

§ 456.709

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(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 encoun-

tered, 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