

AMENDMENT NO. \_\_\_\_\_ Calendar No. \_\_\_\_\_

Purpose: In the nature of a substitute.

**IN THE SENATE OF THE UNITED STATES—114th Cong., 2d Sess.**

**S. 1455**

To provide access to medication-assisted therapy, and for other purposes.

Referred to the Committee on \_\_\_\_\_ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended to be proposed by Mr. ALEXANDER

Viz:

1 Strike all after the enacting clause and insert the fol-

2 lowing:

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Recovery Enhancement

5 for Addiction Treatment Act” or the “TREAT Act”.

6 **SEC. 2. EXPANSION OF PATIENT LIMITS UNDER WAIVER.**

7 Section 303(g)(2)(B) of the Controlled Substances

8 Act (21 U.S.C. 823(g)(2)(B)) is amended—

9 (1) in clause (i), by striking “physician” and in-

10 sserting “practitioner”;

11 (2) in clause (iii)—

1 (A) by striking “The total number” and  
2 inserting “(I) The total number”;

3 (B) by striking “30” and inserting “100”;

4 (C) by striking “, unless, not sooner” and  
5 all that follows through “of this subparagraph”;  
6 and

7 (D) by adding at the end the following:

8 “(II) If a patient is referred by a quali-  
9 fying practitioner that is a physician to another  
10 qualifying practitioner that is a physician that  
11 provides short-term services (such as induction  
12 or titration), the patient shall only be included  
13 in the total number of such patients of the  
14 qualifying physician that makes the referral.

15 “(III) In this clause, the term ‘the total  
16 number of such patients’ shall not include a pa-  
17 tient to whom a qualifying practitioner that is  
18 a physician meeting the requirements described  
19 in clause (iv)(I), or an authorized agent of such  
20 qualifying practitioner that is a physician, di-  
21 rectly administers such drugs or combination  
22 drugs.”; and

23 (4) by adding at the end the following:

24 “(iv) Not earlier than 1 year after the date on  
25 which a qualifying practitioner that is a physician

1       obtained an initial waiver pursuant to clause (iii),  
2       such qualifying practitioner may submit a second  
3       notification to the Secretary of the need and intent  
4       of such qualifying practitioner to treat 500 patients,  
5       if such qualifying practitioner—

6               “(I)(aa) satisfies the requirements of item (aa),  
7       (bb), (cc), or (dd) of subparagraph (G)(ii)(I); and

8               “(bb) agrees to fully participate in the Prescrip-  
9       tion Drug Monitoring Program of the State in which  
10       the qualifying practitioner is licensed, pursuant to  
11       applicable State guidelines; or

12               “(II)(aa) satisfies the requirements of item (ee),  
13       (ff), or (gg) of subparagraph (G)(ii)(I);

14               “(bb) agrees to fully participate in the Prescrip-  
15       tion Drug Monitoring Program of the State in which  
16       the qualifying practitioner is licensed, pursuant to  
17       applicable State guidelines; and

18               “(cc) has completed not less than 24 hours of  
19       training (through classroom situations, seminars at  
20       professional society meetings, electronic communica-  
21       tions, or otherwise) with respect to the treatment  
22       and management of opiate-dependent patients for  
23       substance use disorders provided by the American  
24       Society of Addiction Medicine, the American Acad-  
25       emy of Addiction Psychiatry, the American Medical

1 Association, the American Osteopathic Association,  
2 the American Psychiatric Association, or any other  
3 organization that the Secretary determines is appro-  
4 priate for purposes of this subclause.

5 “(v) The qualifying practitioner shall maintain  
6 records relating to the dispensing of drugs or com-  
7 binations of drugs to treat patients under this para-  
8 graph, including—

9 “(I) whether the qualifying practitioner  
10 provides counseling services on-site, and how  
11 frequently patients are using such services;

12 “(II) whether the qualifying practitioner  
13 referred patients for counseling services off-site,  
14 the percentage of the patients of the qualifying  
15 practitioner using such services, and how fre-  
16 quently the patients are using such services;  
17 and

18 “(III) the frequency with which patients  
19 being treated under this paragraph terminate  
20 the treatment against medical advice.”.

