115TH CONGRESS
2D SESSION

S. _____

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

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

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms Act of 2018'' and as the ''DISARM Act of 2018''.

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

(a) ADDITIONAL PAYMENT FOR DISARM ANTIMICROBIAL DRUGS UNDER MEDICARE.—

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

''(M)(i) Effective for discharges beginning on or after October 1, 2021, the Secretary shall, after notice and opportunity for public comment (in the publications required by subsection (e)(5) for a fiscal year or otherwise), provide for an additional payment under a mechanism (separate from the mechanism established under subparagraph (K)), with respect to such discharges involving any DISARM antimicrobial drug, in an amount equal to—

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

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

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

"(ii) For purposes of this subparagraph, a DISARM antimicrobial drug is—

"(I) a drug—

"(aa) that—

"(AA) is approved by the Food and Drug Administration;

"(BB) is designated by the Food and Drug Administration as a qualified infectious disease product under subsection (d) of section 505E of the Federal Food, Drug, and Cosmetic Act; and

"(CC) has received an extension of its exclusivity period pursuant to subsection (a) of such section; and

"(bb) that has been designated by the Secretary pursuant to the process established under clause (iv)(I)(bb); or

"(II) an antibacterial or antifungal biological product—

"(aa) that is licensed for use, or an antibacterial or antifungal biological product for which an indication is first licensed for use, by the Food and Drug Administration on or after June 5, 2014, under section 351(a) of the Public Health Service Act for human use to treat serious or life-threatening infections, as determined by the Food and Drug Administration, including those caused by, or likely to be caused by—

"(AA) an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens; or

"(BB) a qualifying pathogen (as defined under section 505E(f) of the Federal Food, Drug, and Cosmetic Act); and

"(bb) has been designated by the Secretary pursuant to the process established under clause (iv)(I)(bb).

''(iii) The mechanism established pursuant to clause (i) shall provide that the additional payment under clause (i) shall—

''(I) with respect to a discharge, only be made to a subsection (d) hospital that, as determined by the Secretary, is participating in the National Healthcare Safety Network Antimicrobial Use and Resistance Module of the Centers for Disease Control and Prevention or a similar reporting program, as specified by the Secretary, relating to antimicrobial drugs; and

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

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

''(aa) a manufacturer or sponsor of a drug or biological product to request the Secretary to designate the drug or biological product as a DISARM antimicrobial drug; and

''(bb) the designation by the Secretary of drugs and biological products as DISARM antimicrobial drugs.

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

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

''(bb) the request for such designation contained an untrue statement of material fact; or

''(cc) clinical or other information that was not available to the Secretary at the time such designation was made shows that—

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

''(BB) an alternative to such drug or biological product is an ad-

vance that substantially improves the diagnosis or treatment of such individuals.

"(III) Not later than October 1, 2021, and annually thereafter, the Secretary shall publish in the Federal Register a list of the DISARM antimicrobial drugs designated under this subparagraph pursuant to the process established under clause (iv)(I)(bb).

"(v)(I) For purposes of determining additional payment amounts under clause (i), a manufacturer or sponsor of a drug or biological product that submits a request described in clause (iv)(I)(aa) shall submit to the Secretary information described in section 1927(b)(3)(A)(iii).

"(II) The penalties for failure to provide timely information under clause (i) of subparagraph (C) section 1927(b)(3) and for providing false information under clause (ii) of such subparagraph shall apply to manufacturers and sponsors of a drug or biological product under this section with respect to information under subclause (I) in the same manner as such penalties apply to manufacturers under such

clauses with respect to information under subparagraph (A) of such section.

''(vi)(I) The mechanism established pursuant to clause (i) shall provide that—

''(aa) except as provided in item (bb), no additional payment shall be made under this subparagraph for discharges involving a DISARM antimicrobial drug if any additional payments have been made for discharges involving such drug as a new medical service or technology under subparagraph (K);

''(bb) additional payments may be made under this subparagraph for discharges involving a DISARM antimicrobial drug if any additional payments have been made for discharges occurring prior to the date of enactment of this subparagraph involving such drug as a new medical service or technology under subparagraph (K).

''(cc) no additional payment shall be made under subparagraph (K) for discharges involving a DISARM antimicrobial drug as a new medical service or technology if any additional payments for dis-

charges involving such drug have been made under this subparagraph.''.

(2) CONFORMING AMENDMENT.—Section 1886(d)(5)(K)(ii)(III) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(K)(ii)(III)) is amended by striking ''provide'' and inserting ''subject to subparagraph (M)(vii), provide''.

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

(1) STUDY.—The Comptroller General of the United States (in this subsection referred to as the ''Comptroller General'') shall, in consultation with the Director of the National Institutes of Health, the Commissioner of Food and Drugs, the Administrator of the Centers for Medicare & Medicaid Services, and the Director of the Centers for Disease Control and Prevention, conduct a study to—

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

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

(2) REPORTS.—

(A) INTERIM REPORT.—Not later than 3 years after the date of the enactment of this Act, the Comptroller General shall submit to Congress an interim report containing the preliminary results of the study conducted under paragraph (1), together with recommendations for such legislation and administrative action as the Comptroller General determines appropriate.

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