

113TH CONGRESS
2^D SESSION

H. R. 4187

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

IN THE HOUSE OF REPRESENTATIVES

MARCH 11, 2014

Mr. ROSKAM (for himself and Mr. DANNY K. DAVIS of Illinois) 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 new 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 2014” and as the “DISARM Act of 2014”.

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

3 (a) ADDITIONAL PAYMENT FOR NEW 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 “(M)(i) Effective for discharges beginning on or after
10 October 1, 2014, the Secretary shall, after notice and op-
11 portunity for public comment (in the publications required
12 by subsection (e)(5) for a fiscal year or otherwise), recog-
13 nize the costs of new antimicrobial drugs under the pay-
14 ment system established under this subsection.

15 “(ii) Pursuant to clause (i), the Secretary shall pro-
16 vide for additional payment to be made under this sub-
17 section with respect to discharges involving new anti-
18 microbial drugs in the amount provided for under section
19 1847A for drugs and biologicals that are described in sec-
20 tion 1842(o)(1)(C).

21 “(iii) For purposes of this subparagraph, the term
22 ‘new antimicrobial drug’ means a product that is approved
23 for use, or a product for which an indication is first ap-
24 proved for use, by the Federal Food and Drug Administra-
25 tion on or after January 1, 2014, and that—

1 “(I) is indicated to treat an infection caused by,
2 or likely to be caused by, a qualifying pathogen (as
3 defined under section 505E(f) of the Federal Food,
4 Drug, and Cosmetic Act (21 U.S.C. 355f(f))) for
5 which there is an unmet medical need and which is
6 associated with high rates of mortality or significant
7 patient morbidity (as determined by the Secretary,
8 in consultation with the Director of the Centers for
9 Disease Control and Prevention and the infectious
10 disease professional community); and

11 “(II) is used in facilities that participate in the
12 Antimicrobial Use and Resistance Module of the Na-
13 tional Healthcare Safety Network of the Centers for
14 Disease Control and Prevention (or, in the case that
15 such Module is not available, is used in facilities that
16 participate in such successor or similar reporting
17 module or program relating to antimicrobials as the
18 Secretary shall specify to the extent available to
19 such facilities, as determined by the Secretary).

20 “(iv) Not later than July 1, 2014, the Secretary shall
21 first publish in the Federal Register a list of the new anti-
22 microbial drugs.”.

23 (2) BUDGET NEUTRALITY.—Section
24 1886(d)(3)(C) of the Social Security Act (42 U.S.C.

1 1395ww(d)(3)(C)) is amended by adding at the end
2 the following new clause:

3 “(iii) MAINTAINING BUDGET NEUTRALITY FOR
4 CERTAIN ANTIMICROBIAL DRUGS.—For discharges
5 occurring in a fiscal year beginning with fiscal year
6 2015, the Secretary shall further reduce each of the
7 average standardized amounts in an amount equal
8 to the amount of the net additional expenditures, if
9 any, in such fiscal year resulting from the applica-
10 tion of paragraph (5)(M).”.

11 (b) STUDY AND REPORT ON REMOVING BARRIERS TO
12 DEVELOPMENT OF NEW ANTIMICROBIAL DRUGS.—

13 (1) STUDY.—The Comptroller General of the
14 United States shall, in consultation with the Direc-
15 tor of the United States Patent and Trademark Of-
16 fice, the Director of the National Institutes of
17 Health, the Commissioner of Food and Drugs, and
18 the Director of the Centers for Disease Control and
19 Prevention, conduct a study to—

20 (A) identify and examine the barriers that
21 prevent the development of new antimicrobial
22 drugs, as defined in section 1886(d)(5)(M)(iii)
23 of the Social Security Act (42 U.S.C.
24 1395ww(d)(5)(M)(iii)); and

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

4 (2) REPORT.—Not later than one year after the
5 date of the enactment of this Act, the Comptroller
6 General shall submit to Congress a report on the
7 study conducted under paragraph (1).

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