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### PATIENT ACCESS TO DISPOSABLE MEDICAL TECHNOLOGY ACT OF 2015

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JULY 30, 2015.—Ordered to be printed  
—————

Mr. HATCH, from the Committee on Finance,  
submitted the following

### R E P O R T

[To accompany S. 1253]

The Committee on Finance, to which was referred the bill (S. 1253) to amend title XVIII of the Social Security Act to provide coverage of certain disposable medical technologies under the Medicare program, and for other purposes, having considered the same, reports favorably thereon with an amendment and an amendment to the title and recommends that the bill, as amended, do pass.

#### I. LEGISLATIVE BACKGROUND

##### *Background and need for legislative action*

The Medicare Supplementary Medical Insurance Program (Part B) currently covers a wide variety of durable medical equipment (DME) if they are medically necessary and are ordered by a physician or qualified non-physician practitioner.

Durable medical equipment (DME) is equipment that (1) can withstand repeated use, (2) has an expected life of at least three years (effective for items classified as DME after January 1, 2012), (3) is used to serve a medical purpose, (4) generally is not useful in the absence of an illness or injury, and (5) is appropriate for use in the home. DME also includes the drugs necessary for the proper function of certain DME, and supplies, such as surgical dressings, used in conjunction with the DME.

In the past, Medicare has struggled to cover disposable medical technologies because they did not fit neatly into the criteria for DME. Beneficiaries were often denied coverage of these products and therefore could not take advantage of the benefits of potentially more efficient and effective products.

Under current law, Medicare beneficiaries may receive negative pressure wound therapy (NPWT), which uses a vacuum pump and special dressings to promote wound healing. If a home health agency (HHA) furnishes a beneficiary with durable NPWT, Medicare makes a payment to the HHA for the visit and to a DME supplier for the NPWT. If the HHA uses a disposable NPWT, Medicare does not make an additional payment and the HHA absorbs the cost of the disposable NPWT.

This bill specifically provides for a new add-on payment to home health agencies (HHAs) that furnish disposable NPWT equipment to Medicare beneficiaries, in the home setting.

#### PRESENT LAW

##### *In general*

Under Section 1861 of title XVIII of the Social Security Act,<sup>1</sup> Medicare covers durable medical equipment (DME) if it is medically necessary and prescribed by a physician. Specifically the criteria requiring that a piece of equipment have an expected life of at least three years, has kept some disposable products that would otherwise serve the same function, from being covered by Medicare.

#### REASONS FOR CHANGE

The Committee recognizes the importance of allowing Medicare beneficiaries to have access to new and innovative medical technologies that could make their lives better, both through high quality healthcare products and convenience in use. Most DME products would never have a disposable counterpart (i.e., hospital beds, wheelchairs, etc.), so this bill—which is limited to disposable NPWT—is a first step in coverage of disposable medical technologies.

## II. EXPLANATION OF THE BILL

This bill, as modified by the committee, amends Medicare to provide a new add-on payment to HHAs that furnish disposable negative pressure wound therapy (NPWT) to Medicare beneficiaries. This device, called an applicable disposable device, is defined as an integrated system comprising a non-manual vacuum pump, a receptacle for collecting exudate and dressings for the purpose of wound therapy. In addition, it is a substitute for and used in lieu of a durable NPWT that would otherwise be covered.

The Secretary would be required to establish the separate payment amount for 2017, 2018 and 2019 at the greater of (1) the amount that would be paid for applicable disposable devices under the hospital outpatient department (OPD) prospective payment system (PPS) for the year involved or (2) an amount equal to 150 percent of the amount paid for applicable disposable devices under the OPD PPS for 2015. For those services furnished after 2019, the payment amount would be the payment that would be made for applicable disposable devices under the OPD PPS for the year involved.

Traditional coinsurance of 20 percent for Medicare beneficiaries will continue to apply for disposable NPWT.

<sup>1</sup> Pub. L. No. 74-271.

Not later than 18 months after enactment, the GAO would submit a report on the value of disposable devices and the role of disposable devices as substitutes for durable medical equipment, along with recommendations for any legislation and administrative actions, as appropriate. Not later than four years after enactment, the GAO would submit a report on the impact of coverage of, and payment for disposable NPWT as established by this bill. The report will include the impact on utilization and program and beneficiary spending as a result of this bill, and would also contain recommendations for any legislation and administrative actions, as appropriate.

