

STATE OF TENNESSEE Changes to Pharmacy and Medical 340B Claims



UPDATES to 340B changes starting 5/1/2021

- 340B processes for pharmacy claims remain unchanged
- TennCare and its Managed Care Organizations will not implement changes to the current pricing logic for 340B medical claims
- Changes effect professional and facility encounters containing line item drugs that meet the definition of "covered outpatient drugs" as defined in section 1927(k) of the Social Security Act and types of encounter claims must still include one of the modifiers (i.e., JG, TG, or UD for 340B acquired drugs, OR UC for non-340B acquired drugs). TennCare's MCOs will begin accepting the claims with 340B modifiers beginning May 1, 2021.
- Effective for dates of service starting with July 1, 2021, encounters with separately payable drug line items submitted without a 340B indicator of JG, TB, or UD will be considered eligible for rebate collection.
- Effective for dates of service starting with December 1, 2021, if required information is not included on encounters containing separately payable drugs, that line of the claim will be disallowed. However, the remaining lines of the encounter claim may be eligible for payment



Introductions

TennCare

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Agenda

- Overview
- Definition of 340B Covered Entities
- Pharmacy Claims vs. Medical Claims
- Pharmacy 340B Claims
 - Current Submission Requirements
 - Current Reimbursement
 - Changes to Reimbursement Effective 5/1/2021
 - 340B Estimated Ceiling Price
- Medical 340B Claims
 - Current Submission Requirements
 - Changes to Submission Requirements: 5/1/2021
 - Changes to Submission Requirements: 12/1/2021
- Federal Rebate Collection Process
- Provider Resources



Overview

Who?

TennCare 340B covered entities and pharmacies.

What?

Changes to the claim submission requirements and reimbursement for 340B pharmacy and 340B medical claims.

Why?

Ensure compliance with TennCare's State Plan Amendment (17-0003) and 340B regulations.

When?

Changes effective on date of service of **5/1/2021 and 12/1/2021**.



Definition of 340B Covered Entities

"340B covered entities (CEs) are providers that participate in the 340B Drug Pricing Program and that fill enrollees' prescriptions with drugs purchased at prices authorized under Section 340B of the Public Health Service Act."

(Tennessee State Plan Amendment (SPA) #17-0003)



Pharmacy Claims vs. Medical Claims

- Pharmacy Covered Outpatient Drug Claims:
 - Drugs are dispensed to the patient, or to a Long-Term-Care facility or shipped directly to a provider's office for administration.
 - These claims are transmitted by the provider (usually a pharmacy) to TennCare's Pharmacy Benefit Manager vendor and processed online and in real time, and then reimbursed by TennCare.
- Medical Covered Outpatient Drug Claims:
 - Drugs that are administered by the provider in the provider's office or in an outpatient setting.
 - These claims are submitted by the provider to the member's MCO and reimbursed by the member's MCO.



Pharmacy 340B Claims



Pharmacy 340B Claims Current Submission Requirements

- TennCare 340B pharmacies are currently required to identify 340B claims by:
 - Entering a value of 20 in the Submission Clarification Code field (420-DK).

-AND-

- Entering a value of 08 in the Basis of Cost Determination field (423-DN).
- In addition to properly identifying 340B claims with the values listed above, 340B pharmacies are required to submit their:
 - Actual 340B acquisition cost in the Ingredient Cost Submitted field (409-D9).
 -AND-
 - Normal usual and customary rate in the Usual and Customary Charge field (426-DQ).



Pharmacy 340B Claims Current Reimbursement

- 340B pharmacies receive a \$15.40 professional dispensing fee (PDF) for 340B claims.
- 340B pharmacies are currently being reimbursed for their ingredient cost as follows:

Provider Type	First	Second	Third	Fourth	Fifth	Sixth
340B	340B covered entity's submitted acquisition cost, plus PDF.	FUL, plus PDF, if lower.	AAAC, plus PDF, if lower or no FUL exists.	NADAC, plus PDF, if lower or no FUL or AAAC exists.	lf no FUL, AAAC, or NADAC exists, WAC - 3% (Brands) WAC - 6% (Generics), plus PDF, if lower.	U&C, if lower.



