



July 2017

MEDICARE

CMS Should Evaluate Providing Coverage for Disposable Medical Devices That Could Substitute for Durable Medical Equipment

Accessible Version

GAO Highlights

Highlights of [GAO-17-600](#), a report to congressional committees

Why GAO Did This Study

In 2015, Medicare spent \$6.7 billion for DME. CMS's definition of DME generally precludes potential disposable DME substitutes from coverage. Congress included a provision in law for GAO to review the potential role of disposable medical devices as substitutes for DME.

This report examines (1) potential disposable DME substitutes and their possible benefits and limitations; (2) the incentives and disincentives stakeholders identified for developing these substitutes, including the possible influence of health insurance coverage; and (3) issues related to benefit category designation—including legal authority and potential payment methodologies—if Medicare coverage were expanded to include disposable DME substitutes. GAO reviewed agency documents and literature on disposable DME substitutes and Medicare payment policy; interviewed CMS officials; and interviewed various stakeholders, including representatives of device manufacturers, beneficiary advocates, health care providers, and insurers, for their perspectives.

What GAO Recommends

GAO recommends that CMS, within the Department of Health and Human Services (HHS), evaluate the possible costs and savings of using disposable devices as substitutes for DME, and, if appropriate, seek legislative authority to cover them. HHS stated that such an evaluation was premature. However, GAO continues to believe an evaluation is needed to help HHS anticipate and plan for significant changes using a forward-looking process.

View [GAO-17-600](#). For more information, contact Kathleen M. King at (202) 512-7114 or kingk@gao.gov.

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CMS Should Evaluate Providing Coverage for Disposable Medical Devices That Could Substitute for Durable Medical Equipment

What GAO Found

While disposable medical devices are generally not covered by Medicare, GAO identified eight that could potentially substitute for durable medical equipment (DME) items that are covered. These disposable DME substitutes fall into existing Medicare DME categories—infusion pumps, including insulin pumps; blood glucose monitors; sleep apnea devices; and nebulizers. Stakeholders GAO interviewed identified multiple benefits of using disposable substitutes, such as better health outcomes and potential cost-savings. However, they also cited factors that limit their use, including that these substitutes may not lead to cost-savings in all cases.

Stakeholders identified several market incentives, such as a growing demand, as reasons to develop disposable DME substitutes, but mostly cited lack of coverage by Medicare as a disincentive to development. Disposable DME substitutes are generally precluded from Medicare coverage under the DME benefit because they do not meet the Centers for Medicare & Medicaid Services' (CMS) regulatory definition of "durable"—able to withstand repeated use, with an expected lifetime of at least 3 years. Stakeholders noted this also decreases their chances of obtaining coverage from other insurers, which may follow Medicare payment policy. Some stakeholders noted that CMS's DME definition is a disincentive to technological innovation, and the agency has already faced challenges making coverage decisions with some devices. According to federal internal control standards, management should anticipate and plan for significant changes using a forward-looking process, but CMS officials said the agency has not considered the possibility of reexamining its definition. As a result, the agency may not be taking advantage of the potential benefits of these devices.

If Medicare coverage were expanded to include disposable DME substitutes, CMS would need to consider issues related to benefit category designation. GAO identified three possible options for covering disposable DME substitutes: an expansion of the current DME benefit, an expansion of the current home health benefit, or establishment of a new benefit category. The table lists the options GAO identified, which are not exhaustive. CMS would also need to consider its authority to provide for expanded coverage and evaluate potential reimbursement options.

Possible Options for Medicare Coverage of Disposable DME Substitutes

Medicare benefit	Authority	Reimbursement options
Durable medical equipment (DME) benefit	Regulatory change could redefine "durable" to accommodate substitutes with shorter life expectancy, but congressional action likely necessary for single and short-term use devices	Use current fee schedule or a reduced percentage of the fee schedule amount <u>or</u> establish payment through the competitive bidding program
Home health benefit	Congressional action required	Establish a separate payment <u>or</u> adjust the home health bundle to include disposables
Newly established benefit for disposable devices	Congressional action required	Would depend on congressional action taken in establishing the new benefit

Source: GAO analysis of applicable laws and regulations. | GAO-17-600

Contents

Letter	1
Background	4
Some Potential Disposable Substitutes for DME Exist, and These Substitutes May Have Benefits in Some Cases	7
Stakeholders Identified Market Incentives for Developing Potential Disposable DME Substitutes, but Cited Medicare Payment Policy as a Disincentive	17
CMS Would Need to Consider Issues Related to Benefit Categorization, Including Legal Authority and Potential Payment Methodologies, If Medicare Coverage Were Expanded to Disposable DME Substitutes	21
Conclusions	27
Recommendation for Executive Action	27
Agency Comments and Our Evaluation	28
Appendix I: List of Stakeholders Interviewed	31
Appendix II: Comments from the Department of Health and Human Services	33
Appendix III: GAO Contact and Staff Acknowledgments	35
Appendix IV: Accessible Data	36
Agency Comment Letter	36
Under ' What GAO Found' ,second paragraph, second sentence:	38
HHS suggests the following change:	38
Under 'What GAO Found', second paragraph, fourth sentence :	38
HHS suggests the following change:	38
Under 'What GAO Found', second paragraph, fifth sentence:	38
HHS suggests the following change:	39
HHS suggests the following change:	40
HHS suggests the following change:	40
HHS suggests the following change:	41
HHS suggests the following change :	41
HHS suggests the following change:	42

HHS suggests the following change:	42
HHS suggests the following change:	43
HHS suggests the following change:	44

Tables

Table 1: Manufacturer Examples of Potential Cost-savings Associated with Disposable Substitutes for Durable Medical Equipment (DME)	16
Table 2: Possible Options for Covering Disposable Durable Medical Equipment (DME) Substitutes	21
Under 'What GAO Found', second paragraph, second sentence:	38
HHS suggests the following change:	38
Under 'What GAO Found', second paragraph, fourth sentence :	38
HHS suggests the following change:	38
Under 'What GAO Found', second paragraph, fifth sentence:	38
HHS suggests the following change:	39
HHS suggests the following change:	40
HHS suggests the following change:	40
HHS suggests the following change:	41
HHS suggests the following change :	41
HHS suggests the following change:	42
HHS suggests the following change:	42
HHS suggests the following change:	43
HHS suggests the following change:	44

Figures

Figure 1: Durable Infusion Pump and Potential Disposable Substitutes	8
Figure 2: Durable Insulin Pump and Potential Disposable Substitutes	10
Figure 3: Durable Blood Glucose Monitor and Potential Disposable Substitute	11
Figure 4: Durable Sleep Apnea Device and Potential Disposable Substitutes	13
Figure 5: Durable Nebulizer and Potential Disposable Substitute	14
Under 'What GAO Found', second paragraph, second sentence:	38

HHS suggests the following change:	38
Under 'What GAO Found', second paragraph, fourth sentence :	38
HHS suggests the following change:	38
Under 'What GAO Found', second paragraph, fifth sentence:	38
HHS suggests the following change:	39
HHS suggests the following change:	40
HHS suggests the following change:	40
HHS suggests the following change:	41
HHS suggests the following change :	41
HHS suggests the following change:	42
HHS suggests the following change:	42
HHS suggests the following change:	43
HHS suggests the following change:	44

Abbreviations

CMS	Centers for Medicare & Medicaid Services
CPAP	continuous positive airway pressure
DME	durable medical equipment
HHS	Department of Health and Human Services
MAC	Medicare administrative contractor

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July 17, 2017

Congressional Committees

Medicare, the federal health insurance program administered by the Centers for Medicare & Medicaid Services (CMS), within the Department of Health and Human Services (HHS), spent \$6.7 billion in 2015 for durable medical equipment (DME).¹ DME includes items such as hospital beds, wheelchairs, and blood glucose monitors. Medicare covers DME that serves a medical purpose, can be used in the home, and has an expected lifetime of at least 3 years, among other things. According to industry stakeholders, some new medical technology that is disposable may have the potential to substitute for DME and achieve better results and give better value to Medicare. Because these disposable DME substitutes do not meet the definition of DME, they cannot be covered by Medicare under the DME benefit.²

The Consolidated Appropriations Act, 2016, included a provision for GAO to report to Congress on the role of disposable devices as substitutes for DME.³ This report examines

1. potential disposable DME substitutes and the possible benefits and limitations of their use;
2. incentives and disincentives stakeholders have identified regarding the development of disposable DME substitutes, including the possible influence of health insurance coverage; and

¹The amount that Medicare paid for DME in 2015 includes prosthetics, orthotics, and related supplies for beneficiaries. The amount paid is for Medicare Part B fee-for-service payments and does not include Medicare Advantage. In addition, it does not include the 20 percent coinsurance that beneficiaries are responsible for paying to suppliers or any additional payments that beneficiaries may have made to suppliers that do not accept assignment. Suppliers who accept assignment must accept the Medicare-approved payment amount and may not charge beneficiaries more than any unmet deductible and 20 percent coinsurance.

²In this report, we define disposable devices as those that meet the following criteria: (1) they have a DME counterpart for which they could potentially substitute and (2) they are intended to treat the same conditions as the DME version. We refer to these devices as disposable DME substitutes.

³Pub. L. No. 114-113 § 504(c), 129 Stat. 2242, 3022 (2015).

3. issues related to benefit category designation—including legal authority and potential payment methodologies—if Medicare coverage were expanded to include disposable DME substitutes.

