



441 G St. N.W.
Washington, DC 20548

August 1, 2016

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

Physician-administered Drugs: Comparison of Payer Payment Methodologies

Dear Mr. Levin:

In 2014, Medicare spent over \$24 billion on drugs covered under Part B, which are drugs that are typically administered by a physician in a physician’s office or hospital outpatient department.¹ Medicare pays for most Part B drugs based on the average sales price (ASP) of the drug plus a fixed percentage.² Some stakeholders have raised questions regarding whether the fixed percentage add-on to ASP may create incentives for providers to use more expensive drugs. However, other stakeholders have suggested that any incentive to use more expensive drugs to maximize subsequent reimbursement may be offset by providers’ expenses associated with acquiring such drugs. In March 2016, the Centers for Medicare & Medicaid Services (CMS) released a proposed rule that outlined the agency’s plan to test various models to improve how Medicare pays for Part B drugs and to support higher-quality care.³ Some members of Congress and other stakeholders have raised questions about some of the proposed models and expressed interest in approaches used by other payers for physician-administered drugs.

¹For more information on spending and utilization for Medicare Part B drugs, see GAO, *Medicare Part B: CMS Should Take Additional Steps to Verify Accuracy of Data Used to Set Payment Rates for Drugs*, [GAO-16-594](#) (Washington, D.C.: July 1, 2016).

²Medicare’s payment methodology for most physician-administered drugs is 106 percent of ASP—the average of manufacturers’ net sales price to all entities, with certain exceptions. However, because of budget cuts associated with sequestration, an automatic, across-the-board cancellation of budgetary resources implemented pursuant to the Budget Control Act of 2011, Part B drug payment rates to both physicians and hospitals have been approximately 104 percent of ASP.

³81 Fed. Reg. 13230, 13258 (Mar. 11, 2016) (to be codified at 42 C.F.R. pt. 511). Under the proposal, the first phase would be implemented in late 2016 and would involve changing the 6 percent add-on to ASP to 2.5 percent plus a flat fee based on specified criteria that for 2016 would be \$16.80 per drug per day. The second phase would be implemented no earlier than January 1, 2017, and would test value-based purchasing approaches, including reference pricing, indications-based pricing, outcomes-based risk sharing agreements with manufacturers, discounting or eliminating cost sharing, and clinical decision support tools. Approaches such as these are described in the enclosure.

You asked us to compare Medicare’s payments for Part B drugs with those of other payers. In this report we provide information on the payment methodologies, drug utilization management strategies, and cost containment approaches for physician-administered drugs that are used by Medicare, Medicaid, the Department of Veterans Affairs (VA), and private payers.⁴

To obtain information on payers’ policies related to physician-administered drugs, we identified relevant laws and regulations, and reviewed reports, articles, and policy documents. We also spoke with agency officials from CMS and VA, as well as representatives of four state Medicaid agencies and two large private payers.⁵ We selected the four states with the highest Medicaid spending for inclusion in our study—California, New York, Pennsylvania, and Texas. Information we present on Medicaid policies related to physician-administered drugs is not generalizable to all states. We selected the two private payers based on their large size and because they offer Medicare Advantage plans, Medicaid managed care plans, and private plans. The two private payers we spoke with may not be representative of all private payers, and therefore the related information we present is not generalizable to private payers. To illustrate how payment rates may vary across federal payers, we also reviewed published fee schedules and other supplemental data to compare Medicare and VA payment rates for 10 high-expenditure physician-administered drugs.⁶ We conducted this performance audit from May to August 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.

In summary, the general payment methodologies for physician-administered drugs varied across the payers we examined. Compared to Medicare, other federal payers generally paid rates that were the same or lower. For example, for 10 high-expenditure drugs, VA paid rates that were no more than 68 percent of Medicare’s rate. In contrast, according to officials we interviewed from the two private payers, their payment rates were often higher than Medicare’s rate. Payers’ drug utilization management and cost-containment approaches for physician-administered drugs also varied. For example, certain payers may be able to leverage purchasing power to negotiate lower payment rates. The enclosure presents tables with additional information that addresses our objective.

We provided The Department of Health and Human Services and VA a copy of this draft report for review and comment. The Departments provided technical comments, which we incorporated as appropriate.

⁴For this report, payment rates represent payer costs for physician-administered drugs and include postpayment rebates from drug manufacturers and discounts from distribution vendors.

⁵We contacted the Department of Defense for inclusion in this study, but we did not receive a response within our time frames.

⁶These 10 drugs are the Medicare Part B drugs paid based on ASP that we previously found to have the highest Medicare expenditures during 2014 (see [GAO-16-594](#)). We limited our comparison of Medicare’s payment rates to VA’s rates because, unlike the other payers, VA’s payment methodology does not allow for a qualitative comparison of potential payment rate differences.

