

CHAPTER

6

**Issues in Medicare's medical
device payment policies**

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Chapter summary

This chapter explores two distinct topics related to medical devices. First, we explore ways to improve Medicare's payment policies for durable medical equipment, prosthetic devices, prosthetics, orthotics, and supplies (DMEPOS). Second, we explore ways to constrain the risks posed by physician-owned distributors (PODs) and to make them more transparent to beneficiaries, enforcement agencies, and others.

Medicare's DMEPOS payment policies

Medicare beneficiaries rely on DMEPOS products to treat their illness or injury and to allow them to remain in their homes, as opposed to seeking care in an institutional setting. DMEPOS as a category comprises a large number of products that vary in cost and complexity, ranging from complex power wheelchairs to diabetes testing supplies to knee braces.

Pursuant to a statutory requirement, CMS implemented the DMEPOS Competitive Bidding Program (CBP) to use market competition to set payment rates and limit fraud and abuse while ensuring beneficiaries retain access to needed DMEPOS products. The CBP began in 2011 in nine large urban areas and was focused on the highest cost and highest volume items with the largest potential for savings. Over time, the CBP has added products and expanded geographically. As of 2016, Medicare's payment rates for DMEPOS products included in the CBP are set either directly through bidding

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or indirectly by administratively setting prices at least partially based on CBP information in areas where the CBP has not been implemented (e.g., rural areas). The CBP has successfully driven down the cost of DMEPOS products for Medicare and beneficiaries. Compared with payment rates in the year before the CBP, Medicare's payment rates for some of the highest expenditure DMEPOS products have fallen by an average of roughly 50 percent. CMS initially estimated that the CBP would save over \$42 billion in the first 10 years of the program—\$25 billion in savings for the program and \$17 billion in savings for beneficiaries.

At the same time, Medicare expenditures for DMEPOS products excluded from the CBP have continued to grow. By 2015, nearly half of all Medicare expenditures on DMEPOS products were for products excluded from the CBP. Medicare pays for these products using a fee schedule that is largely based on supplier charges from 1986 to 1987 (updated for inflation) and undiscounted list prices. Medicare's payment rates for the top 10 non-CBP DMEPOS products in 2015 were a third higher, on average, than private-payer rates for comparable products, and some non-CBP DMEPOS products continue to generate high rates of improper payments, experience high utilization growth, and exhibit patterns of potential fraud and abuse.

To address these issues, some additional products that are not currently competitively bid could be moved into the CBP. We also observe that the participation and balance billing rules for DMEPOS products and suppliers could be strengthened to better protect beneficiaries and to better align those policies with many other Part B services.

Physician-owned distributors

PODs are entities that derive revenue from selling, or arranging for the sale of, devices ordered by their physician-owners for use in procedures the physician-owners perform on their own patients. PODs have the ability to distort the supply chain for medical devices—potentially resulting in an increase in the volume of surgeries performed on beneficiaries, higher costs for hospitals and the Medicare program, and inappropriate care.

The Commission questions the value PODs produce for the Medicare program and beneficiaries. We suggest several ways in which Medicare and policymakers can constrain the risks posed by PODs. We discuss two specific options to revise the Stark law, which is intended to prohibit physicians from referring Medicare beneficiaries to certain health care facilities in which they have a financial interest, and several key topics for policymakers to consider if such changes are made. While the options would likely limit the use of PODs, some PODs might continue to operate even if the Stark law was modified. In addition, the Commission supports

increasing the transparency of POD-physician relationships by requiring all PODs to report under the Open Payments program, a program designed to shed light on financial ties between physicians and certain industries. ■

Introduction

Medicare beneficiaries rely on durable medical equipment, prosthetic devices, prosthetics, orthotics, and supplies (DMEPOS) to treat their illness or injury and to allow them to remain in their homes, as opposed to seeking care in an institutional setting. This chapter provides an overview of Medicare's Competitive Bidding Program (CBP) for DMEPOS products and of Medicare's payment methods for DMEPOS products that are excluded from the CBP. The chapter describes payment policy changes that could be made to improve the accuracy of Medicare's payments for DMEPOS products, to protect beneficiaries, and to enhance program integrity.

This chapter also includes a discussion of issues surrounding physician-owned distributors (PODs), which allow physicians to profit from the sale of medical devices they use. PODs, which have historically been concentrated in the market for implantable medical devices, create an incentive for physicians to base their decisions, such as whether to operate on a patient and which instrumentation to use, on financial rather than clinical considerations. To better protect beneficiaries and the Medicare program, this chapter discusses revisions to the Stark law to limit the use of PODs.

DMEPOS background

DMEPOS, as a category, comprises a wide range of products. Durable medical equipment (DME) comprises products that serve a medical purpose, can withstand repeated use, are generally not useful in the absence of an illness or injury, and are appropriate for use in the home (e.g., wheelchairs). Supplies that are necessary for the effective use of DME are also covered under the DME benefit (e.g., oxygen in oxygen tanks). Prosthetic devices replace all or part of an internal body organ or function (e.g., colostomy bags and parenteral and enteral nutrition). Prosthetics include artificial legs, arms, and eyes. Orthotic devices are defined as providing rigid or semi-rigid support for weak or deformed body parts or restricting or eliminating motion in a diseased or injured part of the body (e.g., leg, arm, back, and neck braces). Other DMEPOS items include surgical dressings and therapeutic shoes and inserts for beneficiaries with diabetes.

DMEPOS spending overview

Medicare sets the payment rates for many DMEPOS products through the CBP. Products excluded from the CBP are primarily paid on a fee schedule basis. The trends in Medicare spending for these two broad categories of products substantially diverged over the last several years.

Medicare expenditures on DMEPOS products included in the CBP have decreased considerably over time. From 2010 to 2015, Medicare expenditures for products included in the CBP fell from \$7.5 billion to \$4.4 billion, a decrease of 42 percent.¹ Expenditures for certain types of products in the CBP declined even faster. For example, between 2010 and 2015, Medicare expenditures on diabetes testing supplies (e.g., blood glucose test strips) fell from \$1.6 billion to \$0.3 billion, a decrease of 79 percent (Table 6-1, p. 138).

Over the same time period, Medicare expenditures on DMEPOS products not included in the CBP continued to increase. Between 2010 and 2015, expenditures for these products grew from \$3.3 billion to \$4.0 billion, a total increase of 23 percent.² Because of the decrease in spending on CBP products and the increase in spending on non-CBP products, the share of total Medicare DMEPOS spending attributable to non-CBP products has increased rapidly. In 2010, non-CBP products represented about 30 percent of Medicare DMEPOS spending; by 2015, non-CBP products accounted for nearly half (48 percent) of all spending.

At the beginning of the program, CMS expected the CBP's overall savings to Medicare and beneficiaries to be more than \$42 billion over the first 10 years. This estimate included \$25 billion in savings for the Medicare program and \$17 billion in savings for beneficiaries, as a result of lower coinsurance payments and the downward effect on premiums (Centers for Medicare & Medicaid Services 2012).

History of DMEPOS payment methods

Before implementing the CBP in 2011, CMS paid for nearly all DMEPOS products on a fee schedule basis. Fee schedule payment rates were largely based on supplier charges from July 1986 through June 1987 and on information such as unadjusted list prices for products introduced after this time period.³ Before 2011, annual payment rate adjustments were generally between zero percent and the consumer price index for all urban consumers (CPI-U). Since 2011, payment rates have

**TABLE
6-1**

Medicare expenditures on CBP products fell while expenditures on non-CBP products increased, 2010–2015

	Total Medicare expenditures (in billions of dollars)		
	2010	2015	Percent change
CBP products (total)	\$7.5	\$4.4	–42%
DMEPOS other than diabetes testing supplies	5.9	4.0	–31
Diabetes testing supplies	1.6	0.3	–79
Non-CBP products	3.3	4.0	23

Note: CBP (Competitive Bidding Program), DMEPOS (durable medical equipment, prosthetic devices, prosthetics, orthotics, and supplies). Figures in table are rounded and include beneficiary spending. If a product was included in any CBP round through 2017, it is included in the CBP product categories in both 2010 and 2015. The totals for CBP products include spending in both competitive bidding areas and non-competitive bidding areas.

Source: MedPAC analysis of 2010 and 2015 Physician/Supplier Procedure Summary file and Competitive Bidding Implementation Contractor’s Healthcare Common Procedure Coding System code lists.

annually been increased by the CPI–U, reduced by the change in economy-wide productivity (Social Security Act Section 1834 (a)(14)(L)). Historically, fee schedule rates were not updated to reflect technological improvements, such as efficiency gains in manufacturing, or changes in market conditions.

As a result of setting payment rates based on supplier charges and largely updating payment rates for inflation over time, many DMEPOS products had become substantially overpriced before the CBP. The Government Accountability Office (GAO) and the Department of Health and Human Services (HHS) Office of Inspector General (OIG) published numerous reports detailing products for which Medicare’s DMEPOS payment rates were higher, often by significant amounts, compared with what suppliers paid to purchase products from manufacturers, what suppliers paid to purchase products from wholesalers, list prices on suppliers’ websites, payment rates of private payers, and payment rates of other government purchasers (Office of Inspector General 2009, Office of Inspector General 2005, Office of Inspector General 2004, Government Accountability Office 1997). For example, based on the 2006 median Medicare fee schedule amount, a 2006 OIG report found that Medicare paid \$7,215 for 36 months’ rental of oxygen concentrators that cost \$587, on average, to purchase (Office of Inspector General 2006).

Excessively high payment rates increased expenditures and likely encouraged inappropriate utilization. After analyzing

2010 and 2011 claims for diabetes testing supplies, OIG found that \$425 million in Medicare-allowed claims had characteristics of questionable billing, such as claims billed by suppliers who had an unusually high share of beneficiaries who received their diabetic testing supplies at perfectly regular intervals (which suggests suppliers automatically provided refills as opposed to beneficiaries specifically requesting refills, which is required by Medicare) (Office of Inspector General 2013a). In another instance, OIG found that 80 percent of claims for power wheelchairs supplied to beneficiaries in the first half of 2007 did not meet Medicare requirements (Office of Inspector General 2011).

The Balanced Budget Act of 1997 instructed the Secretary of HHS to conduct a competitive bidding demonstration for DMEPOS. CMS conducted demonstrations in Polk County, FL (1999 to 2002), and San Antonio, TX (2000 to 2002), that collectively reduced Medicare expenditures for the subject DMEPOS products by 19 percent, or \$9.4 million—\$7.5 million in savings for the Medicare program and \$1.9 million in savings for beneficiaries. The demonstrations had little overall impact on beneficiary access (Karon et al. 2003).

After the successful demonstrations, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) required the Secretary to establish competitive bidding for certain DMEPOS products. The MMA also expressly prohibited certain DMEPOS

products such as Class III devices from being included in competitive bidding.⁴ The law required CMS to implement the CBP in 10 of the largest metropolitan statistical areas (MSAs) initially and expand to additional areas thereafter. The law also gave the Secretary the authority to phase in competitive bidding among the highest cost and highest volume items or those with the largest savings potential.

CMS implemented CBP Round 1 in 2008, but the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) canceled all the contracts two weeks after the program began and instructed CMS to rebid the round. Because the CBP was expected to produce savings for Medicare and beneficiaries, the DMEPOS industry agreed to a 9.5 percent payment reduction for all items that were to be included in the CBP in exchange for delaying the CBP.

In 2011, CMS implemented CBP Round 1 rebid for nine product categories in nine MSAs, referred to as competitive bidding areas (CBAs). This round of the CBP was referred to as a “rebid” because it largely covered the same areas and products as the original Round 1 that was canceled by MIPPA.⁵ Since 2011, CMS has conducted two additional rounds of competitions (i.e., “recompetes”) in the same nine Round 1 MSAs. These rounds are referred to as “Round 1 recompetite” and “Round 1 2017.” As required by statute, CMS also conducted competitions in 90 additional MSAs beginning in July 2013, referred to as “Round 2” and “Round 2 recompetite.” Finally, CMS implemented the National Mail-Order Program for diabetes testing supplies (e.g., blood glucose test strips) in July 2013.⁶ As the name implies, this competition covers the entire country, including both urban and rural areas, but applies only to diabetes testing supplies purchased on a mail-order basis (which include supplies shipped or delivered to a beneficiary’s home, regardless of the method of delivery). As of 2018, two CBP rounds are active (Round 1 2017 and Round 2 recompetite) that together operate in 99 large MSAs, and the National Mail-Order Program recompetite for diabetes testing supplies is also active (Figure 6-1, p. 140).

CMS also uses pricing information from the CBP to adjust fee schedule payment rates for areas and channels not directly covered by the CBP. Pursuant to the American Taxpayer Relief Act of 2012, CMS sets the payment rates for non-mail-order diabetes testing supplies equal to the payment rate determined through the National Mail-Order Program beginning July 2013. Additionally, as required

by the Patient Protection and Affordable Care Act of 2010, CMS began in 2016 to use pricing information from the CBP to adjust the fee schedule payment rates in non-CBAs for DMEPOS items included in the CBP. DMEPOS items that are not included in the CBP, regardless of whether a beneficiary lives in a CBA or non-CBA, are still paid largely on a fee schedule basis.

Suppliers who furnish DMEPOS products included in the CBP must accept assignment (42 CFR § 414.408 (c)). For DMEPOS products not included in the CBP and CBP products used by beneficiaries who live outside a CBA, assignment is generally not mandatory. As a result, DMEPOS suppliers do not have to accept Medicare’s fee schedule rate as payment in full and may balance bill beneficiaries (i.e., bill beneficiaries for the difference between the fee schedule rate and what the supplier decides to charge for a given product). In contrast to other Part B services, there is currently no limit on balance billing for DMEPOS products. For example, physicians may balance bill only up to 115 percent of the allowed amount under the physician fee schedule.

Further, Medicare’s current payment policies do not encourage DMEPOS suppliers to enroll as participating suppliers. Participating suppliers accept assignment on all Medicare claims during the year, whereas nonparticipating suppliers are able to accept or reject assignment on a claim-by-claim basis. Under the physician fee schedule, Medicare reduces the allowed amount to 95 percent of the fee schedule rate for all nonparticipating providers, even if a particular claim is paid on an assignment basis. In contrast, no such payment reduction exists for nonparticipating DMEPOS suppliers.