To examine our objectives, we interviewed representatives from various stakeholder groups, including the medical device industry, health care providers, Medicare beneficiary advocates, a state Medicaid directors group, and health insurers.⁴ We also interviewed manufacturers and developers of the disposable DME substitutes we identified during the course of our work, and we reviewed related documentation, such as journal articles about the devices and user manuals for these substitutes.⁵ (See app. I for a complete list of stakeholders we interviewed.) To supplement our interviews, we conducted a literature search to identify disposable DME substitutes.⁶ Additionally, we reviewed CMS documentation and interviewed CMS officials and representatives of the two DME Medicare administrative contractors (MAC) regarding disposable DME substitutes and Medicare coverage of DME.⁷ We compared CMS's approach to coverage determinations regarding disposable DME substitutes to federal internal control standards for risk

⁴We interviewed 21 stakeholders in total. Specifically, we interviewed 2 medical device manufacturer groups, 2 Medicare beneficiary advocate groups, 4 health care provider groups, 1 state Medicaid directors group, 1 health insurer and 2 health insurer groups, and 9 manufacturers and developers of specific disposable DME substitutes. (We collectively refer to the manufacturers and developers as “manufacturers” in this report.) In addition, we requested to interview 9 other stakeholders—2 Medicare beneficiary advocate groups, 3 health care provider groups, 2 health insurance groups, and 2 manufacturers of a disposable DME substitute. These stakeholders did not respond to our request or declined our invitation. We identified groups to interview through various sources, including our previous work and recommendations provided by interviewees. We also conducted internet searches for manufacturers of those disposable DME substitutes we identified, among other things. The views we obtained during our interviews are not generalizable to all industry stakeholders.

⁵We interviewed manufacturers of 7 of the 8 disposable DME substitutes we identified. We contacted multiple manufacturers of the eighth device type but were unable to obtain an interview with any of them. We identified journal articles about the disposable DME substitutes via internet searches.

⁶Our literature search included peer-reviewed publications, government publications, trade and industry articles, and association and nonprofit publications from January 2006 to October 2016. We reviewed 149 abstracts but did not identify any additional disposable DME substitutes.

⁷CMS has contracted with two companies, Noridian Healthcare Solutions, LLC, and CGS Administrators, LLC, as DME MACs to cover the four geographic areas. The DME MACs administer claims for payment that DME suppliers submit to Medicare on behalf of beneficiaries.

assessment.⁸ In addition, to describe issues related to benefit category designation if Medicare coverage were expanded to include disposable DME substitutes, we reviewed reports on DME and Medicare payment policy that we identified through a targeted literature search and reviewed relevant statutes and regulations.⁹ Additionally, we reviewed our past work on Medicare payment policy.

We conducted this performance audit from August 2016 to July 2017 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

⁸See GAO, *Standards for Internal Control in the Federal Government*, [GAO-14-704G](#) (Washington, D.C.: September 2014). Internal control is a process effected by an entity's oversight body, management, and other personnel that provides reasonable assurance that the objectives of an entity will be achieved.

⁹For our targeted literature search, we reviewed publications obtained via internet databases such as ProQuest and from organizations that research and produce reports on Medicare payment policy, such as the Medicare Payment Advisory Commission.

Background

Medicare Payment for DME

Medicare covers items such as hospital beds, wheelchairs, and blood glucose monitors under its DME benefit because they are specifically included in the Medicare statute's definition of DME.¹⁰ Other items are covered under the Medicare DME benefit based on CMS's interpretation of the statute, which does not elaborate on the meaning of "durable." By regulation, CMS has defined DME as equipment that (1) can withstand repeated use; (2) has an expected lifetime of at least 3 years; (3) is used primarily to serve a medical purpose; (4) is not generally useful in the absence of an illness or injury; and (5) is appropriate for use in the home.¹¹ Most Medicare beneficiaries enroll in Medicare Part B, which provides coverage for DME if the devices are medically necessary and prescribed by a physician.¹² Medicare beneficiaries typically obtain DME from suppliers, who then submit claims for payment to Medicare on behalf of beneficiaries. CMS contracts with DME MACs to process these claims and ensure proper administration of the DME benefit.

Medicare uses three different processes to set the amount it pays for DME.¹³ First, the payment amounts for some types of DME are set in a fee schedule that is based on the average charges Medicare allowed during a 12-month period ending June 30, 1987, subject to national floors and ceilings. These historical fee schedule amounts have been updated in some years by a measure of price inflation and a measure of economy-

¹⁰See 42 U.S.C. § 1395x(n).

¹¹See 42 C.F.R. § 414.202 (2016). The 3-year minimum lifetime requirement is effective for items classified as DME after January 1, 2012.

¹²Related supplies and accessories that are necessary for the effective use of the DME item, such as drugs or tubing, are also covered by Medicare. For diabetic patients, insulin used in an insulin pump that is covered under Part B is covered under the DME benefit. Insulin not used in an insulin pump is covered under Medicare Part D, Medicare's prescription drug program. In addition, Medicare Part D plans may cover medical supplies associated with the injection of insulin, including syringes, needles, alcohol swabs, and gauze.

¹³Medicare pays 80 percent of the lower of the supplier's charge for the item or the fee schedule amount, less any unmet deductible. The beneficiary is responsible for the remaining 20 percent, plus any unmet deductible.

wide productivity.¹⁴ Second, the payments for some DME are set through a competitive bidding program. In that program, qualified DME suppliers with the lowest bids are competitively selected to furnish certain DME product categories to Medicare beneficiaries in designated competitive bidding areas.¹⁵ Third, when CMS classifies a new device on the market as DME, CMS may set the price using the price of a comparable item. If there is no comparable item, then CMS may set the price using the gap-fill methodology.¹⁶ This method takes supplier price lists for the new item and applies a deflation factor to calculate the base-year price—the price for the 12-month period ending June 30, 1987, on which the original fee schedule was based. To then calculate the payment amount, CMS takes the median deflated price and increases it to the current date using the update factors that were applied to the original fee schedule.¹⁷ Similar to the fee schedule, the final price is subject to floors and ceilings.

Disposable Negative Pressure Wound Therapy and Home Health Payments

Typically, when a Medicare beneficiary receives DME in conjunction with home health care, the devices are covered, and payments are made, under the DME benefit.¹⁸ However, prior to January 2017, the home health benefit covered disposable negative pressure wound therapy that

¹⁴For some years, the payment amount was not updated. For example, no update was provided from 1998 through 2000 or in 2002, although updates were provided in 2001, as required by law. See 42 U.S.C. § 1395m(a)(14).

¹⁵A product category is a grouping of related items used to treat a similar medical condition. A competitive bidding area is either a metropolitan statistical area or a part thereof. Metropolitan statistical areas are designated by the Office of Management and Budget and include major cities and the suburban areas surrounding them. Prices for DME product categories under the competitive bidding program are reduced based on information from the program for locations outside of the competitive bidding areas. For more information on the competitive bidding program, see GAO, *Medicare: CMS's Round 2 Durable Medical Equipment and National Mail-order Diabetes Testing Supplies Competitive Bidding Programs*, [GAO-16-570](#) (Washington, D.C.: Sept. 15, 2016).

¹⁶The gap-fill method is established in Medicare's claims processing manual. CMS officials told us it is subject to change should CMS determine another method to be more appropriate.

¹⁷The inflation factors used in the gap-filling process account for the years in which no update was provided.

¹⁸In contrast, in other settings such as a hospital, if a beneficiary received DME, it would be covered under the inpatient payment system rather than the DME benefit.

may substitute for DME as part of the bundled rate CMS pays home health agencies—a single rate for providing treatment and certain related items or services during a 60-day care episode.¹⁹ Beginning in January 2017, the Consolidated Appropriations Act, 2016, unbundled certain disposable negative pressure wound therapy devices that may substitute for DME under the Medicare home health benefit.²⁰ The act provides for a separate payment for disposable negative pressure wound therapy—meaning it is not part of the bundled payment amount—and sets the reimbursement rate for disposable negative pressure wound therapy equal to the rate used in an outpatient setting, where the device is covered.²¹ Furthermore, the act provides separate payment for the disposable negative pressure wound therapy only to beneficiaries who are receiving home health services.

¹⁹The bundled payment rates are based on patients' conditions and service use, adjusted for the geographic area in which the care was provided. If fewer than five visits are delivered during a 60-day episode, the home health agency is paid per visit by visit type, rather than by the episode payment method.

Negative pressure wound therapy applies suction to a wound to remove drainage and debris.

²⁰Pub. L. No. 114-113 § 504(a), (b), 129 Stat.3021 (codified at 42 U.S.C. §§ 1395l(a)(1), 1395m(s) and 1395x(m)(5)).

²¹Under Medicare's outpatient benefit, the disposable negative wound pressure therapy device and services related to providing it are categorized with other wound care items and services into a single payment classification. All services within this classification have the same payment rate. The home health separate payment amount similarly includes both the disposable negative pressure wound therapy device and the services related to providing it.

Some Potential Disposable Substitutes for DME Exist, and These Substitutes May Have Benefits in Some Cases

Some Potential Examples of Disposable Substitutes for DME Exist, according to Industry Stakeholders

We identified a limited number of disposable medical devices that could potentially substitute for DME, based on our literature review and interviews with industry stakeholders. These devices do not necessarily represent a complete list of available disposable devices. Specifically, we identified eight devices that could potentially substitute for DME. These devices fall into existing DME categories used by Medicare—infusion pumps, including insulin pumps; blood glucose monitors; sleep apnea devices; and nebulizers.²² These disposable DME substitutes vary in life expectancy. For example, some of the substitutes are intended to last a day, while others a year or two. A few of the disposable DME substitutes we identified have been on the market for more than a decade; a couple have become available more recently, in the past 3 to 5 years. We also identified a disposable DME substitute that is currently in development.

