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 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 |
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| 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 |
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| 2 | PRACTITIONERS AND PHYSICIAN ASSISTANTS TO BE- |
| 3 | COME 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- |
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| 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 |
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| 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 (e) 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-
- fore a Federal agency;
- 12 "(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.".
- 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-
- section (a)(2) of such section 1176 shall be treated

| 1 | as a reference to 'this subsection (including as ap- |
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| 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; |
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| 1 | "(B) hiring or terms of employment; |
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| 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
- later than 1 year after the date of the enactment of
- 25 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):

(A) Model programs and materials for training health care providers (including physicians, emergency medical personnel, psychiatrists. psychologists, counselors, therapists. nurse practitioners, physician assistants, behavioral health facilities and clinics, care managers, and hospitals, including individuals such as general counsels or regulatory compliance staff who are responsible for establishing provider privacy policies) concerning the permitted uses and disclosures, consistent with the standards and regulations governing the privacy and security of substance use disorder patient records promulgated by the Secretary under section 543 of the Public Health Service Act (42 U.S.C. 290dd– 2), as amended by this section, for the confidentiality of patient records.

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

| 1 | their rights to protect and obtain information |
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| 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.

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