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**OFFICE OF
INSPECTOR GENERAL**

**INTRAVENOUS IMMUNE
GLOBULIN: MEDICARE
PAYMENT AND AVAILABILITY**



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OBJECTIVE

1. To determine whether hospitals and physicians could purchase intravenous immune globulin (IVIG) at prices below the Medicare payment amounts in 2005 and 2006.
2. To determine whether IVIG was readily available to physicians and distributors in 2005 and 2006.

BACKGROUND

Members of the congressional subcommittees on Health within the Energy and Commerce and Ways and Means Committees requested that the Office of Inspector General (OIG) examine the current state of pricing and supply of IVIG. IVIG is a collection of antibodies derived from blood plasma fractionation and administered by infusion to patients with poorly functioning immune systems. Preliminary claims data indicate that Medicare and its beneficiaries paid approximately \$74 million for IVIG administered in physicians' offices and home settings in 2006. Medicare paid an additional \$130 million for IVIG administered in hospital outpatient settings based on claims processed from January through October 2006.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 changed the payment basis for most Part B prescription drugs, including IVIG, from the average wholesale price (AWP) to the average sales price (ASP) for physicians in 2005 and for hospitals in 2006. As a result, physician payment amounts fell 14 percent for powder and liquid IVIG between the fourth quarter of 2004 (the last quarter of AWP-based physician payments) and first quarter of 2005 (the first quarter of ASP-based physician payments). The Medicare payment amounts to hospitals fell 45 percent for powder IVIG and 30 percent for liquid IVIG between the fourth quarter of 2005 (the last quarter of AWP-based hospital payments) and first quarter of 2006.

The Centers for Medicare & Medicaid Services (CMS) established a temporary preadministration-related service payment (for both hospitals and physicians' offices) of approximately \$70 per day of infusion during 2006 in response to concerns about beneficiary access and Medicare payment for IVIG. CMS recently stated that it would continue the add-on payment throughout 2007. In addition to the temporary add-on payment, the ASP-based Medicare payment during

the fourth quarter of 2006 was 17 percent higher for powder IVIG and 8 percent higher for liquid IVIG than it was at the close of 2005.

We conducted a review to examine IVIG availability and Medicare payment from the perspectives of: (1) manufacturers of IVIG, (2) distributors and group purchasing organizations (GPO) identified by the manufacturers as involved in the sale and distribution of IVIG, and (3) randomly selected physicians who billed Medicare for IVIG.

It is important to note that IVIG is a unique pharmaceutical product that presents payment and cost-related issues that may not be typical of other Part B-covered drugs (such as oral anticancer drugs and immunosuppressive drugs, drugs used in conjunction with durable medical equipment, and some vaccines). IVIG is a blood plasma derivative; the amount produced is dependent upon plasma collection and there is a finite amount of raw material. Therefore, the results of this review are applicable only to IVIG.

FINDINGS

In the third quarter of 2006, just over half of IVIG sales to hospitals and physicians were at prices below Medicare payment amounts, which represents a substantial increase over the previous three quarters. During the third quarter of 2006, 56 percent of IVIG sales to hospitals and 59 percent of IVIG sales to physicians by the three largest distributors occurred at prices below the Medicare payment amounts. This represents a dramatic shift from the previous three quarters, when the percentage of IVIG sold at prices below the Medicare payment amounts was as low as 23 percent for hospitals and 4 percent for physicians.

The substantial increase in sales below the Medicare payment amounts appears to be the result of manufacturer price increases in January 2006 that were not reflected in increased Medicare payments until the third quarter of 2006.

Most physicians and distributors reported problems with IVIG availability in 2005 and the first quarter of 2006. The majority (57 percent) of responding physicians reported that they were unable to provide patients with adequate amounts of IVIG during the first quarter of 2006. In addition, distributors responding to our survey also reported problems with IVIG availability in 2005. According to their responses, none of the distributors were able to fulfill all customer requests for IVIG, and all responding distributors have asked

manufacturers for additional product. These respondents stated that problems with availability are typically related to Medicare payment.

CONCLUSION

Based on the data presented in this report, just over half of IVIG sales to hospitals and physicians were at prices below the Medicare payment amounts in the third quarter of 2006, a substantial increase over previous quarters. Distributors and physicians also reported problems with IVIG availability.

The interaction of manufacturer pricing decisions and certain ASP-related issues could partially explain our findings regarding IVIG pricing and availability. Because manufacturer price increases for IVIG in early 2006 were not reflected in Medicare reimbursement until the middle of that year, hospitals and physicians were initially charged more for IVIG without a corresponding increase in payment. If manufacturers were to implement another across-the-board price increase, hospitals and physicians might face issues similar to those that they faced in the first two quarters of 2006.

It is important to note that additional factors, including off-label use, coding, and plasma industry economics, may drive the difficulties with IVIG pricing and availability. Reported recent increases in the use of IVIG for off-label indications may strain the tight supply of this product. Each IVIG product is a unique brand drug, yet Medicare payment is based on a weighted average price of all products. The production of IVIG requires substantial resources not typically associated with other pharmaceutical products. However, this review did not include an in-depth examination of these factors.

AGENCY COMMENTS

CMS commented that this report provides initial information on the availability and pricing for IVIG and sets the stage for further review of certain issues (e.g., off-label use, payment lags, and distributor markups) that can bring greater understanding of how the marketplace operates for this unique product. CMS also noted that the time lag is a feature of the ASP system and applies to all Part B drugs and biologicals. CMS stated that the substantial increase in the percentage of IVIG sold to hospitals and physicians at prices below the Medicare payment amounts is an important development and noted that these findings indicate that Medicare payment has adjusted to increases in

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IVIg market prices over time. CMS stated, “We will carefully consider this report as we continue our dialogue with manufacturers, patient groups, and stakeholders to better understand marketplace developments and issues impacting beneficiary access to quality care. We strongly encourage the OIG to further study some of the issues raised [in CMS’s comments to the draft report].”

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OBJECTIVE

1. To determine whether hospitals and physicians could purchase intravenous immune globulin (IVIG) at prices below the Medicare payment amounts in 2005 and 2006.
2. To determine whether IVIG was readily available to physicians and distributors in 2005 and 2006.

BACKGROUND

Sections 1847A (d) (1) and (2) of the Social Security Act (the Act), as added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Public Law 108-173), directs the Office of Inspector General (OIG) to undertake pricing studies and compare average sales prices (ASPs) with widely available market prices. Related to these provisions, members of the congressional subcommittees on Health within the Energy and Commerce and Ways and Means committees requested that OIG determine the current market prices for IVIG and investigate the current state of IVIG pricing and supply. We previously provided the congressional requestors with the results of our work.

