115TH CONGRESS 2D SESSION H.R. 5807

To amend the Controlled Substances Act to allow for more flexibility with respect to medication-assisted treatment for opioid use disorders and to amend the Public Health Service Act to protect the confidentiality of substance use disorder patient records.

IN THE HOUSE OF REPRESENTATIVES

May 15, 2018

Mr. MULLIN (for himself and Mr. BLUMENAUER) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on 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

A BILL

- To amend the Controlled Substances Act to allow for more flexibility with respect to medication-assisted treatment for opioid use disorders and to amend the Public Health Service Act to protect the confidentiality of substance use disorder patient records.
 - 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 "Substance Use Dis5 order Coordination, Access, Recovery Enhancement Act of
6 2018" or the "SUD CARE Act".

SEC. 2. ALLOWING FOR MORE FLEXIBILITY WITH RESPECT TO MEDICATION-ASSISTED TREATMENT FOR OPIOID USE DISORDERS.

4 (a) CONFORMING APPLICABLE NUMBER.—Subclause
5 (II) of section 303(g)(2)(B)(iii) of the Controlled Sub6 stances Act (21 U.S.C. 823(g)(2)(B)(iii)) is amended to
7 read as follows:

8 "(II) The applicable number is—

9 "(aa) 100 if, not sooner than 1 year after 10 the date on which the practitioner submitted 11 the initial notification, the practitioner submits 12 a second notification to the Secretary of the 13 need and intent of the practitioner to treat up 14 to 100 patients;

15 "(bb) 100 if the practitioner holds addi16 tional credentialing, as defined in section 8.2 of
17 title 42, Code of Federal Regulations (or successor regulations); or

19 "(cc) 100 if the practitioner provides medi-20 cation-assisted treatment (MAT) using covered 21 medications (as defined in section 8.2 of title 22 42, Code of Federal Regulations (or successor 23 regulations)) in a qualified practice setting (as 24 described in section 8.615 of title 42, Code of 25 Regulations Federal (or successor regula-26 tions)).".

(b) EXTENDING THE TIME LIMITATION FOR NURSE
 PRACTITIONERS AND PHYSICIAN ASSISTANTS TO BE COME QUALIFYING PRACTITIONERS.—Section
 303(g)(2)(G)(iii)(II) of the Controlled Substances Act (21)
 U.S.C. 823(g)(2)(G)(iii)(II)) is amended by striking
 "2021" and inserting "2028".

7 SEC. 3. CONFIDENTIALITY AND DISCLOSURE OF RECORDS 8 RELATING TO SUBSTANCE USE DISORDER.

9 (a) CONFORMING CHANGES RELATING TO SUB-10 STANCE USE DISORDER.—Subsections (a) and (h) of sec-11 tion 543 of the Public Health Service Act (42 U.S.C. 12 290dd–2) are each amended by striking "substance 13 abuse" and inserting "substance use disorder".

(b) DISCLOSURES TO COVERED ENTITIES CON15 SISTENT WITH HIPAA.—Paragraph (2) of section 543(b)
16 of the Public Health Service Act (42 U.S.C. 290dd–2(b))
17 is amended by adding at the end the following:

18 "(D) To a covered entity or to a program 19 or activity described in subsection (a), for the 20 purposes of treatment, payment, and health 21 care operations, so long as such disclosure is 22 made in accordance with HIPAA privacy regu-23 lation. Any redisclosure of information so dis-24 closed may only be made in accordance with 25 this section.".

1	(c) DISCLOSURES OF DE-IDENTIFIED HEALTH IN-
2	FORMATION TO PUBLIC HEALTH AUTHORITIES.—Para-
3	graph (2) of section 543(b) of the Public Health Service
4	Act (42 U.S.C. 290dd–2(b)), as amended by subsection
5	(b), is further amended by adding at the end the following:
6	"(E) To a public health authority, so long
7	as such content does not include any individ-
8	ually identifiable health information and meets
9	the standards established in section 164.514 of
10	title 45, Code of Federal Regulations (or suc-
11	cessor regulations) for creating de-identified in-
12	formation.".
10	(d) DEFINITIONS.—Subsection (b) of section 543 of
13	(d) DEFINITIONS.—Subsection (b) of section 343 of
13 14	the Public Health Service Act (42 U.S.C. 290dd–2) is
14	the Public Health Service Act (42 U.S.C. 290dd–2) is
14 15	the Public Health Service Act (42 U.S.C. 290dd–2) is amended by adding at the end the following:
14 15 16	the Public Health Service Act (42 U.S.C. 290dd–2) is amended by adding at the end the following: "(3) DEFINITIONS.—For purposes of this sub-
14 15 16 17	the Public Health Service Act (42 U.S.C. 290dd–2) is amended by adding at the end the following: "(3) DEFINITIONS.—For purposes of this sub- section:
14 15 16 17 18	the Public Health Service Act (42 U.S.C. 290dd–2) is amended by adding at the end the following:
14 15 16 17 18 19	<pre>the Public Health Service Act (42 U.S.C. 290dd-2) is amended by adding at the end the following:</pre>
 14 15 16 17 18 19 20 	the Public Health Service Act (42 U.S.C. 290dd–2) is amended by adding at the end the following: "(3) DEFINITIONS.—For purposes of this sub- section: "(A) COVERED ENTITY.—The term 'cov- ered entity' has the meaning given such term for purposes of HIPAA privacy regulation.
 14 15 16 17 18 19 20 21 	the Public Health Service Act (42 U.S.C. 290dd–2) is amended by adding at the end the following: "(3) DEFINITIONS.—For purposes of this sub- section: "(A) COVERED ENTITY.—The term 'cov- ered entity' has the meaning given such term for purposes of HIPAA privacy regulation. "(B) HEALTH CARE OPERATIONS.—The

