

115TH CONGRESS
2D SESSION

S. 3787

To amend title XVIII of the Social Security Act to encourage the development and use of DISARM antimicrobial drugs, and for other purposes.

IN THE SENATE OF THE UNITED STATES

DECEMBER 19, 2018

Mr. HATCH (for himself and Mr. CASEY) introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

To amend title XVIII of the Social Security Act to encourage the development and use of DISARM antimicrobial drugs, 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 “Developing an Innova-
5 tive Strategy for Antimicrobial Resistant Microorganisms
6 Act of 2018” and as the “DISARM Act of 2018”.

7 **SEC. 2. ENCOURAGING THE DEVELOPMENT AND USE OF**
8 **DISARM ANTIMICROBIAL DRUGS.**

9 (a) **ADDITIONAL PAYMENT FOR DISARM ANTI-**
10 **MICROBIAL DRUGS UNDER MEDICARE.—**

1 (1) IN GENERAL.—Section 1886(d)(5) of the
2 Social Security Act (42 U.S.C. 1395ww(d)(5)) is
3 amended by adding at the end the following new
4 subparagraph:

5 “(M)(i) Effective for discharges beginning
6 on or after October 1, 2021, the Secretary
7 shall, after notice and opportunity for public
8 comment (in the publications required by sub-
9 section (e)(5) for a fiscal year or otherwise),
10 provide for an additional payment under a
11 mechanism (separate from the mechanism es-
12 tablished under subparagraph (K)), with re-
13 spect to such discharges involving any DISARM
14 antimicrobial drug, in an amount equal to—

15 “(I) the amount payable under section
16 1847A for such drug during the calendar
17 quarter in which the discharge occurred; or

18 “(II) if no amount for such drug is
19 determined under section 1847A, an
20 amount to be determined by the Secretary
21 in a manner similar to the manner in
22 which payment amounts are determined
23 under section 1847A based on information
24 submitted by the manufacturer or sponsor

1 of such drug (as required under clause
2 (v)).

3 “(ii) For purposes of this subparagraph, a
4 DISARM antimicrobial drug is—

5 “(I) a drug—

6 “(aa) that—

7 “(AA) is approved by the
8 Food and Drug Administration;

9 “(BB) is designated by the
10 Food and Drug Administration
11 as a qualified infectious disease
12 product under subsection (d) of
13 section 505E of the Federal
14 Food, Drug, and Cosmetic Act;
15 and

16 “(CC) has received an exten-
17 sion of its exclusivity period pur-
18 suant to subsection (a) of such
19 section; and

20 “(bb) that has been designated
21 by the Secretary pursuant to the proc-
22 ess established under clause
23 (iv)(I)(bb); or

24 “(II) an antibacterial or antifungal bi-
25 ological product—

1 “(aa) that is licensed for use, or
2 an antibacterial or antifungal biologi-
3 cal product for which an indication is
4 first licensed for use, by the Food and
5 Drug Administration on or after June
6 5, 2014, under section 351(a) of the
7 Public Health Service Act for human
8 use to treat serious or life-threatening
9 infections, as determined by the Food
10 and Drug Administration, including
11 those caused by, or likely to be caused
12 by—

13 “(AA) an antibacterial or
14 antifungal resistant pathogen, in-
15 cluding novel or emerging infec-
16 tious pathogens; or

17 “(BB) a qualifying pathogen
18 (as defined under section 505E(f)
19 of the Federal Food, Drug, and
20 Cosmetic Act); and

21 “(bb) has been designated by the
22 Secretary pursuant to the process es-
23 tablished under clause (iv)(I)(bb).

1 “(iii) The mechanism established pursuant
2 to clause (i) shall provide that the additional
3 payment under clause (i) shall—

4 “(I) with respect to a discharge, only
5 be made to a subsection (d) hospital that,
6 as determined by the Secretary, is partici-
7 pating in the National Healthcare Safety
8 Network Antimicrobial Use and Resistance
9 Module of the Centers for Disease Control
10 and Prevention or a similar reporting pro-
11 gram, as specified by the Secretary, relat-
12 ing to antimicrobial drugs; and

13 “(II) apply to discharges occurring on
14 or after October 1 of the year in which the
15 drug or biological product is designated by
16 the Secretary as a DISARM antimicrobial
17 drug.

18 “(iv)(I) The mechanism established pursu-
19 ant to clause (i) shall provide for a process
20 for—

21 “(aa) a manufacturer or sponsor of a
22 drug or biological product to request the
23 Secretary to designate the drug or biologi-
24 cal product as a DISARM antimicrobial
25 drug; and

1 “(bb) the designation by the Secretary
2 of drugs and biological products as DIS-
3 ARM antimicrobial drugs.

