United States Government Accountability Office

Report to the Ranking Member, Committee on Ways and Means, House of Representatives

July 2016

MEDICARE PART B

CMS Should Take Additional Steps to Verify Accuracy of Data Used to Set Payment Rates for Drugs

GAO-16-594

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GAO Highlights

Highlights of GAO-16-594, a report to the Ranking Member, Committee on Ways and Means, House of Representatives

Why GAO Did This Study

Medicare Part B covers drugs typically administered by a physician. Medicare pays physicians and other providers for these drugs at an amount generally equal to the ASP of the drug plus a fixed percentage. These payment rates are calculated quarterly by CMS based on price and volume data reported by drug manufacturers. Members of Congress and others have questioned the amount that both Medicare and its beneficiaries spend on Part B drugs.

GAO was asked to examine Medicare spending for and utilization of Part B drugs and the accuracy of the sales price data reported by drug manufacturers. This report (1) describes Medicare spending and utilization for Part B drugs that are paid based on ASP, including variations in spending and utilization by provider and drug characteristics, and (2) examines the steps CMS takes to ensure the accuracy of the sales price data reported by drug manufacturers. To describe Medicare spending and utilization for Part B ASP drugs, GAO analyzed 2014 Medicare claims data. To examine the accuracy of ASP data, GAO interviewed CMS, the HHS Office of Inspector General, and drug manufacturers and reviewed related documentation.

What GAO Recommends

Congress should consider requiring all manufacturers of drugs paid at ASP to submit sales price data to CMS. Further, CMS should periodically verify the data submitted by a sample of drug manufacturers by requesting source documentation. HHS agreed with GAO's recommendation and stated that CMS would take action as warranted.

View GAO-16-594. For more information, contact James Cosgrove at (202) 512-7114 or cosgrovej@gao.gov.

What GAO Found

In 2014, the most recent year for which data were available, the Medicare program and its beneficiaries spent about $21 billion on approximately 46 million administrations of 551 Part B drugs paid based on average sales price (ASP). Six drugs—each exceeding $1 billion in expenditures—accounted for 36 percent of all expenditures on Part B ASP drugs, while a different 10 drugs—each administered over 1 million times—accounted for 37 percent of all administrations. Biologics (drugs made from living entities), drugs without generic versions available, and drugs made by a single manufacturer were associated with the vast majority of expenditures on Part B ASP drugs. In contrast, synthetics (drugs produced from chemical ingredients), drugs with generic versions available, and drugs with multiple manufacturers were associated with the vast majority of administrations. Compared with other types of providers, hematology oncologists were associated with the highest percentage of drug expenditures and administrations.

Drug Characteristics Associated with the Highest Percentage of Expenditures on and Administrations of Part B Drugs Paid Based on Average Sales Price (ASP) (2014)

	Expenditures		Administrations	
Drug characteristic	Characteristic	Percentage of total	Characteristic	Percentage of total
Drug composition	Biologic	68	Synthetic	76
Brand/generic status	Brand only	89	Generic available	66
Single-source/multi-source status	Single-source	81	Multi-source	74

Source: GAO analysis of Centers for Medicare & Medicaid Services, Food and Drug Administration, and RED BOOK data. | GAO-16-594

Note: Expenditures reflect the total amount spent by the Medicare fee-for-service program and its beneficiaries, and administrations reflect the number of claim line items for a drug. Both measures include only those for claim line items that Medicare paid based on ASP.

The Centers for Medicare & Medicaid Services (CMS), an agency within the Department of Health and Human Services (HHS), performs several electronic data checks on the sales price data reported by drug manufacturers each quarter, including checking for missing data or incorrect product information. However, CMS does not routinely verify the underlying data, which is inconsistent with federal internal control standards that call for management to use quality information to achieve its objectives. Without additional verification of the ASP data received from manufacturers, it is possible for the data to be inaccurate, which could result in inaccurate Medicare payment rates. In addition, CMS is unable to use or assess the accuracy of all sales price data because, as directed by statute, only manufacturers with Medicaid drug rebate agreements are required to submit sales price data to CMS. Unless all manufacturers without rebate agreements choose to voluntarily submit sales price data, the payment rates for some drugs will be based on incomplete ASP data or will not be set based on ASP.

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Abbreviations

AMP	average manufacturer price
ASP	average sales price
AWP	average wholesale price
CMS	Centers for Medicare & Medicaid Services
DME	durable medical equipment
ESRD	end-stage renal disease
FDA	Food and Drug Administration
FFS	fee-for-service
HCPCS	Healthcare Common Procedure Coding System
HHS	Department of Health and Human Services
HOPD	hospital outpatient department
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
NDC	National Drug Code
OIG	Office of Inspector General

U.S. GOVERNMENT ACCOUNTABILITY OFFICE
441 G St. N.W.
Washington, DC 20548

July 1, 2016

The Honorable Sander M. Levin
Ranking Member
Committee on Ways and Means
House of Representatives

Dear Mr. Levin:

Medicare spent over $24 billion on drugs covered under Part B in 2014.[1] The majority of these expenditures—over 85 percent—were based on the drug's average sales price (ASP), which the Centers for Medicare & Medicaid Services (CMS) calculates quarterly based on price and volume data reported by drug manufacturers of all sales to all U.S. purchasers, including physicians, hospitals, and wholesale distributors. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) set the Medicare payment rate for most Part B drugs acquired by a physician's office at 106 percent of manufacturers' reported ASP for the drug.[2] The MMA did not specify a payment rate for most Part B drugs acquired by a hospital outpatient department (HOPD) and instead authorized the Department of Health and Human Services (HHS)—the agency that oversees CMS—to annually update the payment rate to reflect HOPDs' acquisition and overhead costs.[3] Since 2013, CMS has set the payment rate for most separately payable Part B drugs acquired

[1]Part B drugs, such as drugs used to treat cancer, are typically administered by a physician or under a physician's close supervision in physicians' offices or hospital outpatient departments. This spending estimate is based on total Medicare fee-for-service (FFS) allowed charges for separately payable Part B drugs and includes spending by the Medicare FFS program, its beneficiaries, and other payers in cases where Medicare is not the primary payer or where beneficiaries receive assistance with their cost sharing. The estimate does not include spending on drugs for which Medicare's payment is bundled with that of a related service—which CMS officials estimated to be about $1.7 billion in 2014—or spending for the administration or dispensing of the drugs.

[2]Pub. L. No. 108-173, § 303(c)(1), 117 Stat. 2066, 2239 (codified as amended at 42 U.S.C. § 1395w-3a). In addition to payment for the drug itself, providers receive a separate payment from Medicare for the administration or supplying of a Part B drug.

[3]Pub. L. No. 108-173, § 621, 117 Stat. 2307 (codified as amended at 42 U.S.C. § 1395l(t)(14)(A)(iii)).

by HOPDs at 106 percent of ASP.[4] Beneficiaries are generally responsible for 20 percent of the payment rate for Part B drugs.

Stakeholders have questioned the amount Medicare spends on Part B drugs and how drug prices affect Medicare beneficiaries' ability to afford needed drugs.[5] For example, members of Congress have noted that due to the high cost of many Part B drugs and the 20 percent cost sharing requirement under Part B, patients who face a serious diagnosis or are living with a chronic health condition are subject to significant financial burdens.[6] Additionally, the HHS Office of Inspector General (OIG) has noted that current manufacturer reporting requirements could result in incomplete information on drug prices being submitted to CMS. In its report, OIG demonstrated how incomplete drug pricing information could affect the accuracy of Part B drug payment rates.[7] We and others also have noted the long-term fiscal challenges facing the Medicare program. Additional information on Medicare Part B drug spending and utilization and the accuracy of the sales price data reported by drug manufacturers may inform congressional efforts to moderate program spending.

[4]Due to the impact of sequestration, an automatic, across-the-board cancellation of budgetary resources implemented pursuant to the Budget Control Act of 2011, most programs, projects, and activities across the federal government received budget cuts. Therefore, Part B drug payment rates to both physicians and hospitals have been approximately 104 percent of ASP. Some Part B drugs, including certain vaccines, radiopharmaceuticals, and new drugs, are not paid based on ASP in either physician's offices or HOPDs. In March 2016, CMS released a proposed rule that outlined the agency's plan to test alternative Part B drug payment designs over a 5-year period. 81 Fed. Reg. 23230, 13258 (Mar. 11, 2016) (to be codified at 42 C.F.R. pt. 511). Under the proposal, the first phase would be implemented in fall 2016 and would involve changing the 6 percent add-on to ASP to 2.5 percent plus a flat fee (in a budget neutral manner) for both physicians and HOPDs. The second phase would be implemented no earlier than January 1, 2017, and would implement value-based purchasing tools similar to those employed by commercial health plans, pharmacy benefit managers, hospitals, and other entities that manage health benefits and drug utilization.

[5]See, for example, Medicare Payment Advisory Commission, *Report to the Congress: Medicare and the Health Care Delivery System* (Washington, D.C.: June 2015), 61-83.

[6]See, for example, Subcommittee on Health of the Committee on Energy and Commerce, *Examining Reforms to Improve the Medicare Part B Drug Program for Seniors,* 113th Cong. 1st session, June 28, 2013.

[7]See Department of Health and Human Services Office of Inspector General*, Limitations in Manufacturer Reporting of Average Sales Price Data for Part B Drugs,* OEI-12-13-00040 (Washington, D.C.: July 2014).

You asked us to examine Medicare spending and utilization for Part B drugs and the accuracy of the sales price data reported by drug manufacturers. In this report, we

- describe Medicare spending and utilization for Part B drugs that are paid based on ASP, including variations in spending and utilization by provider and drug characteristics and
- examine the steps CMS takes to ensure the accuracy of the sales price data reported by drug manufacturers.

