



Medicaid Exclusion Tutorial

Rockville MD 20857

The legislation that created the 340B program¹ required the Secretary of Health and Human Services to set up a mechanism to ensure that manufacturers did not pay a "duplicate discount" on a drug claim. A "duplicate discount" would occur if an up-front 340B discount AND a back-end transaction Medicaid rebate were provided on the same drug. The mechanism the Secretary established to comply with the legislation's mandate to prohibit duplicate discounts is a part of the Office of Pharmacy Affairs (OPA) database called the Medicaid Exclusion File (58 Fed. Reg. 34058 (June 23, 1993) and 59 Fed. Reg. 25110 (May 13, 1994)).

The OPA is part of the federal government and is tasked with administration of the 340B Program and the Medicaid Exclusion File. The data from the Medicaid Exclusion File is used by 340B stakeholders such as State Medicaid Agencies and manufacturers, to ensure that duplicate discounts are not paid on the same drug claim. The Medicaid Exclusion File lists the 340B entities and their associated Medicaid provider numbers and/or National Provider Identifiers (NPI). The entities listed on the Exclusion File have reported to OPA that they intend to fill Medicaid prescriptions with 340B-purchased drugs. The claims for these prescriptions are not eligible for manufacturer's rebates ("duplicate discounts"). The Medicaid agency uses the Exclusion File to determine which entities' claims must be excluded from rebate requests to manufacturers.

1. How is the data gathered for the Medicaid Exclusion File?

Upon enrollment into the 340B Program, OPA collects two critical pieces of information for entry into the Medicaid Exclusion File:

- 1.) whether the entity intends to fill Medicaid prescriptions with 340B-purchased drugs, and
- 2.) the entity's Medicaid provider number/NPI, if the 340B entity is using 340B-purchased drugs for their Medicaid patients' prescriptions.

OPA will post the Medicaid provider number/NPI of the covered entities that use 340B drugs for Medicaid prescriptions in the field "Medicaid Number" on the covered entity's database file. If the entity is not using 340B-purchased drugs for their Medicaid prescriptions, typically called "carving out," this field should indicate "N/A."

The Medicaid Exclusion File is used by different stakeholders to prevent duplicate discounts from occurring. For example, a State Medicaid Agency may use the File to obtain information about which claims to exclude from rebate requests, or a manufacturer may use the File to verify that a rebate should be paid on a claim originating from a particular entity. To use the Exclusion File, click on <http://opanet.hrsa.gov/opa/CE/CEMedicaidExtract.aspx>. To perform a State-specific search for the entities in a specific State that should have their drug claims excluded from Medicaid Rebate submissions, select the appropriate State code and press the "Submit Query" button.

¹Section 602 of Public Law 102-585, <http://www.hrsa.gov/opa/pl102585.htm>

As providers are issued NPIs, as required by CMS, the OPA will be working with States to replace the current Medicaid Provider Number shown in the Medicaid Exclusion File with the corresponding NPI for that provider. During the transition time, the Medicaid Exclusion File will report both the Medicaid Provider Number and the NPI. This will provide stakeholders with two options for identifying entities.

2. What determines whether or not an entity will be listed in the Medicaid Exclusion File?

The decisions made by an entity regarding the utilization of 340B-purchased drugs to fill Medicaid prescriptions for their patients will determine their inclusion in/exclusion from the Medicaid Exclusion File.

Entities are permitted to contract with a pharmacy to provide dispensing services for the entity's 340B drugs. In this arrangement the 340B entity purchases the drugs, and the drugs are usually shipped to the pharmacy (the wholesaler bills the covered entity and the wholesaler ships the drugs to the contract pharmacy).

Generally, 340B entities do not include Medicaid prescriptions as part of the agreement with a contract pharmacy. In this case, all of the prescriptions from the entity are filled by the contract pharmacy using 340B prices **except for** the Medicaid prescriptions. The Medicaid prescriptions are filled by the (contract) pharmacy or any other pharmacy where the patient chooses to take the prescription, using non-340B inventory. 340B purchased drugs are not used to fill these Medicaid prescriptions.

