

Calendar No. 184

114TH CONGRESS
1ST SESSION**S. 1253****[Report No. 114–105]**

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.

IN THE SENATE OF THE UNITED STATES

MAY 7, 2015

Mr. BURR (for himself, Mr. BENNET, and Mr. ALEXANDER) introduced the following bill; which was read twice and referred to the Committee on Finance

JULY 30, 2015

Reported by Mr. HATCH, with an amendment and an amendment to the title
[Strike out all after the enacting clause and insert the part printed in *italic*]

A BILL

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Patient Access to Dis-
5 posable Medical Technology Act of 2015”.

1 **SEC. 2. COVERAGE OF CERTAIN DISPOSABLE MEDICAL**
 2 **TECHNOLOGIES UNDER THE MEDICARE PRO-**
 3 **GRAM.**

4 (a) COVERAGE.—Section 1861 of the Social Security
 5 Act (42 U.S.C. 1395x) is amended—

6 (1) in subsection (n)—

7 (A) by inserting “substitute disposable
 8 medical technologies (as defined in subsection
 9 (iii)) and services and supplies used in conjunc-
 10 tion with such technologies,” after “hospital
 11 beds,”; and

12 (B) by inserting “(unless such equipment
 13 is a substitute disposable medical technology or
 14 a service or supply used in conjunction with
 15 such a technology)” after “rental basis”; and

16 (2) by adding at the end the following new sub-
 17 section:

18 “Substitute Disposable Medical Technology

19 “(iii) The term ‘substitute disposable medical tech-
 20 nology’ means medical equipment that—

21 “(1) is primarily and customarily used to serve
 22 a medical purpose;

23 “(2) would otherwise be covered as durable
 24 medical equipment under this title but for the fact
 25 that such equipment is not durable (as defined by

1 the Secretary for purposes of coverage of durable
 2 medical equipment under this title); and

3 “(3) the Secretary determines substitutes for
 4 durable medical equipment.

5 In making the determination under paragraph (3), the
 6 Secretary shall consult with medical specialty societies,
 7 medical device manufacturers, patient groups, and other
 8 stakeholders as part of the annual rulemaking process for
 9 durable medical equipment under this title.”.

10 (b) PAYMENT PROVISIONS.—Section 1834(a) of the
 11 Social Security Act (42 U.S.C. 1395m(a)) is amended by
 12 adding at the end the following new paragraph:

13 “(23) SPECIAL PAYMENT RULE FOR SUB-
 14STITUTE DISPOSABLE MEDICAL TECHNOLOGIES.—

15 Notwithstanding the preceding provisions of this
 16 subsection, the Secretary shall determine the pay-
 17 ment amount under this subsection for a substitute
 18 disposable medical technology (as defined in section
 19 1861(iii)), and for any related supplies and service
 20 fees incurred in conjunction with the use and main-
 21 tenance of such technology, in accordance with the
 22 following:

23 “(A) SINGLE PAYMENT AMOUNT.—The
 24 Secretary shall determine a single payment
 25 amount that shall be paid for a substitute dis-

1 disposable medical technology and for any related
 2 supplies and service fees incurred in conjunc-
 3 tion with the use and maintenance of such tech-
 4 nology. A payment for such a technology and
 5 for any such related supplies and service fees
 6 made in the amount of such single payment
 7 amount shall constitute full payment under this
 8 title for such technology and such related sup-
 9 plies and service fees.

10 “(B) CALCULATION OF PAYMENT
 11 AMOUNT.—The single payment amount de-
 12 scribed in subparagraph (A) for a substitute
 13 disposable medical technology and for any re-
 14 lated supplies and service fees incurred in con-
 15 junction with the use and maintenance of such
 16 technology shall be calculated by—

17 “(i) calculating the sum of the
 18 amounts of payment that otherwise would
 19 be made under this section for—

20 “(I) the item of durable medical
 21 equipment for which the Secretary de-
 22 termines, pursuant to section
 23 1861(iii)(3), that such substitute dis-
 24 posable medical technology sub-
 25 stitutes; and