- **Infusion pumps.** These devices deliver fluids, including medication, into a patient's body in a controlled manner. In general, a trained technician programs this device, using built-in software, to deliver fluids at specific rates through disposable tubing connected from the device to the patient via a needle. We identified two examples of disposable devices that could potentially substitute for DME—the ambulatory infusion pump and the elastomeric pump. The disposable ambulatory infusion pump has the same characteristics as the DME version, such as being able to deliver fluid at a controlled rate and using a disposable infusion set that is discarded after a single use. However, unlike the durable infusion pump, the ambulatory infusion pump has a life expectancy of 1 year. The disposable elastomeric

²²These eight devices are in addition to the disposable negative pressure wound therapy device already covered under Medicare. Medicare currently covers more than 17 categories of DME, including the ones above, with multiple devices within each of these categories. Some of these categories include manual wheelchairs and power mobility devices, oxygen equipment and accessories, and hospital beds. An insulin pump is a type of infusion pump, but for this report, we created a separate category due to the insulin pump's use as treatment for a chronic illness.

pump is a single-use device that utilizes a stretchable balloon reservoir that relies on the pressure from the elastic walls of the balloon to deliver a single dose of medication before being discarded. (See fig. 1.)

Figure 1: Durable Infusion Pump and Potential Disposable Substitutes



Durable infusion pump

- Consists of an electronic pump and disposable infusion set
- Delivers fluids at specific rates, which can be adjusted



Disposable ambulatory infusion pump

- Consists of a smaller electronic pump and disposable infusion set
- Delivers fluids at specific rates, which can be adjusted
- Intended to last for one year



Disposable elastomeric infusion pump

- Consists of a balloon reservoir, which is filled with medication, and an integrated tubing set
- Delivers fluids at a pre-set flow rate
- Intended for a single use

Source: American Association for Homecare (top image); Zyno Medical LLC (middle image); © 2017 Halyard Health (bottom image); GAO analysis of manufacturer information. | GAO-17-600

- **Insulin pumps.** These devices are infusion pumps specifically used to deliver insulin to patients with diabetes. The DME version of an insulin pump consists of an insulin reservoir and a pumping mechanism that controls the release of insulin to the patient via a disposable infusion set. We identified two potential disposable substitutes—a completely disposable insulin pump and an insulin

pump with both disposable and durable components. The completely disposable insulin pump consists of an adhesive patch containing an insulin reservoir and needle. This patch is attached to the patient's skin, and a needle is inserted into the skin when a button is pressed, allowing insulin to be delivered throughout the day. This type of insulin pump is intended to last for 24 hours and then be discarded. The other device we identified has both disposable and durable components. This device's disposable component contains the insulin reservoir, pumping mechanism, and a transmitter sensor in an adhesive patch that is intended to last for 3 days. Its durable component, which is expected to last for 4 years, includes a remote controller that transmits instructions programmed by the patient to the sensor in the patch, which in turn controls the release of insulin via the pumping mechanism. (See fig. 2.)

Figure 2: Durable Insulin Pump and Potential Disposable Substitutes



Durable insulin pump

- Includes a durable insulin reservoir and pumping mechanism
- Delivers insulin via a disposable infusion set



Completely disposable insulin pump

- Attaches to the body using an adhesive patch that contains an insulin reservoir and a needle
- Intended to last for 24 hours



Insulin pump with disposable and durable components

- Includes a patch containing a disposable insulin reservoir, pumping mechanism, and transmitter sensor
- Durable component under warranty for 4 years
- Disposable components intended to last for 3 days

Source: National Institutes of Health/National Institute of Diabetes and Digestive and Kidney Diseases under license from Click and Photo/Shutterstock.com (top image); V-Go is a registered trademark of Valeritas, Inc. (middle image); Insulet Corporation (bottom image); GAO analysis of agency and manufacturer information. | GAO-17-600

- **Blood glucose monitor.** These devices measure the blood glucose levels in patients. For patients with diabetes, this device provides them with information indicating when an insulin injection is needed. For the DME version of this device, a patient pricks his or her finger, touches the test strip to the blood, and waits for the durable monitor to

display a reading on the patient's blood glucose level. We identified one type of DME substitute. This disposable substitute includes a vial of 50 test strips with a small monitor on the lid. The entire unit is discarded when all of the test strips have been used. (See fig. 3.)

Figure 3: Durable Blood Glucose Monitor and Potential Disposable Substitute



Durable blood glucose monitor

- Includes a durable monitor and special test strips that can be reordered from the manufacturer, as needed
- Requires inserting a test strip into the monitor, on which the blood glucose reading is displayed



Completely disposable blood glucose monitor

- Includes a vial of 50 test strips with a small monitor on the lid
- Requires inserting a test strip into the monitor, on which the blood glucose reading is displayed
- Discarded once all of the test strips have been used

Source: National Institutes for Health/National Institute of Diabetes and Digestive and Kidney Diseases under license from Artfully Photographer/Shutterstock.com (top image); Trividia Health, Inc. (bottom image); GAO analysis of National Institutes for Health, Food and Drug Administration, and manufacturer information. | GAO-17-600

- **Sleep apnea devices.** Called continuous positive airway pressure (CPAP) machines, these devices use mild air pressure to keep a patient's breathing airways open. The DME version of this machine includes a mask or other device that fits over the patient's nose, and sometimes over the mouth. Straps hold the mask in position and a tube is connected to the machine's motor, which blows air into the tube. We identified one potential disposable DME substitute on the market and another in development. The first is a disposable valve that fits into a patient's nose with no mask or associated machine.²³ It is intended to last for one night and then be discarded. The second

²³This disposable substitute operates differently than the durable CPAP device. The CPAP device provides a positive pressure during inhalation and exhalation. In contrast, this disposable substitute creates pressure during exhalation only.

device is a disposable micro-CPAP still under development.²⁴ It involves a device that fits into a patient's nostrils and is intended to last 8 hours and then be discarded. According to the manufacturer, the time limit of 8 hours is linked to the battery life of the device. (See fig. 4.)

²⁴According to the developer, components of the device are being tested; clinical trials have not begun.

Figure 4: Durable Sleep Apnea Device and Potential Disposable Substitutes



Durable sleep apnea device

- Includes a mask that fits over the patient's nose and/or mouth with tubing connected to the machine's motor



Disposable sleep apnea device on the market

- Involves a valve that fits over the patient's nose
- Intended to last for one night



Disposable sleep apnea device in development

- Fits into a patient's nostrils
- Intended to last for one night (approximately 8 hours)

Source: Food and Drug Administration (top image); Provent Sleep Therapy LLC (middle image); Airing, Inc. (bottom image); GAO analysis of agency and manufacturer information. | GAO-17-600

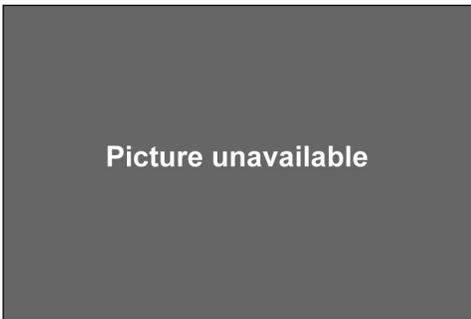
- **Nebulizers.** These devices allow a patient to receive a drug via inhalation. Nebulizers change liquid medicine into fine droplets (in aerosol or mist form) that are inhaled through a mouthpiece or mask and used to treat conditions, such as asthma. Disposable nebulizers are generally smaller than the DME versions and may last for a year. (See fig. 5.)

Figure 5: Durable Nebulizer and Potential Disposable Substitute



Durable nebulizer

- Includes a mouthpiece or mask connected to a compressor



Disposable nebulizer

- Includes a mouthpiece or mask connected to a powered controller
- Not intended to last as long as the DME version

Source: National Institutes of Health/National Heart, Lung, and Blood Institute under license from Shutterstock (top image); GAO analysis of agency and manufacturer information. | GAO-17-600

Note: We were unable to interview a manufacturer of a disposable nebulizer.

Stakeholders Identified Multiple Benefits of Using Disposable DME Substitutes, but Also Cited Limitations to Their Use

Over half of the 21 stakeholders we spoke with—including representatives from device manufacturers discussing their specific devices, Medicare beneficiary advocate groups, providers, and insurers—commented on the multiple benefits of substituting DME with disposable devices. The benefits can be categorized into three areas: (1) patient preference and/or improved quality of life, (2) better health outcomes, and (3) potential cost-savings. Specifically, 12 of the 21 stakeholders mentioned patient preference and/or improved quality of life as a benefit of using disposable substitutes. They said that disposable devices are, for example, often lighter and quieter than durable devices. Thus, in some cases, the substitutes may allow patients more freedom of movement and

be more discreet.²⁵ For example, the disposable insulin pumps do not require users to take additional supplies if they leave the house. Further, several stakeholders said that disposable devices are easier to use, such as the elastomeric pump, which one stakeholder explained had fewer opportunities for error.

Additionally, 9 of the 21 stakeholders we spoke with said these devices can result in better health outcomes due, in part, to better compliance.²⁶ For example, one stakeholder for a company that manufactures a disposable DME substitute to treat sleep apnea said the company specifically targeted its device to non-compliant users of the durable CPAP machine. This stakeholder said that while the durable CPAP machine is still considered the “gold standard” for treating obstructive sleep apnea, a significant proportion of patients do not comply with treatment over time. In addition, a representative for a company that manufactures a disposable insulin pump said that some patients are able to reduce the amount of insulin they need after using this device because of increased compliance. This representative explained that because the insulin is being delivered at a more continuous, consistent rate due to better compliance, users are making more efficient use of their insulin injections.