To describe Medicare spending and utilization for Part B drugs that are paid based on ASP, we used Medicare fee-for service (FFS) claims data from 2014, the most recent full year of claims data available at the time of our analysis.[8] We first identified all Healthcare Common Procedure Coding System (HCPCS) codes, which CMS uses to determine payment for certain Medicare services, for Part B drugs. A single HCPCS code can cover multiple drugs with different National Drug Codes (NDC), which are universal product identifiers assigned by the Food and Drug Administration (FDA). We used the list of HCPCS codes to identify all claim line items for Part B drugs during 2014. We then restricted the claim line items to those that were paid based on ASP by removing claim line items for drugs and facilities that were paid based on other payment methodologies.[9] Next, for each Part B ASP drug, we calculated Medicare spending, defined as the total amount spent by the Medicare FFS program and its beneficiaries, and two measures of utilization: the number of times the drug was administered—defined as the number of claim line items for the drug—and the number of unique beneficiaries who received the drug.[10] To examine variations in spending and utilization by drug characteristics, such as whether the drug was a brand name or generic drug, we used the claims data, FDA's NDC Product Summary

[8]Specifically, we used the June 2015 updates of CMS's 2014 100 percent National Claims History file for physician services and durable medical equipment (DME) services and the hospital outpatient standard analytical file.

[9]We also removed claim line items where Medicare was not the primary payer and thus did not set the payment rate.

[10]The spending and utilization estimates do not include drugs for which Medicare's payment is bundled with that of a related service—which occurs for many drugs administered in hospital outpatient departments—or spending for the administration or dispensing of the drugs.

File, and Truven Health Analytics' RED BOOK.[11] To examine variations by provider characteristics, such as whether the provider was located in a rural or urban area, we used the claims data and HHS and Department of Agriculture's Rural-Urban Commuting Areas geographic taxonomy.[12]

To examine the steps CMS takes to ensure the accuracy of the sales price data reported by drug manufacturers, we spoke with officials from CMS and OIG about the data CMS receives from manufacturers, including the steps the agency takes to ensure the accuracy of the data. We also spoke with CMS officials about the guidance CMS provides to manufacturers for calculating and submitting these data. We also interviewed representatives from four large and two small drug manufacturers to gain their perspective on the process of calculating and submitting ASP data and the guidance provided by CMS.[13] We reviewed CMS's guidance related to ASP data and compared data validation checks conducted by CMS on manufacturers' reported ASP data with GAO standards related to ensuring the completeness and accuracy of data.[14]

To assess the reliability of the Medicare claims and other data used in this report, we reviewed relevant documentation, performed electronic data checks, benchmarked our results against published sources,[15]

[11]RED BOOK publishes drug pricing and product information. Because the level at which Medicare defines a Part B drug differs from the level used in the Product Summary File and RED BOOK, we used CMS crosswalks to generate a list of NDCs associated with a given HCPCS code, and then summarized the NDC-level drug characteristics to a HCPCS-level. Although CMS's crosswalks do not necessarily include a complete list of all NDCs associated with that HCPCS code, we determined this approach was sufficiently reliable for the purposes of this report.

[12]We used the most recent version of the Rural-Urban Commuting Area Codes available at the time of our analysis, which were based on 2010 Census work-commuting data, the 2012 Census Bureau's revised urban area definition based on 2010 Census data, and 2013 zip codes.

[13]We selected manufacturers based on the number of the manufacturer's drugs that were covered under Medicare Part B in 2014. We selected four manufacturers that produced over 100 drugs each and two manufacturers that produced only one drug each.

[14]GAO, *Standards for Internal Control in the Federal Government*, GAO-14-704G (Washington, D.C.: September 2014) and *Assessing the Reliability of Computer-Processed Data*, GAO-09-680G (Washington, D.C.: July 2009).

[15]We found that our results were generally consistent with those published by CMS.

interviewed agency officials and others familiar with these data sources, or some combination of the four. We determined that the data used in this report were sufficiently reliable for the purposes of this report.

We conducted this performance audit from March 2015 to July 2016 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

Medicare Part B Drugs

Medicare Part B generally covers both synthetic drugs and biologicals administered under a physician's direct supervision, including those administered in physician offices and in hospital outpatient departments that are not usually self-administered.[16] These include injectable drugs (such influenza, pneumococcal, and hepatitis B vaccines); drugs inhaled through durable medical equipment (such as certain asthma medications); and oral cancer drugs if the same drug is available in injectable form.[17]

As with all drugs, Part B drugs can be either single-source or multi-source. Single-source drugs have only one manufacturer. Multi-source drugs have at least two, and often several, versions produced by different manufacturers. While each of these versions will have its own NDC, Medicare pays a single rate for any NDC associated with a given HCPCS code.

[16]Synthetic drugs are produced from specific chemical ingredients and have small, well-defined chemical structures. Conversely, biologicals are large compounds that are made in living systems using components from living entities. In this report, we use the term "drugs" to refer to both synthetic drugs and biologicals.

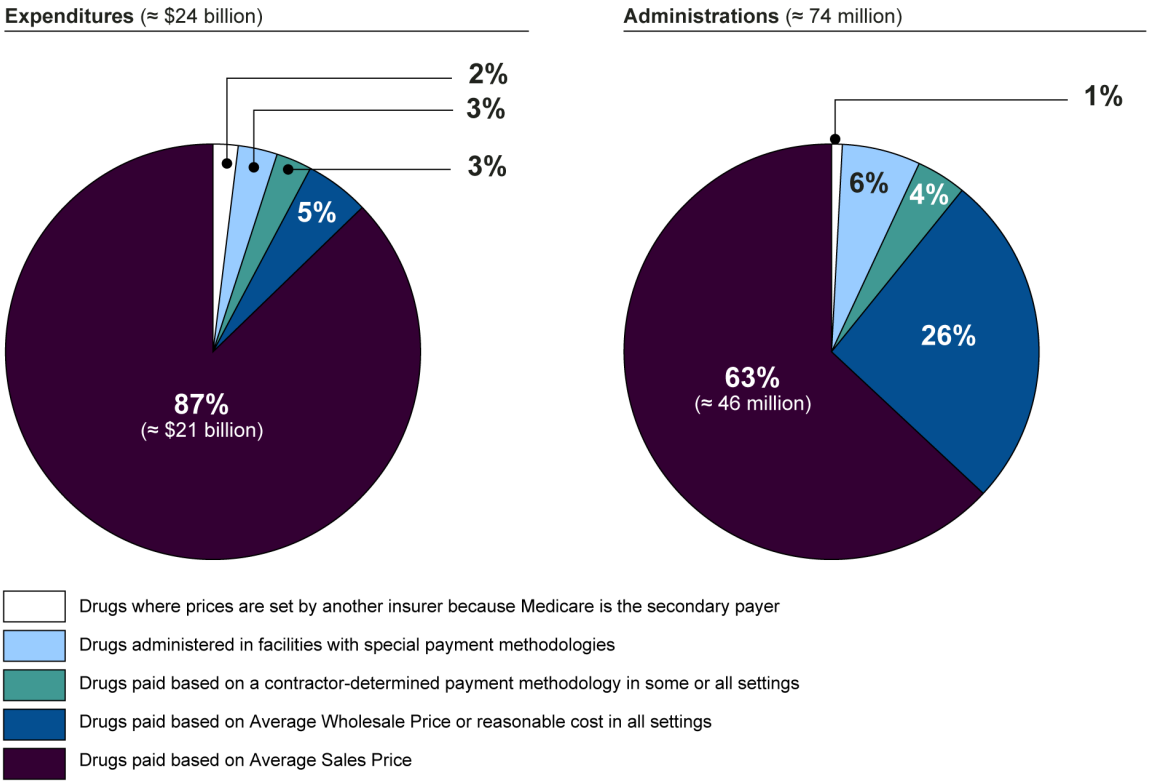
[17]Generally, DME is equipment that serves a medical purpose, can withstand repeated use, is generally not useful in the absence of an illness or injury, and is appropriate for use in the home. *See* 42 C.F.R. § 414.202 (2015).

Medicare Payment for Part B Drugs

Part B drugs administered to Medicare beneficiaries are generally purchased by physicians or hospitals. In 2014, Medicare spent approximately $24 billion on these drugs. The majority of these expenditures—approximately $21 billion, or 87 percent—were for drugs paid based on ASP. The remaining 13 percent of expenditures were for drugs paid based on different methodologies. For example, several Part B drugs, including certain vaccines and drugs provided through DME, are paid for on the basis of average wholesale prices (AWP) or reasonable cost and not on the basis of ASPs.[18] Part B ASP drugs accounted for a somewhat smaller percentage of administrations than expenditures of all Part B drugs in 2014—63 percent—as drugs paid based on AWP or reasonable cost, primarily flu, pneumonia, and hepatitis B vaccines, accounted for 26 percent of all administrations of Part B drugs. (See fig. 1.) Over 9 million Medicare beneficiaries received at least one Part B ASP drug during 2014, which accounted for approximately 43 percent of all beneficiaries who received a Part B drug that year. These 9 million beneficiaries were responsible for 20 percent of Medicare's payment for these drugs via cost-sharing requirements, or about $4 billion in 2014.

[18]See 42 U.S.C. §1395u(o)(1). AWP is often considered the price wholesalers charge retailers. It is based on pricing information reported by manufacturers and is not necessarily based on actual sales transactions. As a result, AWP does not reflect the rebates, discounts, and other price concessions that many of these purchasers receive.

