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 indi-
viduals.

“(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 sub-
paragraph 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

“(II) The penalties for failure to provide
timely information under clause (i) of subpara-
graph (C) section 1927(b)(3) and for providing
false information under clause (ii) of such sub-
paragraph 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 pen-
alties apply to manufacturers under such
clauses with respect to information under sub-
paragraph (A) of such section.

“(vi)(I) The mechanism established pursu-
ant 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 addi-
tional payments have been made for dis-
charges involving such drug as a new med-
ical service or technology under subpara-
graph (K);

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

“(cc) no additional payment shall be
made under subparagraph (K) for dis-
charges involving a DISARM antimicrobial
drug as a new medical service or tech-
nology 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 sub-
paragraph (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 Adminis-
trator of the Centers for Medicare & Medicaid Serv-
ices, 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 anti-
microbial 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 pre-
liminary results of the study conducted under
paragraph (1), together with recommendations
for such legislation and administrative action as
the Comptroller General determines appro-
priate.

(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 Gen-
eral determines appropriate.