

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**COMPARISON OF PRICES FOR
NEGATIVE PRESSURE WOUND
THERAPY PUMPS**



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OBJECTIVES

- (1) To compare the prices that suppliers paid for new negative pressure wound therapy pump models to Medicare's purchase price for the pumps.
- (2) To describe how suppliers acquired these new pumps.
- (3) To describe the extent to which suppliers reported providing required services to Medicare beneficiaries who rented these pumps.

BACKGROUND

Negative pressure wound therapy pumps (the pumps) are portable or stationary devices used for the treatment of ulcers or wounds that have not responded to traditional wound treatment methods. Medicare pays for the pumps under Part B coverage of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) as a capped rental item. Between 2001 and 2007, Medicare payments for these pumps increased 583 percent, from \$24 million to \$164 million.

When Medicare first started covering pumps in 2001, it covered only one model, which was both manufactured and supplied by Kinetic Concepts, Inc. (KCI). Medicare reimbursed KCI for this pump based on the purchase price as identified by KCI. Beginning in 2005, Medicare expanded its coverage to include several new pump models that are manufactured by other companies. Medicare reimburses suppliers for these new pumps based on the purchase price of the KCI pump.

This study compares the prices that suppliers paid for new pump models to Medicare's purchase price. Although the new pump models currently account for a small percentage of the pump market, their market share may grow rapidly if there is a large difference between the amount that suppliers pay for these pumps and the amount that they are reimbursed by Medicare. Wide profit margins may also make pumps vulnerable to fraud, waste, and abuse.

FINDINGS

Suppliers paid an average of \$3,604 for the new pump models, compared to Medicare’s purchase price of \$17,165. Suppliers purchased 171 of the 223 new pump models that were provided to beneficiaries in the first half of 2007. Suppliers paid an average of \$3,604 for these pumps. Medicare reimbursed suppliers for these pumps based on a purchase price of \$17,165, which is more than four times the average price paid by suppliers. On a monthly basis, Medicare reimbursed suppliers \$1,716 for these pumps for the first 3 months. At this rate, suppliers recouped the average cost of a new pump model in about 2 months. Further, beneficiaries’ coinsurance payments for pumps cover a substantial portion of the average cost of a new pump model. After just 4 months of rental, a beneficiary’s coinsurance of \$1,286 covers over one-third (36 percent) of the average cost of a new pump model.

Suppliers acquired one-quarter of the new pump models by leasing, renting, or exchanging them. Suppliers acquired nearly one-quarter (52 of 223) of the new pump models provided to beneficiaries in the first half of 2007 through methods other than purchasing them. They acquired these pumps through lease-to-own agreements, daily rentals, hourly rentals, or exchanges of old pumps for new ones.

Suppliers reported not always communicating with beneficiaries’ clinicians, as required; however, they appeared to meet other standards. Suppliers are required to communicate with the beneficiary’s treating clinician to assess wound healing progress and to determine whether the beneficiary continues to qualify for Medicare coverage of the pump. In addition, suppliers must meet certain standards that include providing delivery and instruction on equipment usage (either from the supplier or another qualified party), maintaining and repairing the equipment as needed, and responding to beneficiaries’ questions and complaints about the equipment. Suppliers reported not having contact with clinicians for almost one-quarter of the beneficiaries. Suppliers reported delivering the pumps and educating almost all of the beneficiaries, as well as providing maintenance and repairs when needed.

RECOMMENDATIONS

Based on the findings in this report, we recommend that CMS:

Reduce Medicare’s reimbursement amount for pumps. CMS should consider two methods to reduce its reimbursement amount for pumps. CMS should:

- **Use its inherent reasonableness authority to reduce the reimbursement amount for pumps.** CMS should consider using its inherent reasonableness authority to reduce the amount that it reimburses suppliers for pumps.
- **Include pumps in the second round of the the Competitive Bidding Acquisition Program.** CMS should include pumps in the second round of the Competitive Bidding Acquisition Program. This could better align Medicare’s reimbursement amount for pumps with the amount that suppliers pay for the new pump models.

In addition, CMS should:

Monitor the growth of the new pump market. CMS should continue to monitor the growth of the new pump market by tracking trends in market share among different suppliers.

Educate suppliers of new pump models on the importance of communication with beneficiaries’ treating clinicians. CMS should educate suppliers of new pump models that the continued need for a pump can be determined only through clinician input and that it is inappropriate for suppliers to submit claims for continued pump use without this input.

Follow up on the pump claims that may be inappropriate. CMS should follow up on the claims in which suppliers: (1) reported having no contact with the beneficiaries’ treating clinicians, (2) could not be located, or (3) did not submit any documentation. To help CMS address this recommendation, we will forward information about these claims in a separate memorandum.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with four of our recommendations and will consider the remaining recommendation. It noted that it has worked on a number of regulatory and administrative initiatives related to the prescription,

E X E C U T I V E S U M M A R Y

coding, and coverage of pumps in response to the significant growth in expenditures for these items.

