NEW YORK STATE OF OPPORTUNITY. Department of Health

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New System Edit to be Implemented to Validate the Ingredient Cost for 340B drugs

As previously communicated in the **January** and **December** issues of the 2018 *Medicaid Update*, 340B drug claims submitted to Medicaid via the National Council for Prescription Drug Programs (NCPDP) D.0 format are:

- required to be properly identified as 340B for both fee-for-service (FFS) and Medicaid Managed Care (MMC) members; as well as
- submitted at the 340B acquisition cost by invoice to the provider for FFS members, net any manufacturer discounts and/or other price reductions.

The following fields are required on Medicaid 340B drug claims submitted via NCPDP:

Field	Medicaid Primary Claim	Medicaid Secondary Claim (Primary: Medicare; Commercial)
420-DK, Submission Clarification Code (SCC)	20	20
423-DN, Basis of Cost Determination (BCD)*	08	No Requirements Specific to Medicaid
409-D9, Ingredient Cost Submitted*	**340B Acquisition Cost**	**No Requirements Specific to Medicaid**
426-DQ, Usual and Customary Cost (U&C) **	Lowest Net Charge to Cash Customers	Lowest Net Charge to Cash Customers

*MMC plans should be consulted on their requirements for this field.
**U&C is defined as the lowest price charged to the general public after all applicable discounts, including promotional discounts and discounted prices associated with loyalty programs.
Note: All 340B claims are subject to audit and investigation; in addition, claims improperly identified as 340B and/or claims with unsubstantiated Acquisition Cost may be considered fraudulent claims.

Effective September 12, 2019, for Medicaid FFS primary claims only, system editing will compare the ingredient cost submitted (NCPDP field 409-DK) with the 340B ceiling price for the product, as defined by Health Resources & Services Administration (HRSA). The 340B ceiling price refers to the maximum amount that a manufacturer can charge a covered entity for the purchase of a 340B covered outpatient drug.

The 340B ceiling price is statutorily defined as the Average Manufacturer Price (AMP) reduced by the rebate percentage, which is commonly referred to as the Unit Rebate Amount (URA). HRSA obtains the AMP and URA data from the Centers for Medicare & Medicaid Services (CMS) as part of quarterly reporting for the Medicaid Drug Rebate Program. This figure is then multiplied by the package size and case package size to produce a price that is used in the marketplace for purchasing covered outpatient drugs. For example, the AMP minus the URA indicates the cost of one pill.

Any pharmacy that submits a 340B drug claim where the ingredient cost submitted is higher than the ceiling price will return MEVS Rx Denial code “708” (Exceeds NY Allowed Maximum) and NCPDP Reject code "23" (M/I Ingredient Cost). The pharmacy would then have to resubmit the claim with the correct ingredient cost.

Billing questions regarding the FFS program should be directed to the eMedNY Call Center at (800) 343–9000. Policy questions regarding NYS Medicaid 340B should be directed to: ppno@health.ny.gov.

Billing questions regarding MMC plans should be directed to the specific MMC plan.

Helpful Information:

- FAQs on HRSA's 340B program, as well as information on how to ask additional questions, can be found on the HRSA website at: https://www.hrsa.gov/opa/faqs/index.html.
- Information on HRSA requirements when Covered Entities use 340B drugs for Medicaid patients can be found at the following site: https://www.hrsa.gov/opa/programrequirements/medicaidexclusion/index.html.
- eMedNY Transaction Instructions: https://www.emedny.org/HIPAA/5010/transactions/index.aspx