Intravenous Immune Globulin

Patients with poorly functioning immune systems receive IVIG infusions to temporarily replace missing antibodies, thus helping to protect them against infectious agents that cause various diseases. IVIG is produced in both powder and liquid form through fractionation of human blood plasma. Fractionation is the process whereby plasma proteins are separated in a purified and concentrated form. Each IVIG product has a distinct brand name.

The Food and Drug Administration (FDA) has approved IVIG to treat several conditions. One condition is primary immune deficiency disease, a group of disorders in which the immune system fails to produce enough antibodies, thereby predisposing individuals to increased risk of infection. Additional FDA-approved indications for IVIG use are acute and chronic idiopathic thrombocytopenia purpura, B-cell chronic lymphocytic leukemia, Kawasaki syndrome, pediatric

human immunodeficiency virus, and bone marrow transplantation.¹ Some providers have reported that the majority of their IVIG use is for off-label (non-FDA-approved) indications (e.g., multiple sclerosis, rheumatoid arthritis, infections in low-birth-weight newborns). Off-label use may have increased, contributing to rising demand.²

IVIG is a unique pharmaceutical product; as a blood plasma derivative, the amount produced is dependent upon plasma collection. Production increases require substantial time and resources not generally associated with other drug products.

Sources of IVIG

Physicians, hospitals, and other providers purchase IVIG through distributors, group purchasing organizations (GPO), and directly from manufacturers.

Manufacturers establish relationships with distributors to sell IVIG to providers. Distributors purchase IVIG from manufacturers and then independently resell IVIG to providers or work in conjunction with GPOs to provide IVIG to GPO members.

GPOs generally provide their members with access to lower-cost products by negotiating prices for specific drugs from manufacturers. GPOs do not purchase drugs themselves; rather, they enter into group purchasing contracts with manufacturers on behalf of their members. The contracts prescribe the prices, conditions, and terms under which GPO members can purchase drug products. GPO members then purchase drugs from distributors or manufacturers at the price specified in the GPO contracts. Distributors do not determine GPO contract prices; they only provide drugs to GPO members at the contract prices.

Medicare Payment for IVIG

According to Medicare claims data, Part B and its beneficiaries paid approximately \$74 million for IVIG administered in physicians' offices and patients' homes in 2006.³ Medicare paid an additional \$130 million

¹ Department of Health and Human Services Advisory Committee on Blood Safety and Availability, "Status of Immune Globulin Intravenous (IVIG) Products." Available online at <http://www.hhs.gov/bloodsafety/igiv.html>. Accessed April 24, 2006.

² Ibid.

³ Medicare Part B Extract and Summary System, updated through December 2006 (90 percent of claims reported), accessed March 26, 2007.

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for IVIG administered in hospital outpatient settings from January through October 2006.⁴

The MMA changed the basis of physician payment for most Medicare Part B prescription drugs, including IVIG, to ASP, effective January 1, 2005.⁵ There is a two-quarter lag between the time manufacturers report ASPs to CMS and the time those prices become the basis for Medicare payment. For example, first-quarter 2006 ASP submissions from manufacturers served as the basis for third-quarter 2006 Medicare payment for most covered drugs. Prior to 2005, Medicare generally used the average wholesale price (AWP) as the basis for Part B payment for prescription drugs. Numerous reports by OIG and the Government Accountability Office found that the AWP is often significantly higher for Part B drugs than the prices that drug manufacturers, wholesalers, and similar entities actually charge the physicians who purchase these drugs.

Medicare continued to use AWP to pay hospitals for outpatient drugs in 2005. However, since January 1, 2006, Medicare payment for most drugs and biologicals, including IVIG, administered in hospital outpatient departments has been based on 106 percent of the manufacturer's ASP, an amount identical to the physician payment amount.⁶

A previous OIG review examined the adequacy of Medicare's new payment methodology among certain specialties (hematology, hematology/oncology, and medical oncology). This review determined that physician practices in these specialties could generally purchase drugs, including IVIG, at less than the MMA-established payment

⁴ This figure is based on hospital claims processed from January through October 27, 2006. This figure includes Medicare and beneficiary payments.

⁵ Pursuant to section 1847A (c) of the Act, the ASP is defined as a manufacturer's sales of a drug to all purchasers in the United States (with certain exceptions) in a calendar quarter divided by the total number of units of the drug sold by the manufacturer in that same quarter. The ASP is net of any price concessions, such as volume, prompt pay, and cash discounts; free goods contingent on purchase requirements; chargebacks; and rebates other than those obtained through the Medicaid drug rebate program.

⁶ "Medicare Announces Payment Rates and Policy Changes for Hospital Outpatient Services in 2006." Available online at <http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1711>. Accessed April 24, 2006.

rates.⁷ An additional review conducted by the Medicare Payment Advisory Commission similarly found that oncologists could purchase most drugs at prices below Medicare’s payment amount.⁸

Concerns Over Medicare Payment and Product Availability

Medicare payment for IVIG. After the MMA changed the basis of physician drug payment from AWP to ASP, patient advocacy groups and physicians expressed concerns over Medicare’s reduced payment amount for IVIG.⁹ Their concerns centered on the claim that, under the new payment methodology, the cost for physicians to acquire IVIG would exceed Medicare’s payment amount. As a result of changes to Medicare’s payment methodology, the physician payment amounts fell 14 percent for powder and liquid IVIG between the fourth quarter of 2004 (the last quarter of AWP-based physician payments) and the first quarter of 2005 (the first quarter of ASP-based physician payments).¹⁰ In addition, manufacturers expressed concern over the fact that the codes used for Medicare payment are based on a weighted average of all liquid or all powder IVIG products.

Similarly, hospital payments also decreased as a result of the shift to ASPs in January 2006. The Medicare payment amounts to hospitals fell 45 percent for powder IVIG and 30 percent for liquid IVIG between the fourth quarter of 2005 (the last quarter of AWP-based hospital payments) and the first quarter of 2006.

IVIG availability. In addition to issues with pricing, it has been reported in the media that there is an inadequate supply of IVIG.¹¹ FDA’s Center for Biologics Evaluation and Research, which has procedures for determining and reporting a shortage, indicates on its Web site that “along with other HHS [Department of Health and Human Services] agencies, the FDA has received reports from stakeholders, patients, and health care providers regarding difficulty in obtaining [IVIG] products.

