

(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 recommendations 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.

§ 456.719

(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

42 CFR Ch. IV (10-1-09 Edition)

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