State of Tennessee, Division of TennCare
340B Program Changes - Frequently Asked Questions

General 340B Information

- *The Division of TennCare[SM] has announced billing requirements for providers whose National Provider Identifier (NPI) is listed on the HRSA Medicaid Exclusion File and participate in the federal 340B Drug Pricing Program.*
- *Effective for dates of service beginning **May 1, 2021**, TennCare has implemented changes to the claim's submission and adjudication requirements for 340B pharmacy claims.*
- *Effective for dates of service beginning **May 1, 2021**, TennCare's MCO's is accepting from participating 340B providers, professional and facility claims with separately payable drug claims for outpatient administered drugs with one of the following modifiers:*
    - ***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)*
    - ***UD** — Drug or biological acquired **with** the 340B drug pricing program discount*
    - ***UC** — Drug or biological acquired **without** the 340B drug pricing program discount*
- *Effective for dates of service beginning **December 1, 2021**, TennCare's MCO's will require the modifiers on all professional and facility encounter with separately payable drug claims for outpatient administered drugs as indicated by the NDC number. If a modifier is not included, that line of the claim will be disallowed, and the remaining lines of the claim may be eligible for payment. Line level denials will be indicated with the following:*
    - *Reason code 16 – Claim/Service lacks information or has submission/billing error(s).*
    - *Remark code N822 – Missing procedure modifier(s).*
- ***There will be no change to the reimbursement of physician administered drugs submitted to TennCare's MCO's.***

- *Effective for dates of service **July 1, 2021**, TennCare will begin to submit all claims for professional and facility encounter with separately payable drug claims for outpatient administered drugs that are not identified as being purchased via the 340B drug pricing program for federal rebates.*

340B Questions from Medical Providers

Q1. Who are 340B covered entities?

Q2. How do I know if I am a participating 340B provider? How can I update my participation status?

Answer: *This definition can be found on the Health Resources & Services Administration's (HRSA's) website: "**Eligible health care organizations/covered entities** are defined in statute and include HRSA-supported health centers and look-alikes, Ryan White clinics and State AIDS Drug Assistance programs, Medicare/Medicaid Disproportionate Share Hospitals, children's hospitals, and other safety net providers. See the full list of eligible organizations/covered entities."*

Providers can check their 340B Participation status.

Q3. How do providers correctly report 10-digit NDC as 11 digits for encounter purposes?

Q4. How are the claims that are not submitted with an 11-digit NDC code handled?

Q5. What happens if the providers bill NDC units on the claim incorrectly?

Answer: *Any medical claim filed with a drug HCPCS code must have fully compliant NDC information, including the 11-digit NDC and unit/unit of measure information. Claims lacking a valid 11-digit NDC code will be rejected. This requirement is aligned with the TennCare Encounter Policy BTC-Pol-Enc-200701-001, NDC Submission for HCPCS Drug Claims, which provides information to providers on how to correctly report 10-digit NDCs as 11 digits for encounter purposes.*

Providers are expected to bill the claim correctly with the appropriate NDC units. Claims are subject to retrospective audit and providers may be contacted for additional supporting NDC information.

Q6. How do you define "Covered Outpatient Drug?"

Answer: *Covered Outpatient Drug is defined in federal regulations at 42 CFR 447.502.*

Q7. How will TennCare identify 340B drugs?

Answer: *For pharmacy claims, TennCare will identify 340B drugs on claims submitted by 340B covered entities with a value of "08" in the submission clarification code field AND a value of "20" in the basis of cost determination field.*

For outpatient medical claims, TennCare will identify 340B drugs on claim lines submitted by 340B covered entities that include the "JG", "TB", or "UD" modifier codes.

Q8. One of the new requirements introduced was to attach a UC modifier for non-340B claims. Are you referring to all non-340B claims submitted to TennCare (e.g., inpatient claims)? Or is this referring ONLY to outpatient medical claims that include a product that is excluded from the 340B program?

