were not met by the total number of facilities for which a showing is required under this subpart.

Subpart K—Drug Use Review (DUR) Program and Electronic Claims Management System for Outpatient Drug Claims

SOURCE: 57 FR 49408, Nov. 2, 1992, unless otherwise noted.

§ 456.700 Scope.

This subpart prescribes requirements for—

(a) An outpatient DUR program that includes prospective drug review, retrospective drug use review, and an educational program;

(b) The establishment, composition, and functions of a State DUR Board; and

(c) An optional point-of-sale electronic claims management system for processing claims for covered outpatient drugs.

§ 456.702 Definitions.

For purposes of this subpart—

Abuse is defined as in § 455.2 of this chapter.

Adverse medical result means a clinically significant undesirable effect, experienced by a patient, due to a course of drug therapy.

Appropriate and medically necessary means drug prescribing and dispensing that is in conformity with the predetermined standards established in accordance with § 456.703.

Criteria is defined as in § 466.1 of this chapter.

Fraud is defined as in § 455.2 of this chapter.

Gross overuse means repetitive overutilization without therapeutic benefit.

Inappropriate and medically unnecessary means drug prescribing and dispensing not in conformity with the definition of *appropriate and medically necessary*.

Overutilization means use of a drug in a quantity, strength, or duration that is greater than necessary to achieve a desired therapeutic goal or that puts the recipient at risk of a clinically significant undesirable effect, or both.

Predetermined standards means criteria and standards that have been established in accordance with the requirements of § 456.703.

Standards is defined as in § 466.1 of this chapter.

Underutilization means use of a drug by a recipient in insufficient quantity, strength, or duration to achieve a desired therapeutic goal or that puts the recipient at risk of a clinically significant undesired effect, or both.

[57 FR 49408, Nov. 2, 1992, as amended at 59 FR 48824, Sept. 23, 1994]

§ 456.703 Drug use review program.

(a) *General.* Except as provided in paragraphs (b) and (c) of this section, in order for FFP to be paid or made available under section 1903 of the Act for covered outpatient drugs, the State must have in operation, by not later than January 1, 1993, a DUR program consisting of prospective drug review, retrospective drug use review, and an educational program that meets the requirements of this subpart. The goal of the State's DUR program must be to ensure appropriate drug therapy, while permitting sufficient professional prerogatives to allow for individualized drug therapy.

(b) *Exception for drugs dispensed to certain nursing facility residents.* Prospective drug review and retrospective drug use review (including interventions and education) under the DUR program are not required for drugs dispensed to residents of nursing facilities that are in compliance with the drug regimen review procedures set forth in part 483 of this chapter. This does not preclude the State agency from making such drugs subject to prospective DUR or retrospective DUR or both, provided the State agency makes the drugs sub-

ject to all the requirements of this subpart applicable to the respective review.

(c) *Exemption for certain covered outpatient drugs dispensed by hospitals and health maintenance organizations.*

(1) The State plan must provide that covered outpatient drugs dispensed by a hospital using drug formulary systems and billed to the plan at no more than the hospital's purchasing costs are not subject to the requirements of this subpart. Individual hospitals requesting this exemption must provide assurances to the State agency that they meet the requirements specified in section 1927(j)(2) of the Act.

(2) The State plan must provide that covered outpatient drugs dispensed by health maintenance organizations are not subject to the requirements of this subpart.

(d) *Use of predetermined standards.* A DUR program must assess drug use information against predetermined standards.

(e) *Source of predetermined standards.* The predetermined standards must be—

(1) Developed directly by the State or its contractor;

(2) Obtained by the State through contracts with commercial vendors of DUR services;

(3) Obtained by the State from independent organizations, such as the United States Pharmacopeial Convention, or entities receiving funding from the Public Health Service, HCFA, or State agencies; or

(4) Any combination of paragraphs (e)(1) through (e)(3) of this section.

(f) *Requirements for predetermined standards.* The predetermined standards used in the DUR program must meet the following requirements:

(1) The source materials for their development are consistent with peer-reviewed medical literature (that is, scientific, medical, and pharmaceutical publications in which original manuscripts are published only after having been critically reviewed by unbiased independent experts) and the following compendia:

(i) American Hospital Formulary Service Drug Information;

(ii) United States Pharmacopeia-Drug Information;

(iii) American Medical Association Drug Evaluations.