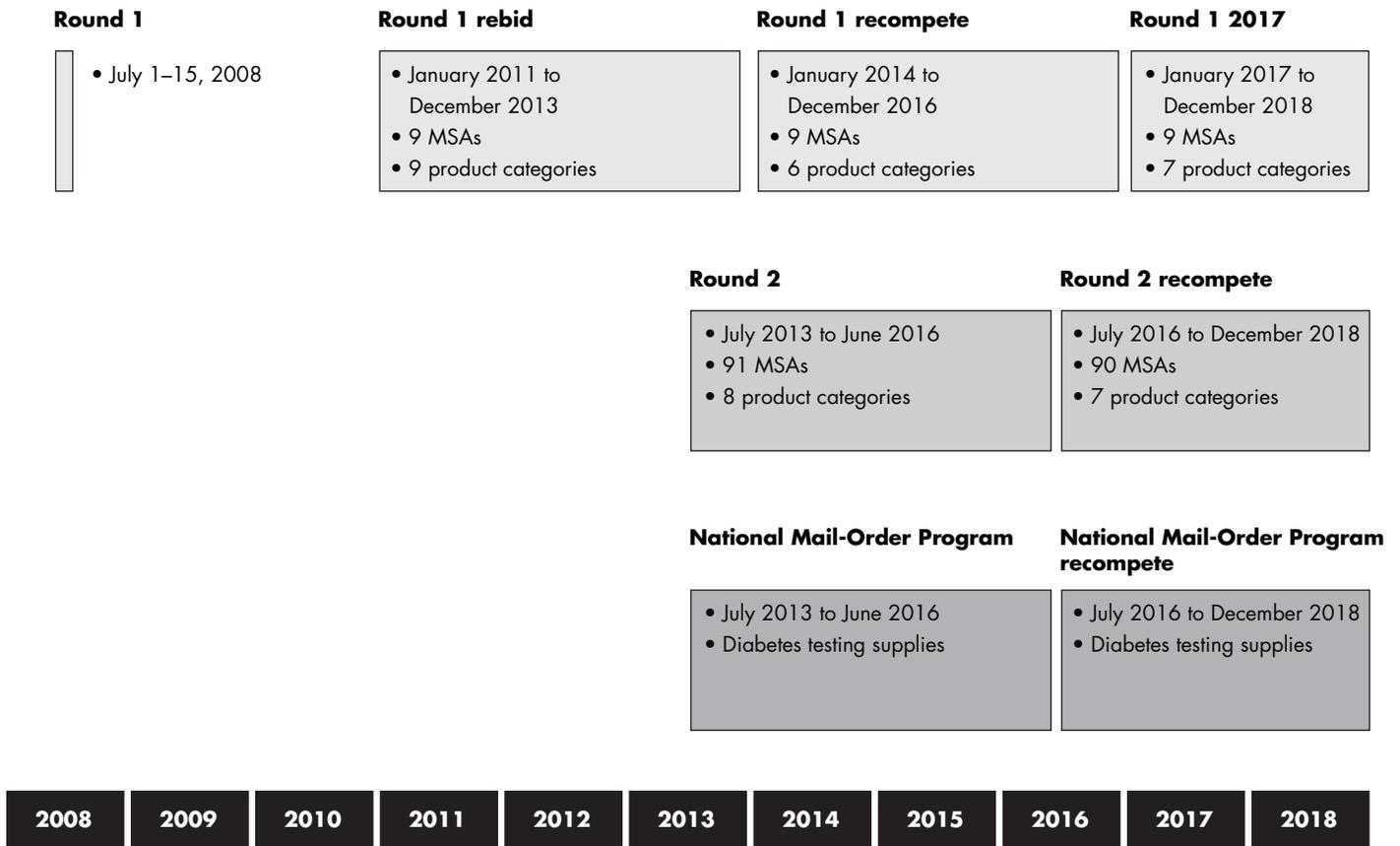
CBP structure

Suppliers are required to meet certain eligibility requirements to be considered for a contract under the CBP. For example, eligible suppliers are required to:

- be enrolled in Medicare and in good standing;
- be accredited by a CMS-approved accrediting organization;
- meet applicable state licensing requirements; and
- submit certain financial documents, including the suppliers’ most recent tax return, financial statements, and credit report (Competitive Bidding Implementation Contractor 2014b).

**FIGURE
6-1**

Time line of DMEPOS Competitive Bidding Program rounds, 2008–2018



Note: DMEPOS (durable medical equipment, prosthetic devices, prosthetics, orthotics, and supplies), MSA (metropolitan statistical area). Round 2 recomplete covers the same geographic areas that were included in Round 2. However, as a result of the Office of Management and Budget’s updates to the original 91 Round 2 MSAs, there are 90 MSAs for Round 2 recomplete. The specific DMEPOS items included in a product category may change between rounds.

Source: Government Accountability Office and CMS.

Eligible suppliers submit bids for one or more product categories in one or more CBAs. For example, a supplier could bid on the standard mobility product category in the Pittsburgh, PA, CBA. Product categories can comprise a number of individual products and can vary greatly in scope. For example, the standard mobility product category in CBP Round 1 2017 includes over 150 different Healthcare Common Procedure Coding System (HCPCS) codes, ranging from walkers to power and manual wheelchairs (Competitive Bidding Implementation Contractor 2017). Other product categories include fewer products. For example, in the same round, the

negative pressure wound therapy pump product category includes only three HCPCS codes (Competitive Bidding Implementation Contractor 2017).

CMS requires bids to be bona fide. To meet this criterion, suppliers should include in their bid the cost to purchase the item, overhead, and profit. Suppliers may be asked to submit a rationale and documentation to verify that they can furnish an item for the bid amount. For example, to prove that their bids are bona fide and that they can supply the products at the price stipulated in their bid, suppliers may be required to submit manufacturer

invoices, receipts (including retail sales receipts), manufacturer price lists, and signed written quotes. If an amount for any one of a bid's products is determined not to be bona fide, then the supplier's entire bid for the product category and CBA is rejected (Competitive Bidding Implementation Contractor 2014a).

In their bids, suppliers indicate the volume of a product they can provide in a given CBA and the price at which they are willing to supply the product. To select winning bids, composite bids are first constructed for each product category. To construct a composite bid, the price that each supplier provides in its bid is multiplied by a weight for each product. The weight for a product is based on the utilization of that item compared with other items within the product category based on historic Medicare claims (Centers for Medicare & Medicaid Services 2007).

Once the suppliers' composite bids are calculated, they are arrayed from least to most expensive. Winning suppliers are then selected, starting with the lowest cost bid, until the "pivotal bid" is reached. The pivotal bid is the lowest composite bid for a product category that includes a sufficient number of suppliers to meet beneficiary demand for the items in that product category (42 CFR § 414.402). All suppliers with composite bids at or below the pivotal bid are offered contracts.

After the winning composite bids are selected, payment rates are determined from among those bids. While winning bids are selected on a composite basis, payment rates are set at the individual HCPCS code level. Specifically, the payment rate for each HCPCS code—referred to as the single payment amount (SPA)—is derived from the median of all winning suppliers' bids for that specific item. The CBP ensures savings to the Medicare program and beneficiaries by requiring that the SPA for any product cannot exceed the fee schedule rate for the same product.

After CMS selects the winning composite bids and calculates SPAs, the agency offers contracts to the winning suppliers. Suppliers are not required to accept contract offers; that is, the bids are nonbinding.⁷ If suppliers accept a contract, they are referred to as contract suppliers. Beneficiaries living in CBAs must get DMEPOS products included in the CBP through contract suppliers, with a few exceptions.⁸

Except for the National Mail-Order Program and cases without a sufficient number of eligible suppliers, CMS

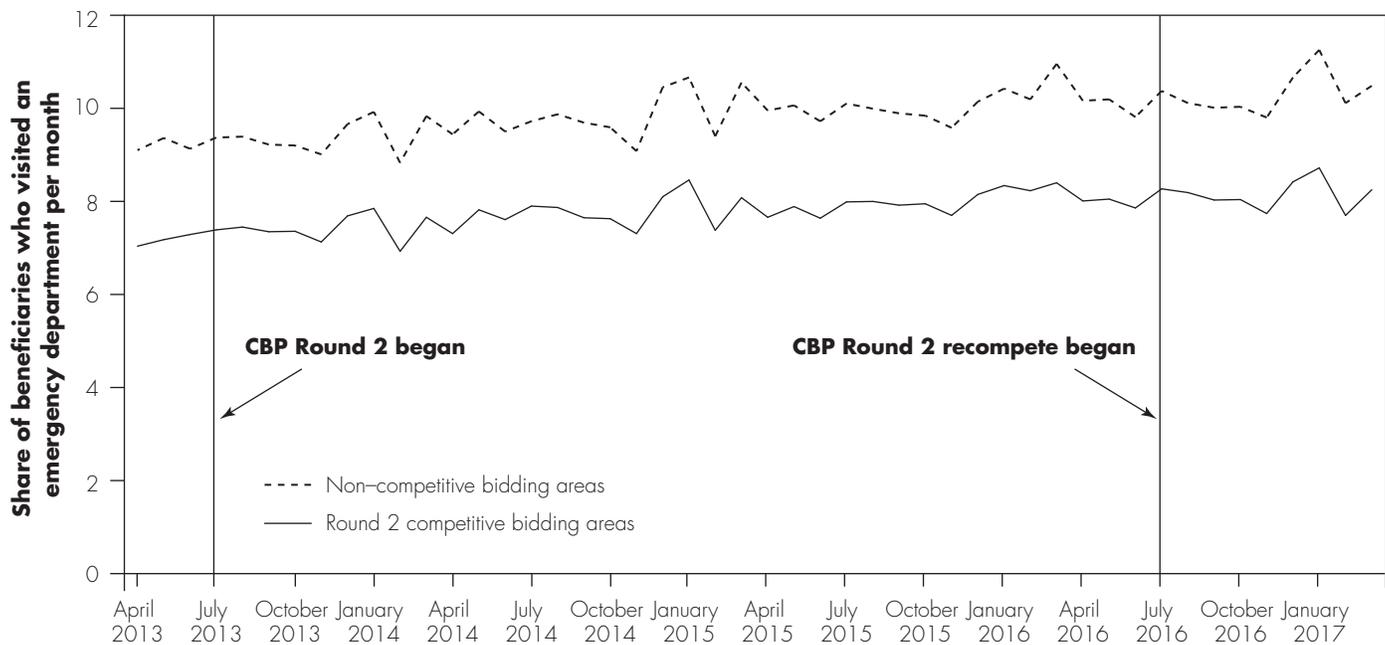
awards at least five contracts per product category and CBA (42 CFR § 414.414 (h)). Accordingly, CMS caps the share of the product category the agency expects a bidder to supply at a maximum of 20 percent of a given market's potential demand. For example, if a supplier's bid indicated that it could supply 70 percent of the demand for a given product category, CMS disregards the 70 percent and assumes that the supplier can supply only 20 percent of the market for the purposes of establishing the pivotal bid. Once contracts are awarded and suppliers begin serving beneficiaries, suppliers are not limited to any specific market share—that is, suppliers are free to compete with other suppliers that won contracts to supply as much of the market as possible.

CMS is also required by statute to ensure that small suppliers have an opportunity to participate in the CBP. To that end, CMS set a target for 30 percent of suppliers under the CBP to be small suppliers. CMS defines small suppliers as those with annual gross revenues of \$3.5 million or less, including Medicare and non-Medicare revenue (42 CFR § 414.402). If fewer than 30 percent of suppliers at or below the pivotal bid are small suppliers, then CMS offers contracts to small suppliers whose composite bids were above the pivotal bid in ascending order based on the proximity of each small supplier's composite bid to the pivotal bid. CMS continues making these offers until 30 percent of the suppliers are small suppliers or until there are no more small suppliers who submitted composite bids for the product category (42 CFR § 414.414 (g)(1)).

Subsequent to the awarding of contracts, CMS also has the discretion to award additional contracts if the agency determines that more suppliers are needed to meet beneficiary demand. To do so, CMS refers to the original arrayed list of composite bids for a product category and offers contracts to suppliers whose composite bids were closest to the pivotal bid. These additional contracts are offered on the same terms and conditions as those awarded to other winning suppliers (42 CFR § 414.414 (i)(1)).

Health status monitoring

Concurrent with the implementation of the CBP, CMS instituted a real-time claims monitoring system that is designed to analyze changes in several key secondary indicators of beneficiary access to medically necessary DMEPOS products—mortality rates, monthly hospital admission rates, monthly emergency room rates, monthly physician visit rates, monthly skilled nursing facility

**FIGURE
6-2****Emergency department use among beneficiaries likely to need home oxygen was lower in Round 2 competitive bidding areas compared with non-competitive bidding areas (West region)**

Note: CBP (Competitive Bidding Program).

Source: CMS health status monitoring data, March 2017 update.

admission rates, average monthly days in a hospital, and average monthly days in a skilled nursing facility.⁹ CMS analyzes these data for each product category and CBA for multiple cohorts of beneficiaries—all fee-for-service (FFS) beneficiaries, beneficiaries who have a claim for one of the CBP products in a given time period, and beneficiaries who are likely to use one of the CBP products on the basis of related health conditions (Centers for Medicare & Medicaid Services 2017b). These data are analyzed multiple times each month using an algorithm designed to identify potential changes in health outcomes (Government Accountability Office 2016). If potential problems are identified in utilization or outcome changes, CMS discusses them internally and has the ability to follow up to determine the specific cause. For example, CMS’s monitoring revealed declines in the use of mail-order blood glucose test strips and continuous positive airway pressure (CPAP) device supplies in certain Round 1 CBAs, so CMS conducted 300 calls to beneficiaries who stopped using the supplies after the CBP was implemented. CMS found that, in virtually

every case, the beneficiary reported having more than enough supplies on hand, often multiple months’ worth, which suggests that beneficiaries had historically received excessive replacement supplies before they were medically necessary (Wilson 2012). Based on the results of the monitoring system, CMS has said that no negative changes in beneficiary health outcomes have resulted from the CBP (Centers for Medicare & Medicaid Services 2017b).

CMS publicly posts aggregated data from its health status monitoring program. In the public data, the results are aggregated by region—Midwest, Northeast, South, and West. The data are also stratified by whether a beneficiary lives in one of the CBP Round 1 areas, Round 2 areas, or a non-CBA. For example, Figure 6-2, using the publicly available data, shows the trend in the share of Medicare FFS beneficiaries who visited an emergency department in each month from April 2013 through March 2017 and had a diagnosis in claims data indicating a potential need for home oxygen (e.g., chronic obstructive pulmonary disease). The data in the figure are limited to beneficiaries

who lived in the West region and are stratified by whether a beneficiary lived in a Round 2 CBA or a non-CBA. The figure reveals several patterns. First, the use of health care services varies across geographic areas, likely for reasons beyond the CBP. In this case, emergency department use was actually lower in CBAs compared with non-CBAs, a trend that also held in the other three geographic regions.¹⁰ Second, there appeared to be a secular trend of higher emergency department use; that is, emergency department use appeared to be increasing for all beneficiaries during the period from 2013 to 2017. In fact, the Commission has documented that emergency department use had been growing for the Medicare population even before the implementation of the CBP (See Chapter 1 of this report). Given these observations, Figure 6-2 does not suggest that a major increase in emergency department utilization occurred among beneficiaries likely to need home oxygen in the months after either of the CBP Round 2 competitions began.

