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118TH CONGRESS
2D SESSION

H. R. 7312

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

FEBRUARY 9, 2024

Ms. KUSTER (for herself, Mr. BALDERSON, and Ms. LETLOW) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Education and the Workforce, Ways and Means, and the Judiciary, 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

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A BILL

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, 2026, 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 paragraphs (4) and (5), 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 by the plan or coverage that is transmitted by such a participating provider for such a participant, beneficiary, or enrollee be electronically transmitted 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, the Secretary of Labor, and the Secretary of the Treasury) to the requirements of paragraph (2) of such section 1860D–4(e).

''(2) EXCEPTION FOR CERTAIN CIRCUMSTANCES.—The Secretary, the Secretary of Labor, and the Secretary of the Treasury 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 issued when the participating provider and dispensing pharmacy are the same entity;

''(B) a prescription issued that cannot be transmitted electronically under the most recently implemented version of the National Council for Prescription Drug Programs SCRIPT Standard;

''(C) a prescription issued by a participating provider who received a waiver (which

may include a waiver obtained pursuant to section 1860D–4(e)(7)(B)(iii) of the Social Security Act) or a renewal thereof for a period of time as determined by the Secretary, the Secretary of Labor, and the Secretary of the Treasury, not to exceed one year, from the requirement to use electronic prescribing due to demonstrated economic hardship, technological limitations that are not reasonably within the control of the participating provider, or other exceptional circumstance demonstrated by the participating provider;

''(D) a prescription issued by a participating provider under circumstances in which, notwithstanding the participating provider's ability to submit a prescription electronically as required by this subsection, such participating provider reasonably determines that it would be impractical for the individual involved to obtain substances prescribed by electronic prescription in a timely manner, and such delay would adversely impact the individual's medical condition involved;

"(E) a prescription issued by a participating provider prescribing a drug under a research protocol;

"(F) a prescription issued by a participating provider for a drug for which the Food and Drug Administration requires a prescription to contain elements that are not able to be included in electronic prescribing, such as a drug with risk evaluation and mitigation strategies that include elements to assure safe use;

"(G) 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);

"(H) 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, the Secretary of Labor, and the Secretary of the Treasury through rulemaking; and

"(I) a prescription issued by a participating provider allowing for the dispensing of a non-patient specific prescription pursuant to a standing order, approved protocol for drug therapy, collaborative drug management, or com-

prehensive medication management, in response to a public health emergency or other circumstances under which the participating provider 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 participating provider, with respect to a prescription for 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, 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 by the plan or coverage to designate a particular dispenser to dispense a prescribed controlled substance to the extent consistent with the requirements under this subsection.

"(4) REGULATIONS ON POLICY REQUIREMENTS.—The Secretary, the Secretary of Labor, and the Secretary of the Treasury shall promulgate regulations specifying requirements for the policies established by group health plans and health insurance issuers under paragraph (1). Such regulations shall include requirements for—

"(A) a uniform process by which plans and issuers are required to set the e-prescribing requirements;

"(B) a process by which plans and issuers are required to grant waivers and exceptions to participating providers pursuant to paragraph (2); and

"(C) a mechanism for plans and issuers to recognize waivers issued to participating providers under part D of title XVIII of the Social Security Act, pursuant to paragraph (2)(C).

"(5) 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 participating provider 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 participating provider's compliance with such policies;

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

''(D) require a participating provider to use a specific vendor for electronic prescribing or a specific electronic prescribing product or system.

''(6) ATTESTATION OF COMPLIANCE.—Beginning on January 1, 2026, each group health plan and health insurance issuer offering group or individual health insurance coverage shall annually submit to the Secretary, the Secretary of Labor, and the Secretary of the Treasury an attestation of compliance with the requirements of this subsection.

