

AN	IENDMENT NO Calendar No
Pu	rpose: To provide for requirements for electronic-pre- scribing for controlled substances under group health plans and group and individual health insurance cov- erage.
IN	THE SENATE OF THE UNITED STATES-118th Cong., 1st Sess.
	S. 3393
То	reauthorize the SUPPORT for Patients and Communities Act, and for other purposes.
R	eferred to the Committee on and ordered to be printed
	Ordered to lie on the table and to be printed
Viz	AMENDMENT intended to be proposed by Ms. HASSAN for herself and senator Mulh
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	At the appropriate place in title I, insert the fol-
2	lowing:
3	SEC REQUIREMENTS FOR ELECTRONIC-PRE-
4	SCRIBING FOR CONTROLLED SUBSTANCES
5	UNDER GROUP HEALTH PLANS AND GROUP
6	AND INDIVIDUAL HEALTH INSURANCE COV-
7	ERAGE.
8	(a) Public Health Service Act Amendment.—
9	Section 2799A-7 of the Public Health Service Act (42
10	U.S.C. 300gg-117) is amended by adding at the end the
	following new subsection:

1	"(d) REQUIREMENTS FOR ELECTRONIC-PRE
2	SCRIBING FOR CONTROLLED SUBSTANCES.—
3	"(1) In general.—Except as provided pursu-
4	ant to paragraph (2), for plan years beginning on or
5	after January 1, 2026, a group health plan and a
6	health insurance issuer offering group or individual
7	health insurance coverage, with respect to a partici-
8	pating provider, as defined in section 2799-1(a)(3),
9	shall have in place policies, subject to paragraphs
10	(4) and (5), that require any prescription for a
11	schedule II, III, IV, or V controlled substance (as
12	defined by section 202 of the Controlled Substances
13	Act) covered by the plan or coverage that is trans-
14	mitted by such a participating provider for such a
15	participant, beneficiary, or enrollee be electronically
16	transmitted consistent with standards established
17	under paragraph (3) of section 1860D-4(e) of the
18	Social Security Act, under an electronic prescription
9	drug program that meets requirements that are sub-
20	stantially similar (as jointly determined by the Sec-
21	retary, the Secretary of Labor, and the Secretary of
22	the Treasury) to the requirements of paragraph (2)
23	of such section 1860D-4(e).
24	"(2) EXCEPTION FOR CERTAIN CIR-
25	CUMSTANCES.—The Secretary, the Secretary of

1	Labor, and the Secretary of the Treasury shall joint
2	ly, through rulemaking, specify circumstances and
3	processes by which the requirement under paragraph
4	(1) may be waived, with respect to a schedule II, III,
5	IV, or V controlled substance that is a prescription
6	drug covered by a group health plan or group or in-
7	dividual health insurance coverage offered by a
8	health insurance issuer, including in the case of—
9	"(A) a prescription issued when the par-
10	ticipating provider and dispensing pharmacy are
1	the same entity;
2:	"(B) a prescription issued that cannot be
3	transmitted electronically under the most re-
4	cently implemented version of the National
15	Council for Prescription Drug Programs
16	SCRIPT Standard;
17	"(C) a prescription issued by a partici-
18	pating provider who received a waiver (which
19	may include a waiver obtained pursuant to sec-
20	tion 1860D-4(e)(7)(B)(iii) of the Social Secu-
21	rity Act) or a renewal thereof for a period of
22	time as determined by the Secretary, the Sec-
23	retary of Labor, and the Secretary of the
24	Treasury, not to exceed one year, from the re-
25	quirement to use electronic prescribing due to

1	demonstrated economic hardship, technological
2	limitations that are not reasonably within the
3	control of the participating provider, or other
4	exceptional circumstance demonstrated by the
.5	participating provider;
6	"(D) a prescription issued by a partici-
7	pating provider under circumstances in which,
8:	notwithstanding the participating provider's
9	ability to submit a prescription electronically as
10	required by this subsection, such participating
11	provider reasonably determines that it would be
12	impractical for the individual involved to obtain
13	substances prescribed by electronic prescription
14	in a timely manner, and such delay would ad-
15	versely impact the individual's medical condition
16	involved;
17	"(E) a prescription issued by a partici-
18	pating provider prescribing a drug under a re-
19	search protocol;
20	"(F) a prescription issued by a partici-
21	pating provider for a drug for which the Food
22	and Drug Administration requires a prescrip-
23	tion to contain elements that are not able to be
24	included in electronic prescribing, such as a

