

**AMENDMENT IN THE NATURE OF A SUBSTITUTE  
TO H.R. 3545  
OFFERED BY MR. MULLIN OF OKLAHOMA**

Strike all after the enacting clause and insert the following:

**1 SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Overdose Prevention  
3 and Patient Safety Act”.

**4 SEC. 2. CONFIDENTIALITY AND DISCLOSURE OF RECORDS**

**5 RELATING TO SUBSTANCE USE DISORDER.**

**6 (a) SUBSTANCE USE DISORDER DEFINED.—**

7 (1) DEFINITION.—Subsection (a) of section 543  
8 of the Public Health Service Act (42 U.S.C. 290dd–  
9 2) is amended by adding at the end the following:  
10 “For purposes of this section, the term ‘substance  
11 use disorder’ means a cluster of cognitive, behav-  
12 ioral, and physiological symptoms indicating that an  
13 individual continues using alcohol or a controlled  
14 substance despite significant substance-related prob-  
15 lems (such as impaired control, social impairment,  
16 risky use, and pharmacological tolerance and with-  
17 drawal).”.

1           (2) CONFORMING CHANGES.—Subsections (a)  
2           and (h) of section 543 of the Public Health Service  
3           Act (42 U.S.C. 290dd–2) are each amended by  
4           striking “substance abuse” and inserting “substance  
5           use disorder”.

6           (b) DISCLOSURES BY COVERED ENTITIES CON-  
7           SISTENT WITH HIPAA.—Paragraph (2) of section 543(b)  
8           of the Public Health Service Act (42 U.S.C. 290dd–2(b))  
9           is amended by adding at the end the following:

10                   “(D) To a covered entity by a covered enti-  
11                   ty, or to a covered entity by a program or activ-  
12                   ity described in subsection (a), for purposes of  
13                   treatment, payment, and health care operations  
14                   under HIPAA privacy regulation, so long as  
15                   such disclosure is made in accordance with such  
16                   regulation.”.

17           (c) DISCLOSURES OF DE-IDENTIFIED HEALTH IN-  
18           FORMATION TO PUBLIC HEALTH AUTHORITIES.—Para-  
19           graph (2) of section 543(b) of the Public Health Service  
20           Act (42 U.S.C. 290dd–2(b)), as amended by subsection  
21           (b), is further amended by adding at the end the following:

22                   “(E) To a public health authority, so long  
23                   as such content does not include any individ-  
24                   ually identifiable health information and meets  
25                   the standards established in section 164.514 of

1 title 45, Code of Federal Regulations (or suc-  
2 cessor regulations) for creating de-identified in-  
3 formation.”.

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

7 “(3) DEFINITIONS.—For purposes of this sub-  
8 section:

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

12 “(B) HEALTH CARE OPERATIONS.—The  
13 term ‘health care operations’ has the meaning  
14 given such term for purposes of HIPAA privacy  
15 regulation.

16 “(C) HIPAA PRIVACY REGULATION.—The  
17 term ‘HIPAA privacy regulation’ has the mean-  
18 ing given such term under section 1180(b)(3) of  
19 the Social Security Act.

20 “(D) INDIVIDUALLY IDENTIFIABLE  
21 HEALTH INFORMATION.—The term ‘individually  
22 identifiable health information’ has the meaning  
23 given such term for purposes of HIPAA privacy  
24 regulation.

1           “(E) PAYMENT.—The term ‘payment’ has  
2           the meaning given such term for purposes of  
3           HIPAA privacy regulation.

4           “(F) TREATMENT.—The term ‘treatment’  
5           has the meaning given such term for purposes  
6           of HIPAA privacy regulation.”.

7           (e) USE OF RECORDS IN CRIMINAL, CIVIL, OR AD-  
8           MINISTRATIVE INVESTIGATIONS, ACTIONS, OR PRO-  
9           CEEDINGS.—Subsection (c) of section 543 of the Public  
10          Health Service Act (42 U.S.C. 290dd–2) is amended to  
11          read as follows:

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

17                 “(1) be entered into evidence in any criminal  
18                 prosecution or civil action before a Federal or State  
19                 court;

20                 “(2) form part of the record for decision or oth-  
21                 erwise be taken into account in any proceeding be-  
22                 fore a Federal agency;

23                 “(3) be used to conduct any investigation of a  
24                 plaintiff; or

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

1 (f) PENALTIES.—

2 (1) IN GENERAL.—Subsection (f) of section 543  
3 of the Public Health Service Act (42 U.S.C. 290dd–  
4 2) is amended to read as follows:

5 “(f) PENALTIES.—The provisions of section 1176 of  
6 the Social Security Act shall apply to a violation of this  
7 section to the extent and in the same manner as such pro-  
8 visions apply to a violation of part C of title XI of such  
9 Act.”.

