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

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Electronic Prescribing for Controlled Substances Act'' or the ''EPCS 2.0 Act''.

SEC. 2. REQUIREMENTS FOR ELECTRONIC-PRESCRIBING FOR CONTROLLED SUBSTANCES UNDER GROUP HEALTH PLANS AND GROUP AND INDIVIDUAL HEALTH INSURANCE COVERAGE.

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

''(d) REQUIREMENTS FOR ELECTRONIC-PRESCRIBING FOR CONTROLLED SUBSTANCES.—

''(1) IN GENERAL.—Except as provided pursuant to paragraph (2), for plan years beginning on or after January 1, 2025, a group health plan and a health insurance issuer offering group or individual health insurance coverage, with respect to a participating provider, as defined in section 2799–1(a)(3), shall 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, beneficiary, or enrollee 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).

''(2) EXCEPTION FOR CERTAIN CIRCUMSTANCES.—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 plan 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 for an individual who receives hospice care or for a resident of a nursing facility (as defined in section 1919(a) of the Social Security Act);

''(C) 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

''(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.

''(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 authority of a group health plan or group or individual health insurance coverage offered by a health insurance issuer to cover, or the authority of a dispenser to continue to dispense, a prescription drug if the prescription for such drug is an otherwise valid written, oral, or fax prescription that is consistent with applicable law.

"(C) PATIENT CHOICE.—Nothing in this subsection shall be construed as affecting the ability of an individual who is a participant, beneficiary, or enrollee of a group health plan or group or individual health insurance coverage offered by a health insurance issuer and who is 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 a prescribed 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, 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 prescription drug claim in order to confirm a practitioner's compliance with such policies; or

"(C) reject, deny, or recoup reimbursement for a prescription drug claim based on the format in which the prescription was issued.

"(5) CONSULTATION REQUIREMENT FOR RULEMAKING.—In promulgating regulations to carry out this subsection, the Secretary, Secretary of the Treasury, and Secretary of Labor shall jointly consult with dispensers of controlled substances, State insurance regulators, and health care practitioners.".

(b) EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974 AMENDMENT.—Section 722 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185k)

is amended by adding at the end the following new subsection:

"(d) REQUIREMENTS FOR ELECTRONIC-PRESCRIBING FOR CONTROLLED SUBSTANCES.—

"(1) IN GENERAL.—Except as provided pursuant to paragraph (2), for plan years beginning on or after January 1, 2025, a group health plan and a health insurance issuer offering group health insurance coverage, with respect to a participating provider, as defined in section 716(a)(3), shall 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).

''(2) EXCEPTION FOR CERTAIN CIRCUMSTANCES.—The Secretary, Secretary of the Treasury, and Secretary of Health and Human Services 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 plan or group 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 for an individual who receives hospice care or for a resident of a nursing facility (as defined in section 1919(a) of the Social Security Act);

''(C) 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 Health and Human Services through rulemaking; and

"(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.

"(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 authority of a group health plan or group health insurance coverage offered by a

health insurance issuer to cover, or the authority of a dispenser to continue to dispense, a prescription drug if the prescription for such drug is an otherwise valid written, oral, or fax prescription that is consistent with applicable law.

''(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 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 a prescribed 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 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 prescription drug claim in order to confirm a practitioner's compliance with such policies; or

"(C) reject, deny, or recoup reimbursement for a prescription drug claim based on the format in which the prescription was issued.

"(5) CONSULTATION REQUIREMENT FOR RULEMAKING.—In promulgating regulations to carry out this subsection, the Secretary, Secretary of the Treasury, and Secretary of Health and Human Services shall jointly consult with dispensers of controlled substances, State insurance regulators, and health care practitioners.".

(c) INTERNAL REVENUE CODE OF 1986 AMENDMENT.—Section 9822 of the Internal Revenue Code of 1986 is amended by adding at the end the following new subsection:

"(d) REQUIREMENTS FOR ELECTRONIC-PRESCRIBING FOR CONTROLLED SUBSTANCES.—

"(1) IN GENERAL.—Except as provided pursuant to paragraph (2), for plan years beginning on or

after January 1, 2025, a group health plan, with respect to a participating provider, as defined in section 9816(a)(3), shall 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 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).

''(2) EXCEPTION FOR CERTAIN CIRCUMSTANCES.—The Secretary, Secretary of Health and Human Services, 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 pre-

scription drug covered by a group health, 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 for an individual who receives hospice care or for a resident of a nursing facility (as defined in section 1919(a) of the Social Security Act);

"(C) 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 Health and Human Services, and Secretary of Labor through rulemaking; and

"(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.

''(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 affecting the ability of a group health plan to cover, or the ability of a dispenser 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 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 a prescribed 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 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 prescription drug claim in order to confirm a practitioner's compliance with such policies; or

''(C) reject, deny, or recoup reimbursement for a prescription drug claim based on the format in which the prescription was issued.

''(5) CONSULTATION REQUIREMENT FOR RULEMAKING.—In promulgating regulations to carry out this subsection, the Secretary, Secretary of Health and Human Services, and Secretary of Labor shall jointly consult with dispensers of controlled sub-

stances, State insurance regulators, and health care practitioners.''.

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