

116TH CONGRESS
1ST SESSION

S. 1712

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

JUNE 4, 2019

Mr. ISAKSON (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 2019” and as the “DISARM Act of 2019”.

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)(I) Effective for discharges beginning on or
6 after October 1, 2020, subject to subclause (II), the Sec-
7 retary shall, after notice and opportunity for public com-
8 ment (in the publications required by subsection (e)(5) for
9 a fiscal year or otherwise), provide for an additional pay-
10 ment under a mechanism (separate from the mechanism
11 established under subparagraph (K)), with respect to such
12 discharges involving any DISARM antimicrobial drug, in
13 an amount equal to—

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

17 “(bb) if no amount for such drug is determined
18 under section 1847A, an amount to be determined
19 by the Secretary in a manner similar to the manner
20 in which payment amounts are determined under
21 section 1847A based on information submitted by
22 the manufacturer or sponsor of such drug (as re-
23 quired under clause (v)).

24 “(II) In determining the amount payable under sec-
25 tion 1847A for purposes of items (aa) and (bb) of sub-

1 clause (I), subparagraphs (A) and (B) of subsection (b)(1)
 2 of such section shall be applied by substituting ‘102 per-
 3 cent’ for ‘106 percent’ each place it appears and para-
 4 graph (8)(B) of such section shall be applied by sub-
 5 stituting ‘2 percent’ for ‘6 percent’.

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

8 “(I) a drug—

9 “(aa) that—

10 “(AA) is approved by the Food and
 11 Drug Administration;

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

17 “(CC) has received an extension of its
 18 exclusivity period pursuant to subsection
 19 (a) of such section; and

20 “(bb) that has been designated by the Sec-
 21 retary pursuant to the process established
 22 under clause (iv)(I)(bb); or

23 “(II) an antibacterial or antifungal biological
 24 product—

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

11 “(AA) an antibacterial or antifungal
 12 resistant pathogen, including novel or
 13 emerging infectious pathogens; or

14 “(BB) a qualifying pathogen (as de-
 15 fined under section 505E(f) of the Federal
 16 Food, Drug, and Cosmetic Act); and

17 “(bb) has been designated by the Secretary
 18 pursuant to the process established under
 19 clause (iv)(I)(bb).

20 “(iii) The mechanism established pursuant to clause
 21 (i) shall provide that the additional payment under clause
 22 (i) shall—

23 “(I) with respect to a discharge, only be made
 24 to a subsection (d) hospital that, as determined by
 25 the Secretary—

1 “(aa) is participating in the National
2 Healthcare Safety Network Antimicrobial Use
3 and Resistance Module of the Centers for Dis-
4 ease Control and Prevention or a similar report-
5 ing program, as specified by the Secretary, re-
6 lating to antimicrobial drugs; and

7 “(bb) has an antimicrobial stewardship
8 program that aligns with the Core Elements of
9 Hospital Antibiotic Stewardship Programs of
10 the Centers for Disease Control and Prevention
11 or the Antimicrobial Stewardship Standard set
12 by the Joint Commission; and

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

17 “(iv)(I) The mechanism established pursuant to
18 clause (i) shall provide for a process for—

19 “(aa) a manufacturer or sponsor of a drug or
20 biological product to request the Secretary to des-
21 ignate the drug or biological product as a DISARM
22 antimicrobial drug; and

23 “(bb) the designation by the Secretary of drugs
24 and biological products as DISARM antimicrobial
25 drugs.

1 “(II) A designation of a drug or biological product
2 as a DISARM antimicrobial drug may be revoked by the
3 Secretary if the Secretary determines that—

4 “(aa) the drug or biological product no longer
5 meets the requirements for a DISARM antimicrobial
6 drug under clause (ii);

7 “(bb) the request for such designation con-
8 tained an untrue statement of material fact; or

9 “(cc) clinical or other information that was not
10 available to the Secretary at the time such designa-
11 tion was made shows that—

12 “(AA) such drug or biological product is
13 unsafe for use or not shown to be safe for use
14 for individuals who are entitled to benefits
15 under part A; or

16 “(BB) an alternative to such drug or bio-
17 logical product is an advance that substantially
18 improves the diagnosis or treatment of such in-
19 dividuals.

