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(Original Signature of Member)

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

Mr. MULLIN introduced the following bill; which was referred to the Committee on _____

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 Dis-
5 order Coordination, Access, Recovery Enhancement Act of
6 2018” or the “SUD CARE Act”.

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

4 (a) CONFORMING APPLICABLE NUMBER.—Subclause
5 (II) of section 303(g)(2)(B)(iii) of the Controlled Sub-
6 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 addi-
16 tional credentialing, as defined in section 8.2 of
17 title 42, Code of Federal Regulations (or suc-
18 cessor 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 Federal Regulations (or successor regula-
26 tions)).”.

1 (b) EXTENDING THE TIME LIMITATION FOR NURSE
2 PRACTITIONERS AND PHYSICIAN ASSISTANTS TO BECOME
3 QUALIFYING PRACTITIONERS.—Section
4 303(g)(2)(G)(iii)(II) of the Controlled Substances Act (21
5 U.S.C. 823(g)(2)(G)(iii)(II)) is amended by striking
6 “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”.

14 (b) DISCLOSURES TO COVERED ENTITIES CON-
15 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.”.

13 (d) DEFINITIONS.—Subsection (b) of section 543 of
14 the Public Health Service Act (42 U.S.C. 290dd–2) is
15 amended by adding at the end the following:

16 “(3) DEFINITIONS.—For purposes of this sub-
17 section:

18 “(A) COVERED ENTITY.—The term ‘cov-
19 ered entity’ has the meaning given such term
20 for purposes of HIPAA privacy regulation.

21 “(B) HEALTH CARE OPERATIONS.—The
22 term ‘health care operations’ has the meaning
23 given such term for purposes of HIPAA privacy
24 regulation.

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:

1 “(c) USE OF RECORDS IN CRIMINAL, CIVIL, OR AD-
2 MINISTRATIVE CONTEXTS.—Except as otherwise author-
3 ized by a court order under subsection (b)(2)(C) or by the
4 consent of the patient, a record referred to in subsection
5 (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 oth-
10 erwise be taken into account in any proceeding be-
11 fore a Federal agency;

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

15 “(4) be used in any application for a warrant.”.

16 (f) PENALTIES.—Subsection (f) of section 543 of the
17 Public Health Service Act (42 U.S.C. 290dd–2) is amend-
18 ed to read as follows:

19 “(f) PENALTIES.—The provisions of section 1176 of
20 the Social Security Act shall apply to a violation of this
21 section to the extent and in the same manner as such pro-
22 visions apply to a violation of part C of title XI of such
23 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
14 adding at the end the following:

15 “(j) NOTIFICATION IN CASE OF BREACH.—

16 “(1) APPLICATION OF HITECH NOTIFICATION
17 OF BREACH PROVISIONS.—The provisions of section
18 13402 of the HITECH Act (42 U.S.C. 17932) shall
19 apply to a program or activity described in sub-
20 section (a), in case of a breach of records described
21 in subsection (a), to the same extent and in the
22 same manner as such provisions apply to a covered
23 entity in the case of a breach of unsecured protected
24 health information.

1 “(2) DEFINITIONS.—In this subsection, the
2 terms ‘covered entity’ and ‘unsecured protected
3 health information’ have the meanings given to such
4 terms for purposes of such section 13402.”.

5 (i) SENSE OF CONGRESS.—It is the sense of the Con-
6 gress that any person treating a patient through a pro-
7 gram or activity with respect to which the confidentiality
8 requirements of section 543 of the Public Health Service
9 Act (42 U.S.C. 290dd–2) apply should access the applica-
10 ble State-based prescription drug monitoring program as
11 a precaution against substance use disorder.

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

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

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

1 ices (referred to in this subsection as the “Sec-
2 retary”), in consultation with appropriate experts,
3 shall identify the following model programs and ma-
4 terials (or if no such programs or materials exist,
5 recognize private or public entities to develop and
6 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 for
25 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).

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