117TH CONGRESS 2D SESSION

H. R. 8988

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 HOUSE OF REPRESENTATIVES

September 26, 2022

Mr. O'HALLERAN introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Education and Labor, and 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 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, 2024, a group health plan and a
14	health insurance issuer offering group or individual
15	health insurance coverage shall, with respect to
16	health care practitioners that have a contractual re-
17	lationship with such plan or issuer for furnishing
18	items or services to participants and beneficiaries
19	under such plan or coverage, have in place policies,
20	subject to paragraph (4), that require any prescrip-
21	tion for a schedule II, III, IV, or V controlled sub-
22	stance (as defined by section 202 of the Controlled
23	Substances Act) covered under the plan or coverage
24	that is transmitted by such a health care practi-
25	tioner for such a participant or beneficiary be elec-
26	tronically transmitted in accordance with such

1 standards, consistent with standards established 2 under paragraph (3) of section 1860D-4(e) of the 3 Social Security Act, under an electronic prescription 4 drug program that meets requirements that are sub-5 stantially similar (as jointly determined by the Sec-6 retary, Secretary of the Treasury, and Secretary of 7 Labor) to the requirements of paragraph (2) of such 8 section 1860D-4(e).

- "(2) EXCEPTION FOR CERTAIN CIR-CUMSTANCES.—The Secretary, Secretary of the Treasury, and Secretary of Labor shall jointly, through rulemaking, specify circumstances and processes by which the requirement under paragraph (1) may be waived, with respect to a schedule II, III, IV, or V controlled substance that is a prescription drug covered by a group health or group or individual health insurance coverage offered by a health insurance issuer, including in the case of—
 - "(A) a prescription described in any of clauses (i) through (vi) of section 1860D–4(e)(7)(B) of the Social Security Act;
 - "(B) a prescription issued under circumstances in which electronic prescribing is not available due to temporary technological or electrical failure, as specified jointly by the Sec-

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retary, Secretary of the Treasury, and Secretary of Labor through rulemaking; and

"(C) 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.

"(3) Rules of construction.—

"(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).

"(B) AUTHORITY TO DISPENSE.—Nothing in this subsection shall be construed as affect-

ing the ability of a group health plan or group or individual health insurance coverage offered by a health insurance issuer to cover, or the ability of a pharmacist to continue to dispense, a prescription drug if the prescription for such drug is an otherwise valid written, oral, or fax prescription that is consistence with applicable laws and regulations.

"(C) Patient Choice.—Nothing in this subsection shall be construed as affecting the ability of an individual who is a participant or beneficiary of a group health plan or group or individual health insurance coverage offered by a health insurance issuer and who is being prescribed a schedule II, III, IV, or V controlled substance that is a prescription drug covered under the plan or coverage to designate a particular pharmacy to dispense such controlled substance to the extent consistent with the requirements under this subsection.

"(4) Prohibitions.—The policies established pursuant to paragraph (1) by a group health plan or health insurance issuer offering group or individual health insurance coverage may not—

"(A) require dispensers of a schedule II, 1 2 III, IV, or V controlled substance to confirm 3 that the prescription for the controlled sub-4 stance was electronically issued by a health care practitioner in accordance with such policies, as 6 described in paragraph (1); 7 "(B) require dispensers of such controlled substances to submit information or data be-8 9 yond what is otherwise required to process a 10 prescription drug claim in order to confirm a 11 practitioner's compliance with such policies; or "(C) reject, deny, or recoup reimbursement 12 13 for a prescription drug claim based on the for-14 mat in which the prescription was issued. 15 "(5) Consultation requirement for rule-16 MAKING.—In promulgating regulations to carry out 17 this subsection, the Secretary, Secretary of the 18 Treasury, and Secretary of Labor shall jointly con-19 sult with dispensers of controlled substances, State 20 insurance regulators, and health care practitioners.". 21 (b) Employee Retirement Income Security Act OF 1974 AMENDMENT.—Section 722 of the Employee Re-23 tirement Income Security Act of 1974 (29 U.S.C. 1185k) is amended by adding at the end the following new sub-

section:

1 "(d) REQUIREMENTS FOR ELECTRONIC-PRE-2 SCRIBING FOR CONTROLLED SUBSTANCES.—

"(1) In general.—Except as provided pursuant to paragraph (2), for plan years beginning on or after January 1, 2024, a group health plan and a health insurance issuer offering group health insurance coverage shall, with respect to health care practitioners that have a contractual relationship with such plan or issuer for furnishing items or services to participants and beneficiaries under such plan or coverage, have in place policies, subject to paragraph (4), that require any prescription for a schedule II, III, IV, or V controlled substance (as defined by section 202 of the Controlled Substances Act) covered under the plan or coverage that is transmitted by such a health care practitioner for such a participant or beneficiary be electronically transmitted in accordance with such standards, consistent with standards established under paragraph (3) of section 1860D-4(e) of the Social Security Act, under an electronic prescription drug program that meets requirements that are substantially similar (as jointly determined by the Secretary, Secretary of the Treasury, and Secretary of Labor) to the requirements of paragraph (2) of such section 1860D-4(e).

