

THE MEDICAID EXCLUSION FILE: IMPORTANT CLARIFICATIONS

OPA MONTHLY UPDATE – OCTOBER 2015

340B Medicaid Exclusion File

Pursuant to section 340B(a)(5)(A)(ii), HRSA established the 340B Medicaid Exclusion File (MEF) as the mechanism to assist 340B covered entities and States in the prevention of duplicate discounts for drugs subject to Medicaid rebates. The 340B MEF is available on HRSA's public database (<http://opanel.hrsa.gov/opa/CEMedicaidExtract.aspx>). HRSA publishes the 340B MEF, which lists all of the covered entities that choose to bill Medicaid for the 340B drugs used for their Medicaid patients (carve-in), as the official data source to facilitate the prevention of duplicate discounts. In December 2014, HRSA issued Policy Release No. 2014-1, "Clarification on Use of the Medicaid Exclusion File".

<http://www.hrsa.gov/opa/programrequirements/policyreleases/clarificationmedicaidexclusion.pdf>

This OPA Update addresses some specific questions that warrant further clarification based on feedback received from stakeholders.

1. What do the key fields in the Medicaid Exclusion File mean?

- The date in the "start date" column is the first date that the entity began participating in the 340B Program. The date in the "term date" column is the effective date the entity is no longer participating in the 340B Program. These dates DO NOT relate to the covered entity's MEF determination as carve-in or carve-out. The quarterly published MEF is found on the MEF homepage in the 340B Database and reflects the decisions of covered entities that have chosen to "carve-in" Medicaid for a given calendar quarter and captures a snapshot of carve-in decisions on the 15th day of the month prior to the start of each quarter, irrespective of weekends or holidays. The MEF can be downloaded for use by program stakeholders.
- The "Medicaid State" field identifies the state that is billed with the Medicaid Number listed in the MEF. The "State" field simply lists the state jurisdiction where the covered entity is located.

2. **What changes may be made to the Medicaid Exclusion File from one quarter to the next?**

The quarterly MEF contains all covered entities that have chosen to “carve-in” Medicaid and includes for each covered entity listed at least one Medicaid provider number (MPN) or one National Provider Identifier (NPI) registered with OPA as of the snapshot for that quarter. Covered entities may request changes to their “carve-in” decision and/or the specific identifiers listed at any time; however, these changes *only take effect* the following quarter and only if the change request is received, approved and processed by OPA before the time of the snapshot (i.e., the 15th day of the month prior to the start of the quarter). HRSA generally does not make retroactive changes to the quarterly MEF once it is published. On rare occasion, a technical system issue may warrant an immediate modification. If retroactive changes are necessary, HRSA will communicate this to the 340B Program stakeholders.

3. **Are all of a covered entity’s provider identifiers listed in the Medicaid Exclusion File?**

The provider identifiers in the MEF are a reflection of what the covered entities submit to OPA when providing the requisite information to indicate their decision to carve-in Medicaid for 340B drugs. It is a covered entity’s responsibility to ensure the information is accurate in order to avoid duplicate discounts and possible repayment to manufacturers. Every covered entity included in the MEF has a MPN, a NPI or both. If the State is unable to find an MPN or NPI where expected, this may be due to the covered entity not having submitted that data to HRSA. Covered entities are strongly encouraged to check the MEF at the start of each quarter for the accuracy of their specific Medicaid billing information to help ensure the overall validity of the data in the file and to avoid duplicate discounts. Covered entities are also required to ensure the information in the MEF is accurate at the time of annual recertification. HRSA audits this information and covered entities may be found in violation of program requirements if the information in the MEF is inaccurate.

HRSA recognizes that the Medicaid marketplace has grown increasingly complex for 340B stakeholders (state Medicaid agencies, covered entities, and manufacturers), posing challenges for duplicate discount prevention. HRSA continues to work closely with the Centers for Medicare and Medicaid Services (CMS) on policy related to the prevention of duplicate discounts and the use of the MEF. We encourage stakeholders to continue to communicate with HRSA to share best practices and inform the policy development process. HRSA has an email box in place (opaexclusion@hrsa.gov) for stakeholders to communicate issues and concerns regarding the MEF.

If you have any questions, or need further information, the team at ApexusAnswers-a service of the 340B contracted Prime Vendor Program-stands ready to assist by email (ApexusAnswers@340bvp.com) or by phone (888-340-2787).