1 “(H) all related supplies and
2 service fees incurred in conjunction
3 with the use and maintenance of such
4 item of durable medical equipment;

5 “(ii) calculating the amount that is 95
6 percent of the sum calculated under clause
7 (i); and

8 “(iii) calculating the single payment
9 amount for the substitute disposable med-
10 ical technology and for any related supplies
11 and service fees incurred in conjunction
12 with the use and maintenance of such tech-
13 nology such that the sum of the payments
14 under this subsection for—

15 “(I) all substitute disposable
16 medical technologies that the Sec-
17 retary determines, pursuant to section
18 1861(iii)(3), will be necessary to pro-
19 vide a substitute for the item of dura-
20 ble medical equipment described in
21 clause (i)(I); and

22 “(H) any related supplies and
23 service fees incurred in conjunction
24 with the use and maintenance of such
25 technologies;

1 and is equal to the amount calculated
2 under clause (ii). In making such calcula-
3 tion, the Secretary shall consult with med-
4 ical specialty societies, medical device man-
5 ufacturers, patient groups, and other
6 stakeholders to ensure that an appropriate
7 comparison is made that captures use of
8 the various technologies (including related
9 supplies, if any) over an average course of
10 therapy for a typical patient.

11 “(C) LUMP-SUM PAYMENT.—The single
12 payment amount described in subparagraph (A)
13 for a substitute disposable medical technology
14 and for any related supplies and service fees in-
15 curred in conjunction with the use and mainte-
16 nance of such technology shall be made in a
17 lump-sum amount.

18 “(D) PAYMENT FOR PHYSICIANS’ AND
19 HOSPITAL OUTPATIENT DEPARTMENT SERV-
20 ICES.—Nothing in this paragraph should be
21 construed as limiting or changing payment for
22 items or services for which payment is made
23 under section 1848 or section 1833(t).”.

1 (e) CONFORMING AMENDMENT.—Section
 2 1847(a)(7)(B) of the Social Security Act (42 U.S.C.
 3 ~~1395w-3(a)(7)(B)~~) is amended—

4 (1) in clause (i), by striking “and” at the end;

5 (2) in clause (ii), by striking the period at the
 6 end and inserting “; and”; and

7 (3) by adding at the end the following new
 8 clause:

9 “(iii) that are substitute disposable
 10 medical technologies (as defined in section
 11 1861(iii)).”.

12 (d) EFFECTIVE DATE.—The provisions of, and
 13 amendments made by, this section shall apply with respect
 14 to items and services furnished on or after January 1,
 15 2016.

16 (e) RULE OF CONSTRUCTION; IMPLEMENTATION.—

17 (1) RULE OF CONSTRUCTION.—Nothing in this
 18 section or the amendments made by this section
 19 shall be construed as—

20 (A) affecting the ability of a physician (or
 21 any other prescribing practitioner) to exercise
 22 their judgment in prescribing or ordering for a
 23 Medicare beneficiary appropriate durable med-
 24 ical equipment or other medical device or tech-

nology for the treatment of an illness, injury, or
condition of the Medicare beneficiary; or

(B) affecting the ability of the Medicare
beneficiary to access appropriate durable med-
ical equipment or other appropriate medical de-
vice or technology for such treatment.

(2) IMPLEMENTATION.—The Secretary shall
implement the provisions of, and amendments made
by, this section in a manner such that the meth-
odologies for determining coverage of an item of du-
rable medical equipment (as defined in section
1861(n) of the Social Security Act (42 U.S.C.
1395x(n))) (other than such an item that is a sub-
stitute disposable medical technology (as defined in
section 1861(iii))) and the payment amount for the
item of durable medical equipment (other than such
an item that is a substitute disposable medical tech-
nology (as so defined)) under section 1834 or 1847
of such Act (42 U.S.C. 1395m, 1395w-3), as the
case may be, is not affected by the coverage of and
payment amount for a substitute disposable medical
technology under sections 1861(iii) and 1834(a)(23)
of such Act, respectively, as added by subsections (a)
and (b), respectively.