''(7) CONSULTATION REQUIREMENT FOR RULEMAKING.—In promulgating regulations to carry out this subsection, the Secretary, the Secretary of the Labor, and the Secretary of the Treasury shall jointly consult with dispensers of controlled substances, State insurance regulators, health insurance issuers offering group or individual health insurance coverage, 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, 2026, 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 paragraphs (4) and (5), 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 by the plan or coverage that is transmitted by such a participating provider for such a participant or beneficiary be electronically transmitted 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, the Secretary of Health and Human Services, and the Secretary of the Treasury) to the requirements of paragraph (2) of such section 1860D–4(e).

"(2) EXCEPTION FOR CERTAIN CIRCUMSTANCES.—The Secretary, the Secretary of Health and Human Services, and the Secretary of the Treasury 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 issued when the participating provider and dispensing pharmacy are the same entity;

"(B) a prescription issued that cannot be transmitted electronically under the most recently implemented version of the National Council for Prescription Drug Programs SCRIPT Standard;

"(C) a prescription issued by a participating provider who received a waiver (which may include a waiver obtained pursuant to section 1860D–4(e)(7)(B)(iii) of the Social Security Act) or a renewal thereof for a period of time as determined by the Secretary, the Sec-

retary of Health and Human Services, and the Secretary of the Treasury, not to exceed one year, from the requirement to use electronic prescribing due to demonstrated economic hardship, technological limitations that are not reasonably within the control of the participating provider, or other exceptional circumstance demonstrated by the participating provider;

''(D) a prescription issued by a participating provider under circumstances in which, notwithstanding the participating provider's ability to submit a prescription electronically as required by this subsection, such participating provider reasonably determines that it would be impractical for the individual involved to obtain substances prescribed by electronic prescription in a timely manner, and such delay would adversely impact the individual's medical condition involved;

''(E) a prescription issued by a participating provider prescribing a drug under a research protocol;

''(F) a prescription issued by a participating provider for a drug for which the Food and 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 mitigation strategies that include elements to assure safe use;

''(G) 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);

''(H) 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, the Secretary of Health and Human Services, and the Secretary of the Treasury through rulemaking; and

''(I) a prescription issued by a participating provider 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 participating provider 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 participating provider, with respect to a prescription for 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, 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 by the plan or coverage to designate a particular dispenser to dispense a prescribed controlled substance to the extent consistent with the requirements under this subsection.

''(4) REGULATIONS ON POLICY REQUIREMENTS.—The Secretary, the Secretary of Health and Human Services, and the Secretary of the Treasury shall promulgate regulations specifying requirements for the policies established by group health plans and health insurance issuers under paragraph (1). Such regulations shall include requirements for—

''(A) a uniform process by which plans and issuers are required to set the e-prescribing requirements;

''(B) a process by which plans and issuers are required to grant waivers and exceptions to participating providers pursuant to paragraph (2); and

''(C) a mechanism for plans and issuers to recognize waivers issued to participating pro-

viders under part D of title XVIII of the Social Security Act, pursuant to paragraph (2)(C).

''(5) 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 participating provider 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 participating provider's compliance with such policies;

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

''(D) require a participating provider to use a specific vendor for electronic prescribing or a specific electronic prescribing product or system.

''(6) ATTESTATION OF COMPLIANCE.—Beginning on January 1, 2026, each group health plan and health insurance issuer offering group health insurance coverage shall annually submit to the Secretary, the Secretary of Health and Human Services, and the Secretary of the Treasury an attestation of compliance with the requirements of this subsection.

''(7) CONSULTATION REQUIREMENT FOR RULEMAKING.—In promulgating regulations to carry out this subsection, the Secretary, the Secretary of Health and Human Services, and the Secretary of the Treasury shall jointly consult with dispensers of controlled substances, State insurance regulators, health insurance issuers offering group or individual health insurance coverage, 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, 2026, a group health plan, with re-

spect to a participating provider, as defined in section 9816(a)(3), shall have in place policies, subject to paragraphs (4) and (5), 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 by the plan that is transmitted by such a participating provider for such a participant or beneficiary be electronically transmitted 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, the Secretary of Health and Human Services, and the Secretary of Labor) to the requirements of paragraph (2) of such section 1860D–4(e).

