340B Drug Price Ceiling

State of Utah
Division of Integrated Healthcare
January 2024

To:	Social Services Appropriations Subcommittee
From:	Jennifer Strohecker, State Medicaid Director
Subject:	340B Drug Price Ceiling

Purpose

In its June 2024 interim meeting, the Social Services Appropriations Subcommittee approved the following reporting request (#4):

> *Request the Department of Health and Human Services to report to the Social Services Appropriations Subcommittee by January 1, 2025 on (1) an update on establishing a 340B drug price ceiling and (2) estimated savings to the State by funding source.*

As requested by the Social Services Appropriations, the Department of Health and Human Services (DHHS) submits the following report.

Executive summary

Section 340B of the Public Health Service Act requires pharmaceutical manufacturers participating in Medicaid to sell outpatient drugs at discounted prices to health care organizations that care for many uninsured and low-income patients; this program has been in place for over 30 years. Medicaid programs may not seek rebates under the Medicaid Drug Rebate Program (MDRP) for 340B eligible drugs. Providers billing Utah Medicaid add 340B identifiers to their claims, alerting Medicaid of a 340B dispensed product, so that Medicaid does not pursue manufacturer drug rebates. Those claims are excluded from the invoices to manufacturers for MDRP rebates.

Utah Medicaid does not have differential prices for 340B versus non-340B drugs. Instead, providers billing 340B drugs are required to submit their actual acquisition cost (AAC) of the 340B drug.[1]

Over time, Utah Medicaid has observed that some providers may not have billed using the AAC for

[1] See the Pharmacy Provider Manual, Section VI.A.

their 340B dispensed drugs. Utah Medicaid made referrals to the Utah Office of Inspector General of Medicaid Services (UOIG) for investigation.

While it appears providers may be billing more appropriately, there are still some that are not billing AAC. To address that, beyond the UOIG, Utah Medicaid is working towards implementing an automated system control mechanism to ensure compliance with 340B reimbursement requirements; this will be done with the new Pharmacy Benefit Manager (PBM) contract with the Point-of-Sale system (*estimated implementation in March 2026)*. A 340B ceiling price will be established and serve as an upper payment limit at the point-of-sale (POS) for Fee-For-Service (FFS) drug claims. Claims indicated as 340B that have billed charges in excess of the "ceiling price" will be reimbursed at the most current ceiling price available . Given the billing policy, that claim should be billed at AAC.

Looking at claims data, if we were to have limited to not paying more than the ceiling price, Utah Medicaid could have saved an estimated $226,600 (Total Funds) from January 2023 to September 2023. Additional savings would be realized with a requirement for Accountable Care Organizations (ACOs) to follow this same policy.

Expansion Funds	$11,900
General Funds	$39,800
Federal Funds	$174,900
Total Funds	**$226,600**

Background

The 340B program was established in 1992 by Section 340B of the federal Public Health Service Act. This program requires pharmaceutical manufacturers that participate in the Medicaid program (essentially all pharmaceutical manufacturers) to sell covered outpatient drugs at greatly discounted prices (at or below 340B ceiling price) to Covered Entities. Covered entities are certain healthcare providers and programs that meet certain eligibility requirements and typically serve high volumes of low-income patients.

Per the American Hospital Association, "These organizations include federal grantee organizations and several types of hospitals, including critical access hospitals (CAHs), sole community hospitals (SCHs), rural referral centers (RRCs), and public and nonprofit disproportionate share hospitals (DSH) that serve low-income and indigent populations.

The program allows 340B hospitals to stretch limited federal resources to reduce the price of outpatient pharmaceuticals for patients and expand health services to the patients and communities they serve. Hospitals use 340B savings to provide, for example, free care for uninsured patients, offer free vaccines, provide services in mental health clinics, and implement medication management and community health programs.

According to the Health Resources and Services Administration (HRSA), which is responsible for administering the 340B program, enrolled hospitals and other covered entities can achieve average savings of 25% to 50% in pharmaceutical purchases."[2]

340B eligible drugs are not eligible for rebates under the MDRP since duplicate discounts are prohibited (42 USC 256b (a) (5) (A) (i); therefore, manufacturers cannot be invoiced by states for Medicaid rebates for drugs purchased at a 340B discount.

Need for additional action

As outlined in the Utah State Plan Amendment (SPA), Attachment 4.19-B (S), Utah Medicaid requires Fee-for-Service (FFS) providers to bill their 340B claims at AAC to ensure Utah Medicaid also sees a benefit of the lower cost drugs to the provider. In addition to the drug reimbursement, a pharmacy would also receive a reasonable professional dispensing fee. This requirement does not currently apply to Accountable Care Organization (ACO) POS claims.

For many years, the Centers for Medicare and Medicaid Services (CMS) has been pushing Medicaid agencies to reimburse AAC on drugs in addition to a reasonable professional dispensing fee. Some of CMS' efforts include the implementation of a National Average Drug Acquisition Cost (NADAC) fee schedule. Utah Medicaid uses NADAC among other pricing options to ensure Medicaid is paying closest to AAC to cover the costs of the drug and not excessive profits.

340B providers that do not bill the 340B AAC effectively circumvent the AAC concept. Medicaid staff, who have identified providers that don't appear to align with policy in this area, have referred the providers to the UOIG for investigation and subsequent action.

In order to continually educate providers on 340B billing, many Medicaid Information Bulletins were published, including:

- Jan 2014; article 14-09
- July 2014; article 14-104
- Oct 2014; articles 14-125 and 14-126
- July 2015; article 15-58
- Jan 2016; article 16-08
- July 2018; article 18-73
- Oct 2018; article 18-97
- Nov Interim 2018; article 18-102
- Feb Interim 2019; article 19-22
- Feb Interim 2020; article 20-21

Even with all those efforts, not all providers bill appropriately. Therefore, as an additional compliance step, Utah Medicaid is implementing a "ceiling price" for the 340B POS drug claims with the new PBM POS in March 2026. This will ensure providers will not be reimbursed more

[2] https://www.aha.org/fact-sheets/fact-sheet-340b-drug-pricing-program

than the calculated 340B ceiling price. In some cases, it could be possible that the 340B indicator was put on the claim and the drug was not 340B eligible. In either case, correction to the claim is warranted. With the proposed policy for managed care pharmacy PDL alignment and reimbursement, ACOs would be required to follow Medicaid reimbursement methodology, which requires reimbursement of 340B claims at AAC. The ceiling price is confidential and can't be shared with the ACOs to be used for claims adjudication; therefore, Utah intends to re-adjudicate the ACO 340B claims in the new POS system to identify claims out of compliance.

Conclusion

To guarantee compliance with 340B requirements, Medicaid must prevent reimbursing 340B providers more than their AAC, as duplicate discounts are prohibited. Currently, Utah Medicaid relies on referrals to the UOIG to ensure compliance. Beginning in Spring 2026, Utah Medicaid will have its new POS claims system apply the 340B ceiling price to reimburse claims, ensuring reimbursement does not exceed this price. This will also require a SPA to implement these changes, which must be approved by CMS. Ongoing provider education and claim reviews will be conducted to maintain system controls and ensure both providers and the Medicaid program adhered to the 340B program requirements. Application of this policy within the ACO pharmacy programs would further contribute to realized savings. In conclusion, these efforts are critical for compliance and to maximize cost-savings for the program.

Recommendations

There are no recommendations.