April 14, 2004

Manufacturer Submission of Average Sales Price Data for Medicare Part B Drugs and Biologicals: CMS Interim Final Rule

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the “MMA”) requires that manufacturers report data on average sales price (“ASP”) of certain Medicare Part B drugs and biologicals. This ASP calculation will replace the average wholesale price as the basis for Medicare reimbursement of physicians for covered Part B drugs and biologicals.

ASP reports must be made on a quarterly basis, starting with the first quarter of 2004. On April 1, 2004, CMS issued an interim final rule implementing these requirements (the “Rule”). The Rule becomes effective on April 30, 2004, and will therefore govern the first quarterly manufacturer reports, which are due on April 30, 2004.

The Rule was published in the Federal Register on April 6, 2004. 1

Comments are due within 60 days of publication. This memorandum summarizes key facets of the Rule.

I. Scope of Covered Drugs and Biologicals

Starting in the first quarter of 2004, manufacturers must make ASP data reports for “certain drugs and biologicals covered under Part B of Title XVIII of the [Social Security Act (“the Act”)] that are paid under sections 1842(o)(1)(D), 1847A, and

1881(b)(13)(A)(ii) of the Act.” In general, this includes drugs administered incident to a physician’s service, some cancer chemotherapy drugs, immunosuppressive drugs following a Medicare-covered organ transplant, erythropoietin for persons with chronic renal failure who are on dialysis, and hemophilia clotting factors. Any drug or biological that is not paid under these sections of the Act will not be subject to the ASP reporting requirement. The preamble to the Rule specifically notes, for example, that radiopharmaceuticals are not paid under these sections of the Act and are therefore not subject to ASP reporting requirements, but does not provide any further detail regarding the scope of covered products.

II. Calculation of ASP

A. Basic Calculation Methodology

According to the Rule, ASP is calculated by taking the manufacturer’s “sales to all purchasers in the United States” in a given quarter (excluding units associated with exempt sales) and dividing that by the total “number of units sold by the manufacturer in that quarter” (excluding units sold through exempt sales). The Rule defines a “unit” as the product represented by the standardized 11-digit National Drug Code (“NDC”) as defined in section 1847A(b)(2)(B) of the Act. Section 1847A(b)(2)(B) of the Act, in turn, provides the following definition of the term “unit”:

with respect to each National Drug Code (including package size) associated with a drug or biological, the lowest identifiable quantity (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological

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2 42.C.F.R. § 414.800.
3 42.C.F.R. § 414.804(a)(1).
4 42.C.F.R. § 414.802.
that is dispensed, exclusive of any diluent without reference to volume measures pertaining to liquids.\textsuperscript{5}

The Rule also provides a definition of the term “manufacturer.” Under the Rule, a manufacturer is any entity that is engaged in the following:

1. Production, preparation, propagation, compounding, conversion or processing of prescription drug\textsuperscript{6} products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis.

2. The packaging, repackaging, labeling, relabeling, or distribution of prescription drug products.\textsuperscript{7}

The definition does not provide either an “and” or an “or” between the two activities cited above. The Rule does not define the term “United States.”

B. Certain Transactions Included in ASP Calculation

The Rule requires that in calculating the ASP, manufacturers must include each of the following types of transactions (the “Included Transactions”):

1. Volume discounts;

2. Prompt pay discounts;

3. Cash discounts

4. Free goods that are contingent on any purchase requirement;

5. Chargebacks and rebates (other than rebates under the Medicaid drug rebate program).\textsuperscript{8}

\textsuperscript{5} 42 U.S.C. § 1395w-3a(b)(2)(B).

\textsuperscript{6} The Rule defines the term “drug” to include both drugs and biologicals. 42 C.F.R. § 802.

\textsuperscript{7} 42 C.F.R. § 802. The Rule’s definition of the term “manufacturer” specifically excludes a wholesale distributor of drugs or a retail pharmacy licensed under state law.

\textsuperscript{8} 42 C.F.R. § 414.804(a)(2).
C. Certain Excluded Sales

The Rule excludes certain sales from the computation of ASP. First, the Rule requires that ASP must exclude sales that are exempt from the Medicaid best price calculation under sections 1927(c)(1)(C)(i) and (ii)(III) of the Act. Under section 1927(c)(1)(C)(i), the following sales are exempt from the Medicaid best price calculation: (a) any prices charged on or after October 1, 1992 to the Indian Health Service, a State home receiving funds under 38 U.S.C. § 1741, or certain enumerated federal agencies and departments; (b) any prices charged under the Federal Supply Schedule of the General Services Administration; (c) any price charged under a State pharmaceutical assistance program; and (d) any depot prices and single award contract prices, as defined by the Secretary, of any agency of the Federal government.