In response to our recommendations, CMS concurred that it has the authority to adjust payment rates using Medicare's inherent reasonableness authority. It stated that it will consider whether it would be able to gather valid and reliable data, as the statute requires, to make a determination that the payment amount for pumps is grossly deficient or excessive and to establish, if needed, a new amount that is realistic and equitable. CMS also stated that it will consider including pumps when designing the second round of the Competitive Bidding Acquisition Program. Further, CMS stated that it will monitor and track trends in utilization of pumps and track the market share among different pump suppliers. CMS also concurred with our recommendation to educate pump suppliers on the importance of communication with beneficiaries' treating clinicians. Lastly, CMS concurred with our recommendation to follow up on pump claims that may be inappropriate and stated that it is working with its contractors to strengthen its oversight in this area.

We support CMS's efforts to address these issues and encourage it to continue to make progress in these areas.

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OBJECTIVES

- (1) To compare the prices that suppliers paid for new negative pressure wound therapy pump models to Medicare's purchase price for pumps.
- (2) To describe how suppliers acquired these new pumps.
- (3) To describe the extent to which suppliers reported providing required services to Medicare beneficiaries who rented these pumps.

BACKGROUND

Negative pressure wound therapy pumps (the pumps) are portable or stationary devices used for the treatment of ulcers or wounds that have not responded to traditional wound treatment methods. Medicare pays for pumps under Part B coverage of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) as a capped rental item.¹ Between 2001 and 2007, Medicare payments for these pumps increased 583 percent, from \$24 million to \$164 million.

When Medicare first started covering pumps in 2001, it covered only one model, which was both manufactured and supplied by Kinetic Concepts, Inc. (KCI). Medicare reimbursed KCI for this pump based on the purchase price as identified by KCI. Beginning in 2005, Medicare expanded its coverage to include several new pump models that are manufactured by other companies.² Medicare reimburses suppliers for these new pumps based on the purchase price of the KCI pump.

There are indications that Medicare's purchase price for pumps may be high compared to what suppliers pay for the new pump models. In fact, an executive from one of the manufacturers that produces new pump models publicly stated that Medicare's current reimbursement is too high for this type of equipment.³ This manufacturer further noted that

¹ 42 CFR § 414.210(b)(2); 42 CFR § 414.229.

² We refer to all non-KCI pump models as the new pump models to distinguish them from the KCI pumps.

³ Market Wire, "Bluesky Medical Requests a Decrease in the Reimbursement for Negative Pressure Wound Therapy Market," June 2002. Available online at http://www.findarticles.com/p/articles/mi_pwwi/is_200206/ai_mark09043751. Accessed on May 4, 2007.

it could provide its pumps for a significantly lower reimbursement amount.⁴

In addition, although the new pump models currently account for a small percentage of the pump market, their market share may grow rapidly if there is a large difference between the amount that suppliers pay for these pumps and the amount that they are reimbursed by Medicare.⁵ Wide profit margins may also make pumps vulnerable to fraud, waste, and abuse.

Negative Pressure Wound Therapy Pumps

A pump is a wound therapy option for individuals with specific types of wounds and ulcers. The devices apply controlled negative or subatmospheric pressure to the affected site and assist in removing fluid, increasing blood flow to the site, and stimulating the growth of granulation tissue.⁶ The Food and Drug Administration (FDA), under its 510(k) approval process, considers pumps to be medical devices that are substantially equivalent to previously approved powered suction pumps.⁷

Presently, KCI is the principal manufacturer and supplier of pumps for Medicare beneficiaries. Unlike other companies, KCI manufactures its own pump and rents it directly to beneficiaries. In contrast, the new pump models are manufactured by a number of companies, including Smith & Nephew;⁸ Superior Healthcare Concepts, Inc.; Boehringer Wound Systems, LLC; Medela; Innovative Therapies, Inc.; and Prospera. These companies sell their pumps to suppliers, which then rent them to Medicare

⁴ Travis E. Poling, “KCI Hit by Stunning Court Loss,” San Antonio Express-News, August 4, 2006, at 01D.

⁵ The new pump models accounted for about 1 percent of the pump market in the first half of 2007.

⁶ Granulation tissue is a specialized tissue that is rich in tiny blood vessels and is created by the body as a response to injury.

⁷ Section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 360(k)) requires device manufacturers to notify FDA, at least 90 days in advance, of their intent to market a medical device. A device must be “substantially equivalent” to a device on the market prior to May 28, 1976 (a “predicate device”), in terms of design, material, chemical composition, energy source, manufacturing process, or intended use. Before marketing a device, each submitter must receive an order, in the form of a letter from FDA, that finds the device to be substantially equivalent and states that the device may be marketed in the United States. This order “clears” the device for commercial distribution. See 21 CFR § 878.4780 for product identification and classification information for the powered suction pump.

⁸ In May 2007, Smith & Nephew acquired Bluesky Medical Group, Inc.

beneficiaries. They use the same Healthcare Common Procedure Coding System (HCPCS) code as the KCI pump to bill Medicare for the new pump models.