⁷ “Adequacy of Medicare Part B Drug Reimbursement to Physician Practices for the Treatment of Cancer Patients.” Department of Health and Human Services, OIG (A-06-05-00024). September 2005.

⁸ “Effects of Medicare Payment Changes on Oncology Services.” Medicare Payment Advisory Commission. January 2006.

⁹ “Law Impedes Flow of Immunity in a Vial.” New York Times. July 19, 2005.

¹⁰ The Medicare physician payment amounts were identical for powder and liquid IVIG in the fourth quarter of 2004 as well as in the first quarter of 2005.

¹¹ “Law Impedes Flow of Immunity in a Vial.” New York Times. July 19, 2005. “IVIG Shortage Driving Patients to Hospitals.” Drug Topics. August 22, 2005.

From discussions with manufacturers, distributors, providers, and consumers, it is clear that availability and treatment patterns have shifted; but we did not find clear evidence that there is currently a shortage. This is a multi-faceted and fluid situation.”¹² Further, HHS officials have told Congress that, among other factors, because IVIG is derived from human plasma, it takes significant startup time to increase supply, and supply has historically been cyclical.¹³

This is not the first time patient advocacy groups and physicians have expressed concern over IVIG availability. According to a media report, as well as an OIG interview with a manufacturer, there was a shortage of IVIG in the late 1990s after two companies halted production in their factories to make changes in order to meet new quality standards.¹⁴ When the factories came back online, production increased, leading to excess product and reduced prices. At that time, three manufacturers left the business. Other issues with IVIG availability surfaced in 2003 when one manufacturer, while staying in business, reportedly closed dozens of plasma collection centers.¹⁵

Recent Increases in Medicare Payment for IVIG

In response to concerns about beneficiary access to IVIG and Medicare payment, CMS established a temporary preadministration-related service payment (for both hospitals and physician offices) of approximately \$70 per day of infusion during calendar year 2006. This additional payment covers the preadministration-related services required to locate and acquire adequate IVIG product and prepare for an infusion of IVIG.

In a press release dated November 2, 2005, CMS stated “that the pricing for IVIG is accurate, and that there is no overall product shortage. However, in the face of such factors as increasing IVIG demand . . . physician office staff has to expend extra resources on locating and obtaining appropriate IVIG products and scheduling patient infusions.” CMS went on to state that “for calendar year 2006

¹² “Biological Product Shortages.” Available online at <http://www.fda.gov/cber/shortage/shortage.htm>. Accessed February 6, 2007.

¹³ Testimony of Herb B. Kuhn, CMS, before the Subcommittee on Health of the House Committee on Ways and Means, July 13, 2006. Available online at <http://waysandmeans.house.gov/hearings.asp?formmode=view&id=5108>. Accessed November 28, 2006.

¹⁴ “Law Impedes Flow of Immunity in a Vial.” New York Times. July 19, 2005.

¹⁵ Ibid.

only, physicians and hospitals will be permitted to bill this add-on code to compensate for the administrative burdens associated with IVIG administration during this time of some volatility in IVIG product availability.”¹⁶ CMS recently stated that it will maintain the add-on payment for IVIG in 2007 to help ensure appropriate patient access to IVIG.¹⁷

In addition to the temporary add-on payment, the Medicare payment amounts for IVIG rose in 2006. The ASP-based payment during the fourth quarter of 2006 was 17 percent higher for powder IVIG and 8 percent higher for liquid IVIG than it was at the close of 2005.¹⁸

SCOPE AND METHODOLOGY

Scope

We conducted this review to examine the pricing and availability of IVIG from the perspectives of: (1) manufacturers of IVIG, (2) distributors and GPOs identified by the manufacturers as involved in the sale and distribution of IVIG, and (3) randomly selected physicians who billed Medicare for IVIG.

IVIG is a unique pharmaceutical product that presents payment-related issues that may not be typical of other Part B-covered drugs.¹⁹ IVIG is a blood plasma derivative; the amount produced is dependent upon plasma collection and there is a finite amount of raw material. Therefore, the results of this review are applicable only to IVIG. This review did not examine the availability of or Medicare payment for any other drug products.

¹⁶ The full text of the press release is located on CMS's Web site: <http://new.cms.hhs.gov/apps/media/press/release.asp?Counter=1709>. Accessed February 9, 2006.

¹⁷ Final Rule, 71 Federal Register 69624, 69679 (December 1, 2006).

¹⁸ In the fourth quarter of 2005, the Medicare physician payment amounts were \$43.10 per gram of powder IVIG and \$56.30 per gram of liquid IVIG. For the same quarter, the Medicare hospital payment amounts were \$80.68 per gram of liquid and powder IVIG. In the fourth quarter of 2006, the Medicare payment amounts were \$50.53 per gram of powder IVIG and \$60.65 per gram of liquid IVIG.

¹⁹ Medicare Part B covers only a limited number of outpatient prescription drugs. Covered drugs include injectable drugs administered by a physician; certain self-administered drugs, such as oral anticancer drugs and immunosuppressive drugs; drugs used in conjunction with durable medical equipment; and some vaccines.

Methodology: Data Sources and Sample

Manufacturers. We collected 2005 sales prices, sales volume, and production volume from the five IVIG manufacturers producing IVIG at the time of the review (December 2005). These manufacturers also completed a written survey on IVIG pricing and availability.

Distributors. From August to October 2006, we collected sales and pricing data from the three largest distributors for the first three quarters of 2006 to gather IVIG sales prices to hospitals and physicians.²⁰ In addition, between January and April 2006, we collected sales prices and sales volume for 2005 from 13 distributors (including the 3 largest distributors) identified by IVIG manufacturers.²¹

Physicians. In April 2006, we sent written surveys on pricing and availability to 255 randomly selected physicians who billed Medicare for IVIG. We asked the physicians how much they paid for IVIG during the first quarter of CY 2006, taking into account discounts and rebates. We also asked them to submit invoices to document all IVIG purchases. Between May and August 2006, 157 physicians (62 percent) responded to our written survey and 100 physicians (39 percent) provided their purchase volume and acquisition costs for IVIG.

Data Analysis: Pricing and Sales Data From 2006

Distributors. We examined 2006 sales and pricing data from the three largest IVIG distributors for the first three quarters of 2006. We calculated the percentage of IVIG sales to hospitals and physicians at prices above and below the Medicare payment amounts for the first three quarters of 2006.

Physicians. Based on the information provided by responding physicians, we calculated the percentage of IVIG purchased at prices above and below the first-quarter 2006 Medicare physician payment amounts. We also determined the percentage of IVIG purchased by physicians that was subject to discounts and rebates and examined physician responses to our written survey.