21 **SEC. 3. DEFINITIONS.**

22 Section 303(g)(2)(G) of the Controlled Substances  
23 Act (21 U.S.C. 823(g)(2)(G)) is amended by striking  
24 clause (ii) and inserting the following:

1                   “(ii) The term ‘qualifying practitioner’  
2 means the following:

3                   “(I) A physician who is licensed under  
4 State law and who meets 1 or more of the  
5 following conditions:

6                   “(aa) The physician holds a  
7 board certification in addiction psychi-  
8 atry or addiction medicine from the  
9 American Board of Medical Special-  
10 ties.

11                   “(bb) The physician holds an ad-  
12 diction certification from the Amer-  
13 ican Society of Addiction Medicine or  
14 the American Board of Addiction  
15 Medicine.

16                   “(cc) The physician holds a  
17 board certification in addiction medi-  
18 cine from the American Osteopathic  
19 Association.

20                   “(dd) The physician holds a  
21 board certification from the American  
22 Board of Addiction Medicine.

23                   “(ee) The physician has com-  
24 pleted not less than 8 hours of train-  
25 ing (through classroom situations,

1 seminars at professional society meet-  
2 ings, electronic communications, or  
3 otherwise) with respect to the treat-  
4 ment and management of opiate-de-  
5 pendent patients for substance use  
6 disorders provided by the American  
7 Society of Addiction Medicine, the  
8 American Academy of Addiction Psy-  
9 chiatry, the American Medical Asso-  
10 ciation, the American Osteopathic As-  
11 sociation, the American Psychiatric  
12 Association, or any other organization  
13 that the Secretary determines is ap-  
14 propriate for purposes of this sub-  
15 clause, after notice and the oppor-  
16 tunity for comment.

17 “(ff) The physician has partici-  
18 pated as an investigator in 1 or more  
19 clinical trials leading to the approval  
20 of a narcotic drug in schedule III, IV,  
21 or V for maintenance or detoxification  
22 treatment, as demonstrated by a  
23 statement submitted to the Secretary  
24 by this sponsor of such approved  
25 drug.

1                   “(gg) The physician has such  
2                   other training or experience as the  
3                   Secretary determines will demonstrate  
4                   the ability of the physician to treat  
5                   and manage opiate dependent pa-  
6                   tients.

7                   “(II) A nurse practitioner or physi-  
8                   cian assistant who is licensed under State  
9                   law and meets all of the following condi-  
10                  tions:

11                   “(aa) The nurse practitioner or  
12                   physician assistant is licensed under  
13                   State law to prescribe schedule III,  
14                   IV, or V medications.

15                   “(bb) The nurse practitioner or  
16                   physician assistant has completed not  
17                   fewer than 24 hours of training  
18                   (through classroom situations, semi-  
19                   nars at professional society meetings,  
20                   electronic communications, or other-  
21                   wise) with respect to the treatment  
22                   and management of opiate-dependent  
23                   patients for substance use disorders  
24                   provided by the American Society of  
25                   Addiction Medicine, the American

1 Academy of Addiction Psychiatry, the  
2 American Medical Association, the  
3 American Osteopathic Association, the  
4 American Psychiatric Association, the  
5 American Association of Nurse Practi-  
6 tioners, the American Academy of  
7 Physician Assistants, or any other or-  
8 ganization that the Secretary deter-  
9 mines is appropriate for purposes of  
10 this subclause, after notice and oppor-  
11 tunity for comment.

12 “(cc) If required by State law,  
13 the nurse practitioner or physician as-  
14 sistant prescribes opioid addiction  
15 therapy in collaboration with or under  
16 the supervision of, as applicable, a  
17 physician.”.

