

DISPUTE RESOLUTION – BEST PRACTICES SUGGESTIONS FOR RESOLVING 340B-RELATED DISPUTES

Background

The drug rebate program was amended by the Veterans Health Care Act of 1992 (VHCA). Under VHCA, Congress created the 340B program which is administered by the Health Resources and Services Administration (HRSA), Office of Pharmacy Affairs (OPA). The 340B program requires manufacturers of drugs that are paid for by state Medicaid programs to enter into an agreement with HRSA to provide statutory discounts on drugs to “covered entities”. The covered entities that participate in the program and bill Medicaid separately for drugs purchased at 340B prices will be identified by their Medicaid provider number(s) on the OPA Information System (OPAIS) covered entity database to prevent the manufacturers from being charged the combination of a 340B discount and Medicaid rebate for the same drug.

The following information is being provided to assist with 340B disputes. Please keep in mind that this information was compiled from conversations with OPA staff and from working through 340B disputes with states and manufacturers and should not be used as guidance.

- OPA maintains several files and databases for the 340B program.
 - The Covered Entity Database is a searchable database of all of the providers that participate in the 340B program.
 - The Medicaid Exclusion File is a subset of the covered entity database and it includes only those providers who have indicated to OPA that they will bill Medicaid for drugs purchased under the 340B program. This is the file that we ask state Medicaid agencies to use in avoiding double dipping. If the provider number for the covered entity is on this file, rebates are not due because the provider purchased these drugs at the 340B discount price.
- Each 340B covered entity is required to retain records of purchases of covered outpatient drugs under the 340B Program and any claims for reimbursement submitted for such drugs under Medicaid. Outpatient drug claims from covered entities which bill Medicaid separately for drugs purchased under the 340B program must be excluded from drug utilization data used to calculate Medicaid rebates. These entities should be on the 340B Medicaid exclusion file.
- If the state is dealing with Medicaid disputes spanning several quarters or more in the past, they will need to reference historical information. The 340B Medicaid Exclusion Files reflect real-time information as provided to OPA by a covered entity. States and manufacturers are strongly encouraged to download the 340B Medicaid Exclusion file on a quarterly basis and maintain their own archive files. OPAIS does not archive this data. There may be situations where a manufacturer and state may need to rely on more than the 340B web site to determine if a drug was dispensed within a 340B covered entity. Further research and additional contacts may need to occur between both parties in an effort to determine if the drug was sold/purchased at the 340B discount price, and/or whether the drug was dispensed by a 340B covered entity pharmacy or a physician, clinic, etc within that 340B covered entity.

- OPA realizes that there are structural problems within the 340B covered entity dispensing where, at times, Medicaid drugs are being dispensed outside of the pharmacy. For example, where drugs are administered by a physician within the 340B entity and the Medicaid claim submitted to the state identifies the physician ID number rather than the 340B provider Medicaid ID number. This complicates matters even more for those states that choose to capture these physician administered drugs for rebate invoicing by performing a J-code to NDC crosswalk. For those claims reflecting the physician ID and not the 340B Covered Entity Medicaid ID Number, the state will not realize that these drugs were actually dispensed by a 340B covered entity and should not be invoiced for rebates. In situations like this, it is always good to work with the manufacturer and see if they can provide the “charge back sales” to show that their drugs were actually purchased at the 340B discount. You may also want to contact the 340B entity directly to receive verification or documentation to support whether the drugs in questions were purchased at the discounted price and/or bill to Medicaid.
- 340B providers may keep dual inventory. They should especially if they are dispensing both for 340B and non-340B drugs.
- 340B covered entities may still bill Medicaid even if it does not list its Medicaid billing number on the HRSA website. In such a case, the covered entity would be exercising the "Medicaid carve-out," in which the covered entity maintains a separate inventory of non-340B drugs for purposes of dispensing to Medicaid patients and billing to States at the regular Medicaid rate. States would then invoice manufacturers for rebates for these drugs.
- OPA said that there is a dispute process available for manufacturers if they have issues with the 340B Provider Entity. Also, if a state claims that the 340B discount was not passed to the State Agency, this should be pursued with the 340B covered entity.
- OPA Contact for web site info:
Jae Choi
 1-800-628-6297 / FAX - 301-594-4982
 Website - www.hrsa.gov/opaemail – opastaff@hrsa.gov

Information pertaining to the HRSA/OPA and 340B Drug Pricing Program may be found at: <http://www.hrsa.gov/opa> or for the Medicaid Exclusion File: <https://opanet.hrsa.gov/OPA/CE/CEMedicaidExtract.aspx>

Office of Pharmacy Affairs now has a Medicaid Exclusion Tutorial available on their website at: <http://www.hrsa.gov/opa/medicaidexclusion.htm>

In our experience, the longer that disputes go unresolved, the more difficult it is to obtain the necessary data for resolution; therefore, we strongly urge the resolution of all aged disputes. We hope you find these suggestions helpful in your dispute resolution efforts.