Medicare Pricing for Pumps

Medicare covers pumps under a capped rental arrangement.⁹ Under this arrangement, Medicare pays suppliers a monthly fee schedule amount for each month that they rent the pumps to beneficiaries. Medicare uses the purchase price for the KCI pump to calculate the monthly fee schedule amounts. Similar to other capped rental items, for the first 3 months of rental, the monthly fee schedule amount equals 10 percent of the purchase price.¹⁰ For months 4 through 13, the monthly fee schedule amount equals 7.5 percent of the purchase price.¹¹ After the 13th continuous month of rental, the supplier must transfer title of the equipment to the beneficiary.¹²

The fee schedule amount for pumps is the same in all 50 States and the District of Columbia. In 2007, Medicare's purchase price for pumps was \$17,165. The monthly fee schedule amount was \$1,716 for the first 3 months and \$1,287 for months 4 through 13. Medicare reimburses suppliers 80 percent of the monthly fee schedule amount. Beneficiaries' coinsurance payments are typically 20 percent, which amounted to \$343 for the first 3 months and \$257 for months 4 through 13 in 2007.¹³

The Competitive Bidding Acquisition Program

As required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, CMS started to implement a competitive bidding acquisition program for certain DMEPOS in 2007.¹⁴ The goal of the program was to reduce beneficiary out-of-pocket costs and improve

⁹ 42 CFR § 414.229.

¹⁰ 42 U.S.C. § 1395m(a)(7)(A)(i); 42 CFR § 414.229(b)(2).

¹¹ *Ibid.*

¹² 42 U.S.C. § 1395m(a)(7)(A)(ii); 42 CFR § 414.229(f)(2).

¹³ 42 U.S.C. § 1395cc(a)(2)(A)(ii); 42 CFR § 489.30(b)(5).

¹⁴ Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. No. 108-173, § 302(b) (codified as amended at 42 U.S.C. §1395w-3).

the accuracy of Medicare payments.¹⁵ The pump was 1 of 10 DMEPOS in the program. The program included the 10 largest Metropolitan Statistical Areas (MSAs) in the first round and was expected to include 80 MSAs in the second round.¹⁶

In the spring of 2008, CMS announced the winning suppliers for the first round, known as contract suppliers, and the monthly fee schedule amounts based on the winning purchase prices. KCI did not participate in the first round; therefore, these amounts were based on bids from suppliers that provided the new pump models. All of the amounts were lower than Medicare's current reimbursement amount and averaged about \$1,446 per month.¹⁷ See Appendix A for a list of the monthly fee schedule amounts for the first round of competitive bidding.

In July 2008, Congress enacted the Medicare Improvements for Patients and Providers Act of 2008, which delayed the first round of the Competitive Bidding Acquisition Program until 2011. The law also excluded pumps from the first round of the program and, instead, required the Department of Health and Human Services to evaluate the HCPCS code for pumps to ensure accurate reporting and billing and to consider whether coding changes are needed.¹⁸ According to CMS staff, CMS plans to conduct this evaluation but, as of November 2008, has not initiated the study.

CMS Authority for Price Revisions

CMS or a Medicare carrier may establish limits on payment amounts in special circumstances through regulations that govern criteria for determining reasonable charges for Part B services.¹⁹ Specifically, CMS

¹⁵ CMS Medicare Fact Sheet, "Expansion of Competitive Bidding Program for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies," issued January 8, 2008. Available online at <http://www.cms.hhs.gov/apps/media/press/factsheet.asp?Counter=2812&intNumPerPage=10&checkDate>. Accessed on August 6, 2008.

¹⁶ MSAs are areas designated by the Office of Management and Budget that include major cities and the suburban areas surrounding them.

¹⁷ These amounts reflect the first 3 months of rental. From months 4 through 13, the fee schedule amounts are equivalent to 7.5 percent of the winning purchase prices.

¹⁸ Medicare Improvements for Patients and Providers Act of 2008, P.L. No. 110-275, § 154(c)(3) (to be codified at 42 U.S.C. § 1395m note).

¹⁹ 42 CFR § 405.502(g). Note that Medicare carriers are under contract with CMS to process Medicare Part B claims. There are four carriers, known as Durable Medical Equipment (DME) Medicare Administrative Contractors, that specifically process DME claims.

may use its inherent reasonableness authority to deviate from standard payment methodologies if the application of these methodologies results in a payment amount that is determined to be grossly excessive or deficient. In these cases, CMS or its carriers may establish special payment limits that are realistic and equitable.

Medicare DMEPOS Supplier Requirements

The Local Coverage Determination (LCD) for pumps specifies the clinical circumstances under which pumps are considered to be reasonable and necessary.²⁰ The LCD states that suppliers must communicate with the beneficiary's treating clinician to determine whether the beneficiary continues to qualify for Medicare coverage of the pump. The supplier may contact the clinician by verbal or written communication to ascertain that wound healing is occurring from month to month. Appendix B provides information regarding the relevant LCD requirement.

In addition, to obtain Medicare billing privileges, suppliers must meet certain quality standards. Among other things, suppliers are required to deliver the DMEPOS, provide instruction on equipment use (either through the supplier or another qualified party), maintain and repair the equipment as needed, and respond to questions and complaints about the equipment.²¹ Appendix C provides a list of the applicable supplier standards.

