Frequently Asked Questions: 340B Drug Pricing Program

OHIO DEPARTMENT OF MEDICAID

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Prescribed drugs purchased through the 340B drug discount pricing program are not eligible for Medicaid drug rebates. ODM has developed the following practices to assist 340B covered entities (CE) in their obligation to avoid duplicate discounts.

Does Ohio Medicaid seek drug rebates under the Medicaid Drug Rebate Program for covered outpatient drugs dispensed/administered in its fee-for-service (FFS) program? Yes.

Does Ohio Medicaid seek drug rebates under the Medicaid Drug Rebate Program for covered outpatient drugs dispensed/administered in its managed care programs (MCP)?

To facilitate 340B CEs' ability to identify Medicaid managed care plans from other lines of business with the same parent company and/or PBM, we have asked each of the managed care plans to use a BIN/PCN combination that is specific to Medicaid, and does not apply to any other lines of business (e.g., Medicare, commercial). The list is on our website at http://pharmacy.medicaid.ohio.gov under the link "MyCare Ohio and MCP Pharmacy Reference Guide". The first page is Medicaid only, the second page is our Medicare/Medicaid plans (pharmacy is primarily Medicare Part D, not Medicaid).

For 340B CEs that choose to place themselves on HRSA's Exclusion File, does Ohio Medicaid utilize the Exclusion File to exclude a CE's covered outpatient FFS drug claims from Medicaid rebate invoicing?

For pharmacy claims (NCPDP format), ODM requires the covered entity to identify claims for drugs purchased through the 340B program, and to submit the 340B actual acquisition cost plus cost of dispensing as the Gross Amount Due (NCPDP Field 43Ø-DU). The claim must be identified as 340B by submitting Submission Clarification Code (NCPDP Field 42Ø-DK) = 20 and Basis of Cost (NCPDP Field 423-DN) = 08.

For hospitals and non-institutional providers ODM will use claim indicator (modifier) SE as the only source that the drug should be excluded from rebate for outpatient and professional FFS claims. The use of the SE modifier is limited to only those providers that are 340B covered entities. The use of the SE modifier by non-340B covered entities will result in claim denial beginning 9/1/18. ODM will use HRSA's Covered Entity Daily Report instead of the Medicaid exclusion file for this new process. HRSA's publicly available daily report lists all active and inactive covered entities in the 340B program. Using a daily file in this process provides more accuracy as compared to the exclusion file, which is updated quarterly. This new process will ensure ODM remains in compliance with 340B drug pricing program regulations and the Medicaid Drug Rebate Program.

For CEs who choose to place themselves on HRSA's Exclusion File, may the CEs seek reimbursement from Ohio Medicaid for drugs dispensed to Ohio Medicaid FFS patients?

Yes. However, in order to offset the rebate loss to Medicaid for each 340B drug dispensed or administered to a Medicaid patient, the charge submitted to Medicaid on a pharmacy (NCPDP) claim must be for the CE's actual acquisition cost of the drug plus the CE's cost of dispensing.

Does Ohio Medicaid recognize a 340B CE's contract pharmacy, and exclude those claims from rebate?

The Contract Pharmacy Services Guidelines published in the Federal Register (March 5, 2010; 75(43): 10278) states that, "Neither party will use drugs purchased under section 340B to dispense Medicaid prescriptions, unless the contract pharmacy and the state Medicaid agency have established an arrangement to prevent duplicate discounts."

Ohio Medicaid has established no arrangements with contract pharmacies, and in this way prohibits the use of contract pharmacies for 340B drugs dispensed/administered to Medicaid patients.

Does Ohio Medicaid seek rebates for orphan drugs used for orphan designations?

Yes, for certain CEs that are excluded from access to 340B drug pricing when it is used for a rare disease or condition (free-standing cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals), Medicaid will seek drug rebates.