Report to Congress—Report on Sales of Drugs and Biologicals to Large Volume Purchasers

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Executive Summary

Section 303(c)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) requires that the Secretary of Health and Human Services conduct a study on sales of drugs and biologicals covered by Medicare Part B to large volume purchasers such as pharmacy benefit managers (PBMs) and health maintenance organizations (HMOs), to determine whether the prices that such purchasers pay are representative of the prices available to prudent physicians. By January 1, 2006, the Secretary is required to submit a report to Congress on the study, which should include recommendations on whether sales to large volume purchasers should be excluded from the computation of a manufacturer's average sales price (ASP). CMS contracted with Abt Associates to conduct the study, the final report for which is attached.

While the contractor made extensive efforts to collect data to analyze these issues, the sensitive and proprietary nature of prescription drug pricing data made it extremely difficult to obtain the data necessary for this report. Other than finding that clinics (including physician offices) and hospitals are the predominant purchasers of the types of drugs covered by Medicare Part B, the report was unable to draw conclusions on the key questions of interest. Abt Associates sought, but was unable to obtain, data on ASP by type of purchaser from drug manufacturers. The study was also unable to determine how the net prices available to physicians compare to those paid by other purchasers, because while some pricing data was available, data that reflected the combined effect of invoice prices, discounts, and rebates was not. While the data and anecdotal information gathered provided some indication of variation across types of purchasers in invoice prices and discounts and rebates separately, the combined effect on net acquisition costs is unclear.

Without data on average sales price by type of purchaser or net acquisition costs by type of purchaser, it is not possible to analyze the impact of removing large volume purchasers from the computation of a manufacturer's ASP. Given that the ASP was designed to broadly reflect market prices and that it may be too early to discern whether the ASP system has had an impact on potential price variation across purchasers, we have no basis for recommending the exclusion of large volume purchasers from the calculation of ASP. Therefore, we recommend continuation of the current law requirement that a manufacturer's ASP incorporate the broadest range of sales.

In assessing the adequacy of Medicare reimbursement for drugs, the fundamental question is whether physicians and other providers that furnish Part B drugs to Medicare beneficiaries can acquire these drugs at prices under Medicare's reimbursement rate (that is, average sales price plus six percent (ASP+6)). For example, studies by the Government Accountability Office[1], Department of Health and Human Services' Office of the Inspector General (OIG)[2], and

[1] Government Accountability Office. *Medicare Chemotherapy Payments: New Drug and Administration Fees Are Closer to Providers' Costs*, No. GAO-05-142R, Washington, D.C., December 1, 2004.

[2] Office of Inspector General, Department of Health and Human Services. *Adequacy of Medicare Part B Drug Reimbursement to Physician Practices for the Treatment of Cancer Patients, Report To Congress*, No. A-06-05-00024. Washington, D.C., September 2005.

MedPAC[3] suggest that oncologists can generally purchase drugs for the treatment of cancer at less than ASP+6. Furthermore, the OIG study found that this was true for both large and small practices. These studies suggest that the ASP system has resulted in Medicare paying more appropriately for oncology drugs. The Department plans to continue to monitor payment adequacy and access to care for drugs under the ASP system.

Summary of Study Conducted

Section 303(c)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) requires that the Secretary of Health and Human Services conduct a study on sales of drugs and biologicals covered by Part B of Medicare to large volume purchasers such as pharmacy benefit managers and health maintenance organizations, to determine whether the prices that such purchasers pay are representative of the prices available to prudent physicians. By January1, 2006, the Secretary is required to submit a report to Congress on the study, which should include recommendations on whether sales to large volume purchasers should be excluded from the computation of a manufacturer's average sales price. CMS contracted with Abt Associates to conduct the study, the final report for which is attached.