1	drug with risk evaluation and mitigation strate
2	gies that include elements to assure safe use;
.3	"(G) a prescription issued for an individual
4	who receives hospice care or for a resident of a
5	nursing facility (as defined in section 1919(a)
6	of the Social Security Act);
7	"(H) a prescription issued under cir-
8	cumstances in which electronic prescribing is
9	not available due to temporary technological or
10	electrical failure, as specified jointly by the Sec-
11	retary, the Secretary of Labor, and the Sec-
12	retary of the Treasury through rulemaking; and
13	"(I) a prescription issued by a partici-
14	pating provider allowing for the dispensing of a
15	non-patient specific prescription pursuant to a
16	standing order, approved protocol for drug ther-
17	apy, collaborative drug management, or com-
18	prehensive medication management, in response
19	to a public health emergency or other cir-
20	cumstances under which the participating pro-
21	vider may issue a non-patient specific prescrip-
22	tion.
23	"(3) Rules of construction.—
24	"(A) VERIFICATION.—Nothing in this sub-
25	section shall be construed as requiring a dis-

penser 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

1	who is prescribed a schedule II, III, IV, or V
2	controlled substance that is a prescription drug
3	covered by the plan or coverage to designate a
4	particular dispenser to dispense a prescribed
5	controlled substance to the extent consistent
6	with the requirements under this subsection.
7	"(4) REGULATIONS ON POLICY REQUIRE-
8	MENTS.—The Secretary, the Secretary of Labor,
9	and the Secretary of the Treasury shall promulgate
10	regulations specifying requirements for the policies
11	established by group health plans and health insur-
12	ance issuers under paragraph (1). Such regulations
13	shall include requirements for—
14	"(A) a uniform process by which plans and
15	issuers are required to set the e-prescribing re-
16	quirements;
17	"(B) a process by which plans and issuers
18	are required to grant waivers and exceptions to
19	participating providers pursuant to paragraph
20	(2); and
21	"(C) a mechanism for plans and issuers to
22	recognize waivers issued to participating pro-
23	viders under part D of title XVIII of the Social
24	Security Act, pursuant to paragraph (2)(C).

1	(5) PROHIBITIONS.—The policies established
2	pursuant to paragraph (1) by a group health plan or
3	health insurance issuer offering group or individual
4	health insurance coverage may not—
5	"(A) require dispensers of a schedule II,
6	III, IV, or V controlled substance to confirm
7	that the prescription for the controlled sub-
8	stance was electronically issued by a partici-
9	pating provider in accordance with such poli-
10	cies, as described in paragraph (1);
11	"(B) require dispensers of such controlled
12	substances to submit information or data be-
13	yond what is otherwise required to process a
14	prescription drug claim in order to confirm a
15	participating provider's compliance with such
16	policies;
17	"(C) reject, deny, or recoup reimbursement
18	for a prescription drug claim based on the for-
19	mat in which the prescription was issued; or
20	"(D) require a participating provider to
21	use a specific vendor for electronic prescribing
22	or a specific electronic prescribing product or
23	system.
24	"(6) ATTESTATION OF COMPLIANCE.—Begin-
25	ning on January 1, 2026, each group health plan

and health insurance issuer offering group or indi-1 2 vidual health insurance coverage shall annually sub-3 mit to the Secretary, the Secretary of Labor, and 4 the Secretary of the Treasury an attestation of com-5 pliance with the requirements of this subsection. 6 "(7) Consultation requirement for rule-7 MAKING.—In promulgating regulations to carry out 8 this subsection, the Secretary, the Secretary of the 9 Labor, and the Secretary of the Treasury shall joint-10 ly consult with dispensers of controlled substances, 11 State insurance regulators, and health care practi-12 tioners.". 13 (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) 16 is amended by adding at the end the following new subsection: 17 "(d) REQUIREMENTS FOR ELECTRONIC-PRESCRIBING 18 19 FOR CONTROLLED SUBSTANCES.— 20 "(1) IN GENERAL.—Except as provided pursu-21 ant to paragraph (2), for plan years beginning on or 22 after January 1, 2026, a group health plan and a 23 health insurance issuer offering group health insur-24 ance coverage, with respect to a participating pro-

