

117TH CONGRESS
1ST SESSION

H. R. 4127

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 HOUSE OF REPRESENTATIVES

JUNE 24, 2021

Mr. DANNY K. DAVIS of Illinois (for himself and Mrs. WALORSKI) introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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 2021” and as the “DISARM Act of 2021”.

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

3 (a) ADDITIONAL PAYMENT FOR DISARM ANTI-
4 MICROBIAL DRUGS UNDER MEDICARE.—

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

9 “(N)(i)(I) Effective for discharges beginning on or
10 after October 1, 2021, or such sooner date as specified
11 by the Secretary, subject to subclause (II), the Secretary
12 shall, after notice and opportunity for public comment (in
13 the publications required by subsection (e)(5) for a fiscal
14 year or otherwise), provide for an additional payment
15 under a mechanism (separate from the mechanism estab-
16 lished under subparagraph (K)), with respect to such dis-
17 charges involving any DISARM antimicrobial drug, in an
18 amount equal to—

19 “(aa) the amount payable under section 1847A
20 for such drug during the calendar quarter in which
21 the discharge occurred; or

22 “(bb) if no amount for such drug is determined
23 under section 1847A, an amount to be determined
24 by the Secretary in a manner similar to the manner
25 in which payment amounts are determined under
26 section 1847A based on information submitted by

1 the manufacturer or sponsor of such drug (as re-
2 quired under clause (v)).

3 “(II) In determining the amount payable under sec-
4 tion 1847A for purposes of items (aa) and (bb) of sub-
5 clause (I), subparagraphs (A) and (B) of subsection (b)(1)
6 of such section shall be applied by substituting ‘102 per-
7 cent’ for ‘106 percent’ each place it appears and para-
8 graph (8)(B) of such section shall be applied by sub-
9 stituting ‘2 percent’ for ‘6 percent’.

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

12 “(I) a drug—

13 “(aa) that—

14 “(AA) is approved by the Food and
15 Drug Administration;

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

21 “(CC) has received an extension of its
22 exclusivity period pursuant to subsection
23 (a) of such section; and

1 “(bb) that has been designated by the Sec-
2 retary pursuant to the process established
3 under clause (iv)(I)(bb); or

4 “(II) an antibacterial or antifungal biological
5 product—

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

16 “(AA) an antibacterial or antifungal
17 resistant pathogen, including novel or
18 emerging infectious pathogens; or

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

22 “(bb) has been designated by the Secretary
23 pursuant to the process established under
24 clause (iv)(I)(bb).

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

4 “(I) with respect to a discharge, only be made
5 to a subsection (d) hospital that, as determined by
6 the Secretary—

7 “(aa) is participating in the National
8 Healthcare Safety Network Antimicrobial Use
9 and Resistance Module of the Centers for Dis-
10 ease Control and Prevention; and

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

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

21 For purposes of this clause, in the case of a similar report-
22 ing program described in item (aa), a subsection (d) hos-
23 pital shall be treated as participating in such a program
24 if the entity maintaining such program identifies to the
25 Secretary such hospital as so participating.

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

3 “(aa) a manufacturer or sponsor of a drug or
4 biological product to request the Secretary to des-
5 ignate the drug or biological product as a DISARM
6 antimicrobial drug; and

7 “(bb) the designation (and removal of such des-
8 ignation) by the Secretary of drugs and biological
9 products as DISARM antimicrobial drugs.

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

13 “(aa) the drug or biological product no longer
14 meets the requirements for a DISARM antimicrobial
15 drug under clause (ii);

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

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

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

1 “(BB) an alternative to such drug or bio-
2 logical product is an advance that substantially
3 improves the diagnosis or treatment of such in-
4 dividuals.

5 “(III) Not later than October 1, 2021, the Secretary
6 shall publish in the Federal Register a list of the DISARM
7 antimicrobial drugs designated under this subparagraph
8 pursuant to the process established under subclause
9 (I)(bb). The Secretary shall annually update such list.

