

118TH CONGRESS
1ST SESSION

S. 2666

To amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, and the Internal Revenue Code of 1986 to provide for requirements for electronic-prescribing for controlled substances under group health plans and group and individual health insurance coverage.

IN THE SENATE OF THE UNITED STATES

JULY 27, 2023

Ms. HASSAN (for herself and Mr. MULLIN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, and the Internal Revenue Code of 1986 to provide for requirements for electronic-prescribing for controlled substances under group health plans and group and individual health insurance coverage.

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 “Electronic Prescribing
5 for Controlled Substances Act” or the “EPCS 2.0 Act”.

1 **SEC. 2. REQUIREMENTS FOR ELECTRONIC-PRESCRIBING**
2 **FOR CONTROLLED SUBSTANCES UNDER**
3 **GROUP HEALTH PLANS AND GROUP AND IN-**
4 **DIVIDUAL HEALTH INSURANCE COVERAGE.**

5 (a) PUBLIC HEALTH SERVICE ACT AMENDMENT.—
6 Section 2799A–7 of the Public Health Service Act (42
7 U.S.C. 300gg–117) is amended by adding at the end the
8 following new subsection:

9 **“(d) REQUIREMENTS FOR ELECTRONIC-PRE-**
10 **SCRIBING FOR CONTROLLED SUBSTANCES.—**

11 “(1) IN GENERAL.—Except as provided pursu-
12 ant to paragraph (2), for plan years beginning on or
13 after January 1, 2025, a group health plan and a
14 health insurance issuer offering group or individual
15 health insurance coverage, with respect to a partici-
16 pating provider, as defined in section 2799–1(a)(3),
17 shall have in place policies, subject to paragraph (4),
18 that require any prescription for a schedule II, III,
19 IV, or V controlled substance (as defined by section
20 202 of the Controlled Substances Act) covered under
21 the plan or coverage that is transmitted by such a
22 health care practitioner for such a participant, bene-
23 ficiary, or enrollee be electronically transmitted in
24 accordance with such standards, consistent with
25 standards established under paragraph (3) of section
26 1860D–4(e) of the Social Security Act, under an

1 electronic prescription drug program that meets re-
2 quirements that are substantially similar (as jointly
3 determined by the Secretary, Secretary of the Treas-
4 ery, and Secretary of Labor) to the requirements of
5 paragraph (2) of such section 1860D–4(e).

6 “(2) EXCEPTION FOR CERTAIN CIR-
7 CUMSTANCES.—The Secretary, Secretary of the
8 Treasury, and Secretary of Labor shall jointly,
9 through rulemaking, specify circumstances and proc-
10 esses by which the requirement under paragraph (1)
11 may be waived, with respect to a schedule II, III,
12 IV, or V controlled substance that is a prescription
13 drug covered by a group health plan or group or in-
14 dividual health insurance coverage offered by a
15 health insurance issuer, including in the case of—

16 “(A) a prescription described in any of
17 clauses (i) through (vi) of section 1860D–
18 4(e)(7)(B) of the Social Security Act;

19 “(B) a prescription issued for an individual
20 who receives hospice care or for a resident of a
21 nursing facility (as defined in section 1919(a)
22 of the Social Security Act);

23 “(C) a prescription issued under cir-
24 cumstances in which electronic prescribing is
25 not available due to temporary technological or

1 electrical failure, as specified jointly by the Sec-
2 etary, Secretary of the Treasury, and Sec-
3 retary of Labor through rulemaking; and

4 “(D) a prescription issued by a practi-
5 tioner allowing for the dispensing of a non-pa-
6 tient specific prescription pursuant to a stand-
7 ing order, approved protocol for drug therapy,
8 collaborative drug management, or comprehen-
9 sive medication management, in response to a
10 public health emergency or other circumstances
11 under which the practitioner may issue a non-
12 patient specific prescription.

13 “(3) RULES OF CONSTRUCTION.—

14 “(A) VERIFICATION.—Nothing in this sub-
15 section shall be construed as requiring a dis-
16 penser to verify that a health care practitioner,
17 with respect to a prescription for a schedule II,
18 III, IV, or V controlled substance that is a pre-
19 scription drug covered under a group health
20 plan or group or individual health insurance
21 coverage offered by a health insurance issuer,
22 has a waiver (or is otherwise exempt) under
23 paragraph (2) from the requirement under
24 paragraph (1).

