

HEALTH AND HUMAN SERVICES COMMISSION

Chapter 35. Pharmacy Services Subchapter H. Texas Drug Code Index- Addition, Retention, and Deletion of Drugs

§354.1921 Application for Addition of Drugs to the Texas Drug Code Index

- (a) Any drug company that has a valid rebate agreement under the Social Security Act, §1927, is allowed to apply to the Commission for addition of a drug not currently listed in the Texas Drug Code Index (TDCI). Drug companies include any manufacturer, own label distributor or re-labeler.
- (b) The drug company must complete the questionnaire provided by the Commission to request the addition of a drug to the TDCI. All questions on the questionnaire must be answered and all statements must be complete. For a multi-source drug, the drug company may reference the actual manufacturer's data, if the manufacturer's drug is listed in the TDCI.
- (c) Sources other than drug companies may request the addition of a drug not currently listed in the TDCI. If the request is not from a drug company, the Commission requests the manufacturer to submit the questionnaire as described in subsection (b) of this section.
- (d) The drug company and other sources, if applicable, are entitled to receive notification of approved or denied requests. If the requests have been denied, the Commission states the reasons for denial.

§354.1923 Review and Evaluation

(a) The Commission reviews each request to determine the need for a drug to be added to the Texas Drug Code Index and to determine the need for restrictions, when appropriate. In determining need, the Commission considers the following:

- (1) Expansion of the prescriber's armamentarium by a new drug or an additional multisource drug;
- (2) predominant use of the drug in an outpatient setting;
- (3) the cost of the drug to pharmacies compared to:
 - (A) wholesale estimated acquisition cost (WEAC) or direct estimated acquisition costs (DEAC) listed in the Redbook (Annual Pharmacists' Reference);
 - (B) the Average Manufacturer's Price (AMP) as defined by 42 U.S.C. §1396r-8(k), as amended; and

(C) other generically equivalent drug products.

(b) The Commission returns a questionnaire for any of the following reasons:

(1) discovery of false, erroneous, or incomplete information or documentation on the questionnaire;

(2) failure of the drug company to provide the Commission with documentation of the:

(A) approved new drug application (NDA) or abbreviated new drug application (ANDA), if applicable; or

(B) Food and Drug Administration (FDA) approval for marketing;

(3) failure of the drug company to provide the Commission with the national drug code (NDC), as defined by and filed with FDA, for the drug product as shown on the drug product container sold to the pharmacy;

(4) failure of the drug company to provide the Commission with the current DEAC to a pharmacy, cost to a wholesaler, estimated wholesale cost to a pharmacy, or AMP. The allowable WEAC and DEAC are the costs to a pharmacy, as determined by review of published or non-published prices resulting from routine marketing practices. The drug company shall update the AMP each quarter at the same time the information is reported to the Secretary of Health and Human Services.

(c) The Commission may deny a request if it determines that the drug is included in one or more of the following classes: **NOTE: Nutritional (Food & Food Substitutes) Products are not Drugs.**

(1) amphetamines, when used for weight loss, and obesity control drugs;

(2) appliances;

(3) cosmetics;

(4) DESI-ineffective products;

(5) diagnostic aids;

(6) durable medical equipment (rental or purchase);

(7) elastic stockings;

(8) experimental drugs;

(9) fertility drugs;

(10) first aid supplies;

(11) immunizing agents;

- (12) irrigating sets;
- (13) IV sets;
- (14) medical devices;
- (15) medical supplies;
- (16) oxygen;
- (17) products unsuitable for use outside of physician offices or health care facilities;
- (18) shampoos, unless medicated for parasite control;
- (19) skin lotions and creams (nonlegend cosmetic types);
- (20) soaps and soap substitutes;
- (21) supports and suspensories;
- (22) syringes and needles;
- (23) unit-dose or convenience packaging; and
- (24) vitamin and antianemia combinations.

§354.1925 Resubmittal of a Denied Request

- (A) Upon initial denial, the drug company may seek reconsideration of the decision. The request is presented to the Commission for reconsideration.

- (B) If a request for reconsideration for an addition is denied, the drug company may not resubmit the request for six months. At its option, however, the Commission may reconsider a denied request at anytime.

§354.1927 Retention and Deletion of Drugs

(a) The Commission reviews the Texas Drug Code Index to evaluate the need for retaining or deleting drugs according to the following criteria:

- (1) If the drug company fails to remove from pharmacies any drug recalled by the Food and Drug Administration (FDA) or fails to meet other federal requirements, the Commission has the right to request that Health and Human Services (HHS) allow deletion of the drug. If the drug company repeatedly fails to meet FDA or other federal requirements, the Commission may request permission to delete all drugs manufactured by the company.
- (2) If the drug company fails to provide the Commission the current drug costs That include the direct estimated acquisition cost (DEAC) to a pharmacy, the cost to a wholesaler, the Average Manufacturer's Price (AMP), and the estimated wholesale cost to a pharmacy, the Commission is allowed to request that HHS allow deletion of the drug. If the Commission retains a drug for which the cost was not reported, the Commission establishes the cost. The allowable wholesale estimated acquisition cost (WEAC) and DEAC are the cost to a pharmacy, as determined by review of published or non-published prices resulting from routine marketing practices.
- (3) The Commission deletes a legend drug if the same drug becomes available as an over-the-counter drug.
- (4) Effective upon notification, the Commission deletes discontinued or permanently recalled drugs. This provision applies to:
 - (A) drugs permanently recalled by the manufacturer;
 - (B) drugs permanently recalled by the FDA; and
 - (C) drugs no longer manufactured.
- (5) The Commission deletes drugs for which federal matching funds are no longer available. Federal matching funds are not available for:
 - (A) drugs for which a rebate is not available under Public Law 101-508; and
 - (B) drugs for which notice of opportunity for hearing has been published in the Federal Register.

(b) If a drug is deleted, the drug company is entitled to be notified and given an opportunity to request reconsideration of the decision, unless the deletion is based on criteria in subsection (a)(3)-(5) of this section.