Medicare Part B covers a limited number of prescription drugs and biologicals (henceforth simply referred to as drugs). These drugs are usually provided by physicians in their offices or through pharmacy suppliers that provide drugs used with durable medical equipment. Physicians are reimbursed separately for the drugs and for drug administration services. Sections 303, 304 and 305 of the MMA revised the payment method for most of these drugs. Prior to 2005, the payment for these drugs was based on the "average wholesale price", which is similar to a list price. Beginning in 2005, the payment for these drugs is 106 percent of the average sales price (ASP). The manufacturer's ASP is calculated based on sales to all purchasers other than sales exempt from best price and sales at nominal charge (such as federally negotiated 340B prices) and is net of 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 study conducted by Abt Associates was designed to investigate, using both primary and secondary data, whether there are any differences between the net acquisition costs of these drugs for physicians and large volume purchasers. The price purchasers actually pay is their net acquisition cost. Net acquisition cost is the invoice price less any off-invoice special pricing terms between the purchaser and supplier and also manufacturer rebates that reduce the acquisition cost below the invoice price. The study also attempted to obtain data from drug manufacturers on average sales price by type of purchaser, to assess the potential effect of excluding large volume purchasers from ASP calculations. Extensive efforts to obtain data on net acquisition costs and average sales price by type of purchaser were unsuccessful due to the sensitive and proprietary nature of prescription drug pricing. None of the manufacturers contacted for the study provided ASP data by type of purchaser. In addition, while some pricing data was available from various sources, net acquisition cost data that reflected the combined effect of invoice prices, discounts, and rebates was not.

[3] Medicare Payment Advisory Commission. October 6-7, 2005 meeting brief on the *Report on Oncology Site Visits* is available at http://www.medpac.gov/public_meetings/transcripts/1005_oncologystudy_JS_cov.pdf

For the study, information gathering and primary data collection was planned through interviews of industry experts, manufacturers of drugs covered by Medicare Part B, market intermediaries such as wholesaler and group purchasing organizations (GPOs), health maintenance organizations (HMOs), pharmacy benefit managers (PBMs) and purchasers such as physicians and hospitals. In addition, purchasers were asked to submit written data on discounts, rebates and invoice prices, while manufacturers were asked to provide data on average sales price by type of purchaser. The discussions and data collection efforts focused on six drugs with significant Medicare expenditures[4].

Letters detailing the Congressionally mandated study, including the promise of confidentiality for participants' identities, were initially sent to 177 potential respondents[5]. These letters were followed by telephone calls that reiterated the purpose and importance of the study and answered any questions or concerns. Despite these efforts, response rates were very low, and only 36 interviews were completed[6]. Even when an interview was completed, requested data on drug prices, rebates and discounts available to different categories of purchasers were often not provided[7]. No manufacturer reported data on ASP by class of trade. Due to the small sample sizes, any meaningful statistical analysis of the data was not possible. The interviews took place during April and May of 2005, soon after ASP was implemented and before the market had an opportunity to fully adjust to the ASP system.

Secondary data analysis was conducted for 25 drugs (HCPCS codes) with significant Medicare expenditures. Invoice prices from IMS Health's National Sales Perspective database were used to calculate average invoice prices (AIP) for each HCPCS code for different categories of purchasers. Several features of the IMS data, however, limited its utility for the purposes of this study. Invoice prices do not include special pricing terms or manufacturer rebates and therefore do not necessarily reflect net acquisition costs. Another limitation of this data is that it is grouped into very broad classes of trade which contain different sub-categories believed to receive differential pricing (e.g., the "hospital" category includes hospital inpatient departments only, while the "clinic" category includes physicians' offices and clinics, along with hospital outpatient departments, including those eligible for federally negotiated 340B pricing). In addition, the IMS data available for this study was for the third quarter of 2004, before ASP was implemented.

The goal of the study was to answer the following questions:

- What shares of the top drugs covered by Part B of Medicare are purchased by various types of purchasers?
- Do different types of purchasers face the same net acquisition costs for prescription drugs covered by Part B of Medicare?

[4] The six drugs were darbepoetin alfa, erythropoietin alpha, goserelin, leuprolide acetate, paclitaxel, and trastuzumab.

[5] Interviews were solicited from 14 experts, 11 manufacturers, 8 GPOs, 20 wholesalers, 72 physicians, 20 hospitals, 18 HMOs, 14 PBMs.

