

(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 subject to all the requirements of this subpart applicable to the respective review.

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

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

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

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

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

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

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

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

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

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

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

(i) American Hospital Formulary Service Drug Information;

(ii) United States Pharmacopeia-Drug Information;

(iii) American Medical Association Drug Evaluations.

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

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

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

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

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

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

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

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

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

[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;