

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE PAYMENTS FOR
VACUUM ERECTION SYSTEMS ARE
MORE THAN TWICE AS MUCH AS THE
AMOUNTS PAID FOR THE SAME OR
SIMILAR DEVICES BY
NON-MEDICARE PAYERS**

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Office of Inspector General

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EXECUTIVE SUMMARY

Medicare currently pays more than twice as much for vacuum erection systems as non-Medicare payers pay for these types of devices. If Medicare reduced payment to the level of non-Medicare payers, the Federal Government could save about \$18 million and Medicare beneficiaries could save about \$4.5 million each year.

WHY WE DID THIS REVIEW

During a previous Office of Inspector General review of one of the Nation's major suppliers of male vacuum erection systems (VES), we noted that Medicare payments for VES were significantly greater than the prices available to non-Medicare payers. Additionally, an August 1999 edition of the Federal Register included a notice that proposed, for six categories of durable medical equipment (DME), prosthetics, orthotics, and supplies (DMEPOS), special payment limits to replace the current fee schedule amounts for these items. VES were included as one of the six categories. The notice stated that the Medicare fee schedule amounts in effect at the time for VES were—in terms used in relevant Federal regulations—grossly excessive and, therefore, not inherently reasonable. The Centers for Medicare & Medicaid Services (CMS) did not finalize the proposed notice, and as a result, the fee schedule amounts for VES were not replaced by the special payment limit.

The objective of this review was to determine whether the Medicare payment amounts for VES remained grossly excessive compared with the amounts paid by non-Medicare payers.

BACKGROUND

Under the provisions of the Social Security Act (the Act), Medicare Part B provides supplementary medical insurance for medical and other health services, including coverage of DMEPOS. VES are a type of DMEPOS that is eligible for Part B coverage.

Generally, Federal statute requires CMS to use a fee schedule payment methodology to pay DMEPOS suppliers. Medicare Part B has different payment methodologies for different categories of medical equipment and supplies. For example, the Medicare fee schedule payment amounts for orthotic and prosthetic devices are based on historical supplier charges, which may become inconsistent with market prices over time.

Generally, to determine the Medicare payment for DMEPOS, the DME Medicare administrative contractors must first determine the allowable amount, which is the lower of the actual charge for the item or the fee schedule amount. Then, the beneficiary's unmet deductible is subtracted from the allowable amount. Medicare pays 80 percent and the beneficiary pays 20 percent of any remaining allowable amount.

Federal statutes and regulations give CMS the authority to determine whether the standard methods of determining the fee schedule amounts have resulted in unreasonably high or low payment amounts for particular items or services. In such cases, CMS also has the authority to use different pricing methods to align payment amounts with the current market prices for the

same or similar items or services. Currently, CMS has the authority to adjust payment amounts using the inherent reasonableness process and to hold competitions in the DMEPOS Competitive Bidding Program. Both methods are applicable to DMEPOS; this review focused on the cost savings that could be realized through the application of either method to VES.

The inherent reasonableness process is promulgated by language in the Act and Federal regulations, which provides that if CMS determines that the standard methods of determining fee schedule amounts have resulted or will result in “grossly deficient or excessive amounts” (42 CFR § 405.502(g)(1)(ii) – (iii)), CMS may establish special payment limits that are realistic and equitable for a category of items or services to replace the current fee schedule amounts. These regulations also specify the process through which CMS must announce and implement new payment rates.

Federal legislation in 2003 mandated that CMS establish a Competitive Bidding Program for certain DMEPOS items and services. Under this program, CMS awards contracts to enough suppliers to meet beneficiary demand for the items that it has designated for competitive bidding (bid items). The new, lower payment amounts resulting from the competition replace the Medicare DMEPOS fee schedule amounts for the bid items in competitive bidding areas.

Subsequent legislation in 2008 included mail-order items in the Competitive Bidding Program. Implementation of this program in the context of DMEPOS is relatively recent, and at present is limited to certain items and services. During our review of one of the Nation’s major suppliers of VES, we noted that the majority of these devices are ordered by phone, email, Internet, or mail and shipped or delivered to the beneficiary’s residence, thus meeting the definition of a mail-order item. However, prosthetic devices such as VES are currently not included in the Competitive Bidding Program.

