

Union Calendar No. 582

115TH CONGRESS
2D SESSION

H. R. 3528

[Report No. 115–748, Part I]

To amend title XVIII of the Social Security Act to require e-prescribing for coverage under part D of the Medicare program of prescription drugs that are controlled substances.

IN THE HOUSE OF REPRESENTATIVES

JULY 28, 2017

Ms. CLARK of Massachusetts (for herself and Mr. MULLIN) 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

JUNE 12, 2018

Additional sponsors: Mr. HIGGINS of New York, Ms. ESTY of Connecticut, Mr. HIMES, Mr. KENNEDY, Mr. KELLY of Pennsylvania, Mr. TONKO, Mr. PANNETTA, Mr. DONOVAN, Mr. KING of New York, Mr. BUDD, Mr. KATKO, Mr. LONG, Mr. THOMPSON of Pennsylvania, Ms. STEFANIK, Mr. COLLINS of New York, Mr. MACARTHUR, Ms. SHEA-PORTER, Ms. SLAUGHTER, Mrs. WALORSKI, Mr. NORCROSS, Mr. MOULTON, Mr. JENKINS of West Virginia, Mr. KRISHNAMOORTHY, Mr. FLORES, Mr. RYAN of Ohio, Ms. JENKINS of Kansas, Mr. PAYNE, Ms. HANABUSA, Mr. KNIGHT, Mr. SCHNEIDER, Mr. SCHWEIKERT, Ms. TITUS, Mr. FASO, Ms. KUSTER of New Hampshire, Ms. DEGETTE, Mr. YARMUTH, Mr. POCAN, Ms. WASSERMAN SCHULTZ, Ms. BONAMICI, Mr. COHEN, Mr. O'HALLERAN, Mr. RENACCI, Mr. HASTINGS, Mrs. BLACKBURN, Mr. POLIQUIN, Mrs. HANDEL, Mr. WALDEN, Mr. FITZPATRICK, Mr. CRAMER, and Mr. BROOKS of Alabama

JUNE 12, 2018

Reported from the Committee on Energy and Commerce with an amendment

[Strike out all after the enacting clause and insert the part printed in *italic*]

JUNE 12, 2018

The Committee on Ways and Means discharged; committed to the Committee of the Whole House on the State of the Union and ordered to be printed

[For text of introduced bill, see copy of bill as introduced on July 28, 2017]

A BILL

To amend title XVIII of the Social Security Act to require e-prescribing for coverage under part D of the Medicare program of prescription drugs that are controlled substances.

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 “Every Prescription Con-*
 5 *veyed Securely Act”.*

6 **SEC. 2. REQUIRING E-PRESCRIBING FOR COVERAGE OF**
 7 **COVERED PART D CONTROLLED SUB-**
 8 **STANCES.**

9 *(a) IN GENERAL.—Section 1860D–4(e) of the Social*
 10 *Security Act (42 U.S.C. 1395w–104(e)) is amended by add-*
 11 *ing at the end the following:*

12 *“(7) REQUIREMENT OF E-PRESCRIBING FOR CON-*
 13 *TROLLED SUBSTANCES.—*

14 *“(A) IN GENERAL.—Subject to subpara-*
 15 *graph (B), a prescription for a covered part D*
 16 *drug under a prescription drug plan (or under*
 17 *an MA–PD plan) for a schedule II, III, IV, or*
 18 *V controlled substance shall be transmitted by a*
 19 *health care practitioner electronically in accord-*
 20 *ance with an electronic prescription drug pro-*
 21 *gram that meets the requirements of paragraph*
 22 *(2).*

23 *“(B) EXCEPTION FOR CERTAIN CIR-*
 24 *CUMSTANCES.—The Secretary shall, pursuant to*
 25 *rulemaking, specify circumstances with respect*

1 *to which the Secretary may waive the require-*
2 *ment under subparagraph (A), with respect to a*
3 *covered part D drug, including in the case of—*

4 *“(i) a prescription issued when the*
5 *practitioner and dispenser are the same en-*
6 *tity;*