(2) Differences between source materials were resolved by physicians and pharmacists developing consensus solutions. The consensus process means the reliance, by the criteria developers, on the expertise of physicians and pharmacists to evaluate differences in criteria source materials and to come to agreement on how differences should be resolved.

(3) They are non-proprietary and readily available to providers of services. Systems and algorithms using the predetermined standards may remain proprietary.

(4) They are clinically-based and scientifically valid.

(5) The review based on clinical criteria uses predetermined standards to determine the population at risk of a clinically significant adverse medical result and applies standards, appropriate to this population, across providers and patients to determine the provider outliers whose prescribing, dispensing, or consumption practices may not conform to accepted standards of care. Various statistical measures (including mean, range, or other measures at the discretion of the State) may be applied to these data. Standards may be considered in deciding if an in-depth review is needed to determine whether to intervene once the potential therapeutic problems have been identified through the use of clinical criteria.

(6) They have been tested against claims data prior to adoption in order to validate the level of possibly significant therapeutic problems without undue levels of false positives.

(7) The predetermined standards for prospective and retrospective DUR are compatible.

(8) They are subjected to ongoing evaluation and modification either as a result of actions by their developer or as a result of recommendations by the DUR Board.

(g) *Access to predetermined standards.* Upon their adoption, predetermined standards must be available to the public. Pharmacists and physicians must be informed of the existence of predetermined standards and of how they can obtain copies of them.

(h) *Confidentiality of patient related data.* In implementing the DUR program, the agency must establish, in regulations or through other means, policies concerning confidentiality of patient related data that are consistent with applicable Federal confidentiality requirements at part 431, subpart F of this chapter; the State Pharmacy Practice Act; and the guidelines adopted by the State Board of Pharmacy or other relevant licensing bodies.

[57 FR 49408, Nov. 2, 1992, as amended at 59 FR 48824, Sept. 23, 1994]

§ 456.705 Prospective drug review.

(a) *General.* Except as provided in §§ 456.703 (b) and (c), the State plan must provide for a review of drug therapy before each prescription is filled or delivered to a recipient, and applicable State law (including State Board policy incorporated in the State law by reference) must establish standards for counseling of the recipient or the recipient's caregiver. The State must provide pharmacies with detailed information as to what they must do to comply with prospective DUR requirements, including guidelines on counseling, profiling, and documentation of prospective DUR activities by the pharmacists. The pharmacies, in turn, must provide this information to their pharmacists. This information is to be based on guidelines provided by this subpart and by other sources that the State may specify.

(b) *Point-of-sale or point-of-distribution review.* Except as provided in §§ 456.703 (b) and (c), the State plan must provide for point-of-sale or point-of-distribution review of drug therapy using predetermined standards before each prescription is filled or delivered to the recipient or the recipient's caregiver. The review must include screening to identify potential drug therapy problems of the following types:

(1) Therapeutic duplication, that is, the prescribing and dispensing of two or more drugs from the same therapeutic class such that the combined daily dose puts the recipient at risk of an adverse medical result or incurs additional program costs without additional therapeutic benefit.

(2) Drug-disease contraindication, that is, the potential for, or the occurrence of—

(i) An undesirable alteration of the therapeutic effect of a given drug because of the presence, in the patient for whom it is prescribed, of a disease condition; or

(ii) An adverse effect of the drug on the patient's disease condition.

(3) Adverse drug-drug interaction, that is, the potential for, or occurrence of, a clinically significant adverse medical effect as a result of the recipient using two or more drugs together.

(4) Incorrect drug dosage, that is, the dosage lies outside the daily dosage specified in predetermined standards as necessary to achieve therapeutic benefit. Dosage is the strength multiplied by the quantity dispensed divided by day's supply.

(5) Incorrect duration of drug treatment, that is, the number of days of prescribed therapy exceeds or falls short of the recommendations contained in the predetermined standards.

(6) Drug-allergy interactions, that is, the significant potential for, or the occurrence of, an allergic reaction as a result of drug therapy.

(7) Clinical abuse/misuse, that is, the occurrence of situations referred to in the definitions of abuse, gross overuse, overutilization, and underutilization, as defined in § 456.702, and incorrect dosage and incorrect duration, as defined in paragraphs (b)(4) and (b)(5) of this section, respectively.

