Manufacturer Submission of Average Sales Price Data for Medicare Part B Drugs and Biologicals: CMS Final Rule on ASP Calculation Methodology

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. Beginning January 1, 2005, this ASP calculation replaces the average wholesale price as the basis for Medicare reimbursement of physicians for covered Part B drugs and biologicals. On April 6, 2004, CMS published an interim final rule in the Federal Register implementing these requirements (the “Interim Rule”).

CMS received 79 timely comments in response to the Interim Rule addressing a wide variety of concerns. One of the most prevalent concerns focused on the ASP calculation methodology established by the Interim Rule, particularly where data on discounts and rebates are available only on a lagged basis. The comments suggested that the estimation methodology for such pricing concessions proposed in the Interim Rule would lead to an unnecessarily high degree of volatility in ASPs.

In response to these comments, on September 13, 2004, CMS issued a Final Rule in which it revised its estimation methodology for pricing concessions in ASP reporting (the “Final Rule”). The Final Rule addresses only this price concession calculation issue, and reserves action on other comments and suggestions for future rulemakings. This memorandum provides a brief summary of the Final Rule and the changes it makes to the Interim Rule.

Price Concession Estimation Methodology Proposed in the Interim Rule

The Interim Rule proposed a basic calculation methodology for ASP. According to the Interim 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). A manufacturer must include in its ASP calculation volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under the Medicaid drug rebate program) (the “Price Concessions”).


3 Interim Rule, 69 Fed. Reg. at 17938 (proposing new 42 C.F.R. § 414.804(a)(1)). Throughout this memorandum, total sales refers to the total in dollars for sales subject to the ASP reporting requirement.

4 Id. (proposing new 42 C.F.R. § 414.804(a)(2)).
The Interim Rule recognized that, in practice, data on certain Price Concessions may not be available at the close of a given quarter, and may be available only on a lagged basis. In such circumstances, the Interim Rule proposed a methodology for calculating an estimated Price Concession value to be applied to ASP for a given reported quarter. This methodology required manufacturers to sum up the Price Concessions for the most recent twelve-month period available and divide by four. That estimated Price Concession value is then deducted from the total sales dollar amount, and the result is divided by the total number of units sold for that National Drug Code to arrive at ASP for the quarter.⁵

In comments submitted to CMS, some stakeholders suggested that this methodology would result in unnecessary ASP volatility, and could even result in a negative ASP values under certain circumstances. The Pharmaceutical Research and Manufacturers of America (“PhRMA”) provided an example of the problem in its comments.⁶ In PhRMA’s example, a manufacturer sells its product at $1 per unit. In 1Q04, the manufacturer sells 1,000,000 units, so its total sales for the quarter are $1 million. Because Price Concession data is available only on a lagged basis, it must estimate the deduction. Sales for calendar year 2003 were $40 million (on 40 million units sold) and total Price Concessions were $6 million for that period.

Using the estimation methodology proposed in the Interim Rule, the manufacturer would take its total Price Concessions from 2003 ($6 million), and divide by four, resulting in an estimated Price Concession Figure of $1.5 million. The manufacturer would then deduct this figure from total sales ($1 million - $1.5 million = $-500,000). The resulting figure is divided by the number of NDC units sold ($-500,000/1 million) resulting in a negative ASP of -50¢.⁷

The Revised Methodology in the Final Rule

To address this problem, the Final Rule provides a revised methodology for estimating the Price Concession deduction. Under the Final Rule’s methodology, the Price Concession deduction is calculated as a percentage, rather than an absolute figure. As in the Interim Rule’s methodology, the manufacturer sums all of the Price Concessions for the most recent twelve-month period available. However, the manufacturer then calculates a percentage, taking the summed Price Concession figure as the numerator, and the total sales figure from the same twelve-month period as the denominator.⁸ The manufacturer must then take this percentage and multiply it by the total sales for the ASP reporting quarter in order to arrive at a Price Concession amount for that quarter. The Price Concession amount is then subtracted from the total sales dollar amount for the ASP reporting quarter, and the result is divided by the total number of units sold in that quarter.⁹

Under the revised methodology in the Final Rule, the ASP in the PhRMA example would be calculated as follows. Again, total sales for 2003 were $40 million, and total Price Concessions were $6 million. The percentage is calculated by dividing $6 million by $40 million, which equals 15%. This percentage is applied to total sales for the ASP quarter being submitted (15% of $1 million) for a Price Concession amount for the quarter of $150,000. This is subtracted from total sales for the ASP quarter being submitted ($1 million - $150,000 = $850,000) divided by total units sold ($850,000/1 million units) for a total ASP of 85¢.¹⁰

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⁵ Id. (proposing new 42 C.F.R. § 414.804(a)(3)).
⁶ See PhRMA, Comments to Interim Final Rule, CMS file code CMS-1380-IFC, at 15 (June 7, 2004) (hereinafter, PhRMA Comments).
⁷ See id.
⁸ (Price Concessions/total sales).
⁹ Final Rule, at 6-7.
¹⁰ PhRMA Comment, at 15.
Revised Methodology Effective Immediately

CMS normally provides an effective date 30 days after the date that a final rule is published in the *Federal Register*. However, because CMS believes that such a delay would be unnecessary and contrary to the public interest, it has waived this procedure and made the Final Rule effective immediately. Manufacturers must file the next quarterly report of ASP data with CMS no later than October 30, 2004.

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We are continuing to analyze the new ASP reporting system required by the MMA and implemented in CMS’ Interim Rule, as well as all of the implications of the MMA. As CMS issues additional final rules to address other issues raised by the comments submitted to the Interim Rule, we will provide our clients with additional updates.

This information is not intended as legal advice, which may often turn on specific facts. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

If you have any questions concerning the material discussed in this client alert, please call any of the following members of our Employee Benefits Group:

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