

March 2006

MEDICARE DURABLE MEDICAL EQUIPMENT

Class III Devices Do Not Warrant a Distinct Annual Payment Update





Highlights of [GAO-06-62](#), a report to congressional committees

Why GAO Did This Study

Medicare fee schedule payments for durable medical equipment (DME) that the Food and Drug Administration (FDA) regulates as class III devices, those that pose the greatest potential risk, increased by 215 percent from 2001 through 2004. From 2004 through 2006, and for 2008, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) provided for a payment update for class III DME equal to the increase in the consumer price index for all urban consumers (CPI-U). For 2007, MMA requires the Secretary of Health and Human Services to determine the payment update. MMA also requires that other DME receive a 0 percent update from 2004 through 2008. MMA directed GAO to report on an appropriate payment update for 2007 and 2008 for class III DME. In this report, GAO (1) examined whether class III devices have unique premarketing costs and (2) determined how the fee schedule rate-setting methodology accounts for the premarketing costs of such devices.

What GAO Recommends

The Congress should consider establishing a uniform payment update to the DME fee schedule for 2008 for class II and III devices. GAO recommends that the Secretary of Health and Human Services establish a uniform payment update to the DME fee schedule for 2007 for class II and class III devices. The agency agreed with GAO's recommendation. www.gao.gov/cgi-bin/getrpt?GAO-06-62.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Kathleen M. King at (202) 512-7119 or kingk@gao.gov.

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Class III Devices Do Not Warrant a Distinct Annual Payment Update

What GAO Found

GAO found that manufacturers of class III devices, with limited exceptions, have higher premarketing costs than do manufacturers of class II devices that are similar to class III devices. Premarketing costs consist of FDA user fees and research and development costs, both for any clinical data the manufacturer is required to submit and for other research and development costs. Manufacturers of class III devices pay higher FDA user fees, because of the more complex FDA review required prior to marketing, than do manufacturers of class II devices. Specifically, the user fee for class III devices subject to this review in 2005 was \$239,237, while the fee for class II devices in 2005 was \$3,502. The FDA application and approval process takes longer for class III manufacturers, which lengthens the time it takes before they can market their devices and begin receiving revenue. FDA requires that manufacturers submit clinical data for class III devices, but only occasionally requires the same for class II devices. In interviews with GAO, class III manufacturers stated that they incur higher premarketing costs for other research and development, such as labor costs related to designing a device, compared to manufacturers of class II devices. Class II manufacturers also told GAO that they incur substantial costs related to other research and development. GAO did not evaluate proprietary data to determine whether a difference in other premarketing research and development costs exists between the two types of manufacturers.

GAO found that the Medicare DME fee schedule rate-setting methodology accounts for the respective premarketing costs of class II and class III devices in a consistent manner. Regardless of device classification, the Medicare DME fee schedule payment rate for a device is based on either the manufacturer's retail price or historic reasonable Medicare charges, which the Centers for Medicare & Medicaid Services considers equivalent measures. In interviews with GAO, manufacturers of class III devices stated that when setting their retail prices, they take into account the premarketing costs of complying with federal regulatory requirements, including the costs of required clinical data collection and other research and development. These manufacturers accounted for over 96 percent of class III DME payments in 2004. Manufacturers of class II devices also stated that they take into account these costs when setting retail prices.

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Abbreviations

AdvaMed	Advanced Medical Technology Association
CMS	Centers for Medicare & Medicaid Services
CPI-U	consumer price index for all urban consumers
DME	durable medical equipment
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
ODE	Office of Device Evaluation
PMA	premarket approval

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United States Government Accountability Office
Washington, DC 20548

March 1, 2006

Congressional Committees

Medicare pays for durable medical equipment (DME)¹ provided to beneficiaries based on a fee schedule. Until 2004, annual updates to DME fee schedule payment rates had been applied uniformly to all items on the fee schedule. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) provided for an annual payment rate update equal to the annual percentage increase in the consumer price index for all urban consumers (CPI-U) from 2004 through 2006 to Medicare fee schedule payment rates for DME regulated as class III medical devices² by the Food and Drug Administration (FDA).³ For these devices, in 2007, MMA provided for an annual payment update to be determined by the Secretary of Health and Human Services, and in 2008, for an update equal to the annual percentage increase in the CPI-U. MMA also provided that from 2004 through 2008, all other DME will receive a 0 percent update. Although payments for class III devices are less than 1 percent of total Medicare DME payments, they increased from \$16.9 million to \$53.2 million, or by 215 percent, from 2001 through 2004. Osteogenesis stimulators, devices used to promote bone growth in difficult-to-heal fractures or following spinal fusion surgery, accounted for a large proportion of class III DME payments during this time, representing over 96 percent of the total in 2004.