Q9. Do the new changes apply to all medical claims or just outpatient or physician administered drugs?

Q10. Do the new changes apply to drugs paid by the PBM only, or will the MCC's be requiring claims modifiers and using the CP file?

Answer: *Effective for dates of service beginning* ***May 1, 2021****, TennCare's MCO's is accepting from participating 340B providers, professional and facility claims for outpatient administered drugs with one of the following modifiers: "JG", "TB", "UD" or "UC".*

The "UC" modifier requirement applies to all outpatient medical claims that are for drugs that were not purchased via the 340B pricing program, and the MCO's will begin to accept the "UC" modifier, along with the other modifiers effective with dates of service beginning ***May 1, 2021****.*

Effective for dates of service beginning ***December 1, 2021****, TennCare's MCO's will require the use of all modifiers, on all professional and facility encounter with separately payable drug claims for outpatient administered drugs as indicated by the NDC number. If a modifier is not included, that line of the claim will be disallowed, and the remaining lines of the claim may be eligible for payment. Line level denials will be indicated with the following:*

- *Reason code 16 – Claim/Service lacks information or has submission/billing error(s).*

- *Remark code N822 – Missing procedure modifier(s).*

These requirements apply only to drugs paid by TennCare's MCO's. **The ceiling price will not be used and there will be no change to the reimbursement of physician administered drugs submitted to TennCare's MCO's.**

Q11. What is the benefit for 340B providers to identify claims?
Q12. Is this change mandated by the Federal government or what is the reason we want to make this change?

Answer: *TennCare is making this change to comply with CMS's mandate that all claims for covered outpatient drugs be submitted for federal rebates, and to ensure that TennCare, as a payor of last resort, does not overpay for covered outpatient drugs that are submitted as purchased via the 340B drug pricing program.*

Since TennCare is required by CMS to submit all claims paid for covered outpatient drugs for federal rebates, it is a benefit for the 340B provider to correctly identify claims with covered outpatient purchased outside of the 340B drug pricing program, so the State will not submit claims that were purchased via the 340B drug pricing program, and thereby avoid duplicate discounts, which would result in audits and other possible actions against the covered entity.

Q13. For dual eligible patients, can both the JG or TB modifier and the UD modifier be on the claim?

Q14. For dual-eligible patients, TennCare MCOs are only requiring one modifier, correct. Providers would not also need to add the UD modifier.

Q15. For patients only with TennCare coverage, will all medications that are purchased at 340B pricing be required to have the UD modifier? This would include medications with CMS Status Indicator of K that that would have a JG modifier for dual eligible patients and medications with CMS Status Indicator of G that would have a TB modifier for dual eligible patients.

Q16. Materials shared on the webinar reference JG and TB drugs, which are status indicator K and Status Indicator G drugs with Medicare. The drugs subject to JG and TB are a subset of all drugs administered in a hospital outpatient setting. We are interpreting the guidance that UD and
UC modifiers would only apply to the equivalent of JG and TB drugs for Medicare. Assuming status indicator "F", "L", "M", and "N' Drugs are not required to have

UD/UC modifier, please confirm. Future changes in the submission of UD/UC modifier would be tied to changes in the guidance.
CMS publishes to JG and TB modifiers. Please confirm.

Q17. Will the UD/UC Modifier would only apply to UB-04 Revenue Codes for drugs of 634, 635, 636, and 891; and exclude any revenue codes 25X.

Q18. Will drugs administered to ED and Observation patients be included in the modifier process?

Answer: *Only one of the four modifiers is required. "JG", "TB", or "UD" will be used to identify claims that contain a drug purchased via the 340B drug pricing program and "UC" will used for any other professional and facility claims for outpatient administered drugs that were not purchased via 340B.*

As long as the claim contains any of the "JG", "TB" or "UD" modifiers, TennCare will recognize the claim as being submitted for a covered outpatient physician-administered drug that was purchased via the 340B drug pricing program, and will not submit such claims for federal rebates.

