

Report in Brief

September 2016
OEI-12-16-00340

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL



Why This Review Matters

Unlike most other Part B drugs, Medicare payment amounts for drugs infused through durable medical equipment (DME) are still based on list prices – known as AWP – from 2003. Prior Office of Inspector General (OIG) studies found that AWP was a flawed benchmark for determining payments, because it does not adequately reflect market prices. Paying based on flawed, out-of-date AWP may create access issues for vital drugs or lead to excessive billing. For example, payments that are below costs could make providers less willing to provide a drug, while payments that substantially exceed costs create incentives to overutilize a product.

How We Did This Review

In February 2013, OIG issued a report to the Centers for Medicare & Medicaid Services (CMS) regarding Medicare payments for DME infusion drugs. In that report, we made one recommendation and suggested two options for its implementation (see graphic on the right). Because CMS had not taken steps to address our recommendation, and payments continued to be misaligned with drug costs, OIG revisited this issue in a 2015 report.

This current report, following up on our earlier recommendation, builds on previous OIG findings by illustrating the impact of the current payment methodology on provider reimbursement rates for two vital DME infusion drugs: pump-administered insulin and milrinone lactate.

CMS Should Address Medicare's Flawed Payment System for DME Infusion Drugs

What We Found

OIG published its first report recommending changes to Medicare payments for DME infusion drugs 3 years ago, yet CMS still reimburses for these drugs at prices that are unrelated to the amounts providers pay to acquire them. Under Medicare's current reimbursement methodology, which is based on average wholesale prices (AWPs) from October 2003, Medicare paid suppliers 65 percent less than their cost for pump-administered insulin – hindering beneficiary access to the drug. Using this same reimbursement methodology, Medicare paid suppliers of milrinone lactate, an infusion drug used to treat congestive heart failure, 20 times the drug's cost, thereby creating incentives for overutilization and improper billing.

Troubling reimbursement rates for two vital DME infusion drugs underscore the need to address Medicare's flawed payment methodology

What We Recommend

OIG again recommends that CMS take action to address payment issues associated with DME infusion drugs. The agency could seek a legislative change that would require payments for DME infusion drugs to be based on average sales prices (ASPs), as is the case with most other Part B drugs. Alternatively, CMS could address our recommendation by using its existing authority to include DME infusion drugs in the competitive bidding program.

CMS should take action to address the payment issues associated with DME infusion drugs.



Seek a legislative change that would require payments for DME infusion drugs to be based on ASPs

OR



Use its existing authority to include DME infusion drugs in the competitive bidding program



CMS Should Address Medicare's Flawed Payment System for DME Infusion Drugs

BACKGROUND

Medicare reimburses providers of most Part B-covered prescription drugs on the basis of average sales prices (ASPs) – a pricing benchmark defined by Federal law and calculated using actual sales data.¹ However, as required by statute, Medicare sets payment amounts for drugs infused through durable medical equipment (DME infusion drugs) at 95 percent of the average wholesale prices (AWPs) in effect on October 1, 2003.^{2, 3} AWP, which represent list prices rather than actual marketplace prices, have been long been recognized as a flawed pricing benchmark.⁴ Prior Office of Inspector General (OIG) work consistently found that AWP, even when timely, had little relation to provider acquisition costs.⁵

In a February 2013 report, we found that, overall, the AWP-based Medicare payment amounts for DME infusion drugs substantially exceeded estimated provider acquisition costs, and that paying on the basis of ASPs, instead, would have reduced Medicare expenditures by hundreds of millions of dollars between 2005 and 2011.⁶ To ensure that payment amounts for DME infusion drugs more accurately reflect acquisition costs, we recommended that the Centers for Medicare & Medicaid Services (CMS) either (1) seek a legislative change requiring that DME infusion drugs are paid using the ASP-based methodology or (2) include DME infusion drugs in the next round of the competitive bidding program.⁷ As of August 2016, CMS had not taken steps toward seeking legislation. CMS has stated that it is considering phasing in competitive bidding for DME infusion drugs.

