340B PVP Tools

Medicaid Exclusion File (MEF) Checklist

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 340B Office of Pharmacy Affairs Information System (OPAIS) and MEF on a quarterly basis.

Background: Incorrect 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 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). The covered entity would need to reach out to the manufacturer in good faith to resolve the issue and determine if the infraction met the material breach threshold needed to self-report to HRSA.

Core Understandings:

1. "Carve-in" describes a covered entity, child site (hospital), or associated site (FQHC / FQHC-LA) that dispenses 340B drugs to Medicaid patients.
2. National Provider Identifier (NPI) numbers referenced in this document are type-2 (organizational) and not tied to an individual.
3. Covered entities are responsible for providing each Medicaid state it plans to bill for 340B drugs and the associated billing number(s) for each of its sites listed on 340B OPAIS. Some states have placed additional requirements regarding the prevention of duplicate discounts.
4. (Hospitals) If a parent and child site both carve-in using the same NPI number, BOTH the parent and child should each roster that NPI number.

	Common Errors	Why is this important?	How can you fix this?
☐	Typographical errors; incorrect or transposed national provider identifiers (NPI) or Medicaid provider numbers (MPN).	OPAIS does not validate entries in length or accuracy.	Ask your billing department to review OPAIS-rostered 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.
☐	Listing only an MPN, but billing using the NPI.	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.	Routinely review the MEF with your billing department to ensure that the rostered provider identifier billing information matches your billing practices. If an error/omission is found, the PC or AO will need to submit an OPAIS change request.
☐	OPAIS does not reflect all states that receive Medicaid fee-for-service (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 roster the appropriate NPI/MPNs paired with the corresponding state in OPAIS.	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 rostered in OPAIS and paired with the appropriate state.

☐	Change in billing practice does not correspond with change in OPAIS (effective date).	A covered entity may change its Medicaid information in OPAIS at any time; however, changes do not take effect until a new MEF is created (normally 15 days before the start of a new quarter). Covered entities should time their operational changes to coincide with the first day of the quarter that reflects the new billing status.	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.
☐	A federally qualified health center (FQHC) is providing 340B drugs to Medicaid patients but sites are listed as carving out.	FQHCs bill and receive reimbursement from Medicaid using a prospective payment system (PPS) which includes all “incident-to” services including administration of 340B drugs. Since 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 roster 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 those covered entities with retail pharmacies:

☐	[Retail Pharmacy]: Failing to roster the NPI/MPN for an entity-owned, retail pharmacy (aka in-house pharmacy) that dispenses 340B medications to patients of the covered entity (aka carve-in).	Failing to roster an NPI/MPN in this instance would very likely lead to duplicate discounts.	Review the MEF and verify every retail pharmacy’s NPI/MPN is rostered under all sites 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.
☐	[Retail Pharmacy]: Failing to roster the NPI/MPNs for all entity-owned retail pharmacies (aka 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 rostered in OPAIS. Therefore, the only way to indicate that 340B drugs will be dispensed to Medicaid patients at these locations is to roster the appropriate NPI/MPN 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 NPI/MPN is rostered 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.

☐	[Retail Pharmacy]: Responding "No" to the MEF question* when the parent/primary site does not provide 340B drugs to Medicaid patients, but its entity-owned retail pharmacy does.	An entity-owned retail pharmacy subpart cannot be separately rostered in OPAIS. The only way to indicate 340B drugs will be dispensed at these locations is to roster the appropriate NPI/MPN under the parent/ primary site (and any affected child/associated sites), even if the entity does not dispense 340B drugs to its acute care patients.	In OPAIS, make sure the answer to the Medicaid billing question* is "yes" and the retail pharmacy's NPI/MPN is rostered. 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 center):

☐	Submitting claims to Medicaid under a single NPI but carving in for some claims AND carving out for other claims under that same NPI, e.g., administering 340B drugs to Medicaid patients at the parent site/primary site, but not administering 340B drugs to Medicaid patients at a child/associated site when both locations use the same NPI for billing Medicaid.	The rostering of an NPI in OPAIS is intended to be an all or nothing declaration for Medicaid claims filed with 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.	Options include: a. Change operations to be 100% carve-in or carve-out across a single NPI. b. Obtain a second NPI; use the one rostered in OPAIS for carve-in claims and use the other for carve-out claims. c. 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. 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.

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