



Special Advisory Bulletin

AVERAGE MANUFACTURER PRICE AND AVERAGE SALES PRICE REPORTING REQUIREMENTS

September 2010

Introduction

This Advisory Bulletin notifies drug manufacturers of the Office of Inspector General (OIG) enforcement initiative concerning the timely submission of data necessary to the effective operation of the Medicaid Drug Rebate Program, the 340B Drug Pricing Program (340B Program), the Federal Upper Limit (FUL) Program, and the Medicare Part B outpatient prescription drug benefit. OIG has learned that certain manufacturers have failed to submit required product and pricing data in a timely fashion. The Medicaid Drug Rebate Program provides for the imposition of penalties of \$10,000 per day for failure to provide and certify timely and accurate pricing and product information. Given the importance of the product and pricing information to the Centers for Medicare & Medicaid Services (CMS) for establishing pricing and payment amounts, OIG intends to pursue enforcement actions against noncompliant manufacturers as appropriate.

A. REPORTING REQUIREMENTS AND THE MEDICAID DRUG REBATE PROGRAM, THE 340B PROGRAM, AND THE FUL PROGRAM

Congress established the Medicaid Drug Rebate Program in 1990. See section 1927 of the Social Security Act (Act). The Medicaid Drug Rebate Program requires participating drug manufacturers to enter into and have in effect national rebate agreements with the Secretary of Health & Human Services in order for Federal Medicaid payments to be available for manufacturers' covered outpatient drugs. Manufacturers are required to submit and certify product and pricing information to the Department of Health & Human Services (HHS) and pay rebates to the State Medicaid programs for each unit of the covered outpatient drugs that the State Medicaid programs reimburse.

Manufacturers must submit to HHS and certify average manufacturer price (AMP) and best price data in addition to other information. See Act § 1927(b)(3)(A). CMS uses the reported data to calculate a unit rebate amount (URA) for State verification purposes. Manufacturers pay States for each unit of the drug on the basis of the URA.

Participation in the Medicaid Drug Rebate Program requires that manufacturers submit and certify pricing information both quarterly and monthly. These obligations are spelled out in the statute and implementing regulations. In addition, CMS provides Medicaid Drug Rebate Program participants with detailed guidance on the data requirements imposed by the rebate agreements.

In 1992, Congress established the 340B Program to provide a mechanism for certain “covered entities” to purchase prescription drugs at or below specified maximum prices. These prices are known as the 340B ceiling prices. Generally speaking, covered entities are safety net health care providers (including, for example, federally qualified health centers and disproportionate share hospitals). When it established the 340B Program, Congress amended section 1927 of the Act to specify that to qualify for Federal Medicaid payments for their drugs, manufacturers must also enter agreements with HHS under which manufacturers commit to sell their products to covered entities at prices equal to or lower than the 340B ceiling prices. The 340B ceiling prices are based, in part, on the same AMP data that manufacturers must report for the purposes of the Medicaid Drug Rebate Program.

Medicaid’s FUL Program is designed to ensure that the Federal Government acts as a prudent buyer by taking advantage of current market prices for multiple-source drugs. The Deficit Reduction Act of 2005 (DRA), Public Law 109-171, made significant changes to the FUL Program. Section 6001 of the DRA requires AMP data to be reported monthly by manufacturers. Section 2503(a)(1)(B) of the Patient Protection and Affordable Care Act, Public Law 111-148, establishes monthly AMP data as the basis for CMS to calculate FUL amounts. Accordingly, CMS’s ability to ensure that the Federal Government acts as a prudent buyer depends upon manufacturers’ timely and accurate submission of monthly AMP data.

B. REPORTING REQUIREMENTS FOR MEDICARE PART B

Although Medicare Part D covers most outpatient prescription drugs, CMS continues to cover a limited number of outpatient prescription drugs and biologicals under the Medicare Part B outpatient drug benefit. See Act § 1842(o). In setting Part B payment amounts CMS relies on average sales price (ASP) data reported by manufacturers. See Act § 1847A(c)(3). Medicare payment amounts for most Part B-covered drugs and biologicals are equal to 106 percent of the volume-weighted ASPs based on reported Healthcare Common Procedure Coding System codes, which define drugs by name and billing unit size.

