

(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.

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(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.

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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