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 to the Administrator of CMS, the Secretary of Veterans Affairs, and other interested parties. In addition, the report will be 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 Gregory Giusto, Assistant Director; Alison Binkowski; George Bogart; Alexander Cattran; Michael Erhardt; Elizabeth T. Morrison; and Aubrey Naffis. Other contributors include Brandon Nakawaki and Dharani Ranganathan.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'James Cosgrove', written in a cursive style.

James Cosgrove
Director, Health Care

Enclosure

Information about Payers' Drug Payment Methodologies, Utilization Management, and Cost-containment Approaches

Within this enclosure, table 1 summarizes payers' payment methodologies for physician-administered drugs, table 2 summarizes payers' drug utilization management approaches, and table 3 summarizes payers' cost-containment approaches.

Table 1: Comparison of Payers' General Payment Methodologies for Physician-administered Drugs

	Medicare fee-for-service (FFS)	Medicaid FFS ^a	Veterans Affairs (VA)	VA's Veterans Choice program ^b	Two large private payers ^c
Payment rate	Reimburse providers at 106% of average sales price (ASP). ^d	Reimburse providers at their acquisition cost, as defined by the state. States often define acquisition costs at Medicare's rate—106% of ASP. Drug manufacturers provide postpayment rebates to states that lower states' net drug costs. ^e	Purchase drugs based on rates negotiated with manufacturers or rates based on statutory price ceilings. ^f Drugs are purchased from manufacturers via a contracted distribution vendor that further discounts the drugs. ^g	Reimburse providers at negotiated rates that, in general, cannot exceed, and are usually equal to, Medicare's rate—106% of ASP.	Medicare's rate—106 % of ASP— may be used as a benchmark for negotiation. According to the payers, rates are often above 106% of ASP. Drug manufacturers may provide postpayment rebates to payers, which lowers payers' net drug costs.
Costs covered by payment rate	Not specified when provided in physician offices; covers providers' ingredient acquisition and overhead costs when provided in hospital outpatient departments.	Providers' ingredient acquisition costs.	Program's ingredient acquisition costs.	Not specified.	Providers' ingredient acquisition costs and, in some cases, overhead costs.
Beneficiary cost-sharing requirements	20% coinsurance, after any deductible is met.	None	None	None	Copayment or coinsurance that varies by plan. Beneficiaries are eligible for manufacturer coupon discounts for specific drugs. ^h

Source: GAO analysis of information from the Centers for Medicare & Medicaid Services, VA, and two large private payers. | GAO-16-780R

Notes: This table summarizes payers' general payment methodology for physician-administered drugs provided in either physicians' offices or hospital outpatient departments. Information in this table is based on documents and interviews with agency and private payer officials. This table does not address separate payments for the administration of the drug or related physician services. Each payer may have exceptions that are not addressed in this table.

^aInformation is from CMS and the four state Medicaid programs we examined, but is not generalizable to all states.

^bVA's Veterans Choice program allows eligible beneficiaries to receive care from contracted, non-VA providers on a FFS basis.

^cInformation is not generalizable to all private payers.

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^dLow-cost and certain other drugs provided in hospital outpatient departments are not paid for separately. ASP is the average of manufacturers' net sales price to all entities, with certain exceptions, and is updated quarterly by CMS. Because of budget cuts associated with sequestration, an automatic, across-the-board cancellation of budgetary resources implemented pursuant to the Budget Control Act of 2011, Part B drug payment rates to both physicians and hospitals have been approximately 104 percent of ASP. Additionally, under the first phase of implementation of its proposed rule, for 2016, CMS proposes to change the 6 percent add-on to ASP to 2.5 percent plus a flat fee based on specified criteria. 81 Fed. Reg. 13230, 13258 (Mar. 11, 2016) (pertinent provision to be codified at 42 C.F.R. § 511.300). CMS has determined that, for 2016, the flat fee would be \$16.80 per drug per day.

^eThe basic rebate for brand name drugs is the greater of the difference between the average manufacturer price (AMP) and the best price for the drug, or 23.1 percent of AMP; manufacturers must also provide an additional rebate for drugs with prices that increased faster than inflation. For generic drugs, the rebate is 13 percent of AMP. States may also negotiate additional supplemental rebates. For more information on Medicaid prescription drug rebates, see GAO, *Prescription Drugs: Comparison of DOD, Medicaid, and Medicare Part D Retail Reimbursement Prices*, [GAO-14-578](#) (Washington, D.C.: June 30, 2014).