Figure 1: Medicare Expenditures on and Administrations of Part B Drugs, by Payment Methodology (2014)



Source: GAO analysis of Centers for Medicare & Medicaid Services data. | GAO-16-594

Note: In 2014, Medicare spent about $24 billion on approximately 74 million administrations of 814 Part B drugs. These estimates include spending by the Medicare fee-for-service program, its beneficiaries, and other payers in cases where Medicare is not the primary payer or where beneficiaries receive assistance with their cost sharing. These estimates do not include spending for or administrations of drugs for which Medicare's payment is bundled with that of a related service—approximately 88 million administrations in 2014—or spending for the administration or dispensing of the drugs.

Manufacturer Reporting of Sales Price Data

According to statute, drug manufacturers that participate in the Medicaid Drug Rebate Program are required to submit data to CMS on sales of Part B drugs to most U.S. purchasers, including physicians, hospitals, and wholesale distributors within 30 days of the end of every calendar

quarter.[19] Sales must be reported net of rebates, discounts, and other price concessions.[20] CMS officials have stated that most manufacturers participate in the Medicaid Drug Rebate Program. Other manufacturers may voluntarily submit sales price data to CMS. CMS reviews these data, which are typically reported at the NDC level, and calculates payment rates at the HCPCS level. According to CMS officials, the agency then publicly releases the revised quarterly payment rates so that stakeholders can comment on the new rates before they take effect. These officials noted that due to the time it takes for manufacturers to submit the data to CMS, CMS to review the data and then update the payment rates, and the public to review and comment on the revised rates, there is a two-quarter (6-month) lag between the sale and when the payment rate takes effect.

CMS produces a web page titled "Medicare Part B Drug Average Sales Price" that provides guidance for drug manufacturers on submitting ASP data.[21] Manufacturers submit two forms to CMS: the ASP Data Collection Form—an Excel document in which manufacturers insert all relevant sales data—and the ASP Certification Form signed by the manufacturer's CEO or CFO to affirm the accuracy of the submitted data.[22] Where there is no specific guidance in federal statute or regulations regarding how to calculate ASP, CMS has indicated that it allows manufacturers to make reasonable assumptions in their calculations of ASP and to submit these

[19]42 U.S.C. § 1396r-8(a)(1), (b)(3)(A); 42 C.F.R. § 414.804(a)(5) (2015). The Medicaid Drug Rebate Program helps to offset the federal and state costs of most outpatient prescription drugs dispensed to Medicaid patients. A drug manufacturer must enter into, and have in effect, a national rebate agreement with the Secretary of HHS in exchange for state Medicaid coverage of most of the manufacturer's drugs.

[20]Rebates are price concessions given to providers by manufacturers subsequent to receipt of the product. Discounts are price concessions given by manufacturers that are reflected in the purchase price—the price providers pay at the time of delivery.

[21]See Centers for Medicare & Medicaid Services, *Medicare Part B Drug Average Sales Price*, accessed March 21, 2016, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html.

[22]This form may also be signed by an individual who has delegated authority to sign for, and who reports directly to, the manufacturer's CEO or CFO.

assumptions with the required data.[23] CMS's web page also includes a common e-mail address for manufacturers to send ASP-related questions to the agency.

OIG Studies of CMS Oversight of ASP Data

The OIG has conducted two studies related to manufacturer reporting and CMS oversight of ASP data.[24] The first report, published in 2010, found that CMS lacks complete ASP data for certain drugs because not all manufacturers of Part B drugs are required to report ASPs. OIG recommended that CMS consider seeking a legislative change to require all manufacturers of Part B drugs to submit ASPs. CMS did not concur with this recommendation, stating that the President's budget for the upcoming fiscal year did not include any proposals to require manufacturers of Part B drugs to submit ASPs. The second report, published in 2014, further explored this policy and found that at least one-third of the more than 200 manufacturers of Part B drugs included in the study did not submit ASPs for some of their products in the third quarter of 2012, despite being required to do so. An additional 45 manufacturers of Part B drugs were not required to report ASPs that quarter. OIG again recommended that CMS seek a legislative change to directly require all manufacturers of Part B drugs to submit ASPs. CMS again did not concur with this recommendation, stating that the President's budget for the upcoming fiscal year did not include any proposals to require manufacturers of Part B drugs to submit ASPs. However, the agency said it would take the recommendation into consideration in the future. These reports also recommended that CMS develop or implement an automated system for the submission of ASP data to potentially limit the possibility of data entry errors, reduce the amount of time it takes to calculate ASP-based payment amounts and adjust ASP payment limits, and enable CMS to track ASPs with greater ease. CMS concurred with these recommendations.

[23]CMS has indicated that allowing submission of reasonable assumptions in the absence of specific guidance is consistent with the general requirements and intent of the Social Security Act, federal regulations, and the customary business practices of manufacturers. 71 Fed. Reg. 69624, 69666-7 (Dec. 1, 2006) (preamble II.F.1.b.).

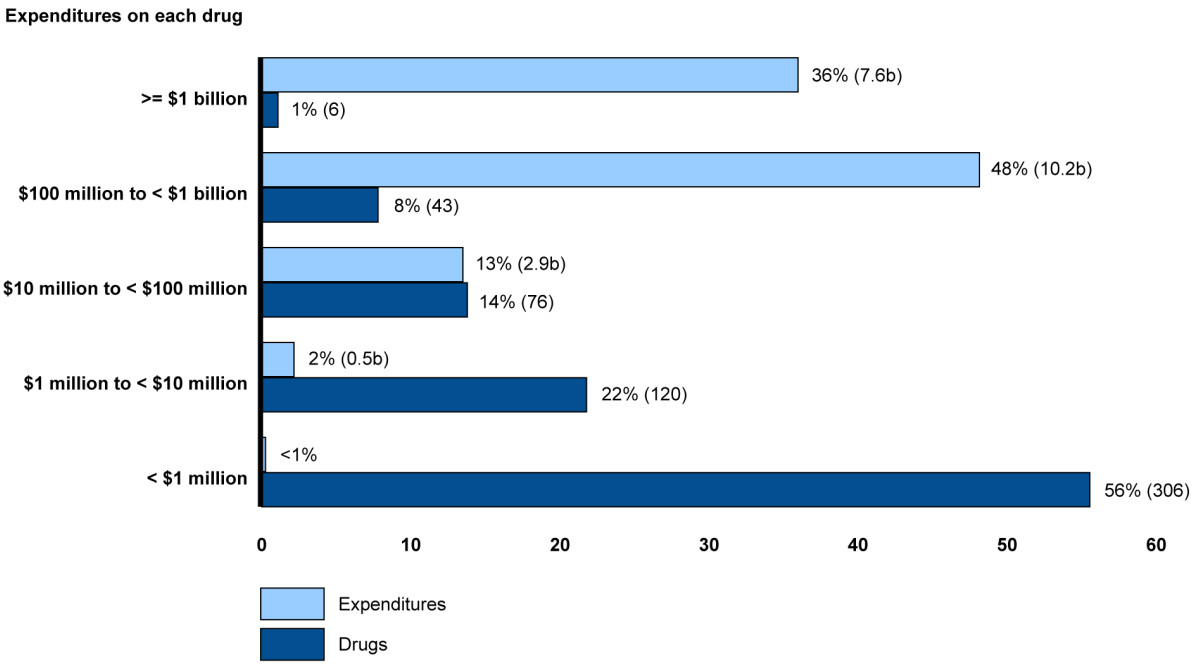
[24]See Department of Health and Human Services Office of Inspector General, *Average Sales Prices: Manufacturer Reporting and CMS Oversight,* OEI-03-80-00480 (Washington, D.C.: Feb. 2010) and OEI-12-13-00040.

Medicare Expenditures on and Administrations of Part B ASP Drugs Were Concentrated in a Small Number of Drugs in 2014

Expenditures on and Administrations of Part B ASP Drugs Were Each Concentrated in a Small Number of Drugs, with Few Drugs among Highest in Both

Medicare expenditures were concentrated in a small number of the 551 Part B drugs that were paid based on ASP in 2014. (See fig. 2.) In particular, 6 drugs each had expenditures of over $1 billion and collectively accounted for 36 percent of all expenditures on Part B ASP drugs that year. (See table 1 and, for a list of characteristics associated with the highest expenditure drugs in 2014, see table 6 in app. I.) Beyond the 6 highest expenditure drugs, an additional 43 drugs each had between $100 million and $1 billion in expenditures and collectively accounted for an additional 48 percent of expenditures on Part B ASP drugs. In contrast, 306 drugs (56 percent of all Part B ASP drugs) each had less than $1 million in expenditures and collectively accounted for less than 1 percent of all expenditures on Part B ASP drugs. (For a list of the 50 Part B ASP drugs with the highest expenditures in 2014, see table 7 in app. I.)

Figure 2: Percentage of Total Medicare Expenditures on and Number of Part B Drugs Paid Based on ASP, by Expenditures on Each Drug (2014)



Source: GAO analysis of Centers for Medicare & Medicaid Services data. | GAO-16-594

Note: In 2014, Medicare spent about $21 billion on 551 Part B drugs paid based on average sales price (ASP). We defined expenditures as the total amount spent by the Medicare fee-for-service program and its beneficiaries, and included only those for claim line items that Medicare paid based on ASP. We defined a drug at the Health Care Common Procedure Coding System level and counted it as a Part B ASP drug if it had at least one claim line item paid based on ASP.