OIG revisited this issue in an April 2015 report and again found that payment amounts for DME infusion drugs did not accurately reflect acquisition costs.⁸ We found that because Medicare reimbursement rates still were set at prices from more than a decade earlier, payment amounts for approximately one-quarter of DME infusion drugs were below provider acquisition costs – potentially leading to beneficiary access issues. However, because payment amounts for most of the drugs exceeded acquisition costs – sometimes substantially – we also found that Medicare expenditures for DME infusion drugs could have been \$251 million lower during one 18-month period if the ASP-based payment methodology OIG recommended had been implemented the quarter after that report was issued.⁹

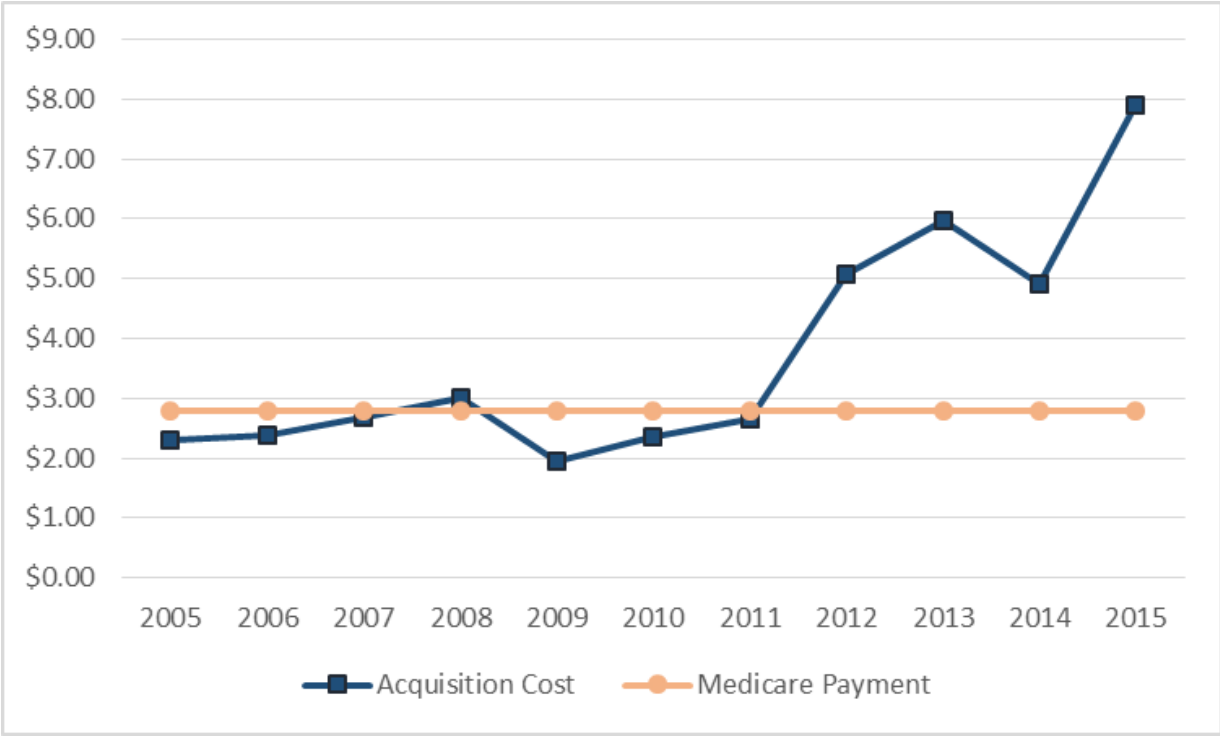
In this recommendation followup report, we build on our earlier work by illustrating the impact of the AWP-based payment methodology on provider reimbursement for two vital DME infusion drugs: pump-administered insulin (used to treat diabetes) and milrinone lactate (used to treat congestive heart failure).¹⁰ Further, we detail how current payment rates may affect beneficiary access to vital drugs and may encourage overutilization and excessive billing.

RESULTS

Suppliers have been substantially under-reimbursed for pump-administered insulin since 2012, potentially creating barriers to patient access

Since 2012, Medicare has consistently reimbursed suppliers of pump-administered insulin at amounts substantially below the prices suppliers paid to acquire the drug. By the fourth quarter of 2015, the average cost of insulin had risen to \$7.91 per 50 units, almost triple its cost 4 years earlier. Medicare’s payment amount – set by law at 95 percent of the AWP from October 2003 – was just \$2.80 for the same number of units. In other words, the average supplier would lose \$5.11 (or 65 percent of the cost) on every 50 units billed to Medicare.