²⁰ Based on data obtained from all distributors, OIG determined that the three largest IVIG distributors accounted for approximately 90 percent of distributor-reported sales in the fourth quarter of 2005.

²¹ The sales volume and pricing data presented were provided by distributors and include IVIG sales and prices to GPO and non-GPO members.

Pricing and Sales Data From 2005

Manufacturers. Based on the information provided by the five manufacturers, we identified the amount of IVIG sold in 2005 to each type of customer. In addition, we analyzed manufacturer responses to the written survey on pricing and availability.

Distributors and group purchasing organizations. For the 13 distributors that provided pricing and sales data, we identified the amount of IVIG sold in the fourth quarter of 2005 to each type of customer and at contract and noncontract prices. For sales to hospitals, we determined the percentage of IVIG sold at prices above and below both the Medicare outpatient hospital payment amount and the Medicare physician payment amount for the fourth quarter of 2005 (the new hospital reimbursement amount for the following quarter). For physicians, sales prices were compared to the fourth-quarter 2005 physician payment amounts only. We calculated the percentage of sales to hospitals and physicians at contract and noncontract prices.²² We also examined distributor and GPO responses to the written survey on pricing and availability. See Appendix A for a detailed description of our methodology.

Limitations

The findings presented are based only on self-reported data received from manufacturers, distributors, GPOs, and physicians. We did not verify the data or invoices that we received from manufacturers, distributors, GPOs, or physicians. In addition, this analysis applies only to responding physicians from our sample; we were unable to make projections to the universe of all physicians who billed Medicare for IVIG because of the response rate.

Standards

This study was conducted in accordance with the “Quality Standards for Inspections” issued by the President’s Council on Integrity and Efficiency and the Executive Council on Integrity and Efficiency.

²² For the purposes of this review, IVIG sales to GPO members by distributors at the contract prices are considered “contract” sales. The independent resale of IVIG by distributors to providers is considered a “noncontract” sale. Distributors typically mark up manufacturer sales prices prior to reselling noncontract IVIG directly to customers.

► FINDINGS

In the third quarter of 2006, just over half of IVIG sales to hospitals and physicians were at prices below Medicare payment amounts, which represents a substantial increase over the previous three quarters

During the third quarter of 2006, 56 percent of IVIG sales to hospitals and 59 percent of IVIG sales to physicians by the three largest distributors occurred at prices below the Medicare payment amounts.²³

This represents a dramatic shift from the previous three quarters, when the percentage of IVIG sold at prices below the Medicare payment amounts was as low as 23 percent for hospitals and 4 percent for physicians. As Tables 1 and 2 illustrate, the percentage of IVIG sold at prices at least 10 percent above the Medicare reimbursement amount declined substantially in the third quarter of 2006 as well.

Table 1. Distributor Sales to Hospitals From Fourth Quarter of 2005 to Third Quarter of 2006

| IVIG Price Range | 4 th Quarter 2005 | 1 st Quarter 2006 | 2 nd Quarter 2006 | 3 rd Quarter 2006 |
|--|------------------------------|------------------------------|------------------------------|------------------------------|
| Below Medicare payment | 37.3% | 25.5% | 22.8% | 56.0% |
| 0.01%–5.00% greater than Medicare payment | 51.2% | 30.7% | 31.4% | 6.1% |
| 5.01%–10.00% greater than Medicare payment | 2.7% | 11.5% | 9.6% | 33.6% |
| 10.01%–20.00% greater than Medicare payment | 6.5% | 5.1% | 5.2% | 3.2% |
| 20.01%–25.00% greater than Medicare payment | 0.4% | 25.1% | 29.7% | 0.7% |
| More than 25.01% greater than Medicare payment | 1.9% | 2.1% | 1.4% | 0.5% |

Source: IVIG pricing and sales data from the three largest distributors.
 Note: Totals may not add because of rounding.

Table 2. Distributor Sales to Physicians From Fourth Quarter of 2005 to Third Quarter of 2006

| IVIG Price Range | 4 th Quarter 2005 | 1 st Quarter 2006 | 2 nd Quarter 2006* | 3 rd Quarter 2006 |
|--|------------------------------|------------------------------|-------------------------------|------------------------------|
| At or below Medicare payment* | 33.0% | 10.5% | 3.5% | 58.6% |
| 0.01%–5.00% greater than Medicare payment | 48.5% | 44.4% | 53.9% | 8.3% |
| 5.01%–10.00% greater than Medicare payment | 0.1% | 7.0% | 0.9% | 14.0% |
| 10.01%–20.00% greater than Medicare payment | 11.0% | 11.6% | 18.8% | 15.8% |
| 20.01%–25.00% greater than Medicare payment | 1.2% | 18.0% | 15.4% | 2.4% |
| More than 25.01% greater than Medicare payment | 6.3% | 8.4% | 7.6% | 1.0% |

Source: IVIG pricing and sales data from the three largest distributors.
 Note: Totals may not add because of rounding.

*Less than 1 percent of sales to physicians during this quarter were at the same price as the Medicare payment amount.

²³ The three largest IVIG distributors accounted for approximately 90 percent of distributor-reported sales in the fourth quarter of 2005, including 97 percent of sales to hospitals and 66 percent of sales to physicians. Because these distributors account for almost all hospital purchases, these data are representative of hospital costs. Most sales by these distributors were to GPO members at contract prices. Virtually no IVIG sold by the remaining 10 distributors was subject to GPO contracts. However, 34 percent of physician purchases came from smaller distributors at noncontract prices, and the percentages in Table 2 may overestimate actual amounts of IVIG sales below Medicare payment amounts.

F I N D I N G S

Purchase prices and invoices supplied by responding physicians for the first quarter of 2006 corroborate the distributor data presented in Table 2. The pricing data illustrate that approximately 10 percent of physician purchases (after subtracting discounts and rebates) were made at prices below the Medicare physician payment amounts in the first quarter of 2006.²⁴

The substantial increase in sales below the Medicare payment amounts appears to be the result of manufacturer price increases in January 2006 that were not reflected in increased Medicare payments until the third quarter of 2006

According to data provided by manufacturers, all planned to increase IVIG prices at the beginning of 2006. The data provided by distributors indicate that these price increases were then passed on to customers. However, Medicare payment amounts in the first two quarters of 2006 were still based on older sales prices from 2005. Therefore, even though hospitals and physicians had to pay more for IVIG in early 2006, their Medicare payment did not increase at the same time. It appears that payment amounts for IVIG started to “catch up” with actual sales prices during the third quarter of 2006, and this is reflected in the increase in the percentage of sales at prices below the Medicare payment amounts shown in Tables 1 and 2. Table 3 below illustrates that Medicare payment amounts for IVIG have risen over the last four quarters. The largest increase in Medicare payments occurred between the second and third quarters of 2006, reflecting manufacturer price increases from two quarters prior.