Table 1: The Six Part B Drugs Paid Based on ASP with Over $1 Billion in Medicare Expenditures in 2014

Drug brand name	Drug description	HCPCS	Expenditures (millions of dollars)	Percentage of total	Examples of conditions treated[a]
Rituxan	Rituximab injection	J9310	1,513	7.1	Cancer
Lucentis	Ranibizumab injection	J2778	1,352	6.4	Wet age-related macular degeneration
Eylea	Aflibercept injection	J0178	1,315	6.2	Wet age-related macular degeneration
Remicade	Infliximab injection	J1745	1,184	5.6	Crohn's disease
Neulasta	Pegfilgrastim injection	J2505	1,183	5.6	Reduce infection in patients treated for cancer
Avastin	Bevacizumab injection	J9035	1,072	5.1	Cancer

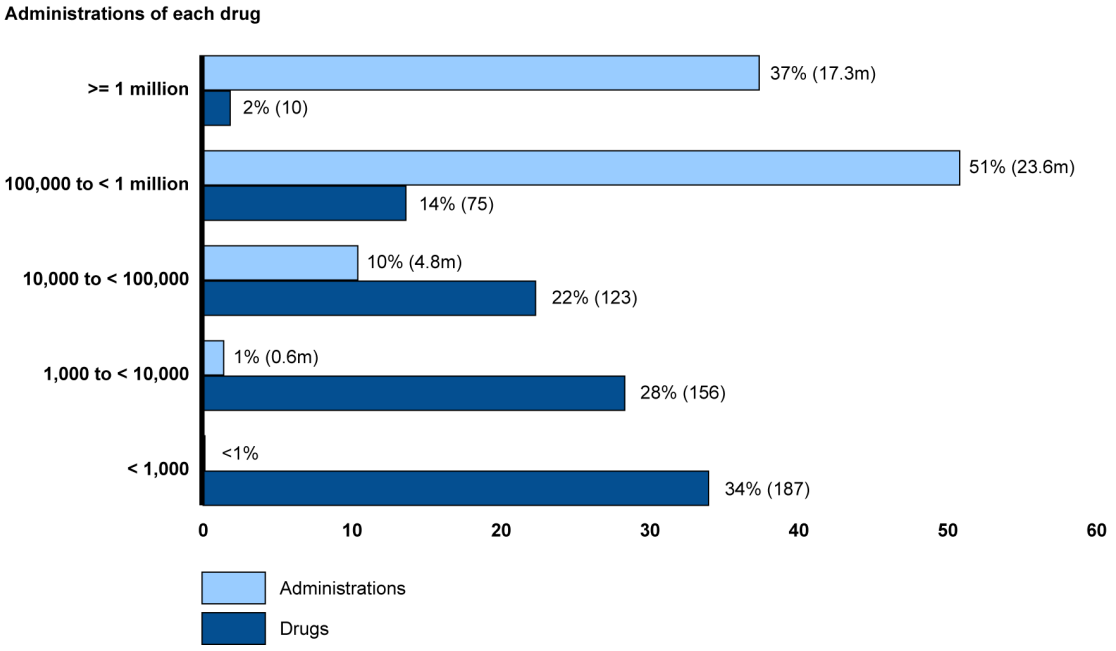
Source: GAO analysis of Centers for Medicare & Medicaid Services data and National Library of Medicine publications. | GAO-16-594

Note: In 2014, Medicare spent about $21 billion on 551 Part B drugs paid based on average sales price (ASP). We defined expenditures as the total amount spent by the Medicare fee-for-service program and its beneficiaries, and included only those for claim line items that Medicare paid based on ASP. We defined a drug at the Health Care Common Procedure Coding System (HCPCS) level and counted it as a Part B ASP drug if it had at least one claim line item paid based on ASP.

[a]These descriptions do not reflect off-label uses of each drug. For example, Avastin is also used to treat wet age-related macular degeneration.

Administrations of Part B ASP drugs were also concentrated in a small number of drugs in 2014. (See fig. 3.) In particular, 10 drugs were each administered over 1 million times and collectively accounted for 37 percent of all administrations of Part B ASP drugs that year. (See table 2 and, for a list of characteristics associated with the highest administration drugs in 2014, see table 8 in app. I.) Beyond the 10 drugs with the highest number of administrations, an additional 75 drugs were each administered between 100,000 and 1 million times, and collectively accounted for an additional 51 percent of all administrations of Part B drugs paid based on ASP. In contrast, 187 drugs (34 percent of all Part B ASP drugs) were each administered fewer than 1,000 times and collectively accounted for less than 1 percent of all administrations of Part B ASP drugs. (For a list of the 50 Part B ASP drugs with the highest number of administrations in 2014, see table 9 in app. I.)

Figure 3: Percentage of Total Administrations and Number of Medicare Part B Drugs Paid Based on ASP, by Administrations of Each Drug (2014)



Source: GAO analysis of Centers for Medicare & Medicaid Services data. | GAO-16-594

Note: In 2014, there were about 46 million administrations of 551 Part B drugs paid based on average sales price (ASP). We defined administrations as the number of Medicare fee-for-service claim line items for a drug, and included only those claim line items that Medicare paid based on ASP. We defined a drug at the Health Care Common Procedure Coding System level and counted it as a Part B ASP drug if it had at least one claim line item paid based on ASP.

Table 2: The 10 Part B Drugs Paid Based on ASP with Over 1 Million Administrations in 2014

Drug brand name example	Drug description	HCPCS	Administrations (thousands)	Percentage of total	Examples of conditions treated[a]
Kenalog	Triamcinolone acetonide injection	J3301	2,661	5.7	Inflammation associated with various conditions, such as allergic states, dermatologic diseases, and endocrine disorders
N/A[b]	Dexamethasone sodium phosphate injection	J1100	2,465	5.3	Inflammation associated with various conditions, such as allergic states, dermatologic diseases, and endocrine disorders
N/A[b]	Vitamin B-12 cyanocobalamin injection	J3420	2,315	5.0	Vitamin B-12 deficiency due to malabsorption
Depo-Medrol	Methylprednisolone acetate injection (40mg)	J1030	1,896	4.1	Inflammation associated with various conditions, such as allergic states, dermatologic diseases, and endocrine disorders
Accuneb	Albuterol inhalation solution	J7613	1,659	3.6	Chronic obstructive pulmonary disease
DuoNeb	Albuterol and ipratropium bromide inhalation solution	J7620	1,517	3.3	Chronic obstructive pulmonary disease
Depo-Medrol	Methylprednisolone acetate injection (80mg)	J1040	1,502	3.2	Inflammation associated with various conditions, such as allergic states, dermatologic diseases, and endocrine disorders
Optiray	Low osmolar contrast material	Q9967	1,192	2.6	N/A[c]
Celestone Soluspan	Betamethasone acetate and betamethasone sodium phosphate injection	J0702	1,123	2.4	Inflammation associated with various conditions, such as allergic states, dermatologic diseases, and endocrine disorders
Rocephin	Ceftriaxone sodium injection	J0696	1,019	2.2	Certain infections caused by bacteria, such as meningitis

Source: GAO analysis of Centers for Medicare & Medicaid Services data and National Library of Medicine and Food and Drug Administration publications. | GAO-16-594

Note: In 2014, there were about 46 million administrations of 551 Part B drugs paid based on average sales price (ASP). We defined administrations as the number of Medicare fee-for-service claim line items for a drug, and included only those claim line items that Medicare paid based on ASP. We defined a drug at the Health Care Common Procedure Coding System (HCPCS) level and counted it as a Part B ASP drug if it had at least one claim line item paid based on ASP.

[a]These descriptions do not reflect potential off-label uses of each drug.

[b]These drugs had generic versions only.

[c]Low osmolar contrast material is used to improve the quality of images obtained during certain radiology procedures.

Few Part B ASP drugs were among both the highest expenditure and the highest administration drugs in 2014. For example, no Part B ASP drug had over $1 billion in expenditures and over 1 million administrations that year. Additionally, of the 102 Part B ASP drugs with either $100 million or more in expenditures or 100,000 or more administrations, only 32 were in both categories. These 32 drugs included all 6 drugs with expenditures over $1 billion, but none of the 10 drugs with over 1 million administrations.

Drug Characteristics Associated with the Highest Percentage of Expenditures Generally Differed from Those Associated with the Highest Percentage of Administrations

The characteristics of drugs associated with the majority of expenditures on Part B ASP drugs tended to differ from the characteristics of drugs associated with the majority of administrations. For example, the majority of Medicare expenditures for Part B ASP drugs in 2014 were for biologics, brand name drugs, drugs made by a single manufacturer, and drugs that came onto the market since 2000. In contrast, the majority of administrations of Part B ASP drugs were for synthetics, generics, drugs made by multiple manufacturers, and drugs that came onto the market prior to 2000. Additionally, the therapeutic categories associated with the largest percentage of expenditures tended to differ from the categories associated with the largest percentage of administrations. However, injections accounted for the majority of both expenditures and administrations (See table 3.)

Table 3: Drug Characteristics Associated with the Highest Percentage of Expenditures and Administrations for Part B Drugs Paid Based on ASP (2014)

	Expenditures		Administrations	
Drug characteristic	**Characteristic**	**Percentage of total**	**Characteristic**	**Percentage of total**
Drug composition	Biologic	68	Synthetic	76
Brand/generic status	Brand only	89	Generic available	66
Single-source/multi-source status	Single-source	81	Multi-source	74
First year on the market	2000-2009	59	Prior to 2000	64
	2010-2014	19		
Therapeutic category	Immunological agents	28	Endocrine metabolic agents	26
	Anti-neoplastic agents[a]	27	Respiratory agents	13
	Blood modifier agents[b]	14	Immunological agents	10
	Ophthalmologic agents	13	Anti-neoplastic agents[a]	9
Route of administration	Injection	84	Injection	67

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS), Food and Drug Administration, and RED BOOK data. | GAO-16-594

Note: In 2014, Medicare spent about $21 billion on approximately 46 million administrations of Part B drugs paid based on average sales price (ASP). We defined expenditures as the total amount spent by the Medicare fee-for-service program and its beneficiaries, and administrations as the number of claim line items for a drug. Both measures included only those for claim line items that Medicare paid based on ASP. We assigned drug characteristics at the Health Care Common Procedure Coding System (HCPCS) level by summarizing the characteristics of the National Drug Codes (NDC) that CMS associated with each HCPCS. For example, we classified a drug as brand only if all NDCs for a HCPCS were classified as such in RED BOOK, and otherwise classified the drug as generic available.