Twelve of the 21 stakeholders we spoke with noted different ways that disposable devices may result in potential cost-savings for the Medicare program and beneficiaries than their DME counterparts in some cases. For example, for patients that have acute conditions, such as those needing a course of antibiotics, it could be more financially prudent for Medicare and the beneficiary to use multiple elastomeric pumps for several days to administer the medication rather than pay for a durable pump, which is usually paid for on a monthly basis under Medicare. Also, four stakeholders said that disposable DME substitutes may generate

²⁵For example, see N. Ramchandani and R. Heptulla, “New Technologies for Diabetes: A Review of the Present and the Future,” *International Journal of Pediatric Endocrinology*, vol. 28 (2012).

²⁶These cited benefits were supported by some of the literature we identified in our review. For example, see M. Riaz et al., “Nasal Expiratory Positive Airway Pressure Devices (Provent) for OSA: A Systematic Review and Meta-Analysis,” *Sleep Disorders*, vol. 2015 (2015); A. Winter et al., “V-Go Insulin Delivery System Versus Multiple Daily Insulin Injections for Patients with Uncontrolled Type 2 Diabetes Mellitus,” *Journal of Diabetes Science and Technology*, vol. 9, no. 5 (2015); and Y. Reznik and O. Cohen, “Insulin Pump for Type 2 Diabetes – Use and Misuse of Continuous Subcutaneous Insulin Infusion in Type 2 Diabetes,” *Diabetes Care*, vol. 36, sup. 2 (2013).

potential savings because they do not have the cleaning and maintenance costs associated with DME, which can be reused. Further, one study we reviewed noted that nurses using elastomeric pumps reported a reduced workload for maintenance and education.²⁷ Table 1 shows examples of the potential cost-savings associated with using disposable DME substitutes compared to their DME counterparts, as noted by manufacturers of disposable DME substitutes.

Table 1: Manufacturer Examples of Potential Cost-savings Associated with Disposable Substitutes for Durable Medical Equipment (DME)

Type of device	Medicare payment for DME, supplies	Cost of disposable DME substitute ^a	Potential savings with disposable DME substitute
Durable electronic infusion pump and disposable elastomeric pump ^b	\$383.13 (average cost for DME and supplies at month one)	\$83.00 (cost for 2 elastomeric pumps at month one)	\$300.13 (potential savings using an elastomeric pump at month one)
Durable CPAP machine and disposable CPAP substitute (in development) ^c	\$242.58 (average cost for CPAP machine and supplies at month one)	\$90.00 (estimated cost for disposable CPAP substitute in development at month one) ^d	\$152.58 ^e (potential savings with disposable CPAP substitute in development at month one)

Source: GAO analysis of data from the Centers for Medicare & Medicaid Services and manufacturers. | GAO-17-600

^aCosts of disposable DME substitutes were provided by the manufacturers or developers (referred to collectively as “manufacturers”) of these devices.

^bThis comparison is of the costs for an electronic infusion pump and supplies (including for maintenance) and an elastomeric pump and supplies for two treatments of 5Fu chemotherapy treatment for colorectal cancer, with treatments being administered every 2 weeks. The costs do not include the cost of the medication; according to CMS, the cost of two treatments of 5Fu chemotherapy is \$1,840. The costs to Medicare and beneficiaries reflect the average non-rural fee schedule payment based on calendar year 2017 payment amounts.

^cThis comparison is of the costs in month one for a beneficiary using a nasal cannula continuous positive airway pressure (CPAP) system (including the nasal device, headgear, chinstrap, pressure tubing, a humidifier, and a non-disposable filter) to a disposable CPAP substitute still in development. The costs to Medicare and beneficiaries reflect the average non-rural fee schedule payment based on calendar year 2017 payment amounts.

^dThis estimate from the developer is subject to change if and when the device is approved for marketing.

^eThe potential savings with a disposable CPAP substitute compared to the durable CPAP machine vary over time. For example, in month two, the potential savings with the disposable CPAP substitute in this scenario is \$84.08. The difference is attributed to the different life expectancies of the supplies used in conjunction with the durable CPAP machine. For example, the estimated life expectancy of one non-disposable filter is about 6 months, while the estimated life expectancy of one item of pressure tubing is about 3 months.

Despite the potential benefits of disposable substitutes, stakeholders also noted limitations to using these devices regarding health outcomes and

²⁷See J. Heath and S. Jones, “Utilization of an Elastomeric Continuous Infusion Device to Maintain Catheter Patency,” *Journal of Intravenous Nursing*, vol. 24, no. 2 (March/April 2001).

potential cost-savings. For example, stakeholders and officials from both DME MACs said there are few studies comparing the effectiveness of disposable substitutes with their DME counterpart. Additionally, stakeholders noted that DME might be more appropriate than disposable DME substitutes in some cases, such as when dosing of medication needs to be precise. For example, two stakeholders said that the elastomeric infusion pump might not be appropriate when the rate of medication delivery needs to be specific, such as with some chemotherapy treatments or for patients with chronic conditions that require long-term treatment. Regarding potential cost-savings, four stakeholders noted that potential cost-savings might not be obtained for all disposable DME substitutes. For example, for patients with chronic conditions that require use of DME for extended periods, it might be more cost-effective to use a durable device rather than disposable substitutes that would need to be replaced regularly.

Stakeholders Identified Market Incentives for Developing Potential Disposable DME Substitutes, but Cited Medicare Payment Policy as a Disincentive

Stakeholders we spoke with—including representatives from device manufacturers, Medicare beneficiary advocate groups, providers, and insurers—cited several market incentives for developing potential disposable DME substitutes. For example, 12 of the 21 stakeholders noted that there is an international market for disposable devices, an increasing demand for some types of devices resulting from a growing patient population, a general movement resulting from advancing technology, and that some disposable devices can be sold as a “cash product”: that is, the product could be sold at relatively low cost without insurance coverage.

However, over half of the stakeholders we interviewed said lack of insurance coverage for disposable DME substitutes—particularly Medicare—was a disincentive to developing such products. Specifically, 13 of the 21 stakeholders cited lack of insurance coverage as a disincentive to developing disposable DME substitutes, including representatives from all of the manufacturer organizations and two-thirds of the manufacturers we interviewed. Further, 9 of these 13 stakeholders—including 4 out of 9 manufacturers—specifically cited lack

of Medicare benefit coverage as a barrier, with 2 of these 4 manufacturers noting that disposable substitutes do not meet CMS's 3-year minimum lifetime requirement to be categorized as DME. Eight of the 13 stakeholders also said that lack of Medicare coverage decreased their chances for obtaining benefit coverage from Medicaid and insurers, which often follow Medicare payment policy.

Based on our analysis of interviews with these stakeholders, we found limited coverage for the potential disposable substitutes we identified.²⁸ Specifically, according to the manufacturers we spoke with,

- the disposable elastomeric infusion pump is covered by Medicaid in some states and is covered by some health insurance plans;²⁹
- the completely disposable insulin pump is covered by Medicare under Part D by some plans, some Medicaid, and other insurance programs, including TRICARE;³⁰
- the insulin pump with disposable and durable components has Medicaid coverage in some states and extensive insurance coverage;³¹ and
- the disposable sleep apnea device has some coverage via insurance and other programs, including the Department of Veterans Affairs.

In addition, manufacturers noted that neither the disposable ambulatory infusion pump nor the completely disposable blood glucose monitor is covered by Medicare, Medicaid, or other insurance programs.

²⁸We identified two other potential disposable substitutes not included—a micro-CPAP device and nebulizers. We were unable to obtain coverage information for these devices: according to the developer, the micro-CPAP device is still under development, and we were unable to include a manufacturer of a disposable nebulizer in our analysis.

²⁹For this disposable device and for the others that we identified, if at least one state was identified that provided Medicaid coverage or one health insurer provided coverage, the device was included.

³⁰According to the manufacturer, the completely disposable insulin pump is coverable under Medicare Part D as a supply for the injection of insulin rather than under Part B as DME. Medicare Part D covers insulin and certain supplies used for the injection of insulin, such as syringes, gauze, and alcohol swabs. The manufacturer also noted that health insurance coverage of the completely disposable insulin pump is generally under the medical benefit rather than the pharmacy benefit.

³¹According to CMS officials, the agency is currently evaluating whether this device is eligible for coverage under Medicare Part D.

Stakeholders also raised concerns about how CMS determines whether a device with disposable components meets the definition of DME. As technology has advanced, manufacturers have developed potential substitutes for DME with both durable and disposable components. However, according to CMS officials, in order for a device to be covered by Medicare, the agency must determine that the medically necessary function of the device is performed by a durable component, not a disposable one. Two of the stakeholders we spoke with expressed concerns about CMS's approach to making durability determinations—and thus benefit coverage determinations—based on whether the durable or disposable component performs the medically necessary function. They said CMS should make such decisions based on the whole device and not its individual parts. If the durable component is essential to the device, then that should be sufficient.