#### EFFECTIVE DATE

The provision applies to services furnished on or after January 1, 2017.

### III. BUDGET EFFECTS OF THE BILL

#### A. COMMITTEE ESTIMATES

In compliance with paragraph 11(a) of rule XXVI of the Standing Rules of the Senate, the following statement is made concerning the estimated budget effects of the revenue provisions of the “Patient Access to Disposable Medical Technology Act of 2015” as reported.

The bill is estimated to have the following effects on Federal budget receipts for fiscal years 2015–2025:

FISCAL YEARS												
[Millions of dollars]												
2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2016–20	2016–25
---	0	4	4	1	1	0	-5	-7	-8	-10	9	-21

NOTE: Details do not add to totals due to rounding.  
Source: Estimate provided by the staff of the Congressional Budget Office.

#### B. BUDGET AUTHORITY AND TAX EXPENDITURES

##### *Budget authority*

In compliance with section 308(a)(1) of the Congressional Budget and Impoundment Control Act of 1974 (“Budget Act”),<sup>2</sup> the Committee states that no provisions of the bill as reported involve new or increased budget authority.

##### *Tax expenditures*

In compliance with section 308(a)(1) of the Budget Act, the Committee states that the revenue-reducing provisions of the bill involve increased tax expenditures (see revenue table in Part A., above).

##### *S. 1253—Patient Access to Disposable Medical Technology Act of 2015*

Summary: S. 1253 would modify Medicare coverage and payment rules for negative pressure wound therapy (NPWT) equipment that

<sup>2</sup>Pub. L. No. 93–344.

includes a disposable pump. CBO estimates that enacting S. 1253 would reduce direct spending by about \$21 million over the 2016–2025 period. Pay-as-you-go procedures apply because enacting the legislation would affect direct spending. Enacting the legislation would not affect revenues.

S. 1253 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA).

Estimated cost to the Federal Government: The estimated budgetary effect of S. 1253 is shown in the following table. The costs of this legislation fall within budget function 570 (Medicare).

	By fiscal year, in millions of dollars—												
	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2016–2020	2016–2025	
	CHANGES IN DIRECT SPENDING <sup>a</sup>												
Estimated Budget Authority ..	0	4	4	1	1	0	–5	–7	–8	–10	9	–21	
Estimated Outlays .....	0	4	4	1	1	0	–5	–7	–8	–10	9	–21	

<sup>a</sup> Enacting S. 1253 would also affect spending subject to appropriation but CBO estimates that spending would total less than \$500,000 per year and over the 2016–2025 period.

Basis of estimate: For this estimate, CBO assumes that S. 1253 will be enacted near the end of fiscal year 2015.

Under current law, Medicare beneficiaries may receive NPWT, which uses a vacuum pump and special dressings to promote wound healing. NPWT equipment is available using either a durable pump or a disposable pump, which can be used at home, in a physician’s office, or in a hospital. If a home health agency (HHA) furnishes a beneficiary with NPWT using a durable form of the pump, Medicare makes a payment to the home health agency for the home health visits and to the supplier of the durable medical equipment. If instead the HHA uses a disposable pump, Medicare does not make an additional payment for the NPWT equipment and the HHA absorbs that cost.<sup>1</sup>

S. 1253 would establish a new add-on payment to HHAs that furnish disposable NPWT equipment to Medicare beneficiaries. In 2017, 2018, and 2019, that rate would be the greater of 150 percent of the amount paid in 2015 for the disposable NPWT equipment in the outpatient hospital setting or the actual amount paid in 2017 in that setting. After 2019, the payment would equal the rate paid in the hospital outpatient setting.

CBO estimates that, in 2017, the monthly payment for NPWT with a durable pump, including the associated dressings and equipment, will be about \$1,200. CBO projects that Medicare’s payment for the disposable version and the necessary ancillaries would be about \$700 per month in 2017 and would be lower than the payment for the durable pump throughout the 2017–2025 period.