Price and utilization changes under the CBP

The payment rates for DMEPOS products have declined substantially since the CBP's implementation. Among the 25 highest expenditure DMEPOS products included in the CBP (based on 2015 Medicare expenditures), the median payment rate decrease was 53 percent from 2010 (the year before the CBP began) to the most current CBP round, which is CBP Round 1 2017 for most products. Among these 25 products, price declines ranged from 25 percent for certain standard power wheelchairs (HCPCS code K0823) to 75 percent for blood glucose test strips (HCPCS code A4253) (Table 6-2, p. 144).

Utilization of DMEPOS products included in the CBP declined more in CBAs compared with non-CBAs after the implementation of competitive bidding. In a 2016 report, GAO analyzed the change in the number of beneficiaries utilizing a particular product and number of items received in the year before and after the implementation of CBP Round 2 in July 2013. GAO found that the number of beneficiaries receiving a product included in CBP Round 2 declined by 17 percent in CBAs compared with 6 percent in non-CBAs (Government Accountability Office 2016).¹¹ The utilization changes varied substantially among the eight product categories included in CBP Round 2. Seven of eight product categories saw declines in the number of beneficiaries receiving products after the CBP was implemented, and most of the declines were larger than the declines for the same products in non-CBAs. For example, the

number of beneficiaries receiving hospital beds declined 37 percent for CBAs and 28 percent for non-CBAs after CBP Round 2 was implemented (Government Accountability Office 2016). For one product category—CPAPs—both the number of beneficiaries and items received increased in both CBAs and non-CBAs after implementation of CBP Round 2. Specifically, after CBP Round 2 was implemented, the number of CPAP items received in CBAs increased by 25 percent compared with a 17 percent increase in non-CBAs (Government Accountability Office 2016).

Critiques of the CBP

The DMEPOS industry, economists, and others have criticized the CBP. The criticisms generally fall into three categories—criticisms of the CBP's structure, how CBP information is used to adjust fee schedule payment rates in non-CBAs, and the structure of the health status monitoring program. Regarding the CBP's structure, the four main critiques are that:

- the bids are nonbinding (i.e., a supplier can win a bid and then reject the contract);
- SPAs are set using the median price of all winning bids as opposed to the price of the pivotal bid (i.e., the market-clearing price);
- composite bids are used; and
- the program lacks transparency (167 Concerned Auction Experts on Medicare Competitive Bidding Program 2010).

Critics of the CBP contend that these issues, especially the first two, will have several negative consequences. First, they suggest that using nonbinding bids encourages “low-ball” bids whereby suppliers bid at unreasonably low rates to ensure that they are offered a contract. Then, after the SPAs are announced, the low-ball bidders can decline the contract. Second, using the median of winning bids to set SPAs results in half of winning bidders being offered contracts at prices less than their bids, which could result in many suppliers rejecting contracts or supplying products at a loss.¹² In addition, critics suggest that using the median of winning bids further encourages low-ball bids, since a low bid increases the chances of a supplier being offered a contract but has a modest effect on the SPA. In total, critics of the CBP believe that these design issues will lead to supply shortages, as suppliers refuse to offer unprofitable products, and a deterioration in the quality

**TABLE
6-2**

Change in Medicare payment rates from 2010 to current round of CBP for 25 highest expenditure DMEPOS products included in the CBP

HCPCS code	Description	Total Medicare expenditures (in millions) (2015)	Median Medicare fee schedule payment rate (2010)	Median competitive bidding single payment amount (2017)	Percent change in payment rate
E1390	Oxygen concentrator	\$1,216	\$173	\$79	-55%
A4253	Blood glucose test strips	311	33	8	-75
E0601	Continuous positive airway pressure (CPAP) device	205	101	42	-58
A7030	Full face mask used with positive airway pressure device	151	171	90	-47
A7034	Nasal interface used with positive airway pressure device	128	106	56	-47
E2402	Negative pressure wound therapy electrical pump	112	1,553	659	-58
A7031	Face mask interface, replacement for full face mask	94	63	34	-46
E0431	Portable gaseous oxygen system	91	29	17	-40
E0260	Hospital bed, semi-electric, with any type side rails, with mattress	89	127	60	-53
E0470	Respiratory assist device, bi-level pressure capability, without backup rate feature, used with noninvasive interface (e.g., facial mask)	85	232	109	-53
A7032	Cushion for use on nasal mask interface, replacement only	82	37	19	-47
B4035	Enteral feeding supply kit	78	11	5	-53
E0562	Humidifier, heated, used with positive airway pressure device	76	273	140	-49
E0471	Respiratory assist device, bi-level pressure capability, with back-up rate feature, used with noninvasive interface (e.g., facial mask)	66	581	276	-53
K0823	Power wheelchair, group 2 standard, captain's chair, patient weight capacity up to and including 300 pounds	57	364	273	-25
B4152	Enteral formula, nutritionally complete, calorically dense	53	0.54	0.30	-44
E0143	Walker, folding, wheeled, adjustable or fixed height	52	109	48	-56
A7033	Pillow for use on nasal cannula type interface, replacement only	50	26	16	-39
A7035	Headgear used with positive airway pressure device	48	36	18	-50
A7037	Tubing used with positive airway pressure device	46	37	12	-68
K0001	Standard wheelchair	45	56	26	-54
E0570	Nebulizer, with compressor	43	17	7	-56
B4154	Enteral formula, nutritionally complete, for special metabolic needs	43	1.18	0.68	-42
B4150	Enteral formula, nutritionally complete	42	0.65	0.37	-43
A7038	Filter, disposable, used with positive airway pressure device	38	4.83	2.00	-59

Note: CBP (Competitive Bidding Program), DMEPOS (durable medical equipment, prosthetic devices, prosthetics, orthotics, and supplies), HCPCS (Healthcare Common Procedure Coding System). Numbers may be rounded. The unit of payment for the payment rates listed in the table varies (e.g., per month, per device, etc.). Some HCPCS code descriptions are shortened for brevity. All CBP prices were based on Round 1 2017 single payment amounts except A4253, which was based on the National Mail-Order Program recompute. Fee schedule rates for 2010 were calculated as a median of the state-level payment amounts except enteral nutrition codes, which were based on a national fee schedule. HCPCS codes E1007, A4221, and E0784 were excluded from this table because they were excluded from the current rounds of competitive bidding (Round 2 recompute and Round 1 2017).

Source: MedPAC analysis of CBP single payment amounts, 2015 Physician/Supplier Procedure Summary file, and DMEPOS and parenteral and enteral nutrition fee schedules.

of products, as suppliers engage in a “race to the bottom” to offer only the cheapest products to beneficiaries (167 Concerned Auction Experts on Medicare Competitive Bidding Program 2010).¹³ If beneficiaries cannot access

needed DMEPOS products, CBP critics contend that Medicare costs might actually increase as beneficiaries seek care in more expensive settings (e.g., hospitals) (Crampton et al. 2015).

The DMEPOS industry has also criticized the use of information from the CBP to set prices in non-CBAs. Non-CBAs generally consist of small and moderate-size urban areas and rural areas. The primary criticism is that applying CBP rates to non-CBAs is inappropriate because the CBP's design flaws result in prices that are artificially low. Critics also contend that suppliers in non-CBAs cannot accept CBP payment rates because they cannot serve the volume of beneficiaries that suppliers in CBAs do because CBAs have higher populations and the number of suppliers in CBAs is limited based on the number of contracts awarded. Finally, critics suggest that the cost to supply DMEPOS products can be higher in rural areas (e.g., higher costs to deliver products in more remote locations) (American Association for Homecare 2017).

Critics of the CBP have alternately criticized CMS's health status monitoring program but then also used the program's data to suggest that beneficiaries living in CBAs are negatively affected by the CBP. One criticism is that not all beneficiaries who might need DMEPOS products are tracked because of relatively short look-back periods used to identify beneficiaries as having a specific diagnosis (Lewis 2012). For example, CMS tracks outcomes for beneficiaries with diabetes to ensure diabetics have sufficient access to diabetes testing supplies, which are included in the National Mail-Order Program. CMS defines diabetics by searching through FFS claims for four months—the month for which the outcome is measured and three previous months. Critics contend that this four-month look-back period is insufficient because many diabetics might not have generated a claim in the previous four months. Other criticisms of the health status monitoring program include the lack of transparency, unsteady cohorts (i.e., the beneficiaries tracked by CMS change over time), and lack of a matched control group (National Minority Quality Forum 2015). While some stakeholders have criticized CMS's health status monitoring program as inadequate, other industry representatives have asserted that these same data contradict the agency's claims of no negative health outcomes related to the CBP. For example, industry representatives have pointed to the increase in emergency department use among diabetics to suggest that diabetics do not have sufficient access to diabetes testing supplies. However, we have seen emergency department use increase among both beneficiaries with diabetes and those without diabetes. Also, as we note in the readmissions chapter (Chapter 1) in this report, emergency department

use had been growing for the Medicare population before the implementation of the CBP, so increasing emergency department use appears to be a secular trend with many likely contributing factors beyond the CBP.

Non-CBP DMEPOS products

In 2015, non-CBP products represented \$4 billion in Medicare spending, nearly half of all Medicare spending on DMEPOS. Unlike products under the CBP, payment rates for non-CBP products are not routinely evaluated for accuracy, and the payment rate for many products continues to be based on historical supplier charges. As a result, some non-CBP products are likely mispriced. As was seen before CMS instituted the CBP in 2011, mispriced DMEPOS products can lead to rapid growth in expenditures, inappropriately high utilization, and potential fraud and abuse.

There are a large number of non-CBP DMEPOS products, but spending is concentrated among relatively few of them. While the number of products varies over time, Medicare paid suppliers for roughly 1,500 non-CBP DMEPOS products in each year from 2010 through 2015, compared with about 400 DMEPOS products that have ever been included in the CBP. Average spending per product is lower for non-CBP DMEPOS products compared with CBP products, reflecting the fact that CMS included higher expenditure DMEPOS products in the CBP first. Notwithstanding the lower average, a relatively small number of non-CBP products have substantial expenditures associated with them and account for a disproportionate share of the total non-CBP DMEPOS spending. For example, the top 25 products in spending represented about half of the \$4 billion in non-CBP DMEPOS spending in 2015 (Table 6-3, p. 146).

Rapid growth in expenditures for non-CBP DMEPOS products

In contrast to the rapid decline in spending for products included in the CBP, Medicare spending on non-CBP products has grown. Since the implementation of competitive bidding, non-CBP DMEPOS products have more commonly experienced rapid growth in expenditures compared with CBP products. For example, among all DMEPOS products with at least \$10 million in expenditures in 2015, 9 of the 10 products with the fastest growth in expenditures from 2014 to 2015 were

**TABLE
6-3****The 25 highest expenditure non-competitively bid DMEPOS products, 2015**

HCPCS code	Total Medicare expenditures (in millions)	Product description
E0464	\$343	Pressure support ventilator used with non-invasive interface (e.g., mask)
K0606	179	Automatic external defibrillator, with integrated electrocardiogram analysis, garment type
A4351	133	Intermittent urinary catheter, straight tip
L0650	114	Lumbar-sacral orthosis, off-the-shelf
L1833	105	Knee orthosis, off-the-shelf
A4352	103	Intermittent urinary catheter, curved tip
E0748	97	Osteogenesis stimulator, electrical, non-invasive, spinal applications
B4197	90	Parenteral nutrition solution, 74 to 100 grams of protein
A5500	76	For diabetics only, fitting, custom preparation and supply of off-the-shelf depth-inlay shoe
E0463	69	Pressure support ventilator used with invasive interface (e.g., tracheostomy tube)
L0648	63	Lumbar-sacral orthosis, off-the-shelf
A5513	54	For diabetics only, multiple density insert, custom fabricated
A4353	54	Intermittent urinary catheter, with insertion supplies
L5673	53	Addition to lower extremity, below knee/above knee, custom fabricated from existing mold or prefabricated
A5512	50	For diabetics only, multiple density insert, direct formed, molded to foot after external heat source of 230 degrees Fahrenheit or higher, prefabricated
L5301	47	Below knee, molded socket, shin, SACH foot, endoskeletal system
K0861	43	Power wheelchair, group 3 standard, multiple power option, sling/solid seat/back, patient weight capacity up to and including 300 pounds
B4199	42	Parenteral nutrition solution, over 100 grams of protein
L0637	41	Lumbar-sacral orthosis, prefabricated item that has been customized to fit a specific patient by an individual with expertise
L5856	40	Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s)
A6021	39	Collagen dressing, sterile, size 16 sq. in. or less
L5700	38	Replacement, socket, below knee, molded to patient model
B4193	38	Parenteral nutrition solution, 52 to 73 grams of protein
A4407	35	Ostomy skin barrier, with flange, extended wear, with built-in convexity, 4x4 inches or smaller
E0483	31	High frequency chest wall oscillation air-pulse generator system

Note: DMEPOS (durable medical equipment, prosthetic devices, prosthetics, orthotics, and supplies), HCPCS (Healthcare Common Procedure Coding System), SACH (solid ankle cushion heel). Expenditures are rounded and include beneficiary cost sharing. Some HCPCS code descriptions are shortened for brevity.

Source: MedPAC analysis of 2015 Physician/Supplier Procedure Summary file.

non-CBP products, with the lone CBP product being tubing commonly used in conjunction with CPAP devices (A4604). Among the 25 highest expenditure non-CBP DMEPOS products, Medicare spending from 2014 to 2015 grew 21 percent. Several non-CBP products grew even faster than this average, such as back braces (see text box on off-the-shelf orthotics).¹⁴

The growth in expenditures for these products is largely due to growth in utilization; the increases in payment rates and number of Part B FFS beneficiaries between 2014 and 2015 were modest.¹⁵ These large, one-year growth rates were also not likely driven by changes in beneficiary health, given that the relative health status of the Medicare population is unlikely to change substantially over such a

Rapid growth and potentially inappropriate utilization of off-the-shelf orthotics

Broadly, the orthotics market can be separated into three segments—off-the-shelf, custom-fitted, and custom-fabricated products. Off-the-shelf orthotics are prefabricated products that require minimal self-adjustment for appropriate use (42 CFR § 414.402). Custom-fitted orthotics are also prefabricated but require substantial modification by a certified orthotist or someone with equivalent training. Custom-fabricated orthotics are the most individualized type of orthotic and are individually fabricated for the patient.

Medicare spending on off-the-shelf orthotics has grown rapidly in the last several years. From 2014 to 2016, Medicare expenditures on off-the-shelf orthotics roughly doubled, from \$255 million to \$547 million. There are currently over 50 off-the-shelf products payable by Medicare, but spending is concentrated on relatively few products. For example, in 2016, spending for one back brace product (Healthcare Common Procedure Coding System code L0650) was \$190 million and for one knee brace product (L1833) was \$107 million. Expenditures for these two codes also grew rapidly. From 2014 to 2016, Medicare expenditures for the back brace product grew by 311 percent (from \$46 million to \$190 million), while expenditures for the knee brace product grew by 81 percent (from \$59 million to \$107 million).