The modifiers will be required on all professional and facility claims for outpatient physician-administered drugs, regardless of the CMS Status Indicator, or Revenue Codes.

*Effective for dates of service beginning **May 1, 2021**, TennCare's MCO's is accepting from participating 340B providers, professional and facility encounter with separately payable drug claims for outpatient administered drugs, for all CMS Status Indicator types and Revenue Code types, with one of the following modifiers: "JG", "TB", "UD" or "UC".*

*Effective for dates of service beginning **December 1, 2021**, TennCare's MCO's will require the modifiers on all professional and facility encounters with separately payable drug claims for outpatient administered drugs as indicated by the NDC number, for all CMS Status Indicator types and Revenue Code types. If a modifier is not included, that line of the claim will be disallowed, and the remaining lines of the claim may be eligible for payment. Line level denials will be indicated with the following:*

- *Reason code 16 – Claim/Service lacks information or has submission/billing error(s).*
- *Remark code N822 – Missing procedure modifier(s).*

Q19. Will TennCare publish a schedule of the calculated 340B estimated ceiling price and will all MCOs use the same schedule? How often will the 340B estimated ceiling price be updated?
Q20. Please confirm that TennCare MCOs are not changing or intending to change the current billing practice for hospitals other than requiring a modifier.

Answer: *TennCare will not publish the 340B estimated ceiling price, and the 340B estimated ceiling price file will not be used by the MCO's to reimburse claims for physician administered drugs.* ***There will be no change to the reimbursement of physician administered drugs submitted to TennCare's MCO's.***

The modifier requirement is the only billing change. Hospitals/providers should already be including the NDCs and NDC quantity information on all drug line items. Please refer to the TennCare Policy regarding submission of NDC Submission for HCPCS Drug Claims for additional detail.

Q21. The threat of non-payment or denial due to the appropriate modifier being missing is alarming when modifiers might need to be added through a manual process due to the issues claims systems have in building out logic. The more complicated the process, the more likely MCOs or the PBM would deny payment due to a minor data entry error. What action steps are being taken to streamline this process?

Q22. First, related to the modifiers, hospitals are very worried about not having enough time to implement the necessary systems changes by May 1 and Due to the additional requirements and the short notice for providers, THA is requesting that TennCare delay the May 1 deadline for the implementation and allow sufficient time for hospitals' questions to be answered, systems changes to be made, and for hospitals to perform necessary audits to ensure they are sharing accurate information with the agency.

Answer: *TennCare has made changes to the timeline for implementing the 340B changes to medical providers:*

Effective for dates of service beginning ***May 1, 2021****, TennCare's MCO's* ***is accepting*** *from participating 340B providers, professional and facility encounter with separately payable drug claims for outpatient administered drugs with one of the following modifiers: "JG", "TB", "UD" or "UC".*

*Effective for dates of service beginning **December 1, 2021**, TennCare's MCO's **will require** the modifiers on all professional and facility encounters with separately payable drug claims for outpatient administered drugs, as indicated by the NDC number. If a modifier is not included, that line of the claim will be disallowed, and the remaining lines of the claim may be eligible for payment. Line level denials will be indicated with the following:*

- *Reason code 16 – Claim/Service lacks information or has submission/billing error(s).*
- *Remark code N822 – Missing procedure modifier(s).*

*Effective for dates of service **July 1, 2021**, TennCare will begin to submit all claims for professional and facility encounter with separately payable drug claims for outpatient administered drugs that are not identified as being purchased via the 340B drug pricing program for federal rebates.*

Q23. Since some programs administered by the State of Tennessee are under TennCare contracts but not specifically TennCare Medicaid, such as CoverKids, can you confirm which programs will be requiring the 340B billing requirements?

Answer: *Both the TennCare Medicaid and CoverKids will require 340B billing changes.*

Q24. Why does TennCare exclude contract pharmacies from their 340B program?