Table 3. Medicare Payment for IVIG From the Fourth Quarter of 2005 to the Third Quarter of 2006

| IVIG Form | 4 th Quarter 2005 ²⁵ | 1 st Quarter 2006 | 2 nd Quarter 2006 | 3 rd Quarter 2006 |
|----------------------|--|------------------------------|------------------------------|------------------------------|
| Liquid IVIG (1 gram) | \$56.30 | \$56.72 | \$58.18 | \$60.23 |
| Powder IVIG (1 gram) | \$43.10 | \$44.44 | \$44.52 | \$49.80 |

Source: CMS 2005 and 2006 ASP drug pricing files.

²⁴ Approximately 90 percent of physician-reported purchases were at prices above the Medicare payment amount in the first quarter of 2006. In addition, 133 of 157 responding physicians (85 percent) reported that they could not purchase either liquid or powder IVIG at a price below the Medicare payment amount for that quarter.

²⁵ These are the Medicare physician payment amounts for the fourth quarter of 2005. The Medicare hospital payment amount for this quarter was \$80.68 per gram.

In the fourth quarter of 2005, IVIG obtained by hospitals and physicians through GPO contracts was more likely to be sold at prices below the Medicare payment amounts than IVIG not obtained through GPO contracts.

Physicians are less likely than hospitals to obtain IVIG through GPO contracts. Most distributor sales to hospitals (87 percent) were at contract prices in the fourth quarter of 2005; however, a much smaller portion of distributor sales to physicians (44 percent) were at contract prices during the same quarter.²⁶

According to sales data collected from 13 distributors (including the 3 largest IVIG distributors), 39 percent of contract sales were at prices below the Medicare payment amounts during the fourth quarter of 2005 (see Table 4 on the next page). In contrast, only 2 percent of noncontract IVIG was sold at prices below the Medicare physician payment amounts during the same quarter. Furthermore, almost one-third of noncontract sales exceeded Medicare payment amounts by at least 20 percent. Less than 1 percent of contract sales exceeded the Medicare payment amounts by that amount.

Noncontract prices may be higher than contract prices because they are subject to additional distributor markups.²⁷ Distributors typically mark up manufacturer sales prices prior to reselling IVIG to customers, such as physicians or hospitals. Distributor markups have a greater effect on noncontract prices because contract prices are set, prenegotiated prices between the GPO and manufacturers. Distributors do not determine these prices, and any markup is limited by the terms of the contracts. The markup limitations do not typically apply to IVIG sold outside of a GPO contract, although some manufacturers place limits on distributor markups. In the fourth quarter of 2005, distributor markups for noncontract sales ranged from 5 to 49 percent.

²⁶ For the purposes of this review, IVIG sales to GPO members at the contract prices by distributors are considered “contract” sales. Not all sales by distributors are subject to GPO contracts. In contrast to the contract sales, sales of IVIG by distributors to providers are considered “noncontract” sales. Distributors typically mark up manufacturer sales prices prior to reselling noncontract IVIG directly to customers, such as physicians or hospitals.

²⁷ We are defining markup as the difference between how much a distributor pays the manufacturer for IVIG and how much the distributor charges customers for IVIG.

F I N D I N G S

Table 4. Contract and Noncontract Sales Prices for IVIG in the Fourth Quarter of 2005

| IVIG Price Range | Percentage of Contract Sales | Percentage of Noncontract Sales |
|--|------------------------------|---------------------------------|
| Below Medicare physician reimbursement | 39.2% | 1.7% |
| 0.01%–5.00% greater than Medicare physician reimbursement | 55.9% | 24.6% |
| 5.01%–20.00% greater than Medicare physician reimbursement | 4.7% | 40.5% |
| 20.01%–50.00% greater than Medicare physician reimbursement | 0.2% | 24.9% |
| More than 50.01% greater than Medicare physician reimbursement | 0.0% | 8.3% |

Source: IVIG pricing and sales data from distributors.

Note: Totals may not add because of rounding.

Most physicians and distributors reported problems with IVIG availability in 2005 and the first quarter of 2006

The majority (57 percent) of responding physicians reported that they were unable to provide patients with adequate amounts of IVIG during the first quarter of 2006.

These physicians stated that problems with IVIG availability were typically related to Medicare payment.

A small number of responding physicians said that they had stopped providing IVIG to Medicare beneficiaries altogether. One responding physician stated that payment issues led him to turn patients away: “The reimbursement from Medicare does not cover the cost of medication. We are unable to provide care for new patients.” Another physician added: “We can no longer treat [Medicare] patients with IVIG due to losing hundreds of dollars each time.” A third physician cited supply issues for the inability to treat patients: “Due to insufficient supply, we are forced to turn away patients requiring IVIG.”

All 13 distributors responding to our January 2006 survey also reported problems with IVIG availability. One summarized the situation by stating: “Customers have requested more product, but we are unable to obtain the extra product needed from the manufacturer.” According to their responses, none of the distributors were able to fulfill all customer requests for IVIG, and all distributors have asked manufacturers for additional product. Most distributors reported that manufacturers were unable to provide them with additional IVIG.

One important reason distributors are unable to obtain additional IVIG from manufacturers is that manufacturers are contractually obligated to fulfill their GPO allocations first, and, when additional product is available, manufacturers reportedly provide it to GPO members first (at a noncontract price). Therefore, hospitals and physicians who are not GPO members do not have the same access to IVIG products.

Manufacturers, distributors, and physicians reported that patients were being shifted from physicians' offices to hospitals to receive IVIG

Manufacturers responded that they received reports in 2005 of some patients being moved from physicians' offices to hospitals for IVIG treatment because of payment differentials between the settings at that time. Similarly, in responses to our January 2006 survey, a majority of the distributors noted that patients were being moved from physicians' offices to hospitals to receive IVIG treatment because of changes in Medicare's physician payment amounts. Physicians also noted in their response to our April 2006 survey that an increasing number of patients were receiving IVIG treatment in hospitals. Sixty-one percent of responding physicians indicated that they had sent patients to hospitals for IVIG treatment because of their inability to acquire adequate amounts of IVIG or problems with Medicare payment. The most common explanation for the shift to hospitals was Medicare payment, specifically the inability of physicians to purchase IVIG at prices below the Medicare payment amounts.