CMS has made benefit coverage determinations for at least two devices with disposable and durable components. The first device is a specific continuous glucose monitor, which CMS classified as DME. This device includes an adhesive patch containing a disposable sensor and a wireless transmitter that sends information to a durable electronic receiver that displays a patient's blood glucose level accurately enough for a patient to make treatment decisions.³² CMS determined that for this device, the medically necessary function performed is the displaying of the blood glucose level, and therefore this particular continuous glucose monitor could be classified as DME. The second device involves one of the disposable insulin pumps we identified. This particular device includes an adhesive patch containing an insulin reservoir, pumping mechanism, and a transmitter sensor that delivers insulin after receiving instructions transmitted from a programmable durable electronic device. According to the manufacturer of this device, although the durable component meets CMS's 3-year minimum lifetime requirement, CMS determined that for this device, the medically necessary function is the pumping mechanism that delivers insulin. Therefore, because the pumping mechanism is disposable, CMS determined that this insulin pump is not considered DME.³³

³²Continuous glucose monitors measure and report a patient's glucose levels at regular intervals (for example, every 5 minutes). In contrast, a blood glucose monitor provides information only when the patient actively tests his or her blood.

³³The manufacturer of this device told us that they were still in discussion with CMS regarding the device's classification.

Furthermore, 6 of the 21 stakeholders we spoke with noted that technology is advancing in the area of medical device development. Five of these stakeholders specifically cited CMS's definition of DME as a disincentive to technological innovation, such as the development of disposable substitutes. As advancing technology results in changes to the functionality of devices, including the development of disposable substitutes, CMS will likely have to consider how its benefit coverage policies will apply to them. CMS has already faced issues accommodating new technology related to smartphone applications; for example, the continuous glucose monitor we described above, which CMS classified as DME, sends information to a durable electronic receiver that displays a patient's blood glucose level. Alternatively, this information can be displayed using a smartphone application; however, officials from one DME MAC that we spoke with said the receiver would not be covered by Medicare if information was obtained from the smartphone. CMS officials explained that the smartphone application is not considered DME because the smartphone itself is not primarily and customarily used to serve a medical purpose and is useful to an individual in the absence of illness or injury and therefore is not considered a medical device, although it may be used to track medical information.

As technology advances, manufacturers may continue to incorporate these advances into devices that have the potential to substitute for DME, and more disposable devices may be developed in the future. Federal internal control standards state that management should identify, analyze, and respond to change, including anticipating and planning for significant changes using a forward-looking process.³⁴ CMS has already begun facing issues related to advancing technology, such as making policy determinations for devices with both durable and disposable components based on the functionality of different parts of the device. However, Medicare currently does not cover most potential disposable DME substitutes because they do not meet Medicare's definition of "durable," which CMS has interpreted to mean withstanding repeated use and having an expected minimum lifetime of 3 years, among other things.³⁵ Further, CMS officials told us that the agency continues to regard this interpretation of the Medicare statute as appropriate and has not considered the possibility of reexamining it in order to accommodate disposable substitutes. Without such consideration for Medicare

³⁴GAO-14-704G, Internal Control 9.03.

³⁵See 21 C.F.R. § 414.202 (2016).

coverage, CMS and other insurers that follow Medicare payment policy may not be taking advantage of the possible benefits of these devices.

CMS Would Need to Consider Issues Related to Benefit Categorization, Including Legal Authority and Potential Payment Methodologies, If Medicare Coverage Were Expanded to Disposable DME Substitutes

If Medicare coverage were expanded to include disposable DME substitutes, CMS would need to consider issues related to benefit category designation. We identified three possible options that CMS could consider as benefit categories for expanding coverage: (1) using the DME benefit, (2) using the home health benefit, or (3) establishing a new benefit. (See table 2.) Under each scenario, CMS would need to consider its authority to provide for such expanded coverage. In addition, CMS would need to evaluate potential payment methodologies for reimbursement, taking into consideration its responsibility to be a prudent purchaser of medical care. Although we identify several possibilities in this report, this is not intended to be an exhaustive list of potential benefit categories and payment methodologies to be considered if Medicare coverage were expanded to disposable DME substitutes.

Table 2: Possible Options for Covering Disposable Durable Medical Equipment (DME) Substitutes

Medicare benefit category	Authority	Reimbursement options
DME benefit	Regulatory change could redefine “durable” to accommodate substitutes with shorter life expectancy, but congressional action likely necessary for single and short-term use devices	Use current fee schedule or a reduced percentage of the fee schedule amount or Establish payment through the competitive bidding program
Home health benefit	Congressional action required	Establish a separate payment for home health beneficiaries using disposable DME substitutes or Adjust the home health bundle to include disposables
Newly established benefit for disposable devices	Congressional action required	Would depend on congressional action taken in establishing the new benefit

Source: GAO analysis of applicable laws and regulations. | GAO-17-600

Note: The possible options presented in this table are not intended to be an exhaustive list.

DME Benefit Category

Because the disposable DME substitutes we identified generally treat the same conditions as some DME items, consideration could be given to expanding eligibility for the DME benefit to cover similar disposable items.³⁶ Although the CMS regulation interpreting the statutory definition of DME includes a requirement that such equipment can withstand repeated use and have a life expectancy of at least 3 years, CMS officials acknowledged their authority to promulgate rules amending the regulation to potentially shorten the minimum lifetime expectancy.³⁷ However, it is uncertain whether CMS could reasonably interpret “durable” in such a way that allows for coverage of all of the disposable DME substitutes we identified—many of which are intended for single or short-term use.³⁸ Thus, providing Medicare coverage to all of these disposable DME substitutes would likely require congressional action.

Some stakeholders also noted that using the DME benefit would require several coverage decisions to be made, either through CMS’s national coverage determination process or through the local process conducted by the DME MACs.³⁹ For example, one decision point three stakeholders noted is whether Medicare would cover a disposable DME substitute as a

³⁶Similarly, in 2012, the Medicare Payment Advisory Commission noted that disposable infusion pumps were not covered by Medicare but that Congress could potentially extend the DME benefit to include them. See Medicare Payment Advisory Commission, *Report to the Congress: Medicare and the Health Care Delivery System, June 2012* (Washington, D.C.: June 15, 2012).

³⁷42 C.F.R. § 414.202 (2016). In the preamble to the 2011 final rule establishing the standard for lifetime expectancy, CMS referenced multiple sources for setting the standard at 3 years, including the Department of Commerce’s durability standard for consumer durable goods. See 76 Fed. Reg. 70228, 70287 (preamble IV, D) (Nov. 10, 2011).

³⁸The term “durable medical equipment” is established in statute, but the statutory definition does not elaborate on the specific meaning of “durable.” See 42 U.S.C. § 1395x(n). CMS officials referred to a statutory payment rule authorizing the replacement of certain items of durable medical equipment that have been continuously used for a period or “reasonable useful lifetime” of at least 5 years as a basis for assuming that the DME benefit is for equipment intended to be used over multiple years. See 42 U.S.C. § 1395(m)(a)(7)(C).

³⁹National and local coverage determinations are policies that identify the items and services and the circumstances under which they are covered by Medicare. CMS develops national coverage determinations, which apply to all beneficiaries across the country. DME MACs develop local coverage determinations related to DME, and these apply to the states in their jurisdictions, which can lead to geographic variation in Medicare coverage.

potential replacement for its durable counterpart in all cases or only under certain circumstances. Another consideration mentioned by another three stakeholders is whether there would be limits to the benefit, such as whether Medicare would cover a disposable DME substitute only for a certain number of months. Limiting coverage in such a way could encourage the use of disposable DME substitutes for acute conditions over chronic conditions. Three stakeholders suggested that some disposable DME substitutes, such as in the case of elastomeric infusion pumps, are more likely to result in cost-savings as compared to their durable counterparts when used to treat acute conditions. However, limiting coverage of disposable DME substitutes to a certain length of time could impede beneficiary access to their preferred medical equipment.

We identified two approaches CMS could consider within the DME benefit for setting reimbursement rates for disposable DME substitutes. Specifically, payments for disposable DME substitutes could be based on the payment rates of their DME counterparts, or they could be treated separately, making use of the typical procedures for establishing payment rates for new DME. For the first approach, CMS could set the reimbursement rate for a disposable DME substitute at the same price as the DME counterpart, or—recognizing that disposable devices may be less costly than DME—at a reduced percentage of the rate for the DME counterpart.⁴⁰ However, we have previously reported that the historical charges on which the fee schedule rates are based are outdated and do not reflect current costs.⁴¹ As a result, the reimbursement rates increase costs to both the federal government and Medicare beneficiaries. In addition, four stakeholders raised concerns about this type of “one-size-fits-all” approach to disposable DME substitutes. For example, one stakeholder noted that disposable DME substitutes could vary widely in cost, quality, and the length of time a beneficiary requires the device. The

⁴⁰For example, S. 1253, introduced in the Senate in May 2015, would have expanded Medicare coverage to certain disposable medical technology that would otherwise be covered as DME at a payment rate of 95 percent of the DME item for which it would substitute. This bill was amended in committee to specifically pertain to negative pressure wound therapy devices, and language from this bill eventually became law as part of the Consolidated Appropriations Act, 2016, which provided a separate payment for disposable negative pressure wound therapy at a rate equal to the amount paid under the outpatient payment system. See S.1253 as reported by Senate Finance on Jul. 30, 2015, at 9.

⁴¹See GAO, *Medicare: Competitive Bidding for Medical Equipment and Supplies Could Reduce Program Payments, but Adequate Oversight Is Critical*, [GAO-08-767T](#) (Washington, D.C.: May 6, 2008).

cost of certain disposable DME substitutes may not be similar to the cost of their DME counterparts. Therefore, basing the rates for all disposable devices on the DME rates might result in significant over- or underpayments.

Using the second approach, separate payment rates could be established for disposable DME substitutes using one of the two existing DME payment methodologies: the fee schedule based on historical charges or the competitive bidding program.

