

HEALTH AND HUMAN SERVICES COMMISSION

Public Notice: Supplemental Drug Rebate Agreement

The Texas Health and Human Services Commission (HHSC) announces its intent to submit transmittal number 18-0001 to the Texas State Plan for Medical Assistance, under Title XIX of the Social Security Act.

The purpose of this amendment (SPA 18-0001) is to update the section of the State Plan that addresses State Medicaid Supplemental Rebate Agreements. The requested effective date for the proposed amendment is February 15, 2018.

42 U.S.C. §1396r-8 and Texas Government Code § 531.070 authorize the Texas Medicaid program to enter into Supplemental Rebate Agreements with drug manufacturers and labelers to obtain rebates for covered drugs in addition the rebates already collected under the Medicaid Drug Rebate Program.

Texas Government Code §531.072 directs HHSC to include on the Texas Medicaid Preferred Drug List (PDL) a drug provided by a manufacturer or labeler that enters into Supplemental Rebate Agreement with HHSC. HHSC also may include a drug on the PDL if the drug provides certain non-monetary program benefits or HHSC determines the drug has no negative cost impact to the state.

SPA 18-0001 proposes to amend the state plan to provide for the use of an updated model supplemental rebate agreement template. The proposed template replaces the previous template, which was submitted to the Centers for Medicare & Medicaid Services (CMS) on January 29, 2004.

The Supplemental Rebate Agreement is being revised to:

1. Tie definitions to the definitions in Section 1927(k)(1) of the Social Security Act (42 U.S.C. §1396r-8(k)(1)).
2. Repurpose Article II to describe the Preferred Drug List, and replace references to the Pharmaceutical and Therapeutics Committee (P&T Committee) with references to the Drug Use Review (DUR) Board. The P&T Committee was discontinued by statute on January 1, 2016.
3. Reorganize and combine sections of HHSC Obligations.
4. Under Manufacturer's/Labeler's Obligations:
 - a. Clarify that a rebate amount cannot be negative;
 - b. Clarify supplemental rebate calculation when a Manufacturer/Labeler does not submit pricing to the Centers for Medicare & Medicaid Services; and
 - c. Reorganize and combine sections of Manufacturer's/Labeler's Obligations.

5. Under Term and Termination:
 - a. Clarify and define the Effective Date and Termination Date of the Agreement and text within the section;
 - b. Reorganize and move "Breach," "Without Cause," and "Accrued Obligations/Remedies,"
 - c. Add language specifying that manufacturers and labelers on the United States Office of Inspector General's (OIG's) List of Excluded Individuals/Entities (Exclusion List) or the State of Texas of Inspector General's (TXOIG's) List of Excluded Individuals/Entities (Exclusion List) will be subject to immediate termination from the Medicaid program unless and until the Manufacturer/Labeler is reinstated by the OIG or TXOIG; and
 - d. Add language specifying that if HHSC terminates the Supplemental Rebate Agreement for cause, the Manufacturer/Labeler is prohibited from entering into another rebate agreement with HHSC for at least one Rebate Period from the effective date of the termination,

6. Under General Terms & Conditions:
 - a. Update the Notice section;
 - b. Update the Record Keeping and Audit section to require a Manufacturer/Labeler to maintain records seven full years after the end of the Agreement and to include other appropriate state agencies in the list of parties that can audit the contract;
 - c. Change the Indemnification section;
 - d. Restructure the Confidentiality section ;
 - e. Revise the Force Majeure section;
 - f. Extend responsibilities to HHSC and Manufacturer/Labeler's contractors;
 - g. Move Over/Under Payment to the Manufacturer's/Labeler's Obligation section; and
 - h. Strengthen the Confidentiality section.
 - i. Add requirement that in accordance with Texas Government Code, Chapter 2270, may not enter into a contract with a company for goods or services unless the contract contains a written verification from the company that it: (1) does not boycott Israel; and (2) will not boycott Israel during the term of the contract.

7. Update Attachment A.

The proposed amendment is estimated to have no fiscal impact, as it is not expected to have an effect on Medicaid utilization or cost.

To obtain copies of the proposed amendment, interested parties may contact Doneshia Ates, State Plan Policy Advisor, by mail at the Health and Human Services Commission, PO Box 13247, Mail Code H-600, Austin, Texas 78711; by telephone at (512) 428-1963; by facsimile at (512) 730-7472; or by e-mail at Doneshia.Ates@hhsc.state.tx.us. Copies of the proposal will also be made available for public review at the local offices of the Texas Health and Human Services Commission.