Related Work

In 2007, the Office of Inspector General (OIG) released a report that found that almost one-quarter of pump claims in 2004, which were all from KCI, did not meet Medicare coverage criteria, resulting in approximately \$21 million in improper payments.²² Specifically, 15 percent of all pump claims were insufficiently documented, another

²⁰ LCDs provide guidance to the public and the medical community within their jurisdictions. CMS requires that LCDs be the same for each jurisdiction to ensure uniformity for DMEPOS suppliers that operate nationally. The four LCDs are entitled "LCD for Negative Pressure Wound Therapy Pumps." The four relevant LCD policy numbers are L5008, L11489, L27025, and L11500. We used the version of the LCDs that was effective during our sample timeframe. Because all four LCDs are the same, we refer to them as "the LCD" for the purposes of this report.

²¹ 42 CFR § 424.57(c).

²² OIG, "Medicare Payments for Negative Pressure Wound Therapy Pumps in 2004," OEI-02-05-00370, June 2007.

6 percent were undocumented, and an additional 3 percent were not medically necessary. Virtually all pump claims met supplier documentation requirements. OIG recommended that CMS educate suppliers and wound care providers about the appropriate use of pumps. In response, the carriers issued an article reiterating the documentation requirements stated in the LCD.²³

METHODOLOGY

This study compares the prices that suppliers paid for the new pump models provided to beneficiaries in the first half of 2007 to Medicare's purchase price for the pumps. In addition, this study provides information about how suppliers acquired these new pumps and about the services that suppliers reported providing to Medicare beneficiaries who rented the pumps.

We based this study on two sources of data: (1) a review of suppliers' purchase invoices, contracts, and other financial documents for the new pump models provided to Medicare beneficiaries in the first half of 2007; and (2) a survey completed by suppliers about the services that they provided to the Medicare beneficiaries who rented these pumps.

Identification of Claims for New Pump Models

We used the 2007 National Claims History File to identify all of the paid claims for the new pump models that: (1) had a service date between January 1 and June 30, 2007; and (2) were received by September 30, 2007. We used the supplier contact information from the National Supplier Clearinghouse to identify the suppliers associated with these claims.

We identified a total of 327 paid claims for the new pump models in the first half of 2007, representing 38 suppliers and 237 beneficiaries. These claims represented all of the paid claims for the new pump models that were provided to beneficiaries in the first half of 2007. Of the 38 suppliers associated with these claims, 34 responded to the

²³ The carriers issued the article entitled "Negative Pressure Wound Therapy LCD Documentation" nationally under four different article numbers: A47170, A45699, A45750, and A45722.

request for documentation.²⁴ We received documentation for a total of 304 of the 327 claims, for a response rate of 93 percent.

Review of Supplier Documentation

We requested from the suppliers the purchase invoice related to the pump associated with each claim. Because the same pump could be associated with multiple claims and because multiple beneficiaries could be associated with the same pump, we compared the serial and model numbers of the pumps listed on the invoices to identify the unique pumps that were provided to beneficiaries in the first half of 2007. In total, we identified 240 unique pumps from the 304 claims that we reviewed. We received usable documentation for 223 of the 240 identified pumps. These pumps included four different models: Medela Vario, Bluesky Versatile 1, Bluesky V1STA Versatile 1, and Boehringer Engenex.

The purchase invoices included the price that the supplier paid for the pumps and any documentation on discounts and shipping charges. To calculate the net purchase price for each pump, we identified the purchase price on the invoice and subtracted any discounts that were listed. We did not include shipping charges in our calculations because of the inconsistencies in how suppliers reported the information.²⁵

We calculated the range and the average prices for the different pump models. Because the number of pumps of each model varied, we also calculated the weighted average price for all of the new pump models. We compared the weighted average price and average prices for the different new pump models to Medicare's purchase price.

For the pumps that were not purchased, we reviewed documents related to the arrangements that the suppliers had with other companies to acquire these pumps. These documents included leasing contracts, rental contracts, rental invoices, and invoices reflecting pump exchanges. We used these documents to describe the different arrangements and to determine the number of pumps that were acquired under each arrangement.

²⁴ Two suppliers could not be located. In addition, one supplier did not submit any documentation and another submitted documentation after the study timeframe.

²⁵ Based on the available information, regular ground shipping for one pump cost an average of \$10. In limited instances, manufacturers used overnight or other forms of expedited shipping, which cost an average of \$53 for one pump.

Analysis of Supplier Services

We surveyed by mail all of the suppliers that provided new pump models to beneficiaries in the first half of 2007. Using a standardized data collection instrument, we requested that suppliers report all services that they provided to beneficiaries for the entire rental period. We specifically asked the suppliers about communication with beneficiaries' clinicians. We also asked about services in the following categories: delivery, equipment maintenance and repairs, education and training, communication with beneficiaries and/or their caregivers, and any additional services. The suppliers provided information for 215 of the 237 beneficiaries.

Limitations

The description of the services that suppliers provided to beneficiaries during the rental period is based on self-reported data from the suppliers. We did not independently verify their responses.

Standards

This review was conducted in accordance with the "Quality Standards for Inspections" issued by the President's Council on Integrity and Efficiency and the Executive Council on Integrity and Efficiency.

► FINDINGS

Suppliers paid an average of \$3,604 for the new pump models, compared to Medicare's purchase price of \$17,165

Suppliers purchased 171 of the 223 new pump models that were provided to beneficiaries in the first half of 2007. Suppliers paid an average of \$3,604 for these pumps.