- Setting payment rates via the historical fee schedule would likely entail using the gap-fill method because the disposable DME substitutes we identified did not exist at the time the historical charges for most DME were set. In this case, the gap-fill method would rely on taking current supplier prices and resetting them to the 12-month period ending June 30, 1987, used in the original fee schedule by a deflation factor based on the consumer price index for all urban consumers, followed by re-inflating the price using an inflation factor limited to the years in which a DME inflation update was provided.⁴² One stakeholder expressed concern regarding the gap-fill method, though, stating that the process results in pricing that does not accurately represent market prices. In addition, as with the fee schedule amounts for DME, the payments for disposable DME substitutes could become outdated over time and increase costs to both the federal government and Medicare beneficiaries.
- A competitive bidding program that would reflect market prices could be established for disposable DME substitutes, as CMS has done for certain DME items. We previously found that, among other things, the competitive bidding method has generally led to reduced payments for those DME included in the program.⁴³ We have also previously reported that CMS's monitoring of the competitive bidding program indicated that beneficiary DME access and satisfaction had not been

⁴²CMS officials noted that while the gap-fill method is an administrative process, it is based on statutory requirements for setting the DME fee schedule amounts. See 42 U.S.C. § 1395m(a).

⁴³See GAO, *Medicare: Bidding Results from CMS's Durable Medical Equipment Competitive Bidding Program*, [GAO-15-63](#) (Washington, D.C.: Nov. 7, 2014).

affected, but noted some stakeholders' concerns, such as difficulty locating a contract supplier.⁴⁴

Home Health Benefit Category

Disposable DME substitutes could potentially be covered under Medicare's home health benefit. There is precedent for such coverage: disposable negative pressure wound therapy devices are covered under the home health benefit. Previously, they were covered as part of the bundled rate, but the Consolidated Appropriations Act, 2016, required certain disposable negative pressure wound therapy devices to be paid separately under Medicare home health services.⁴⁵ Coverage under the home health benefit could potentially be expanded to include other types of disposable DME substitutes that we identified. However, coverage under this benefit would only be applicable in cases where a beneficiary is receiving Medicare home health services, which excludes beneficiaries who are not homebound and do not have a need for skilled care. Furthermore, because disposable DME substitutes are not among the existing covered services for home health, covering these disposable devices under this benefit would likely require legislation.⁴⁶ We identified two options for setting payment rates within the home health benefit: as a separate payment or as part of bundled payments.

- Under the home health benefit, a separate payment amount could be set for disposable DME substitutes. For the disposable negative pressure wound therapy device, Congress established a separate payment amount equal to the amount paid under the outpatient payment system. However, according to manufacturers we spoke with, the disposable DME substitutes we identified are not currently covered under the outpatient benefit, and therefore no such rates exist for Congress to do the same for these devices. Additionally, we have previously found that generous separate payments can

⁴⁴See GAO, *Medicare: CMS's Round 2 Durable Medical Equipment and National Mail-order Diabetes Testing Supplies Competitive Bidding Programs*, [GAO-16-570](#) (Washington, D.C.: Sept. 15, 2016).

⁴⁵Pub. L. No. 114-113 § 504(a), (b), 129 Stat. 3021 (codified at 42 U.S.C. §§ 1395I(a)(1), 1395m(s), and 1395x(m)(5)).

⁴⁶The home health services benefit includes skilled nursing care, physical therapy, occupational therapy, speech-language pathology services, home health aide services, medical social services, and medical supplies (such as catheters). See 42 U.S.C. § 1861(m).

incentivize a specific medical practice even if it is not always entirely warranted. For example, we found that the separate payments for injectable drugs used in treating end-stage renal disease exceeded the costs of acquiring them and provided an incentive to use more of the drugs than necessary.⁴⁷

- Alternatively, disposable DME substitutes could be included in the home health bundle. CMS sets the bundled payment's national average base amount as the amount that would be paid for a typical home health patient residing in an average market. Including disposable DME substitutes in the bundle might subsequently mean recalculating the base rate. However, as one stakeholder noted, including disposable DME substitutes in the bundle would mean they are treated differently than their DME counterparts, which are paid for as separate payments under the DME benefit for beneficiaries receiving home health services. Literature and two of our stakeholder interviews noted that bundled payment can incentivize using the device that the provider has determined to be more cost-effective, but if DME and disposable DME substitutes were paid differently, providers might not have an incentive to choose the more cost-effective device.⁴⁸

New Benefit Category

A new benefit category could be established to specifically cover the disposable DME substitutes we identified, or—more broadly—to cover a category of disposable devices that could potentially substitute for DME, including those not yet on the market. Only Congress has the authority to create new Medicare benefit categories. If Congress created such a benefit, it could establish a new payment methodology, use one of the payment methodologies discussed in this report, or use an existing

⁴⁷See GAO, *End-Stage Renal Disease: Bundling Medicare's Payment for Drugs with Payment for All ESRD Services Would Promote Efficiency and Clinical Flexibility*, [GAO-07-77](#) (Washington, D.C.: Nov. 13, 2006). These drugs were subsequently included in the end-stage renal disease bundle, and their use declined—utilization in the first year the drugs were included in the bundle was about 23 percent lower, on average, than it had been 4 years previously. See GAO, *End-Stage Renal Disease: Reduction in Drug Utilization Suggests Bundled Payment Is Too High*, [GAO-13-190R](#) (Washington, D.C.: Dec. 7, 2012).

⁴⁸See R. Mechanic and S. Altman, "Payment Reform Options: Episode Payment Is a Good Place to Start," *Health Affairs*, vol. 28, no. 2 (2009); and Urban Institute and Catalyst for Payment Reform, *Payment Methods: How They Work* (Washington, D.C.: Urban Institute, 2016).

payment methodology we have not discussed here. For example, one stakeholder suggested emulating a payment mechanism established under the Protecting Access to Medicare Act of 2014 for clinical laboratory tests: beginning in 2018, the Medicare rate would reflect private payer rates for these tests.⁴⁹ Regardless of the methodology established, the rate would ideally be set to account for the costs of relatively efficient providers of the devices, and provide sufficient access to the devices for beneficiaries.

Conclusions

Some disposable medical devices may have the potential to substitute for DME and may offer advantages in some cases, such as cost-savings and better health outcomes. While a few of these disposable DME substitutes have been on the market for several years, a couple we identified are more recent. As technology advances, more manufacturers could develop new disposable devices, and stakeholders we interviewed identified incentives to do so, such as a growing patient population. However, Medicare currently does not cover most disposable DME substitutes because they do not meet Medicare's definition of durability. CMS officials stated that they continue to regard this definition as appropriate and have not considered the possibility of extending DME coverage to these substitutes. As we noted, there may be ways to cover disposable DME substitutes other than with the DME benefit and its associated payment methodologies, such as the home health benefit. According to federal internal control standards, management should anticipate and plan for significant changes using a forward-looking process. Without considering whether disposable DME substitutes should be covered by Medicare, CMS and other insurers that follow Medicare payment policy may not recognize advances in technology that may provide potential cost-savings and better health outcomes.

Recommendation for Executive Action

We recommend that the Administrator of CMS evaluate the possible costs and savings of using disposable devices that could potentially substitute for DME, including options for benefit categories and payment

⁴⁹See Pub. L. No. 113-93, § 216, 128 Stat. 1040, 1053 (codified at 42 U.S.C. § 1395m-1).

methodologies that could be used to cover these substitutes, and, if appropriate, seek legislative authority to cover these devices.

Agency Comments and Our Evaluation

We provided a draft of this report to HHS for comment. HHS's written comments are reproduced in appendix II. HHS also provided technical comments, which we incorporated as appropriate.

In its written comments, although HHS did not state whether it agreed or disagreed with the recommendation, the agency stated that it is premature to conduct the study we recommended of the possible costs and savings of using disposable devices that could potentially substitute for DME. HHS emphasized that only Congress has the authority to create new benefit categories and payment systems for potential disposable DME substitutes and that additional information is needed on whether disposable devices are appropriate clinical substitutes before conducting an analysis of possible costs and savings. We agree, and our report states, that CMS may lack the authority to interpret "durable" in a way that allows for coverage of all the disposable DME substitutes we identified and that congressional action may be required for Medicare to cover some of these devices. However, without conducting a study to identify the potential costs and benefits of covering such devices, CMS will lack the necessary clinical and cost information to determine if it would be beneficial to reassess current statutory and regulatory coverage rules. In other instances, CMS has used the national and local coverage determination processes to establish clinically based policies related to DME. Moreover, CMS—which oversees the implementation of complex Medicare payment rules—is uniquely positioned to consider the extent to which coverage of any clinically appropriate substitutes would benefit the federal government and beneficiaries.

For these reasons, we disagree with HHS that an evaluation of potential disposable DME substitutes is premature. As we state in the report, management should anticipate and plan for significant changes using a forward-looking process, according to federal internal control standards. The study we recommended is such a forward-looking process. Unless it is undertaken, neither HHS nor Congress will have the information it needs to reassess whether the current statutory and regulatory framework makes good clinical and fiscal sense.

We are sending copies of this report to the appropriate congressional committees, the Secretary of Health and Human Services, and other

interested parties. In addition, the report is available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or kingk@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix III.



