



<b>ISSUE DATE</b> May 16, 2013	<b>EFFECTIVE DATE</b> May 1, 2013	<b>NUMBER</b> 99-13-08
<b>SUBJECT</b>  340B Drug Pricing Program Provider Requirements and Billing Instructions - Pharmacy Services		<b>BY</b>    Vincent D. Gordon, Deputy Secretary Office of Medical Assistance Programs

**PURPOSE:**

The purposes of this Medical Assistance (MA) Bulletin (bulletin) are to:

1. Remind 340B covered entities that bill the MA Fee-for-Service (FFS) program and/or a MA Program managed care organization (MCO) for drugs purchased under the 340B Drug Pricing Program (340B Program) and dispensed to MA program recipients (Medicaid recipients) of the following requirements:
  - a. To report to the Health Resources and Services Administration (HRSA) if they are billing Medicaid (FFS and/or a MA program MCO) for drugs purchased under the 340B Program;
  - b. To be listed on HRSA’s Medicaid Exclusion File on the HRSA website if they are billing Medicaid (FFS and/or a MA program MCO) for drugs purchased under the 340B Program; and
  - c. To ensure that the information in the HRSA Medicaid Exclusion File is accurate, complete, and verifiable.
2. Provide billing instructions for reporting usual and customary charge on claims submitted by a 340B covered entity to the FFS program for drugs dispensed to MA Program recipients in FFS.

**SCOPE:**

This bulletin applies to all 340B covered entities enrolled in the MA Program and providing pharmacy services in the FFS and/or the managed care delivery system(s), including pharmacy services to residents of long term care facilities.

**BACKGROUND:**

Under the Federal Drug Rebate Program, states are required to invoice manufacturers for Medicaid drug rebates for covered outpatient drugs dispensed to Medicaid beneficiaries. This requirement applies to drugs dispensed under both the FFS and managed care delivery

**COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:**

The appropriate toll free number for your provider type.  
 Questions regarding the 340B Program should be directed to [DPWPharmacyServices@pa.gov](mailto:DPWPharmacyServices@pa.gov)

Visit the Office of Medical Assistance Programs Web site at  
<http://www.dpw.state.pa.us/provider/healthcaremedicalassistance/index.htm>

systems. Drugs dispensed to Medicaid beneficiaries that were purchased under the 340B Program do not qualify for Medicaid rebates. In order to ensure that the Department of Public Welfare (Department) does not claim Medicaid rebates on drugs purchased under the 340B Program, the Department relies on the Medicaid Exclusion File located on the HRSA website at <http://opanet.hrsa.gov/opa/CEMedicaidExtract.aspx> to identify claims for 340B-purchased drugs in both FFS and managed care. A recent report by the Office of Inspector General (OIG), and the Department's own experience, indicates that there are inaccuracies in the Medicaid Exclusion File. For example, Department staff noted that some covered entities reported an inaccurate MA provider identification number and did not report a corresponding NPI.

## **DISCUSSION:**

HRSA requires that all 340B covered entities inform HRSA at the time they enroll in the 340B Program whether they will purchase and dispense 340B drugs for their Medicaid patients. HRSA defines covered entities as nonprofit health care organizations that have certain Federal designations or receive funding from specific Federal programs; they include Federally Qualified Health Centers, Ryan White HIV/AIDS Program grantees, and certain types of hospitals and specialized clinics. Covered entities may choose not to dispense 340B-purchased drugs to their Medicaid patients, and instead to dispense drugs that were purchased outside of the 340B program. 340B covered entities that will dispense 340B-purchased drugs for their Medicaid patients must report to HRSA their accurate MA program provider identification numbers and location codes or corresponding NPIs. HRSA posts this information on its Medicaid Exclusion File so that states and manufacturers will know that drugs purchased under that Medicaid identification number are not eligible for a Medicaid rebate. It is the responsibility of the 340B covered entity to ensure that the information in the HRSA Medicaid Exclusion File is accurate and up to date.

HRSA also requires covered entities to report any changes in billing of 340B-purchased drugs to Medicaid to the HRSA Office of Pharmacy Affairs before implementing the billing change. 340B covered entities that originally reported that they would dispense 340B-purchased drugs to their Medicaid patients and subsequently decide to dispense drugs that are purchased outside of the 340B program to their Medicaid patients, and vice versa, must report that change to HRSA to ensure that the information on the Medicaid Exclusion File is accurate and up to date.

## **PROCEDURES:**

### **340B Covered Entity Responsibility to Report to HRSA**

To ensure that the information reported to HRSA is accurate, 340B covered entities should:

1. Review the information listed for the covered entity on the Medicaid Exclusion File located on the HRSA website at <http://opanet.hrsa.gov/opa/CEMedicaidExtract.aspx> for accuracy and identify any inaccurate or missing information

2. Report all changes and corrections to HRSA

### **340B Covered Entity Billing for Drugs in Fee-for-Service**

When submitting a claim through PROMISe™ for a drug dispensed by a covered entity to a MA recipient in the FFS program, the following regulations apply:

1. 55 Pa. Code § 1121.55. Method of payment. (c) The provider shall bill the Department at its usual and customary charge to the general public.
2. 55 Pa. Code § 1121.2. Definitions. *Usual and customary charge* – The pharmacy’s lowest net charge an MA recipient would pay for a prescription as a non-Medicaid patient at the time of dispensing for the same quantity and strength of a particular drug or product, including applicable discounts, such as special rates to nursing home residents, senior citizens, or other discounts extended to a particular group of patients, including generic drug discount and savings programs.

- **For 340B-Purchased Drugs**

When submitting a claim through PROMISe™ for a 340B-purchased drug dispensed by a covered entity to a MA recipient in the FFS program, the covered entity must enter the lowest net charge a non-Medicaid 340B-eligible patient would pay for the prescription in the Usual and Customary Charge field. For example:

- The charge to a non-Medicaid 340B-eligible patient for a 30 day supply of Drug A purchased under the 340B program is \$4.00.
- The entry in the Usual and Customary Charge field on a claim for the same prescription (a 30 day supply of Drug A purchased under the 340B program) for a MA recipient would be \$4.00.

- **For Drugs Purchased Outside of the 340B Program**

When submitting a claim through PROMISe™ for a drug purchased outside of the 340B program and dispensed by a covered entity to a MA recipient in the FFS program, the covered entity must enter the lowest net charge a non-Medicaid patient would pay for the prescription in the Usual and Customary Charge field. For example:

- The charge to a non-Medicaid patient for a 30 day supply of Drug A purchased outside of the 340B program is \$10.00.
- The entry in the Usual and Customary Charge field on a claim for the same prescription (a 30 day supply of Drug A purchased outside of the 340B program) for a MA recipient would be \$10.00.

**340B Covered Entity Billing for Drugs in Managed Care**

340B covered entities rendering pharmacy services to beneficiaries in the MA managed care delivery system should address any questions related to submission of claims to the appropriate managed care organization.

**MA Program Monitoring**

Department staff will continue to monitor and verify the accuracy of information listed for 340B covered entities on the Medicaid Exclusion File located on the HRSA website to ensure correct billing in the Fee-for-Service program and accurate invoicing for Medicaid rebates on non-340B drugs dispensed under both the FFS and managed care delivery systems.