Figure 1: Medicare Payments for Insulin do not Reflect Cost Increases for the Drug



Source: OIG analysis of CMS ASP and payment amount data for pump-administered insulin, 2016.
Note: Costs and payment amounts are from the fourth quarter of each year.

As Figure 1 illustrates, suppliers have been under-reimbursed for pump-administered insulin in each of the last 4 years (2012—2015), as rising costs have not been accompanied by corresponding increases in payments. As a result, suppliers are subject to escalating losses when providing the drug to Medicare beneficiaries. If the average cost of insulin holds at \$7.91 through 2016, Medicare suppliers could expect to face an annual net loss of \$30 million on the drug, or approximately \$2,100 per beneficiary receiving pump-administered insulin.¹¹

The media also has taken note of the significant rise in insulin prices and the complex array of factors driving these increases (see Figure 2).¹² However, despite the skyrocketing prices for

pump-administered insulin, Part B payment amounts remain the same as they were a dozen years ago. In contrast, Medicare reimbursement rates for injectable insulin, which is covered under Part D, can be much more responsive to market price fluctuations, as plan sponsors regularly renegotiate the amount they pay suppliers.¹³ For some beneficiaries, continuously infused insulin offers significant clinical benefits over injectable insulin, meaning their medical needs are better met by continuing treatment with insulin pumps, covered under Part B, than by switching to injectable insulin, covered under Part D.

Figure 2: Recent Headlines Addressing the Rising Cost of Insulin



Several sources report that beneficiaries are having difficulties finding suppliers who accept Medicare payment for pump-administered insulin

In the 2013 CMS Medicare Ombudsman’s report to Congress, the agency stated that it had heard from beneficiaries who could not find an insulin supplier willing to accept Medicare after their previous suppliers ceased accepting Medicare for the drug.¹⁴

[CMS] received feedback that some suppliers, including mail-order companies and local retail pharmacies, were refusing to submit claims to Medicare because the rate for Medicare reimbursement did not cover the cost of the drug, making it difficult for some beneficiaries to secure a supplier [...] As a result, some beneficiaries have had to change suppliers several times, while others have been unable to find another supplier and had to pay out of pocket for insulin. CMS caseworkers assisted beneficiaries in these instances as much as possible, but it has become increasingly difficult.

Also in 2013, the Congressional Research Service (CRS) contacted OIG regarding potential access issues for insulin. According to CRS, “One [Congressional] staffer is receiving complaint(s) from Medicare beneficiaries because they are not able to buy insulin for their insulin pumps (paid for under the Part B DME benefit).”

Similarly, the Lincoln Journal Star reported on a Medicare beneficiary who was having difficulty finding a provider for pump-administered insulin:

“For about nine months, Carr has had increasing difficulty finding a pharmacy willing to supply his insulin on a long-term basis because he is a money-losing proposition for any business. And he's not the only one facing the bureaucratic problem[...] First Liberty Medical, a mail order firm Carr traditionally has used, stopped providing insulin for Medicare Part B. Carr, who lives in Wymore, got his insulin one month from a local pharmacy, then from Walmart, then from another mail order company. He's had nine providers in the past year.”¹⁵

The access issues cited above are not caused by insulin shortages, but by Medicare reimbursement practices that make it uneconomic for suppliers to provide the drug to beneficiaries. As a result, beneficiaries face difficulties in finding suppliers who accept Medicare reimbursement for insulin, so they may have to pay out-of-pocket for a drug they need to survive.

Large suppliers of pump-administered insulin have stopped providing the drug to Medicare beneficiaries

In July 2010, OIG and CMS received a letter from one of Medicare’s largest suppliers of pump-administered insulin. The supplier claimed that the company was unable to purchase insulin from manufacturers at prices below or equal to Medicare payment rates and stated that “[w]ithout swift action to correct these inequitable policies, [we] will have no choice but to stop supplying rapid-acting insulin to people with Medicare who use insulin pumps.” In 2011, this supplier provided pump-administered insulin to 56 percent (7,739) of the Medicare beneficiaries who received the drug; in 2012, just 4 beneficiaries received pump-administered insulin from this supplier, and future years, 1 or 0.

FORMER MEDICARE INSULIN SUPPLIER:

“[w]ithout swift action to correct these inequitable policies, [we] will have no choice but to stop supplying rapid-acting insulin to people with Medicare who use insulin pumps.”

