

TennCare Policy Manual	Section: Providers
Policy No: PRO 13-002 (Rev. 3)	Date: June 23, 2021

## 340B Drug Pricing Program

### Background

The 340B Drug Pricing Program, along with the Medicaid Drug Rebate Program (MDRP), is a partnership between the federal government and drug manufacturers to help offset the cost of outpatient prescription drugs, including physician-administered drugs, dispensed to Medicaid enrollees.

The MDRP requires drug manufacturers to enter into rebate agreements with the U.S. Department of Health and Human Services (HHS) in exchange for Medicaid coverage of the manufacturers' drugs. Under the MDRP, manufacturers pay a rebate on covered drugs each time that they are dispensed to Medicaid enrollees. These Medicaid drug rebates ("federal rebates") are shared by state Medicaid programs and the federal government in order to offset the overall cost of prescription drugs in the Medicaid program.

In addition to entering into rebate agreements with HHS, drug manufacturers are required to enter into a pricing agreement for the 340B Drug Pricing Program in order to have their drugs covered by Medicaid. The 340B Drug Pricing Program enables eligible health care providers and organizations ("covered entities") to purchase outpatient drugs at discounted rates. Covered entities eligible to participate in the 340B Drug Pricing Program are defined in statute and include federally qualified health centers, disproportionate share hospitals, children's hospitals, and other safety net providers.<sup>1</sup> TennCare's pharmacy provider network includes several pharmacies that qualify to participate in the 340B Drug Pricing Program.

While drug manufacturers may participate in both the Medicaid Drug Rebate Program and the 340B Drug Pricing Program, they are only required to provide a single discount on a drug furnished to a Medicaid enrollee. In other words, either the state may submit the claim to the manufacturer for the rebate under the MDRP; or, a provider may receive the discounted price under the 340B Drug Pricing Program (and the discounted price is then passed on to the state). However, the manufacturer must only pay either the rebate to the state or provide the discount to the provider, but not both.<sup>2</sup>

In order to ensure that the state and federal governments receive the full benefit of the MDRP and 340B Drug Pricing Program while also ensuring that manufacturers do not provide duplicate discounts for drugs furnished to Medicaid enrollees, 340B covered entities are required to indicate to TennCare whether they intend to participate in the 340B Drug Pricing Program, and to identify through claims drugs that have been purchased at 340B-discounted prices.

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<sup>1</sup> See Section 340B of the Public Health Service Act (Pub. L. 102-585), as amended by the Patient Protection and Affordable Care Act (Pub. L. 111-148), the Health Care and Education Reconciliation Act (Pub. L. 111-152), and the Medicare and Medicaid Extenders Act (Pub. L. 111-309), codified at 42 U.S. Code § 256b.

<sup>2</sup> See U.S. Code § 256b(a)(5)(A).

TennCare Policy Manual	Section: Providers
Policy No: PRO 13-002 (Rev. 3)	Date: June 23, 2021

When registering to participate as a 340B provider, covered entities must declare whether they intend to use 340B drugs for TennCare patients (“carve-in”), or whether they intend not to use 340B drugs for *any* TennCare patients (“carve-out”). Covered entities that carve-in for Medicaid are listed in the Health Resources & Services Administration’s (HRSA’s) searchable and downloadable 340B Medicaid Exclusion File (“340B MEF”), which is published and updated at least quarterly.

TennCare payment to 340B covered entities that are carved-in is governed by Tennessee’s Medicaid State Plan. These covered entities are reimbursed for 340B covered outpatient drugs at the lesser of:

- a) The 340B ceiling price, or
- b) The 340B covered entity’s acquisition cost.

Therefore, 340B covered entities are required to provide their 340B-discounted acquisition cost to TennCare to determine the applicable reimbursement.

If a covered entity chooses to carve-out of the 340B program, the covered entity may still provide covered outpatient drugs to Medicaid enrollees; however, the entity must use only drugs that have been purchased through normal channels, outside of the 340B Drug Pricing Program. These claims are then accepted by TennCare as non-340B claims and are submitted to drug manufacturers for federal rebates through the MDRP.

Should a covered entity that is carved-out provide a 340B-discounted drug to a Medicaid enrollee, or should a covered entity that is carved-in provide a 340B-discounted drug to a Medicaid enrollee that is not identified as a 340B drug, either scenario would result in duplicate discounts, as in both scenarios, the claim would be submitted by TennCare for federal rebates through the MDRP.

## **Policy**

It is the policy of TennCare to require 340B covered entities that are carved-in to provide drugs purchased via the 340B Drug Pricing Program to Medicaid enrollees as evidenced by the presence of their NPI number on HRSA’s Medicaid Exclusion File, and to use modifiers to identify whether claims are filled with drugs purchased via the 340B Drug Pricing Program. The modifiers will differ based on whether the provider is a pharmacy submitting claims to TennCare’s pharmacy benefit manager (PBM) vendor, or a medical provider submitting physician-administered drug claims as medical claims to one of TennCare’s managed care organization (MCO) partners.