Kathleen M. King
Director, Health Care

List of Committees

The Honorable Orrin G. Hatch
Chairman

The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate

The Honorable Greg Walden
Chairman

The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Kevin Brady
Chairman

The Honorable Richard Neal
Ranking Member
Committee on Ways and Means
House of Representatives

Appendix I: List of Stakeholders Interviewed

Medical Device Manufacturer Groups

1. Advanced Medical Technology Association
2. Medical Device Manufacturers Association

Medicare Beneficiary Advocate Groups

1. American Diabetes Association
2. Center for Medicare Advocacy

Health Care Provider Groups

1. Alliance for Home Health Quality and Innovation
2. American Association for Homecare
3. National Association for the Support of Long Term Care
4. National Home Infusion Association

State Medicaid Directors Group

1. National Association of Medicaid Directors

Insurers and Insurer Groups

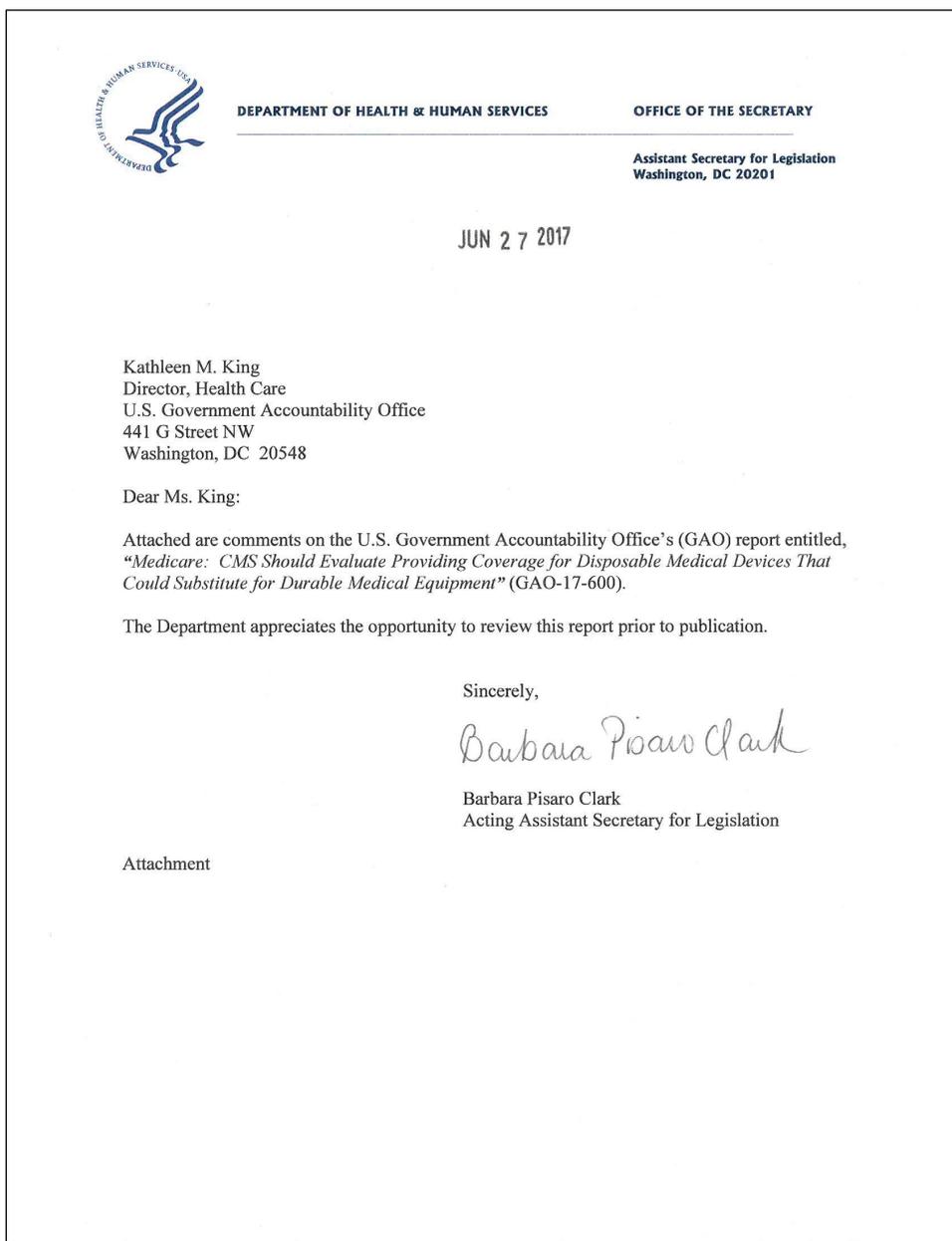
1. Alliance of Community Health Plans
2. America's Health Insurance Plans
3. Kaiser Permanente

Manufacturers and Developers of Specific Disposable Medical Devices

1. Airing
2. B. Braun Medical Inc.
3. Halyard Health, Inc.

4. Insulet Corporation
5. Provent Sleep Therapy, LLC
6. Smith & Nephew
7. Trividia Health, Inc.
8. Valeritas, Inc.
9. Zyno Medical

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



GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: CMS SHOULD EVALUATE PROVIDING COVERGAE FOR DISPOSABLE MEDICAL DEVICES THAT COULD SUBSTITUTE FOR DURABLE MEDICAL EQUIPMENT (DME) (GAO-17-600)

The Department of Health and Human Services (HHS) appreciates the opportunity to review and comment on the Government Accountability Office's (GAO) draft report. HHS strives to provide Medicare beneficiaries with access to high quality health care while protecting taxpayer dollars.

As technology advances, new items and services, including disposable medical devices, must be evaluated. HHS and Congress must work together to explore new and innovative ways to incorporate technological advances into the Medicare benefit. This is a highly complex process that requires in-depth analysis to fully evaluate various coverage and payment considerations, and HHS looks forward to working with our partners in Congress to evaluate how these new technologies could potentially be incorporated. HHS recognizes the importance of continuing to provide Medicare beneficiaries with access to medically necessary services while at the same time, ensuring these services comply with Federal laws and requirements.

The Medicare Part B benefit for Durable Medical Equipment (DME) is a benefit for rental of equipment such as ventilators, oxygen equipment, hospital beds, wheelchairs, power-operated vehicles, and blood glucose monitors for use in the home. The statutorily specified payment rules are set up based on rental of items that have a repeated use over a period of time. Payment for certain items can be made on a lump sum purchase basis in addition to rental; however, the item cannot be replaced until the five year reasonable useful lifetime for the item has expired. Medicare defines DME as equipment that can withstand repeated use (i.e., can be rented), has an expected lifetime of at least three years, is used primarily to serve a medical purpose, is not generally useful in the absence of an illness or injury, and is appropriate for use in the home. Disposable medical devices, which are items that are intended to treat medical conditions but are not designed to withstand repeated use, do not qualify as DME and therefore are not covered under the current Medicare benefit.

GAO's recommendations and HHS's responses are below.

GAO Recommendation

The GAO recommends that the Administrator of the Centers for Medicare & Medicaid Services (CMS) evaluate the possible costs and savings of using disposable devices that could potentially substitute for DME, including options for benefit categories and payment methodologies that could be used to cover these substitutions, and, if appropriate, seek legislative authority to cover these devices.

HHS Response

As only Congress has the authority to create new benefit categories and payment systems for these items and there important clinical issues, it may be premature for HHS to conduct a formal study. In particular, additional information is needed on whether disposable items are appropriate clinical substitutes for DME before HHS could do an analysis on the possible costs and savings of such devices. HHS reviews devices on a case by case basis to determine whether the item qualifies under statute for coverage. Regardless, it is premature for HHS to conduct a formal study on all possible devices that could potentially substitute for DME.

Appendix III: GAO Contact and Staff Acknowledgments

GAO Contact

Kathleen M. King, (202) 512-7114 or kingk@gao.gov

Staff Acknowledgments

In addition to the contact named above, Martin T. Gahart, Assistant Director; Hannah Marston Minter, Analyst-in-Charge; George Bogart; Ricky Harrison; Gay Hee Lee; Elizabeth T. Morrison; and Alison Smith made key contributions to this report.

Appendix IV: Accessible Data

Agency Comment Letter

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

Page 1

Kathleen M. King Director, Health Care

U.S. Government Accountability Office

441 G Street NW Washington, DC 20548

Dear Ms. King:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "Medicare: CMS Should Evaluate Providing Coverage for Disposable Medical Devices That Could Substitute for Durable Medical Equipment" (GAO-17-600).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Barbara Pisaro Clark

Acting Assistant Secretary for Legislation

Attachment

Page 2

The Department of Health and Human Services (HHS) appreciates the opportunity to review and comment on the Government Accountability Office's (GAO) draft report. HHS strives to provide Medicare beneficiaries with access to high quality health care while protecting taxpayer dollars.

As technology advances, new items and services, including disposable medical devices, must be evaluated. HHS and Congress must work together to explore new and innovative ways to incorporate technological advances into the Medicare benefit. This is a highly complex process that requires in-depth analysis to fully evaluate various coverage and payment considerations, and HHS looks forward to working with our partners in Congress to evaluate how these new technologies could potentially be incorporated. HHS recognizes the importance of continuing to provide Medicare beneficiaries with access to medically necessary services while at the same time, ensuring these services comply with Federal laws and requirements .

The Medicare Part B benefit for Durable Medical Equipment (DME) is a benefit for rental of equipment such as ventilators, oxygen equipment, hospital beds, wheelchairs , power-operated vehicles, and blood glucose monitors for use in the home. The statutorily specified payment rules are set up based on rental of items that have a repeated use over a period of time. Payment for certain items can be made on a lump sum purchase basis in addition to rental; however, the item cannot be replaced until the five year reasonable useful lifetime for the item has expired.

Medicare defines DME as equipment that can withstand repeated use (i.e., can be rented), has an expected lifetime of at least three years, is used primarily to serve a medical purpose, is not generally useful in the absence of an illness or injury, and is appropriate for use in the home.

Disposable medical devices, which are items that are intended to treat medical conditions but are not designed to withstand repeated use, do not qualify as DME and therefore are not covered under the current Medicare benefit.