(c) *Drug counseling.* (1) As part of the prospective drug review program, standards for counseling by pharmacists of recipients or the recipients' caregivers must be established by State law or other method that is satisfactory to the State agency. A State agency's counseling standards must address special situations where the patient or the patient's representative, is not readily available to receive the offer to counsel or the actual counseling, for example, prescriptions delivered offsite or through the mail. The State agency, at a minimum, must also address the following issues in their counseling standards:

(i) Whether the offer to counsel is required for new prescriptions only, or for both new and refill prescriptions;

(ii) Whether pharmacists must make the offer to counsel or auxiliary personnel are authorized to make the offer;

(iii) Whether only a patient's refusal of the offer to counsel must be documented, or whether documentation of all offers is required;

(iv) Whether documentation of counseling is required; and

(v) Whether counseling is required in situations where the patient's representative is not readily available to receive a counseling offer or the counseling itself.

(2) The standards must meet the following requirements:

(i) They must require pharmacists to offer to counsel (in person, whenever practicable, or through access to a telephone service that is toll-free for long-distance calls) each recipient or recipient's caregiver who presents a prescription. A pharmacist whose primary patient population is accessible through a local measured or toll-free exchange need not be required to offer toll-free service. Mail order pharmacies are required to provide toll-free telephone service for long distance calls.

(ii) They need not require a pharmacist to provide consultation when a Medicaid recipient or the recipient's caregiver refuses that consultation.

(iii) They must specify what documentation by the pharmacy of refusal of the offer of counseling is required.

(3) The standards must specify that the counseling include those matters listed in paragraphs (c)(3)(i) through (c)(3)(viii) of this section that, in the exercise of his or her professional judgement (consistent with State law regarding the provision of such information), the pharmacist considers significant as well as other matters the pharmacist considers significant.

(i) The name and description of the medication;

(ii) The dosage form, dosage, route of administration, and duration of drug therapy;

(iii) Special directions and precautions for preparation, administration, and use by the patient;

(iv) Common severe side or adverse effects or interactions and therapeutic

contraindications that may be encountered, including their avoidance, and the action required if they occur;

(v) Techniques for self-monitoring drug therapy;

(vi) Proper storage;

(vii) Prescription refill information; and

(viii) Action to be taken in the event of a missed dose.

(d) *Profiling.* The State agency must require that, in the case of Medicaid recipients, the pharmacist make a reasonable effort to obtain, record, and maintain patient profiles containing, at a minimum, the information listed in paragraphs (d)(1) through (d)(3) of this section.

(1) Name, address, telephone number, date of birth (or age), and gender of the patient;

(2) Individual history, if significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices; and

(3) Pharmacist's comments relevant to the individual's drug therapy.

[57 FR 49408, Nov. 2, 1992, as amended at 59 FR 48824, Sept. 23, 1994]

§ 456.709 Retrospective drug use review.

(a) *General.* The State plan must provide for a retrospective DUR program for ongoing periodic examination (no less frequently than quarterly) of claims data and other records in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and Medicaid recipients, or associated with specific drugs or groups of drugs. This examination must involve pattern analysis, using predetermined standards, of physician prescribing practices, drug use by individual patients and, where appropriate, dispensing practices of pharmacies. This program must be provided through the State's mechanized drug claims processing and information retrieval systems approved by HCFA (that is, the Medicaid Management Information System (MMIS)) or an electronic drug claims processing system that is integrated with MMIS. States that do not have MMIS systems may use existing systems provided that the

results of the examination of drug claims as described in this section are integrated within their existing system.

(b) *Use of predetermined standards.* Retrospective DUR includes, but is not limited to, using predetermined standards to monitor for the following:

(1) Therapeutic appropriateness, that is, drug prescribing and dispensing that is in conformity with the predetermined standards.

(2) Overutilization and underutilization, as defined in § 456.702.

(3) Appropriate use of generic products, that is, use of such products in conformity with State product selection laws.

(4) Therapeutic duplication as described in § 456.705(b)(1).

(5) Drug-disease contraindication as described in § 456.705(b)(2).

(6) Drug-drug interaction as described in § 456.705(b)(3).

(7) Incorrect drug dosage as described in § 456.705(b)(4).

(8) Incorrect duration of drug treatment as described in § 456.705(b)(5).

(9) Clinical abuse or misuse as described in § 456.705(b)(7).