[6] Interviews were conducted with 6 experts, 3 manufacturers, 3 GPOs, 1 wholesaler, 7 physicians, 12 hospitals, 2 HMOs and 2 PBMs.

[7] Requested data was received from 2 GPOs, 6 physician offices, 12 hospitals, 1 HMO and 1 PBM. One manufacturer provided the overall ASP but not the requested ASP by type of purchaser.

- Which purchasers face lower and higher net acquisition costs?
- If differences in net acquisition costs exist, do they vary by drug?
- Would differences in net acquisition costs for different types of purchasers be reflected in ASP if it were calculated by class of trade?
- Are there differences in ASP when it is calculated for different types of purchasers?
- Does excluding hospitals, HMOs or other large purchasers affect ASP calculation?

Due to the challenges and data limitations discussed previously, the study was only able to draw conclusions on the first question. The study found that clinics (including physician offices) and hospitals are the major purchasers of drugs covered by Medicare Part B. Whether clinics or hospitals had the largest market share varied by drug; the majority of the time clinics had the largest market share and hospitals had the second largest. With a few exceptions, HMOs and PBMs usually do not directly purchase drug products. They do, however, receive manufacturer rebates. All purchaser and non-purchaser rebates (other than rebates under the Medicaid drug rebate program) are included in the calculation of a manufacturer's ASP.

The study was unable to determine how the net prices available to physicians compare to those paid by large volume purchasers, because only some, not all, of the data necessary to determine net acquisition costs was available, and the data that was available had substantial limitations. The invoice price data obtained from IMS health suggested that for the majority of physician-administered drugs examined, clinics (the class of trade that included physicians' offices) had lower invoice prices than hospitals. Interviews with experts, market intermediaries, and providers offered some anecdotal information suggesting that hospitals may have more favorable access to volume discounts and rebates than physicians. The study was unable to obtain data that reflected the combined effect of invoice prices, discounts and rebates to assess how the net prices paid by physicians compared with those paid by hospitals.

Due to lack of data on ASP by class of trade, it was also not possible to assess the effect on ASP of excluding the large volume purchasers.

Recommendations of the Secretary

Despite extensive efforts, the study contractor was unable to obtain net acquisition cost data and average sales price data by type of purchaser due to issues with the sensitive and proprietary nature of pricing information. Without this data, it is not possible to analyze the impact of removing large volume purchasers from the computation of a manufacturer's ASP. Given that the ASP was designed to broadly reflect market prices and that it may be too early to discern whether the ASP system has had an impact on potential price variation across purchasers, we have no basis for recommending the exclusion of large volume purchasers from the calculation of ASP. Therefore, we recommend continuation of the current law requirement that a manufacturer's ASP incorporate the broadest range of sales.

In assessing the adequacy of Medicare reimbursement for drugs, the fundamental question is whether physicians and other providers that furnish Part B drugs to Medicare beneficiaries can acquire these drugs at prices under Medicare's reimbursement rate (that is, average sales price

plus six percent (ASP+6)). For example, studies by the Government Accountability Office[8], Department of Health and Human Services' Office of the Inspector General (OIG)[9], and MedPAC[10] suggest that oncologists can generally purchase drugs for the treatment of cancer at less than ASP+6. Furthermore, the OIG study found that this was true for both large and small practices. These studies suggest that the ASP system has resulted in Medicare paying more appropriately for oncology drugs. The Department plans to continue to monitor payment adequacy and access to care for drugs under the ASP system.

[8] Government Accountability Office. *Medicare Chemotherapy Payments: New Drug and Administration Fees Are Closer to Providers' Costs*, No. GAO-05-142R, Washington, D.C., December 1, 2004.
[9] Office of Inspector General, Department of Health and Human Services. *Adequacy of Medicare Part B Drug Reimbursement to Physician Practices for the Treatment of Cancer Patients, Report To Congress*, No. A-06-05-00024. Washington, D.C., September 2005.
[10] Medicare Payment Advisory Commission. October 6-7, 2005 meeting brief on the *Report on Oncology Site Visits* is available at http://www.medpac.gov/public_meetings/transcripts/1005_oncologystudy_JS_cov.pdf