4 “(II) A designation of a drug or biological
5 product as a DISARM antimicrobial drug may
6 be revoked by the Secretary if the Secretary de-
7 termines that—

8 “(aa) the drug or biological product
9 no longer meets the requirements for a
10 DISARM antimicrobial drug under clause
11 (ii);

12 “(bb) the request for such designation
13 contained an untrue statement of material
14 fact; or

15 “(cc) clinical or other information
16 that was not available to the Secretary at
17 the time such designation was made shows
18 that—

19 “(AA) such drug or biological
20 product is unsafe for use or not shown
21 to be safe for use for individuals who
22 are entitled to benefits under part A;
23 or

24 “(BB) an alternative to such
25 drug or biological product is an ad-

1 vance that substantially improves the
2 diagnosis or treatment of such indi-
3 viduals.

4 “(III) Not later than October 1, 2021, and
5 annually thereafter, the Secretary shall publish
6 in the Federal Register a list of the DISARM
7 antimicrobial drugs designated under this sub-
8 paragraph pursuant to the process established
9 under clause (iv)(I)(bb).

10 “(v)(I) For purposes of determining addi-
11 tional payment amounts under clause (i), a
12 manufacturer or sponsor of a drug or biological
13 product that submits a request described in
14 clause (iv)(I)(aa) shall submit to the Secretary
15 information described in section
16 1927(b)(3)(A)(iii).

17 “(II) The penalties for failure to provide
18 timely information under clause (i) of subpara-
19 graph (C) section 1927(b)(3) and for providing
20 false information under clause (ii) of such sub-
21 paragraph shall apply to manufacturers and
22 sponsors of a drug or biological product under
23 this section with respect to information under
24 subclause (I) in the same manner as such pen-
25 alties apply to manufacturers under such

1 clauses with respect to information under sub-
2 paragraph (A) of such section.

3 “(vi)(I) The mechanism established pursu-
4 ant to clause (i) shall provide that—

5 “(aa) except as provided in item (bb),
6 no additional payment shall be made under
7 this subparagraph for discharges involving
8 a DISARM antimicrobial drug if any addi-
9 tional payments have been made for dis-
10 charges involving such drug as a new med-
11 ical service or technology under subpara-
12 graph (K);

13 “(bb) additional payments may be
14 made under this subparagraph for dis-
15 charges involving a DISARM antimicrobial
16 drug if any additional payments have been
17 made for discharges occurring prior to the
18 date of enactment of this subparagraph in-
19 volving such drug as a new medical service
20 or technology under subparagraph (K);
21 and

22 “(cc) no additional payment shall be
23 made under subparagraph (K) for dis-
24 charges involving a DISARM antimicrobial
25 drug as a new medical service or tech-

1 nology if any additional payments for dis-
 2 charges involving such drug have been
 3 made under this subparagraph.”.

4 (2) CONFORMING AMENDMENT.—Section
 5 1886(d)(5)(K)(ii)(III) of the Social Security Act (42
 6 U.S.C. 1395ww(d)(5)(K)(ii)(III)) is amended by
 7 striking “provide” and inserting “subject to sub-
 8 paragraph (M)(vii), provide”.

9 (b) STUDY AND REPORTS ON REMOVING BARRIERS
 10 TO THE DEVELOPMENT OF DISARM ANTIMICROBIAL
 11 DRUGS.—

12 (1) STUDY.—The Comptroller General of the
 13 United States (in this subsection referred to as the
 14 “Comptroller General”) shall, in consultation with
 15 the Director of the National Institutes of Health,
 16 the Commissioner of Food and Drugs, the Adminis-
 17 trator of the Centers for Medicare & Medicaid Serv-
 18 ices, and the Director of the Centers for Disease
 19 Control and Prevention, conduct a study to—

20 (A) identify and examine the barriers that
 21 prevent the development of DISARM anti-
 22 microbial drugs (as defined in section
 23 1886(d)(5)(M)(ii) of the Social Security Act, as
 24 added by subsection (a)); and

1 (B) develop recommendations for actions
2 to be taken in order to overcome any barriers
3 identified under subparagraph (A).

4 (2) REPORTS.—

5 (A) INTERIM REPORT.—Not later than 3
6 years after the date of the enactment of this
7 Act, the Comptroller General shall submit to
8 Congress an interim report containing the pre-
9 liminary results of the study conducted under
10 paragraph (1), together with recommendations
11 for such legislation and administrative action as
12 the Comptroller General determines appro-
13 priate.

14 (B) FINAL REPORT.—Not later than 5
15 years after the date of the enactment of this
16 Act, the Comptroller General shall submit to
17 Congress a report containing the results of the
18 study conducted under paragraph (1), together
19 with recommendations for such legislation and
20 administrative action as the Comptroller Gen-
21 eral determines appropriate.

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