1	"(C) HIPAA PRIVACY REGULATION.—The
2	term 'HIPAA privacy regulation' has the mean-
3	ing given such term under section $1180(b)(3)$ of
4	the Social Security Act.
5	"(D) Individually identifiable
6	HEALTH INFORMATION.—The term 'individually
7	identifiable health information' has the meaning
8	given such term for purposes of HIPAA privacy
9	regulation.
10	"(E) PAYMENT.—The term 'payment' has
11	the meaning given such term for purposes of
12	HIPAA privacy regulation.
13	"(F) PUBLIC HEALTH AUTHORITY.—The
14	term 'public health authority' has the meaning
15	given such term for purposes of HIPAA privacy
16	regulation.
17	"(G) TREATMENT.—The term 'treatment'
18	has the meaning given such term for purposes
19	of HIPAA privacy regulation.".
20	(e) Use of Records in Criminal, Civil, or Ad-
21	MINISTRATIVE INVESTIGATIONS, ACTIONS, OR PRO-
22	CEEDINGS.—Subsection (c) of section 543 of the Public
23	Health Service Act (42 U.S.C. 290dd-2) is amended to
24	read as follows:

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"(c) USE OF RECORDS IN CRIMINAL, CIVIL, OR AD MINISTRATIVE CONTEXTS.—Except as otherwise author ized by a court order under subsection (b)(2)(C) or by the
 consent of the patient, a record referred to in subsection
 (a) may not—

6 "(1) be entered into evidence in any criminal
7 prosecution or civil action before a Federal or State
8 court;

9 "(2) form part of the record for decision or oth10 erwise be taken into account in any proceeding be11 fore a Federal agency;

"(3) be used by any Federal, State, or local
agency for a law enforcement purpose or to conduct
any law enforcement investigation of a patient; or

"(4) be used in any application for a warrant.".
(f) PENALTIES.—Subsection (f) of section 543 of the
Public Health Service Act (42 U.S.C. 290dd–2) is amended to read as follows:

"(f) PENALTIES.—The provisions of section 1176 of
the Social Security Act shall apply to a violation of this
section to the extent and in the same manner as such provisions apply to a violation of part C of title XI of such
Act. In applying the previous sentence—

24 "(1) the reference to 'this subsection' in sub-25 section (a)(2) of such section 1176 shall be treated

1	as a reference to 'this subsection (including as ap-
2	plied pursuant to section 543(f) of the Public Health
3	Service Act)'; and
4	"(2) in subsection (b) of such section 1176 —
5	"(A) each reference to 'a penalty imposed
6	under subsection (a)' shall be treated as a ref-
7	erence to 'a penalty imposed under subsection
8	(a) (including as applied pursuant to section
9	543(f) of the Public Health Service Act)'; and
10	"(B) each reference to 'no damages ob-
11	tained under subsection (d)' shall be treated as
12	a reference to 'no damages obtained under sub-
13	section (d) (including as applied pursuant to
14	section 543(f) of the Public Health Service
15	Act)'.''.
16	(g) ANTIDISCRIMINATION.—Section 543 of the Public
17	Health Service Act (42 U.S.C. 290dd–2) is amended by
18	adding at the end the following:
19	"(i) ANTIDISCRIMINATION.—
20	"(1) IN GENERAL.—No entity shall discrimi-
21	nate against an individual on the basis of informa-
22	tion received by such entity pursuant to a disclosure
23	made under subsection (b) in—
24	"(A) admission or treatment for health
25	care;