Answer: *The 340B program is very difficult to operationalize for states and for covered entities. By adding contract pharmacies to the scenario, it becomes much more difficult.*

U.S. Department of Health & Human Services, Office of Inspector General "has identified a number of challenges and inconsistencies arising from the widespread use of contract pharmacy arrangements."[2] Please find the Presentation made by OIG to the U.S. Senate in 2018 which describes these challenges on pages 5 through 9.

340B Questions from Pharmacy Providers

Q1. What is happening?

Answer: *Effective for dates of service beginning **May 1, 2021**, a 340B estimated ceiling price is available and 340B claims are reimbursing at the lower of the 340B estimated ceiling price plus the pharmacy's PDF, the pharmacy's submitted 340B acquisition cost plus PDF, or the pharmacy's U&C.*

Q2. Who are 340B covered entities?
Q3. How do I know if I am a participating 340B provider? How can I update my participation status?

Answer: *This definition can be found on the Health Resources & Services Administration's (HRSA's) website: "***Eligible health care organizations/covered entities** are defined in statute and include HRSA-supported health centers and look-alikes, Ryan White clinics and State AIDS Drug Assistance programs, Medicare/Medicaid Disproportionate Share Hospitals, children's hospitals, and other safety net providers. See the full list of eligible organizations/covered entities."

Providers can check their 340B participation status anytime.

Providers can contact HRSA directly to update their participation status. The participating status listing includes the provider's NPI.

Q4. How will the reimbursement be calculate using ceiling price?

Answer: *Effective with dates of service beginning **May 1, 2021**, any 340B identified drug that is processed via OptumRx, TennCare's PBM, is compared to the TennCare 340B Quarterly Ceiling Price. The total reimbursement for a 340B drug is the lesser of the pharmacy's submitted acquisition cost plus the pharmacy's Professional Dispensing Fee (PDF) , the pharmacy's Usual and Customary price (U&C) or the 340B estimated ceiling price plus the pharmacy's PDF.*

The Division of TennCare provides an updated ceiling price file to the PBM on a quarterly basis and the file is loaded on a prospective basis. The ceiling price for each 340B identified drug is calculated based on the NDC unit information submitted on the claim.

The ceiling price file will only be used to reimburse claims processed by the PBM.

Q5. How do providers know what the ceiling price is for a specific drug?

Answer: *The providers can log in to the HRSA 340B website using their organization's Federal username and password to see the ceiling price of a drug.*

Q6. What happens if the provider disagrees with the ceiling price of their claim?

Answer: *If the pharmacy disagrees with how the ceiling price was applied to their claim reimbursement, they should contact their applicable OptumRx provider educator for assistance. The claim will be reviewed and the educator will inform the provider that the claim was processed using the lower of the 340B estimated ceiling price plus PDF, the provider's submitted 340B acquisition cost plus PDF, or the U&C. See below for claim scenarios:*

Scenario 1:
Provider Submitted 340B Acquisition Cost plus PDF: $50.00
U&C: $100.00
Ceiling Price plus PDF: $110.00

This claim would be reduced to the submitted amount of $50.00 since it is the least of the three rates.

Scenario 2:
Provider Submitted 340B Acquisition Cost plus PDF: $500.00
U&C: $205.00
Ceiling Price plus PDF: $50.00

This claim would be reduced to the ceiling price amount of $50.00 since it is the least of the three rates.

If the pharmacy continues to disagree with the claims that have been reimbursed using the ceiling price and they have verified the ceiling price rate through the HRSA 340B website, they can contact Myers and Stauffer for assistance at:
Phone: 800-591-1183
Email: tnpharmacy@mslc.com

References:

Health Resources & Services Administration (HRSA)
U.S. Department of Health & Human Services Office of Inspector General, Testimony Before the United States Senate Committee on Health, Education, Labor and Pensions, “Examining Oversight Reports on the 340B Drug Pricing Program”