Given the rapid growth in expenditures for off-the-shelf orthotics, we examined in greater depth one type of prefabricated back brace with high Medicare spending for signs of inappropriate utilization.¹⁶ We identified several patterns involving physicians and suppliers suggesting that a meaningful portion of the increased use of off-the-shelf orthotics since 2014 could represent supplier-induced demand or even potential fraud and abuse.

- ***A limited number of physicians ordered a disproportionate share of back braces.*** In 2016, over 50,000 physicians ordered at least one of the back braces we examined for a Medicare fee-for-service (FFS) beneficiary. However, only 25 physicians ordered 20 percent of all such braces in 2016.
- ***Physicians ordered braces for beneficiaries without billing Medicare for other services.*** The 25 top-ordering physicians ordered back braces for roughly 38,000 FFS beneficiaries in 2016. These physicians billed Medicare for other physician services, such as an office visit or surgical procedure, for less than 1 percent of these beneficiaries. In contrast, we randomly sampled roughly 500 physicians who ordered at least one back brace in 2016 but were not among the top 100 physicians in terms of back braces ordered and found that the physician who ordered the brace also billed a physician service for the same beneficiary over 80 percent of the time.
- ***Physicians ordered braces for beneficiaries from across the country.*** Many top-ordering physicians ordered back braces for beneficiaries from across the country. For example, in 2016, one physician ordered at least 100 of the back braces we studied for beneficiaries who resided in 9 geographically distant states—California, Connecticut, Florida, Indiana, Maryland, Massachusetts, New York, Ohio, and Virginia.
- ***Top-ordering physicians have a history of disciplinary actions.*** Of the 12 physicians who ordered the highest number of back braces in 2016, we identified 9, or 75 percent, who had previously been disciplined by at least one state medical board or were under investigation when their medical license expired. In contrast, in 2015, less than 0.5 percent of the general population of physicians was sanctioned by a state medical board.¹⁷ Among the top-ordering physicians, the severity of the actions that triggered state medical boards to act ranged from submitting false or misleading information on their medical license applications to participating in inappropriate referral schemes. For example, one top-ordering physician was put on probation for participating in a referral scheme in which she was paid \$30 per patient to speak with patients over the phone and then write prescriptions for pharmaceuticals.

(continued next page)

Rapid growth and potentially inappropriate utilization of off-the-shelf orthotics (cont.)

- **Suppliers were concentrated in Florida.** Roughly 7 percent of Medicare FFS beneficiaries reside in Florida. However, roughly 30 percent of the spending increase from 2014 to 2016 on the back brace product we studied was attributable to suppliers located in Florida. Suppliers located in Florida have a history of elevated rates of fraud and abuse.
- **Suppliers—especially new ones—drove the increase in expenditures.** In 2016, suppliers of durable medical equipment, prosthetic devices, prosthetics, orthotics, and supplies (DMEPOS) furnished two-thirds of the back braces we studied, while physicians, physical therapists, and orthotists furnished most of the remaining third. From 2014 to 2016, DMEPOS suppliers accounted for over 80 percent of the growth in Medicare expenditures on the back brace products we studied, while the growth attributable to physicians, physical therapists, and orthotists was much smaller. Among the 25 suppliers with the highest Medicare expenditures for the back brace product we studied in 2016, 18 of them did not bill Medicare for those products in 2014.

The physicians who are driving the increasing utilization appear to be ordering braces for beneficiaries with whom they have a limited

relationship (based on their lack of Medicare claims and the geographic distance between the physicians and beneficiaries) from suppliers who often ship their products to beneficiaries (based on the geographic distance between suppliers and beneficiaries). Based on a review of several telehealth companies' websites and other public documents, we found that several of the top back brace-ordering physicians were employed by telehealth companies. All of this information appears to be consistent with the existence of supplier-funded telehealth arrangements that some industry analysts have warned could violate the anti-kickback statute (Baird 2016). Under one type of such arrangement, a supplier pays a lead-generation company to recruit Medicare beneficiaries who might want a back brace (e.g., through television advertising); the lead-generation company pays a telehealth company; the telehealth company pays a physician to conduct a telehealth visit with beneficiaries; the physician orders back braces; and suppliers ship the braces to beneficiaries and bill Medicare. This nexus of relationships between certain physicians, telehealth companies, lead-generation companies, and suppliers who predominantly mail orthoses to their customers appears to be driven more by financial considerations than by clinical ones. Independent of including orthoses in the Competitive Bidding Program, policymakers may want to consider policies designed to limit such practices. ■

short time period. Given these facts, some of the growth in utilization could be supplier induced and represent potentially inappropriate utilization.

Improper payment rates and potential fraud and abuse

In addition to rapid expenditure growth, many non-CBP DMEPOS products tend to have high improper payment rates, and some have been involved in cases of fraud and abuse over the last several years.

While all payments made as a result of fraud are considered “improper payments,” not all improper

payments are fraudulent. In fact, improper payments typically do not involve fraud. Rather, insufficient documentation errors caused the vast majority (80.4 percent) of improper payments for DMEPOS in 2016 (Centers for Medicare & Medicaid Services 2016d). Claims are placed into this category when the documentation submitted is inadequate to support payment for the services billed. For example, a few of the more common missing pieces of documentation for DMEPOS products include an order form for the product, a certificate of medical necessity, and a physician evaluation (Centers for Medicare & Medicaid Services 2016d). Even

though improper payments are predominantly not related to fraud, such high rates of improper payments make it difficult to determine whether all DMEPOS utilization is appropriate.

Compared with other Part B services, DMEPOS products are prone to high improper payment rates.¹⁸ As part of its Comprehensive Error Rate Testing (CERT), CMS found the improper payment rate for all DMEPOS products to be 46.3 percent compared with 11.7 percent for all other Part B services in 2016 (Centers for Medicare & Medicaid Services 2016d). Several categories of non-CBP DMEPOS products had improper payment rates above the already high DMEPOS average. For example, shoes designed to be worn by diabetics had an improper payment rate of 64.0 percent, and surgical dressings had an improper payment rate of 84.3 percent (Centers for Medicare & Medicaid Services 2016d). In addition to the CERT report, DME Medicare administrative contractors (MACs) have also initiated targeted service-specific prepayment reviews (Centers for Medicare & Medicaid Services 2017d). The results of these service-specific reviews generally substantiate the CERT findings that DMEPOS products are prone to high improper payment rates. For example, from January through April 2017, one MAC found that the potential improper payment rate was 89 percent or higher for several non-CBP DMEPOS products—parenteral nutrition (Healthcare Common Procedure Coding System code B4197), diabetic shoes (A5500), off-the-shelf back braces (L0650), and off-the-shelf knee braces (L1833) (Noridian Healthcare Solutions 2017a, Noridian Healthcare Solutions 2017b, Noridian Healthcare Solutions 2017c, Noridian Healthcare Solutions 2017d). The text box (p. 151) describes some policy options, beyond competitive bidding, to reduce potentially inappropriate utilization of DMEPOS products.

While documented cases of fraud are far less common than improper payments, there have been several documented fraud cases involving non-CBP DMEPOS products in recent years. One high-profile case of fraud and abuse involved bone growth stimulators. Bone growth stimulators, or osteogenesis stimulators, are used to promote bone healing in difficult-to-heal fractures or fusions by applying electrical or ultrasonic current to the site of the fracture or fusion. As part of a settlement announced in December 2012, the government detailed how one large manufacturer of bone growth stimulators obstructed a federal audit and manipulated certificates of medical necessity, including having its employees fill out the entire form and forging physician signatures

(Department of Justice 2012). The case also saw several company employees (including company officers ranking as high as a vice president of sales) and providers plead guilty to or be convicted of charges including paying kickbacks to induce providers to prescribe the company's products, falsifying beneficiary medical records to fraudulently induce Medicare to pay for the company's bone growth stimulators, and making a false statement to a grand jury (Department of Justice 2014, Department of Justice 2012).

Potentially excessive payment rates

Excessive payment rates can lead to inappropriately high utilization and expenditure growth and encourage potential fraud and abuse. To examine whether any of the highest expenditure non-CBP DMEPOS products had excessive payment rates, we evaluated Medicare's payment rates for the 10 highest expenditure non-CBP DMEPOS products in 2015. To do so, we reviewed CMS's payment policy changes since 2015 (if any) that were made to address overpriced products and compared Medicare's payment rates with private-payer rates and direct-purchase prices for two orthoses. The results suggest that Medicare is substantially overpaying for many non-CBP DMEPOS products.

Comparison to private-payer rates

To compare Medicare rates with private-payer rates, we first determined the median Medicare payment rate for each non-CBP DMEPOS product because payment rates can vary by state. We then calculated the median payment rate from a private-payer database.¹⁹ Finally, we compared these two rates to determine the difference and the amount Medicare and beneficiaries would have saved if Medicare had paid for the DMEPOS product at the median private-payer rate in 2015.

The median Medicare payment rate was higher than the comparable private-payer rate in 2015 for 9 of the top 10 non-CBP DMEPOS products. For those nine products, we found Medicare's median payment rates were 18 percent to 57 percent higher than median private-payer rates. In dollars, Medicare's median payment rates ranged from \$0.60 higher per item for one type of catheter to over \$1,100 higher per item for one type of bone growth stimulator (Table 6-4, p. 150).

For two ventilator products, we found Medicare's payment rates were higher than private-payer rates in 2015, but CMS lowered the payment rates in 2016. (For

**TABLE
6-4**

Comparison of private-payer rates to Medicare rates for the 10 highest expenditure non-CBP DMEPOS products, 2015

HCPCS code	Product description	Median private payer rate	Median Medicare fee schedule rate	Percentage more (or less) Medicare paid relative to private-payer rate	Potential savings if Medicare paid median private-payer rate (in millions)
E0464	Pressure support ventilator used with non-invasive interface (e.g., mask)	\$1,153	\$1,561	35%	\$89
K0606	Automatic external defibrillator, with integrated electrocardiogram analysis, garment type	2,945	2,795	(5)	N/A
A4351	Intermittent urinary catheter, straight tip	1.33	1.93	45	41
L0650	Lumbar-sacral orthosis, off-the-shelf	877	1,130	29	25
L1833	Knee orthosis, off-the-shelf	436	650	49	34
A4352	Intermittent urinary catheter, curved tip	4.55	7.13	57	37
E0748	Osteogenesis stimulator, electrical, non-invasive, spinal applications	3,191	4,318	35	25
B4197	Parenteral nutrition solution, 74 to 100 grams of protein—premix	260	322	24	17
A5500	For diabetics only, fitting, custom preparation and supply of off-the-shelf depth-inlay shoe	60	71	18	11
E0463	Pressure support ventilator used with invasive interface (e.g., tracheostomy tube)	1,125	1,561	39	19

Note: CBP (Competitive Bidding Program), DMEPOS (durable medical equipment, prosthetic devices, prosthetics, orthotics, and supplies), HCPCS (Healthcare Common Procedure Coding System), N/A (not applicable). Some of the figures are rounded. Because of data limitations, we were unable to determine the specific month of the capped rental period for K0606 in the private-payer data, which can affect the payment rate. Given this limitation and the fact that most Medicare beneficiaries use K0606 for three or fewer months, all private claims for K0606 were assumed to be from the first three months, which means that the private-payer rate in the above table is likely a lower bound in terms of comparing the rate to the Medicare payment rate for the first three months.

Source: MedPAC analysis of 2015 MarketScan Commercial Claims and Encounters Database; 2015 Medicare durable medical equipment and parenteral and enteral nutrition fee schedules; and 2015 Physician/Supplier Procedure Summary File.

more information, see the text box on payment rates for ventilators, p. 152.) For one product, a wearable automatic external defibrillator (AED), the Medicare and private-payer rates were relatively comparable. For the remaining seven products, roughly \$192 million dollars would have been saved in 2015 if Medicare paid the median private-payer rate for all such products—approximately \$154 million in savings for the Medicare program and \$38 million in savings for beneficiaries.

Medicare could likely save substantially more than \$192 million per year if non-CBP DMEPOS products' payment rates were set more appropriately, for two reasons. First, private-payer rates for some products outside the top 10 non-CBP DMEPOS products are lower compared with Medicare's payment rates. Second, in some instances,

Medicare could likely achieve a lower payment rate compared with private-payer rates; that is, private-payer rates likely represent an upper bound on appropriate Medicare DMEPOS payment rates.

Medicare's payment rates for some non-CBP DMEPOS products outside the top 10 highest expenditure products are higher than private-payer rates. For example, the two off-the-shelf orthotic codes included in Table 6-4 represented approximately \$218 million of the \$433 million in Medicare expenditures on off-the-shelf orthotics in 2015. For the remaining off-the-shelf orthotic codes with at least \$1 million in Medicare expenditures in 2015, we found that Medicare's payment rates ranged from 20 percent to 50 percent higher compared with private-payer rates and that Medicare would have saved an additional

Efforts to reduce potentially inappropriate utilization

In addition to implementing the competitive bidding program (CBP), CMS over the last several years has implemented broader initiatives that could reduce the rate of potentially inappropriate utilization, such as taking additional steps to identify aberrant or suspicious billing patterns among all Medicare fee-for-service claims before making payments and implementing new safeguards to better screen existing and new Medicare suppliers (Government Accountability Office 2016). Some have suggested expanding certain efforts to cover a broader range of products. Three examples of initiatives that could be expanded include:

- **Prior authorization.** Prior authorization is a process through which suppliers request a preliminary determination from CMS that a product is covered before submitting an actual claim. One advantage of prior authorization is that it stops many improper payments before they are made, instead of trying to recoup payments after they are made. CMS currently maintains a list of durable medical equipment, prosthetic devices, prosthetics, orthotics, and supplies (DMEPOS) products that could be subject to prior authorization, referred to as the “master list.” To be added to the master list, products must have an average fee schedule purchase price of \$1,000 or greater, or an average rental fee schedule of \$100 or greater (adjusted annually for inflation), and have been identified by the Office of Inspector General, Government Accountability Office, or CMS as susceptible to high rates of fraud, unnecessary utilization, or improper payments (42 CFR § 414.234).²⁰ From among the products on the master list, CMS has required prior authorization nationally for two power wheelchair products (Healthcare Common Procedure Coding System (HCPCS) codes K0856 and K0861) since July 2017. Separate from the national prior authorization process for these two codes, CMS has been running the Prior Authorization of Power Mobility Devices Demonstration since 2012. For the original seven states included in the demonstration, Medicare expenditures fell from roughly \$12 million per month to \$3 million per month one year after implementation and remained relatively steady thereafter (Centers for Medicare & Medicaid Services 2015c). Because prior authorization disproportionately affects suppliers who furnish products inappropriately, such a process could help reduce improper payment rates.
- **Face-to-face visits.** CMS requires face-to-face visits for some DMEPOS items, such as certain hospital beds, but not for others (e.g., knee or back braces).²¹ To meet the requirement, a physician, physician assistant, nurse practitioner, or a clinical nurse specialist must have had a face-to-face encounter with the beneficiary on the date the DMEPOS item was ordered or within six months before such date (42 CFR § 410.38(g)). The intent of requiring a face-to-face visit for certain items is to ensure that a beneficiary needs a particular DMEPOS product, based on a needs assessment conducted by a physician or other practitioner, before a product is dispensed.
- **Pricing, Data Analysis, and Coding (PDAC) contractor letters.** Among other duties, the PDAC contractor provides coding guidance to manufacturers on the proper use of HCPCS codes. Manufacturers submit a product to the PDAC contractor, and within 90 days the contractor issues a coding verification letter that delineates the HCPCS code(s) under which a product is billable. Some DMEPOS items already require a PDAC letter before suppliers can bill for them while others do not. Requiring PDAC letters for a broader array of items could represent a modest step to help limit “upcoding”—that is, suppliers furnishing a relatively inexpensive product and then submitting a claim for a more expensive product. ■

\$55 million in 2015 if Medicare’s payment rates were equal to the median private-payer rate of the comparable product.²² Other families of products, including bone growth stimulators, catheters, parenteral nutrition, and

diabetic shoes/inserts, also have products not included in Table 6-4 for which Medicare could have achieved additional savings if Medicare’s payment rates were lowered to private-payer rates.