For calendar years (CYs) 2006 to 2011, Medicare paid 473,620 VES claims totaling approximately \$172.4 million. Over the same 6-year period, the yearly claimed amount for VES nearly doubled, from \$20.6 million in CY 2006 to \$38.6 million in CY 2011.

WHAT WE FOUND

Medicare payment amounts for VES remain grossly excessive compared with the amounts that non-Medicare payers pay. Medicare currently pays suppliers more than twice as much for VES as the Department of Veterans Affairs and consumers over the Internet pay for these types of devices.

Processes exist to remedy this imbalance by adjusting Medicare payment rates for VES. Use of the inherent reasonableness process would achieve cost savings. If the Medicare fee schedule amount for VES had been adjusted to approximate the amount paid for the same or similar devices by non-Medicare payers, the Federal Government would have saved an average of approximately \$14.4 million for each of the 6 years reviewed, and Medicare beneficiaries would have saved approximately \$3.6 million annually. We are unable to calculate precise cost savings that would be achieved through application of the Competitive Bidding Program to VES. However, CMS recently announced that the latest round of competitive bidding will reduce

prices by 45 percent for certain types of DMEPOS and by 72 percent for mail-order diabetic testing supplies nationwide.

Further, we estimate that if claim levels remain the same in future years as they were on average for CYs 2009 through 2011, the potential annual savings to the Federal Government and Medicare beneficiaries through adjusted VES payment rates would be approximately \$18 million and \$4.5 million, respectively.

WHAT WE RECOMMEND

We recommend that CMS:

- use its authority under the inherent reasonableness regulations to determine whether the payments for VES are grossly excessive and, if so, establish a special payment limit or
- seek legislative authority to include VES in the Competitive Bidding Program and then implement a National Mail-Order Competitive Bidding Program for VES.

CMS COMMENTS

In written comments to our draft report, CMS concurred with both of our recommendations. CMS stated that it would consider whether valid and reliable data required by the inherent reasonableness regulations are available for use in determining whether the Medicare-allowed payment amounts are grossly excessive. CMS also said that it would consider the inclusion of VES in the Competitive Bidding Program when it develops the next President's budget proposal.

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INTRODUCTION

WHY WE DID THIS REVIEW

During a previous Office of Inspector General review¹ of one of the Nation's major suppliers of male vacuum erection systems (VES), we noted that Medicare payments for VES were significantly greater than the prices available to non-Medicare payers. Additionally, an August 1999 edition of the Federal Register² included a notice that proposed, for six categories of durable medical equipment (DME), prosthetics, orthotics, and supplies (DMEPOS), special payment limits to replace the current fee schedule amounts for these items. VES were included as one of the six categories. The notice stated that the Medicare fee schedule amounts in effect at the time for VES were—in terms used in relevant Federal regulations—grossly excessive and, therefore, not inherently reasonable. The Centers for Medicare & Medicaid Services (CMS) did not finalize the proposed notice, and as a result, the fee schedule amounts for VES were not replaced by the special payment limit.

OBJECTIVE

Our objective was to determine whether the Medicare payment amounts for VES remained grossly excessive compared with the amounts paid by non-Medicare payers.

BACKGROUND

Medicare Coverage of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies

Under the provisions of Title XVIII of the Social Security Act (the Act), the Medicare program provides health insurance for people aged 65 and over, people with disabilities, and people with permanent kidney disease. CMS administers the Medicare program.

Under the provisions of sections 1832(a)(1), 1861(s)(6), (s)(8), and (s)(9), and 1861(n) of the Act, Medicare Part B provides supplementary medical insurance for medical and other health services, including coverage of DMEPOS. Section 1862(a)(1)(A) of the Act requires that, to be paid by Medicare, a service or an item be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

As a result of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA),³ CMS contracted with four DME Medicare administrative contractors (DME MACs) to process and pay suppliers' Medicare Part B claims for DMEPOS.

¹ *Pos-T-Vac Medical Did Not Meet Medicare Documentation Requirements for Over Half of Sampled Claims for Male Vacuum Erection Systems* (A-07-11-05016), issued June 14, 2012.

² 64 Fed. Reg. 44227 (Aug. 13, 1999).