[a]Anti-neoplastic agents are substances that inhibit or prevent the proliferation of neoplasms, which are abnormal growths of tissue, often associated with cancer.

[b]Blood modifier agents enhance or inhibit the clotting or thinning of blood.

The majority of expenditures were for drugs with average expenditures per beneficiary over $10,000 and for drugs received by fewer than 100,000 beneficiaries. The majority of administrations were for drugs with average expenditures per beneficiary under $100 and for drugs received by over 100,000 beneficiaries. (See table 4.)

Table 4: Spending and Utilization Characteristics Associated with the Highest Percentage of Expenditures and Administrations for Part B Drugs Paid Based on ASP (2014)

	Expenditures		Administrations	
Drug characteristic	**Characteristic**	**Percentage of total**	**Characteristic**	**Percentage of total**
Average expenditures per administration	$1,000 up to $10,000	73	Less than $10	42
	$10,000+	8	$10 up to $100	19
Average expenditures per beneficiary	$1,000 up to $10,000	36	Less than $10	29
	$10,000+	59	$10 up to $100	29
Average administrations per beneficiary	3 to 5 times per year	50	1 to 2 times per year	42
	6 to 9 times per year	23	3 to 5 times per year	36
Number of beneficiaries	Fewer than 10,000	25	100,000+	61
	10,000 up to 100,000	47		

Source: GAO analysis of Centers for Medicare & Medicaid Services data. | GAO-16-594

Note: In 2014, Medicare spent about $21 billion on approximately 46 million administrations of Part B drugs paid based on average sales price (ASP). We defined expenditures as the total amount spent by the Medicare fee-for-service program and its beneficiaries, and administrations as the number of claim line items for a drug. Both measures included only those for claim line items that Medicare paid based on ASP.

Provider Characteristics Associated with the Highest Percentage of Expenditures and the Highest Percentage of Administrations Were Generally Similar

Expenditures on and administrations of Part B ASP drugs were generally associated with the same provider characteristics in 2014. In particular, the majority of expenditures and administrations occurred in physicians' offices (rather than hospital outpatient departments or other settings) and in urban areas (rather than suburban or rural areas). Additionally, the highest percentage of both expenditures and administrations generally were for Part B ASP drugs that were prescribed by the same provider specialty: hematology oncology.[25] (See table 5.)

[25]For additional information on the physician specialties that provided Part B ASP drugs in 2014, see fig. 4 in app. I.

Table 5: Provider Characteristics Associated with the Highest Percentage of Expenditures and Administrations for Part B Drugs Paid Based on ASP (2014)

	Expenditures		Administrations	
Provider characteristic	**Characteristic**	**Percentage of total**	**Characteristic**	**Percentage of total**
Place of service	Physician's office	56	Physician's office	74
Geographic area	Urban core	86	Urban core	80
Provider specialty/type	Hematology oncology	27	Hematology oncology	17
	Internal medicine	15	DME supplier	15
	Ophthalmology	13	Internal medicine	11

Source: GAO analysis of Centers for Medicare & Medicaid Services data. | GAO-16-594

Note: In 2014, Medicare spent about $21 billion on approximately 46 million administrations of Part B drugs paid based on average sales price (ASP). We defined expenditures as the total amount spent by the Medicare fee-for-service program and its beneficiaries, and administrations as the number of claim line items for a drug. Both measures included only those for claim line items that Medicare paid based on ASP.

CMS Checks Reported Sales Prices for Potential Data Errors, but Does Not Routinely Verify the Underlying Data or Receive All Relevant Data

CMS Performs Several Electronic Data Checks on Manufacturer-Reported Sales Price Data, but these Checks Do Not Verify the Accuracy of the Underlying Data

CMS takes three main steps to validate that the sales price data reported by drug manufacturers are complete and accurate. First, CMS requires that, before a manufacturer submits a report containing data to CMS, the CEO, CFO, or authorized official of each drug manufacturer attests to the accuracy of the information provided in that report by signing the ASP Certification Form.[26] Second, according to CMS officials, once CMS receives the sales data from the manufacturer, it performs a series of electronic data checks to assess the completeness of the submitted data. CMS's data checks include

[26]*See* 42 C.F.R. § 414.804(a)(7) (2015).

- checking for missing data or duplicate entries,
- checking for incorrect product information, and
- comparing submissions to those of previous quarters.

In cases where CMS identifies discrepancies through its data checks, agency officials stated that they attempt to resolve the issue directly with the manufacturer. If CMS is unable to resolve the issue directly with the manufacturer, the agency refers the case to OIG and OIG determines appropriate enforcement, if needed. Third, officials from CMS stated the agency holds a 7 to 10 day public comment period where manufacturers and providers have an opportunity to comment on the payment amounts before they are published.

CMS officials believe that the steps the agency takes to validate manufacturer-reported sales price data are sufficient, but CMS does not verify that the reported data reflect actual sales prices. Federal standards for internal control call for management to use quality information to achieve its objectives. According to GAO's guidance for assessing the reliability of computer-processed data, completeness and accuracy are the two key components of quality data.[27] CMS officials noted that, since 2009, only one drug manufacturer has incurred civil monetary penalties as a result of OIG's review of manufacturer reporting discrepancies. CMS officials told us that there have been few other issues with drug manufacturers' ASP submissions over the past couple of years and that any issues that did arise were minor. These officials also noted that during the public comment period, they receive few comments from stakeholders. Additionally, CMS's electronic data checks described earlier are consistent with recommendations in GAO's guidance related to verifying the completeness of data.[28] Specifically, examples of GAO's guidance include

- testing electronic data for missing or duplicate data,
- looking for values outside of a desired range, and
- testing relationships between data elements.

[27]Data are considered complete if relevant records are present and fields in each record are populated appropriately. Data are considered accurate if the recorded data reflect the actual underlying information. See GAO-09-680G.

[28]GAO-09-680G, 18.

However, CMS does not take sufficient steps to verify the accuracy of the data. Officials from CMS told us that they do not routinely verify the underlying data from manufacturers either by tracing the data to and from source documents, such as sales invoices, or through CMS's referrals to OIG. The Social Security Act authorizes CMS to survey manufacturers that have Medicaid drug rebate agreements when necessary to verify ASP.[29] However, CMS officials told us that this authority does not allow them to conduct blanket surveys to routinely collect information regarding manufacturers' ASP data beyond what is on the ASP data collection form. CMS officials indicated they may also request that OIG use its authority to audit ASP data submitted by manufacturers.[30] However, CMS has limited such referrals to situations where the agency has identified potential consistent or repeated problems with calculating and reporting ASP data. In situations where CMS requires additional information about the data submission, the agency officials stated that the requests are typically for information that could be considered public.[31]

Officials from CMS indicated the agency is developing an automated ASP submission system to use with drug manufacturers; however, the new system will not help to ensure the accuracy of the underlying sales price data. According to OIG, this automated system could limit the possibility of data entry errors, reduce the amount of time it takes to calculate and adjust ASP payments, and enable CMS to track ASPs with greater ease and efficiency.[32] CMS began working on an automated system following a 2010 OIG recommendation.[33] CMS officials told us that the agency is still testing the system and hopes to begin implementation at the end of 2016. Four of the six drug manufacturers we spoke with stated that implementation of an automated submission system would improve the

[29]42 U.S.C. § 1396r-8(b)(3)(B).

[30]42 U.S.C. § 1396r-8(b)(3)(A).

[31]For example, according to CMS officials, the agency may request updated package inserts to confirm the amount of a drug associated with the sales price submitted by the manufacturer.

[32]OEI-03-08-00480, iii.

[33]OEI-03-08-00480, 18.

ASP submission process.[34] The two manufacturers that did not believe an automated submission system would improve the ASP submission process already submit their data exclusively via e-mail instead of by mail. CMS officials stated that due to the time it takes for manufacturers to calculate and submit ASP data and for CMS to review the data and update the payment rates, the automated system may not reduce the two-quarter lag between when drugs are sold and CMS receives all data and updates the payment rates.[35]

CMS Is Unable to Assess the Accuracy of All Sales Price Data because Not All Manufacturers Submit Sales Price Data

CMS is unable to assess the accuracy of all drug manufacturers' sales price data because not all drug manufacturers submit these data to CMS. As stated previously, only drug manufacturers with Medicaid drug rebate agreements are required to submit ASP data on a quarterly basis. However, not all manufacturers of Medicare Part B drugs have these agreements; therefore, not all manufacturers are required to submit ASP data to CMS. Further, CMS officials said that the agency lacks the authority to require manufacturers not participating in the Medicaid Drug Rebate Program to submit ASP data. CMS officials also said that most manufacturers of Part B drugs do submit sales price data because they have Medicaid drug rebate agreements or submit the data voluntarily, but not all do. Without complete data from manufacturers that have been assessed for accuracy by CMS, the agency risks setting payment rates based on inaccurate information. This is inconsistent with federal standards for internal control, which call for management to use quality information to achieve objectives.[36]

Drugs manufactured by multiple sources are more likely to have inaccurate payment rates than are drugs manufactured by a single source because, according to CMS officials, the payment system provides an

[34]Noted potential improvements were providing a better system for record retention, simplifying the ASP submission process for manufacturers and CMS, and providing extra time for the manufacturers to calculate and validate the data because they would not need to be mailed to CMS, which is currently the preferred method of submission per CMS's web page.