### Claims Submitted by Pharmacy Providers to TennCare’s PBM Vendor

Pharmacies that are carved-in as 340B covered entities are required to identify 340B claims by submitting the following modifiers:

- Submission Clarification Code (420-DK) = “20”
- Basis of Cost Determination (423-DN) = “08”

TennCare Policy Manual	Section: Providers
Policy No: PRO 13-002 (Rev. 3)	Date: June 23, 2021

It is also required that the 340B covered entity pharmacy provider submit the following:

- Pharmacy’s Actual Acquisition Cost in the Ingredient Cost Submitted field (409-D9), and
- Pharmacy’s normal Usual and Customary rate in the Usual and Customary Charge field (426-DQ)

If the drug was not purchased via the 340B Drug Pricing Program, the 340B covered entity pharmacy must transmit the claim without the information above, with the exception of the pharmacy’s Usual and Customary rate.

Claims Submitted to MCOs

Beginning with dates of service on or after May 1, 2021, TennCare will accept claims submitted to TennCare’s MCO partners with the following modifiers to identify drugs purchased via the 340B Drug Pricing Program by 340B covered entity medical providers for physician-administered drugs:

- **JG** — Drug or biological acquired **with** the 340B Drug Pricing Program discount for Medicare Part B drugs for TennCare dual-eligible members,
- **TB** — Drug or biological acquired **with** the 340B Drug Pricing Program discount for Medicare Part B drugs for TennCare dual-eligible members (reported for informational purposes), and
- **UD** — Drug or biological acquired **with** the 340B Drug Pricing Program discount.

It is also required that the 340B covered entity medical provider submit the following:

- The drug product’s HCPCS Code,
- The drug product’s HCPCS unit quantity billed,
- The drug product’s National Drug Code (NDC Code), and
- The drug product’s NDC Code unit quantity billed.

Beginning with dates of service on or after May 1, 2021, if a drug was not purchased via the 340B Drug Pricing Program, TennCare will accept claims submitted to TennCare’s MCO partners by the 340B covered entity medical provider using the following modifier:

- **UC** — Drug or biological acquired **without** the 340B drug pricing program discount.

Beginning with dates of service on or after December 1, 2021, any claim submitted by a 340B covered entity for a physician-administered drug is required to contain one of the modifiers listed above (“**JG**”, “**TB**”, “**UD**”, “**UC**”). If a claim for a physician-administered drug is submitted without one of the required modifiers, the line of the claim containing the drug will be disallowed by the MCO.

340B Estimated Ceiling Price File

TennCare will provide the PBM vendor with an Estimated 340B Ceiling Price file on a quarterly basis, to be used by the PBM solely during the claims adjudication process to compare with submitted pricing.

TennCare Policy Manual	Section: Providers
Policy No: PRO 13-002 (Rev. 3)	Date: June 23, 2021

- Beginning with dates of service on or after May 1, 2021, pharmacies' reimbursement for the cost of drugs will be the lowest of their Submitted Actual Acquisition Cost, their Usual and Customary Price, or the Estimated 340B Ceiling Price.

#### Claims Submission to Drug Manufacturers for Federal MDRP Rebates

It is TennCare's policy to submit all possible drug claims from all pharmacy and medical providers to drug manufacturers for federal MDRP rebates. Any claim from a 340B covered entity that has been identified as purchased via the 340B Drug Pricing Program will be excluded from the federal rebate submission; however, beginning with dates of service on or after May 1, 2021, all drug claims from 340B covered entity pharmacy providers that are not identified as purchased via the 340B Drug Pricing Program, and beginning with dates of service on July 1, 2021, all drug claims from 340B covered entity medical providers that are either not identified as purchased via the 340B Drug Pricing Program, or identified as not purchased via the 340B Drug Pricing Program will be submitted on a quarterly basis for federal rebates, and be subject to investigative audit from TennCare and the drug manufacturer.

With the enactment of this policy, TennCare has defined to all 340B covered entities that are carved-in to provide drugs purchased via the 340B Drug Pricing Program how to identify whether a drug has been purchased via the 340B Drug Pricing Program. It is the covered entity's responsibility to submit claims in a manner that ensures that claims will not be submitted to drug manufacturers that would result in duplicate discounts, which are not permitted.

### **Offices of Primary Responsibility**

Division of Managed Care Operations  
Chief Medical Office, Pharmacy Unit

### **References**

42 USC § 256b

<http://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/pdf/USCODE-2010-title42-chap6A-subchapII-partD-subpartvii-sec256b.pdf>

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