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.

<table>
<thead>
<tr>
<th>Drug Characteristic</th>
<th>Percentage of total</th>
<th>Characteristic</th>
<th>Percentage of total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug composition</td>
<td>Biologic</td>
<td>68</td>
<td>Synthetic</td>
</tr>
<tr>
<td>Brand/generic status</td>
<td>Brand only</td>
<td>89</td>
<td>Generic available</td>
</tr>
<tr>
<td></td>
<td>Single-source/multi-source status</td>
<td>81</td>
<td>Multi-source</td>
</tr>
</tbody>
</table>

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.