Clear Process for Including Prescription Drugs on the Texas Drug Code Index

As Required by

2018-19 General Appropriations Act, Senate Bill 1, 85th Legislature, Regular Session, 2017 (Article II, Health and Human Services Commission, Rider 204)

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Executive Summary

The *Clear Process for Including Prescription Drugs On the Texas Drug Code Index* report is submitted in compliance with the 2018-19 General Appropriations Act, Senate Bill (S.B.) 1, 85th Legislature, Regular Session, 2017 (Article II, Health and Human Services Commission[HHSC], Rider 204). Rider 204 directs HHSC to streamline the Vendor Drug Program's (VDP) process for reviewing and adding drugs to the Texas Drug Code Index (TDCI).

Drugs must be added within 90 days when they meet federal and state requirements for the Medicaid and Children's Health Insurance Program (CHIP) prescription drug benefits. In most cases, the current process[1] for adding drugs to the TDCI allows drugs to be added within the 90-day timeframe. New drugs on the market or drugs that have a high fiscal impact may take longer due to the additional analysis required or the unavailability of utilization data required to estimate the drug's fiscal impact.

By December 1, 2017, HHSC will implement the following changes to streamline the process for adding drugs to the TDCI:

- VDP will complete initial analyses of new drugs within 30 days of receiving the completed Certificate of Information (COI) to ensure System Forecasting and HHSC Executive Leadership have at least 60 days to complete the fiscal analysis and obtain approval from the Legislative Budget Board (LBB) for non-orphan drugs.
- VDP will alert System Forecasting sooner if new drugs will potentially exceed the $500,000 threshold for LBB approval to allow more time to complete a fiscal impact analysis, if possible.

[1] See: https://www.txvendordrug.com/sites/txvendordrug/files/docs/downloads/drug-addition-process.pdf

- VDP will identify orphan drugs[2] that qualify for coverage and add such drugs to the TDCI. Notification regarding a new or increased rate for orphan drugs will be submitted to the LBB and Governor within 60 days.

[2] Special Provision 17 defines “orphan drugs” as orphan drug must meet criteria specified in the federal Orphan Drug Act and regulations at 21 Code of Federal Regulations (C.F.R.) § 316, and are required to be covered by the Medicaid program under federal law.

1. Introduction

Rider 204 requires HHSC to submit, before December 1, 2017, a one-time report to the Governor and LBB. The report must discuss the steps taken to streamline the process for including prescription drugs on the TDCI for Medicaid and CHIP prescription drug benefits.

The rider directs HHSC to make the process clear and specifies that it must allow for completion of all steps within 90 days of receiving a completed application for coverage from the drug manufacturer. Several steps must be completed within the 90-day timeframe:

- Initiation of drug review
- Clinical evaluation
- Rate setting
- LBB notification
- Making the product available

2. Background

VDP reviews outpatient drug applications, known as the COI, to ensure all federal and state requirements applicable to Medicaid and CHIP prescription drug benefits are met prior to a drug's addition to the TDCI.

Drugs must have a rebate agreement in place and certain high-cost drugs may require LBB approval prior to their addition to the TDCI.

In accordance with 2018-19 General Appropriations Act, S.B. 1, 85th Legislature, Regular Session, 2017 (Article II, Special Provisions Relating to All Health and Human Services Agencies, Section 17), drugs that are estimated to exceed $500,000 in annual General Revenue-related Funds or Temporary Assistance for Needy Families Federal Funds require approval from the LBB and the Governor, with the exception of drugs that are defined as orphan drugs.

Special Provision 17 has no LBB or Governor's approval requirement for the addition of orphan drugs to the TDCI; however, notification of a new or increased rate for an orphan drug must be submitted to the LBB and Governor within 60 days following expenditures for the purpose.

3. Clear Process for Including Drugs on the Texas Drug Code Index

HHSC collaborated with agency partners and the LBB to streamline and update the process for including prescription drugs on the TDCI.

Process Streamlining

VDP will implement the following process improvements by December 1, 2017. Changes will ensure drugs are added to the TDCI, upon approval from the LBB, no later than 90 days after receipt of the COI:

- VDP will complete initial analyses of new drugs no later than 30 days after receipt of the completed COI to ensure System Forecasting and HHSC Executive Leadership will have at least 60 days to complete the fiscal analysis and obtain LBB approval after completion of VDP analysis.
- VDP will alert System Forecasting sooner (at approximately Day 15 of the Clear Process) to new drugs that potentially may exceed the $500,000 threshold for LBB approval to provide that area more time to complete a fiscal impact, if possible.
- VDP will identify orphan drugs that qualify for coverage and add such drugs to the TDCI. Notification regarding a new or increased rate for orphan drugs will be submitted to the LBB and Governor within 60 days.

Complete New Process

Based on the opportunities for streamlining identified above, HHSC developed a new, complete process for including prescription drugs on the TDCI. VDP coordinated with appropriate agency staff, particularly System Forecasting, to confirm each area understands its role and applicable timelines for competing tasks associated with the process. For reference, the current process is posted on the VDP website.[3]

[3] See: https://www.txvendordrug.com/sites/txvendordrug/files/docs/downloads/drug-addition-process.pdf

Stage 1: Determine TDCI Eligibility – Begins Day 1

A completed COI is received from a drug manufacturer requesting addition of their drug to the TDCI. VDP will:

1. Check the Centers for Medicare & Medicaid Services (CMS) rebate file to determine if the drug has a rebate agreement:
   a. If the National Drug Code (NDC) is not on file, the process stops.
   b. If the NDC is on file, proceed to next step.
2. Determine if the drug is:
   a. Designated as an orphan drug by checking the U.S. Food and Drug Administration website.[4]
   b. Covered as a clinician administered drug (CAD) via the medical benefit:
      i. If not covered as a medical benefit, proceed to Stage 2.
      ii. If covered as a medical benefit, use clinical expertise to determine if the CAD is appropriate for distribution through a pharmacy:
         (1) If not appropriate for distribution through a pharmacy, the drug coverage will be handled as a medical benefit and not added to the TDCI.
         (2) If appropriate for distribution through a pharmacy, proceed to Stage 2.