''(2) EXCEPTION FOR CERTAIN CIRCUMSTANCES.—The Secretary, the Secretary of Health and Human Services, and the 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, including in the case of—

"(A) a prescription issued when the participating provider and dispensing pharmacy are the same entity;

"(B) a prescription issued that cannot be transmitted electronically under the most recently implemented version of the National Council for Prescription Drug Programs SCRIPT Standard;

"(C) a prescription issued by a participating provider who received a waiver (which may include a waiver obtained pursuant to section 1860D–4(e)(7)(B)(iii) of the Social Security Act) or a renewal thereof for a period of time as determined by the Secretary, the Secretary of Health and Human Services, and the Secretary of Labor, not to exceed one year, from the requirement to use electronic prescribing due to demonstrated economic hardship, technological limitations that are not reasonably within the control of the participating provider, or other exceptional circumstance demonstrated by the participating provider;

"(D) a prescription issued by a participating provider under circumstances in which, notwithstanding the participating provider's

ability to submit a prescription electronically as required by this subsection, such participating provider reasonably determines that it would be impractical for the individual involved to obtain substances prescribed by electronic prescription in a timely manner, and such delay would adversely impact the individual's medical condition involved;

''(E) a prescription issued by a participating provider prescribing a drug under a research protocol;

''(F) a prescription issued by a participating provider for a drug for which the Food and Drug Administration requires a prescription to contain elements that are not able to be included in electronic prescribing, such as a drug with risk evaluation and mitigation strategies that include elements to assure safe use;

''(G) 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);

''(H) 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, the Secretary of Health and Human Services, and the Secretary of Labor through rulemaking; and

''(I) a prescription issued by a participating provider 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 participating provider 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 participating provider, with respect to a prescription for a schedule II, III, IV, or V controlled substance that is a prescription drug covered by 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 by the plan to designate a particular dispenser to dispense a prescribed controlled substance to the extent consistent with the requirements under this subsection.

"(4) REGULATIONS ON POLICY REQUIREMENTS.—The Secretary, the Secretary of Health and Human Services, and the Secretary of Labor shall promulgate regulations specifying requirements for the policies established by group health plans under paragraph (1). Such regulations shall include requirements for—

"(A) a uniform process by which plans are required to set the e-prescribing requirements;

"(B) a process by which plans are required to grant waivers and exceptions to participating providers pursuant to paragraph (2); and

"(C) a mechanism for plans to recognize waivers issued to participating providers under part D of title XVIII of the Public Health Service Act, pursuant to paragraph (2)(C).

"(5) 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 participating provider 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 participating provider's compliance with such policies;

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

"(D) require a participating provider to use a specific vendor for electronic prescribing or a specific electronic prescribing product or system.

"(6) ATTESTATION OF COMPLIANCE.—Beginning on January 1, 2026, each group health plan shall annually submit to the Secretary, the Secretary of Health and Human Services, and the Secretary of Labor an attestation of compliance with the requirements of this subsection.

"(7) CONSULTATION REQUIREMENT FOR RULEMAKING.—In promulgating regulations to carry out this subsection, the Secretary, the Secretary of Health and Human Services, and the Secretary of Labor shall jointly consult with dispensers of controlled substances, State insurance regulators, health insurance issuers offering group or individual health insurance coverage, and health care practitioners.".

(d) UPDATE OF BIOMETRIC COMPONENT OF MULTIFACTOR AUTHENTICATION.—Not later than 1 year after the date of enactment of this Act, the Attorney General shall finalize a regulation updating the requirements for

the biometric component of multifactor authentication with respect to electronic prescriptions of controlled substances, as required under section 2003(c) of the SUPPORT for Patients and Community Act (Public Law 115–271).

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