³ P.L. No. 108-173 § 911(a) (adding Social Security Act, § 1874A, 42 U.S.C. § 1395kk-1).

Fee Schedule Payment Methodology

Generally, Federal statute⁴ requires CMS to use a fee schedule payment methodology to pay DMEPOS suppliers. The methodology depends on the category of DMEPOS. For example, the Medicare fee schedule payment amounts for orthotic and prosthetic devices are based on historical supplier charges. Because Medicare's payments are based on historical data, they may become inconsistent with market prices over time.

Generally, to determine the Medicare payment for DMEPOS the DME MAC must first determine the allowable amount, which is the lower of the actual charge for the item or the fee schedule amount. Then, the beneficiary's unmet deductible is subtracted from the allowable amount. Medicare pays 80 percent and the beneficiary pays 20 percent of any remaining allowable amount.

Methods With Which CMS May Adjust Payment Amounts

Federal statutes and regulations give CMS the authority to determine whether the standard methods of determining the fee schedule amounts have resulted in unreasonably high or low payment amounts for particular items or services. In such cases, CMS also has the authority to use different pricing methods to align payment amounts with the current market prices for the same or similar items or services. Currently, CMS has the authority to adjust payment amounts using the inherent reasonableness process and to hold competitions in the DMEPOS Competitive Bidding Program.

Inherent Reasonableness Process

Federal regulations provide that if CMS determines that the standard methods of determining fee schedule amounts for certain categories of items or services (identified in section 1861(s) of the Act) will result in "grossly deficient or excessive amounts" (42 CFR § 405.502(g)(1)(ii) – (iii)), CMS may replace the current fee schedule amounts with special payment limits that are realistic and equitable. CMS defines a payment amount to be grossly excessive or deficient if an overall payment adjustment of 15 percent or more is necessary to produce a realistic and equitable payment amount.

Federal regulations provide examples of factors or considerations that may result in grossly deficient or excess payment amounts (42 CFR § 405.502(g)(1)(vii)). CMS uses these factors to determine whether fee schedule amounts for a category of items or services are inherently unreasonable and should be adjusted upward or downward. These factors include, but are not limited to, the following:

⁴ Specifically, see section 4062(b) of the Omnibus Budget Reconciliation Act (OBRA) of 1987 (P.L. No. 100-203), which added section 1834(a) to the Social Security Act. OBRA of 1990 (P.L. No. 101-508) added a separate subsection, 1834(h), specifically for prosthetics and orthotics.

- Payment amounts are grossly higher or lower than acquisition or production costs for the category of items or services.
- Payment amounts are grossly higher or lower than the payments made for the same category of items or services by other purchasers in the same locality.

Any changes that CMS makes to the payment amounts through the inherent reasonableness process apply nationally (42 CFR § 405.502(g)(1)(iii)). Before adopting new payment amounts for a category of items or services, CMS must publish proposed and final notices in the Federal Register (42 CFR § 405.502(g)(3)(i)). These notices provide the criteria and circumstances, if any, under which a DME MAC may grant an exception to the payment amount.

Competitive Bidding Program

The MMA mandates the establishment of the DMEPOS Competitive Bidding Program, which requires that CMS replace the current fee schedule payment methodology for selected DMEPOS items with a competitive bid process in competitive bidding areas. Under this program, CMS awards contracts to enough suppliers to meet beneficiary demand for items that it has designated for competitive bidding (bid items); not all items are subject to competitive bidding. The new, lower payment amounts resulting from the competition replace the Medicare DMEPOS fee schedule amounts. Generally, Federal law limits the Competitive Bidding Program to DME and medical supplies, enteral nutrition, and off-the-shelf orthotics.⁵ Accordingly, prosthetic devices are currently not included in the Competitive Bidding Program.

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA)⁶ temporarily delayed the Competitive Bidding Program. As a result, the first round of the Competitive Bidding Program, referred to as the Round 1 Rebid, became effective on January 1, 2011. In addition, the MIPPA authorized national mail-order competitions after 2010 and set forth special rules that apply to competitions for diabetic test supplies, including national mail-order competitions. The first national mail-order competitive bidding program became effective in July 2013, but it was limited to diabetic test supplies. Other types of DMEPOS were not included.