Distributor sales data support this claim and indicate that hospitals received more IVIG in the fourth quarter of 2005 than in the fourth quarter of 2004, while sales to physicians decreased. At that time, prices to hospitals were generally lower than prices to physicians, while Medicare payment to hospitals for IVIG administered in an outpatient setting was substantially higher than Medicare payment to physicians in 2005.²⁸ In keeping with the payment reforms in the MMA, CMS began paying for most Part B drugs and biologicals administered in hospital outpatient departments based on 106 percent of the manufacturer's ASP on January 1, 2006.²⁹ Despite the reduction in hospital payments following the change in payment methodology, data from the three largest distributors indicate that total sales to hospitals continued to increase through the first half of 2006.

The priority given to GPO contract customers is related to the shift in patients to hospitals, because the GPO market comprises primarily

²⁸ In 2005, CMS reimbursed hospitals for outpatient drugs at 83 percent of the AWP. The CMS hospital payment for both powder and liquid IVIG was \$80.68 per gram in the fourth quarter of 2005, compared to 56.30 (liquid IVIG) and \$43.10 (powder IVIG) for physicians.

²⁹ "Medicare Announces Payment Rates and Policy Changes for Hospital Outpatient Services in 2006." Available online at <http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1711>. Accessed April 24, 2006.

F I N D I N G S

hospitals and nursing homes (although some physicians can purchase IVIG through GPOs). According to distributor data, most hospitals receive IVIG through their GPO memberships and, as previously stated, contract prices are generally lower than noncontract prices. One distributor summarized the potential problems with hospitals acquiring larger portions of available IVIG by stating: “The product [IVIG] allocation is normally based on historical usage data. To meet the new increased demands in the hospital outpatient setting, [the distributor] used noncontract product to meet those needs. This decreased the amount of IVIG available to the noncontract market (e.g., physicians, home care and pharmacies).”

► C O N C L U S I O N

Based on the data presented in this report, just over half of IVIG sales to hospitals and physicians were at prices below the Medicare payment amounts in the third quarter of 2006, a substantial increase over previous quarters. Distributors and physicians also reported problems with IVIG availability.

The interaction of manufacturer pricing decisions and certain ASP-related issues could partially explain our findings regarding IVIG pricing and availability. For example, the results of this review indicate that the two-quarter lag between manufacturer price increases and corresponding increases in Medicare payment amounts may have played a major role in substantially increasing the percentage of IVIG sales at prices below the Medicare payment amounts in the third quarter of 2006.

Because manufacturer price increases for IVIG in early 2006 were not reflected in Medicare reimbursement until the middle of that year, hospitals and physicians were initially being charged more for IVIG without a corresponding increase in payment. If manufacturers were to implement another across-the-board price increase, hospitals and physicians might face issues similar to those that they faced in the first two quarters of 2006.

Furthermore, ASPs include manufacturer sales to all classes of trade and do not explicitly include distributor markup, which may cause the actual acquisition cost of IVIG to exceed the Medicare payment amount (especially in a time when increased demand creates incentives for distributors to increase markups on noncontracted sales). In the case of IVIG, the combination of the two-quarter lag and distributor markups could result in a gap between provider acquisition costs and Medicare payment amounts, which could lead providers to shift patients to other sites of service. When this occurs, beneficiaries may have difficulty obtaining treatment in their preferred settings.

It is important to note that additional factors, including off-label use, coding, and plasma industry economics, may drive the difficulties with IVIG pricing and availability. Reported recent increases in the use of IVIG for off-label indications may strain the tight supply of this product. Each IVIG product is a unique brand drug, yet Medicare payment is based on a weighted average price of all products. The production of

C O N C L U S I O N

IVIG requires substantial resources not typically associated with other pharmaceutical products. However, this review did not include an in-depth examination of these factors.

AGENCY COMMENTS

CMS commented that this report provides initial information on the availability and pricing of IVIG and sets the stage for further review of certain issues (e.g., off-label use, payment lags, and distributor markups) that can bring greater understanding of how the marketplace operates for this unique product. CMS also noted that the time lag is a feature of the ASP system and applies to all Part B drugs and biologicals. CMS stated that the substantial increase in the percentage of IVIG sold to hospitals and physicians at prices below the Medicare payment amounts is an important development and noted that these findings indicate that Medicare payment has adjusted to increases in IVIG market prices over time. CMS stated, “We will carefully consider this report as we continue our dialogue with manufacturers, patient groups, and stakeholders to better understand marketplace developments and issues impacting beneficiary access to quality care. We strongly encourage the OIG to further study some of the issues raised [in CMS’s comments to the draft report].”

DETAILED SCOPE AND METHODOLOGY

Detailed Scope

We conducted a multiphase review to examine the pricing and availability of intravenous immune globulin (IVIG) from the perspectives of: (1) the manufacturers of IVIG, (2) distributors and group purchasing organizations (GPOs) identified by the manufacturers as involved in the sale and distribution of IVIG, and (3) randomly selected physicians who billed Medicare for IVIG.

Manufacturers. We collected data from the five IVIG manufacturers producing IVIG at the time of the survey (December 2005). We did not include the American Red Cross in this study because it announced its exit from the plasma therapeutics business in July 2005.

Distributors and group purchasing organizations. Based on information collected from the 5 IVIG manufacturers, we identified 17 distributors and 7 GPOs involved with the sale and distribution of IVIG. We collected data only from distributors and GPOs identified by the manufacturers. IVIG manufacturers identified four additional companies as distributors in their responses to the Office of Inspector General (OIG). We did not include three of these in our analysis because these companies do not consider themselves distributors, as none of them resells IVIG. The fourth company identified itself as a “small independent distributor” and “was not set up to breakout the kind of information [OIG] is requesting.”

For the three largest IVIG distributors, we collected sales and pricing data for the first three quarters of 2006. We did not collect any 2006 sales and pricing data from smaller distributors, who tend to charge customers more for IVIG.

Physicians. We randomly selected physicians who billed Medicare for two IVIG procedure codes during the third quarter of 2005. The procedure codes are: Q9941—injection, immune globulin, intravenous, lyophilized (powder), 1 gram; and Q9943—injection, immune globulin, intravenous, nonlyophilized (liquid), 1 gram. These two codes accounted for the majority of Medicare payment for IVIG during the last three quarters of 2005 (the effective dates of these codes). There were two additional IVIG procedure codes in effect during 2005: Q9942 and Q9944, which were 10-milligram doses of powder and liquid IVIG, respectively. We did not include these two codes in our analysis.