1 “(B) AUTHORITY TO DISPENSE.—Nothing
2 in this subsection shall be construed as affecting
3 the authority of a group health plan or
4 group or individual health insurance coverage
5 offered by a health insurance issuer to cover, or
6 the authority of a dispenser to continue to dis-
7 pense, a prescription drug if the prescription
8 for such drug is an otherwise valid written,
9 oral, or fax prescription that is consistent with
10 applicable law.

11 “(C) PATIENT CHOICE.—Nothing in this
12 subsection shall be construed as affecting the
13 ability of an individual who is a participant,
14 beneficiary, or enrollee of a group health plan
15 or group or individual health insurance cov-
16 erage offered by a health insurance issuer and
17 who is prescribed a schedule II, III, IV, or V
18 controlled substance that is a prescription drug
19 covered under the plan or coverage to designate
20 a particular pharmacy to dispense a prescribed
21 controlled substance to the extent consistent
22 with the requirements under this subsection.

23 “(4) PROHIBITIONS.—The policies established
24 pursuant to paragraph (1) by a group health plan or

1 health insurance issuer offering group or individual
2 health insurance coverage may not—

3 “(A) require dispensers of a schedule II,
4 III, IV, or V controlled substance to confirm
5 that the prescription for the controlled sub-
6 stance was electronically issued by a health care
7 practitioner in accordance with such policies, as
8 described in paragraph (1);

9 “(B) require dispensers of such controlled
10 substances to submit information or data be-
11 yond what is otherwise required to process a
12 prescription drug claim in order to confirm a
13 practitioner’s compliance with such policies; or

14 “(C) reject, deny, or recoup reimbursement
15 for a prescription drug claim based on the for-
16 mat in which the prescription was issued.

17 “(5) CONSULTATION REQUIREMENT FOR RULE-
18 MAKING.—In promulgating regulations to carry out
19 this subsection, the Secretary, Secretary of the
20 Treasury, and Secretary of Labor shall jointly con-
21 sult with dispensers of controlled substances, State
22 insurance regulators, and health care practitioners.”.

23 (b) EMPLOYEE RETIREMENT INCOME SECURITY ACT
24 OF 1974 AMENDMENT.—Section 722 of the Employee Re-
25 tirement Income Security Act of 1974 (29 U.S.C. 1185k)

1 is amended by adding at the end the following new sub-
2 section:

3 “(d) REQUIREMENTS FOR ELECTRONIC-PRE-
4 SCRIBING FOR CONTROLLED SUBSTANCES.—

5 “(1) IN GENERAL.—Except as provided pursu-
6 ant to paragraph (2), for plan years beginning on or
7 after January 1, 2025, a group health plan and a
8 health insurance issuer offering group health insur-
9 ance coverage, with respect to a participating pro-
10 vider, as defined in section 716(a)(3), shall have in
11 place policies, subject to paragraph (4), that require
12 any prescription for a schedule II, III, IV, or V con-
13 trolled substance (as defined by section 202 of the
14 Controlled Substances Act) covered under the plan
15 or coverage that is transmitted by such a health care
16 practitioner for such a participant or beneficiary be
17 electronically transmitted in accordance with such
18 standards, consistent with standards established
19 under paragraph (3) of section 1860D-4(e) of the
20 Social Security Act, under an electronic prescription
21 drug program that meets requirements that are sub-
22 stantially similar (as jointly determined by the Sec-
23 retary, Secretary of the Treasury, and Secretary of
24 Labor) to the requirements of paragraph (2) of such
25 section 1860D-4(e).

