

Purpose: This tool is a checklist of common errors reflected in the Medicaid Exclusion File (MEF) that can increase a covered entity's risk of causing duplicate discounts. As a best practice, covered entities should review their information in 340B Office of Pharmacy Affairs Information System (OPAIS) and MEF on a quarterly basis.

Background: Incorrect or incomplete information in 340B OPAIS will be reflected in the extracted MEF and could result in duplicate discounts or inaccurate database findings. Action steps when recognizing an error should always include determining whether the error caused any state to inappropriately submit a manufacturer rebate claim and, if so, whether the claim was paid by the manufacturer (a duplicate discount) as well as determining whether the error caused any state to forgo a rebate that should have been collected (e.g. the covered entity was listed on the MEF but did not use 340B). Duplicate discounts are prohibited for both fee-for-service (FFS) Medicaid and Medicaid provided through a managed care organization (MCO). The covered entity would need to work with the state and to reach out to the manufacturer in good faith to resolve the issue and determine whether the infraction met the material breach threshold needed to self-report to HRSA.

Core Understandings:

Medicaid Exclusion File

1. On the Medicaid billing tab in OPAIS, each covered entity site answers "yes" or "no" to the question, "At this site, will the covered entity bill Medicaid FFS for drugs purchased at 340B prices?" When the site answers "yes", it then lists each state billed and the associated billing number(s) used to bill the state. The MEF is specific to FFS Medicaid.
2. The term "carve-in" describes a site's practice to dispense 340B drugs to certain state's Medicaid FFS beneficiaries.
3. The billing number(s) used to bill a state are most often assigned to the organization (not a specific provider) and are listed in box 56 (NPI) and 57 (other provider ID) on UB-04 / CMS-1450 billing forms.
4. Each covered entity site (each 340B ID for the parent hospital, hospital child site, grantee site or grantee associated site) is responsible for listing each state it plans to bill for 340B drugs (carve-in) and the associated billing number(s) in OPAIS such that the information can then be reflected on the quarterly MEF.
5. (Hospitals) If a parent and child site both carve in using the same NPI number, the parent and child should each register that NPI number.
6. If a material breach needs to be reviewed or if self-reporting to HRSA is required, the following additional resources for these areas may be helpful:
 - a. Prime Vendor Program Tool: [Establishing Material Breach Threshold](#)
 - b. Prime Vendor Program Tool: [Self-Disclosure to HRSA and Manufacturer Template](#)

Duplicate Discount Prevention

1. Some states have instituted additional requirements regarding the prevention of duplicate discounts for FFS claims. These may include, but are not limited to, claim modifiers and claim review processes. Check with each state in which you are billing Medicaid FFS to ensure that all requirements are met and that duplicate discounts are prevented. Regardless of a state's additional requirements, each covered entity site is responsible to maintain accurate information on the MEF.
2. Some states have placed additional and/or different requirements regarding the prevention of duplicate discounts for MCO claims. These may include but are not limited to claim modifiers and claim review processes. Check with each state in which you are billing a Medicaid MCO to ensure that all requirements are met and that duplicate discounts are prevented.

	Common Errors	Why Is This Important?	How Can You Fix This?
<input type="checkbox"/>	Typographical errors; incorrect or transposed billing number(s) such as National Provider Identifiers (NPIs) or Medicaid provider numbers (MPNs).	OPAIS does not validate entries for accuracy.	Ask your billing department to review OPAIS-registered NPI/MPN entries for accuracy. If an error/omission is found, the primary contact (PC) or authorizing official (AO) will need to submit an OPAIS change request.
<input type="checkbox"/>	Listing only an MPN, but billing using the NPI or listing only an NPI, but billing using the MPN.	Historically, MPNs were used by entities to submit state Medicaid claims. Post-HIPAA, all providers are required to obtain and use NPIs when submitting claims to CMS. Covered entities must bill Medicaid use the proper combination of NPI, MPN, or both the NPI and MPN based on the state-specific requirements.	Routinely review the MEF with your billing department to ensure that the registered provider identifier billing information matches your billing practices and the state's expected billing requirements. If an error/omission is found, the PC or AO will need to submit an OPAIS change request.
<input type="checkbox"/>	OPAIS does not reflect <u>all</u> states that receive Medicaid FFS claims from your covered entity for drugs purchased at 340B prices.	An entity can choose to dispense 340B drugs to Medicaid patients from multiple states. To do so, the entity must list each state carved-in with the associated billing number(s) in OPAIS such that the information is listed on the quarterly MEF.	Work with your billing department to identify any states that receive Medicaid FFS claims for drugs purchased at 340B prices. Confirm that the appropriate NPI/MPNs on those claims are registered in OPAIS and paired with the appropriate state.
<input type="checkbox"/>	Change in billing practice does not correspond with change in listing on the MEF (effective date).	A covered entity may change its Medicaid information in OPAIS at any time. However, changes are not reflected on the MEF until the start of the next quarter and only if the covered entity updated its OPAIS record 15 day before the start of the next quarter. Covered entities should time changes to their carve-in or carve-out practice to coincide with their listing on the quarterly MEF.	Make sure that you are considering the timing of the MEF changes when changing your billing practices. Ensure that you are aware of the timing between your change request being approved by HRSA and the date that it will be reflected in the new MEF. Confirm that your new billing information is accurate and published in the quarterly MEF. https://340bopais.hrsa.gov/medicaidExclusionFiles