vider, as defined in section 716(a)(3), shall have in

place policies, subject to paragraphs (4) and (5), 1 2 that require any prescription for a schedule II, III, 3 IV, or V controlled substance (as defined by section 4 202 of the Controlled Substances Act) covered by 5 the plan or coverage that is transmitted by such a participating provider for such a participant or bene-6 7 ficiary be electronically transmitted consistent with 8 standards established under paragraph (3) of section 9 1860D-4(e) of the Social Security Act, under an 10 electronic prescription drug program that meets re-11 quirements that are substantially similar (as jointly 12 determined by the Secretary, the Secretary of 13 Health and Human Services, and the Secretary of 14 the Treasury) to the requirements of paragraph (2) 15 of such section 1860D-4(e). "(2)16 EXCEPTION FOR CERTAIN CIR-17 CUMSTANCES.—The Secretary of 18 Health and Human Services, and the Secretary of 19 Treasury shall jointly, through rulemaking, 20 specify circumstances and processes by which the re-21 quirement under paragraph (1) may be waived, with 22 respect to a schedule II, III, IV, or V controlled sub-23 stance that is a prescription drug covered by a group 24 health plan or group health insurance coverage of-

1	fered by a health insurance issuer, including in the
2.	case of—
3	"(A) a prescription issued when the par-
4	ticipating provider and dispensing pharmacy are
5	the same entity;
6	"(B) a prescription issued that cannot be
7	transmitted electronically under the most re-
8	cently implemented version of the National
9	Council for Prescription Drug Programs
10	SCRIPT Standard;
11	"(C) a prescription issued by a partici-
12	pating provider who received a waiver (which
13	may include a waiver obtained pursuant to sec-
14	tion 1860D-4(e)(7)(B)(iii) of the Social Secu-
15	rity Act) or a renewal thereof for a period of
16	time as determined by the Secretary, the Sec-
17	retary of Health and Human Services, and the
18	Secretary of the Treasury, not to exceed one
19	year, from the requirement to use electronic
20	prescribing due to demonstrated economic hard-
2.1	ship, technological limitations that are not rea-
22	sonably within the control of the participating
23	provider, or other exceptional circumstance
24	demonstrated by the participating provider;

1	"(D) a prescription issued by a partici-
2	pating provider under circumstances in which,
3	notwithstanding the participating provider's
4	ability to submit a prescription electronically as
5	required by this subsection, such participating
6	provider reasonably determines that it would be
7	impractical for the individual involved to obtain
8	substances prescribed by electronic prescription
9	in a timely manner, and such delay would ad-
10	versely impact the individual's medical condition
11	involved;
12	"(E) a prescription issued by a partici-
13	pating provider prescribing a drug under a re-
14	search protocol;
15	"(F) a prescription issued by a partici-
16	pating provider for a drug for which the Food
17	and Drug Administration requires a prescrip-
18	tion to contain elements that are not able to be
19	included in electronic prescribing, such as a
20	drug with risk evaluation and mitigation strate-
21	gies that include elements to assure safe use;
22	"(G) a prescription issued for an individual
23	who receives hospice care or for a resident of a
24	nursing facility (as defined in section 1919(a)
25	of the Social Security Act);

25

1 "(H) a prescription issued under cir-2 cumstances in which electronic prescribing is 3 not available due to temporary technological or 4 electrical failure, as specified jointly by the Sec-5 retary, the Secretary of Health and Human 6 Services, and the Secretary of the Treasury 7 through rulemaking; and "(I) a prescription issued by a partici-8 9 pating provider allowing for the dispensing of a 10 non-patient specific prescription pursuant to a 11 standing order, approved protocol for drug ther-12 apy, collaborative drug management, or com-13 prehensive medication management, in response 14 to a public health emergency or other cir-15 cumstances under which the participating pro-16 vider may issue a non-patient specific prescrip-17 tion. 18 "(3) Rules of construction.— 19 "(A) VERIFICATION.—Nothing in this sub-20 section shall be construed as requiring a dis-21 penser to verify that a participating provider, 22 with respect to a prescription for a schedule II, 23 III, IV, or V controlled substance that is a pre-

scription drug covered by a group health plan

or group or individual health insurance cov-

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erage 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

"(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.