Effective January 1, 2006, CMS replaced these four procedure codes with two new codes: J1566 and J1567.

Detailed Methodology: Data Sources and Sample

Manufacturers. The five manufacturers producing IVIG at the time of the survey (December 2005) provided OIG with 2005 IVIG sales prices and sales volume. In addition, we asked manufacturers to complete a written survey about IVIG access and availability, distribution methods, resale policies, customers, and future production plans.

Distributors and GPOs. Manufacturers identified 17 distributors and 7 GPOs involved with the sale and distribution of IVIG. Between January and April 2006, 14 distributors and 6 GPOs completed a written survey concerning IVIG. Two of the seventeen distributors submitted survey responses after the deadline for data collection. The remaining distributor and one GPO did not complete the survey or provide sales and pricing data. Based on manufacturer sales data, these nonrespondents made up a very small portion of IVIG sales.

Thirteen of these distributors also provided us with their sales prices and sales volume for 2005. The sales volume and pricing data were provided by distributors and include IVIG sales and prices to GPO and non-GPO members.

Based on distributor-reported data, we determined that the three largest IVIG distributors accounted for approximately 90 percent of distributor-reported sales in the fourth quarter of 2005. We collected sales and pricing data from these three largest distributors for the first three quarters of 2006.

Physicians. We extracted all paid Medicare Part B physician claims for two IVIG procedure codes from CMS's 2005 National Claims History File with dates of service in the third quarter of 2005 (the most recent claims data available at the time we selected our sample). We summarized the claims by the physician's Unique Physician Identification Number (UPIN) and profiling identification number. After we summarized third-quarter 2005 claims data by UPIN and profiling identification number, there were 1,111 observations for Q9941 and 1,350 observations for Q9943.

We then selected a simple random sample of 130 physicians for each of the two procedure codes. OIG investigative concerns prevented us from contacting a small number of physicians; we excluded these physicians from our sample. The final sample contained 129 physicians for

procedure code Q9941 and 126 physicians for procedure code Q9943, for a total of 255 physicians.

In April 2006, we sent written surveys on pricing and availability to the 255 randomly selected physicians in our sample. We asked physicians how much they paid for IVIG during the first quarter of 2006, taking into account all discounts and rebates. We asked physicians to submit invoices to document all IVIG purchases. We also asked physicians how available and accessible IVIG is, what happens when they are unable to provide patients with adequate amounts of IVIG, and from what sources they purchase IVIG products.

Between May and August 2006, 157 physicians (62 percent) responded to our written survey and 100 physicians (39 percent) provided their purchase volume and acquisition costs for IVIG. Some respondents reported IVIG purchases and purchase prices for individual physicians in our sample, while others provided IVIG purchases and prices for physicians' group practices. We could not identify fundamental differences between responding and nonresponding physicians.

Data Analysis: Pricing and Sales Data From 2006

Distributors. We examined sales and pricing data for the first three quarters of 2006 from the three largest IVIG distributors. We calculated the percentage of IVIG sales to hospitals and physicians at prices above and below the Medicare payment amounts and identified trends in IVIG availability related to increases in IVIG purchase prices and Medicare payment.

Physicians. Based on the information provided by the responding physicians, we calculated the percentage of IVIG purchased by responding physicians at prices above and below the first-quarter 2006 Medicare physician payment amounts, which were based on average sales prices reflecting manufacturer sales from July through September 2005. For this analysis, we compared physician-reported prices that take into account discounts and rebates with the Medicare physician payment amounts. We also determined the percentage of IVIG purchased by physicians that was subject to discounts and rebates. We examined physician responses to our survey to identify what product availability issues exist, what concerns physicians have about Medicare payment, from what sources physicians purchase IVIG products, how physicians use IVIG, and any other specified issues.

Pricing and Sales Data From 2005

Manufacturers. Based on the information provided by the five manufacturers, we identified the amount of IVIG sold in 2005 to each type of customer (e.g., distributor, GPO member, direct customer, and home care company). In addition, we analyzed manufacturer responses to questions about IVIG access and availability, distribution methods, resale policies, customers, future prices, and future production plans.

Distributors and GPOs. We identified the amount of IVIG sold in the fourth quarter of 2005 to each type of customer (e.g., hospital, physician, clinic, home care company, etc.). For sales to hospitals, we determined the percentage of IVIG sold at prices above and below both the Medicare outpatient hospital payment amount and the Medicare physician payment amount for the fourth quarter of 2005. We also calculated the percentage of sales to hospitals and physicians at contract and noncontract prices. For physicians, sales prices were compared only to the fourth-quarter 2005 physician payment amounts.

We identified the amount of IVIG sold in the fourth quarter of 2005 at contract and noncontract prices, regardless of customer type. For the purposes of this review, IVIG sales to GPO members at the contract prices by distributors are considered “contract” (encumbered) sales. One distributor that works extensively with GPO members summarized the relationship in the following way: “The GPO sends [distributor] the allocation spreadsheets that list their members along with the IVIG allotment that is agreed upon between the provider and the GPO . . . The GPO members call to order their IVIG and [the distributor] ships product to the GPO members based on the allocation spreadsheets.”

Not all sales by distributors are subject to GPO contracts. In contrast to the contract sales described above, sales of IVIG that distributors independently resell to providers are considered “noncontract” (unencumbered) sales. Distributors typically markup manufacturer sales prices prior to reselling noncontract IVIG directly to customers, such as physicians or pharmacies. Each manufacturer allows distributors to sell a portion of their IVIG at noncontract prices.

We also examined distributor and GPO responses to the pricing and availability survey to identify distribution methods, manufacturer relationships, resale policies, product availability, pricing, and other specified issues.

▶ A P P E N D I X ~ B

Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

APR 12 2007

TO: Daniel R. Levinson
Inspector General

FROM: Leslie V. Norwalk, Esq. *Leslie V. Norwalk*
Acting Administrator

SUBJECT: Office of Inspector General's Draft Report: "Intravenous Immune Globulin: Medicare Payment and Availability" (OEI-03-05-00404)

Thank you for the opportunity to review the above referenced report. We appreciate the Office of Inspector General's (OIG) efforts to provide information about the supply chain for intravenous immune globulin (IVIG). We believe this report provides some initial information on the availability and pricing for this product and as discussed below, sets the stage for further review of key issues that can bring greater understanding of how the marketplace operates for this product.