Stage 2: Estimate Number of Clients

The number of Medicaid clients who may use the drug is estimated. The VDP pharmacist:

1. Checks the NDC package insert and review indications.
2. Researches compendia and/or clinical studies for information on epidemiology.
3. If applicable, in situations when a manufacturer replaces one NDC with another, performs a query of claim and encounter history to review utilization.

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[4] See: https://www.accessdata.fda.gov/scripts/opdlisting/oopd/. This page searches the Orphan Drug Product designation database. Searches may be run by entering the product name, orphan designation, and dates.

4. Checks the CMS website[5] to see if other states have reported drug utilization data for the NDC. When available, the data includes state, drug name, NDC, number of prescriptions, and dollars reimbursed.
5. As needed, checks other sources, such as specialty pharmacies, manufacturers, and various foundations to gather additional information.
6. Determines if the drug needs a clinical prior authorization and develops the clinical criteria, as needed.
7. Uses clinical judgement and information gathered in the steps above to estimate the number of clients in fee-for-service and managed care who meet the criteria for coverage.

Stage 3: Estimate the Cost per Prescription

The cost per prescription is estimated. The VDP pharmacist:

1. Queries First Data Bank to obtain the National Average Drug Acquisition Cost or the Wholesale Acquisition Cost price.
2. If not available, gets the Average Wholesaler Pricing and the Net Cost to Wholesaler price from the COI.
3. Reviews the drug package insert, determines any requirements that might limit the quantity and/or duration of drug therapy, and calculates the maximum quantity allowed.
4. Calculates the estimated cost per prescription.

Stage 4: Estimate Fiscal Impact – Ends Day 30

The fiscal impact is estimated. The VDP pharmacist:

1. Performs the following calculations to determine the estimated cost:
   a. Estimated number of prescriptions: multiply the estimated number of clients who may use the drug by the average number of prescriptions per year.
   b. Estimated cost: multiply the estimated number of prescriptions by the cost per prescription.
2. Calculates the Federal Financial Participation and General Revenue (GR) of the estimated costs determined above.

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[5] https://www.medicaid.gov/medicaid/prescription-drugs/state-drug-utilization-data/index.html

3. For orphan drugs and any drug for which the estimated GR cost meets or exceeds $450,000 per state fiscal year, engages VDP Policy and System Forecasting staff for further evaluation:
    a. If the estimated GR cost falls below $450,000 per state fiscal year, then the drug is added within the allowable timeframes.[6]
    b. If there is any potential for a drug cost to exceed $500,000 per state fiscal year GR once added, the drug is referred for further analysis even if the estimated fiscal impact falls below $450,000 per state fiscal year GR.
    c. If identified as an orphan drug, the drug is added to the TDCI and VDP will coordinate with System Forecasting to prepare and submit the required orphan drug notification within 60 days, as required under Special Provision 17. LBB approval is not required for orphan drugs.

Stage 5: Fiscal Impact Analysis – Begins Day 31 if Cost Exceeds $500,000 per State Fiscal Year GR

A projected fiscal impact is completed to obtain rate approval for the drug's potential addition. System Forecasting:

1. Obtains necessary data to perform the analysis.[7]
2. Completes gross drug cost projection analysis by calculating number of utilizers, cost per prescription, ingredient cost, and dispensing fee.
3. Calculates net drug cost by incorporating rebate revenue estimates for federal and supplemental (if applicable) rebates.
4. Calculates overall net cost impact after consideration of any potential cost offsets resulting from utilization of the drug under review.

Stage 6: Review of Fiscal Analysis – Ends Day 90, As Needed

The fiscal analysis is reviewed internally by VDP and Actuarial Analysis and prepared for submission to external parties.

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[6] The dispensing fee is not included when estimating fiscal impact

[7] This is an interactive process with VDP staff to obtain drug pricing/dispensing fee data, rebate revenue data, potential drug cost offsets, and utilization assumptions. Other data collection is performed and varies by drug.

1. Actuarial Analysis reviews to determine if the expected cost of the drug impacts managed care rates.
2. VDP and Actuarial Analysis determine payment methodology.
3. Actuarial Analysis determines if approval is needed by the Governor and LBB.[8] If approval is required, VDP and the Financial Services Division coordinate to obtain necessary approval.

[8] Pursuant to the 2016-2017 General Appropriations Act, House Bill 1, 84th Legislature, Regular Session, 2015 (Article II, Special Provisions Relating to All Health and Human Services Agencies, Section 43).

4. Conclusion

In accordance with Rider 204, HHSC developed a new clear process for including drugs on the TDCI no later than 90 days after receipt of a completed COI.

All impacted areas within HHSC have agreed to the included timelines for ensuring access to new drugs added in a timely manner. The modified drug review and prioritization process will ensure drugs which may have high fiscal impact are identified, analyzed, and added to the TDCI within the required timeframe.

List of Acronyms

Acronym	Full Name
CAD	Clinician Administered Drug
CHIP	Children's Health Insurance Program
CMS	Centers for Medicare & Medicaid Services
COI	Certificate of Information
GR	General Revenue
HHSC	Texas Health and Human Services Commission
LBB	Legislative Budget Board
NDC	National Drug Code
TDCI	Texas Drug Code Index
VDP	Vendor Drug Program