GAO's recommendations and HHS's responses are below.

GAO Recommendation

The GAO recommends that the Administrator of the Centers for Medicare & Medicaid Services (CMS) evaluate the possible costs and savings of using disposable devices that could potentially substitute for DME, including options for benefit categories and payment methodologies that could be used to cover these substitutions, and, if appropriate, seek legislative authority to cover these devices.

HHS Response

As only Congress has the authority to create new benefit categories and payment systems for these items and there important clinical issues, it may be premature for HHS to conduct a formal study. In particular, additional information is needed on whether disposable items are appropriate clinical substitutes for DME before HHS could do an analysis on the possible costs and savings of such devices. HHS reviews devices on a case by case basis to determine whether the item qualifies under statute for coverage. Regardless, it is premature for HHS to conduct a formal study on all possible devices that could potentially substitute for DME.

Page 3

Under 'What GAO Found', second paragraph, second sentence:

HHS would like to clarify that the requirement that Durable Medical Equipment (DME) also have an expected minimum lifetime of at least three years was added to the regulations to clarify how long equipment must be able to withstand repeated use in order to be considered DME. The three-year minimum lifetime requirement is not the sole requirement for equipment to be considered durable medical equipment for Medicare purposes .

HHS suggests the following change:

Disposable substitutes are generally precluded from Medicare coverage under DME benefit do not meet the Center for Medicare & Medicaid Services' (CMS) regulatory definition of "durable medical equipment" - specifically can withstand repeated use and an expected lifetime of at least 3 years.

Under 'What GAO Found', second paragraph, fourth sentence :

HHS is not clear as to how the clarifying guidance has led to challenges with coverage of some devices with durable and disposable components.

HHS suggests the following change:

"Some stakeholders noted that CMS' definition of DME is a disincentive to technological innovation."

Under 'What GAO Found', second paragraph, fifth sentence:

HHS suggests deleting this sentence. HHS would like to clarify that the definition of DME has been longstanding. The 3-year minimum lifetime requirements was added in 2012 to clarify how long an item must be able to withstand repeated use to be considered DME for Medicare purposes. It seems to be a mischaracterization to state that the agency has not considered the possibility of reexamining its definition since this requirement was added relatively recently.

As discussed, HHS does not have the statutory authority to cover disposable substitutes by reexamining the definition. The DME benefit is a benefit for rental of equipment such as ventilators, oxygen tanks, hospital beds, and wheelchairs for use in the home. The statutorily specified payment rules are set up based on rental of items that have a repeated use over a period of time, not for disposable items. The statute also specifies a 5-year reasonable useful lifetime for DME before payment can be made for replacement of an item of DME. This requirement conveys statutory intent that the DME benefit is for equipment intended to be used over multiple years. HHS does not believe that a regulatory change could be made to cover disposable items and that coverage of disposable items could only be done through a legislative change.

Page 4

Page 6

HHS would like to clarify that disposable negative pressure wound therapy (NPWT) devices were covered under the Medicare home health benefit prior to the Consolidated Appropriations Act, 2016. HHS notes that physicians can also bill under the Physician Fee Schedule for furnishing negative pressure wound therapy using disposable NPWT devices. Therapists in independent practice and home health agencies can also bill under the Physician Fee Schedule for furnishing negative pressure wound therapy using disposable NPWT devices when a patient is not under a home health plan of care.

HHS suggests the following change:

"However, beginning in January 2017, the Consolidated Appropriations Act, 2016 unbundled certain disposable negative pressure wound therapy that may substitute for DME from the Medicare home health payment to be paid separately under the Medicare home health benefit."

"The act provides separate payment for disposable negative pressure wound therapy-meaning it is not part of the bundled payment amount-and sets the reimbursement rate for disposable negative pressure wound therapy equal to the rate used in an outpatient setting.

"Furthermore, the act provides separate payment for the disposable negative pressure wound therapy to beneficiaries who are receiving home health services, whereas the DME benefit would not include that restriction."

Page 7-12, Section "Some Potential Examples of Disposable Substitutes for DME Exists, according to Industry Stakeholders":

Please consider including additional information regarding how the eight disposable items were determined to be considered appropriate clinical substitutes for current DME. It would be helpful to understand how these items were determined to be reasonable and necessary for the treatment of the same illness or injury or to improve the same function of a malformed body member.

Page 16, second bullet:

For clarity, please consider noting that completely disposable insulin pumps are covered by Medicare Part D.

HHS suggests the following change:

- the completely disposable insulin pumps is covered by Medicare under Part D, some Medicaid..

Page 17, second paragraph, sixth sentence:

HHS would like to clarify that smartphones are not considered DME because in addition to not being primarily and customarily used for medical purposes, they cannot be useful to an individual in the absence of illness or injury

HHS suggests the following change:

Page 5

"CMS officials explained that smart phone application is not considered DME because they the smartphone itself is not primarily and customarily used to serve a medical purpose and cannot be useful to an individual in

the absence of illness or injury and therefore not considered a medical device, although it may be used to track medical information.

Page 18, first paragraph, third sentence:

HHS is does not believe that the clarifying guidance has resulted in challenges with coverage of some devices with durable and disposable components.

HHS suggests the following change:

"CMS has already made coverage determinations for devices with both durable and disposable components based on the functionality of different parts of the device."

Page 18, first paragraph, fourth sentence:

As noted earlier, HHS cannot cover disposable devices through administrative action and legislation would be needed.

HHS suggests the following change :

"Medicare currently does not cover disposable DME substitutes because they do not meet Medicare's regulatory definition of "durable medical equipment", which CMS has interpreted to mean- includes withstanding repeated use and an expected minimum lifetime of 3 years. CMS officials told us that there needs to be a legislative change in order to accommodate disposable substitutes."

Page 20-22

Please consider addressing whether key features of current payment methodologies could be used for the selected disposable substitute devices. For example, many DME items are paid on a monthly basis and capped after 13 or 36 months. It would be useful to understand whether a monthly payment methodology could be used to pay for disposable devices as opposed to lump sum purchase, and whether there should be financial or utilization cap, and how these methodologies could result in costs or savings to the Medicare program.

Please also consider addressing why and when patients would typically utilize a disposable device (e.g., an elastomeric pump after surgery) and whether it would be more appropriate for payment for a disposable device

to be part of a bundled payment (e.g., included in the payment amount for a procedure or hospital stay}, or paid separately.

Page 21, first bullet point, third sentence:

Please clarify that the DME fee schedule amounts are specified in statute. The gap-filling process of the DME fee schedule amounts is an administrative process based on section 1834(a) of the Social Security

Page 6

Act that fee schedule amounts be calculated for DME based on average allowed charges for the items from 1986 and 1987, increased by annual covered item update factors.

HHS suggests the following change:

"One stakeholder expressed concern regarding the gap-fill method, though, stating that the process results in pricing that does not accurately represent market prices. The gap-filling process is based on what is required in law for setting the DME fee schedule amounts."

Page 21-22

HHS would like to clarify that the Durable Medical Equipment, Prosthetics, Orthotics and Supplies

{DMEPOS) competitive bidding program was implemented as required by law and through notice and comment rulemaking. HHS suggests either striking the statement raised by stakeholders, or providing context on how CMS implemented the DMEPOS competitive bidding program, and what a traditional auction would look like and whether it would meet the current requirements.

Page 22, second paragraph, second sentence:

As noted earlier, the Consolidated Appropriations Act, 2016 did not set a coverage precedence for disposable NPWT devices. Rather, it unbundled disposable negative pressure wound therapy from the home health 60-day episode payment amount.

HHS suggests the following change:

The Consolidated Appropriations Act, 2016 required disposable negative pressure wound therapy devices to be paid separately under Medicare home health services.

Page 22, second paragraph, third sentence:

HHS notes that there is no discretion of the criteria to be covered under the Medicare Home Health Benefit. The requirements in sections 1814(a) and 1835(a) of the Act state a beneficiary must be considered confined to the home, must have a skilled need (skilled nursing, physical therapy (PT), speech- language pathology {SLP) or a continuing need for occupational therapy after the need for skilled nursing, PT or SLP have ceased}, must be under the care of a physician, must be receiving services under a plan of care developed and reviewed by a physician, and must have had a face-to-face encounter with an allowed provider type.

HHS suggests the following change:

"However, coverage under this benefit would only be applicable in cases where a beneficiary is receiving Medicare home health services, which excludes beneficiaries who are not homebound and do not have a skilled need."

Page 7

Page 22-23, Section "Home Health Benefit Category":

HHS would like to emphasize that as noted in the report, Medicare home health coverage is limited to patients that are homebound and have a skilled need. Regardless if a separate payment were made or whether the device was included in the home health bundled payment, the coverage would be limited to a sub-set of the population with distinct clinical needs. As such, the home health benefit would not be an appropriate or viable option for coverage for disposable devices.

Page 24, Section "Conclusions", fourth sentence:

HHS would like to clarify that the DME benefit is a benefit for rental of equipment such as ventilators, oxygen tanks, hospital beds, and wheelchairs for use in the home. The statutorily specified payment rules are set up based on rental of items that have a repeated use over a period of time, not for disposable items. The statute also specifies a 5-year reasonable useful lifetime for DME before payment can be made

for replacement of an item of DME. This requirement conveys statutory intent that the DME benefit is for equipment intended to be used over multiple years. HHS does not believe that a regulatory change could be made to cover disposable items and that coverage of disposable items could only be done through a legislative change.

HHS suggests the following change:

"Medicare does not cover most disposable DME substitutes because they do not meet Medicare's benefit category for durable medical equipment."

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