[35]Drug manufacturers have 30 days following the end of a quarter to submit ASP data to CMS. CMS officials stated that it then takes them approximately 5 weeks to review the data and calculate new payment rates which are then posted for 7 to10 days for the public to view and comment.

[36]GAO-14-704G.

incentive for single-source manufacturers to report their data. CMS officials told us that single-source drug manufacturers have an incentive to report ASP data so that health care providers will know Medicare's payment rate for their drug. These officials stated that providers prefer to use drugs with published Medicare payment rates because they know what they will be paid. If the manufacturer of a single-source drug did not submit sales price data, ASP data for that billing code would be unavailable, and CMS would substitute ASP with another metric that might be less accurate. Other metrics include rates published in national pricing compendia such as Truven Health Analytics' RED BOOK or First Databank's National Drug Data File, which publish product information for drugs such as strength, package size, and package quantity. OIG has found that prices published in national pricing compendia do not accurately reflect actual market prices.[37] In contrast, CMS officials told us if a manufacturer did not submit ASP data for a drug that is manufactured by multiple sources, the sales price would still be based on ASP data submitted by the other manufacturers of the drug. This gives multi-source drug manufacturers less incentive to report ASP data, particularly if the inclusion of their data would result in a lower Medicare payment rate for the drug.

To assess the potential impact of manufacturers without rebate agreements that do not voluntarily report ASP data, in its 2014 report, OIG looked at 50 high-expenditure multi-source Part B drugs in the third quarter of 2012.[38] These drugs included those with payment rates that used sales price data from both manufacturers that were required to report their data and manufacturers that voluntarily reported their data. If manufacturers had not voluntarily reported their data, 12 of the 50 drug payment rates would have changed. Payment rates would have increased for 5 drugs (between 3 and 40 percent) and decreased for 7 drugs (between 1 and 49 percent). Payment rates for the remaining 38 drugs would have stayed the same.

Conclusions

In 2014, Medicare spent approximately $21 billion on Part B drugs paid based on ASP. The substantial expenditures for Part B ASP drugs underscore how important it is that CMS ensure that the data on which

[37]OEI-12-13-00040, 9.

[38]OEI-12-13-00040, 9.

the agency bases Medicare's payment rates for these drugs are accurate. Federal standards for internal control call for management to use quality information to achieve its objectives. According to GAO's guidance for assessing the reliability of computer-processed data, completeness and accuracy are the two key components of quality data. CMS conducts certain data checks to assess the completeness of the ASP data submitted by drug manufacturers. However, CMS does not verify the accuracy of the underlying data by tracing the data to and from source documents, such as sales invoices. Because CMS does not verify the accuracy of the underlying data used to determine Medicare payment rates, the resulting payment rates may be inaccurate if drug manufacturers do not report accurate data.

CMS is unable to assess the accuracy of all sales price data because the agency does not receive data from all drug manufacturers. Currently, only drug manufacturers with Medicaid drug rebate agreements are required to submit ASP data to CMS. Although agency officials told us that most drug manufacturers have rebate agreements or choose to voluntarily submit ASP data, some manufacturers do not. Federal standards for internal control call for management to use quality information to achieve its objectives. Without complete data from all manufacturers that have been assessed for accuracy by CMS, the agency risks setting payment rates based on inaccurate information.

Matter for Congressional Consideration

To help the Department of Health and Human Services ensure accuracy in Part B drug payment rates, Congress should consider requiring all manufacturers of Part B drugs paid at ASP, not only those with Medicaid drug rebate agreements, to submit sales price data to CMS, and ensure that CMS has authority to request source documentation to periodically validate all such data.

Recommendation for Executive Action

CMS should periodically verify the sales price data submitted by a sample of drug manufacturers by requesting source documentation from manufacturers to corroborate the reported data, either directly or by working with OIG as necessary.

Agency Comments and Our Evaluation

We provided a draft of this report for review to HHS and received written comments that are summarized below and reprinted in appendix II.

In its comments, HHS agreed with our recommendation. HHS stated that CMS will work with OIG as appropriate regarding collecting source documentation from drug manufacturers and that CMS will take action as it is warranted. To fulfill this recommendation, CMS will have to take additional actions relative to what it has done in the past. As we noted in the report, CMS has previously requested that OIG use its authority to audit ASP data submitted by manufacturers when it has identified potential consistent or repeated problems with calculating and reporting ASP data. HHS also noted in its comments that the OIG reviews average manufacturer price (AMP) data for Part B drugs and that CMS has the authority to adjust the ASP-based payment amount in situations where the OIG finds that ASP exceeds AMP by a certain threshold percentage. However, AMP data are also reported by manufacturers and would be inaccurate if the data do not represent actual manufacturer prices.

As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies of this report to the Secretary of Health and Human Services and other interested parties. In addition, the report is available at no charge on the GAO website at http://www.gao.gov.

If you or your staff have any questions regarding this report, please contact me at (202) 512-7114 or cosgrovej@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix III.

Sincerely yours,

James Cosgrove
Director, Health Care

Appendix I: Characteristics Associated with the Part B Drugs Paid Based on ASP with the Highest Expenditures and Highest Number of Administrations (2014)

Table 6: Drug Characteristics Associated with the 6 Part B Drugs Paid Based on ASP with Over $1 Billion in Expenditures and the 10 Drugs with Over 1 Million Administrations (2014)

Drug brand name example	Drug description	HCPCS	Drug composition	Single-source/multi-source status	First year on the market	Brand/generic status	Route of administration
Highest expenditure drugs							
Rituxan	Rituximab	J9310	Biologic	Single-source	1997	Brand only	Injection
Lucentis	Ranibizumab	J2778	Biologic	Single-source	2006	Brand only	Injection
Eylea	Aflibercept	J0178	Biologic	Single-source	2011	Brand only	Injection
Remicade	Infliximab	J1745	Biologic	Single-source	1998	Brand only	Injection
Neulasta	Pegfilgrastim	J2505	Biologic	Single-source	2002	Brand only	Injection
Avastin	Bevacizumab	J9035	Biologic	Single-source	2004	Brand only	Injection
Highest administration drugs							
Kenalog	Triamcinolone acetonide	J3301	Synthetic	Multi-source	1989	Generic available	Injection
N/A[a]	Dexamethasone sodium phosphate	J1100	Synthetic	Multi-source	1977	Generic available	Injection
N/A[a]	Vitamin B-12 cyanocobalamin	J3420	Synthetic	Multi-source	1974	Generic available	Multiple
Depo-Medrol	Methylprednisolone acetate (40mg)	J1030	Synthetic	Multi-source	1987	Generic available	Injection
Accuneb	Albuterol	J7613	Synthetic	Multi-source	1996	Generic available	Inhalation
DuoNeb	Albuterol and ipratropium bromide	J7620	Synthetic	Multi-source	2001	Generic available	Inhalation
Depo-Medrol	Methylprednisolone acetate (80mg)	J1040	Synthetic	Multi-source	1987	Generic available	Injection
Optiray	Low osmolar contrast material	Q9967	Synthetic	Multi-source	1986	Brand-only	Injection
Celestone Soluspan	Betamethasone acetate and betamethasone sodium phosphate	J0702	Synthetic	Multi-source	1986	Generic available	Injection
Rocephin	Ceftriaxone sodium	J0696	Synthetic	Multi-source	1985	Generic available	Multiple

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS), Food and Drug Administration, and RED BOOK data. | GAO-16-594

Note: In 2014, Medicare spent about $21 billion on approximately 46 million administrations of Part B drugs paid based on average sales price (ASP). We defined expenditures as the total amount spent by the Medicare fee-for-service program and its beneficiaries, and administrations as the number of claim line items for a drug. Both measures included only those for claim line items that Medicare paid based on ASP. We assigned drug characteristics at the Health Care Common Procedure Coding System (HCPCS) level by summarizing the characteristics of the National Drug Codes (NDC) that CMS associated with each HCPCS. For example, we classified a drug as brand only if all NDCs for a HCPCS were classified as such in RED BOOK, and otherwise classified the drug as generic available.

[a]These drugs had generic versions only.