7 *“(ii) a prescription issued that cannot*
8 *be transmitted electronically under the most*
9 *recently implemented version of the Na-*
10 *tional Council for Prescription Drug Pro-*
11 *grams SCRIPT Standard;*

12 *“(iii) a prescription issued by a prac-*
13 *titioner who has received a waiver or a re-*
14 *newal thereof for a specified period deter-*
15 *mined by the Secretary, not to exceed one*
16 *year, from the requirement to use electronic*
17 *prescribing, pursuant to a process estab-*
18 *lished by regulation by the Secretary, due to*
19 *demonstrated economic hardship, techno-*
20 *logical limitations that are not reasonably*
21 *within the control of the practitioner, or*
22 *other exceptional circumstance dem-*
23 *onstrated by the practitioner;*

24 *“(iv) a prescription issued by a practi-*
25 *tioner under circumstances in which, not-*

1 *withstanding the practitioner’s ability to*
2 *submit a prescription electronically as re-*
3 *quired by this subsection, such practitioner*
4 *reasonably determines that it would be im-*
5 *practical for the individual involved to ob-*
6 *tain substances prescribed by electronic pre-*
7 *scription in a timely manner, and such*
8 *delay would adversely impact the individ-*
9 *ual’s medical condition involved;*

10 “(v) a prescription issued by a practi-

11 *tioner allowing for the dispensing of a non-*
12 *patient specific prescription pursuant to a*
13 *standing order, approved protocol for drug*
14 *therapy, collaborative drug management, or*
15 *comprehensive medication management, in*
16 *response to a public health emergency, or*
17 *other circumstances where the practitioner*
18 *may issue a non-patient specific prescrip-*
19 *tion;*

20 “(vi) a prescription issued by a practi-

21 *tioner prescribing a drug under a research*
22 *protocol;*

23 “(vii) a prescription issued by a prac-

24 *itioner for a drug for which the Food and*
25 *Drug Administration requires a prescrip-*

tion to contain elements that are not able to
be included in electronic prescribing, such
as a drug with risk evaluation and mitiga-
tion strategies that include elements to as-
sure safe use; and

“(viii) a prescription issued by a prac-
titioner for an individual who—

“(I) receives hospice care under
this title; or

“(II) is a resident of a skilled
nursing facility (as defined in section
1819(a)), or a medical institution or
nursing facility for which payment is
made for an institutionalized indi-
vidual under section 1902(q)(1)(B), for
which frequently abused drugs are dis-
pensed for residents through a contract
with a single pharmacy, as determined
by the Secretary in accordance with
this paragraph.

“(C) *DISPENSING.*—Nothing in this para-
graph shall be construed as requiring a sponsor
of a prescription drug plan under this part, MA
organization offering an MA–PD plan under
part C, or a pharmacist to verify that a practi-

1 *tioner, with respect to a prescription for a cov-*
2 *ered part D drug, has a waiver (or is otherwise*
3 *exempt) under subparagraph (B) from the re-*
4 *quirement under subparagraph (A). Nothing in*
5 *this paragraph shall be construed as affecting the*
6 *ability of the plan to cover or the pharmacists’*
7 *ability to continue to dispense covered part D*
8 *drugs from otherwise valid written, oral or fax*
9 *prescriptions that are consistent with laws and*
10 *regulations. Nothing in this paragraph shall be*
11 *construed as affecting the ability of the bene-*
12 *ficiary involved to designate a particular phar-*
13 *macy to dispense a prescribed drug to the extent*
14 *consistent with the requirements under sub-*
15 *section (b)(1) and under this paragraph.*

16 *“(D) ENFORCEMENT.—The Secretary shall,*
17 *pursuant to rulemaking, have authority to en-*
18 *force and specify appropriate penalties for non-*
19 *compliance with the requirement under subpara-*
20 *graph (A).”.*

21 *(b) EFFECTIVE DATE.—The amendment made by sub-*
22 *section (a) shall apply to coverage of drugs prescribed on*
23 *or after January 1, 2021.*

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