CMS revised the payment rates for ventilators in 2016

In 2015, 2 of the 10 highest expenditure durable medical equipment, prosthetic devices, prosthetics, orthotics, and supplies (DMEPOS) products excluded from Medicare's Competitive Bidding Program (CBP) were ventilators (Healthcare Common Procedure Coding System (HCPCS) codes E0464 and E0463). Billing for these products grew rapidly from 2010 through 2015. For example, Medicare expenditures for noninvasive pressure support ventilators (E0464) grew from \$9 million to \$343 million over that time period, an average annual growth rate of 107 percent. In a 2016 report, the Office of Inspector General noted that the rise in ventilator billing was related to a change in technology that allowed the same machine to function as a ventilator, continuous positive airway pressure (CPAP) device, or respiratory assist device (RAD) (Office of Inspector General 2016). Compared with ventilators, CPAPs and RADs are used to treat lower acuity patients.

Beginning in 2016, CMS changed the way it paid for ventilators by collapsing five ventilator HCPCS codes into two codes (Centers for Medicare & Medicaid Services 2015b). Specifically, in 2015, CMS was paying for five ventilator HCPCS codes using two different

methodologies. Since being added to the fee schedule in 2005, the payment rates for E0464 and E0463 were based on manufacturer suggested retail prices; these codes were intended to represent specific types of ventilators, such as those used by pediatric patients. In contrast, the payment rates for the older ventilator codes were based on supplier charges from 1986 to 1987. The latter payment method resulted in substantially lower payment rates. As evidence of abuse related to the newer, higher paid codes (E0464 and E0463) mounted, CMS, beginning in 2016, used its authority to base DMEPOS payment rates on 1986–1987 supplier charges for all ventilators. Between 2015 and 2016, this change resulted in the median monthly rental rate for products historically billed under E0464 and E0463 going from \$1,561 to \$1,055, a reduction of 32 percent.

While the change reduced overpayments, it is unclear whether the new payment rates represent appropriate prices. Specifically, the payment rates are still based on supplier charges that are 30 years old, updated over time for inflation. CMS proposed including noninvasive pressure support ventilators in CBP Round 1 2017 but removed the product before the round began. ■

While private payers might have negotiated payment rates that were lower than Medicare for products excluded from the CBP, private-payer rates might not represent the best price that Medicare could achieve. Recent research suggests that average CBP Round 1 rebid payment rates were 8.1 percent lower than commercial prices for several common DMEPOS products (Newman et al. 2017). Further, Medicare's payment rates generally continued to fall in subsequent CBP rounds. To further illustrate the point that private-payer rates likely represent an upper bound on Medicare rates, we looked at the direct-purchase price—that is, the price at which beneficiaries could purchase a DMEPOS product outside of insurance coverage—for two off-the-shelf orthotic codes.

Direct-purchase price for off-the-shelf orthotic codes

To identify specific products (e.g., manufacturer and model) that could be billed under the off-the-shelf orthotic

codes—L0650 (back brace) and L1833 (knee brace)—we identified what products were certified as payable under those two HCPCS codes through CMS's Pricing, Data Analysis, and Coding contractor. We then selected several approved products and conducted an internet search to determine the prices at which these products could be directly purchased. For the off-the-shelf back brace, the median private-payer rate in 2015 was \$877; we found multiple products eligible to be billed under that HCPCS code that could be purchased for less than \$250. For the off-the-shelf knee brace, the median private-payer rate in 2015 was \$436; we found multiple products eligible to be billed under that HCPCS code that could be purchased for less than \$150.

A large number of braces can be billed under each of these HCPCS codes we examined. The limited number of examples we examined were not designed to be statistically representative, and other braces

that are billable under these HCPCS codes could be substantially more expensive. However, previous OIG work substantiates our finding. Specifically, in 2012, OIG reported that, for one type of back brace, Medicare paid an average of \$919 compared with an average of \$191 paid by suppliers to acquire the braces (Office of Inspector General 2012). Furthermore, the magnitude of the differences between the private-payer rates and the direct-purchase prices suggest that the private-payer rates, while already below Medicare's rates, do not necessarily represent the lowest payment rates that Medicare could potentially obtain.

Policy options to improve the accuracy of Medicare's payment rates for non-CBP DMEPOS products and protect beneficiaries

Shifting additional products into the CBP

The Commission supports shifting additional DMEPOS products from being paid on a fee schedule basis to being included in the CBP. Medicare's reliance on outdated and inflated pricing information (e.g., 30-year-old supplier charges and unadjusted list prices) to set payment rates for non-competitively bid DMEPOS products results in excessive payment rates. Setting payment rates too high also creates incentives for higher volume, financially burdens beneficiaries and taxpayers, and encourages fraud and abuse. Shifting more products into the CBP is consistent with the Commission's long-held support of payment accuracy in FFS payment systems. Payment rates should be high enough to ensure beneficiary access to needed products and low enough to encourage efficient provision of those products.

The CBP has been operating for over seven years and has effectively reduced excessive payment rates, reduced the financial burden on beneficiaries and taxpayers, and been an important tool to combat fraud and abuse. CMS's health status monitoring program has helped ensure beneficiaries maintain access to needed DMEPOS items and is more advanced than outcomes monitoring in many other sectors.

CMS currently has the authority to include some additional products in the CBP. Examples of such products include chest wall oscillation devices, ventilators, and off-the-shelf orthotics.

However, CMS is statutorily prohibited from including other groups of products in the CBP. Many of these products are likely good candidates for the CBP because multiple suppliers furnish the products, and Medicare's payment rates appear to be substantially higher than private-payer rates. For example, CMS is statutorily prohibited from including parenteral nutrition in the CBP, despite the fact that we found Medicare's payment rate for the highest expenditure parenteral nutrition product was 24 percent higher compared with private-payer rates in 2015, and the agency already has substantial experience successfully bidding out a similar product—enteral nutrition. In another case, Medicare's payment rate for the highest expenditure bone growth stimulator product is even higher relative to private payers—roughly 35 percent higher—but CMS is prohibited from including such products in the CBP because they are Class III devices.²³

For a third group of products, CMS's authority is unclear or additional legislative authority would likely be beneficial. In the case of ostomy, tracheostomy, and urological supplies (e.g., catheters), we found two products for which Medicare's payment rates were 45 percent and 57 percent higher than private-payer rates. CMS has stated that it has the authority to include certain medical supplies in the CBP (Centers for Medicare & Medicaid Services 2007). However, compared with other products, the legal authority to do so appears to be less clear. An explicit grant of authority could accelerate the inclusion of these products into the CBP and protect the agency from potential legal challenges. In the case of orthotics, CMS has the authority to include only off-the-shelf products in the CBP. Including only off-the-shelf orthotics in the CBP would likely lower costs and reduce inappropriate unitization. However, including a broader array of orthoses in the CBP would likely better protect Medicare by eliminating the incentive that suppliers would have to shift utilization from off-the-shelf products to more customizable products. For example, if only off-the-shelf orthotics were included in the CBP, some suppliers who did not win a contract might simply switch to billing for more custom-fitted braces, which are prefabricated products that require substantial modification by a trained practitioner. This behavior would be especially likely, given that many prefabricated products are approved to be billed under two codes—an off-the-shelf code if no customization is done and a custom-fitted code if the device is customized. We have found that, in the past, suppliers have rapidly shifted the types of products they bill for based on the incentives they face (see text box on back braces, p. 154).

Suppliers can rapidly shift utilization between off-the-shelf and custom-fitted back braces

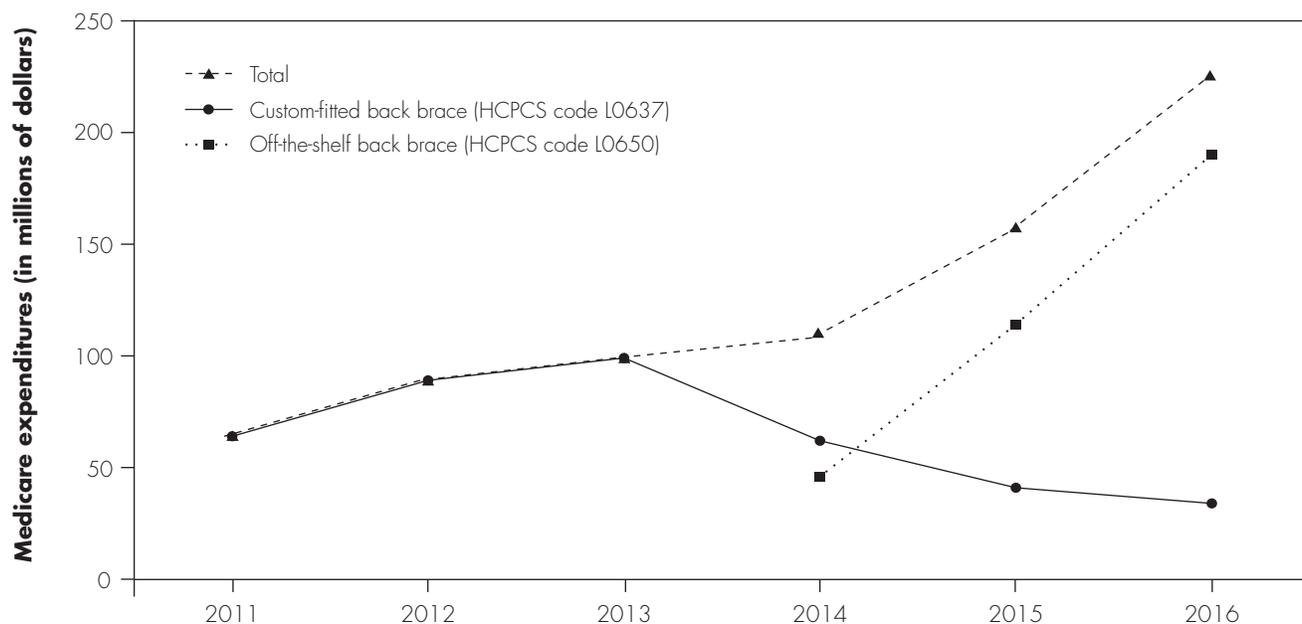
In 2014, CMS split many orthotic Healthcare Common Procedure Coding System (HCPCS) codes into two separate codes—one for off-the-shelf products (prefabricated products that require minimal self-adjustment) and another for custom-fitted products (prefabricated products that require substantial modification by a trained practitioner). For example, CMS split a back brace product into L0650 (an off-the-shelf product) and L0637 (a custom-fitted product). The payment rates for the new codes are the same, but suppliers that bill for custom-fitted products are subjected to additional quality requirements (e.g., Appendix C of the DMEPOS Quality Standards) (Centers for Medicare & Medicaid Services 2016c).

Therefore, suppliers currently have an incentive to furnish off-the-shelf instead of custom-fitted products.

Suppliers quickly responded to this incentive. In the three years following this coding change, Medicare spending for the off-the-shelf back brace increased rapidly, while spending for the custom-fitted brace decreased rapidly. Specifically, from 2014 to 2016, Medicare's expenditures for the off-the-shelf back brace increased by over 300 percent (\$46 million to \$190 million) compared with a decrease of nearly 50 percent for the custom-fitted back brace (\$62 million to \$34 million) over the same time period (Figure 6-3). This example suggests that suppliers can rapidly shift utilization between off-the-shelf and custom-fitted orthoses. ■

FIGURE 6-3

Suppliers rapidly shifted to billing for off-the-shelf back braces following a 2014 coding change



Note: HCPCS (Healthcare Common Procedure Coding System).

Source: MedPAC analysis of Medicare fee-for-service durable medical equipment claims.

If the Congress grants CMS additional authority, then requiring a date by which the products must be incorporated into the CBP could be helpful, but flexibility regarding the manner in which the products are

incorporated is likely important. In the past, the Congress has mandated that CMS make changes to the CBP by certain dates, which, to some extent, protects the agency from industry pressure to delay the program. The deadline

should reflect the level of effort required by CMS. For instance, the agency would need to design any special rules for the new product categories, solicit industry feedback, and incorporate the new products into its health status monitoring program. To expedite the inclusion of new products, the agency could be given the flexibility to phase in bidding in a small number of areas or bid out the new products only in a limited number of areas and use that information to adjust the fee schedule in the rest of the country.

As the agency has done in the past, CMS could consider allowing physicians and other providers, such as hospitals, to furnish CBP products to their own patients at the single payment amount without bidding or being contract suppliers. To further encourage continuity of care, policymakers could also consider allowing hospitals to furnish certain products to their patients without undergoing a DMEPOS accreditation process, similar to the accreditation exemptions currently allowed for physicians and other suppliers.²⁴ While allowing noncontract suppliers to provide DMEPOS products could drive down the value of winning a contract and result in higher single payment amounts, they could also allow for greater convenience and continuity of care for beneficiaries. We found that physicians, hospitals, physical therapists, and orthotists furnished a minority of the off-the-shelf back brace product we studied and are not driving the increase in utilization and expenditures for such products. Therefore, for the back braces we examined, exempting such providers would likely increase continuity of care without substantially affecting the operation of the CBP. CMS could also monitor the implementation of such policies to make sure that the exceptions were not abused.

DMEPOS products that are not good candidates for the CBP

Regardless of CMS's authority to add certain products to the CBP, some DMEPOS products are not good candidates for inclusion in the CBP. Two such types of products are those with small Medicare FFS markets and those without a sufficient number of suppliers to produce lower prices through competition.²⁵

First, even if there is sufficient competition, DMEPOS products with a small Medicare FFS market could be excluded from the CBP. The principle underlying this notion is that the administrative costs of incorporating products into the CBP should not exceed the potential savings.²⁶ Second, the CBP relies on competition among suppliers to produce lower payment rates. If insufficient

competition exists, the CBP will not produce savings, but CMS will still incur the administrative costs of including such products in the CBP. Table 6-5 (p. 156) provides some basic information on the competitiveness of the 25 highest expenditure non-CBP DMEPOS products in 2015, using Medicare FFS claims.