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1	"(2) Exception for certain cir-
2	CUMSTANCES.—The Secretary, Secretary of the
3	Treasury, and Secretary of Labor shall jointly,
4	through rulemaking, specify circumstances and proc-
5	esses by which the requirement under paragraph (1)
6	may be waived, with respect to a schedule II, III,
7	IV, or V controlled substance that is a prescription
8	drug covered by a group health or group health in-
9	surance coverage offered by a health insurance
10	issuer, including in the case of—
11	"(A) a prescription described in any of
12	clauses (i) through (vi) of section 1860D-
13	4(e)(7)(B) of the Social Security Act;
14	"(B) a prescription issued under cir-
15	cumstances in which electronic prescribing is
16	not available due to temporary technological or
17	electrical failure, as specified jointly by the Sec-
18	retary, Secretary of the Treasury, and Sec-
19	retary of Labor through rulemaking; and
20	"(C) a prescription issued by a practitioner
21	allowing for the dispensing of a non-patient spe-
22	cific prescription pursuant to a standing order,

approved protocol for drug therapy, collabo-

rative drug management, or comprehensive

medication management, in response to a public

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health emergency or other circumstances under which the practitioner may issue a non-patient specific prescription.

"(3) Rules of Construction.—

"(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).

"(B) Authority to dispense.—Nothing in this subsection shall be construed as affecting the ability of a group health plan or group health insurance coverage offered by a health insurance issuer to cover, or the ability of a pharmacist to continue to dispense, a prescription drug if the prescription for such drug is an otherwise valid written, oral, or fax prescription that is consistence with applicable laws and regulations.

1 "(C) Patient Choice.—Nothing in this 2 subsection shall be construed as affecting the 3 ability of an individual who is a participant or 4 beneficiary of a group health plan or group or 5 individual health insurance coverage offered by 6 a health insurance issuer and who is being pre-7 scribed a schedule II, III, IV, or V controlled 8 substance that is a prescription drug covered 9 under the plan or coverage to designate a par-10 ticular pharmacy to dispense such controlled 11 substance to the extent consistent with the re-12 quirements under this subsection.

- "(4) Prohibitions.—The policies established pursuant to paragraph (1) by a group health plan or health insurance issuer offering group health insurance coverage may not—
 - "(A) require dispensers of a schedule II, III, IV, or V controlled substance to confirm that the prescription for the controlled substance was electronically issued by a health care practitioner in accordance with such policies, as described in paragraph (1);
 - "(B) require dispensers of such controlled substances to submit information or data beyond what is otherwise required to process a

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1 prescription drug claim in order to confirm a 2 practitioner's compliance with such policies; or 3 "(C) reject, deny, or recoup reimbursement 4 for a prescription drug claim based on the for-5 mat in which the prescription was issued. 6 "(5) Consultation requirement for rule-7 MAKING.—In promulgating regulations to carry out 8 this subsection, the Secretary, Secretary of the 9 Treasury, and Secretary of Labor shall jointly con-10 sult with dispensers of controlled substances, State 11 insurance regulators, and health care practitioners.". 12 (c) Internal Revenue Code of 1986 Amend-MENT.—Section 9822 of the Internal Revenue Code of 14 1986 is amended by adding at the end the following new 15 subsection: 16 "(d) REQUIREMENTS ELECTRONIC-PRE-FOR

17 SCRIBING FOR CONTROLLED SUBSTANCES.—

"(1) In General.—Except as provided pursuant to paragraph (2), for plan years beginning on or after January 1, 2024, a group health plan shall, with respect to health care practitioners that have a contractual relationship with such plan for furnishing items or services to participants and beneficiaries under such plan, have in place policies, subject to paragraph (4), that require any prescription

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1 for a schedule II, III, IV, or V controlled substance 2 (as defined by section 202 of the Controlled Sub-3 stances Act) covered under the plan that is trans-4 mitted by such a health care practitioner for such a 5 participant or beneficiary be electronically trans-6 mitted in accordance with such standards, consistent with standards established under paragraph (3) of 7 8 section 1860D-4(e) of the Social Security Act, 9 under an electronic prescription drug program that 10 meets requirements that are substantially similar (as 11 jointly determined by the Secretary, Secretary of the 12 Treasury, and Secretary of Labor) to the require-13 ments of paragraph (2) of such section 1860D-4(e). 14 "(2)EXCEPTION FOR CERTAIN CIR-15 CUMSTANCES.—The Secretary, Secretary of the 16 Treasury, and Secretary of Labor shall jointly, 17 through rulemaking, specify circumstances and proc-18 esses by which the requirement under paragraph (1) 19 may be waived, with respect to a schedule II, III, 20 IV, or V controlled substance that is a prescription 21 drug covered by a group health, including in the 22 case of— 23 "(A) a prescription described in any of 24 clauses (i) through (vi) of section 1860D-

4(e)(7)(B) of the Social Security Act;

"(B) a prescription issued under circumstances in which electronic prescribing is not available due to temporary technological or electrical failure, as specified jointly by the Secretary, Secretary of the Treasury, and Secretary of Labor through rulemaking; and

"(C) 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.

"(3) Rules of construction.—

"(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, has a waiver (or is otherwise exempt) under paragraph (2) from the requirement under paragraph (1).

"(B) AUTHORITY TO DISPENSE.—Nothing in this subsection shall be construed as affect-ing the ability of a group health plan to cover, or the ability of a pharmacist to continue to dispense, a prescription drug if the prescription for such drug is an otherwise valid written, oral, or fax prescription that is consistence with applicable laws and regulations.

- "(C) Patient Choice.—Nothing in this subsection shall be construed as affecting the ability of an individual who is a participant or beneficiary of a group health plan and who is being prescribed a schedule II, III, IV, or V controlled substance that is a prescription drug covered under the plan to designate a particular pharmacy to dispense such controlled substance to the extent consistent with the requirements under this subsection.
- "(4) Prohibitions.—The policies established pursuant to paragraph (1) by a group health plan may not—
- "(A) require dispensers of a schedule II,
 III, IV, or V controlled substance to confirm
 that the prescription for the controlled substance 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 Labor shall jointly con-
15	sult with dispensers of controlled substances, State

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insurance regulators, and health care practitioners.".