¹DME is equipment that primarily and customarily serves a medical purpose, can withstand repeated use, is generally not useful to an individual in the absence of an illness or injury, and is appropriate for use in the home. 42 C.F.R. § 414.202.

²Pub. L. No. 108-173, § 302(c)(1)(A), 117 Stat. 2066, 2230-31.

³FDA regulates devices using a three-part classification system. Class III devices are generally those that support or sustain human life, are of substantial importance in preventing impairment of human health, or present unreasonable risk of illness or injury. These devices typically pose the greatest potential risk for human use and have the highest level of FDA regulation. An example of a class III device is an automatic external defibrillator. Class II devices generally pose less risk and require less regulatory oversight. An example of a class II device is an infusion pump. Class I devices generally pose the lowest risk for use by humans and require the least regulatory oversight. An example of a class I device is a patient examination glove.

MMA directed us to report on an appropriate payment update percentage for 2007 and 2008 to the DME fee schedule for class III devices provided to Medicare beneficiaries.⁴ To report on an appropriate payment update percentage, as agreed with the committees of jurisdiction, we (1) examined whether there are unique premarketing costs associated with class III devices compared to similar devices in other classes on the DME fee schedule and (2) determined how the DME fee schedule rate-setting methodology accounts for the premarketing costs of these devices.

To address these objectives, we interviewed officials from the Centers for Medicare & Medicaid Services (CMS), the agency that administers Medicare; FDA; two DME regional carriers, the contractors responsible for processing DME claims; and the Statistical Analysis DME Regional Carrier, the contractor that provides data analysis support to CMS. To examine the premarketing costs of devices, we obtained the fees that FDA charges for device review, known as user fees, which are published on the FDA Web site. We also reviewed the FDA device approval process and data on the length of time it takes for device review from FDA's Office of Device Evaluation (ODE)⁵ *2004 Annual Report*. We interviewed manufacturers of class III devices about the types of costs they incur in producing the devices, including FDA fees for device review and the costs of research and development, both for any clinical data the manufacturer is required to submit and for other research and development costs, such as labor costs. We also interviewed manufacturers of certain class II devices on the DME fee schedule that CMS identified as similar to the class III devices on the schedule in terms of complexity. We did not evaluate proprietary data to determine whether a difference in other premarketing research and development costs exists between the two types of manufacturers. To determine how the DME fee schedule accounts for premarketing costs, we interviewed CMS officials and reviewed CMS documents on the DME fee schedule rate-setting methodology. We also interviewed officials from a trade organization that represents manufacturers of medical devices, industry organizations for orthopedic surgeons and pain physicians, and two private health insurance companies. Appendix I contains a more complete description of our methodology. We conducted our work from

⁴Pub. L. No. 108-173, § 302(c)(1)(B), 117 Stat. 2231.

⁵ODE is a part of FDA's Center for Devices and Radiological Health. It is responsible for the program areas under which medical devices are evaluated or cleared for clinical trials and marketing.

December 2004 through February 2006 in accordance with generally accepted government auditing standards.

Results in Brief

Manufacturers of class III devices, with limited exceptions, have higher premarketing costs than do manufacturers of class II devices. Premarketing costs consist of FDA user fees and the costs of research and development, including the costs of submitting clinical data. Manufacturers of class III devices pay higher FDA user fees for review of their devices, because of the more complex FDA review required prior to marketing, than do manufacturers of class II devices. Specifically, the user fee for class III devices in 2005 was \$239,237, while the fee for class II devices in 2005 was \$3,502. In addition, according to FDA data, compared to class II manufacturers, the FDA application and approval process takes longer for class III manufacturers, which lengthens the time it takes before they can market their devices and begin receiving revenue. FDA also requires that manufacturers submit clinical data for class III devices, for which manufacturers incur costs. FDA only occasionally requires the submission of clinical data for class II devices. Class III manufacturers stated that they incur higher premarketing costs for other research and development compared to manufacturers of class II devices. However, class II manufacturers also stated that they incur substantial premarketing costs related to research and development. Because we did not evaluate proprietary data on other premarketing research and development costs, we could not determine whether a difference in premarketing research and development costs, other than clinical data collection costs, exists between class III and class II manufacturers.