As the results in Table 6-5 indicate, in 2015, wearable AEDs (HCPCS code K0606) did not have sufficient competition to include them in the CBP. From 2010 to 2016, Medicare FFS expenditures on wearable AEDs totaled \$760 million and grew at an average annual rate of 42 percent per year, reaching \$204 million in 2016 alone. Medicare's payment rate for wearable AEDs is likely excessive as a result of basing the rate on the undiscounted manufacturer suggested retail price of the only company who manufactured the product (see text box on wearable AEDs, p. 157, for more information).

Allowing manufacturers or suppliers, and especially those who face little competition, to functionally set Medicare's payment rates for their own products and then largely increase those rates by inflation over time leads to excessive payment rates. Given the fact that large payment declines have occurred when products are added to the CBP, policymakers could consider directing CMS to reduce the payment rates for wearable AEDs and other products that are excluded from the CBP and that meet certain other criteria, such as rapid utilization growth, that indicate a potentially mispriced product. Future Commission work could also further examine how to more rationally set fee schedule rates for DMEPOS products when including them in the CBP is not practical.

Limiting balance billing and encouraging supplier participation to protect beneficiaries

Another policy option for policymakers to consider is changing Medicare's assignment and participation rules for DMEPOS products and suppliers to better protect beneficiaries. Unlike many other suppliers, DMEPOS suppliers are generally not required to accept Medicare's payment rate as payment in full (i.e., assignment is not mandatory) outside of CBP products furnished to beneficiaries who reside in CBAs, and there is no limit on balance billing (i.e., billing beneficiaries beyond the standard 20 percent coinsurance) when assignment is not mandatory.²⁷ Also, DMEPOS suppliers do not face the 5 percent payment reduction that physicians do when they enroll as nonparticipating (a status that allows physicians and other suppliers to bill unassigned on a claim-by-claim basis).²⁸ As a result, DMEPOS suppliers are far more

**TABLE
6-5**

Number of companies supplying products varied among the 25 highest expenditure non-CBP DMEPOS products in 2015

HCPCS code	Product description	Number of companies		Share of product's allowed charges accounted for by top three companies
		All	With at least 1 percent of product's allowed charges	
E0464	Pressure support ventilator used with non-invasive interface (e.g., mask)	633	11	44%
K0606	Automatic external defibrillator, with integrated electrocardiogram analysis, garment type	1	1	100
A4351	Intermittent urinary catheter, straight tip	3,086	15	43
L0650	Lumbar-sacral orthosis, off-the-shelf	1,073	23	15
L1833	Knee orthosis, off-the-shelf	1,402	19	33
A4352	Intermittent urinary catheter, curved tip	1,492	16	45
E0748	Osteogenesis stimulator, electrical, non-invasive, spinal applications	137	4	87
B4197	Parenteral nutrition solution, 74 to 100 grams of protein	345	19	27
A5500	For diabetics only, fitting, custom preparation and supply of off-the-shelf depth-inlay shoe	8,861	4	6
E0463	Pressure support ventilator used with invasive interface (e.g., tracheostomy tube)	402	15	20
L0648	Lumbar-sacral orthosis, off-the-shelf	1,307	17	16
A5513	For diabetics only, multiple density insert, custom fabricated	5,413	7	9
A4353	Intermittent urinary catheter, with insertion supplies	937	17	31
L5673	Addition to lower extremity, below knee/above knee, custom fabricated from existing mold or prefabricated	1,267	4	23
A5512	For diabetics only, multiple density insert, direct formed, molded to foot after external heat source of 230 degrees fahrenheit or higher, prefabricated	6,816	2	4
L5301	Below knee, molded socket, shin, SACH foot, endoskeletal system	1,176	3	23
K0861	Power wheelchair, group 3 standard, multiple power option, sling/solid seat/back, patient weight capacity up to and including 300 pounds	501	15	29
B4199	Parenteral nutrition solution, over 100 grams of protein	249	21	27
L0637	Lumbar-sacral orthosis, prefabricated item that has been customized to fit a specific patient by an individual with expertise	1,913	10	6
L5856	Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s)	444	8	27
A6021	Collagen dressing, sterile, size 16 sq. in. or less	656	11	48
L5700	Replacement, socket, below knee, molded to patient model	1,102	4	23
B4193	Parenteral nutrition solution, 52 to 73 grams of protein	268	13	32
A4407	Ostomy skin barrier, with flange, extended wear, with built-in convexity, 4x4 inches or smaller	2,114	10	49
E0483	High frequency chest wall oscillation air-pulse generator system	96	3	93

Note: CBP (Competitive Bidding Program), DMEPOS (durable medical equipment, prosthetic devices, prosthetics, orthotics, and supplies), HCPCS (Healthcare Common Procedure Coding System), SACH (solid ankle cushion heel). We define "companies" as unique tax ID numbers.

Source: 2015 durable medical equipment 100 percent standard analytic file.

Rapid expenditure growth and high Medicare payment rates for wearable AEDs

The wearable automatic external defibrillator (AED) was approved by the Food and Drug Administration in 2001 and is designed for patients at risk of sudden cardiac death who are not immediate candidates for an implantable cardioverter-defibrillator (ICD), such as patients at risk of sudden cardiac death but who have an active infection or whose clinical condition continues to improve (and therefore might not need an ICD) (Piccini et al. 2016). While technologically similar to nonwearable AEDs, wearable AEDs have the clinical advantage of not needing another individual present to initiate defibrillation.

Between 2010 and 2016, Medicare expenditures for wearable AEDs increased from approximately \$25 million to \$204 million, an average annual growth rate of 42 percent. Wearable AEDs are capped rental items, meaning that Medicare pays a monthly fee for beneficiaries to rent the product from a supplier for up to 13 months. If the beneficiary uses the device for less than 13 months, the device is returned to the supplier; if the beneficiary uses the device for 13 months, ownership is transferred to the beneficiary. In 2018, Medicare's payment rate for a wearable AED is about \$2,800 per month for the first 3 months and about \$2,100 for months 4 through 13. Given Medicare's formula for determining the monthly payment rates for capped rental items (i.e., the payment rate for the first month is 10 percent of the purchase price), Medicare's implied purchase price for a wearable AED is over \$28,000 in 2018.

The implied purchase price for wearable AEDs is substantially higher compared with direct-purchase prices of nonwearable AEDs. Specifically, nonwearable AEDs can commonly be purchased directly for \$1,500 to \$2,000 (American Heart Association 2017). Thus, Medicare's implied purchase price for a wearable AED is roughly 15 times higher than the purchase price of a nonwearable AED.

While a reasonable payment rate for wearable AEDs is likely based on a price somewhat higher than the purchase price of nonwearable AEDs (e.g., to account for the additional functionality, the cost of refurbishing the device between beneficiary rentals, etc.), several facts—beyond the magnitude of the price difference between wearable and nonwearable AEDs—suggest that Medicare's payment rate is potentially excessive. First, Medicare's payment rate is based on the undiscounted manufacturer suggested retail price of the only company that manufactured the product (Centers for Medicare & Medicaid Services 2006). The lack of competition means the sole manufacturer had an opportunity to set a price as high as possible. Second, the manufacturer's own data, submitted as part of the Healthcare Common Procedure Coding System code assignment process, suggested the median manufacturing cost was under \$8,000 in 2003 (Centers for Medicare & Medicaid Services 2006). Medicare's \$28,000 implied purchase price far exceeds that figure and leads to high gross profit margins. For example, for the fiscal year ending in October 2011, the gross profit margin for wearable AEDs appears to be greater than 50 percent (Zoll Medical Corporation 2011).²⁹ ■

likely to enroll as nonparticipating suppliers compared with other providers. For example, in 2016, more than 60 percent of DMEPOS claim lines were submitted by nonparticipating suppliers. In contrast, less than 5 percent of physicians generally enroll as nonparticipating (Boccuti 2016).

Historically, DMEPOS assignment rates have remained high despite the fact that suppliers have commonly enrolled as nonparticipating suppliers (and therefore have the ability to bill on an unassigned basis). One

explanation could be that payment rates have generally been adequate or excessive, so suppliers that routinely balance billed beneficiaries would have likely lost business to other DMEPOS suppliers that could profitably furnish the products on an assignment basis. As payment rates for DMEPOS products are reduced to more appropriate levels and less efficient suppliers drop out of the market, the remaining DMEPOS suppliers could try to account for some of their lost revenues by balance billing beneficiaries.

Therefore, while nonparticipating suppliers have largely not exercised their ability to bill on a nonassigned basis, the large pool of nonparticipating suppliers poses a risk to Medicare beneficiaries should these suppliers begin to balance bill in response to falling payment rates. To mitigate that risk and to better align DMEPOS policies with the rest of Medicare, policymakers could consider capping balance billing and reducing the allowed fee schedule amount by 5 percent for nonparticipating DMEPOS suppliers. The balance billing cap could be set equal to the physician fee schedule cap—115 percent—or somewhat higher (e.g., 125 percent) to the extent policymakers want to allow for added flexibility.

Physician-owned distributors

Physician-owned distributors (PODs) allow physicians to profit from the sale of medical devices they use. Specifically, PODs are entities that derive revenue from selling, or arranging for the sale of, devices ordered by their physician-owners for use in procedures the physician-owners perform on their own patients. The primary concern with PODs is that such entities create an incentive for physicians to base their preferences, such as whether to operate on a patient and which instrumentation to use, on financial rather than clinical considerations.

PODs have historically been concentrated in the market for implantable medical devices (IMDs), and the spinal implant market in particular.³⁰ The IMD market is particularly fertile ground for PODs for several reasons. First, hospitals typically purchase IMDs, so any higher costs associated with POD-supplied devices are not borne by the physician-owners. Second, physicians have traditionally had significant influence on hospitals' purchasing decisions, so they can help channel hospitals' device purchases to their PODs. According to a 2013 OIG report, 94 percent of hospitals that purchased from PODs reported that surgeon preference influenced their decision to purchase from PODs (Office of Inspector General 2013c). Hospitals have historically been willing to accommodate such preferences due to physicians' ability to control patient referrals and the profitability of surgical lines of business.

Types of PODs

PODs are commonly structured using one of three models—a distributor, manufacturer, or group purchasing organization (GPO) model:

- **Distributor model.** IMD manufacturers traditionally sell and distribute their products directly to hospitals. Under the distributor model, PODs operate as intermediaries between device manufacturers and hospitals; that is, a device manufacturer sells a device to a POD, and the POD resells the device to a hospital at a higher price.
- **Manufacturer model.** Under the manufacturer model, PODs typically sell devices that another company manufactures on their behalf. For example, a manufacturer POD might obtain a Food and Drug Administration clearance to market a relatively simple device, such as a surgical screw, and outsource its production to a contract manufacturer.
- **GPO model.** Under this model, physicians reportedly form a POD to aggregate their purchasing power and get bulk discounts from manufacturers. However, given the small size of PODs, it is unclear the amount of negotiating leverage such entities would have with manufacturers relative to the hospital itself or other, larger GPOs.

Prevalence of PODs and their impact on Medicare

Relatively little is known about the current prevalence of PODs. OIG found that PODs supplied spinal devices for nearly one in five spinal fusion surgeries billed to Medicare in 2011 and that roughly a third of hospitals purchased such devices from PODs in the same year (Office of Inspector General 2013c).^{31,32} While these data suggest that the use of PODs was relatively widespread as of 2011, OIG released a special fraud alert in 2013, calling PODs “inherently suspect” under the anti-kickback statute (AKS) (Office of Inspector General 2013b). The special fraud alert caused some hospitals to reevaluate whether purchasing devices from PODs was worth the legal risk, and some ceased doing business with PODs. However, industry stakeholders have suggested that, while the special fraud alert slowed the spread of PODs, many PODs continue to operate, and a 2016 report from the Senate Finance Committee found PODs were operating in 43 states as of December 2015 (U.S. Senate Committee on Finance 2016).

Even though Medicare does not directly pay for most IMDs, PODs raise several concerns for the Medicare program and beneficiaries:

- **Increased volume.** Physicians who own PODs have an incentive to refer more patients for surgery because more surgeries result in more devices used. For some

spinal conditions, appropriate treatments can range from physical therapy to intensive surgical procedures, so physician-induced demand could be a larger issue in this area compared with areas in which clinical guidelines are more prescriptive.

- **Increased intensity.** Physicians who own PODs have an incentive to use more devices in a given case or refer patients for more intense procedures that require more devices.
- **Inappropriate care.** PODs' financial incentives could encourage physicians to refer patients for surgery inappropriately, and, because they have a financial interest in choosing devices that their PODs sell, to use devices of inferior quality or that are not best suited for a procedure (U.S. Senate Committee on Finance 2016).
- **Higher device costs.** PODs profit from selling or arranging for the sale of devices at the highest possible price. Higher device prices put pressure on hospital margins and can contribute to calls for higher reimbursements from Medicare.

Data from OIG and an example from a POD prosecuted by the Department of Justice substantiate some of the concerns about PODs. Specifically, OIG found the following:

- The rate of spinal surgery grew faster among hospitals that began purchasing devices from PODs compared with all hospitals (16 percent vs. 5 percent, respectively).
- The rate of spinal fusions—a subset of spinal surgeries that are more likely to use devices—grew faster among hospitals that acquired devices from PODs compared with all hospitals (21 percent vs. 9 percent, respectively).
- None of the six types of spinal devices examined was less costly per unit when purchased through a POD, and one—spinal plates—cost \$845 more on average when supplied by a POD (\$2,475 vs. \$1,630) (Office of Inspector General 2013c).³³

One example of a POD's financial incentives warping clinical judgment involves a series of cases brought by the Department of Justice against Dr. Aria Sabit, a POD in which Sabit was an investor (Apex Medical Technologies), and others (e.g., Reliance Medical Systems). Sabit was allegedly paid an average of \$17,000 per month by the

POD in which he invested over the course of more than two years (United States of America vs. Reliance Medical Systems et al. 2014). Three other physician-owners are alleged to have received similar or higher monthly payments from their PODs (United States of America vs. Reliance Medical Systems et al. 2014). In one of these cases, Sabit pled guilty and was sentenced in 2017 (Department of Justice 2017). In connection with his guilty plea, Sabit admitted the following:

- The financial incentives provided to him by his POD caused him to use more spinal implant devices than were medically necessary to treat his patients in order to generate more sales revenue for his POD, which resulted in serious bodily injury to his patients.
- The money he made from using his POD's spinal implant devices motivated him either to refer patients for unnecessary spine surgeries or for more complex procedures that they did not need (Department of Justice 2017).