Section 1927 of the Act sets forth ASP reporting requirements. Manufacturers with rebate agreements are required to provide CMS with ASP and sales volume data on a quarterly basis. See Act § 1927(b)(3); 42 C.F.R. § 414.804(a)(5).

C. FAILURE TO MEET REPORTING REQUIREMENTS

The failure by a manufacturer to submit and certify timely quarterly product and pricing data for a drug may impede CMS's ability to calculate a URA for that drug and may impede the States' ability to collect appropriate rebate amounts. Historically, CMS has notified manufacturers when quarterly product and pricing data are late. Late data submitted after CMS has calculated URAs are included in the following quarter's transmission to States. If manufacturers fail to submit timely monthly AMP information, CMS may be unable to establish appropriate AMP-based FUL amounts in the future. The failure by a manufacturer to submit timely ASP information may impede CMS's ability to calculate an accurate Medicare payment amount for Part B drugs.

OIG has conducted reviews of the 340B Program and identified the lack of reported AMP data as an impediment to the establishment of accurate 340B ceiling prices. For example, the October 2005 report, "Deficiencies in the Oversight of the 340B Drug Pricing Program" (OEI-05-02-00072), discussed the need for pharmaceutical manufacturers to provide complete and timely pricing data as required under the Medicaid Drug Rebate Program. The September 2010 report, "Drug Manufacturers' Noncompliance With Average Manufacturer Price Reporting Requirements" (OEI-03-09-00060), found that in 2008, more than half of the drug manufacturers that were required to submit and certify quarterly AMP data failed to comply with reporting and/or certification requirements in at least one quarter. During that same year, more than three-fourths of manufacturers failed to comply with monthly AMP reporting requirements.

OIG has also reviewed the Medicare Part B prescription drug benefit and identified the lack of reported ASP data as an impediment to the accurate calculation of Part B payment amounts. For example, the February 2010 report, "Average Sales Prices: Manufacturer Reporting and CMS Oversight" (OEI-03-08-00480), noted that the failure of manufacturers to meet deadlines for reporting ASPs introduces the potential for inefficiency and error in payments for Medicare Part B-covered drugs.

These reviews reinforce the importance of timely and accurate price reporting to the efficient operation and administration of the Medicaid Drug Rebate Program, the 340B Program, the FUL Program, and the Medicare Part B drug benefit. The OIG reports recommend that CMS refer manufacturers that fail to report product and pricing information on time to OIG for the consideration of potential administrative actions.

D. OIG ENFORCEMENT INITIATIVE

Section 1927(b)(3)(C) of the Act provides for civil money penalties (CMP) of \$10,000 per day for manufacturers that fail to provide and certify timely or accurate information in complying with their reporting requirements under the Medicaid Drug Rebate Program and the 340B Program. These requirements include the provision of ASP and sales volume data on a quarterly basis. See Act § 1927(b)(3)(A)(iii). The responsibility to impose CMPs pursuant to section 1927(b)(3)(C) of the Act has been delegated to OIG by the Secretary of HHS.

OIG today announces an enforcement initiative to promote increased compliance with the reporting requirements related to the Medicaid Drug Rebate Program, the 340B Program, the FUL Program, and the Medicare Part B drug benefit. The timely submission of this information is critical to effective and efficient program operations. HHS's past approach of promoting voluntary compliance has not been fully effective. OIG will now impose CMPs on manufacturers that fail to comply with their drug product and price reporting obligations. OIG and CMS are working together to identify and penalize noncompliant manufacturers through the CMP process.

OIG was established at HHS by Congress in 1976 to identify and eliminate fraud, abuse, and waste in HHS programs and to promote efficiency and economy in operations. OIG carries out this mission through a nationwide program of audits, investigations, and inspections.

The Fraud and Abuse Control Program, established by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), authorized OIG to provide guidance to the health care industry to prevent fraud and abuse and to promote the highest level of ethical and lawful conduct. To further these goals, OIG issues Special Advisory Bulletins about industry practices or arrangements that potentially implicate the fraud and abuse authorities subject to OIG enforcement.