

340B Program



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Correctional Managed Health Care Committee
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Agenda

- Provide an overview of 340B Drug Pricing Program
- Quantify 340B Savings
- Explain why 340B compliance is important
- Highlight the 340B Program key compliance cornerstones
- Summarize UTMB's 340B compliance program
- Outline current threats to 340B Program

340B Drug Pricing Program

- UTMB participates in the federal 340B Drug Pricing Program which requires participating manufacturers to provide “covered entities” serving the most vulnerable patient populations with discounts on covered outpatient drugs.
- Participating drug manufacturers agree to provide covered outpatient drugs at reduced prices. Prices are often up to 50% lower than typical market prices.
- The program enables covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.
- The program is overseen by the Health Resources and Services Administration’s (HRSA) Office of Pharmacy Affairs.

Role of HRSA

The Health Resources and Services Administration (HRSA) oversees the 340B Program

- Maintains the database of participating manufacturers and eligible entities
- Establishes program rules through policy releases and publication of FAQs
- Provides technical assistance and is available to answer questions
- Oversees program integrity including
 - Program enrollment
 - Annual recertification
 - **Audits of covered entities**



HRSA has audited UTMB's 340B Program on December 3-5, 2013, and May 15-16, 2023.

Eligible Covered Entities

Covered entities fall into two categories and are generally considered safety net providers.

Certain Federal Designees or Grantees
Federally qualified health centers (FQHC) and look-alikes
Title X family planning clinics
Ryan White HIV/AIDS clinics
Hemophilia clinics
TB Clinics
STD Clinics

Certain Hospitals
Disproportionate share hospitals*
Children's hospitals
Cancer hospitals
Sole community hospitals
Rural referral centers
Critical access hospitals

***UTMB** qualifies as a disproportionate share hospital (DSH).

Eligibility of UTMB's TDCJ Patients

- UTMB implemented the 340B program for its TDCJ patients because of legislation passed in 2001. Senate Bill 347, Regular Session, required a good faith effort to qualify CMC patients for 340B pricing using UTMB's status as a disproportionate share hospital.
- UTMB was able to demonstrate that its TDCJ patients meet the definition of a patient...UTMB has an established, ongoing health care relationship with its TDCJ patients, care is provided by a UTMB provider, and UTMB maintains the medical record.
- Federal approval was granted in April, and the program began in May 2002.
- UTMB's participation in the 340B Program generates significant savings for pharmaceuticals for the Texas prison system and ultimately Texas taxpayers

Patient & Location Eligibility

- Not all areas and clinics are eligible to participate in the 340B Program.
- 340B drugs can only be administered or dispensed to UTMB outpatients, resulting from an order written by a UTMB provider, at an eligible location.
- Patients located in the UTMB sector are eligible
 - **Note:** *New locations are ineligible pending HRSA registration*
- Patients located in the Texas Tech sector are not eligible for the 340B Program.
- Healthcare staff and security staff are not eligible for the 340B Program because they do not meet the 340B definition of a patient.

340B Savings

CMC began participating in the 340B Program in May 2002. The estimated total savings to date is > \$1.4 billion.



FY25 340B Impact

CMC Impact	
CMC Savings	\$132,324,013
Apexus share back of funds	\$13,843
Manufacturer repayments to CMC	\$3,633
340B compliance maintenance costs	(\$851,123)
340B net financial impact	\$131,490,366



Importance of 340B Compliance

Ongoing compliance is critical

- Covered entities can face sanctions for non-compliance including
 - Removal from the 340B Program
 - Repayment to drug manufacturers for the time period for which the violation occurred
 - Termination of offsite facilities from the program if non-compliance is linked to a particular location
 - The findings from HRSA-conducted 340B audits may be used to refer matters to the Office of Inspector General or Department of Justice.
- Removal from the program would result in UTMB losing access to 340B prices and the associated 340B savings

Compliance Framework

It is important to be familiar with the major compliance cornerstones of the program.