20 “(III) Not later than October 1, 2020, and annually
21 thereafter, the Secretary shall publish in the Federal Reg-
22 ister a list of the DISARM antimicrobial drugs designated
23 under this subparagraph pursuant to the process estab-
24 lished under clause (iv)(I)(bb).

1 “(v)(I) For purposes of determining additional pay-
2 ment amounts under clause (i), a manufacturer or sponsor
3 of a drug or biological product that submits a request de-
4 scribed in clause (iv)(I)(aa) shall submit to the Secretary
5 information described in section 1927(b)(3)(A)(iii).

6 “(II) The penalties for failure to provide timely infor-
7 mation under clause (i) of subparagraph (C) under section
8 1927(b)(3) and for providing false information under
9 clause (ii) of such subparagraph shall apply to manufac-
10 turers and sponsors of a drug or biological product under
11 this section with respect to information under subclause
12 (I) in the same manner as such penalties apply to manu-
13 facturers under such clauses with respect to information
14 under subparagraph (A) of such section.

15 “(vi)(I) The mechanism established pursuant to
16 clause (i) shall provide that—

17 “(aa) except as provided in item (bb), no addi-
18 tional payment shall be made under this subpara-
19 graph for discharges involving a DISARM anti-
20 microbial drug if any additional payments have been
21 made for discharges involving such drug as a new
22 medical service or technology under subparagraph
23 (K);

24 “(bb) additional payments may be made under
25 this subparagraph for discharges involving a DIS-

1 ARM antimicrobial drug if any additional payments
 2 have been made for discharges occurring prior to the
 3 date of enactment of this subparagraph involving
 4 such drug as a new medical service or technology
 5 under subparagraph (K); and

6 “(cc) no additional payment shall be made
 7 under subparagraph (K) for discharges involving a
 8 DISARM antimicrobial drug as a new medical serv-
 9 ice or technology if any additional payments for dis-
 10 charges involving such drug have been made under
 11 this subparagraph.”.

12 (2) CONFORMING AMENDMENT.—Section
 13 1886(d)(5)(K)(ii)(III) of the Social Security Act (42
 14 U.S.C. 1395ww(d)(5)(K)(ii)(III)) is amended by
 15 striking “provide” and inserting “subject to sub-
 16 paragraph (M)(vii), provide”.

17 (b) STUDY AND REPORTS ON REMOVING BARRIERS
 18 TO THE DEVELOPMENT OF DISARM ANTIMICROBIAL
 19 DRUGS.—

20 (1) STUDY.—The Comptroller General of the
 21 United States (in this subsection referred to as the
 22 “Comptroller General”) shall, in consultation with
 23 the Director of the National Institutes of Health,
 24 the Commissioner of Food and Drugs, the Adminis-
 25 trator of the Centers for Medicare & Medicaid Serv-

1 ices, and the Director of the Centers for Disease
2 Control and Prevention, conduct a study to—

3 (A) identify and examine the barriers that
4 prevent the development of DISARM anti-
5 microbial drugs (as defined in section
6 1886(d)(5)(M)(ii) of the Social Security Act, as
7 added by subsection (a)); and

8 (B) develop recommendations for actions
9 to be taken in order to overcome any barriers
10 identified under subparagraph (A).

11 (2) REPORTS.—

12 (A) INTERIM REPORT.—Not later than 3
13 years after the date of the enactment of this
14 Act, the Comptroller General shall submit to
15 Congress an interim report containing the pre-
16 liminary results of the study conducted under
17 paragraph (1), together with recommendations
18 for such legislation and administrative action as
19 the Comptroller General determines appro-
20 priate.

21 (B) FINAL REPORT.—Not later than 5
22 years after the date of the enactment of this
23 Act, the Comptroller General shall submit to
24 Congress a report containing the results of the
25 study conducted under paragraph (1), together

- 1 with recommendations for such legislation and
- 2 administrative action as the Comptroller Gen-
- 3 eral determines appropriate.

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