1	(4) REGULATIONS ON POLICY REQUIRE-
2	MENTS.—The Secretary, the Secretary of Health
3	and Human Services, and the Secretary of the
4	Treasury shall promulgate regulations specifying re-
5	quirements for the policies established by group
6	health plans and health insurance issuers under
7	paragraph (1). Such regulations shall include re-
8	quirements for—
9	"(A) a uniform process by which plans and
10	issuers are required to set the e-prescribing re-
11	quirements;
12	"(B) a process by which plans and issuers
13	are required to grant waivers and exceptions to
14	participating providers pursuant to paragraph
15	(2); and
16	"(C) a mechanism for plans and issuers to
17	recognize waivers issued to participating pro-
18	viders under part D of title XVIII of the Social
19	Security Act, pursuant to paragraph (2)(C).
20	"(5) Prohibitions.—The policies established
21	pursuant to paragraph (1) by a group health plan or
22	health insurance issuer offering group health insur-
23	ance coverage may not—
24	"(A) require dispensers of a schedule II,
25	III, IV, or V controlled substance to confirm

1	that the prescription for the controlled sub-
2	stance was electronically issued by a partici-
3	pating provider in accordance with such poli-
4	cies, as described in paragraph (1);
5	"(B) require dispensers of such controlled
6	substances to submit information or data be-
7	yond what is otherwise required to process a
8	prescription drug claim in order to confirm a
9	participating provider's compliance with such
10	policies;
11	"(C) reject, deny, or recoup reimbursement
12	for a prescription drug claim based on the for-
13	mat in which the prescription was issued; or
14	"(D) require a participating provider to
15	use a specific vendor for electronic prescribing
16	or a specific electronic prescribing product or
17	system.
18	"(6) ATTESTATION OF COMPLIANCE.—Begin-
19	ning on January 1, 2026, each group health plan
20	and health insurance issuer offering group health in-
21	surance coverage shall annually submit to the Sec-
22	retary, the Secretary of Health and Human Services,
23	and the Secretary of the Treasury an attestation of
24	compliance with the requirements of this subsection.

1	"(7) Consultation requirement for rule
2	MAKING.—In promulgating regulations to carry out
3	this subsection, the Secretary, the Secretary of
4	Health and Human Services, and the Secretary of
5	the Treasury shall jointly consult with dispensers of
6	controlled substances, State insurance regulators,
7	and health care practitioners.".
8	(c) Internal Revenue Code of 1986 Amend-
9	MENT.—Section 9822 of the Internal Revenue Code of
10	1986 is amended by adding at the end the following new
11	subsection:
12	"(d) REQUIREMENTS FOR ELECTRONIC-PRE-
13	SCRIBING FOR CONTROLLED SUBSTANCES.—
14	"(1) In general.—Except as provided pursu-
15	ant to paragraph (2), for plan years beginning on or
16	after January 1, 2026, a group health plan, with re-
17	spect to a participating provider, as defined in sec-
18	tion 9816(a)(3), shall have in place policies, subject
19	to paragraphs (4) and (5), that require any prescrip-
20	tion for a schedule II, III, IV, or V controlled sub-
21	stance (as defined by section 202 of the Controlled
22	Substances Act) covered by the plan that is trans-
23	mitted by such a participating provider for such a
24	participant or beneficiary be electronically trans-
25	mitted consistent with standards established under

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1	paragraph (3) of section 1860D-4(e) of the Social
2	Security Act, under an electronic prescription drug
3	program that meets requirements that are substan-
4	tially similar (as jointly determined by the Secretary,
5	the Secretary of Health and Human Services, and
6	the Secretary of Labor) to the requirements of para-
7	graph (2) of such section 1860D-4(e).
8	"(2) EXCEPTION FOR CERTAIN CIR-
9	CUMSTANCES.—The Secretary, the Secretary of
0	Health and Human Services, and the Secretary of
[1	Labor shall jointly, through rulemaking, specify cir-
12	cumstances and processes by which the requirement
13	under paragraph (1) may be waived, with respect to
14	a schedule II, III, IV, or V controlled substance that
15	is a prescription drug covered by a group health, in
16	cluding in the case of—
17	"(A) a prescription issued when the par-
18	ticipating provider and dispensing pharmacy are
19	the same entity;
20	"(B) a prescription issued that cannot be
21	transmitted electronically under the most re-
22	cently implemented version of the National
23	Council for Prescription Drug Programs
24	SCRIPT Standard;

11.