^fVA can purchase physician-administered drugs under federal pricing arrangements, including Federal Supply Schedule prices and Big 4 prices. Federal Supply Schedule prices are available to all direct federal purchasers, and prices for physician-administered drugs must be no more than the prices manufacturers charge their most-favored nonfederal customers. Big 4 prices are available to the four largest federal purchasers—VA, Department of Defense, the Public Health Service, and the U.S. Coast Guard—and prices for covered, branded drugs, must be at least 24 percent lower than the non-federal AMP. For more information on VA's drug purchasing, see GAO, *Prescription Drugs: Comparison of DOD and VA Direct Purchase Prices*, [GAO-13-358](#) (Washington, D.C.: Apr. 19, 2013).

^gVA contracts with a distribution vendor that provides a fixed percentage discount of about 9 percent off purchased drugs. We compared VA's payment rates for 10 high-expenditure drugs to Medicare's rates and found that VA's rates ranged from 55 to 68 percent of Medicare's rates. The physician-administered drugs we compared were the 10 Part B drugs paid based on ASP that had the highest Medicare expenditures in 2014 (see GAO, *Medicare Part B: CMS Should Take Additional Steps to Verify Accuracy of Data Used to Set Payment Rates for Drugs*, [GAO-16-594](#) (Washington, D.C.: July 1, 2016)). VA's payment rates for the 10 drugs were based on Big 4 prices and include the discount provided by the distribution vendor.

^hManufacturer use of coupon discounts to induce or reward the use of certain drugs is prohibited in federal health care programs.

Table 2: Comparison of Payers' General Drug Utilization Management Approaches for Physician-administered Drugs

	Medicare fee-for-service (FFS)	Medicaid FFS ^a	Veterans Affairs (VA)	VA's Veterans Choice program ^b	Two large private payers ^c
Conditions of coverage or use					
Limit coverage of certain drugs (closed formulary)	No	No	Maintains formulary and non-formulary drugs provided based on medical necessity	Maintains formulary and non-formulary drugs provided based on medical necessity	No
Require payer approval (prior authorization)	No	No ^d	Not applicable	No ^e	Yes, for certain drugs.
Require use of lower-cost drugs before more costly drugs (step therapy)	No	No	Yes, for certain drugs. ^f	Yes, for certain drugs. ^f	Yes
Quantity limits	No ^g	No ^d	Yes, for certain drugs. ^f	Yes, for certain drugs. ^f	One of the payers uses for certain drugs.
Evidence-based treatment plans (clinical pathways) ^h	No	No	Yes, for certain drugs. ^f	Yes, for certain drugs. ^f	One payer provides rewards for oncology drugs provided under clinical pathways. ⁱ
Provider clinical decision support					
Giving providers evidence-based information and guidelines on appropriate drug use	No ^j	No ^d	Yes, for certain drugs. ^f	Yes, for certain drugs. ^f	One of the payers does.
Giving providers information on their drug prescribing and utilization patterns	No ^j	No ^d	Yes	No	One payer said no.

Source: GAO analysis of information from the Centers for Medicare & Medicaid Services, VA, and two private payers. | GAO-16-780R

Notes: This table summarizes payers' general drug utilization management approaches for physician-administered drugs provided in either physicians' offices or hospital outpatient departments. Information in this table is based on documents and interviews with agency and private payer officials. Each payer may have exceptions that are not addressed in this table.

^aInformation is from CMS and the four state Medicaid programs we examined, but is not generalizable to all states.

^bVA's Veterans Choice program allows eligible beneficiaries to receive care from contracted, non-VA providers on a FFS basis.

^cInformation is not generalizable to all private payers.

^dPennsylvania's Medicaid FFS program uses the same utilization management approaches for all outpatient covered drugs, regardless of whether they are physician-administered or provided through a pharmacy. These approaches include prior authorization, quantity limits, decision support tools, and drug utilization reviews.

^eVA's Veterans Choice program requires beneficiaries to obtain approval for episodes of care outside of VA facilities, though they do not specifically need to obtain prior authorization for physician administered drugs.

^fVA maintains clinical use guidelines for its practitioners to ensure safe and appropriate drug use, and to promote cost-effective prescribing practices. These guidelines apply criteria for drug use that may involve prior use of other therapies or drugs, adherence to treatment plans, and limits on drug use.

^gMedicare limits excessive quantities of certain drugs through Medically Unlikely Edits.

^hClinical pathways are guidelines for specific diagnoses that include the sequence and timing of interventions by providers.

ⁱThe Medicare Payment Advisory Commission has reported that the use of clinical pathways for physician-administered drugs is widely used in oncology care.

^jUnder the second phase of implementation of its proposed rule, no earlier than 2017 CMS proposes to test value-based purchasing approaches, including clinical decision support tools, such as an online provider education tool and provider feedback on drug

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utilization. 81 Fed. Reg. 13230, 13244, 13258 (Mar. 11, 2016) (preamble, III.B.3.) (pertinent provision to be codified at 42 C.F.R. § 511.305(b)(2)).