Medicare reimbursed suppliers for these pumps based on a purchase price of \$17,165, which is more than four times the average price paid by suppliers for these new pump models. On a monthly basis, Medicare reimbursed suppliers \$1,716 for these pumps for the first 3 months. At this rate, suppliers recouped the average cost of a new pump model in approximately 2 months. Suppliers generally reported that the new pump models have an estimated lifespan of 3 to 5 years. As one supplier noted, pumps are commonly rented to one beneficiary, sanitized, and then rented to another beneficiary.

Further, beneficiaries' coinsurance payments for the pumps cover a substantial portion of the average cost of a new pump model. After just 4 months of rental, a beneficiary's coinsurance of \$1,286 covers over one-third (36 percent) of the average cost of a new pump model. If a beneficiary were to rent the pump for all of the 13 months allowed by Medicare, the beneficiary's coinsurance alone (\$3,599) would cover almost the entire average cost of a new pump model.

In addition, as shown in Table 1 on the next page, the average prices for all three of the pump models that suppliers purchased were substantially lower than Medicare's purchase price.²⁶ The average price that suppliers paid for the three different models ranged from \$1,955 to \$4,970.²⁷ The pump that was most commonly provided to beneficiaries in the first half of 2007 had an average price of \$2,934.

²⁶ Suppliers did not purchase the fourth pump model. That model was acquired only through another arrangement described in the second finding.

²⁷ Note that the median price for each of the pump models is similar to the average price.

Table 1: Prices That Suppliers Paid for the New Pump Models*				
Model	Number of Pumps	Range of Prices	Average Price	Difference Between Average Price and Medicare Purchase Price
Model 1	8	\$1,085–\$2,825	\$1,995	\$15,170
Model 2	60	\$3,448–\$6,173	\$4,970	\$12,195
Model 3	103	\$2,449–\$3,950	\$2,934	\$14,231
Weighted average			\$3,604	\$13,561

* The prices include documented discounts but not shipping charges.

Source: OIG analysis of supplier documentation, 2008.

The individual prices for all of the pumps that suppliers purchased were also substantially lower than Medicare’s purchase price. The lowest price that suppliers paid for one of the pumps was \$1,085, a difference of \$16,080 from Medicare’s purchase price. The highest price that suppliers paid for one of the pumps was \$6,173, a difference of \$10,992. The price for the pump that was most commonly provided to beneficiaries ranged from \$2,449 to \$3,950.

Suppliers acquired one-quarter of the new pump models by leasing, renting, or exchanging them

Suppliers acquired nearly one-quarter (52 of 223) of the new pump models provided to beneficiaries in the first half of 2007 through methods other than

purchasing them. Suppliers acquired these pumps through lease-to-own agreements, daily rentals, hourly rentals, or exchanges of old pumps for new ones.²⁸

As shown in Table 2 on the next page, suppliers acquired nearly half of the new pumps that were not purchased (24 of 52) through lease-to-own agreements. These suppliers commonly obtained financing from leasing companies to make bulk purchases of pumps. The leasing companies maintained ownership of the pumps until the suppliers paid for them in

²⁸ Suppliers acquired all four pump models through these methods.

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full.²⁹ The prices that these leasing companies paid for these pumps were similar to the prices that suppliers paid to purchase them. The suppliers that leased the pumps cited the high cost of the pumps and general cash flow problems as the reasons why they leased the pumps rather than purchasing them.

Table 2: Methods for Acquiring New Pump Models	
	Number of Pumps
Lease-to-own	24
Daily rental	16
Hourly rental	8
Exchange of older pumps	4
Total	52

Source: OIG analysis of supplier documentation, 2008.

Suppliers rented slightly more than a quarter of these new pumps (16 of 52) on a daily basis. Under this arrangement, suppliers rented pumps from another DMEPOS supplier for the days that beneficiaries used them. Suppliers paid \$30 to \$45 per day for these pumps. In addition, suppliers rented another eight of the pumps on an hourly basis. These suppliers purchased “clinical hours” directly from the manufacturer at a rate of \$1.44 per hour. They typically bought a block of 2,160 hours for each rental.

Suppliers acquired the remaining pumps (4 of 52) by exchanging older pumps with the manufacturer for newer pumps. These pumps were exchanged without cost to the supplier based on a 2:1 ratio (i.e., two old pumps for one new pump).

²⁹ The leasing terms ranged from 24 to 72 months.

Suppliers reported not always communicating with beneficiaries’ clinicians, as required; however, they appeared to meet other standards

Suppliers are required to communicate with the beneficiaries’ treating clinicians to assess wound healing progress and to determine whether the beneficiary continues to qualify for Medicare coverage of the

pump.³⁰ In addition, to obtain Medicare billing privileges, suppliers must meet certain standards that include providing delivery and instruction on equipment usage (either from the supplier or another qualified party), maintaining and repairing the equipment as needed, and responding to beneficiaries’ questions and complaints about the equipment.³¹

Suppliers reported not having contact with clinicians for almost one-quarter of the beneficiaries

Suppliers reported having no contact with the treating clinicians for almost one-quarter (28 of 123) of the beneficiaries who rented the new pump models for multiple months. In the absence of clinician input, suppliers cannot determine whether there is a continued medical need for a pump. Therefore, these claims may be inappropriate.