§ 456.711 Educational program.

The State plan must provide for ongoing educational outreach programs that, using DUR Board data on common drug therapy problems, educate practitioners on common drug therapy problems with the aim of improving prescribing and dispensing practices. The program may be established directly by the DUR Board or through contracts with accredited health care educational institutions, State medical societies or State pharmacists associations/societies, or other organizations. The program must include the interventions listed in paragraphs (a) through (d) of this section. The DUR Board determines the content of education regarding common therapy problems and the circumstances in which each of the interventions is to be used.

(a) Dissemination of information to physicians and pharmacists in the State concerning the duties and powers of the DUR Board and the basis for the standards required by § 456.705(c) for use in assessing drug use.

(b) Written, oral, or electronic reminders containing patient-specific or drug-specific information (or both) and suggested changes in prescribing or dispensing practices. These reminders must be conveyed in a manner designed to ensure the privacy of patient-related information.

(c) Face-to-face discussions, with follow up discussions when necessary, between health care professionals expert in appropriate drug therapy and selected prescribers and pharmacists who have been targeted for educational intervention on optimal prescribing, dispensing, or pharmacy care practices.

(d) Intensified review or monitoring of selected prescribers or dispensers.

§ 456.712 Annual report.

(a) *DUR Board report.* The State must require the DUR Board to prepare and submit an annual DUR report to the Medicaid agency that contains information specified by the State.

(b) *Medicaid agency report.* The Medicaid agency must prepare and submit, on an annual basis, a report to the Secretary that incorporates the DUR Board's report and includes the following information:

(1) A description of the nature and scope of the prospective drug review program.

(2) A description of how pharmacies performing prospective DUR without computers are expected to comply with the statutory requirement for written criteria.

(3) Detailed information on the specific criteria and standards in use. After the first annual report, information regarding only new or changed criteria must be provided and deleted criteria must be identified.

(4) A description of the steps taken by the State to include in the prospective and retrospective DUR program drugs dispensed to residents of a nursing facility that is not in compliance with the drug regimen review procedures set forth in part 483 of this chapter. After the first annual report, only changes must be reported.

(5) A description of the actions taken by the State Medicaid agency and the DUR Board to ensure compliance with the requirements for predetermined standards at § 456.703(f) and with the ac-

cess to the predetermined standards requirement at § 456.703(g). After the first annual report, only changes must be reported.

(6) A description of the nature and scope of the retrospective DUR program.

(7) A summary of the educational interventions used and an assessment of the effect of these educational interventions on the quality of care.

(8) A description of the steps taken by the State Agency to monitor compliance by pharmacies with the prospective DUR counseling requirements contained in Federal and State laws and regulations. After the first annual report, only changes must be reported.

(9) Clear statements of purpose that delineate the respective goals, objectives, and scopes of responsibility of the DUR and surveillance and utilization (SUR) functions. These statements must clarify the working relationships between DUR and SUR functions and other entities such as the Medicaid Fraud Control Unit and State Board of Pharmacy. The annual report also must include a statement delineating how functional separation will be maintained between the fraud and abuse activities and the educational activities. After the first annual report, only changes must be reported.

(10) An estimate of the cost savings generated as a result of the DUR program. This report must identify costs of DUR and savings to the Medicaid drug program attributable to prospective and retrospective DUR.

§ 456.714 DUR/surveillance and utilization review relationship.

(a) The retrospective DUR requirements in this subpart parallel a portion of the surveillance and utilization review (SUR) requirements in subpart A of this part and in part 455 of this chapter.

(b) A State agency may direct DUR staffs to limit review activities to those that focus on what constitutes appropriate and medically necessary care to avoid duplication of activities relating to fraud and abuse under the SUR program.

[59 FR 48825, Sept. 23, 1994]

§ 456.716 DUR Board.

(a) *State DUR Board requirement and member qualifications.* Each State must establish, either directly or through a contract with a private organization, a DUR Board. The DUR Board must include health care professionals who have recognized knowledge and expertise in at least one of the following:

- (1) Clinically appropriate prescribing of covered outpatient drugs.
- (2) Clinically appropriate dispensing and monitoring of covered outpatient drugs.
- (3) Drug use review, evaluation, and intervention.
- (4) Medical quality assurance.

(b) *Board composition.* At least one-third but not more than 51 percent of the DUR Board members must be physicians, and at least one-third of the Board members must be pharmacists. These physicians and pharmacists must be actively practicing and licensed.