Other large suppliers appear to have made the same decision. Three companies (including the company referenced above) supplied 70 percent of the insulin paid for under Medicare Part B in 2011. Just 4 years later, these companies didn’t have a single paid claim for the drug, meaning that more than 10,000 Medicare beneficiaries had to find new suppliers — suppliers willing to incur a loss when providing insulin.

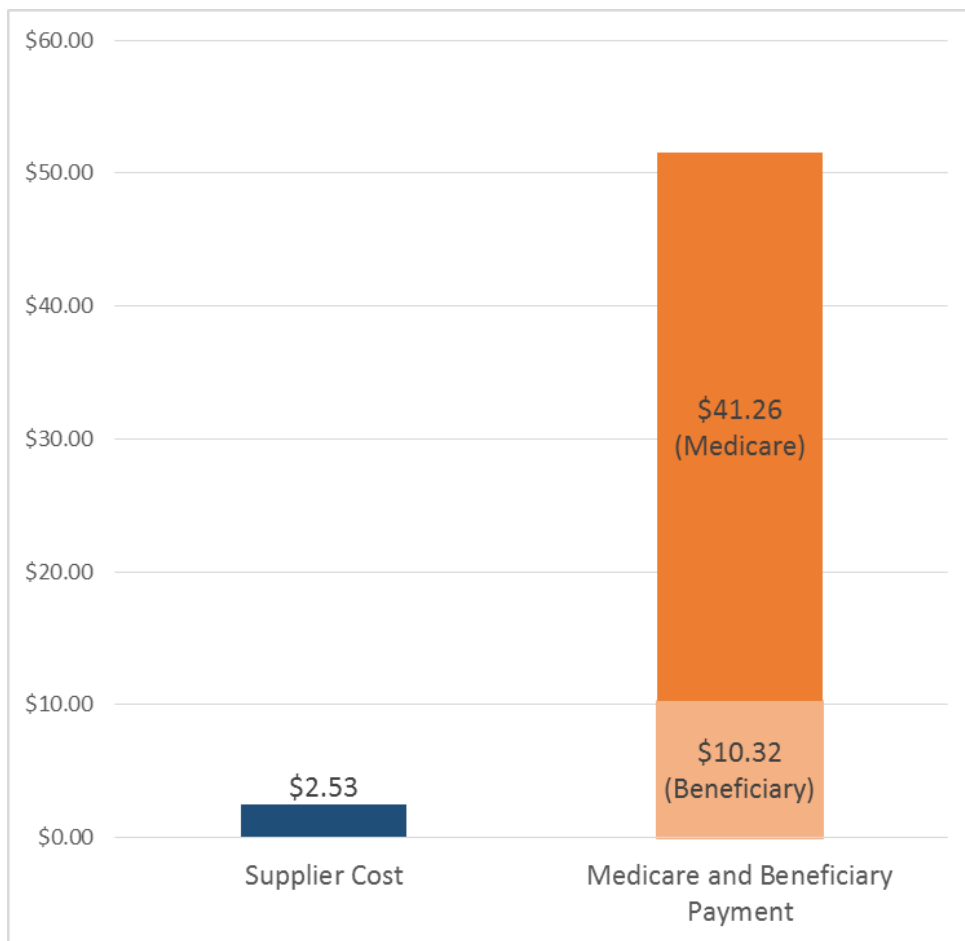
As large suppliers have stopped providing pump-administered insulin to Medicare beneficiaries, smaller “low-volume” suppliers have become the primary billers. In 2015, 80 percent of the insulin paid under Part B was provided by “low-volume” suppliers, i.e., suppliers associated with 3 or fewer Medicare beneficiaries. In 2011, just 27 percent of pump-administered insulin was

provided by low-volume suppliers. Because these smaller suppliers are losing money on every Medicare prescription they fill for the drug, eventually they may follow the lead of large suppliers and stop accepting Medicare for pump-administered insulin.

Medicare’s payment amount for milrinone lactate was 20 times its acquisition cost in the fourth quarter of 2015, creating potential incentives for overbilling

Milrinone lactate, a life-saving drug used to treat congestive heart failure, is consistently one of the highest-expenditure DME infusion products. In the fourth quarter of 2015, Medicare reimbursed suppliers \$51.58 per 5 mg of milrinone lactate; during this same period, suppliers of the drug paid an average of \$2.53 per 5 mg. Medicare beneficiaries were responsible for a copayment of \$10.32 per 5 mg – more than 4 times the cost of the drug. Medicare covered the remaining \$41.26 (see Figure 3). To put this in perspective, the average Medicare beneficiary who was prescribed milrinone lactate in 2015 received 6,500 mg of the drug, resulting in copayments of approximately \$13,000 per patient that year.