In the instances when suppliers reported communicating with clinicians, they most frequently had contact with beneficiaries’ home health staff, followed by physicians. Suppliers noted that they discussed the beneficiaries’ wound progress and supply needs with these clinicians.

Suppliers reported delivering pumps and providing education to almost all of the beneficiaries, as well as providing maintenance and repairs when needed

Suppliers reported delivering pumps to 96 percent (206 of 215) of the beneficiaries who rented new pump models in the first half of 2007. A small number of beneficiaries picked up their pumps at the supplier’s store. For almost all of the remaining beneficiaries, delivery was provided by the company from which the supplier rented the pump.³² Suppliers most commonly reported delivering pumps to the

³⁰ “LCD for Negative Pressure Wound Therapy Pumps.”

³¹ 42 CFR § 424.57(c).

³² One supplier did not give a reason why it did not provide delivery.

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beneficiaries' homes, while in other instances they delivered them to the hospital shortly before the beneficiaries' discharge. Most suppliers reported delivering the pumps themselves, rather than relying on a third-party delivery service.

Suppliers reported that they educated 95 percent (205 of 215) of beneficiaries on the use of pumps. Many reported providing training on the day of delivery. Beneficiaries and/or their caregivers were the most common recipients of the training, although in many instances, the beneficiaries' home health, hospital, or wound care center provider also received training.

Suppliers reported pump malfunctions for 13 percent (28 of 215) of the beneficiaries. In most cases, the suppliers reported replacing the pumps; in a few cases, they reported repairing them. Suppliers noted that a few beneficiaries had problems with multiple pumps, necessitating a number of replacements.

Finally, suppliers reported communicating with approximately two-thirds (144 of 215) of the beneficiaries or their caregivers during their rental period. Most commonly, suppliers spoke with the beneficiaries and their caregivers about supply needs or wound progress. Suppliers reported that, in a few instances, they visited the beneficiaries in their homes.

Medicare's purchase price for pumps was established when there was only one manufacturer in the market. Since then, a number of manufacturers have introduced new pump models to the market and are charging substantially less for them. Specifically, we found that the prices that suppliers paid for the new pump models were significantly less than Medicare's purchase price. Suppliers paid an average of \$3,604 for these pumps, compared to Medicare's purchase price of \$17,165. This price is more than four times the average price paid by suppliers for the new pump models. Aside from our pricing analysis, the winning amounts for the first round of competitive bidding also indicate that suppliers could provide the pump at a lower reimbursement amount than Medicare currently provides.

We also found that suppliers acquired one-quarter of the new pump models provided to beneficiaries in the first half of 2007 through lease-to-own agreements, daily rentals, hourly rentals, or exchanges of old pumps for new ones. Additionally, we found that suppliers reported not always communicating with beneficiaries' clinicians, as required; however, they appeared to meet other standards.

Based on the findings in this report, we recommend that CMS:

Reduce Medicare's Reimbursement Amount for Pumps

CMS should consider two methods to reduce its reimbursement amount for pumps. CMS should:

- **Use its inherent reasonableness authority to reduce the reimbursement amount for pumps**

CMS should consider using its inherent reasonableness authority to reduce the amount that it reimburses suppliers for the pump.

- **Include pumps in the second round of the Competitive Bidding Acquisition Program**

CMS should include pumps in the second round of the Competitive Bidding Acquisition Program. This could better align Medicare's reimbursement amount for pumps with the amount that suppliers pay for the new pump models. In addition, if the pump is included in the program, CMS should use the data from this report to assess suppliers' bids for the pump.

R E C O M M E N D A T I O N S

In addition, CMS should:

Monitor the Growth of the New Pump Market

CMS should continue to monitor the growth of the new pump market by tracking trends in market share among different suppliers. Substantial growth in the new pump market may indicate that CMS needs to further align reimbursement with the prices that suppliers pay for the new pump models.

Educate Suppliers of New Pump Models on the Importance of Communication With Beneficiaries' Treating Clinicians

CMS should educate suppliers of new pump models that the continued need for the pump can be determined only through clinician input and that it is inappropriate for suppliers to submit claims for continued pump use without this input.

Follow Up on Pump Claims That May Be Inappropriate

CMS should follow up on the claims in which suppliers: (1) reported having no contact with the beneficiaries' treating clinicians, (2) could not be located, or (3) did not submit any documentation. CMS should determine whether these claims are inappropriate and should not have been paid. To help CMS address this recommendation, we will forward information about these claims in a separate memorandum.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with four of our recommendations and will consider the remaining recommendation. It noted that it has worked on a number of regulatory and administrative initiatives related to the prescription, coding, and coverage of pumps in response to the significant growth in expenditures for these items.

In response to our first recommendation, CMS concurred that it has the authority to adjust payment rates using Medicare's inherent reasonableness authority. It stated that it will consider whether it would be able to gather valid and reliable data, as the statute requires, to make a determination that the payment amount for pumps is grossly deficient or excessive and to establish, if needed, a new amount that is realistic and equitable.