The CMS rate-setting methodology for Medicare's DME fee schedule accounts for all premarketing costs of class II and class III devices in a consistent manner. Regardless of device classification, the Medicare DME fee schedule payment rate for a device is based on either the manufacturer's retail price or historic reasonable Medicare charges, which CMS considers equivalent measures. Manufacturers of class III devices we spoke with, whose devices accounted for over 96 percent of class III DME payments in 2004, stated that when setting their retail prices, they take into account the costs of complying with federal regulatory requirements, including the costs of required clinical data collection and other research and development. Manufacturers of class II devices also stated that they take into account these costs when setting retail prices.

The Congress should consider establishing a uniform payment update to the DME fee schedule for 2008 for class II and class III devices. Similarly, we recommend that the Secretary of Health and Human Services establish a uniform payment update to the DME fee schedule for 2007 for class II and class III devices. In commenting on a draft of this report, the Department of Health and Human Services (HHS) agreed with our recommendation to establish a uniform payment update to the DME fee schedule for 2007 for class II and class III devices. The agency did not comment on whether the Congress should consider establishing a uniform payment update to the DME fee schedule for 2008 for these devices. Industry representatives who reviewed a draft of this report did not agree or disagree with our matter for congressional consideration or our recommendation for executive action. They did, however, express concern that we did not recommend a specific update percentage for class III devices. Our report recommends a uniform payment update to the DME fee schedule for class II and class III devices; we believe that this recommendation satisfies the requirement in MMA to make recommendations on the appropriate update percentage for class III devices. Industry representatives were also concerned that we did not examine all the costs they incur in marketing a device. Specifically, they were concerned that we did not include some regulatory costs; labor costs for services provided to beneficiaries and physicians; and research and development costs to improve or find new uses for a device. Based on our discussions with the manufacturers of class II and class III devices, we believe labor and regulatory costs are included in our analysis. Further, we believe the research and development costs incurred for a future device are premarketing costs related to that new device and not costs related to marketing the existing device.

Background

FDA is responsible for regulating the marketing of medical devices⁶ to provide reasonable assurance of their safety and effectiveness for human

⁶The Federal Food, Drug, and Cosmetic Act defines a medical device as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory that is (a) recognized in the National Formulary or the United States Pharmacopeia or any supplement to them, (b) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or other animals, or (c) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals, nor required to be metabolized to achieve its primary intended purposes. 21 U.S.C § 321(h).

use. As part of its regulatory responsibility, FDA reviews applications from manufacturers that wish to market their medical devices in the United States. Prior to marketing new devices, manufacturers must apply for FDA marketing approval through either the premarket notification (also referred to as 510(k)) process, or the premarket approval (PMA) process, a more rigorous regulatory review. New devices are subject to PMA, unless they are substantially equivalent⁷ to an already marketed device, in which case they need to comply only with the premarket notification requirements. Applications for premarket notification are generally reviewed more quickly than applications for PMA and do not usually require clinical data.⁸

Medical devices are regulated using a three-part classification system and are subject to different levels of control based upon their classifications as class I, II, or III devices. Class I devices are generally those with the lowest risk for use by humans and require the least regulatory oversight. These devices are subject to general controls, which include standards for good manufacturing practices, and requirements related to manufacturer registration, maintenance of records, and reporting. Examples of class I devices are patient examination gloves, canes, and crutches. Class II devices are generally of higher risk and are also subject to general controls; however, FDA can establish special controls for these devices, such as development and dissemination of guidance documents, mandatory performance standards, and postmarket surveillance. Examples of class II devices are blood glucose test systems and infusion pumps.

Class III devices typically pose the greatest risk and thus have the highest level of regulation. This classification includes most devices that support or sustain human life, are of substantial importance in preventing impairment of human health, or present a potential unreasonable risk of illness or injury. Because general and special controls may not be sufficient to ensure safety and effectiveness, these devices, with limited

⁷Substantially equivalent means that a device has (1) the same intended use and the same technological characteristics as a marketed device or (2) the same intended use and different technological characteristics, but is as safe and effective as the marketed device and does not raise different questions of safety and effectiveness. 21 U.S.C. §360c(i)(1).