1 **SECTION 1. SHORT TITLE.**

2 *This Act may be cited as the “Patient Access to Dispos-*
 3 *able Medical Technology Act of 2015”.*

4 **SEC. 2. TREATMENT OF DISPOSABLE DEVICES.**

5 *(a) IN GENERAL.—Section 1834 of the Social Security*
 6 *Act (42 U.S.C. 1395m) is amended by adding at the end*
 7 *the following new subsection:*

8 *“(s) PAYMENT FOR APPLICABLE DISPOSABLE DE-*
 9 *VICES.—*

10 *“(1) SEPARATE PAYMENT.—The Secretary shall*
 11 *make a payment (separate from the payments other-*
 12 *wise made under section 1895) in the amount estab-*
 13 *lished under paragraph (3) to a home health agency*
 14 *for an applicable disposable device (as defined in*
 15 *paragraph (2)) when furnished on or after January*
 16 *1, 2017, to an individual who receives home health*
 17 *services for which payment is made under section*
 18 *1895(b).*

19 *“(2) APPLICABLE DISPOSABLE DEVICE.—In this*
 20 *subsection, the term ‘applicable disposable device’*
 21 *means a disposable device that, as determined by the*
 22 *Secretary, is—*

23 *“(A) a disposable negative pressure wound*
 24 *therapy device that is an integrated system com-*
 25 *prised of a non-manual vacuum pump, a recep-*

1 *tacle for collecting exudate, and dressings for the*
 2 *purposes of wound therapy; and*

3 *“(B) a substitute for, and used in lieu of,*
 4 *a negative pressure wound therapy durable med-*
 5 *ical equipment item that is an integrated system*
 6 *of a negative pressure vacuum pump, a separate*
 7 *exudate collection canister, and dressings that*
 8 *would otherwise be covered for individuals for*
 9 *such wound therapy.*

10 *“(3) PAYMENT AMOUNT.—The Secretary shall es-*
 11 *tablish the separate payment amount for an applica-*
 12 *ble disposable device such that such amount is equal*
 13 *to—*

14 *“(A) for 2017, 2018, and 2019, the greater*
 15 *of—*

16 *“(i) the payment that would be made*
 17 *under section 1833(t) (relating to payment*
 18 *for covered OPD services) for the year for*
 19 *the Level I Healthcare Common Procedure*
 20 *Coding System (HCPCS) code for which the*
 21 *description for a professional service in-*
 22 *cludes the furnishing of such device; or*

23 *“(ii) an amount equal to 150 percent*
 24 *of the payment that applied under such sec-*

1 *tion 1833(t) for 2015 for such HCPCS code;*

2 *and*

3 *“(B) for 2020 and each subsequent year, the*
 4 *payment that would be made under such section*
 5 *1833(t) for the year for such HCPCS code.”.*

6 *(b) CONFORMING AMENDMENTS.—*

7 *(1) COINSURANCE.—Section 1833(a)(1) of the*
 8 *Social Security Act (42 U.S.C. 1395l(a)(1)) is*
 9 *amended—*

10 *(A) by striking “and” before “(Z)”;* *and*

11 *(B) by inserting before the semicolon at the*
 12 *end the following: “, and (AA) with respect to an*
 13 *applicable disposable device (as defined in para-*
 14 *graph (2) of section 1834(s)) furnished to an in-*
 15 *dividual pursuant to paragraph (1) of such sec-*
 16 *tion, the amount paid shall be equal to 80 per-*
 17 *cent of the lesser of the actual charge or the*
 18 *amount determined under paragraph (3) of such*
 19 *section”.*

20 *(2) HOME HEALTH.—Section 1861(m)(5) of the*
 21 *Social Security Act (42 U.S.C. 1395x(m)(5)) is*
 22 *amended by inserting “and applicable disposable de-*
 23 *vices (as defined in section 1834(s)(2))” after “dura-*
 24 *ble medical equipment”.*