Figure 3: Medicare and Beneficiaries Together Pay More than \$50 for a Drug that Costs Suppliers Approximately \$2.50



Source: OIG analysis of fourth-quarter 2015 Medicare payment data and ASP data for milrinone lactate, 2016.

In contrast to suppliers of pump-administered insulin, who have been subject to substantial losses on each prescription, suppliers of milrinone lactate have benefited from years of being reimbursed at amounts considerably higher than their costs for the drug. From 2006 through 2015, average provider acquisition costs for 5 mg of milrinone lactate have ranged from \$1.89 to \$5.51, while Medicare payment has remained at \$51.58. OIG previously found that Medicare expenditures for milrinone lactate would have been reduced by almost \$166 million during an 18-month period if reimbursement for the drug, instead, had been set at 106 percent of ASP.¹⁶

The substantial difference between Medicare payment amounts and supplier acquisition costs for milrinone lactate provides incentives for overutilization and improper billing

The 357 suppliers who Medicare paid for milrinone lactate in 2015 could each expect to net about \$64,000 annually per beneficiary based on the difference between payment amounts and acquisition costs.¹⁷ Thirty-five of these suppliers each would capture over \$1 million a year above cost, with the top supplier netting approximately \$7 million.¹⁸

The substantial difference between Medicare payment amounts and supplier acquisition costs for milrinone lactate creates incentives for overutilization and improper billing. Two prepayment reviews for milrinone lactate, completed by a Medicare DME contractor in 2015, shed light on the extent of overutilization and improper billing that may be occurring. The first involved prepayment medical reviews of 102 milrinone lactate claims.¹⁹ Eighty-two of the 102 claims were either completely denied or partially denied, resulting in an overall charge denial rate of 73.4 percent (the overall charge denial rate equals the dollar amount of services determined to be billed in error divided by the dollar amount of services under review). The second involved prepayment medical reviews of 75 claims, 60 of which were either completely denied or partially denied, resulting in an overall charge denial rate of 75.6 percent.²⁰

In both reviews, the reasons cited for denying payment included: (1) claims not meeting coverage criteria; (2) missing, incomplete, or invalid written orders; and (3) proof-of-delivery issues. These reasons call into question whether milrinone lactate should have been provided in all of these cases and whether it was over-supplied because of the financial incentives.

CONCLUSION

OIG studies have repeatedly shown that Medicare's reimbursement methodology for DME infusion drugs has resulted in payment amounts that bear little relationship to provider acquisition costs. Rather, payment amounts for DME infusion drugs are determined using 13 year-old AWP – a benchmark that, even when timely, has been shown to be a flawed basis for setting provider reimbursement rates.

The troubling payment-related issues for two vital DME infusion drugs, as discussed in this report, illustrate why Medicare's current reimbursement methodology must be revised. Under-reimbursement for pump-administered insulin has led some suppliers to cease providing the drug to Medicare beneficiaries, which may make it difficult for vulnerable patients to obtain their life-saving medicine. In contrast, when Medicare payments greatly exceed provider acquisition costs, as is the case with milrinone lactate, there may be incentives for providers to overutilize a particular drug, resulting in excessive Medicare payments.

Moreover, the reimbursement practices affecting the two drugs presented in this analysis are not anomalies. In our previous work, we found that approximately one-quarter of DME infusion drugs were reimbursed at amounts that, like insulin, were below their acquisition costs. Further, Medicare reimbursed at least 42 percent of DME infusion drugs at amounts that, like milrinone lactate, were more than twice their estimated acquisition costs.

Therefore, OIG continues to recommend that:

CMS take action to ensure that Medicare payment amounts for DME infusion drugs more accurately reflect provider acquisition costs.

The agency could choose to seek a legislative change that would require payments for DME infusion drugs to be based on ASPs. We recognize that seeking such a change through the legislative proposal process would not, in itself, change payments unless Congress chooses to enact this change. Another available option would be for CMS to use its existing authority to include DME infusion drugs in the competitive bidding program as soon as possible.