⁸For additional information on FDA's review of medical device applications, see GAO, *Food and Drug Administration, Limited Data Available Indicate That FDA Has Been Meeting Some Goals for Review of Medical Device Applications*, [GAO-05-1042](#) (Washington, D.C.: Sept. 30, 2005).

exceptions, must obtain PMA. To obtain PMA, the manufacturer must provide FDA with sufficient valid scientific evidence providing reasonable assurance that the device is safe and effective for its intended use. Once approved, changes to the device affecting safety or effectiveness require the submission and approval of a supplement to its PMA. Examples of class III devices include automatic external defibrillators and implantable infusion pumps used to administer medication.

Some class III devices are provided as part of a hospital visit; Medicare pays for these devices through the hospital inpatient or outpatient prospective payment systems. Five categories of class III devices, however, can be provided in physicians' offices or prescribed by physicians for use in the home; Medicare pays for these devices through the DME fee schedule.⁹

In 2004, Medicare payments for class III devices under the DME fee schedule were \$53.2 million, which represented less than 1 percent of total DME payments. The Medicare DME fee schedule payment rate for a device is based on either the manufacturer's retail price or historic reasonable Medicare charges,¹⁰ which CMS considers equivalent measures. MMA provided for a 0 percent annual update for most Medicare DME fee schedule payment rates from 2004 through 2008. However, under MMA, class III devices were excluded from the 0 percent update and received payment updates equal to the annual percentage increase in the CPI-U in 2004, 2005, and 2006.¹¹ For these devices, MMA provides, in 2007 for a payment update as determined by the Secretary of Health and Human Services, and in 2008, for a payment update equal to the annual percentage increase in the CPI-U.

⁹Medicare pays for osteogenesis stimulators, infusion pumps and their related supplies, neuromuscular stimulators, and certain ultraviolet light therapy systems and automatic external defibrillators and related supplies as class III devices under the DME fee schedule.

¹⁰If the actual charge for an item is less than the fee schedule payment rate, the Medicare payment is limited to the actual charge.

¹¹Class III devices received payment updates of 2.1 percent in 2004, 3.3 percent in 2005, and 2.5 percent in 2006.

Class III Devices Have Higher Premarketing Costs than Class II Devices

We found that with limited exceptions, manufacturers of class III devices have higher premarketing costs than do manufacturers of class II devices. Manufacturers of class III devices pay higher FDA user fees for review of their devices, because of the more complex FDA review required prior to marketing, than do manufacturers of class II devices. According to FDA data, compared to class II manufacturers, class III manufacturers have a longer period before approval during the FDA application process, which lengthens the time before they can market their devices and begin receiving revenue. FDA requires that manufacturers submit clinical data for class III devices, but only occasionally requires the same for class II devices. In addition, class III manufacturers stated they incur higher premarketing costs for other research and development than do manufacturers of class II devices. However, class II manufacturers also stated that they incur substantial premarketing costs related to other research and development. Because we did not evaluate proprietary data on other premarketing research and development costs, we could not determine whether a difference in other premarketing research and development costs exists between class III and class II manufacturers.

Manufacturers of class III devices pay higher FDA user fees for review of their devices, because of the more complex FDA review required prior to marketing, than do manufacturers of class II devices. Specifically, manufacturers of class III devices subject to this review pay the FDA user fee for PMA, which in 2005 was \$239,237 for each PMA.¹² Most PMA supplements, which must be filed when a manufacturer makes a change to a class III device that affects its safety or effectiveness, also require payment of a fee, which ranged from \$6,546 to \$239,237. Manufacturers of class II devices pay the FDA user fee for each premarket notification, which in 2005 was \$3,502.¹³ When a manufacturer makes a change to a class II device, a new premarket notification application must be filed; there is no supplement process for these devices.

Manufacturers of class III devices have a longer period before approval during the FDA application process, which they stated delays the marketing of their devices and the receipt of revenue. According to ODE's *2004 Annual Report*, in 2004, the average time for PMA review was

¹²In 2005, for businesses with \$30 million or less in annual gross sales and revenue, PMA fees were reduced to \$90,910 and the first PMA submitted by such a business was free.

¹³In 2005, for businesses with \$30 million or less in annual gross sales and revenue, premarket notification fees were reduced to \$2,802.