R E C O M M E N D A T I O N S

In response to our second recommendation, CMS stated that when designing the second round of the Competitive Bidding Acquisition Program, it will consider including pumps.

In response to our third recommendation, CMS concurred and stated that it will monitor and track trends in pump usage and track the market share among different pump suppliers.

In response to our fourth recommendation, CMS concurred that the continued need for pumps can be determined only through clinical input. In addition, it agreed that suppliers need continued education on local coverage determination requirements for continued coverage of the equipment.

In response to our fifth recommendation, CMS concurred and stated that it will strongly encourage its contractors to closely monitor supplier compliance with the local coverage determination requirements. It also stated that it will investigate the need for a claim modifier to be used by suppliers to attest that the prescribing physician has followed up on the beneficiary's care within the last 30 days. CMS further stated that it is working with its contractors to strengthen its oversight in this area.

We support CMS's efforts to address these issues and encourage it to continue to make progress in these areas. The full text of CMS's comments is provided in Appendix D.



**Durable Medical Equipment, Prosthetics, Orthotics, and Supplies
Competitive Bidding Acquisition Program: First-Round Monthly Fee
Schedule Amounts**

In March 2008, the Centers for Medicare & Medicaid Services released the monthly fee schedule amounts for the first round of the Competitive Bidding Acquisition Program. The following is a list of the monthly amounts for pumps in each of the 10 competitive bidding areas.³³ As a means of comparison, the monthly fee schedule amount in noncompetitive bidding areas is \$1,716.³⁴

Table 1: Monthly Fee Schedule Amounts for First Round of DMEPOS³⁵ Competitive Bidding Acquisition Program	
Competitive Bidding Area	Winning Monthly Fee Schedule Amount
Charlotte, North Carolina-South Carolina	\$1,458.99
Cincinnati, Ohio-Kentucky-Indiana	\$1,373.17
Cleveland, Ohio	\$1,381.18
Dallas, Texas	\$1,373.17
Kansas City, Missouri-Kansas	\$1,499.08
Miami, Florida	\$1,373.17
Orlando, Florida	\$1,192.94
Pittsburgh, Pennsylvania	\$1,371.58
Riverside, California	\$1,587.72
San Juan, Puerto Rico	\$1,853.84
Average monthly fee schedule amount	\$1,446.48

Source: CMS DMEPOS Competitive Bidding Acquisition Program First Round data, 2008.

³³ These amounts reflect the first 3 months of rental. For months 4 through 13, the fee schedule amounts are equivalent to 7.5 percent of the winning purchase prices.

³⁴ Before competitive bidding, the monthly fee schedule amount for San Juan, Puerto Rico, was approximately \$2,060.

³⁵ Durable Medical Equipment, Prosthetics, Orthotics, and Supplies.



Local Coverage Determination for Negative Pressure Wound Therapy Pumps

This Appendix contains the documentation requirements that were effective between January 1 and June 30, 2007, for negative pressure wound therapy pumps, as they appeared in the local coverage determination (LCD). We have included only the section relevant to our study. Full copies of the LCD can be found at <http://www.cms.hhs.gov/mcd/search.asp>.

General Information: Documentation Requirements

Documentation of wound evaluation and treatment, recorded in the patient's medical record, must indicate regular evaluation and treatment of the patient's wounds, as detailed in the Coverage and Payment Section. Documentation of quantitative measurements of wound characteristics including wound length and width (surface area), and depth, and amount of wound exudate (drainage), indicating progress of healing must be entered at least monthly. The supplier of the negative pressure wound therapy equipment and supplies must obtain from the treating clinician, an assessment of wound healing progress, based upon the wound measurement as documented in the patient's medical record, in order to determine whether the equipment and supplies continue to qualify for Medicare coverage. (The supplier need not view the medical records in order to bill for continued use of [negative pressure wound therapy] NPWT. Whether the supplier ascertains that wound healing is occurring from month to month via verbal or written communication is left to the discretion of the supplier. However, the patient's medical records may be requested by the [durable medical equipment regional carrier] DMERC³⁶ in order to corroborate that wound healing is/was occurring as represented on the supplier's claims for reimbursement.)

³⁶ DMERCs have subsequently been replaced by Durable Medical Equipment Medicare Administrative Contractors.



Supplier Standards for Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies

This Appendix contains selected Medicare supplier standards. We have included only the sections of the supplier standards that are relevant to our study. The full text of the standards appears in 42 CFR § 424.57(c).

Application certification standards. The supplier must meet and must certify in its application for billing privileges that it meets and will continue to meet the following standards. The supplier:

(6) Honors all warranties expressed and implied under applicable State law. A supplier must not charge the beneficiary or the Medicare program for the repair or replacement of Medicare-covered items or for services covered under warranty. This standard applies to all purchased and rented items, including capped rental items, as described in Sec. 414.229 of this subchapter. The supplier must provide, upon request, documentation that it has provided beneficiaries with information about Medicare-covered items covered under warranty, in the form of copies of letters, logs, or signed notices;

(12) Must be responsible for the delivery of Medicare covered items to beneficiaries and maintain proof of delivery. (The supplier must document that it or another qualified party has at an appropriate time, provided beneficiaries with necessary information and instructions on how to use Medicare-covered items safely and effectively);

(13) Must answer questions and respond to complaints a beneficiary has about the Medicare-covered item that was sold or rented. A supplier must refer beneficiaries with Medicare questions to the appropriate carrier. A supplier must maintain documentation of contacts with beneficiaries regarding complaints or questions;

(14) Must maintain and replace at no charge or repair directly, or through a service contract with another company, Medicare-covered items it has rented to beneficiaries. The item must function as required and intended after being repaired or replaced. . . .

