



Medicaid Exclusion File Basics

Rockville MD 20857

The 340B statute expressly prohibits covered entities from billing to Medicaid a drug purchased under 340B if a State can also seek a rebate on that drug under section 1927 of the Social Security Act (a “duplicate discount”). Pursuant to the statute, the Secretary implemented the Medicaid Exclusion File as the mechanism in place to prevent duplicate discounts (58 Fed. Reg. 34058 (June 23, 1993) and 59 Fed. Reg. 25110 (May 13, 1994)). Accordingly, all covered entities that use 340B and bill Medicaid MUST follow these rules:

1. If you plan to bill Medicaid for any covered outpatient drugs purchased under the 340B Drug Pricing Program, you must provide to the Office of Pharmacy Affairs (OPA) the Medicaid provider number or National Provider Identification (NPI) number used to bill Medicaid for 340B covered outpatient drugs. If the appropriate Medicaid billing number is not listed on the OPA database, and you use 340B drugs to fill Medicaid prescriptions, you should contact OPA immediately to include the correct number on the OPA exclusion file database.
2. If you do not bill Medicaid for drugs purchased under the 340B Drug Pricing Program, you should not provide your Medicaid provider number/NPI to the OPA. The purchase by 340B covered entities of Medicaid prescriptions outside of the 340B Program is commonly referred to as “carving out” Medicaid prescriptions. If you “carve out” Medicaid, but your Medicaid provider number/NPI is listed on the OPA exclusion file database you should contact OPA to remove it immediately.
3. At the outset, it is the decision of the covered entity to decide whether or not to use 340B purchased outpatient drugs when billing Medicaid under a particular Medicaid provider number/NPI, however, the covered entity must be consistent. If the covered entity decides to bill to Medicaid for drugs purchased under 340B with a Medicaid provider number/NPI, then ALL drugs billed to that number must be purchased under 340B and that Medicaid provider number/NPI must be listed on the OPA exclusion file database. If the covered entity decides to purchase drugs from outside the 340B program (i.e. “carve out”) for their Medicaid prescriptions then ALL drugs billed under their Medicaid provider number/NPI must NOT be purchased under 340B, and that Medicaid provider number/NPI should not be listed on the OPA exclusion file database.
4. Any changes in billing Medicaid, involving these rules must be reported to OPA before implementation and it is the entity’s responsibility to ensure that the posted database information is correct.
5. Most covered entities will bill Medicaid under their pharmacy’s Medicaid provider number/NPI, while some may bill Medicaid under the clinic’s Medicaid provider number/NPI. Covered entities should only provide their own Medicaid provider numbers and not those of contractors. If a covered entity bills drugs purchased under 340B with more than one Medicaid provider number/NPI, it must provide all such numbers.
6. To the extent that a covered entity is unable to comply with the above or wishes to utilize alternative methods that also prevent duplicate discounts they should work with their State Medicaid Agencies and the OPA to establish sufficient safeguards.