503 days while the average time for premarket notification review was 100 days.¹⁴ These average times include the total time a PMA or premarket notification was under review by FDA and the time the manufacturer used in responding to any FDA requests for additional information.

FDA requires that class III manufacturers submit clinical data, for which manufacturers incur costs. FDA only occasionally requires the submission of clinical data for class II devices. Specifically, FDA requires manufacturers of class III devices to submit clinical data as part of the PMA process to provide reasonable assurance that the devices are safe and effective for their intended uses. During its review of a device's PMA application, FDA may require that the manufacturer provide additional information, which may require submission of additional clinical data. Manufacturers of class III devices stated that to collect clinical data, they conducted costly animal studies, human preclinical studies, and human clinical trials. Manufacturers of class II devices must satisfy premarket notification requirements; that is, they must submit documentation that a device is substantially equivalent to a legally marketed device. An FDA official stated that manufacturers of class II devices may be required to provide clinical data. They may be required to provide these data, for example, to demonstrate that modifications they have made to a device would not significantly affect its safety or effectiveness, or if a device is to be marketed for a new or different indication. According to FDA, 10 to 15 percent of premarket notification applications include clinical data.

Manufacturers of class III devices we spoke with stated that in addition to collecting clinical data, they incur higher premarketing costs related to other research and development, such as labor costs and manufacturing supplies related to designing a device, than do manufacturers of other classes of devices. They stated that class III devices are highly innovative, complex products that require costly premarketing research and development to produce. One class III manufacturer we spoke with stated that approximately 10 percent of its revenue between 2002 and 2005 was invested in premarketing research and development. Another class III manufacturer stated that approximately 4 percent of its operating budget is spent on premarketing research and development.

¹⁴These average times are for reviews completed in fiscal year 2004, regardless of when the application was received.

However, manufacturers of class II devices we spoke with also stated that they incur substantial premarketing costs related to research and development. Specifically, we spoke with a manufacturer of an insulin pump and two manufacturers of continuous positive airway pressure devices,¹⁵ each of which stated it incurs substantial research and development costs. One class II manufacturer stated that 10 to 15 percent of a device's total cost was attributable to research and development. Another class II manufacturer stated that approximately 7 to 10 percent of its revenue is spent on research and development. Because we did not evaluate proprietary data for other premarketing research and development costs, we were unable to determine whether a difference in other premarketing research and development costs exists between class III and class II manufacturers.

DME Fee Schedule Rate-Setting Methodology Accounts for Premarketing Costs of Class II and III Devices in a Consistent Manner

The CMS rate-setting methodology for Medicare's DME fee schedule accounts for the premarketing costs of class II and class III devices in a consistent manner. The fee schedule payment rate for an item of DME, regardless of device classification, is based on either historic Medicare charges or the manufacturer's retail price, which CMS has determined are equivalent measures. Manufacturers of both class II and class III devices we spoke with stated that when setting their retail prices, they take into account all premarketing costs necessary to bring the device to market.

CMS has two DME fee schedule rate-setting methodologies: one method is for items that belong to a payment category covered by Medicare at the time the DME fee schedule was implemented in 1989, and one method is for items added to the DME fee schedule after 1989 that are not covered by an existing payment category. Regardless of its classification as a class I, II, or III device, the payment rate for an item of DME covered by Medicare when the DME fee schedule was implemented in 1989 is based on its average reasonable Medicare charge from July 1, 1986, through June 30, 1987, for some items, and July 1, 1986, through December 31, 1986, for other items (both referred to as the base year). Historically, these payment rates have been updated by a uniform, statutorily set, percentage, which is usually based on the annual percentage increase in the CPI-U. Generally, for items added to the fee schedule after 1989 that are not covered by an existing payment category, CMS does not have historic Medicare charges

¹⁵Continuous positive airway pressure devices are used to treat, among other things, sleep apnea.

upon which to base the payment rate. CMS has determined that in these cases, the manufacturer's retail price is a sufficient substitute to calculate the fee schedule payment amount, and CMS considers the payment amount that results from this methodology to be equivalent to historic reasonable Medicare charges. To determine the payment rate, CMS obtains the manufacturer's retail price for the new item and uses a formula based on the cumulative annual percentage increase in the CPI-U to deflate the price to what it would have been in the base year. Using a formula based on the statutory DME fee schedule payment updates since the base year, CMS then inflates the base year price to the year in which the item was added to the fee schedule. In succeeding years, the item is updated by the applicable DME fee schedule update. The cumulative updates applied to DME are lower than the corresponding CPI-U increases because, in certain years, the statutory update was less than the CPI-U increase.¹⁶ Therefore, the payment rate of a device is generally lower than its retail price.