▶ A P P E N D I X ~ D



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: FEB - 6 2009

TO: Daniel R. Levinson
Inspector General

FROM: 
Charlene Frizzera
Acting Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Comparison of Prices for the Negative Pressure Wound Therapy Pump" (OEI-02-07-00660)

Thank you for the opportunity to review and comment on the OIG's draft report entitled "Comparison of Prices for the Negative Pressure Wound Therapy Pump," which compares the prices that suppliers paid for new negative pressure wound therapy (NPWT) pumps to Medicare-allowed payment amounts for this equipment.

In recent years, the Centers for Medicare & Medicaid Services (CMS) has worked on a number of important regulatory and administrative initiatives related to the prescription, coding, and coverage of NPWT in response to the significant growth in expenditures for these items under the Medicare program. The goal of these initiatives is to ensure that beneficiaries have access to medically necessary NPWT, and that Medicare payments are appropriate.

We note that, recently, the Agency for Healthcare Research and Quality has commissioned a review of NPWT devices as part of the Technology Assessment Program. The purpose of that review is to provide information to CMS for consideration in Healthcare Common Procedure Coding System (HCPCS) coding decisions. Section 154(c)(3) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) calls for the Secretary of the Department of Health and Human Services to perform an evaluation of the HCPCS codes for NPWT devices.

OIG Recommendation

CMS should consider using its inherent reasonableness (IR) authority to reduce the reimbursement amount for the pump.

CMS Response

The CMS concurs with this recommendation. CMS agrees that it has the authority to adjust rates using Medicare's IR authority. However, in order to make a determination that a payment amount is grossly deficient or excessive, and establish a new amount that is realistic and

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equitable, the Agency must meet certain legal and technical requirements. CMS will consider whether it would be able to gather valid and reliable data, as the statute requires, in making such a determination.

OIG Recommendation

CMS should include the pump in the second round of the Competitive Bidding Acquisition Program.

CMS Response

The CMS will consider this recommendation. When designing the second round of the competitive bidding program, CMS will consider including the NPWT pumps during this phase of implementation.

OIG Recommendation

CMS should continue to monitor the growth of the new pump market by tracking trends in market share among different suppliers.

CMS Response

The CMS concurs with this recommendation. CMS will monitor and track trends in utilization of NPWT pumps and track the market share among different NPWT suppliers.

OIG Recommendation

CMS should educate suppliers of new pump models that the continued need for the pump can be determined only through clinician input and that it is inappropriate for suppliers to submit claims for continued pump use without this input.

CMS Response

The CMS concurs with this recommendation. CMS agrees that the continued need for NPWT can be determined only through clinician input. In addition, we agree that suppliers need continued education on the Durable Medical Equipment Medicare Administrative Contractor (DME MAC) local coverage determination requirements for continued coverage of the equipment. The local coverage determinations for the NPWT pump and supplies state that, “in order for coverage to continue, a licensed medical professional must directly assess the wound(s) on a regular basis, supervise or perform wound dressing changes and document changes in the ulcer’s dimensions and characteristics on a monthly basis. The policy goes on to state that if there are no signs of improvement after each month of NPWT, therapy should be discontinued. The policy also requires that coverage of NPWT cease after 4 months of use, unless additional documentation is received and the DME MAC has determined that NPWT beyond 4 months is medically necessary in each individual case.

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OIG Recommendation

CMS should follow up on the claims in which suppliers: (1) reported having no contact with the beneficiaries' treating clinicians, (2) could not be located, or (3) did not submit any documentation. CMS should determine whether these claims are inappropriate and should not have been paid.

CMS Response

The CMS concurs with this recommendation. CMS will strongly encourage the DME MACs to closely monitor supplier compliance with the local coverage determination requirements. CMS will also investigate the need for a claim modifier to be used by suppliers to attest that the prescribing physician has followed up on the beneficiary's care within the last 30 days. Recent post payment medical review has also identified suppliers who are not following Medicare policies. CMS is working with our contractors to strengthen our oversight in this area.

The CMS would like to thank the OIG for their efforts and insight on this report. This report provides invaluable information CMS can use in efforts to ensure that Medicare coverage of and payment for NPWT is done appropriately. We look forward to working with you further on these issues.



A C K N O W L E D G M E N T S

This report was prepared under the direction of Jodi Nudelman, Regional Inspector General for Evaluation and Inspections in the New York regional office, and Meredith Seife, Deputy Regional Inspector General.

Judy Kellis served as the team leader for this study. Other principal Office of Evaluation and Inspections staff from the New York regional office who contributed to the report include Christine Moundas and Iris Lin. Central office staff who contributed include Kevin Farber and Scott Manley.