Table 7: 50 Part B Drugs Paid Based on ASP with the Highest Expenditures (2014)

	Drug description	HCPCS	Expenditures (millions of dollars)	Administrations (thousands)	Number of beneficiaries (thousands)	Therapeutic category
1	Rituximab	J9310	1,513	300	68	Anti-neoplastic[a]
2	Ranibizumab	J2778	1,352	696	142	Ophthalmologic
3	Aflibercept	J0178	1,315	646	132	Ophthalmologic
4	Infliximab	J1745	1,184	354	59	Immunological
5	Pegfilgrastim	J2505	1,183	358	98	Blood modifier[b]
6	Bevacizumab	J9035	1,072	948	216	Immunological
7	Denosumab	J0897	775	646	293	Immunological
8	Trastuzumab	J9355	564	193	18	Immunological
9	Pemetrexed	J9305	564	118	23	Anti-neoplastic[a]
10	Bortezomib	J9041	476	369	20	Anti-neoplastic[a]
11	Abatacept	J0129	346	167	20	Multiple
12	Octreotide	J2353	344	87	11	Endocrine metabolic
13	Epoetin alfa (non-end-stage renal disease (ESRD) use)	J0885	307	802	96	Blood modifier[b]
14	Bendamustine hcl	J9033	306	100	13	Anti-neoplastic[a]
15	Darbepoetin alfa (non-ESRD use)	J0881	289	371	63	Blood modifier[b]
16	Capecitabine	WW093	279	116	27	Anti-neoplastic[a]
17	Paclitaxel protein-bound particles	J9264	279	157	18	Anti-neoplastic[a]
18	Ipilimumab	J9228	266	9	3	Anti-neoplastic[a]
19	Cetuximab	J9055	260	105	9	Anti-neoplastic[a]
20	Natalizumab	J2323	257	61	7	Immunological
21	Leuprolide acetate	J9217	257	322	142	Multiple
22	Immune globulin	J1561	241	83	9	Immunological
23	Factor viii	J7192	229	14	< 1	Blood modifier[b]
24	Budesonide	J7626	229	753	136	Respiratory
25	Immune globulin	J1569	227	84	11	Immunological
26	Omalizumab	J2357	222	153	11	Respiratory
27	Onabotulinumtoxina	J0585	221	258	106	Musculoskeletal
28	Treprostinil	J7686	209	16	2	Cardiovascular
29	Azacitidine	J9025	196	275	9	Anti-neoplastic[a]
30	Immune globulin	J1459	189	76	9	Immunological
31	Palonosetron	J2469	184	956	158	Gastrointestinal

	Drug description	HCPCS	Expenditures (millions of dollars)	Administrations (thousands)	Number of beneficiaries (thousands)	Therapeutic category
32	Eculizumab	J1300	179	9	< 1	Blood modifier[b]
33	Sipuleucel-T auto CD54+	Q2043	175	5	2	Immunological
34	Fulvestrant	J9395	174	103	15	Anti-neoplastic[a]
35	Carfilzomib	J9047	161	106	4	Anti-neoplastic[a]
36	Arformoterol	J7605	151	412	68	Respiratory
37	Filgrastim	J1442	146	360	44	Blood modifier[b]
38	Hyaluronan or derivative	J7325	144	309	167	Musculoskeletal
39	Tocilizumab	J3262	143	84	10	Immunological
40	Romiplostim	J2796	136	77	4	Blood modifier[b]
41	Mycophenolic acid	J7518	134	211	26	Immunological
42	Zoledronic acid	J3489	126	405	192	Endocrine metabolic
43	Decitabine	J0894	126	102	5	Anti-neoplastic[a]
44	Tacrolimus	J7507	124	687	76	Immunological
45	Certolizumab pegol	J0717	120	54	7	Immunological
46	Regadenoson	J2785	119	574	568	Diagnostic
47	Pertuzumab	J9306	111	24	4	Anti-neoplastic[a]
48	Factor viia	J7189	109	4	< 1	Blood modifier[b]
49	Ado-trastuzumab emtansine	J9354	102	16	2	Anti-neoplastic[a]
50	Cyclophosphamide	J9070	92	151	34	Anti-neoplastic[a]

Source: GAO analysis of Centers for Medicare & Medicaid Services and RED BOOK data. | GAO-16-594

Note: In 2014, Medicare spent about $21 billion on 551 Part B drugs paid based on average sales price (ASP). We defined expenditures as the total amount spent by the Medicare fee-for-service program and its beneficiaries, and administrations as the number of claim line items for a drug. Both measures included only those for claim line items that Medicare paid based on ASP. We defined a drug at the Health Care Common Procedure Coding System (HCPCS) level and counted it as a Part B ASP drug if it had at least one claim line item paid based on ASP.

[a]Anti-neoplastic agents are substances that inhibit or prevent the proliferation of neoplasms, which are new and abnormal growths of tissue, often associated with cancer.

[b]Blood modifier agents enhance or inhibit the clotting or thinning of blood.

Table 8: Spending and Utilization Characteristics Associated with the 6 Part B Drugs Paid Based on ASP with Over $1 Billion in Expenditures and the 10 Drugs with Over 1 Million Administrations (2014)

Drug brand name example	Drug description	HCPCS	Average expenditures per administration (dollars)	Average expenditures per beneficiary (dollars)	Average administrations per beneficiary	Number of beneficiaries (thousands)
Highest expenditure drugs						
Rituxan	Rituximab injection	J9310	5,044	22,105	4.38	68
Lucentis	Ranibizumab injection	J2778	1,944	9,550	4.91	142
Eylea	Aflibercept injection	J0178	2,037	9,923	4.87	132
Remicade	Infliximab injection	J1745	3,349	19,920	5.95	59
Neulasta	Pegfilgrastim injection	J2505	3,301	12,021	3.64	98
Avastin	Bevacizumab injection	J9035	1,131	4,964	4.39	216
Highest administration drugs						
Kenalog	Triamcinolone acetonide injection	J3301	7	12	1.62	1,640
N/A[a]	Dexamethasone sodium phosphate injection	J1100	1	3	2.51	982
N/A[a]	Vitamin B-12 cyanocobalamin injection	J3420	2	8	4.00	579
Depo-Medrol	Methylprednisolone acetate injection (40mg)	J1030	4	7	1.59	1,192
Accuneb	Albuterol inhalation solution	J7613	11	35	3.12	532
DuoNeb	Albuterol and ipratropium bromide inhalation solution	J7620	18	67	3.70	410
Depo-Medrol	Methylprednisolone acetate injection (80mg)	J1040	7	10	1.59	945
Optiray	Low osmolar contrast material	Q9967	13	19	1.44	827
Celestone Soluspan	Betamethasone acetate and betamethasone sodium phosphate injection	J0702	13	21	1.56	721
Rocephin	Ceftriaxone sodium injection	J0696	3	4	1.70	598

Source: GAO analysis of Centers for Medicare & Medicaid Services data. | GAO-16-594

Note: In 2014, Medicare spent about $21 billion on approximately 46 million administrations of Part B drugs paid based on average sales price (ASP). We defined expenditures as the total amount spent by the Medicare fee-for-service program and its beneficiaries, and administrations as the number of claim line items for a drug. Both measures included only those for claim line items that Medicare paid based on ASP. We defined a drug at the Health Care Common Procedure Coding System (HCPCS) level and counted it as a Part B ASP drug if it had at least one claim line item paid based on ASP.

[a]These drugs only had generic versions available.

Table 9: 50 Part B Drugs Paid Based on ASP with the Highest Number of Administrations (2014)

	Drug description	HCPCS	Expenditures (millions of dollars)	Administrations (thousands)	Number of beneficiaries (thousands)	Therapeutic category
1	Triamcinolone acetonide	J3301	20	2,661	1,640	Endocrine metabolic
2	Dexamethasone sodium phosphate	J1100	3	2,465	982	Endocrine metabolic
3	Vitamin B-12 cyanocobalamin	J3420	5	2,315	579	Nutritive
4	Methylprednisolone acetate	J1030	8	1,896	1,192	Endocrine metabolic
5	Albuterol	J7613	18	1,659	532	Respiratory
6	Albuterol and ipratropium bromide	J7620	28	1,517	410	Respiratory
7	Methylprednisolone acetate	J1040	10	1,502	945	Endocrine metabolic
8	Low osmolar contrast material	Q9967	16	1,192	827	Diagnostic
9	Betamethasone acetate and betamethasone sodium phosphate	J0702	15	1,123	721	Endocrine metabolic
10	Ceftriaxone sodium	J0696	3	1,019	598	Anti-infective
11	Palonosetron	J2469	184	956	158	Gastrointestinal
12	Bevacizumab	J9035	1,072	948	216	Immunological
13	Normal saline solution	J7050	< 1	829	195	Nutritive
14	Epoetin alfa (non-end-stage renal disease (ESRD) use)	J0885	307	802	96	Blood modifier[b]
15	Budesonide	J7626	229	753	136	Respiratory
16	Ketorolac tromethamine	J1885	< 1	740	433	Central nervous system
17	Ranibizumab	J2778	1,352	696	142	Ophthalmologic
18	Tacrolimus	J7507	124	687	76	Immunological
19	Diphenhydramine hcl	J1200	< 1	686	145	Respiratory
20	Hyaluronan or derivative	J7321	72	684	132	Musculoskeletal
21	Denosumab	J0897	775	646	293	Immunological
22	Aflibercept	J0178	1,315	646	132	Ophthalmologic
23	Regadenoson	J2785	119	574	568	Diagnostic
24	Testosterone cypionate	J1080	3	525	71	Endocrine metabolic
25	Ipratropium bromide	J7644	5	436	126	Respiratory
26	Arformoterol	J7605	151	412	68	Respiratory