METHODOLOGY

Data Collection and Analysis

We obtained all paid Part B DME claims for pump-administered insulin and milrinone lactate from 2005 through 2015. We obtained the AWP- and ASP-based payment amounts for both drugs in the fourth quarter of each year from CMS's payment limit files.²¹ Because ASPs are based on actual sales in the marketplace, they provide a reasonable estimate of the drug provider's acquisition costs. We used the ASP-based payment amounts to calculate estimated acquisition costs in each quarter by dividing each drug's ASP-based payment amount by 1.06.²² For each quarter, we calculated the difference between the AWP-based payment amount and the estimated acquisition cost for insulin and milrinone lactate.

We summarized annual claims data for insulin and milrinone lactate by national provider identifier to determine the number of suppliers who were paid for the drugs each year and the amount each supplier received in reimbursement. We performed a similar analysis by beneficiary to determine the number of beneficiaries who received insulin and milrinone lactate, as well as the amount each beneficiary received.

Limitations

We did not review Part B DME claims for accuracy, nor did we review any documentation in support of the claims included in our study. We also did not examine any infusion-related services that may have been provided to beneficiaries who received DME infusion drugs.

Under sequestration, the effective payment rate for Part B drugs (including DME infusion drugs) was reduced between 1 and 2 percent.²³ Neither the published pricing data nor CMS expenditure data reflect these reductions. Our acquisition cost comparisons were calculated without regard to sequestration and therefore may be minimally overstated. We did not estimate how a new payment methodology might change provider behavior and Medicare spending.

Standards

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

ACKNOWLEDGMENTS

This report was prepared under the direction of Dave Tawes, Regional Inspector General for Evaluation and Inspections in the Baltimore regional office, and Louise Schoggen, Assistant Regional Inspector General.

Dave Tawes also served as the team leader for this study. Other Office of Evaluation and Inspections staff from the Baltimore regional office who assisted with the study include Bahar Adili. Office of Evaluation and Inspections staff who provided support include Maria Maddaloni, Meghan Kearns, and Joanne Legomsky. Other OIG staff who provided support include Jessica Swanstrom.

ENDNOTES

¹ Section 1847A(c) of the Social Security Act (the Act) defines ASP as a manufacturer's sales of a drug (with certain exceptions) to all purchasers in the United States in a calendar quarter divided by the total number of units of the drug sold by the manufacturer in that same quarter. The ASP is net of any price concessions, such as volume discounts, "prompt pay" discounts, cash discounts, free goods contingent on purchase requirements, chargebacks, and rebates other than those obtained through the Medicaid drug rebate program.

² Section 1842(o)(1)(D)(i) of the Act. According to section 20.1.3 of chapter 17 of the *Medicare Claims Processing Manual*, Pub. No. 100-04, this methodology does not apply if the drug is compounded or furnished incident to a professional service. For DME infusion drugs not listed in the compendia as of October 1, 2003, payments are set at 95 percent of their first published AWP. Also, pursuant to section 1842(o)(1)(D)(ii) of the Act, payments for DME infusion drugs are not based on 95 percent of AWP if subject to competitive bidding.

³ Only a small number of Part B drugs are subject to the DME infusion payment methodology. For example, in an earlier report, OIG found that 31 Part B drugs were paid for under the DME infusion payment methodology from the second quarter of 2013 through the third quarter of 2014. See *Implementing OIG Recommendation Could Have Reduced Payments for DME Infusion Drugs by Hundreds of Millions of Dollars*, OEI-12-15-00110, April 2015.

⁴ National Health Policy Forum, *Average Wholesale Price for Prescription Drugs: Is There a More Appropriate Pricing Mechanism?*, June 2002.

⁵ For example, see *Medicaid Drug Price Comparison: Average Sales Price to Average Wholesale Price*, OEI-03-05-00200, June 2005.

⁶ OIG, *Part B Payments for Drugs Infused Through Durable Medical Equipment*, OEI-12-12-00310, February 2013.

⁷ The DME, Prosthetics, Orthotics, and Supplies Competitive Bidding Program was mandated by section 302 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P. L. No. 108-173, to reduce expenses for Medicare and its beneficiaries. DME suppliers submit bids to become Medicare contract suppliers and to furnish items in competitive bidding areas. 42 C.F.R. § 414.412(a). Payment amounts resulting from the bids replace the fee-schedule payment amounts. Competitive bidding has been implemented in phases beginning with bids for items with the highest cost and highest volume or with the largest savings potential. CMS, *Medicare Claims Processing Manual*, Pub. 100-04, ch. 36, § 20.1.