COMPLIANCE WITH **ELIGIBILITY** REQUIREMENTS



PREVENTION OF **DRUG DIVERSION** TO INELIGIBLE PATIENTS AND/OR USE IN INELIGIBLE LOCATIONS



COMPLIANCE WITH THE **GROUP PURCHASING ORGANIZATION (GPO) PROHIBITION**



PREVENTION OF **MEDICAID DUPLICATE DISCOUNTS**



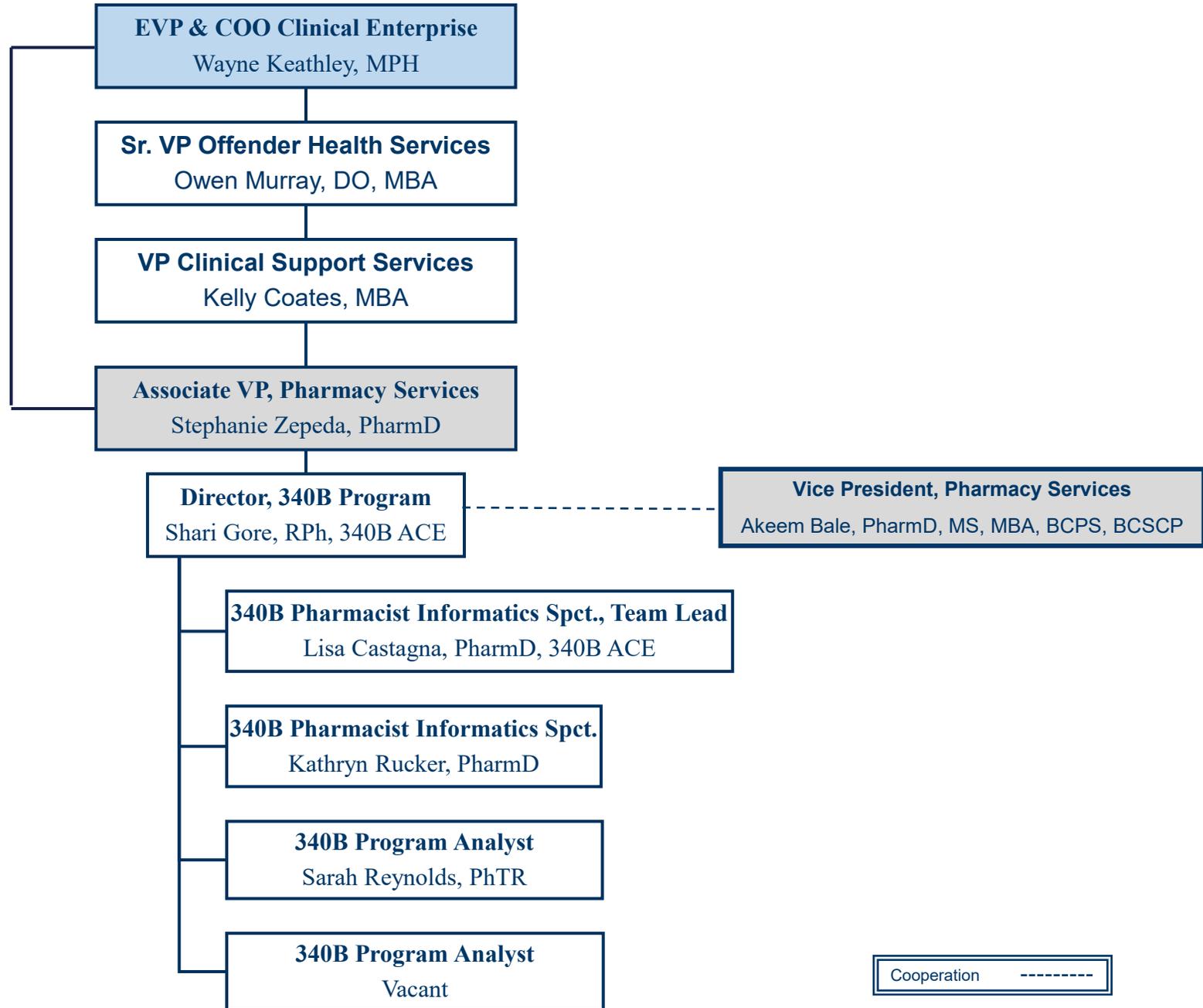
MAINTENANCE OF **ACCURATE INVENTORY AND RECORDS** DEMONSTRATING COMPLIANCE WITH PROGRAM REQUIREMENTS

Program Oversight

- The 340B Team is responsible for program maintenance, policy development, compliance with program rules, education, program optimization, and self-audits to ensure ongoing readiness for HRSA and/or manufacturer audits.
- UTMB maintains a 340B Compliance Committee comprised of key stakeholders from across the institution that meets quarterly to discuss and address issues related to UTMB's 340B Program. This Committee reports to UTMB's Executive Institutional Compliance Committee (EICC).
- Independent, external auditor conducts an annual HRSA mock-audit, benchmarks UTMB's performance against other covered entities, serves as a technical advisor, and shares best practices.



340B Team





Threats to the 340B Program

- HRSA 340B rebate program
- Manufacturer restrictive policies

HRSA 340B Rebate Pilot

Purpose:

- Aims to address conflict between MFP and 340B price
- Voluntary for manufacturers participating in IRA program

Process:

- Eliminates the upfront 340B discount
- Covered entities (CEs) pay full price (WAC) and manufacturers pay rebate

Eligibility:

- Applies to CMS negotiated drugs
- Applies to all payors and is not limited to Medicare

Requirements:

- CEs must submit claims data to manufacturers within 45 calendar days of date dispensed
- Manufacturers must pay approved rebates within 10 calendar days

Manufacturers cannot deny a rebate claim based on concerns about alleged diversion or Medicaid duplicate discounts, though they can do so for other reasons, such as if they already provided a 340B rebate to another CE on the same claim

MFP, or Maximum Fair Price, is a pricing mechanism established by the CMS under the Inflation Reduction Act to negotiate drug prices for Medicare beneficiaries

Impact HRSA 340B Rebate Pilot

- May negatively impact COGS discount with primary wholesaler since favorable discount is based on volume of 340B drugs.
- Additional resources required to submit claims, reconcile rebate payments, and manage denials.
- Increased cashflow is required to purchase drugs upfront at WAC pricing.

Impact for 10 Drugs Initially Proposed for Pilot

WAC Spend	340B Spend	Estimated Annual Upfront Cost
\$16,250,497	\$1,039,711	\$17,290,209

Status of the HRSA 340B Rebate Pilot

- Initially slated to begin January 1, 2026
- Officially suspended after two federal court rulings blocked its implementation after the American Hospital Association and other nonprofit health systems filed a lawsuit arguing HRSA failed to follow the proper notice-and-comment rulemaking process required by Administrative Procedure Act (APA)
 - APA outlines the framework for how federal agencies create rules to ensure that they do not overreach their authority and to promote public participation
- HRSA has taken the first to move forward with implementation and submitted a second proposal to the Office of Management and Budget (OMB) in early February

Manufacturer Restrictive policies

- Two manufacturers have moved forward with policies that look very similar to the HRSA 340B rebate pilot which has been paused
 - Exelixis effective October 1, 2025
 - Lilly effective February 1, 2026
- Both manufactures require covered entities to submit claims data as a requirement to continue to receive 340B pricing
- Advocacy groups are calling on HRSA to put a stop to these efforts

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