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

15 “(II) The penalties for failure to provide timely infor-
16 mation under clause (i) of subparagraph (C) section
17 1927(b)(3) and for providing false information under
18 clause (ii) of such subparagraph shall apply to manufac-
19 turers and sponsors of a drug or biological product under
20 this section with respect to information under subclause
21 (I) in the same manner as such penalties apply to manu-
22 facturers under such clauses with respect to information
23 under subparagraph (A) of such section.

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

1 “(aa) except as provided in item (bb), no addi-
2 tional payment shall be made under this subpara-
3 graph for discharges involving a DISARM anti-
4 microbial drug if any additional payments have been
5 made for discharges involving such drug as a new
6 medical service or technology under subparagraph
7 (K);

8 “(bb) additional payments may be made under
9 this subparagraph for discharges involving a DIS-
10 ARM antimicrobial drug if any additional payments
11 have been made for discharges occurring prior to the
12 date of enactment of this subparagraph involving
13 such drug as a new medical service or technology
14 under subparagraph (K); and

15 “(cc) no additional payment shall be made
16 under subparagraph (K) for discharges involving a
17 DISARM antimicrobial drug as a new medical serv-
18 ice or technology if any additional payments for dis-
19 charges involving such drug have been made under
20 this subparagraph.”.

21 (2) CONFORMING AMENDMENT.—Section
22 1886(d)(5)(K)(ii)(III) of the Social Security Act (42
23 U.S.C. 1395ww(d)(5)(K)(ii)(III)) is amended by
24 striking “provide” and inserting “subject to sub-
25 paragraph (N)(vii), provide”.

1 (b) AUTHORIZATION OF APPROPRIATIONS FOR THE
2 CENTERS FOR DISEASE CONTROL AND PREVENTION.—

3 There is authorized to be appropriated to the Centers for
4 Disease Control and Prevention \$500,000,000, to remain
5 available until expended, to support establishment and im-
6 plementation of antimicrobial stewardship programs and
7 data reporting capabilities to the Antimicrobial Use and
8 Resistance option of the CDC National Healthcare Safety
9 Network, especially in critical access hospitals, rural hos-
10 pitals, and community hospitals, to support detection, sur-
11 veillance, containment, and prevention of resistant patho-
12 gens in the United States and overseas.

13 (c) STUDY AND REPORTS ON REMOVING BARRIERS
14 TO THE DEVELOPMENT OF DISARM ANTIMICROBIAL
15 DRUGS.—

16 (1) STUDY.—The Comptroller General of the
17 United States (in this subsection referred to as the
18 “Comptroller General”) shall, in consultation with
19 the Director of the National Institutes of Health,
20 the Commissioner of Food and Drugs, the Adminis-
21 trator of the Centers for Medicare & Medicaid Serv-
22 ices, and the Director of the Centers for Disease
23 Control and Prevention, conduct a study over a 5-
24 year period of the barriers that prevent the develop-
25 ment of DISARM antimicrobial drugs (as defined in

1 section 1886(d)(5)(N)(ii) of the Social Security Act,
2 as added by subsection (a)), including—

3 (A) patient outcomes in conjunction with
4 the use of DISARM drugs, including—

5 (i) duration of stay in the intensive
6 care unit;

7 (ii) recidivism within 30 days; and

8 (iii) measures of additional follow up
9 care;

10 (B) the effectiveness of antimicrobial stew-
11 ardship and surveillance programs, including—

12 (i) changes in the percentage of hos-
13 pitals in the United States with an anti-
14 microbial stewardship program in place
15 that aligns with the Core Elements of Hos-
16 pital Antibiotic Stewardship Programs, as
17 outlined by the Centers for Disease Control
18 and Prevention;

19 (ii) changes in inpatient care of
20 clostridioides difficile infection; and

21 (iii) changes in inpatient rates of re-
22 sistance to key pathogens; and

23 (C) considerations relating to Medicare
24 payment reform, including—

- 1 (i) changes in the number of qualified
2 antimicrobial products approved;
- 3 (ii) changes in wholesale acquisition
4 cost of individual qualified antimicrobial
5 products over time;
- 6 (iii) changes in year-over-year volume
7 of individual qualified antimicrobial prod-
8 ucts sold; and
- 9 (iv) the overall cost of qualified anti-
10 microbial products to the Medicare pro-
11 gram as a proportion of total Medicare
12 part A spending.

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

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