Pharmacy 340B Claims Changes to Reimbursement <u>Effective 5/1/2021</u>

- There will be **NO** change to the current 340B pharmacy claim submission requirements. Providers should continue submitting the proper 340B claim indicator codes outlined on slide 8.
- Effective with **dates of service** of **5/1/2021**, TennCare will utilize a 340B estimated ceiling price and 340B covered entities will be reimbursed as follows:

Provider Type	First	Second	Third
340B	340B Estimated Ceiling Price (ECP), plus PDF.	340B covered entity's submitted acquisition cost, plus PDF, if lower.	U&C, if lower.



Pharmacy 340B Claims 340B Estimated Ceiling Price Effective Dates of Service 5/1/2021

- The 340B estimated ceiling price will be determined by:
 - Subtracting the unit rebate amount (URA) from the average manufacturer price (AMP), with appropriate unit conversions applied.

-OR-

- In instances where the URA or AMP are not available or a 340B estimated ceiling price could not be determined, the ceiling price will be calculated in accordance with the 340B Civil Monetary Penalties Final Rule which estimates the ceiling price as the wholesale acquisition cost (WAC) minus the applicable rebate percentages are as follows:
 - WAC minus 23.1% for most single-source and innovator drugs.
 - WAC minus 17.1% for clotting factors and drugs approved exclusively for pediatric indications.
 - WAC minus 13.0% for generics.



Medical 340B Claims



Medical 340B Claims Current Submission Requirements

- Effective January 1, 2018, the Centers for Medicare & Medicaid Services (CMS) created two new HCPCS Level II modifiers to identify 340B for Medicare Part B drugs:
 - **JG** Drug or biological acquired **with** the 340B drug pricing program discount.
 - **TB** Drug or biological acquired **with** the 340B drug pricing program discount, reported for informational purposes.
- TennCare 340B covered entities should currently be utilizing these two codes to appropriately identify 340B Medicare Part B drugs for TennCare dual-eligible members.



Medical 340B Claims Changes to Submission Requirements <u>Effective Dates of Service 5/1/2021</u>

- TennCare encourages 340B covered entities to differentiate between 340B and non-340B claims.
- The use of modifier codes will be accepted on all professional and facility encounter with separately payable drug claims submitted by a 340B covered entity:
 - **JG** or **TB** Drug or biological acquired **with** the 340B drug pricing program discount for Medicare Part B drugs for TennCare dual-eligible members.
 - **UD** Drug or biological acquired **with** the 340B drug pricing program discount.
 - **UC** Drug or biological acquired **without** the 340B drug pricing program discount.



Medical 340B Claims Changes to Submission Requirements <u>Effective Dates of Service 12/1/2021</u>

- TennCare requires 340B covered entities to differentiate between 340B and non-340B claims for all professional and facility encounter with separately payable drug claims for outpatient administered drugs.
- All professional and facility encounter with separately payable drug claims for outpatient administered drugs submitted by a 340B covered entity will be required to have one of the following modifiers:
 - **JG** or **TB** Drug or biological acquired **with** the 340B drug pricing program discount for Medicare Part B drugs for TennCare dual-eligible members.
 - **UD** Drug or biological acquired **with** the 340B drug pricing program discount.
 - **UC** Drug or biological acquired **without** the 340B drug pricing program discount.
- Line items lacking a distinctive 340B modifier will be disallowed



Summary of Changes Pharmacy Claims Submission

Claim Type	Current Process	Process Effective <u>5/1/2021</u>
Pharmacy	 Submit a value of "20" in the Submission Clarification Code field (420-DK) -AND- a value of "08" in the Basis of Cost Determination field (423-DN). Enter provider's 340B acquisition cost in the Ingredient Cost Submitted field (409-D9) and the usual and customary (U&C) rate in the Usual and Customary Charge field (426- DQ). Claims reimburse at the lower of the following: The provider's submitted 340B acquisition cost plus PDF, FUL plus PDF, AAAC plus PDF, NADAC plus PDF, WAC – 3% (Brand) WAC – 6% (generic) plus PDF, or U&C. 	 No change to the claims submissions process to identify 340B claims. Effective 5/1/2021, a 340B estimated ceiling price will be available and 340B claims will begin reimbursing at the lower of the 340B estimated ceiling price plus PDF, the provider's submitted 340B acquisition cost plus PDF, or U&C.



Summary of Changes Medical Claims Submission

Claim Type	Current Process	Process Effective <u>5/1/2021</u>
Medical	 Submit claims with JG or TB modifiers to indicate drug was acquired with the 340B drug pricing program discount for Medicare Part B drugs for TennCare dual-eligible members. 	• Effective with dates of service 5/1/2021 , each professional and facility encounter with separately payable drug claims <u>CAN</u> be submitted with the JG , TB , or UD modifiers to indicate the drug was acquired with the 340B drug pricing program discount OR submitted with the UC modifier to indicate non-340B.