⁸ OIG, *Implementing OIG Recommendation Could Have Reduced Payments for DME Infusion Drugs by Hundreds of Millions of Dollars*, OEI-12-15-00110, April 2015.

⁹ *Ibid.*

¹⁰ Medicare Part B only covers insulin when it is administered through an external infusion pump. According to CMS, a continuous subcutaneous insulin infusion pump worn outside the body (external), including the insulin used with the pump, may be covered for some people with Medicare Part B who have diabetes and who meet certain conditions. CMS, *Medicare National Coverage Determinations Manual*, Pub. No. 100-03, ch. 1, part 4, § 280.14(B)(1)(e). Beneficiaries who do not meet these conditions may still receive injectable insulin under Part D. CMS, *Medicare Prescription Drug Benefit Manual*, Pub. No. 100-18, ch. 6, § 10.1 and Appendix B. See also, CMS, *Medicare's Coverage of Diabetes Supplies & Services* at <https://www.medicare.gov/Pubs/pdf/11022.pdf>.

¹¹ Based on our analysis of Part B claims data, the average Medicare beneficiary who used an insulin pump received 411 billing units of the drug in 2015 (1 billing unit is equivalent to 50 units of pump-administered insulin).

¹² Identifying factors that increased manufacturer sales prices for pump-administered insulin was beyond the scope of this study.

¹³ CMS contracts with private companies, known as plan sponsors, which offer prescription drug plans to their beneficiaries. Pharmacy reimbursement for Part D drugs is based on negotiations between plan sponsors and pharmacies (see definition of "negotiated prices" at 42 CFR § 423.100). The Government is prohibited from interfering in these price negotiations (see § 1860D-11(i) of the Act).

¹⁴ Office of the Medicare Ombudsman, *Fiscal Year 2013 Report to Congress*. Accessed online at <https://www.cms.gov/Center/Special-Topic/Ombudsman/2013-Ombudsman-Report-to-Congress-.pdf>.

¹⁵ Nancy Hicks, *Pharmacies unwilling to take loss on insulin for Medicare patients*, Lincoln Star Journal, June 28, 2013. Accessed online at http://journalstar.com/news/local/govt-and-politics/pharmacies-unwilling-to-take-loss-on-insulin-for-medicare-patients/article_185a4e3a-4873-505a-a40d-245550b4c3b4.html.

¹⁶ OIG, *Implementing OIG Recommendation Could Have Reduced Payments for DME Infusion Drugs by Hundreds of Millions of Dollars*, OEI-12-15-00110, April 2015.

¹⁷ This calculation was based on payment levels and acquisition costs from the fourth quarter of 2015.

¹⁸ Calculated based on 2015 billing levels.

¹⁹ NHIC, Corp., *DME MAC Jurisdiction A Resource*, September 2015. Accessed online at https://med.noridianmedicare.com/documents/6547796/6558261/DME_MAC_A_Resource_37_September+2015.pdf/29d07a6c-e427-4989-8c56-3aff1d0ed1dc.

²⁰ NHIC, Corp., *DME MAC Jurisdiction A Resource*, December 2015. Accessed online at https://med.noridianmedicare.com/documents/6547796/6558261/DME_MAC_A_Resource_38_December+2015.pdf/2d32c476-05a7-4a61-a337-bfab84826c31.

²¹ CMS's payment limit file did not include milrinone lactate in the fourth quarter of 2015. Therefore, we obtained the payment amount from CMS's non-published ASP background file.

²² There is a two-quarter lag between the time when ASP sales occur and when Medicare payment amounts reflect those sales. As a result, ASPs in a given quarter were calculated using ASP-based payment amounts from two quarters later.

²³ Part B claims dated on or after April 1, 2013 incur a 2 percent reduction in payment in accordance with the Budget Control Act of 2011 and the American Taxpayer Relief Act of 2012 (i.e., sequestration). For further explanation, see <http://www.cms.gov/outreach-and-education/outreach/ffsprovpartprog/downloads/2013-03-08-standalone.pdf>. Because this mandatory payment reduction is applied after the beneficiary's coinsurance has been determined, the resulting reduction in the effective payment rate is between 1 and 2 percent.