Beginning in 2005, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 required Medicare to pay physicians for most drugs and biologicals, including IVIG, based on 106 percent of the average sales price (ASP + 6 percent). In 2006, Medicare also began paying hospital outpatient departments for IVIG, as well as other drugs and biologicals, based on ASP + 6 percent.

Studies by Medicare Payment Advisory Committee and OIG indicate that physicians are generally able to acquire most drugs and biologicals at prices below the ASP + 6 percent payment rate. While these studies suggest that the supply chain system for ASP is generally working well, we are concerned about reports of problems with product availability and Medicare payment rates for IVIG. We take these reports seriously. The Centers for Medicare & Medicaid Services (CMS), along with the Food and Drug Administration and other components within the Department, continue to actively work with manufacturers, health care providers, patient groups, and others to better understand the present situation and to assess potential actions that will help to ensure an adequate supply of IVIG and patients receiving appropriate and high quality care.

As the report points out, IVIG is a unique product. Since IVIG is derived from blood plasma, the amount produced depends on plasma collection. With constraints on the amount of raw material available, there are constraints on the amount of IVIG that can be produced.

The demand for IVIG has grown significantly in recent years, as off-label use of the product has increased dramatically. While demand has increased, so too has supply.

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The availability for IVIG has historically been cyclical. There have previously been both periods of abundant and tight IVIG supply. The report found that all distributors surveyed indicated that they were not able to obtain additional IVIG from any source and that most distributors were unable to obtain additional IVIG from manufacturers. There are a limited number of IVIG manufacturers, with three companies accounting for 85 percent of IVIG production. This can have significant implications for pricing and the availability of IVIG. In a tight market, increased demand generated by factors, such as additional off-label use, has an impact on IVIG availability for Medicare beneficiaries. It would be helpful to know more about the surge in off-label use, its effectiveness, and the current and planned research in this area.

IVIG products have been put on allocation by manufacturers and thus most IVIG product is not for sale on the open market. Instead, IVIG has been obligated for delivery to Group Purchasing Organizations (GPOs), distributors, and other end purchasers based on long-term contracts with the manufacturers. Higher prices for IVIG obtained outside a GPO or not via a contract may impact access and product availability for some Medicare beneficiaries. Your report also indicates: "Noncontract prices may be higher than contract prices because they are subject to additional distributor markups".

The report contains important information about the key role of distributors, a major player in the supply chain. Your report specifically discusses distributor mark-ups for IVIG. Your report found: "In the fourth quarter of 2005, distributor mark-ups for noncontract sales ranged from 5 to 49 percent." This range contains what some might consider excessive mark-ups and is substantially higher than commonly thought to be typical for other drugs and biologicals. The report did not examine how distributor mark-ups for IVIG compare to distributor mark-ups for other drugs and biologicals where payment is successfully made at ASP plus 6 percent. If distributor mark-ups are materially higher for IVIG than for other drugs and biologicals, it could have a significant impact on IVIG availability.

It would also be useful to know whether the mark-ups charged by the same distributor vary over time. For example, if a distributor increases mark-ups when supply gets tighter, and that mark-up is unrelated to the price the distributor has to pay the manufacturer for IVIG, the mark-up could have an impact on IVIG availability and patient access.

There is also an issue about the role of the secondary market in IVIG pricing and availability. Some believe that the secondary market accounts for 10 percent or more of IVIG distribution. Not only does a significant secondary market raise product integrity issues, but also secondary markets are often characterized by fluctuating prices and product availability, particularly where there is a tight supply of IVIG.

In addition, the OIG report analyzed the difference between distributor sales to physicians and hospitals and Medicare payment amounts. We note that any increase in

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Medicare payment amounts would increase payments to all purchasers, including those purchasers who can currently obtain product at or below Medicare payment amounts.

The study suggests that the two quarter lag in the ASP system and the exclusion of distributor mark-up from ASP may have led to differentials between the Medicare payment amount and providers' acquisition costs for IVIG. We note, however, that these features of the ASP system apply to all Part B drugs and biologicals. Yet, the OIG has found that other drugs and biologicals are generally faring well under the ASP system. It would be helpful if this issue, as it relates to IVIG and distributor mark-ups, were explored further.

With respect to the lag, we note that payment rates under all Medicare payment systems, other than for Part B drugs and biologicals, are adjusted once per year. In contrast, Medicare payment rates for Part B drugs are adjusted quarterly. This system works for other Part B drugs and biologicals. We are concerned that some may misinterpret the information about the relationship between actual sales and Medicare payment amounts to suggest eliminating the lag. We are not sure what it would mean to eliminate the lag or how Medicare payment rates would be determined. We are not sure how Medicare could operate a payment system that would change payment amounts more frequently or with a shorter time lag between data collection and implementation.

In the typical market for a product, an increase in price would lead to an increase in supply. However, given the unique characteristics of IVIG and production issues, it is not clear that an increase in Medicare payment amounts would lead to an increase in IVIG supply. If there is a higher payment amount that would lead manufacturers to increase supply, it is not clear what that higher payment amount is, how it would be determined on a one-time or regular basis, and whether it would increase supply sufficiently for both physicians and hospitals.

In the report, it is encouraging that increasing numbers of physicians and hospitals are able to purchase IVIG below the Medicare ASP+6 payment rates despite these issues. In the third quarter of 2006, Medicare payment rates were higher than 59 percent of sales to physicians and 56 percent of sales to hospitals, a substantial increase in these percentages over the prior 3 quarters. We consider this increase to be an important development, as it suggests that although your report cannot determine the underlying reasons physicians and hospitals have had issues with IVIG product availability, Medicare payment rates, under the ASP+6 system, have adjusted to substantial increases in IVIG market prices over time.

We appreciate the OIG's work in this complex area. We will carefully consider this report as we continue our dialogue with manufacturers, patient groups, and stakeholders to better understand marketplace developments and issues impacting beneficiary access to quality care. We strongly encourage the OIG to further study of some of the issues raised in these comments in order to better understand the IVIG market. Any solution needs to address the underlying problem, otherwise the action could be ineffective, and could lead to severe access problems.



A C K N O W L E D G M E N T S

This report was prepared under the direction of Robert A. Vito, Regional Inspector General for Evaluation and Inspections in the Philadelphia regional office, and David E. Tawes, Director, Prescription Drug Pricing Unit.

Edward K. Burley served as the team leader for this study. Other principal Office of Evaluation and Inspections staff from the Philadelphia regional office who contributed to this report include Roman Strakovsky and Kriti Sehgal; other central office staff who contributed include Linda B. Abbott, Scott Horning, and Barbara Tedesco.