Summary of Changes Medical Claims Submission*

Claim Type	Current Process	Process Effective <u>12/1/2021</u>
Medical	• Submit claims with JG or TB modifiers to indicate drug was acquired with the 340B drug pricing program discount for Medicare Part B drugs for TennCare dual-eligible members.	 Effective with dates of service 12/1/2021, each professional and facility encounter with separately payable drug claims <u>MUST BE</u> <u>submitted</u> with the required descriptive modifiers described. If a modifier and all required HCPCS and NDC information is not included, that line of the claim will be disallowed. TennCare encourages all claims to be submitted with defined 340B modifiers as soon as possible so that the TennCare MCO's can provide technical assistance during implementation.



Summary of Changes Medical Claims Submission*

Claim Type	Current Process and Processes Effective 5/1/2021 and 12/1/2021
Medical	• <u>340B estimated ceiling price will NOT be incorporated into MCO reimbursement</u> <u>methodology</u>



TennCare to Submit Non-340B Claims for Federal Rebates

- TennCare is required by CMS to submit claims paid for Covered Outpatient Drugs to manufacturers for Federal Rebates.
 - Section 1903(i)(10) of the Act prohibits Federal reimbursement for States that do not capture the information necessary for invoicing manufacturers for rebates as described in section 1927(a)(7) of the Act.
 - To invoice for rebates, States must use drug utilization data that identify, by NDC, the number of units of each drug for which the States reimbursed Medicaid providers. The States must capture these drug utilization data and report the information to the manufacturers (the Act § 1927(b)(2)(A)). ¹

¹OIG-HHS Report, Page 2, http://oig.hhs.gov/oas/reports/region2/21601011.pdf



TennCare to Submit Non-340B Claims for Federal Rebates

- Effective with dates of service on and after **5/1/2021**, all pharmacy claims that are not identified as being purchased via the 340B pricing program will be submitted for Federal Rebates and Supplemental Rebates (if applicable).
- Effective with dates of service on and after **7/1/2021**, all physician administered medical claims that are not identified as being purchased via the 340B pricing program will be submitted for Federal and Supplemental Rebates (if applicable).



TennCare to Submit Non-340B Claims for Federal Rebates

- It is imperative that 340B covered entities, both pharmacy and medical, accurately identify and submit each claim as outlined to avoid receiving duplicate discounts from drug manufacturers.
 - Any claim purchased via the 340B pricing program that is not identified correctly by the covered entity will be considered rebate eligible and are subject to investigative audits from TennCare and the drug manufacturer.
- As a reminder, TennCare does <u>**not**</u> recognize contract pharmacies as 340B providers and will continue to submit all claims from contract pharmacies for Federal Rebates and Supplemental Rebates (if applicable).



For questions or issues related to claims processing for 340B pharmacy claims, please contact your Optum Provider Educator:

East Tennessee - Heather Cline

Phone: (952) 324-4308 Email: <u>heather.cline@optum.com</u>

Middle Tennessee - Ginger Stoves Phone: (956) 662-6361 Email: ginger.stoves@optum.com

West Tennessee - Jud Jones Phone: (952) 324-4045 Email: <u>robert.j.jones@optum.com</u>



For questions or issues related to 340B medical claims processing, please contact one of the following:

> Amerigroup Phone: 1-800-454-3730 Email: Intprorel@amerigroup.com

BlueCare

Phone: 1-800-468-9736 Email/Website: Log on to the Availity website at: www.availity.com to contact us via email

UnitedHealthcare Phone: 1-800-690-1616 Email/Website: <u>http://www.uhcprovider.com/</u>



For questions or issues related to upcoming changes for 340B pharmacy or 340B medical policy changes, please contact either of the following individuals at TennCare:

> Ray McIntire, D.Ph. Phone: (615) 507-6497 Email: <u>raymond.mcintire@tn.gov</u> Toni Chavis Phone: (615) 507-6363 Email: <u>toni.chavis@tn.gov</u>



For pharmacy questions or issues related to the 340B estimated ceiling price, please contact the Myers and Stauffer Help Desk at:

> Phone: (800) 591-1183 Email: <u>tnpharmacy@mslc.com</u>





THANK YOU