



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](http://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](mailto:kingk@gao.gov).

# MEDICARE DURABLE MEDICAL EQUIPMENT

## 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.