<input type="checkbox"/>	A federally qualified health center (FQHC) is providing 340B drugs to Medicaid patients but sites are not listed on the MEF.	FQHCs bill and receive reimbursement from Medicaid using a prospective payment system (PPS) that includes all “incident-to” services, including administration of 340B drugs. Because Medicaid is billed for an encounter and 340B drugs were used, the covered entity must answer “yes” to the Medicaid billing question* for that FQHC site and register the appropriate NPI/MPN number on OPAIS.	The PC and AO need to submit a change request to the OPAIS website to add the appropriate NPI/MPN paired with the corresponding state. You will also need to follow state billing requirements.
--------------------------	--	---	---

For covered entities with retail pharmacies:

<input type="checkbox"/>	[Retail pharmacy]: Failing to list the billing number(s) of an entity-owned, retail pharmacy (i.e., in-house pharmacy) on the MEF that dispenses 340B medications to patients of the covered entity (i.e., carve-in).	Failing to list the billing number(s) in this instance would very likely lead to duplicate discounts. The covered entity should have the states and associated billing number(s) listed on the MEF under the 340B ID where the entity-owned pharmacy is located. If the entity-owned pharmacy is not co-located with a registered site (340B ID), the covered entity should list the Medicaid billing information under the parent 340B ID.	Review the MEF and verify that every retail pharmacy’s NPI/MPN is registered under all sites that could refer Medicaid patients to the retail pharmacy. If an error/omission is found, the PC or AO will need to submit a change request through the OPAIS website.
<input type="checkbox"/>	[Retail pharmacy]: Failing to list the billing number(s) on the MEF for all entity-owned retail pharmacies (i.e., in-house pharmacies) dispensing 340B medications to patients of the covered entity, under the parent/main site AND each child/associated site.	An entity-owned retail pharmacy subpart cannot be separately registered in OPAIS. Therefore, the only way to indicate that 340B drugs will be dispensed to Medicaid patients at these locations is to list the billing number(s) under the parent/primary site (and any affected child/associated sites). Listing the MPN or NPI with each child site is the most transparent way to document the practices at the covered entity.	Review the MEF and verify that every retail pharmacy’s billing number(s) are listed on the MEF under all sites that could refer Medicaid patients to the retail pharmacy. If an error/omission is found, the PC or AO will need to submit an OPAIS change request.

<input type="checkbox"/>	[Retail pharmacy]: A covered entity site carves-out physician administered drugs, carves-in at their entity-owned retail pharmacy, and answers “no” to the Medicaid billing question in OPAIS such that the states billed and associated pharmacy billing number(s) are not listed on the MEF.	An entity-owned retail pharmacy cannot be registered as a covered entity site in OPAIS. However, if the pharmacy carves-in, the covered entity must list the pharmacy’s billing number(s) in OPAIS such that they are listed on the MEF (even if physician administered drugs are carved-out). The covered entity should list the states the pharmacy bills with the associated billing number (s) under the parent hospital/ primary grantee 340B ID in OPAIS as well as the child/grant associated site 340B IDs that utilize the pharmacy.	In OPAIS, make sure the answer to the Medicaid billing question* is “yes” and list the states and associated billing number(s). If you haven’t already done this, your PC or AO will need to submit a change request through the OPAIS website to reflect these changes.
--------------------------	--	---	--

For covered entities with different billing practices at child sites (hospitals) or associated sites (health centers):

<input type="checkbox"/>	A covered entity site (340B ID) provides both 340B and non-340B drugs to a specific state’s Medicaid FFS beneficiaries, and bills the state using a single NPI.	The listing of an NPI in OPAIS is intended to be an all-or-nothing declaration for Medicaid claims filed with an associated state. Without an explicit arrangement with the state, it could be interpreted that all dispenses filed on a claim under the single NPI used for 340B drugs.	<p>Options include:</p> <ol style="list-style-type: none"> Change operations to be 100% carve-in or carve-out across a single NPI. Obtain a second NPI; use the one registered in OPAIS for carve-in claims and use the other for carve-out claims. Make arrangement(s) with any affected state(s) to ensure that carved-in dispenses are not submitted for rebates and carved-out dispenses are treated normally. <p>The selected process should be detailed in your entity’s policies and procedures and may include the use of claim modifiers or routine reporting processes.</p>
--------------------------	---	--	--

* “At this site, will the covered entity bill Medicaid fee-for-service for drugs purchased at 340B prices?”

These tools, written to align with Office of Pharmacy Affairs (OPA) policy, are provided only as an example for the purpose of encouraging 340B Program integrity. This information has not been endorsed by OPA and is not dispositive in determining compliance with or participatory status in the 340B Drug Pricing Program. 340B stakeholders are ultimately responsible for 340B Program compliance and compliance with all other applicable laws and regulations. Apexus encourages all stakeholders to include legal counsel as part of their program integrity efforts.