1 “(2) EXCEPTION FOR CERTAIN CIR-
2 CUMSTANCES.—The Secretary, Secretary of the
3 Treasury, and Secretary of Health and Human
4 Services shall jointly, through rulemaking, specify
5 circumstances and processes by which the require-
6 ment under paragraph (1) may be waived, with re-
7 spect to a schedule II, III, IV, or V controlled sub-
8 stance that is a prescription drug covered by a group
9 health plan or group health insurance coverage of-
10 ffered by a health insurance issuer, including in the
11 case of—

12 “(A) a prescription described in any of
13 clauses (i) through (vi) of section 1860D–
14 4(e)(7)(B) of the Social Security Act;

15 “(B) a prescription issued for an individual
16 who receives hospice care or for a resident of a
17 nursing facility (as defined in section 1919(a)
18 of the Social Security Act);

19 “(C) a prescription issued under cir-
20 cumstances in which electronic prescribing is
21 not available due to temporary technological or
22 electrical failure, as specified jointly by the Sec-
23 retary, Secretary of the Treasury, and Sec-
24 retary of Health and Human Services through
25 rulemaking; and

1 “(D) a prescription issued by a practitioner allowing for the dispensing of a non-patient specific prescription pursuant to a standing order, approved protocol for drug therapy, collaborative drug management, or comprehensive medication management, in response to a public health emergency or other circumstances under which the practitioner may issue a non-patient specific prescription.

10 “(3) RULES OF CONSTRUCTION.—

11 “(A) VERIFICATION.—Nothing in this subsection shall be construed as requiring a dispenser to verify that a health care practitioner, with respect to a prescription for a schedule II, III, IV, or V controlled substance that is a prescription drug covered under a group health plan or group or individual health insurance coverage offered by a health insurance issuer, has a waiver (or is otherwise exempt) under paragraph (2) from the requirement under paragraph (1).

22 “(B) AUTHORITY TO DISPENSE.—Nothing in this subsection shall be construed as affecting the authority of a group health plan or group health insurance coverage offered by a

1 health insurance issuer to cover, or the author-
2 ity of a dispenser to continue to dispense, a pre-
3 scription drug if the prescription for such drug
4 is an otherwise valid written, oral, or fax pre-
5 scription that is consistent with applicable law.

6 “(C) PATIENT CHOICE.—Nothing in this
7 subsection shall be construed as affecting the
8 ability of an individual who is a participant or
9 beneficiary of a group health plan or group or
10 individual health insurance coverage offered by
11 a health insurance issuer and who is prescribed
12 a schedule II, III, IV, or V controlled substance
13 that is a prescription drug covered under the
14 plan or coverage to designate a particular phar-
15 macy to dispense a prescribed controlled sub-
16 stance to the extent consistent with the require-
17 ments under this subsection.

18 “(4) PROHIBITIONS.—The policies established
19 pursuant to paragraph (1) by a group health plan or
20 health insurance issuer offering group health insur-
21 ance coverage may not—

22 “(A) require dispensers of a schedule II,
23 III, IV, or V controlled substance to confirm
24 that the prescription for the controlled sub-
25 stance was electronically issued by a health care

1 practitioner in accordance with such policies, as
2 described in paragraph (1);

3 “(B) require dispensers of such controlled
4 substances to submit information or data be-
5 yond what is otherwise required to process a
6 prescription drug claim in order to confirm a
7 practitioner’s compliance with such policies; or

8 “(C) reject, deny, or recoup reimbursement
9 for a prescription drug claim based on the for-
10 mat in which the prescription was issued.

11 “(5) CONSULTATION REQUIREMENT FOR RULE-
12 MAKING.—In promulgating regulations to carry out
13 this subsection, the Secretary, Secretary of the
14 Treasury, and Secretary of Health and Human
15 Services shall jointly consult with dispensers of con-
16 trolled substances, State insurance regulators, and
17 health care practitioners.”.

18 (c) INTERNAL REVENUE CODE OF 1986 AMEND-
19 MENT.—Section 9822 of the Internal Revenue Code of
20 1986 is amended by adding at the end the following new
21 subsection:

22 “(d) REQUIREMENTS FOR ELECTRONIC-PRE-
23 SCRIBING FOR CONTROLLED SUBSTANCES.—

24 “(1) IN GENERAL.—Except as provided pursu-
25 ant to paragraph (2), for plan years beginning on or

1 after January 1, 2025, a group health plan, with re-
2 spect to a participating provider, as defined in sec-
3 tion 9816(a)(3), shall have in place policies, subject
4 to paragraph (4), that require any prescription for
5 a schedule II, III, IV, or V controlled substance (as
6 defined by section 202 of the Controlled Substances
7 Act) covered under the plan that is transmitted by
8 such a health care practitioner for such a participant
9 or beneficiary be electronically transmitted in ac-
10 cordance with such standards, consistent with stand-
11 ards established under paragraph (3) of section
12 1860D–4(e) of the Social Security Act, under an
13 electronic prescription drug program that meets re-
14 quirements that are substantially similar (as jointly
15 determined by the Secretary, Secretary of the Treas-
16 ury, and Secretary of Labor) to the requirements of
17 paragraph (2) of such section 1860D–4(e).