Manufacturers of class III devices we spoke with, whose devices accounted for over 96 percent of class III DME payments in 2004, stated that when setting their retail prices, they take into account the premarketing costs of complying with federal agencies' requirements, including the costs of collecting clinical data, and the costs of research and development. Manufacturers of class II devices similarly stated that they take into account the premarketing costs of complying with federal agencies' requirements and of research and development, including any clinical data they may be required to collect.

Conclusions

From 2004 through 2006, MMA provided for a payment update to the DME fee schedule for class III devices equal to the annual percentage increase in the CPI-U. In addition, for these devices, for 2007, MMA provided for a payment update to be determined by the Secretary of Health and Human Services, and for 2008, a payment update equal to the annual percentage increase in the CPI-U. From 2004 through 2008, for class II devices, however, MMA provided for a 0 percent payment update.

¹⁶In 1991 and 1992, the statutory update was the annual percentage increase in the CPI-U reduced by 1 percentage point. In 1998, 1999, 2000, and 2002, the statutory update was 0 percent.

Manufacturers of class III devices, with limited exceptions, have higher premarketing costs than manufacturers of class II devices, specifically, higher costs related to FDA user fees and submission of clinical data. However, class III and class II manufacturers we spoke with stated they take these premarketing costs, as well as premarketing research and development costs, into account when setting their retail prices. Because the initial payment rates for all classes of devices on the Medicare DME fee schedule are based on these retail prices or an equivalent measure, they account for the costs of class III and similar class II devices in a consistent manner. Distinct updates for two different classes of devices are unwarranted.

Matter for Congressional Consideration

The Congress should consider establishing a uniform payment update to the DME fee schedule for 2008 for class II and class III devices.

Recommendation for Executive Action

We recommend that the Secretary of Health and Human Services establish a uniform payment update to the DME fee schedule for 2007 for class II and class III devices.

Agency and External Reviewer Comments and Our Evaluation

We received written comments on a draft of this report from HHS (see app. II). We also received oral comments from six external reviewers representing industry organizations. The external reviewers were the Advanced Medical Technology Association (AdvaMed), which represents manufacturers of medical devices, and representatives from five class III device manufacturers—the four manufacturers of osteogenesis stimulators and one manufacturer of both implantable infusion pumps and automatic external defibrillators.

HHS Comments

In commenting on a draft of this report, HHS agreed with our recommendation to establish a uniform payment update to the DME fee schedule for 2007 for class II and class III devices. The agency did not comment on whether the Congress should consider establishing a uniform payment update to the DME fee schedule for 2008 for these devices. HHS agreed with our finding that the costs of class II and class III DME have been factored into the fee schedule amounts for these devices, noting that CMS is committed to effectively and efficiently implementing DME payment rules. It stated that our report did a thorough job of reviewing

Medicare payment rules associated with the costs of furnishing class III devices.

HHS also provided technical comments, which we incorporated where appropriate.

Industry Comments and Our Evaluation

Industry representatives who reviewed a draft of this report did not agree or disagree with our matter for congressional consideration or our recommendation for executive action. They did, however, express concern that we did not recommend a specific update percentage for class III devices. Our report recommends a uniform payment update to the DME fee schedule for class II and class III devices; we believe that this recommendation satisfies the requirement in MMA to make recommendations on the appropriate update percentage for class III devices.

Two manufacturers of class III devices commented on the class II device manufacturers we interviewed. One manufacturer stated that it would have been more appropriate to interview manufacturers of class II devices that are not similar to class III devices in terms of complexity. The other manufacturer expressed concern that we did not speak with more class II manufacturers.

The four osteogenesis stimulator manufacturers expressed concern that we did not examine costs they incur after they market a device. Specifically, several stated that they incur labor costs for services provided to beneficiaries and physicians, research and development costs related to FDA-required surveillance on osteogenesis stimulators' safety, and research and development costs to improve or find new uses for a device. In addition, one manufacturer stated that it conducts costly research and development for some products that never come to market.

