

114TH CONGRESS
2D SESSION

H. R. 5145

To amend title XIX of the Social Security Act to exclude abuse-deterrent formulations of prescription drugs from the Medicaid additional rebate requirement for new formulations of prescription drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 29, 2016

Mr. BILIRAKIS (for himself and Mr. YARMUTH) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, 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 XIX of the Social Security Act to exclude abuse-deterrent formulations of prescription drugs from the Medicaid additional rebate requirement for new formulations of prescription 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,*

1 **SECTION 1. EXCLUDING ABUSE-DETERRENT FORMULA-**
2 **TIONS OF PRESCRIPTION DRUGS FROM THE**
3 **MEDICAID ADDITIONAL REBATE REQUIRE-**
4 **MENT FOR NEW FORMULATIONS OF PRE-**
5 **SCRIPTION DRUGS.**

6 (a) IN GENERAL.—The last sentence of section
7 1927(c)(2)(C) of the Social Security Act (42 U.S.C.
8 1396r–8(c)(2)(C)) is amended by inserting before the pe-
9 riod at the end the following: “, but does not include an
10 abuse-deterrent formulation of the drug (as determined by
11 the Secretary), regardless of whether such abuse-deterrent
12 formulation is an extended release formulation”.

13 (b) EFFECTIVE DATE.—The amendment made by
14 subsection (a) shall apply to drugs that are paid for by
15 a State in calendar quarters beginning on or after the date
16 of the enactment of this Act.

17 **SEC. 2. LIMITING DISCLOSURE OF PREDICTIVE MODELING**
18 **AND OTHER ANALYTICS TECHNOLOGIES TO**
19 **IDENTIFY AND PREVENT WASTE, FRAUD, AND**
20 **ABUSE.**

21 (a) IN GENERAL.—Title XI of the Social Security Act
22 is amended by inserting after section 1128J (42 U.S.C.
23 1320a–7k) the following new section:

1 **“SEC. 1128K. DISCLOSURE OF PREDICTIVE MODELING AND**
2 **OTHER ANALYTICS TECHNOLOGIES TO IDENTIFY AND PREVENT WASTE, FRAUD, AND**
3 **ABUSE.**
4

5 “(a) REFERENCE TO PREDICTIVE MODELING TECH-
6 NOLOGIES REQUIREMENTS.—For provisions relating to
7 the use of predictive modeling and other analytics tech-
8 nologies to identify and prevent waste, fraud, and abuse
9 with respect to the Medicare program under title XVIII,
10 the Medicaid program under title XIX, and the Children’s
11 Health Insurance Program under title XXI, see section
12 4241 of the Small Business Jobs Act of 2010 (42 U.S.C.
13 1320a–7m).

14 “(b) LIMITING DISCLOSURE OF PREDICTIVE MOD-
15 ELING TECHNOLOGIES.—In implementing such provisions
16 under such section 4241 with respect to covered algo-
17 rithms (as defined in subsection (c)), the following shall
18 apply:

19 “(1) NONAPPLICATION OF FOIA.—The covered
20 algorithms used or developed for purposes of such
21 section (including by the Secretary or a State (or an
22 entity operating under a contract with a State))
23 shall be exempt from disclosure under section
24 552(b)(3) of title 5, United States Code.

1 “(2) LIMITATION WITH RESPECT TO USE AND
2 DISCLOSURE OF INFORMATION BY STATE AGEN-
3 CIES.—

4 “(A) IN GENERAL.—A State agency may
5 not use or disclose covered algorithms used or
6 developed for purposes of such section except
7 for purposes of administering the State plan (or
8 a waiver of the plan) under the Medicaid pro-
9 gram under title XIX or the State child health
10 plan (or a waiver of the plan) under the Chil-
11 dren’s Health Insurance Program under title
12 XXI, including by enabling an entity operating
13 under a contract with a State to assist the
14 State to identify or prevent waste, fraud and
15 abuse with respect to such programs.

16 “(B) INFORMATION SECURITY.—A State
17 agency shall have in effect data security and
18 control policies that the Secretary finds ade-
19 quate to ensure the security of covered algo-
20 rithms used or developed for purposes of such
21 section 4241 and to ensure that access to such
22 information is restricted to authorized persons
23 for purposes of authorized uses and disclosures
24 described in subparagraph (A).

1 “(C) PROCEDURAL REQUIREMENTS.—
2 State agencies to which information is disclosed
3 pursuant to such section 4241 shall adhere to
4 uniform procedures established by the Sec-
5 retary.

6 “(c) COVERED ALGORITHM DEFINED.—In this sec-
7 tion, the term ‘covered algorithm’—

8 “(1) means a predictive modeling or other ana-
9 lytics technology, as used for purposes of section
10 4241(a) of the Small Business Jobs Act of 2010 (42
11 U.S.C. 1320a–7m(a)) to identify and prevent waste,
12 fraud, and abuse with respect to the Medicare pro-
13 gram under title XVIII, the Medicaid program
14 under title XIX, and the Children’s Health Insur-
15 ance Program under title XXI; and

16 “(2) includes the mathematical expressions uti-
17 lized in the application of such technology and the
18 means by which such technology is developed.”.

19 (b) CONFORMING AMENDMENTS.—

20 (1) MEDICAID STATE PLAN REQUIREMENT.—
21 Section 1902(a) of the Social Security Act (42
22 U.S.C. 1396a(a)) is amended—

23 (A) in paragraph (80), by striking “and”
24 at the end;

1 (B) in paragraph (81), by striking the pe-
 2 riod at the end and inserting “; and”; and

3 (C) by inserting after paragraph (81) the
 4 following new paragraph:

5 “(82) provide that the State agency responsible
 6 for administering the State plan under this title pro-
 7 vides assurances to the Secretary that the State
 8 agency is in compliance with subparagraphs (A),
 9 (B), and (C) of section 1128K(b)(2).”.

10 (2) STATE CHILD HEALTH PLAN REQUIRE-
 11 MENT.—Section 2102(a)(7) of the Social Security
 12 Act (42 U.S.C. 1397bb(a)(7)) is amended—

13 (A) in subparagraph (A), by striking “,
 14 and” at the end and inserting a semicolon;

15 (B) in subparagraph (B), by striking the
 16 period at the end and inserting “; and”; and

17 (C) by adding at the end the following new
 18 subparagraph:

19 “(C) to ensure that the State agency in-
 20 volved is in compliance with subparagraphs (A),
 21 (B), and (C) of section 1128K(b)(2).”.

22 **SEC. 3. MEDICAID IMPROVEMENT FUND.**

23 Section 1941(b)(1) of the Social Security Act (42
 24 U.S.C. 1396w–1(b)(1)) is amended to read as follows:

1 “(1) IN GENERAL.—There shall be available to
2 the Fund, for expenditures from the Fund for fiscal
3 year 2021 and thereafter, \$5,000,000.”.

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