1	"(B) hiring or terms of employment;
2	"(C) the sale or rental of housing; or
3	"(D) access to Federal, State, or local
4	courts.
5	"(2) Recipients of federal funds.—No re-
6	cipient of Federal funds shall discriminate against
7	an individual on the basis of information received by
8	such recipient pursuant to a disclosure made under
9	subsection (b) in affording access to the services
10	provided with such funds.".
11	(h) NOTIFICATION IN CASE OF BREACH.—Section
12	543 of the Public Health Service Act (42 U.S.C. 290dd-
13	2), as amended by subsection (g), is further amended by
13 14	2), as amended by subsection (g), is further amended by adding at the end the following:
14	adding at the end the following:
14 15	adding at the end the following: "(j) NOTIFICATION IN CASE OF BREACH.—
14 15 16	adding at the end the following: "(j) Notification in Case of Breach.— "(1) Application of hitech notification
14 15 16 17	adding at the end the following: "(j) NOTIFICATION IN CASE OF BREACH.— "(1) APPLICATION OF HITECH NOTIFICATION OF BREACH PROVISIONS.—The provisions of section
14 15 16 17 18	adding at the end the following: "(j) NOTIFICATION IN CASE OF BREACH.— "(1) APPLICATION OF HITECH NOTIFICATION OF BREACH PROVISIONS.—The provisions of section 13402 of the HITECH Act (42 U.S.C. 17932) shall
14 15 16 17 18 19	adding at the end the following: "(j) NOTIFICATION IN CASE OF BREACH.— "(1) APPLICATION OF HITECH NOTIFICATION OF BREACH PROVISIONS.—The provisions of section 13402 of the HITECH Act (42 U.S.C. 17932) shall apply to a program or activity described in sub-
 14 15 16 17 18 19 20 	adding at the end the following: "(j) NOTIFICATION IN CASE OF BREACH.— "(1) APPLICATION OF HITECH NOTIFICATION OF BREACH PROVISIONS.—The provisions of section 13402 of the HITECH Act (42 U.S.C. 17932) shall apply to a program or activity described in sub- section (a), in case of a breach of records described
 14 15 16 17 18 19 20 21 	adding at the end the following: "(j) NOTIFICATION IN CASE OF BREACH.— "(1) APPLICATION OF HITECH NOTIFICATION OF BREACH PROVISIONS.—The provisions of section 13402 of the HITECH Act (42 U.S.C. 17932) shall apply to a program or activity described in sub- section (a), in case of a breach of records described in subsection (a), to the same extent and in the

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"(2) DEFINITIONS.—In this subsection, the
 terms 'covered entity' and 'unsecured protected
 health information' have the meanings given to such
 terms for purposes of such section 13402.".

(i) SENSE OF CONGRESS.—It is the sense of the Congress that any person treating a patient through a program or activity with respect to which the confidentiality
requirements of section 543 of the Public Health Service
Act (42 U.S.C. 290dd–2) apply should access the applicable State-based prescription drug monitoring program as
a precaution against substance use disorder.

12 (j) REGULATIONS.—The Secretary of Health and 13 Human Services, in consultation with appropriate Federal agencies, shall make such revisions to regulations as may 14 15 be necessary for implementing and enforcing the amendments made by this section, such that such amendments 16 17 shall apply with respect to uses and disclosures of information occurring on or after the date that is 12 months after 18 the date of enactment of this Act. 19

20 (k) DEVELOPMENT AND DISSEMINATION OF MODEL
21 TRAINING PROGRAMS FOR SUBSTANCE USE DISORDER
22 PATIENT RECORDS.—

(1) INITIAL PROGRAMS AND MATERIALS.—Not
later than 1 year after the date of the enactment of
this Act, the Secretary of Health and Human Serv-

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ices (referred to in this subsection as the "Secretary"), in consultation with appropriate experts,
shall identify the following model programs and materials (or if no such programs or materials exist,
recognize private or public entities to develop and
disseminate such programs and materials):

7 (A) Model programs and materials for 8 training health care providers (including physi-9 cians, emergency medical personnel, psychia-10 trists. psychologists, counselors, therapists. 11 nurse practitioners, physician assistants, behav-12 ioral health facilities and clinics, care managers, 13 and hospitals, including individuals such as gen-14 eral counsels or regulatory compliance staff who 15 are responsible for establishing provider privacy 16 policies) concerning the permitted uses and dis-17 closures, consistent with the standards and reg-18 ulations governing the privacy and security of 19 substance use disorder patient records promul-20 gated by the Secretary under section 543 of the 21 Public Health Service Act (42 U.S.C. 290dd-22 2), as amended by this section, for the con-23 fidentiality of patient records.

24 (B) Model programs and materials for25 training patients and their families regarding

1	their rights to protect and obtain information
2	under the standards and regulations described
3	in subparagraph (A).
4	(2) REQUIREMENTS.—The model programs and
5	materials described in subparagraphs (A) and (B) of
6	paragraph (1) shall address circumstances under
7	which disclosure of substance use disorder patient
8	records is needed to—
9	(A) facilitate communication between sub-
10	stance use disorder treatment providers and
11	other health care providers to promote and pro-
12	vide the best possible integrated care;
13	(B) avoid inappropriate prescribing that
14	can lead to dangerous drug interactions, over-
15	dose, or relapse; and
16	(C) notify and involve families and care-
17	givers when individuals experience an overdose.
18	(3) PERIODIC UPDATES.—The Secretary
19	shall—
20	(A) periodically review and update the
21	model programs and materials identified or de-
22	veloped under paragraph (1); and
23	(B) disseminate such updated programs
24	and materials to the individuals described in
25	paragraph (1)(A).

(4) INPUT OF CERTAIN ENTITIES.—In identi fying, reviewing, or updating the model programs
 and materials under this subsection, the Secretary
 shall solicit the input of relevant stakeholders.

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