Table 3: Comparison of Payers' General Cost-containment Approaches for Physician-administered Drugs

	Medicare fee-for-service (FFS)	Medicaid FFS ^a	Veterans Affairs (VA)	VA's Veterans Choice program ^b	Two large private payers ^c
Leveraging purchasing power to negotiate lower rates	No ^d	Yes, states may be able to negotiate supplemental rebates from drug manufacturers. ^e	Yes, VA may be able to negotiate lower rates by leveraging purchasing power and formulary coverage.	No.	Yes, may be able to negotiate lower rates from providers or rebates from drug manufacturers.
Payment rate incentivizes least costly therapeutic alternative					
Same payment for brands and generics, based on weighted average of sales prices	Yes	Yes, for most states.	No	Yes	Yes
Same payment for group of therapeutically similar drugs (reference pricing)	No ^{f, g}	No	No	No	No
Payment for a drug varies based on effectiveness for given use (indication-based pricing)	No ^g	No	No	No	No
Lower beneficiary cost sharing for cheaper or higher-value therapeutic alternatives (discounted cost sharing)	No ^g	Not applicable	Not applicable	Not applicable	No
Removing or decreasing incentives within payment rate formula that encourage use of more costly therapeutic alternatives	No ^h	No	No	No	One of the payers uses for certain drugs.
Moving away from fee-for-service					
Risk sharing with drug manufacturers based on outcomes (outcomes-based risk sharing)	No ^g	No	No	No	No
Risk sharing with providers, including episode-based or bundled pricing	Yes, for some drugs and settings. ⁱ	No	No	No	No ^j

Source: GAO analysis of information from the Centers for Medicare & Medicaid Services, VA, and two private payers. | GAO-16-780R

Notes: This table summarizes payers' general cost containment approaches for physician-administered drugs provided in either physicians' offices or hospital outpatient departments. Information in this table is based on documents and interviews with agency and private payer officials. Each payer may have exceptions that are not addressed in this table.

^aInformation is from CMS and the four state Medicaid programs we examined, but is not generalizable to all states.

^bVA's Veterans Choice program allows eligible beneficiaries to receive care from contracted, non-VA providers on a FFS basis.

^cInformation is not generalizable to all private payers.

^dMedicare has authority to implement a competitive acquisition program (CAP) for Part B drugs where physicians who choose to enroll receive Part B drugs from a Medicare-selected vendor at a predetermined, competitively set rate, rather than the physicians buying directly and billing Medicare for the drugs. Medicare operated a CAP from mid-2006 through 2008, but then suspended the program because of contractual issues, low physician enrollment, and because the vendor had limited leverage to negotiate discounts.

^eIn exchange for Medicaid coverage of most of their drugs, manufacturers are required to participate in the Medicaid Drug Rebate Program. States may be able to obtain supplemental rebates in addition to the required rebates. Pennsylvania has a waiver that allows it to leverage its purchasing power to negotiate lower rates from selected specialty pharmacies.

^fMedicare implemented local least-costly alternative policies and a national functional equivalence policy between 1995 and 2010, prior to changes to CMS's authority.

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⁹Under the second phase of implementation of its proposed rule, no earlier than 2017, CMS proposes to test value-based purchasing approaches, including reference pricing, indications-based pricing, discounting or eliminating cost sharing, and outcomes-based risk sharing agreements with manufacturers. 81 Fed. Reg. 13230, 13258 (Mar. 11, 2016) (pertinent provisions to be codified at 42 C.F.R. § 305(b)(1)).

^hAs not all therapeutically equivalent or comparable drugs are under the same billing code, some researchers and stakeholders have raised concerns that the current 106 percent of ASP payment methodology may incentivize use of the more expensive drugs. However, other stakeholders have suggested that any incentive to use more expensive drugs to maximize subsequent reimbursement may be offset by expenses associated with acquiring such drugs. To test whether an alternate approach would limit potential incentives to use higher priced drugs, under the first phase of implementation of its proposed rule, for 2016, CMS proposes to change the 6 percent add-on to ASP to 2.5 percent plus a flat fee based on specified criteria. 81 Fed. Reg. 13230, 13258 (Mar. 11, 2016) (pertinent provision to be codified at 42 C.F.R. § 511.300). CMS has determined that, for 2016, the flat fee would be \$16.80 per drug per day.

ⁱMedicare bundles payments for low-cost and certain other physician-administered drugs provided in hospital outpatient departments into the payments for related services. Medicare also bundles its payments for certain physician-administered drugs for end-stage renal disease.

^jOfficials of one private payer said that the payer bundles payments for certain physician-administered drugs for end-stage renal disease into the payments for related services.

Related GAO Products

Medicare Part B: CMS Should Take Additional Steps to Verify Accuracy of Data Used to Set Payment Rates for Drugs, [GAO-16-594](#). Washington, D.C.: July 1, 2016.

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