(c) *Medicaid agency/DUR Board relationship.* The Medicaid agency is ultimately responsible for ensuring that the DUR program is operational and conforms with the requirements of this subpart. The agency has the authority to accept or reject the recommendations or decisions of the DUR Board.

(d) *DUR Board activities.* The State agency must ensure that the operational tasks involved in carrying out the DUR Board activities set forth at section 1927(g)(3)(C) of the Act are assigned, limited only by the requirements of section 1927(g)(3)(C) of the Act, based on consideration of operational requirements and on where the necessary expertise resides. Except as limited by the requirements of section 1927(g)(3)(C) of the Act, the State agency may alter the suggested working relationships set forth in this paragraph.

(1) *Application of predetermined standards: Board's activities.* The DUR Board should perform the following activities:

(i) Review and make recommendations on predetermined standards submitted to it by the Medicaid agency or the agency's contractor.

(ii) Evaluate the use of the predetermined standards, including assessing the operational effect of the predetermined standards in use, and make rec-

ommendations to the Medicaid agency or the agency's contractor concerning modification or elimination of existing predetermined standards or the addition of new ones.

(iii) Recommend guidelines governing written predetermined standards that pharmacies not using approved software must use in conducting prospective DUR.

(2) *Application of predetermined standards: Medicaid agency role.* The Medicaid agency or its contractor should perform the following activities:

(i) Submit predetermined standards to the DUR Board for its review and recommendations before the Medicaid agency applies them to drug claims data.

(ii) If prospective DUR is conducted using an electronic claims management (ECM) system, apply software approved by the Board.

(iii) If prospective DUR is not conducted through an ECM system, as part of general compliance monitoring, ensure that Medicaid participating pharmacies conduct prospective drug review that screens for the potential drug therapy problems listed in section 1927(g)(2)(A) of the Act.

(3) *Retrospective DUR: Board's activities.* The DUR Board should perform the following activities:

(i) Review and make recommendations on predetermined standards submitted to it by the Medicaid agency or the agency's contractor.

(ii) Make recommendations to the Medicaid agency or the agency's contractor concerning modification or elimination of existing predetermined standards or the addition of new ones.

(4) *Retrospective DUR: Medicaid agency role.* The Medicaid agency or its contractor should apply the predetermined standards to drug claims data in order to generate reports that identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care.

(5) *Education program (including interventions): Board's activities.* The DUR Board must perform the following activities:

(i) Identify and develop educational topics if education of practitioners on common drug therapy problems is

needed to improve prescribing or dispensing practices.

(ii) Make recommendations as to which mix of the interventions set forth in §§ 456.711 (a) through (d) would most effectively lead to improvement in the quality of drug therapy. The DUR board recommendations must be based upon an in-depth review of the results of the application of predetermined standards against claims data reports, must be appropriate based upon program experience, and must match the educational program with the drug therapy problems identified.

(iii) Periodically re-evaluate and, if necessary, modify the interventions.

(6) *Education program (including interventions): Medicaid agency's role.* The Medicaid agency or its contractor should perform the following activities.

(i) Apply predetermined standards to drug claims data to generate reports that provide the basis for retrospective education and interventions and furnish those reports to the Board.

(ii) Carry out the educational programs and interventions specified by the Board.

(e) *Funding for the Board.* FFP is available for expenses associated with the operation of the DUR Board in carrying out its responsibilities, and payment is made under procedures established in part 433 of this chapter as follows:

(1) If the requirements for skilled professional medical personnel at § 432.50 of this chapter are met, at the rate of 75 percent.

(2) If the requirements for skilled professional medical personnel at § 432.50 of this chapter are not met, at the rate specified in § 456.719.

[57 FR 49408, Nov. 2, 1992, as amended at 59 FR 48825, Sept. 23, 1994]

§ 456.719 Funding for DUR program.

FFP is available for sums that the Secretary determines are attributable to the Statewide adoption of a DUR program as described in this subpart, and payment is made under procedures established in part 433 of this chapter as follows:

(a) For funds expended by the State during calendar years 1991 through 1993, at the rate of 75 percent.

(b) For funds expended by the State after December 31, 1993, at the rate of 50 percent.

§ 456.722 Electronic claims management system.

