CMS' Interim Final Rule on Average Sales Price (ASP) Reporting Obligations

April 2, 2004

Yesterday, CMS released an interim final rule on Average Sales Price (ASP) reporting obligations for pharmaceutical manufacturers. The effective date is April 30, 2004.1 The rule implements a key provision of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), which requires manufacturers to report the ASP for most drugs and biologicals covered by Medicare Part B beginning with the first quarter of 2004. The first of these quarterly ASP reports must be submitted to the Centers for Medicare and Medicaid Services (CMS) by April 30, 2004. Medicare payments will not be based on ASP until 2005.

The rule will be published in the Federal Register on April 6, 2004, and comments are due within 60 days of publication. Highlights of the rule -- which manufacturers will need to digest quickly -- are summarized briefly below. Manufacturers would benefit from improvements in the rule and should take advantage of the opportunity for comment; the rule provides inadequate guidance on several important points and imposes certification requirements that are not called for by the MMA.

Scope of ASP Reporting

Manufacturers must report ASP for most drugs covered by Medicare Part B, including drugs furnished incident to a physician’s service that are not usually self-administered by patients, drugs administered through durable medical equipment, certain oral anti-cancer drugs, and immunosuppressives. The rule describes the drugs subject to ASP reporting by citing specified sections of the Social Security Act2 and does not tell manufacturers how to determine whether a drug is covered by Medicare Part B. For example, most drugs qualify for coverage because they are furnished incident to a physician’s service and are “not usually self-administered by the patient,” but the “not usually self-administered” test often creates uncertainties about coverage of new drugs. While many manufacturers had hoped for a clear standard that would trigger ASP-reporting obligations, the rule does not provide this.

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1 Medicare Program; Manufacturer Submission of Manufacturer’s Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals, interim final rule with comment period.

2 42 CFR § 414.800 (ASP reporting applies to “certain drugs and biologicals covered under [Medicare Part B] that are paid under sections 1842(o)(1)(D), 1847A, and 1881(b)(13)(A)(ii) of the [Social Security] Act”). The preamble notes that certain drugs (such as radiopharmaceuticals) fall outside these sections of the Act.
ASP Calculations Generally

ASP is a per-unit figure “for a drug or biological represented by a particular 11-digit National Drug Code.” In other words, manufacturers must separately calculate ASP for each 11-digit NDC code. The basic calculation is “the manufacturer’s [quarterly] sales to all purchasers in the United States for that particular 11-digit National Drug Code [net of specified price concessions and excluding exempt sales] divided by the total number of units sold by the manufacturer in that quarter (after excluding units associated with [exempt] sales . . . ).” Exempt sales are the same sales that are exempt from best price calculations under the Medicaid rebate statute.

The sales prices used in calculating ASP must be net of: (1) volume discounts; (2) prompt pay discounts; (3) cash discounts; (4) free goods contingent on any purchase requirement; and (5) chargebacks and rebates (except Medicaid rebates). Thus, the regulations (like the MMA itself) specifically enumerate the types of price concessions that must be factored into ASP calculations; this should help to protect manufacturers from charges that additional items assertedly representing “price concessions” were improperly omitted from their ASP calculations.

“Rolling Average” Methodology for Estimating Price Concessions

Rebates and chargebacks generated by a manufacturer’s sales during a particular quarter are not always known by the close of the quarter. Thus, the MMA provides that rebates and chargebacks should be estimated, using a 12-month rolling average methodology, where “adequate data are not available on a timely basis.” The interim final rule extended this estimation procedure to all of the enumerated categories of price concessions. The rule provides that “[t]o the extent that data on volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks and rebates [other than Medicaid rebates] are available on a lagged basis, the manufacturer should add the data for the most recent 12-month period available and divide by 4” to derive an estimate for the quarterly reporting period.

This estimation procedure is problematic for several reasons. Among other things, the rule fails to note that some price concessions captured in the 12-month average will have
resulted from exempt sales and should therefore be deducted from the estimate in some fashion. For example, exempt sales to Federal agencies or 340B covered entities could generate chargebacks or rebates that would show up in the rolling average figure.

**New Certification Requirements**

CMS is requiring manufacturers to submit ASP reports accompanied by a certification that is not required by the MMA. Specifically, the manufacturer’s CEO, CFO, or an individual “who has delegated authority to sign for, and who reports directly to” the CEO or CFO,\(^8\) must make the following certification:

> 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 contained in this submission may be used for Medicare reimbursement purposes.\(^9\)

**Penalties for Violations**

Several civil money penalty (CMP) provisions may apply to inaccurate or untimely ASP data. Closely paraphrasing the MMA, the interim final rule states that “[i]f . . . a manufacturer has made a misrepresentation in the reporting of ASP data, a [CMP] . . . of up to $10,000 may be applied for each price misrepresentation and for each day in which the price misrepresentation was applied.”\(^10\) The rule further provides that “Section 1927(b)(3)(C) of the [Social Security] Act, as amended by . . . the MMA, specifies the penalties associated with a manufacturer’s failure to submit timely information or the submission of false information.”\(^11\) This refers to the fact that the MMA’s ASP-reporting provisions were incorporated into the Medicaid rebate statute, which already included CMP provisions for untimely or false information. Specifically, these provisions authorize penalties of: (1) up to $10,000 “for each day in which . . . information was not provided” on a timely basis; and (2) up to $100,000 “for each item of false information” a manufacturer knowingly provides\(^12\) (presumably the same conduct covered by the MMA’s new “misrepresentation” penalties).

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For questions about the interim final rule or more information on ASP or other pharmaceutical pricing issues, please feel free to contact one of the following:

Dr. Grant Bagley 202.942.5928 Grant_Bagley@aporter.com
John Bentivoglio 202.942.5508 John_Bentivoglio@aporter.com
Ben Martin 202.942.6441 Ben_Martin@aporter.com
Rosemary Maxwell 202.942.6040 Rosemary_Maxwell@aporter.com

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\(^8\) 42 CFR § 414.804(a)(6).
\(^9\) Interim final rule, Addendum B.
\(^10\) 42 CFR § 414.806 (emphasis added) (citing § 1847A(d)(4) of the Social Security Act, added by MMA § 303(c)(1)).
\(^11\) 42 CFR § 414.806.
\(^12\) Social Security Act § 1927(b)(3)(C).