18 “(2) EXCEPTION FOR CERTAIN CIR-
19 CUMSTANCES.—The Secretary, Secretary of Health
20 and Human Services, and Secretary of Labor shall
21 jointly, through rulemaking, specify circumstances
22 and processes by which the requirement under para-
23 graph (1) may be waived, with respect to a schedule
24 II, III, IV, or V controlled substance that is a pre-

1 scription drug covered by a group health, including
2 in the case of—

3 “(A) a prescription described in any of
4 clauses (i) through (vi) of section 1860D–
5 4(e)(7)(B) of the Social Security Act;

6 “(B) a prescription issued for an individual
7 who receives hospice care or for a resident of a
8 nursing facility (as defined in section 1919(a)
9 of the Social Security Act);

10 “(C) a prescription issued under cir-
11 cumstances in which electronic prescribing is
12 not available due to temporary technological or
13 electrical failure, as specified jointly by the Sec-
14 retary, Secretary of Health and Human Serv-
15 ices, and Secretary of Labor through rule-
16 making; and

17 “(D) a prescription issued by a practi-
18 tioner allowing for the dispensing of a non-pa-
19 tient specific prescription pursuant to a stand-
20 ing order, approved protocol for drug therapy,
21 collaborative drug management, or comprehen-
22 sive medication management, in response to a
23 public health emergency or other circumstances
24 under which the practitioner may issue a non-
25 patient specific prescription.

1 “(3) RULES OF CONSTRUCTION.—

2 “(A) VERIFICATION.—Nothing in this sub-
3 section shall be construed as requiring a dis-
4 penser to verify that a health care practitioner,
5 with respect to a prescription for a schedule II,
6 III, IV, or V controlled substance that is a pre-
7 scription drug covered under a group health
8 plan, has a waiver (or is otherwise exempt)
9 under paragraph (2) from the requirement
10 under paragraph (1).

11 “(B) AUTHORITY TO DISPENSE.—Nothing
12 in this subsection shall be construed as affect-
13 ing the ability of a group health plan to cover,
14 or the ability of a dispenser to continue to dis-
15 pense, a prescription drug if the prescription
16 for such drug is an otherwise valid written,
17 oral, or fax prescription that is consistence with
18 applicable laws and regulations.

19 “(C) PATIENT CHOICE.—Nothing in this
20 subsection shall be construed as affecting the
21 ability of an individual who is a participant or
22 beneficiary of a group health plan and who is
23 prescribed a schedule II, III, IV, or V con-
24 trolled substance that is a prescription drug
25 covered under the plan to designate a particular

1 pharmacy to dispense a prescribed controlled
2 substance to the extent consistent with the re-
3 quirements under this subsection.

4 “(4) PROHIBITIONS.—The policies established
5 pursuant to paragraph (1) by a group health plan
6 may not—

7 “(A) require dispensers of a schedule II,
8 III, IV, or V controlled substance to confirm
9 that the prescription for the controlled sub-
10 stance was electronically issued by a health care
11 practitioner in accordance with such policies, as
12 described in paragraph (1);

13 “(B) require dispensers of such controlled
14 substances to submit information or data be-
15 yond what is otherwise required to process a
16 prescription drug claim in order to confirm a
17 practitioner’s compliance with such policies; or

18 “(C) reject, deny, or recoup reimbursement
19 for a prescription drug claim based on the for-
20 mat in which the prescription was issued.

21 “(5) CONSULTATION REQUIREMENT FOR RULE-
22 MAKING.—In promulgating regulations to carry out
23 this subsection, the Secretary, Secretary of Health
24 and Human Services, and Secretary of Labor shall
25 jointly consult with dispensers of controlled sub-

1 stances, State insurance regulators, and health care
2 practitioners.”.