(a) *Point-of-sale system.* Each Medicaid agency, at its option, may establish, as its principal (but not necessarily exclusive) means of processing claims for covered outpatient drugs, a point-of-sale electronic claims management (ECM) system to perform on-line, real-time (that is, immediate) eligibility verifications, claims data capture, adjudication of claims, and to assist pharmacists and other authorized persons (including dispensing physicians) in applying for and receiving payment. The State determines who must participate in an ECM system and who may decline to do so. If the State exercises this option and wishes to receive FFP for its ECM system, the system must meet the functional and additional procurement and system requirements in paragraphs (b) and (c) of this section.

(b) *Functional requirements.* The ECM system developed by the State must include at least the on-line, real-time capabilities specified in paragraphs (b)(1) through (3) of this section. The real-time requirement for prescriptions filled for nursing facilities and prescriptions filled by mail order dispensers may be waived by the State to permit claims to be processed in the batch mode at the end of the day or other time mutually agreed to by the nursing facility or mail order dispenser and Medicaid agency.

(1) Eligibility verification, including identification of the following:

(i) Third-party payers.

(ii) Recipients in managed care programs.

(iii) Recipients and providers in restricted service programs (for example, lock-in and lock-out).

(iv) Properly enrolled providers.

(2) Claims data capture, including the following:

(i) Transfer of claims information from the pharmacy to the Medicaid agency or the Medicaid agency's contractor.

(ii) Identification of prescriber.

(iii) Minimum data set (as defined in Part 11 of the State Medicaid Manual).

(3) Claims adjudication, including the following:

(i) Performing all edits and audits contained in the State's Medicaid Management Information System (MMIS) applicable to prescription drugs.

(ii) Notifying the pharmacist (or other authorized person, such as the dispensing physician) about the claim status.

(iii) Taking steps up to, but not including, payment of the claim.

(c) *Additional requirements.* In order to receive FFP for its ECM system, the State must meet the following requirements:

(1) The ECM system must be acquired through applicable competitive procurement process in the State and must be the most cost-effective telecommunications network and automatic data processing services and equipment. The procurement must meet the procurement requirements set forth in 45 CFR part 74, subpart P, and appendix G–O of OMB circular A–102. The request for proposal (RFP) may be substituted for the advance planning and implementation documents otherwise required by part 433 of this chapter, 45 CFR 95.205, and 45 CFR part 307. A cost-benefit analysis must accompany the RFP. If in its advance planning document, a State establishes that a separate procurement is not cost-effective, modification of an existing fiscal agent contract will be acceptable. In this case, procurement of network services and equipment (but not software modifications) must be competitively procured.

(2) States wishing to do prospective DUR as part of their ECM must do the following:

(i) Submit a cost benefit analysis showing the cost-effectiveness of such a system. A State's decisions as to who must participate in the ECM system and who may decline to do so must be included in the cost-benefit analysis.

(ii) Establish a central State-wide electronic repository for capturing, storing, and updating data for all pre-

scriptions dispensed and for providing access to such data by all authorized participants.

(iii) Design the system to assess data for a review of drug therapy before each prescription is filled or delivered to a Medicaid recipient. The type of review conducted must meet the requirements for prospective drug review set forth in § 456.705.

(3) ECM is considered a subsystem and must be fully integrated with the remainder of the State's MMIS. In addition, information about ECM claims must be part of the single comprehensive utilization and management reporting system used by the DUR program.

§ 456.725 Funding of ECM system.

(a) For funds expended during calendar quarters in fiscal years 1991 and 1992 and attributable to the design, development, and implementation of an on-line, real-time claims management system (that is, the most cost-effective telecommunications network and automatic data processing services and equipment) that meets the requirements of § 456.722, FFP is available at a matching rate of 90 percent. After fiscal year 1992, ECM subsystems are funded at the standard applicable MMIS enhanced rates, subject to the requirements of part 433, subpart A of this chapter.

(b) FFP is available at a matching rate of 75 percent for funds expended for the following:

(1) Telecommunications equipment and other equipment to directly access MMIS files.

(2) Telecommunications equipment (such as modems and point of sale terminals) furnished to providers.

(3) Operational costs including telecommunications network costs, provided that the ECM system includes eligibility verification systems, electronic claims capture, claims adjudication (except for payment), and a claims data process that is integrated into a single comprehensive utilization and information reporting system.