Application of the anti-kickback statute and Stark law to PODs

Two federal laws are critical to determine the legality of a POD—the AKS and the Stark law. The AKS generally makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce referrals of federal health care program enrollees for the furnishing or arranging for the furnishing of items or services reimbursable by federal health care programs. In the case of PODs, the kickback would be the payment physicians receive from their POD for arranging for the furnishing of the POD's devices purchased by hospitals for use on the physician's patients. To violate the AKS, a person or entity must offer, pay, solicit, or receive remuneration to induce the referral with knowledge that the conduct is wrongful—that is, the government must prove intent.

OIG has suggested that PODs are “inherently suspect” under the AKS, and some industry stakeholders echo that sentiment. However, other industry stakeholders suggest that PODs may be structured to avoid violating the AKS. In practice, government prosecutions of PODs on AKS grounds have been limited. Government enforcement actions against PODs may be rare at least partly because the AKS requires proof of intent, which can be difficult to prove in court. The limited number of prosecutions and the difficulty in proving AKS cases suggest that the Stark law may need to be revised to more effectively limit the use of PODs.

The Stark law is intended to prohibit physicians from referring Medicare beneficiaries to certain health care facilities in which they have a financial interest. Specifically, the Stark law (1) prohibits a physician from making referrals for designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless an exception applies; and (2) prohibits the entity from filing claims with Medicare for those referred DHS, unless an exception applies. This prohibition is based on the premise that physicians have a conflict of interest in such situations because they have significant influence over patient referrals and directly profit from referring their patients to facilities in which they have a financial interest. Opponents of PODs suggest that the incentives inherent in PODs violate the intent of the Stark law and may also often violate the letter of the law (AdvaMed 2016). CMS has also said that PODs may run afoul of the Stark law (Centers for Medicare & Medicaid Services 2008b). However, others believe that PODs can be structured to comply with the Stark law, and, to our knowledge, no POD has yet been prosecuted based on a violation of the Stark law.

The principal sanction for violating the Stark law is denial of payment for any claims involving DHS arising from a prohibited referral. (Knowing violations of the Stark law can also trigger civil monetary penalties and False Claims Act liabilities.) Unlike the AKS, the government does not need to prove intent; instead, parties are strictly liable for Stark law violations, even inadvertent ones.

A wide range of services are considered DHS, including clinical laboratory services, radiology services, and physical therapy services. Importantly for the application of the Stark law to PODs, IMDs are not DHS, but hospital inpatient and outpatient services are. Generally, a “DHS entity” is any person or entity that performs DHS or bills Medicare for DHS. For example, in the case of a physician who refers his or her patient to receive spinal fusion as a hospital inpatient procedure, the DHS is the inpatient facility service, and the DHS entity is the hospital. Even if a POD sold the devices used in the fusion to the hospital, the POD is not a DHS entity because it neither performs nor bills Medicare for the DHS.

Broadly, the Stark law defines two types of financial relationships—ownership/investment arrangements and compensation arrangements. Either type of relationship may be direct, meaning the relationship is between the DHS entity and physician, or indirect, meaning there is

some intervening entity between the DHS entity and the physician. Establishing that a financial relationship exists and the type of relationship is important in applying the Stark law and determining whether an exception applies because some exceptions apply to only one type of financial relationship.

An ownership relationship means that a physician has an ownership or investment interest in a DHS entity (e.g., a physician who owns a clinical laboratory). There are relatively few ownership exceptions, and some believe that the application of the Stark law to ownership/investment relationships has been relatively effective in reducing physician investment in DHS entities and straightforward to regulate compared with compensation arrangements. However, PODs are not DHS entities, so the Stark law does not prohibit physician ownership or investment in PODs.

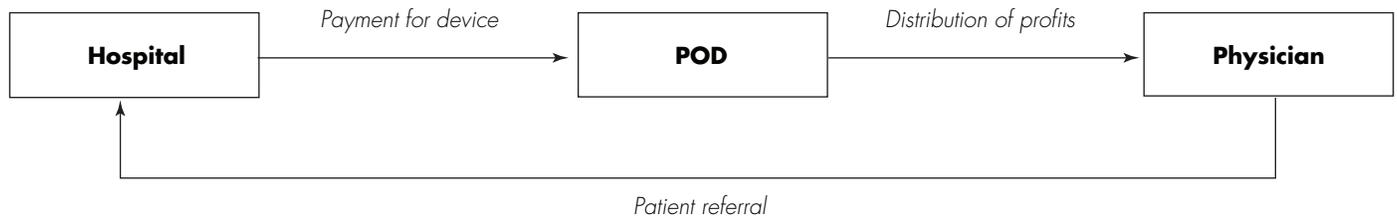
The second type of financial relationship is a compensation arrangement between a DHS entity and a referring physician. Again, compensation arrangements can be either direct or indirect. Because PODs are not DHS entities, financial arrangements between PODs and physicians do not typically create direct compensation arrangements.

The inclusion of indirect compensation arrangements in the Stark law is intended to prevent DHS entities and physicians from circumventing the Stark law by channeling an otherwise prohibited arrangement through other entities. To be categorized as an indirect compensation arrangement for the purposes of the Stark law, three conditions must be met:

- There must be an unbroken chain of financial arrangements between a DHS entity and the referring physician.
- The referring physician receives aggregate compensation from the person or entity in the chain with which the physician has a direct financial relationship (e.g., the POD) that varies with the volume or value of referrals generated by the referring physician for the entity furnishing the DHS (e.g., the hospital).
- The entity furnishing the DHS (e.g., the hospital) knows or recklessly disregards evidence that the referring physician receives aggregate compensation that varies with the volume or value of referrals to the DHS entity.

**FIGURE
6-4**

Illustrative example of an indirect compensation relationship between a hospital and a physician-owner of a POD



Note: POD (physician-owned distributor).

Source: MedPAC analysis of Stark law and POD–physician relationships.

For PODs, the unbroken chain often consists of the physician’s ownership interest in the POD and the POD’s sale of devices to a hospital (Figure 6-4). In general, the referring physician’s aggregate compensation from a POD should vary with the volume or value of referrals generated. For example, a physician’s return on investment is often a portion of the POD profits, which in turn takes into account sales of devices used by the physician in procedures he or she referred to the hospital. Given that devices often cost hospitals thousands of dollars per case, hospitals should be aware that referring physicians who own PODs increase their payments from PODs as the number of referrals increase. Therefore, PODs selling medical devices to a hospital where physician-owners use the devices in their inpatient or outpatient surgeries appears to create an indirect compensation arrangement between the referring physician and the hospital.

Once a financial relationship between a physician and a DHS entity is established, that physician is prohibited from referring Medicare beneficiaries to the DHS entity unless an exception applies. While there are many exceptions for direct compensation arrangements, there is only one for indirect compensation arrangements. The indirect compensation exception has the following key elements:

- the compensation arrangement is set out in writing, signed by the parties, and specifies the services covered by the arrangement;

- the compensation arrangement does not violate the AKS;
- the compensation received by the referring physician from the entity with which he or she has a direct financial relationship must be fair market value; and
- the compensation received by the physician from the entity with which he or she has a direct financial relationship does not take into account the volume or value of referrals by the referring physician for the entity furnishing the DHS.

Meeting the first requirement appears to be perfunctory. As for the second, most PODs that avoid suspect characteristics appear to not violate the AKS or, at least, have not been prosecuted for doing so. With respect to the third element, the compensation received by the referring physician from a POD will generally be at fair market value if the devices sold by the POD are sold at competitive prices. While this provision might prevent substantially aberrant pricing, the price paid for the same device often varies substantially from one hospital to another, so there is likely substantial leeway in how PODs price their devices while still meeting the fair market value test. Regarding the last element, the payments physicians receive from their PODs do vary based on their referrals to the hospital. PODs would therefore appear to fail the last criterion needed to qualify for the indirect compensation exception. However, the compensation can be deemed not to take into account referrals so long as it complies with the “per unit of service” rule.

The “per unit of service” rule states that unit-based compensation is deemed not to take into account the volume or value of referrals if the compensation per unit is fair market value and does not vary during the course of the arrangement in any manner that takes into account referrals of DHS.³⁴ For example, if a hospital agrees to pay a POD \$1,000 per pedicle screw over the course of a year, such an arrangement should meet the “per unit of service” rule so long as \$1,000 is a fair market price for a pedicle screw and the \$1,000 price does not increase or decrease based on referral patterns.

Potential revisions to the Stark law

The Commission questions the value PODs produce for the Medicare program and beneficiaries. The conflict of interest that PODs create is the type of problem the Stark law was designed to solve—providers’ self-interest unduly influencing medical decisions. Unlike the AKS (which has proved ill equipped to limit the use of PODs), the Stark law does not require the government to prove intent for a violation to have occurred. The goal of any change to the Stark law would not be to ban PODs per se, but rather to prohibit physician self-referral involving PODs (i.e., to limit the use of PODs).

While there are several ways the Stark law could be revised to limit the use of PODs, the Commission has discussed two specific revisions: (1) eliminating the application of the “per unit of service” rule to PODs and (2) making PODs DHS entities.

The “per unit of service” rule appears to be key in allowing self-referral involving PODs that would otherwise violate the Stark law. Referring physicians commonly receive *aggregate* compensation from their PODs that varies with the volume or value of referrals to hospitals. Such compensation creates an indirect compensation arrangement for the purposes of the Stark law and would normally result in a prohibition of POD owners referring patients for surgeries in which their PODs supplied the devices. However, the “per unit of service” rule deems such arrangements to not take into account the volume or value of physician referrals if the *per unit* compensation is fair market value and does not vary during the course of the arrangement based on referral patterns. Therefore, the only reason referrals in such arrangements appear to be legal under the Stark law is due to the “per unit of service” rule, and, as a consequence, eliminating the rule’s application to PODs would prohibit physicians from referring their patients for surgeries in which their PODs supplied the devices, unless another exception applied.

There is a precedent for making such a change. In 2008, CMS revisited the “per unit of service” rule as it applied to space and equipment leases. The revised rule prohibited physicians from renting an imaging machine, for instance, on a per unit or “per click” basis to a hospital (i.e., the physician gets paid every time the machine is used) and then referring their patients to use that imaging machine. CMS said that such arrangements create the incentive for overutilization; provide the incentive for the physician lessor to refer patients to the lessee of the physician’s space or equipment (rather than to entities that may employ a different, and possibly more appropriate, treatment modality); and may foster anticompetitive behavior because entities (e.g., hospitals) may enter into such agreements due to fears of losing the physician lessor’s referrals (Centers for Medicare & Medicaid Services 2008a).

In defending its proposal to no longer allow “per click” equipment and space leases, CMS said that the agency monitors financial arrangements in the health care industry and revises its regulatory decisions as evidence of abuse or overutilization changes. Therefore, eliminating the application of the “per unit of service” rule to PODs could be seen as a logical extension of CMS’s regulatory history of modifying the application of the rule as evidence of potential abuse presents. Also, as was the case for the 2008 revision, CMS could possibly make such a change without any new legislative authority.

The second potential revision to the Stark law entails classifying PODs as DHS entities. Under such a change, physicians who have an ownership stake in PODs would have an ownership stake in a DHS entity and would therefore be prohibited from referring their patients for services that use devices supplied by their PODs, unless another exception applied. For example, there is an ownership exception for an entity that furnishes at least 75 percent of its DHS to residents of rural areas. Therefore, if PODs were reclassified as DHS entities, the rural exception would need to be amended to limit the use of PODs in rural areas.

Reclassifying PODs as DHS entities would be a departure from how CMS currently defines a DHS entity and would, therefore, require some additional accommodations. For example, the principal penalty for a Stark law violation is nonpayment of a claim, and given that PODs do not submit claims to Medicare, specific rules stipulating how PODs, hospitals, or both would be held accountable for Stark law violations involving PODs would likely

be needed. Furthermore, CMS will likely require new legislative authority to classify PODs as DHS entities.

If the Stark law is amended, policymakers would face several decisions to adapt the law to limit the use of PODs, including defining a POD, considering whether additional exceptions to protect device innovation are warranted, and implementing any changes.

Defining a POD

The Stark law currently does not define PODs. Therefore, a definition of PODs would need to be added to the Stark law. To ensure that the definition of PODs captures as many PODs as possible (and as few non-POD entities as possible), the definition should include characteristics that are common to all PODs, include characteristics as distinct as possible from non-POD entities, cover all three types of known POD models (distributor, GPO, and manufacturer), and be flexible enough to cover idiosyncratic design features that do not alter the basic incentives of PODs.

The core of any POD definition should be an entity that receives revenue from selling medical devices ordered by a physician-owner for use in procedures performed by a physician-owner. To ensure that the definition applies to all known POD models, language could be explicitly added to include PODs that do not directly sell devices or that do so through contractual relationships. Using these two criteria, a basic definition of a POD could be an entity that receives any of its revenue from selling or arranging for the sale (including through contractual arrangements such as group purchasing organization contracts) of medical devices ordered by a physician-owner for use in procedures performed by a physician-owner.

In response to prior legislative changes such as the establishment of the Open Payments program, PODs have reportedly changed their structure while maintaining the fundamental incentives embodied in PODs (U.S. Senate Committee on Finance 2016). Language could be added to the definition of a POD to ensure that superficial variations in ownership and payment structures do not preclude a POD from being characterized as such. To that end, a POD owner could be defined as a physician who has an ownership or investment interest in a POD, including ownership or investment through agents, trusts, partnerships, limited liability companies, corporations, unincorporated associations, or any other entity. Further, the type of payment a POD owner receives—a commission, return on investment, profit sharing, profit distribution, or any other type of remuneration—should

not allow an entity to avoid being categorized as a POD, so long as the entity's fundamental structure remains unchanged.

To avoid being classified as a POD or being regulated by the Stark law, some physician-owners could try to channel money through immediate family members, become POD employees, or engage in other referral schemes. For the purposes of defining a POD-owner, an immediate family member of the physician-owner should be included in the definition of a physician-owner.³⁵ To prevent PODs from converting their physician-owners to employees to avoid regulation, language could be added to the POD definition to clarify that PODs include entities that generate revenue from selling medical devices ordered by a physician who is an owner, employee, or contractor for use in procedures performed by such physician. To prevent referral schemes that might be designed to circumvent any POD restrictions, language could also be added to the POD definition, although the legality of some of these schemes is likely already questionable under current law.³⁶

Device innovation

While some believe that limiting the use of PODs could inhibit medical device innovation, the Commission concludes that innovation in the medical device market would be largely unaffected by such changes.