The term “mail-order item” means “any item (for example, diabetic testing supplies) shipped or delivered to the beneficiary’s home, regardless of the method of delivery.”⁷ Accordingly, the definition of mail-order item includes items delivered by company-owned or personal vehicles. For example, a beneficiary or caregiver may go to a retail store to pick up diabetic supplies or have them shipped or delivered to the home. Under the National Mail-Order Program, if beneficiaries choose to have their DMEPOS items delivered to their homes by any method, the items must be ordered from national mail order contract suppliers.

⁵ The Act, § 1847(a)(2), 42 U.S.C. § 1395w-3(a)(2).

⁶ P.L. No. 110-275 § 154.

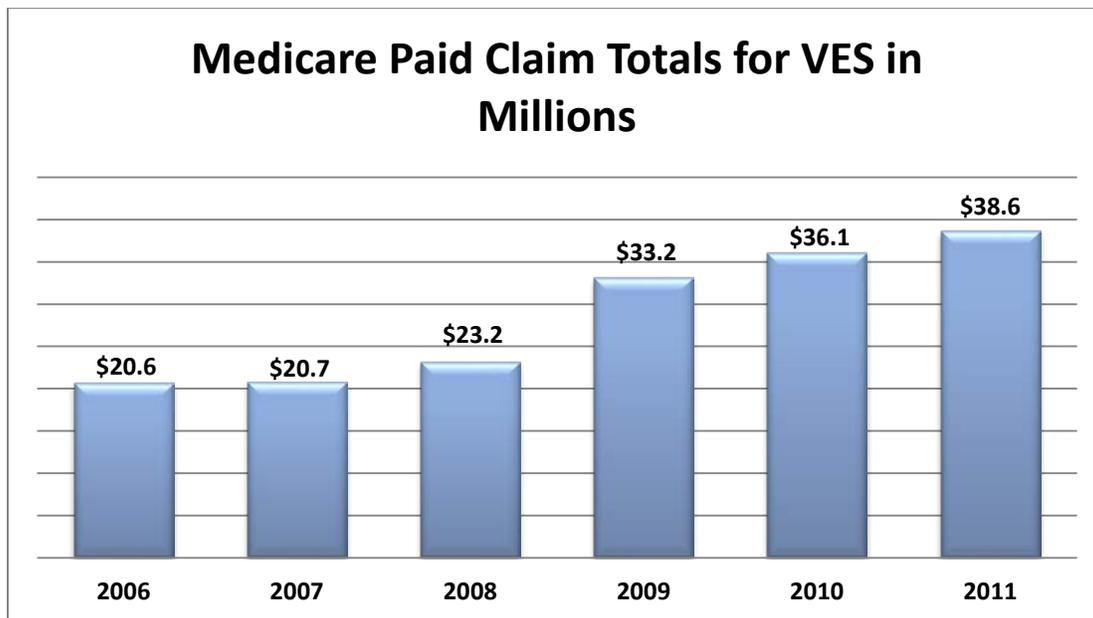
⁷ 42 CFR § 414.402 (as added by 75 Fed. Reg. 73170 (Nov. 29, 2010)). This definition of “mail-order item” did not apply to the Round 1 Rebid competition. 75 Fed. Reg. at 73570.

Vacuum Erection Systems

Because VES are used to treat impotence, and because impotence is a failure of the body part for which the diagnosis, and frequently the treatment, requires medical expertise,⁸ VES constitute a type of DMEPOS eligible for coverage under Part B. Coverage for VES is provided under the prosthetic benefit, which stipulates that the device must be used to replace all or part of an internal body organ. During our review of one of the Nation's major suppliers of VES,⁹ we noted that the majority of these devices are ordered by phone, email, Internet, or mail and shipped or delivered to the beneficiary's residence, thus meeting the definition of a mail-order item.

When submitting claims to DME MACs, suppliers use Healthcare Common Procedure Coding System (HCPCS) codes.¹⁰ Prosthetic suppliers submit claims for VES using HCPCS code L7900.

From calendar years (CYs) 2006 to 2011, Medicare paid 473,620 VES claims totaling approximately \$172.4 million. Over the same 6-year period, the yearly claimed amount for VES nearly doubled from \$20.6 million in CY 2006 to \$38.6 million in CY 2011 (see the figure below).