The availability of separate payments for disposable NPWT equipment in the home health setting under S. 1253 would have competing effects on spending. First, CBO expects that some beneficiaries who would have used durable NPWT equipment would instead use disposable NPWT equipment.<sup>2</sup> Because the price of dis-

<sup>1</sup> Payments for durable NPWT equipment in the home setting are made on a monthly basis for up to 13 months of use. After 13 months, the beneficiary can take ownership of the NPWT equipment or return it to the supplier.

<sup>2</sup> NPWT is generally used for wounds like diabetic ulcers and bedsores. Some beneficiaries may not want to use durable NPWT equipment because the pump limits mobility. The disposable NPWT equipment is more portable and probably more convenient for beneficiaries.

posable NPWT equipment would be lower than the price for durable equipment, that shift would reduce spending. CBO also projects that additional beneficiaries would use NPWT because the new payment rules under S. 1253 would make it more likely that home health agencies would offer beneficiaries the option of using the disposable version, which some people might find more convenient. In the first years of the policy, CBO expects that the effect of greater utilization would increase spending by more than would be saved by switching from durable to disposable NPWT equipment, resulting in an increase in Federal spending. By 2022, however, CBO expects that savings from the lower price of the disposable NPWT equipment would exceed the costs from greater utilization. Over the 2017–2025 period, CBO estimates that enacting S. 1253 would reduce spending by \$21 million, out of total spending for NPWT equipment of about \$1.3 billion.

**Pay-As-You-Go considerations:** The Statutory Pay-As-You-Go Act of 2010 establishes budget-reporting and enforcement procedures for legislation affecting direct spending or revenues. The net changes in outlays that are subject to those pay-as-you-go procedures are shown in the following table.

CBO ESTIMATE OF PAY-AS-YOU-GO EFFECTS FOR S. 1253, THE PATIENT ACCESS TO DISPOSABLE MEDICAL TECHNOLOGY ACT OF 2015, AS ORDERED REPORTED BY THE SENATE COMMITTEE ON FINANCE ON JUNE 24, 2015

	By fiscal year, in millions of dollars—													
	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2015– 2020	2015– 2025	
<b>NET DECREASE IN THE DEFICIT</b>														
Statutory Pay-As-You-Go Impact .....	0	0	4	4	1	1	0	-5	-7	-8	-10	9	-21	

**Intergovernmental and private-sector impact:** S. 1253 contains no intergovernmental or private-sector mandates as defined in UMRA and would impose no costs on state, local, or tribal governments.

**Estimate prepared by:** Federal costs: Lara Robillard; Impact on state, local, and tribal governments: J’nell Blanco Suchy; Impact on the private sector: Amy Petz.

**Estimate approved by:** Holly Harvey, Deputy Assistant Director for Budget Analysis.

#### **IV. VOTES OF THE COMMITTEE**

In compliance with paragraph 7(b) of rule XXVI of the standing rules of the Senate, the Committee states that, with a majority present, the “Patient Access to Disposable Medical Technology Act of 2015,” as modified was ordered favorably reported on June 24, 2015 as follows:

Final Passage of “Patient Access to Disposable Medical Technology Act of 2015”—approved, as modified, by a voice vote.

#### **V. REGULATORY IMPACT AND OTHER MATTERS**

##### **A. REGULATORY IMPACT**

Pursuant to paragraph 11(b) of rule XXVI of the Standing Rules of the Senate, the Committee makes the following statement con-

cerning the regulatory impact that might be incurred in carrying out the provisions of the bill as amended.

*Impact on individuals and businesses, personal privacy and paperwork*

The bill is not expected to impose additional administrative requirements or regulatory burdens on individuals. The bill is expected to reduce administrative requirements and regulatory burdens on some businesses.

The provisions of the bill do not impact personal privacy.

B. UNFUNDED MANDATES STATEMENT

This information is provided in accordance with section 423 of the Unfunded Mandates Reform Act of 1995 (Pub. L. No. 104-4).

The Committee has determined that the bill does not contain any private sector mandates. The Committee has determined that the bill contains no intergovernmental mandate.

**VI. CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED**

In the opinion of the Committee, it is necessary in order to expedite the business of the Senate, to dispense with the requirements of paragraph 12 of rule XXVI of the Standing Rules of the Senate (relating to the showing of changes in existing law made by the bill as reported by the Committee).