"(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;

1	"(E) a prescription issued by a partici
2	pating provider prescribing a drug under a re
3	search protocol;
4	"(F) a prescription issued by a partici
5	pating provider for a drug for which the Food
6	and Drug Administration requires a prescrip-
7	tion to contain elements that are not able to be
8	included in electronic prescribing, such as a
9	drug with risk evaluation and mitigation strate-
10	gies that include elements to assure safe use;
1	"(G) a prescription issued for an individual
2	who receives hospice care or for a resident of a
3	nursing facility (as defined in section 1919(a)
4	of the Social Security Act);
.5	"(H) a prescription issued under cir-
.6	cumstances in which electronic prescribing is
.7	not available due to temporary technological or
.8	electrical failure, as specified jointly by the Sec-
9	retary, the Secretary of Health and Human
20	Services, and the Secretary of Labor through
21	rulemaking; and
.2	"(I) a prescription issued by a partici-
:3	pating provider allowing for the dispensing of a
:4	non-patient specific prescription pursuant to a
5	standing order, approved protocol for drug ther-

apy, 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.

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 and who is
5	prescribed a schedule II, III, IV, or V con-
6	trolled substance that is a prescription drug
7	covered by the plan to designate a particular
8	dispenser to dispense a prescribed controlled
9	substance to the extent consistent with the re-
10	quirements under this subsection.
11	"(4) REGULATIONS ON POLICY REQUIRE-
12	MENTS.—The Secretary, the Secretary of Health
13	and Human Services, and the Secretary of Labor
14	shall promulgate regulations specifying requirements
15	for the policies established by group health plans
16	under paragraph (1). Such regulations shall include
17	requirements for—
18	"(A) a uniform process by which plans are
19	required to set the e-prescribing requirements;
20	"(B) a process by which plans are required
21	to grant waivers and exceptions to participating
22	providers pursuant to paragraph (2); and
23	"(C) a mechanism for plans to recognize
24	waivers issued to participating providers under

1	part D of title XVIII of the Public Health Serv
2	ice Act, pursuant to paragraph (2)(C).
3	"(5) Prohibitions.—The policies established
4	pursuant to paragraph (1) by a group health plan
.5	may not—
6	"(A) require dispensers of a schedule II
7	III, IV, or V controlled substance to confirm
8	that the prescription for the controlled sub-
9	stance was electronically issued by a partici-
10	pating provider in accordance with such poli-
11	cies, as described in paragraph (1);
12	"(B) require dispensers of such controlled
13	substances to submit information or data be-
14	youd what is otherwise required to process a
15	prescription drug claim in order to confirm a
16	participating provider's compliance with such
17	policies;
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; or
21	"(D) require a participating provider to
22	use a specific vendor for electronic prescribing
23	or a specific electronic prescribing product or
24	system.

1	"(6) ATTESTATION OF COMPLIANCE.—Begin
2	ning on January 1, 2026, each group health plar
3	shall annually submit to the Secretary, the Secretary
4	of Health and Human Services, and the Secretary of
5	Labor an attestation of compliance with the require
6	ments of this subsection.
7	"(7) Consultation requirement for rule-
8	MAKING.—In promulgating regulations to carry out
9	this subsection, the Secretary, the Secretary of
10	Health and Human Services, and the Secretary of
11	Labor shall jointly consult with dispensers of con-
12	trolled substances, State insurance regulators, and
13	health care practitioners.".
14	(d) UPDATE OF BIOMETRIC COMPONENT OF MULTI-
15	FACTOR AUTHENTICATION.—Not later than 1 year after
16	the date of enactment of this Act, the Attorney General
17	shall finalize a regulation updating the requirements for
18	the biometric component of multifactor authentication
19	with respect to electronic prescriptions of controlled sub-
20	stances, as required under section 2003(c) of the SUP-
21	PORT for Patients and Community Act (Public Law 115-
22	271).