Limiting the use of PODs through the Stark law would not prohibit physician investment in companies developing new medical devices. Rather, limiting the use of PODs would prohibit Medicare payment for cases where a physician performs surgery using a device supplied by a company in which the referring physician has a financial interest. Some stakeholders believe that this limitation reduces the ability of physicians to profit from their inventions, and, therefore, additional exceptions should be added to the Stark law preserving physicians' abilities to self-refer.³⁷

The Commission concludes that no additional exceptions are needed to protect innovation in the medical device market for several reasons. First, current Stark regulations protect investment interests in companies that are listed on public exchanges and that have a net value of over \$75 million. This provision recognizes that physician ownership in large entities is unlikely to create an inappropriate incentive to refer patients for services because the physician's impact is likely to be attenuated. A similar clause could be added to any new POD provisions.³⁸ Second, the Commission believes physicians

would still be able to profit from contributing significant intellectual capital to the development of medical devices if the use of PODs were limited. The Commission argues that a device is unlikely to be innovative if the only manner in which physicians profit from it is through using it themselves. If a device does represent an actual advancement, other providers will use the device, and the physician who contributed to the invention of the device would continue to profit. Finally, the Commission notes that physicians contributed to medical device innovation before the proliferation of PODs (and will continue to do so if the use of PODs is limited) and that physicians have many nonfinancial incentives to continue innovating.

Implementation issues

The Stark law is intended to be self-implementing to a large degree. The potential for significant Medicare disallowances provides a strong incentive for hospitals to police their arrangements with physicians. As a consequence, many hospitals have implemented conflict-of-interest policies, especially with regard to physician relationships with hospital vendors. If the Stark law were changed to limit the use of PODs, hospitals would likely adopt similar policies to protect against Stark law and additional False Claims Act liabilities by demonstrating they took reasonable measures to comply. To the extent active enforcement is needed, most Stark law cases that are brought by the government are initiated by whistleblowers.

Even if the Stark law is changed to limit the use of PODs, some PODs could continue to exist. First, the Stark law predominantly applies to FFS Medicare, so any new restrictions would not apply to all payers. For example, the Stark law contains an exception for services provided to Medicare Advantage enrollees (42 CFR § 411.355 (c)). Second, while most PODs sell to hospitals, others may sell to non-DHS entities (e.g., ambulatory surgical centers).³⁹ Such sales are not encumbered by the Stark law. Finally, PODs could adapt to the new regulations in some unforeseen manner that would allow them to continue operating. For example, after CMS prohibited per click arrangements for space and equipment leases, some entities began leasing based on a block of time (e.g., renting an MRI machine for a day per week) rather than per use.

Improving transparency of POD–physician relationships

The Commission maintains that the financial relationships between physicians and PODs should be more transparent.

Absent changes in the Stark law, additional transparency could still help beneficiaries make informed decisions and help enforcement agencies, payers, and others better understand the effect of PODs. Also, enhanced transparency could be useful even if Stark law changes are made, given that some PODs could continue to exist.

Under the Open Payments program, manufacturers of drugs, devices, biologics, and supplies are required to annually report to CMS information about certain payments and other transfers of value to physicians and teaching hospitals. GPOs must also report payments and transfers of value to physicians who have an ownership or investment interest. In addition, manufacturers and GPOs are required to report ownership or investment interests that physicians or their immediate family members have in their companies (Medicare Payment Advisory Commission 2017). The intent of the Open Payments program is to shed light on industry ties to providers.

The statute that forms the basis of the Open Payments program does not explicitly mention PODs. However, PODs that fall within the definition of an applicable manufacturer or GPO must report. In its 2013 final rule establishing the Open Payments program, CMS stated that it intended to capture as many PODs as possible in the Open Payments program, but not every POD model may be covered by the program (Centers for Medicare & Medicaid Services 2013). For example, PODs that sell or arrange for the sale of devices to only one hospital may not fit the definition of an applicable GPO and may therefore not be required to report.

In addition, some PODs that are likely covered by the program are failing to report. For example, a 2016 report from the Senate Finance Committee found that many PODs identified by the Committee staff did not appear in the Open Payments data. The report concluded that there were serious gaps in the reporting of POD arrangements under the Open Payments program (U.S. Senate Committee on Finance 2016).⁴⁰

Likely as a result of the incomplete requirement for PODs to report under the Open Payments program and underreporting by covered PODs, very few PODs appear in Open Payments data. For example, using the 2015 Open Payments data (which were released in January 2017), the Commission found that only 8 PODs reported general payments to physicians, and only 16 PODs reported physician ownership (Medicare Payment Advisory Commission 2017).

To address this lack of reporting, the Commission supports requiring all PODs to report under the Open Payments program. When reporting under the Open Payments program, PODs should identify as a POD, as opposed to another type of entity that is required to report. Improving the specificity of the data could improve their utility to policymakers, oversight agencies, researchers, hospitals, and others.

Conclusion

The Commission believes that Medicare can improve its payment policies for both DMEPOS products and IMDs. For DMEPOS products, the CBP has effectively used market competition to reduce payment rates and limit fraud and abuse for over seven years. Medicare could include additional products in the CBP, while at the same

time continuing to ensure beneficiaries maintain access to needed products. In addition, policymakers should also consider making Medicare's DMEPOS payment policies consistent with those of other Part B suppliers and clinicians by capping balance billing and giving suppliers an incentive to enroll as participating suppliers.

Because Medicare does not directly pay for most IMDs, the Commission focused on policy changes to better align the incentives between physicians (who refer beneficiaries for procedures in which IMDs are used) and hospitals (who predominantly pay for IMDs). The Commission supports limiting the use of PODs because they encourage physicians to use more and more-expensive devices without providing countervailing benefits. The Stark law could be modified to achieve that goal, and the Commission discussed two such options, although other viable approaches likely exist. ■

Endnotes

- 1 In this report, we define DMEPOS using Berenson-Eggers Type of Service categories D1A, D1B, D1C, D1D, D1E, D1F, and O1C, with certain exclusions. These categories exclude drugs used in conjunction with DME; we excluded such drugs because their payment rates are set in a manner different from other DMEPOS items.
- 2 Over the same time period, the number of Medicare FFS beneficiaries enrolled in Part B increased by roughly 3 percent (Boards of Trustees 2017).
- 3 For more information on how supplier charges were used to set fee schedule rates, see 42 CFR § 405.502. The time period from which supplier charges were used to set payment rates may vary by payment class. Payment rates for products introduced after that initial time period are set using a gap-filling process that relies on, among other sources, unadjusted list prices.
- 4 The Food and Drug Administration classifies medical devices based on the risks associated with the device. Devices are classified into one of three categories—Class I, Class II, and Class III. Class III devices are generally the highest risk devices and are therefore subject to the highest level of regulatory control.
- 5 There were some differences between the CBP Round 1 and Round 1 rebid. For example, a CBA in Puerto Rico was excluded from the CBP Round 1 rebid.
- 6 Mail-order diabetes testing supplies were originally included in the Round 1 rebid. However, Round 1 rebid contracts for mail-order diabetes testing supplies ended on December 31, 2012, and the supplies were included in the National Mail-Order Program as of July 2013.
- 7 For future CBP rounds, suppliers will have to obtain bid surety bonds of \$50,000 for each CBA. If a supplier rejects a contract and its composite bid for the product category was at or below the median composite bid rate for all suppliers included in the calculation of the single payment amounts, then the supplier will forfeit the bid surety bond (42 CFR § 414.412(h)). This provision was intended to prevent “low ball” bidders who bid unreasonably low (to ensure they are offered a contract) and then accept or reject the contract after the payment rates are known.
- 8 One exception is that beneficiaries may continue to receive certain products from grandfathered suppliers.
- 9 CMS also employs other tools to ensure beneficiary access to needed DMEPOS items under the CBP, including monitoring inquiries to 1-800-MEDICARE, conducting secret shopping calls to DMEPOS suppliers, and conducting beneficiary satisfaction surveys.
- 10 For other product categories or outcome measures, the differences across geographic areas varies. For example, hospital admission rates among beneficiaries with a potential need for home oxygen tended to be higher in CBAs than non-CBAs, both before and after CBP Round 2 was implemented.
- 11 Of the 15 areas with the largest declines in utilization after CBP Round 2 was implemented, 12 were in Texas or California. CMS officials have said that the relatively large decreases in California and Texas were likely because these states historically had high rates of potential fraud and abuse (Government Accountability Office 2016).
- 12 In practice, CMS has reported high contract acceptance rates. For example, suppliers accepted 92 percent of contracts offered in CBP Round 1 2017 (Centers for Medicare & Medicaid Services 2016b).
- 13 As part of its ongoing work to evaluate the CBP, OIG found that CBP Round 2 did not appear to disrupt beneficiary access to CPAP/respiratory assist devices (RADs) (Office of Inspector General 2017). The report was inconclusive about whether access to CPAP/RAD supplies was disrupted.
- 14 Some of the growth in off-the-shelf orthotic codes appears to be attributable to CMS splitting existing codes into two in 2014 (one for the off-the-shelf version and another for the custom-fitted version).
- 15 In 2015, the payment rate increase was 1.5 percent (Centers for Medicare & Medicaid Services 2015a). From 2014 to 2015, the number of Part B FFS beneficiaries increased from roughly 33.2 million to 33.3 million, or 0.25 percent (Boards of Trustees 2017).
- 16 Specifically, we examined the utilization and expenditures for a prefabricated back brace when it was dispensed as an off-the-shelf brace (L0650) or a custom-fitted brace (L0637). Analyzing the combined figures allowed us to determine net increases in utilization and spending, as many suppliers began billing for L0650 instead of L0637 beginning in 2014.
- 17 Specifically, the Federation of State Medical Boards reported that only 4,091 out of 931,921 licensed physicians in the United States were disciplined by a state medical board in 2015 (Federation of State Medical Boards 2016).

- 18 An improper payment is any payment made in error or in an incorrect amount; to an ineligible recipient; for ineligible goods or services; for goods or services not received; that duplicates a payment; that does not account for credit for applicable discounts; without supporting documentation; or for services where documentation is missing or not available (Centers for Medicare & Medicaid Services 2016d).
- 19 The MarketScan Commercial Claims and Encounters Database captures person-specific utilization and expenditures in the outpatient and other settings for active employees, early retirees, COBRA continuees, and dependents insured by employer-sponsored plans.
- 20 Implementing prior authorization involves added administrative costs. Therefore, limiting prior authorization to DMEPOS products above a certain dollar value could help ensure the process results in savings for the Medicare program.
- 21 CMS has largely suspended enforcement of this requirement even for many DMEPOS products that are required to have a face-to-face visit.
- 22 For this analysis, we examined an additional 20 HCPCS codes. (One code with over \$1 million in Medicare expenditures was excluded because of an insufficient number of private-payer claims.)
- 23 CMS is also statutorily prohibited from including inhalation drugs in the CBP and, per the 21st Century Cures legislation, infusion drugs used in conjunction with DME.
- 24 Such an exemption would apply to hospitals, not hospital-owned DMEPOS suppliers or DMEPOS suppliers that are only affiliated with a hospital.
- 25 Other products beyond these two categories might also not be ideal candidates for inclusion in the CBP. For example, many industry representatives have suggested that highly customized products should not be included in the CBP. The Commission could consider this topic in the future.
- 26 At the HCPCS level, there are many non-CBP DMEPOS products with relatively low expenditures. In determining whether a market is large enough to justify inclusion in the CBP, families of HCPCS codes should be considered because any given HCPCS code might have low expenditures, but a related family of products that suppliers often provide together could be large enough to justify inclusion.
- 27 Similar to other suppliers, DMEPOS suppliers are prohibited from balance billing beneficiaries dually eligible for Medicare and Medicaid.
- 28 Assignment is mandatory for many Medicare providers. For example, clinical diagnostic laboratory services, services of nurse practitioners, ambulatory surgical center services, and several other categories of services are required to be billed on an assignment basis under current Medicare payment rules (Centers for Medicare & Medicaid Services 2017c).
- 29 The company that manufactures wearable AEDs (among other products) reported an increase in gross margins between 2010 and 2011 from 54 percent to 57 percent. Part of this increase was attributable to the higher margin wearable-AED business being a larger share of the company's overall sales in 2011 compared with 2010 (Zoll Medical Corporation 2011). Therefore, to contribute to increasing the overall gross margins up to 57 percent, the gross margin for wearable AEDs was likely above 50 percent. In 2012, the company that manufactures wearable AEDs was acquired by the Asahi Kasei Corporation, making access to more recent financial information regarding wearable AEDs more difficult to ascertain (Zoll Medical Corporation 2012).
- 30 Some are concerned that PODs could spread to other types of implants, prosthetics, or orthotics (U.S. Senate Committee on Finance 2016).
- 31 Surgeries can involve multiple devices. If at least one POD-supplied device was used in a surgery, OIG counted that surgery as using a POD-supplied device.
- 32 Among hospitals that purchased spinal devices from PODs, OIG found that approximately three-quarters purchased spinal devices from PODs that manufacture their own devices: 40 percent of hospitals bought only from PODs that manufacture their own devices, 19 percent of hospitals bought only from PODs that buy devices from other entities, 36 percent of hospitals bought from both types of PODs, and 5 percent of hospitals were unclear whether PODs they bought from manufactured their own devices (Office of Inspector General 2013c).
- 33 The OIG study did not substantiate all the concerns that have been expressed regarding PODs. For example, the study found that surgeries in which devices were acquired through PODs involved fewer devices on average (12.3 vs. 14.2 when not acquired through PODs). Also, OIG's findings were mixed with regard to the complexity of surgeries at hospitals that acquired devices through PODs and those that did not.
- 34 See 42 CFR § 411.354(d)(2) and (d)(3) for a description of the unit-based special rules on compensation.

- 35 The concept of a physician’s immediate family member is used throughout the Stark law and means husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild (42 CFR § 411.351).
- 36 For example, the Stark definition of *referrals* reaches referrals by others at a physician’s direction or control and could encompass such arrangements. In addition, there is a civil monetary penalty for circumvention schemes that could apply.
- 37 For example, self-referral could be allowed if PODs generated a certain share of their business (e.g., 60 percent) from non-self-referrals or for products for which a physician holds a patent.
- 38 Under such a provision, physicians would be allowed to refer their patients for surgery in which their POD supplied the devices so long as the net value of the POD was \$75 million or more. We believe that few, if any, PODs would currently meet this threshold, based on conversations with industry.
- 39 To the extent a physician has an ownership stake in an ambulatory surgical center (ASC), his or her incentive to use POD-supplied devices may be attenuated. Physicians that have an ownership stake in ASCs have an incentive to negotiate the lowest price for their devices because the ASC’s profits are the difference between the ASC facility payment and the costs (including device costs) to perform the surgery.
- 40 Applicable manufacturers and GPOs that fail to report required information are subject to civil monetary penalties of up to \$1,150,000 annually—up to \$10,000 per instance of nonreporting (up to an annual maximum of \$150,000) and up to \$100,000 per knowing instance of nonreporting (up to an annual max of \$1,000,000) (42 CFR § 403.912). In the agency’s 2016 and 2017 annual reports to the Congress on the Open Payments program, CMS said it did not impose any civil monetary penalties in program years 2014 or 2015 (Centers for Medicare & Medicaid Services 2017a, Centers for Medicare & Medicaid Services 2016a).

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