Concerning comments about the class II manufacturers we interviewed, as noted in the draft report, our conclusion that class III devices have higher premarketing costs than do manufacturers of class II devices is based on FDA requirements and FDA data that apply to class III and class II manufacturers and not on information obtained from class III and class II manufacturers. According to FDA data, manufacturers of class III devices pay higher FDA user fees and have a longer period of time before approval during the FDA application process. FDA also requires that all class III manufacturers submit clinical data, for which manufacturers incur costs,

and only occasionally requires the submission of clinical data for class II devices.

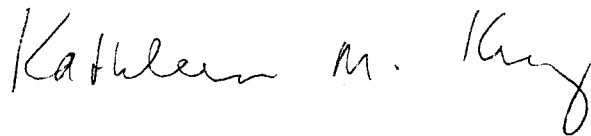
Regarding manufacturers' concerns that we did not examine all of their device-related costs, we included these costs in our analysis, where appropriate. With respect to labor costs for services provided to beneficiaries and physicians, to the extent that suppliers do perform these services, the costs are known prior to marketing the device and can be taken into account when setting their retail price. Two class III manufacturers we spoke with volunteered that they take these labor costs into account when setting retail prices prior to the device going to market. Regarding research and development costs for FDA-required surveillance, both class III and class II devices may be subject to surveillance on a case-by-case basis; prior to marketing, FDA notifies manufacturers that a device will be subject to postmarket surveillance. Also prior to marketing the device, manufacturers must submit, for FDA approval, a plan to conduct the required surveillance. As noted in the draft report, both class III and class II device manufacturers stated, that when setting their retail prices, they take into account the premarketing costs of complying with federal agencies' requirements. With respect to research and development costs to improve or find new uses for a device after it is marketed, these are costs incurred to modify an existing device or develop a new device. Costs incurred for a future device are premarketing costs related to that device and not costs related to marketing the existing device. Finally, we did not examine research and development costs for products that do not come to market because these costs do not directly relate to items on the Medicare DME fee schedule; therefore, it would be inappropriate to consider them when reporting on the appropriate update percentage to items on the fee schedule.

Industry representatives raised several issues that went beyond the scope of our report. These issues included the appropriateness of the DME rate-setting methodology, payment incentives that may lead providers to use one site of service over another, and incentives for manufacturers to bring new devices to the market.

Reviewers also made technical comments, which we incorporated where appropriate.

We are sending copies of this report to the Secretary of Health and Human Services, the Administrators of CMS and FDA, and appropriate congressional committees. We will also make copies available to others on request. In addition, the report is available at no charge on GAO's Web site at <http://www.gao.gov>.

If you or your staffs have any questions, please contact me at (202) 512-7119 or kingk@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix III.

A handwritten signature in black ink that reads "Kathleen M. King". The signature is written in a cursive style with a small dot above the letter 'i' in "King".

Kathleen M. King
Director, Health Care

List of Committees

The Honorable Charles E. Grassley
Chairman

The Honorable Max Baucus
Ranking Minority Member
Committee on Finance
United States Senate

The Honorable Joe L. Barton
Chairman

The Honorable John D. Dingell
Ranking Minority Member
Committee on Energy and Commerce
House of Representatives

The Honorable William M. Thomas
Chairman

The Honorable Charles B. Rangel
Ranking Minority Member
Committee on Ways and Means
House of Representatives

Appendix I: Scope and Methodology

To address our objectives, we interviewed officials from the Centers for Medicare & Medicaid Services (CMS); the Food and Drug Administration (FDA); two of the four durable medical equipment (DME) regional carriers, the contractors responsible for processing DME claims; and the Statistical Analysis DME Regional Carrier, the contractor that provides data analysis support to CMS. To examine the premarketing costs of devices, we obtained the fees that FDA charges for device review, known as user fees, which are published on the FDA Web site. We also reviewed the FDA device approval process, and data on device review times from FDA's Office of Device Evaluation's *2004 Annual Report*. We interviewed the four manufacturers of osteogenesis stimulators and one manufacturer of both implantable infusion pumps and automatic external defibrillators, all class III medical devices, about the types of costs they incur in producing the devices, including FDA fees for device review and the costs of research and development, both for any clinical data the manufacturer is required to submit and for other research and development costs, such as labor costs related to designing a device. These class III manufacturers' devices accounted for over 96 percent of class III Medicare DME payments in 2004. We also spoke with a manufacturer of insulin pumps and two manufacturers of continuous positive airway pressure devices, class II devices on the DME fee schedule that CMS identified as similar to the class III devices on the schedule in terms of complexity. We did not evaluate proprietary data to determine whether a difference in other premarketing research and development costs exists between the two types of manufacturers.