Pursuant to section 1927(c)(1)(C)(ii)(III), sales to an entity that are “nominal in amount” are also excluded from the Medicaid best price calculations. For a definition of “nominal,” the preamble to the Rule states that “[s]ales to an entity that are nominal in amount are defined for purposes of section 1927(c)(1)(C)(ii)(III) of the Act for the Medicaid drug rebate program in the Medicaid drug rebate agreement.” The National Drug Rebate Agreement, in turn, defines the term “nominal price,” for purposes

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10 See 42 U.S.C. 1396r-8(c)(1)(C)(i).
of the exclusion under best price, to be “any price less than 10% of the [Average Manufacturer Price] in the same quarter for which the AMP is computed.”

D. Estimates Where Certain Data Are Unavailable

The Rule recognizes that in certain cases, data necessary for the computation of ASP may not be available. It therefore makes provision for estimation of data values in two specified situations.

1. 12-Month Estimation of Price Discounts and Concessions.

The Rule recognizes that in practice, data on certain Included Transactions may not be available at the close of a given quarter. Therefore, the Rule requires that where data on any of the Included Transactions are not available at the close of a quarter, the manufacture must use an estimated value for that quarter. This estimate is calculated by adding the data for the most recent 12-month period available and dividing the sum by four. This figure must then be applied to calculation of the ASP for the quarter being submitted.

Applying Included Transaction figures from the most recent 12-month period available to current quarterly figures could cause curious results in quarters with wide variations in sales. For example, if the Included Transactions figure from the most recent 12-month period available (divided by four) is quite high, but actual sales for the reported quarter are quite low, it has been suggested that manufacturers might report “negative ASP” figures. The Rule makes no provision for revising reported ASP figures

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14 42 C.F.R. § 414.804(a)(3).
once actual data from the reported quarter become available. This facet of the Rule is likely to garner significant attention in comments.

2. Allocation of Individual NDCs

The preamble to the Rule also recognizes that it may not always be possible to link certain Included Transactions to a specific 11-digit NDC. The preamble therefore states that in this event, the manufacture must allocate the Included Transactions to “associated NDCs.”

This association “will be based on the percentage of sales (in dollars) attributable to each particular NDC within the group of NDCs for which the manufacturer can associate discounts, rebates, free goods, and chargebacks.”

III. Certification

The Rule requires that each quarterly report “must be certified by one of the following:

1. The manufacturer’s Chief Executive Officer (CEO).
2. The manufacturer’s Chief Financial Officer (CFO).
3. An individual who has delegated authority to sign for, and who reports directly to, the manufacturer’s CEO or CFO.”

The text of the required certification, set forth in Addendum B to the Rule, reads as follows:

I certify that the reported Average Sales Prices were calculated accurately and that all information and statements made in this submission are true, complete, and current to the best of my knowledge and belief and are made in good faith. I understand that information

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15 69 Fed. Reg. 17935, 17936. This requirement does not appear in the actual text of the Rule in new subpart J.
16 See id.
17 42 C.F.R. § 414.804(6).
contained in this submission may be used for Medicare reimbursement purposes.\textsuperscript{18}

IV. Penalties for Failure to Submit Timely and Accurate Reports

Section 1847A(d)(4) of the Act provides that the Secretary may assess civil monetary penalties if the Secretary determines that a manufacturer has made a misrepresentation in the reporting of ASP. These penalties may range up to $10,000 for each price misrepresentation and for each day in which the price misrepresentation was applied.\textsuperscript{19} Similarly, section 1927(b)(3)(C) of the Act, as amended by section 303(i)(4) of the MMA, also provides for civil monetary penalties for false statements or failure to provide timely information.\textsuperscript{20} The Rule reiterates both of these civil monetary penalty provisions.\textsuperscript{21}

V. Reporting Deadlines and Format

Manufacturers are required to submit initial ASP reports to CMS by April 30, 2004. Subsequent quarterly reports are due within 30 days after the last day of each calendar quarter.\textsuperscript{22} Manufacturers must provide their quarterly reports to CMS in Microsoft Excel, using a template provided in Addendum A to the April 6, 2004 Federal Register notice.\textsuperscript{23}

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\textsuperscript{18} 69 Fed. Reg. 17935, 17941.
\textsuperscript{19} 42 U.S.C. § 1395w-3a(d)(4)(A).
\textsuperscript{20} 42 U.S.C. § 1396r-8(b)(3)(C). The section provides for penalties of up to $10,000 for each day in which required information has not been provided, and up to $100,000 for each item of false information.
\textsuperscript{21} 42 C.F.R. § 414.806.
\textsuperscript{22} 42 C.F.R. § 414.804(a)(5).
\textsuperscript{23} 69 Fed. Reg. 17935, 17936.
We are continuing to analyze the implications of the MMA and will be following closely as CMS issues additional regulations and takes other actions to implement the AWP reforms and fee schedule revisions. If you would like further information about the implications of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 or other aspects of the Medicare provisions of the Social Security Act, please contact:

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