⁸ This classification appears in national coverage determination for diagnosis and treatment of impotence (230.4).

⁹ See footnote 1.

¹⁰ HCPCS codes are used throughout the health care industry to standardize coding for medical procedures, services, products, and supplies.

Over the same period, the number of Medicare paid claims for VES also nearly doubled, from 61,589 in CY 2006 to 103,448 in CY 2011. The average Medicare payment for VES over this period was \$360.93. The average beneficiary copay amount was \$90.23.

Proposed Special Payment Limits

In August 1999, CMS issued a proposed notice in the Federal Register¹¹ that proposed, for VES and five other DMEPOS devices, special payment limits to replace the current fee schedule amounts. The proposed notice stated that CMS had determined that the Medicare fee schedule amounts for VES were “grossly excessive” and therefore not inherently reasonable. The purpose of the special payment limits was to prevent continuation of excessive payments for the VES. The special payment limits in the proposed notice were based on the median wholesale prices paid by the Department of Veterans Affairs (VA) for these items plus an appropriate markup.

In the proposed notice, CMS stated that the median wholesale payment amount paid by VA for the VES was \$131.65. Then, using a markup of 67 percent, CMS calculated an estimated retail payment amount of \$219.86. Accordingly, CMS proposed that the special payment limit for purchase of the VES would be \$219.86 and that Medicare payment for VES would be equal to 80 percent of the lesser of the actual charge or the special payment limit.

In response to the proposed change, the medical equipment industry expressed concerns about the payment limits. Consequently, Congress included a provision in the Balanced Budget Refinement Act of 1999 that instructed the Government Accountability Office (GAO) to examine the proposed regulation and the use of the inherent reasonableness authority.¹² GAO’s report, issued in July 2000, was generally supportive of CMS’s previous implementation of the inherent reasonableness authority.¹³ CMS issued a final notice in December 2002 that implemented a process for using its inherent reasonableness authority to eliminate excessive payments by reducing reimbursements for Medicare Part B services and equipment when payments are grossly excessive.¹⁴ However, CMS has not used that authority to adjust pricing for VES.

HOW WE CONDUCTED THIS REVIEW

From CMS’s National Claims History file, we extracted Medicare claims for VES that used HCPCS code L7900 for CYs 2006 through 2011. For this period, Medicare paid 473,620 VES claims totaling approximately \$172.4 million. We used this data to determine the total payments for VES by both Medicare and its beneficiaries.

¹¹ See footnote 2.

¹² P.L. No. 106-113 § 223.

¹³ Use of Revised “Inherent Reasonableness” Process Generally Appropriate. GAO/HEHS-00-79, July 5, 2000.

¹⁴ 70 Fed. Reg. 73623 (Dec. 13, 2005).

We compared VA's contracted prices and online prices with the Medicare payment amounts for VES. To determine the current amount that VA paid for VES, we obtained from VA, National Acquisition Center's Socioeconomic Contract Repository, MedSurg Catalog, a listing of contracted prices for VES. To determine the prices at which VES were available to consumers over the Internet, we identified prices using two widely used search engines (Google and Yahoo).

Appendix A contains details of our audit scope and methodology.

We did not perform a detailed review of CMS's internal controls or its process for determining Medicare DMEPOS fee schedule amounts because our objective did not require us to do so. We limited our review to the comparison of prices for VES.

We conducted this performance audit 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.

FINDINGS

Medicare payment amounts for VES remain grossly excessive compared with the amounts that non-Medicare payers pay. Medicare currently pays suppliers more than twice as much for VES as VA and consumers over the Internet pay for these types of devices.

Processes exist to remedy this imbalance by adjusting Medicare payment rates for VES. Use of the inherent reasonableness process would achieve cost savings. If the Medicare fee schedule amount for VES had been adjusted to approximate the amount paid for the same or similar devices by non-Medicare payers, the Federal Government would have saved an average of approximately \$14.4 million for each of the 6 years reviewed, and Medicare beneficiaries would have saved approximately \$3.6 million annually. We are unable to calculate precise cost savings that would be achieved through application of the Competitive Bidding Program to VES. However, CMS recently announced that the latest round of competitive bidding will reduce prices by 45 percent for certain types of DMEPOS and by 72 percent for mail-order diabetic testing supplies nationwide.