18 **SEC. 4. STATE FLEXIBILITY.**

19 Section 303(g)(2) of the Controlled Substances Act  
20 (21 U.S.C. 823(g)(2)) is amended by striking subpara-  
21 graphs (I) and (J), and inserting the following:

22 “(I) Notwithstanding section 708, nothing in  
23 this paragraph shall be construed to preempt any  
24 State law that—



1           “(i) permits a qualifying practitioner to  
2           dispense narcotic drugs in schedule III, IV, or  
3           V, or combinations of such drugs, for mainte-  
4           nance or detoxification treatment in accordance  
5           with this paragraph to a total number of pa-  
6           tients that is more than 30 or less than the  
7           total number applicable to the qualifying practi-  
8           tioner under clause (iv) of subparagraph (B) if  
9           a State enacts a law modifying such total num-  
10          ber and the Attorney General is notified by the  
11          State of such modification; or

12          “(ii) requires a qualifying practitioner to  
13          comply with additional requirements relating to  
14          the dispensing of narcotic drugs in schedule III,  
15          IV, or V, or combinations of such drugs, includ-  
16          ing requirements relating to the practice setting  
17          in which the qualifying practitioner practices  
18          and education, training, and reporting require-  
19          ments.”.

20 **SEC. 5. UPDATE REGULATIONS.**

21          Not later than 1 year after the date of enactment  
22          of this Act, the Attorney General shall update regulations  
23          regarding waived practitioners (as amended by this Act)  
24          to include nurse practitioners and physician assistants to  
25          ensure the quality of patient care and prevent diversion.

1 **SEC. 6. EVALUATIONS.**

2 (a) DEFINITION.—In this section, the term “appro-  
3 priate committees of Congress” means—

4 (1) the Committee on Health, Education,  
5 Labor, and Pensions and the Committee on the Ju-  
6 diciary of the Senate; and

7 (2) the Committee on Energy and Commerce  
8 and the Committee on the Judiciary of the House of  
9 Representatives.

10 (b) HHS.—Not later than 2 years after the date of  
11 enactment of this Act, the Secretary of Health and  
12 Human Services, in coordination with the Attorney Gen-  
13 eral, shall submit to the appropriate committees of Con-  
14 gress a report on the effect on the amendments made by  
15 this title on the availability of evidence-based treatment  
16 and any increased risk in diversion, including the impact  
17 of nurse practitioners and physician assistants as quali-  
18 fying practitioners.

19 (c) GAO.—

20 (1) IN GENERAL.—Four years after the date on  
21 which the first notification under clause (iv) of sec-  
22 tion 303(g)(2)(B) of the Controlled Substances Act  
23 (21 U.S.C. 823(g)(2)(B)), as added by this Act, is  
24 received by the Secretary of Health and Human  
25 Services, the Comptroller General of the United  
26 States shall initiate an evaluation of the effective-

1       ness of the amendments made by this Act, which  
2       shall include an evaluation of—

3               (A) any changes in the availability and use  
4               of medication-assisted treatment for opioid ad-  
5               diction;

6               (B) the quality of medication-assisted  
7               treatment programs;

8               (C) the integration of medication-assisted  
9               treatment with routine healthcare services;

10              (D) diversion of opioid addiction treatment  
11              medication;

12              (E) changes in State or local policies and  
13              legislation relating to opioid addiction treat-  
14              ment;

15              (F) the use of nurse practitioners and phy-  
16              sician assistants who prescribe opioid addiction  
17              medication;

18              (G) the use of Prescription Drug Moni-  
19              toring Programs by waived practitioners to  
20              maximize safety of patient care and prevent di-  
21              version of opioid addiction medication;

22              (H) the findings of Drug Enforcement  
23              Agency inspections of waived practitioners, in-  
24              cluding the frequency with which the Drug En-

1           forcement Agency finds no documentation of  
2           access to behavioral health services; and

3                   (I) the effectiveness of cross-agency col-  
4           laboration between Department of Health and  
5           Human Services and the Drug Enforcement  
6           Agency for expanding effective opioid addiction  
7           treatment.

8                   (2) REPORT.—The Comptroller General shall  
9           submit to the appropriate committees of Congress a  
10          report regarding the evaluation conducted under  
11          paragraph (1).