10 (2) APPLICABILITY.—The amendment made by  
11 paragraph (1) applies only with respect to violations  
12 of section 543 of the Public Health Service Act (42  
13 U.S.C. 290dd–2) occurring on or after the date of  
14 the enactment of this Act.

15 (g) ANTIDISCRIMINATION.—Section 543 of the Public  
16 Health Service Act (42 U.S.C. 290dd–2) is amended by  
17 adding at the end the following:

18 “(i) ANTIDISCRIMINATION.—

19 “(1) PROHIBITIONS.—

20 “(A) IN GENERAL.—No entity shall dis-  
21 criminate against an individual on the basis of  
22 information received by such entity pursuant to  
23 a disclosure made under subsection (b) in—

24 “(i) admission or treatment for health  
25 care;

1                   “(ii) hiring or terms of employment;  
2                   “(iii) the sale or rental of housing; or  
3                   “(iv) access to Federal, State, or local  
4                   courts.

5                   “(B) RECIPIENTS OF FEDERAL FUNDS.—  
6                   No recipient of Federal funds shall discriminate  
7                   against an individual on the basis of informa-  
8                   tion received by such recipient pursuant to a  
9                   disclosure made under subsection (b) in afford-  
10                  ing access to the services provided with such  
11                  funds.

12                  “(2) REGULATIONS.—The Secretary, in con-  
13                  sultation with appropriate Federal agencies, shall  
14                  issue regulations for implementing and enforcing  
15                  paragraph (1). Such regulations shall include proce-  
16                  dures for determining (after opportunity for a hear-  
17                  ing if requested) if a violation of such paragraph has  
18                  occurred, notification of failure to comply with such  
19                  paragraph, and opportunity for a violator to comply  
20                  with such paragraph.”.

21                  (h) NOTIFICATION IN CASE OF BREACH.—Section  
22                  543 of the Public Health Service Act (42 U.S.C. 290dd-  
23                  2), as amended by subsection (g), is further amended by  
24                  adding at the end the following:

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

1           “(1) APPLICATION OF HITECH NOTIFICATION  
2           OF BREACH PROVISIONS.—The provisions of section  
3           13402 of the HITECH Act (42 U.S.C. 17932) shall  
4           apply to a program or activity described in sub-  
5           section (a), in case of a breach of records described  
6           in subsection (a), to the same extent and in the  
7           same manner as such provisions apply to a covered  
8           entity in the case of a breach of unsecured protected  
9           health information.

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

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

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

24           (1) INITIAL PROGRAMS AND MATERIALS.—Not  
25           later than 1 year after the date of the enactment of

1       this Act, the Secretary of Health and Human Serv-  
2       ices (referred to in this subsection as the “Sec-  
3       retary”), in consultation with appropriate experts,  
4       shall identify the following model programs and ma-  
5       terials (or if no such programs or materials exist,  
6       recognize private or public entities to develop and  
7       disseminate such programs and materials):

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



1 (B) Model programs and materials for  
2 training patients and their families regarding  
3 their rights to protect and obtain information  
4 under the standards and regulations described  
5 in subparagraph (A).

6 (2) REQUIREMENTS.—The model programs and  
7 materials described in subparagraphs (A) and (B) of  
8 paragraph (1) shall address circumstances under  
9 which disclosure of substance use disorder patient  
10 records is needed to—

11 (A) facilitate communication between sub-  
12 stance use disorder treatment providers and  
13 other health care providers to promote and pro-  
14 vide the best possible integrated care;

15 (B) avoid inappropriate prescribing that  
16 can lead to dangerous drug interactions, over-  
17 dose, or relapse; and

18 (C) notify and involve families and care-  
19 givers when individuals experience an overdose.

20 (3) PERIODIC UPDATES.—The Secretary  
21 shall—

22 (A) periodically review and update the  
23 model programs and materials identified or de-  
24 veloped under paragraph (1); and

1                   (B) disseminate such updated programs  
2                   and materials to the individuals described in  
3                   paragraph (1)(A).

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