To determine how the DME fee schedule accounts for premarketing costs, we interviewed CMS officials and reviewed CMS documents on the DME fee schedule rate-setting methodology. We interviewed representatives from the Advanced Medical Technology Association; the American Academy of Orthopedic Surgeons; the American Society of Interventional Pain Physicians; and two private insurance companies.

We conducted our work from December 2004 through February 2006 in accordance with generally accepted government auditing standards.

Appendix II: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

FEB -7 2006

Ms. Kathleen M. King
Director, Health Care
U.S. Government Accountability Office
Washington, DC 20548

Dear Ms. King:

Enclosed are the Department's comments on the U.S. Government Accountability Office's (GAO's) draft report entitled, "MEDICARE DURABLE MEDICAL EQUIPMENT: Class III Devices Do Not Warrant a Distinct Annual Payment Update" (GAO-06-62). These comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

The Department provided technical comments directly to your staff.

The Department appreciates the opportunity to comment on this draft report before its publication.

Sincerely,

A handwritten signature in cursive script that reads "Daniel R. Levinson".

Daniel R. Levinson
Inspector General

Enclosure

The Office of Inspector General (OIG) is transmitting the Department's response to this draft report in our capacity as the Department's designated focal point and coordinator for U.S. Government Accountability Office reports. OIG has not conducted an independent assessment of these comments and therefore expresses no opinion on them.

COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES ON THE U.S. GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED, "MEDICARE DURABLE MEDICAL EQUIPMENT: CLASS III DEVICES DO NOT WARRANT A DISTINCT ANNUAL PAYMENT UPDATE" (GAO-06-62)

The Department of Health and Human Services (HHS) appreciates the opportunity to review the Government Accountability Office's (GAO) draft report.

HHS's Centers for Medicare & Medicaid Services (CMS) is committed to effectively and efficiently implementing the payment rules set forth in the Social Security Act for durable medical equipment (DME) and other items and services. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) mandates competitive acquisition programs for DME, excluding devices determined by the Food and Drug Administration to be class III devices under the Federal Food, Drug, and Cosmetic Act, such as bone growth stimulators, implanted infusion pumps, and stair climbing wheelchairs. As part of the transition to competitive acquisition, Congress mandated that the fee schedule amounts for DME, other than class III devices, be frozen at 2003 levels through 2008.

The MMA mandates that for class III DME, an annual update factor based on the percentage change in the consumer price index for urban consumers (CPI-U) is applied to the fee schedule amounts for 2004 through 2006. For 2007, the 2006 fee schedule amounts for class III DME are to be updated by a factor determined to be appropriate by the Secretary of HHS after taking into account recommendations by the GAO study regarding the appropriate update percentage for class III devices for both 2007 and 2008. Also mandated by the MMA, for 2008, the 2007 fee schedule amounts for class III DME are to be increased by an annual update factor based on the percentage change in the CPI-U.

GAO has done a thorough job in reviewing Medicare payment rules and methods and issues associated with the costs of furnishing class III devices. We agree with the finding in the report that the costs of furnishing class II and class III DME devices have been factored into the fee schedule amounts calculated for these devices. We also agree with the recommendation to establish a uniform fee schedule update for 2007 for class II and class III devices. We will take GAO's recommendation into consideration when establishing an update for class III devices as mandated by section 302 (c)(1)(B) of the MMA; GAO's recommendation is necessary for CMS to determine an appropriate fee schedule update factor for 2007 for class III DME.

We thank GAO for their efforts in this report in establishing the covered item update for class III DME for 2007. We look forward to working with GAO on any follow-up issues associated with Medicare payments for class III DME.

Appendix III: GAO Contact and Staff Acknowledgments

GAO Contact

Kathleen M. King, (202) 512-7119 or kingk@gao.gov

Acknowledgments

In addition to the contact named above, Nancy A. Edwards, Assistant Director; Joanna L. Hiatt; and Andrea E. Richardson made key contributions to this report.

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