	Drug description	HCPCS	Expenditures (millions of dollars)	Administrations (thousands)	Number of beneficiaries (thousands)	Therapeutic category
27	Zoledronic acid	J3489	126	405	192	Endocrine metabolic
28	Mycophenolate mofetil	J7517	79	385	47	Immunological
29	Hyaluronan or derivative	J7324	80	376	99	Musculoskeletal
30	Darbepoetin alfa (non-ESRD use)	J0881	289	371	63	Blood modifier[b]
31	Bortezomib	J9041	476	369	20	Anti-neoplastic[a]
32	Filgrastim (g-csf)	J1442	146	360	44	Blood modifier[b]
33	Pegfilgrastim	J2505	1,183	358	98	Blood modifier[b]
34	Ondansetron hydrochloride	J2405	< 1	358	76	Gastrointestinal
35	Infliximab	J1745	1,184	354	59	Immunological
36	Hyaluronan or derivative	J7323	66	345	98	Musculoskeletal
37	Leuprolide acetate	J9217	257	322	142	Multiple
38	Hyaluronan or derivative	J7325	144	309	167	Musculoskeletal
39	Rituximab	J9310	1,513	300	68	Anti-neoplastic[a]
40	Normal saline solution	J7040	< 1	298	86	Nutritive
41	Gadolinium-based magnetic resonance contrast agent	A9579	8	276	246	Diagnostic
42	Azacitidine	J9025	196	275	9	Anti-neoplastic[a]
43	Fosaprepitant	J1453	69	273	64	Central nervous system
44	Daptomycin	J0878	92	259	16	Anti-infective
45	Onabotulinumtoxina	J0585	221	258	106	Musculoskeletal
46	Normal saline solution	J7030	< 1	255	87	Nutritive
47	Methylprednisolone acetate	J1020	1	237	159	Endocrine metabolic
48	Prednisone	J7506	< 1	235	35	Endocrine metabolic
49	Low osmolar contrast material	Q9966	< 1	235	128	Diagnostic
50	Granisetron hydrochloride	J1626	< 1	216	30	Gastrointestinal

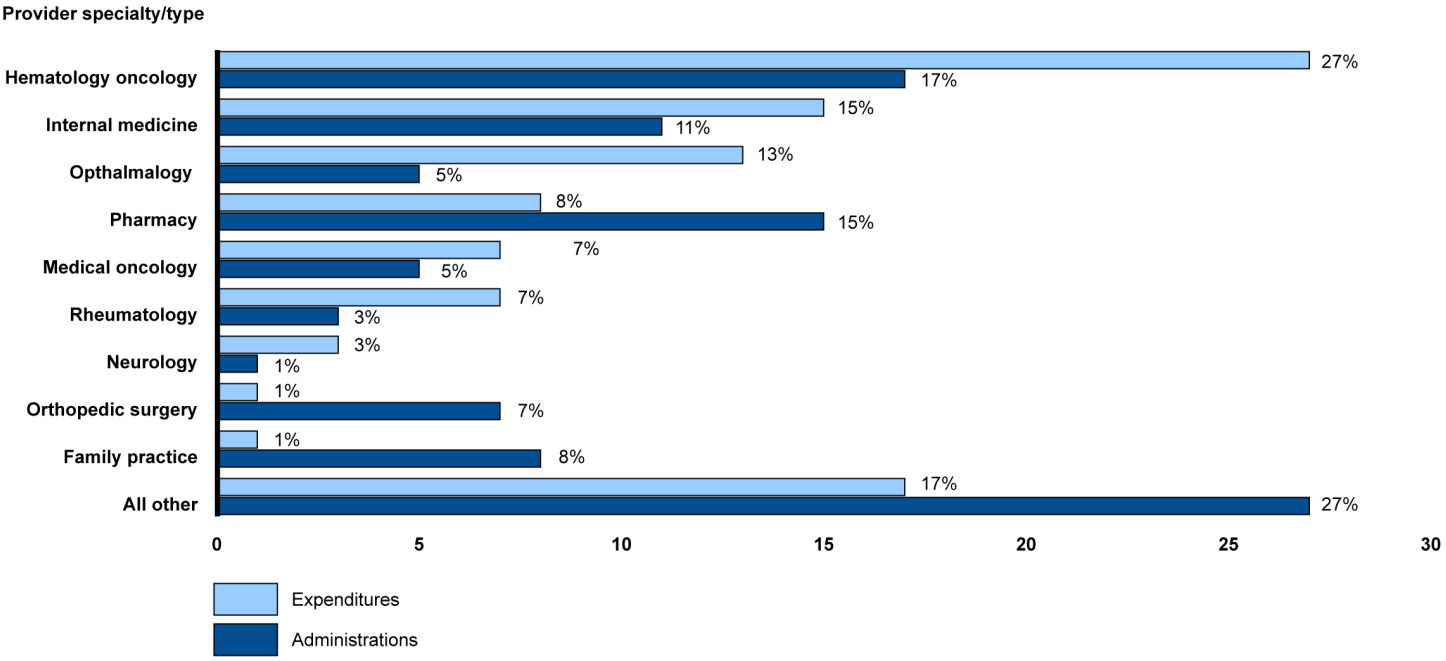
Source: GAO analysis of Centers for Medicare & Medicaid Services and RED BOOK data. | GAO-16-594

Note: In 2014, there were about 46 million administrations of 551 Part B drugs paid based on average sales price (ASP). We defined expenditures as the total amount spent by the Medicare fee-for-service program and its beneficiaries, and administrations as the number of claim line items for a drug. Both measures included only those for claim line items that Medicare paid based on ASP. We defined a drug at the Health Care Common Procedure Coding System (HCPCS) level and counted it as a Part B ASP drug if it had at least one claim line item paid based on ASP.

[a]Anti-neoplastic agents are substances that inhibit or prevent the proliferation of neoplasms, which are new and abnormal growths of tissue, often associated with cancer.

[b]Blood modifier agents enhance or inhibit the clotting or thinning of blood.

Figure 4: Percentage of Total Medicare Expenditures on and Administrations of Part B Drugs Paid Based on ASP, by Provider Specialty/Type (2014)



Source: GAO analysis of Centers for Medicare & Medicaid Services data. | GAO-16-594

Note: In 2014, Medicare spent about $21 billion on approximately 46 million administrations of Part B drugs paid based on average sales price (ASP). We defined expenditures as the total amount spent by the Medicare fee-for-service program and its beneficiaries, and administrations as the number of claim line items for a drug. Both measures included only those for claim line items that Medicare paid based on ASP. The figure includes all provider specialties that accounted for at least 3 percent of expenditures or administrations on Part B ASP drugs.

Appendix II: Comments from the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

JUN 2 1 2016

James Cosgrove
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Mr. Cosgrove:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "*Medicare Part B: CMS Should Take Additional Steps to Verify Accuracy of Data Used to Set Payment Rates for Drugs*" (GAO-16-594).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: MEDICARE PART B: CMS SHOULD TAKE ADDITIONAL STEPS TO VERIFY ACCUARACY OF DATA USED TO SET PAYMENT RATES FOR DRUGS (GAO-16-594)

The U.S. Department of Health and Human Services (HHS) appreciates the opportunity to review and comment on this draft report.

Part B includes a limited drug benefit that encompasses certain drugs and biologicals. Currently covered Part B drugs fall into three general categories: drugs furnished incident to a physician's services, drugs administered via a covered item of durable medical equipment (DME), and other drugs specified by statute. Total Part B payments for separately paid drugs in 2015 were estimated at $22 billion (this includes cost sharing). In 2007, the total payments were $11 billion; the average annual increase since 2007 has been 8.6 percent. This significant growth has largely been driven by spending on separately paid drugs in the hospital outpatient setting, which more than doubled between 2007 and 2015, from $3 billion to $8 billion respectively.

Many Part B drugs, including drugs furnished in the hospital outpatient setting, are paid based on the Average Sales Price (ASP) plus a statutorily mandated 6 percent add-on. Under this methodology, expensive drugs receive higher add-on payment amounts than inexpensive drugs while there are no clear incentives for providing high value care, including drug therapy.

GAO Recommendation
CMS should periodically verify the sales price data submitted by a sample of drug manufacturers by requesting source documentation from manufacturers to corroborate the reported data, either directly or by working with OIG as necessary.

HHS Response
HHS concurs with this recommendation. CMS will work with the OIG as appropriate with regard to collecting source documentation from drug manufacturers and will take action as may be warranted. We note that the OIG currently reviews AMP data and compares ASP to AMP for Part B drugs and that CMS has the authority to adjust the ASP-based payment amount in situations where the OIG finds that ASP exceeds AMP by a certain threshold percent and has implemented regulations to do so.

Appendix III: GAO Contact and Staff Acknowledgments

GAO Contact

James Cosgrove, (202) 512-7114 or cosgrovej@gao.gov

Staff Acknowledgments

In addition to the contact named above, individuals who made key contributions to this report included Gregory Giusto, Assistant Director; Alison Binkowski; George Bogart; Alexander Cattran; Daniel Lee; Lauren Metayer; Elizabeth T. Morrison; and Aubrey Naffis.

Related GAO Products

Medicare Part B: Expenditures for New Drugs Concentrated among a Few Drugs and Most Were Costly for Beneficiaries. GAO-16-12. Washington, D.C.: October 23, 2015.

Medicare: Information on Highest-Expenditure Part B Drugs. GAO-13-739T. Washington, D.C.: June 28, 2013.

Medicare: High-Expenditure Part B Drugs. GAO-13-46R. Washington, D.C.: October 12, 2012.

Medicare Part B Drugs: CMS Data Source for Setting Payments Is Practical but Concerns Remain. GAO-06-971T. Washington, D.C.: July 13, 2006.

Medicare Hospital Pharmaceuticals: Survey Shows Price Variation and Highlights Data Collection Lessons and Outpatient Rate-Setting Challenges for CMS. GAO-06-372. Washington, D.C.: April 28, 2006.

Medicare: Comments on CMS Proposed 2006 Rates for Specified Covered Outpatient Drugs and Radiopharmaceuticals Used in Hospitals. GAO-06-17R. Washington, D.C.: October 31, 2005.

Medicare: Radiopharmaceutical Purchase Prices for CMS Consideration in Hospital Outpatient Rate-Setting. GAO-05-733R. Washington, D.C.: July 14, 2005.

Medicare: Drug Purchase Prices for CMS Consideration in Hospital Outpatient Rate-Setting. GAO-05-581R. Washington, D.C.: June 30, 2005.