25 *(c) REPORTS.—*

(1) *GAO STUDY AND REPORT ON DISPOSABLE
DEVICES.—*

(A) *STUDY.—The Comptroller General of
the United States shall conduct a study on the
value of disposable devices to the Medicare pro-
gram and Medicare beneficiaries and the role of
disposable devices as substitutes for durable med-
ical equipment. Such study shall address the fol-
lowing:*

(i) *The types of disposable devices that
could potentially qualify as being sub-
stitutes for durable medical equipment
under the Medicare program, the similar-
ities and differences between such disposable
devices and the durable medical equipment
for which they would be a substitute, and
the extent to which other payers, including
the Medicaid program and private payers,
cover such disposable devices.*

(ii) *Views of, and information from,
medical device manufacturers, providers of
services, and suppliers on the incentives and
disincentives under current Medicare cov-
erage and payment policies for disposable
devices that are substitutes for durable med-*

1 ical equipment and how such policies affect
2 manufacturers' decisions to develop innova-
3 tive products and providers' and suppliers'
4 decisions to use such products.

5 (iii) *Implications of expanding cov-*
6 *erage under the Medicare program to in-*
7 *clude additional disposable devices that are*
8 *substitutes for durable medical equipment.*

9 (iv) *Payment methodologies that could*
10 *be used to pay for disposable devices that*
11 *are substitutes for durable medical equip-*
12 *ment other than applicable disposable de-*
13 *vices pursuant to the amendments made by*
14 *subsections (a) and (b).*

15 (v) *Other applicable areas determined*
16 *appropriate by the Comptroller General.*

17 (B) *REPORT.*—*Not later than 18 months*
18 *after the date of the enactment of this Act, the*
19 *Comptroller General of the United States shall*
20 *submit to Congress and the Secretary of Health*
21 *and Human Services a report on the study con-*
22 *ducted under subparagraph (A), together with*
23 *recommendations for such legislation and ad-*
24 *ministrative action as the Comptroller General*
25 *determines to be appropriate.*

1 (2) *GAO STUDY AND REPORT ON THE IMPACT OF*
2 *THE PAYMENT OF APPLICABLE DISPOSABLE DE-*
3 *VICES.*—

4 (A) *STUDY.*—*The Comptroller General of*
5 *the United States shall conduct a study on the*
6 *impact of the payment for applicable disposable*
7 *devices (as defined in section 1834(s)(2) of the*
8 *Social Security Act) under the provisions of, and*
9 *amendments made by, subsections (a) and (b).*
10 *Such study shall address the following:*

11 (i) *The impact on utilization and*
12 *Medicare program and beneficiary spending*
13 *as a result of such provisions and amend-*
14 *ments.*

15 (ii) *The type of Medicare beneficiaries*
16 *who, under the home health benefit, use the*
17 *applicable disposable device and the period*
18 *of use of the applicable disposable devices*
19 *compared to the beneficiaries who use the*
20 *substitute durable medical equipment and*
21 *their period of use.*

22 (iii) *How payment rates of other pay-*
23 *ers, including the Medicaid program and*
24 *private payers, for applicable disposable de-*
25 *vices compare to the payment rates for such*

1 *devices under such provisions and amend-*
2 *ments.*

3 *(iv) Other applicable areas determined*
4 *appropriate by the Comptroller General.*

5 *(B) REPORT.—Not later than 4 years after*
6 *the date of the enactment of this Act, the Comp-*
7 *troller General of the United States shall submit*
8 *to Congress and the Secretary of Health and*
9 *Human Services a report on the study conducted*
10 *under subparagraph (A), together with rec-*
11 *ommendations for such legislation and adminis-*
12 *trative action as the Comptroller General deter-*
13 *mines to be appropriate.*

14 *(d) EFFECTIVE DATE.—The amendments made by this*
15 *section shall apply to items furnished on or after January*
16 *1, 2017.*

Amend the title so as to read: “A bill to amend title XVIII of the Social Security Act to provide for the treatment of certain disposable medical technologies under the Medicare program.”.

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1ST Session

S. 1253

[Report No. 114-105]

A BILL

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.

JULY 30, 2015

Reported with an amendment and an amendment to the title