In this scenario, there is no reason for OPA to have the Medicaid number/NPI of the contract pharmacy in the OPA database, since no Medicaid prescriptions are filled using drugs purchased at 340B prices. Providing OPA with the Medicaid number/NPI of the contract pharmacy in this situation might cause the Medicaid agency to unnecessarily forego rebates on Medicaid claims filled by this pharmacy.

There are a few reasons that most 340B entities exclude Medicaid prescriptions from their contracts with contract pharmacies:

-- Contract pharmacies and Medicaid agencies generally have not "establish[ed] an arrangement to prevent duplicate discounting."

The contract pharmacy services guidelines published in the Federal Register (<ftp://ftp.hrsa.gov/bphc/pdf/opa/FR08231996.htm>) state in section C (1) (i): "Both parties will not 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 discounting."

--Clinics sometimes lose money on Medicaid prescriptions when they are filled with 340B purchased drugs.

Clinics that bill Medicaid at cost for drugs purchased under the 340B program must bill at their 340B acquisition cost. The dispensing fee is often inadequate to cover the true costs of dispensing. Therefore, many 340B entities and contract pharmacies prefer to exclude Medicaid prescriptions from the 340B contract pharmacy agreement.

--Most clinics and pharmacies are aware that the Medicaid anti-kickback statute is very broad, and are wary of including Medicaid prescriptions in their contracts.

The contract pharmacy services guidelines published in the Federal Register (<ftp://ftp.hrsa.gov/bphc/pdf/opa/FR08231996.htm>) state in section C (3):

“In negotiating and executing a contracted pharmacy service agreement pursuant to these guidelines, contractors and covered entities should be aware of and take into consideration the provisions of the Medicare and Medicaid anti-kickback statute, 42 U.S.C. 1320a-7b(b). This statute makes it a felony for a person or entity to knowingly and willfully offer, pay, solicit, or receive remuneration with the intent to induce, or in return for the referral of, Medicare or a State health care program business.”

Summary Questions

1. What is the Medicaid Exclusion File?

- It is a data tool on the Internet.
- It helps Medicaid agencies comply with a specific 340B statutory provision: that drugs purchased at 340B prices must be excluded from Medicaid rebate requests to drug manufacturers.
- For certain 340B entities, the Medicaid Exclusion File lists the 340B entity name, and the entity’s Medicaid provider number(s)/NPI.

2. Why must Medicaid agencies forego rebates on 340B purchased drugs?

- The 340B legislation prohibits Medicaid agencies from collecting rebates on drugs purchased at 340B prices because this practice would result in “duplicate discounts.”
- The “duplicate discount” would occur if an up-front 340B discount and back-end Medicaid rebate were provided on the same drug/drug claim.

3. Which Medicaid Provider and NPI numbers should our entity submit to OPA?

- The entity should submit Medicaid Provider and NPI numbers that are associated with the parts of the entity that dispense or administer 340B purchased drugs to Medicaid patients. This is most often the pharmacy’s Medicaid provider number/NPI, but could also be the clinic Medicaid provider number/NPI or a combination of both, depending upon the services at the clinic. For more information, contact PSSC at 1-800-628-6297.

4. What if our entity uses 340B for some Medicaid patients and not for others? What Medicaid Provider Number and NPI should we submit?

- It is the entity’s responsibility to work with the Medicaid Agency in each state to ensure that 340B purchased drugs can be identified by Medicaid Agencies and rebates foregone.
- OPA requests that the information in the Medicaid Exclusion File reflect what is occurring at that entity for ALL of its Medicaid patients. The Medicaid Exclusion File is not intended to support entities which “pick and choose” how they bill Medicaid on a case-by-case basis. If the Medicaid Provider number/NPI is listed in the Medicaid Exclusion File that Medicaid provider number should always be used to bill Medicaid for 340B purchased drugs.

5. Why would 340B entities want to exclude Medicaid prescriptions from their contracts?

- Most contract pharmacies and Medicaid agencies do not “establish an arrangement to prevent duplicate discounting.”
- Clinics sometimes lose money on Medicaid prescriptions when they are filled with 340B purchased drugs.
- Most clinics and pharmacies are aware the Medicaid anti-kickback statute is very broad, and are wary of including Medicaid prescriptions in their contracts.