Further, we estimate that if claim levels remain the same in future years as they were on average for CYs 2009 through 2011, the potential annual savings to the Federal Government and Medicare beneficiaries through adjusted VES payment rates would be approximately \$18 million and \$4.5 million, respectively.

MEDICARE PAYMENT AMOUNTS FOR VACUUM ERECTION SYSTEMS REMAIN GROSSLY EXCESSIVE COMPARED WITH AMOUNTS PAID BY NON-MEDICARE PAYERS

CMS Criteria for the Establishment of Special Payment Limits

Federal regulations provide that if CMS determines that the standard methods of determining fee schedule amounts for certain categories of items or services (identified in section 1861(s) of the Act) will result in “grossly deficient or excessive amounts” (42 CFR § 405.502(g)(1)(ii) – (iii)), CMS may establish special payment limits that are realistic and equitable for a category of items or services.

In the December 13, 2002, interim final rule (67 Fed. Reg. 76684 (Dec. 13, 2002)), CMS clarified when a payment amount is considered grossly excessive or deficient. As specified in 45 CFR § 405.502(g)(1)(ii), a payment amount will not be considered grossly excessive or grossly deficient if the overall payment adjustment is less than 15 percent. The Act provides two different processes once a determination is made that a payment amount is grossly excessive or deficient: a process for adjustments of 15 percent or more in a given year and a simplified process for adjustments of less than 15 percent in a given year (sections 1842(b)(8) and (b)(9) of the Act).

Medicare Payment Amount

On the basis of our review of Medicare VES claims for CYs 2006 through 2011, we determined that the average price paid was \$451.16. Of that amount, Medicare paid an average of \$360.93. Because the beneficiary was responsible for 20 percent of the price paid, plus any unmet deductible, we determined that the beneficiary paid an average of \$90.23.

Non-Medicare Payment Amounts

On the basis of our review of VA’s contracted rates and of Internet prices available to consumers, we determined that the average amount paid by non-Medicare payers was \$175.35.

VA’s MedSurg Catalog’s listings specified 10 VES from 7 different suppliers. The contracted rates for these devices ranged from \$78.19 to \$300.87. The average price for a VES that VA paid was \$185.96.

We identified Internet prices available to consumers using two widely used search engines (Google and Yahoo). Research on 22 different Web sites yielded pricing information for 105 VES from 10 different manufacturers or suppliers. The average Internet price for each of the 105 VES was \$164.74.

Medicare Payment Rate Is More Than Twice the Average Payment Rate for Non-Medicare Payers

On the basis of our review, Medicare payment amounts for VES remain grossly excessive compared with the amounts that non-Medicare payers pay. Specifically, the Medicare fee schedule payment rate is more than twice the average payment rate for the non-Medicare payers. Consequently, the Medicare program and Medicare beneficiaries lose potential cost savings. By adjusting the Medicare fee schedule rate to reflect the average VA payment rate and prices available over the Internet, the potential annual saving to the Federal Government is approximately \$18 million, and the potential cost saving to Medicare beneficiaries is approximately \$4.5 million.¹⁵

CONCLUSION

We encourage CMS to study these audit results and consider the impact of adjusting the fee schedule amount for VES. Because of the method by which VES are frequently ordered and delivered, it is cost-beneficial to add VES to the National Mail-Order Program within the Competitive Bidding Program.

RECOMMENDATIONS

We recommend that CMS:

- use its authority under the inherent reasonableness regulations to determine whether the payments for VES are grossly excessive and, if so, establish a special payment limit or
- seek legislative authority to include VES in the Competitive Bidding Program and then implement a National Mail-Order Competitive Bidding Program for VES.

CMS COMMENTS

In written comments to our draft report, CMS concurred with both of our recommendations. CMS stated that it would consider whether valid and reliable data required by the inherent reasonableness regulations are available for use in determining whether the Medicare-allowed payment amounts are grossly excessive. CMS also said that it would consider the inclusion of VES in the Competitive Bidding Program when it develops the next President's budget proposal.

CMS's comments are included in their entirety as Appendix B.

¹⁵ We calculated these potential cost savings by taking the average annual Medicare payment totals for VES from CYs 2009 through 2011 and dividing them in half on the basis of our conclusion that Medicare payment amounts are twice the amount of non-Medicare payment amounts.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

From CMS's National Claims History file, we extracted Medicare claims for VES that used HCPCS code L7900 for CYs 2006 through 2011. For this period, Medicare paid 473,620 VES claims totaling approximately \$172.4 million.

We did not perform a detailed review of CMS's internal controls or its process for determining Medicare DMEPOS fee schedule amounts because our objective did not require us to do so. We limited our review to the comparison of varying prices for VES.

We conducted our audit work between June 2012 and February 2013.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and program guidance relating to VES;
- interviewed CMS officials about the use of the inherent reasonableness process, the Inherent Reasonableness Authority, and the Competitive Bidding Program, including the National Mail-Order Program;
- obtained the VES claims data for CYs 2006 through 2011 from CMS's National Claims History database;
- obtained from VA National Acquisition Center's Socioeconomic Contract Repository, MedSurg Catalog, a listing of contracted prices for VES;
- obtained prices for 105 VES from 22 different Internet sites containing prices from 10 different manufacturers or suppliers of VES;
- compared the average VES amount from the Medicare claims with the average VES amounts for both VA and prices available over the Internet to demonstrate the difference in what Medicare pays compared with non-Medicare payers;
- calculated potential cost savings to the Medicare program and Medicare beneficiaries based on (1) our conclusion that the total Medicare payment rate is more than twice the non-Medicare payment rates and (2) our assumption that Medicare pays 80 percent of the total payment and the beneficiary is responsible for the remaining 20 percent of the total payment; and
- discussed the results of our review with CMS officials on February 12, 2013.

We conducted this performance audit 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.

APPENDIX B: CMS COMMENTS



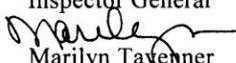
DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

DATE: NOV 27 2013

Administrator
Washington, DC 20201

TO: Daniel R. Levinson
Inspector General

FROM: 
Marilyn Tavenner
Administrator

SUBJECT: Office of Inspector General Draft Report (OIG): "The Medicare Fee Schedule Amounts for Vacuum Erection Systems Are Approximately Twice as Much as the Amounts Paid for the Same or Similar Devices by Non-Medicare Payers" (A-07-12-05024)

Thank you for the opportunity to review and comment on the above subject OIG Draft Report. Section 1842 (b)(8) of the Social Security Act requires that the Secretary promulgate rules describing the factors to be used in determining the cases when Medicare Part B payment results in an amount that, because of its being grossly excessive or grossly deficient, is not inherently reasonable and, in those cases, describing the factors to be considered in determining an amount that is realistic and equitable. A Federal Register notice in August 1999 stated that Medicare fee schedule amounts for Vacuum Erection Systems (VES) were grossly excessive relative to the amount paid for by the Department of Veterans Affairs and therefore not inherently reasonable. The objective of this OIG review was to determine whether the Medicare payment amounts for VES remain grossly excessive compared with the amounts paid by non-Medicare payers. The OIG found that Medicare payment amounts for VES remain grossly excessive compared with the amounts paid by non-Medicare payers. The Medicare payment rate is more than twice the average payment rate for non-Medicare payers.

The OIG recommendations and CMS responses to those recommendations are discussed below.

OIG Recommendation

The OIG recommends that CMS use inherent reasonableness regulation to determine whether the payments for VES are grossly excessive and, if so, establish a special payment limit.

CMS Response

The CMS concurs with this recommendation. CMS will consider whether valid and reliable data required by the inherent reasonableness regulations is available for use in determining whether the Medicare allowed payment amounts are grossly excessive.

OIG Recommendation

The OIG recommends that CMS seek legislative authority to include vacuum erection systems in the Competitive Bidding Program and then implement a National Mail-Order Competitive Bidding Program for VES.

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CMS Response

The CMS concurs with the analysis on this issue. We will consider OIG's recommendation when we develop the next President's budget proposal.

The CMS thanks OIG for their efforts on this issue and looks forward to working with OIG on this and other issues in the future.