

114TH CONGRESS
2D SESSION

H. R. 4981

IN THE SENATE OF THE UNITED STATES

MAY 12, 2016

Received; read twice and referred to the Committee on Health, Education,
Labor, and Pensions

AN ACT

To amend the Controlled Substances Act to improve access
to opioid use disorder treatment.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Opioid Use Disorder
3 Treatment Expansion and Modernization Act”.

4 **SEC. 2. FINDING.**

5 The Congress finds that opioid use disorder has be-
6 come a public health epidemic that must be addressed by
7 increasing awareness and access to all treatment options
8 for opioid use disorder, overdose reversal, and relapse pre-
9 vention.

10 **SEC. 3. OPIOID USE DISORDER TREATMENT MODERNIZA-**
11 **TION.**

12 (a) IN GENERAL.—Section 303(g)(2) of the Con-
13 trolled Substances Act (21 U.S.C. 823(g)(2)) is amend-
14 ed—

15 (1) in subparagraph (B), by striking clauses (i),
16 (ii), and (iii) and inserting the following:

17 “(i) The practitioner is a qualifying practitioner
18 (as defined in subparagraph (G)).

19 “(ii) With respect to patients to whom the prac-
20 titioner will provide such drugs or combinations of
21 drugs, the practitioner has the capacity to provide
22 directly, by referral, or in such other manner as de-
23 termined by the Secretary—

24 “(I) all schedule III, IV, and V drugs, as
25 well as unscheduled medications approved by
26 the Food and Drug Administration, for the

1 treatment of opioid use disorder, including such
2 drugs and medications for maintenance, detoxi-
3 fication, overdose reversal, and relapse preven-
4 tion, as available; and

5 “(II) appropriate counseling and other ap-
6 propriate ancillary services.

7 “(iii)(I) The total number of such patients of
8 the practitioner at any one time will not exceed the
9 applicable number. Except as provided in subclause
10 (II), the applicable number is 30.

11 “(II) The applicable number is 100 if, not soon-
12 er than 1 year after the date on which the practi-
13 tioner submitted the initial notification, the practi-
14 tioner submits a second notification to the Secretary
15 of the need and intent of the practitioner to treat up
16 to 100 patients.

17 “(III) The Secretary may by regulation change
18 such total number.

19 “(IV) The Secretary may exclude from the ap-
20 plicable number patients to whom such drugs or
21 combinations of drugs are directly administered by
22 the qualifying practitioner in the office setting.

23 “(iv) If the Secretary by regulation increases
24 the total number of patients which a qualifying prac-
25 titioner is permitted to treat pursuant to clause

1 (iii)(II), the Secretary shall require such a practi-
2 tioner to obtain a written agreement from each pa-
3 tient, including the patient’s signature, that the pa-
4 tient—

5 “(I) will receive an initial assessment and
6 treatment plan and periodic assessments and
7 treatment plans thereafter;

8 “(II) will be subject to medication adher-
9 ence and substance use monitoring;

10 “(III) understands available treatment op-
11 tions, including all drugs approved by the Food
12 and Drug Administration for the treatment of
13 opioid use disorder, including their potential
14 risks and benefits; and

15 “(IV) understands that receiving regular
16 counseling services is critical to recovery.

17 “(v) The practitioner will comply with the re-
18 porting requirements of subparagraph (D)(i)(IV).”;

19 (2) in subparagraph (D)—

20 (A) in clause (i), by adding at the end the
21 following:

22 “(IV) The practitioner reports to the Secretary,
23 at such times and in such manner as specified by
24 the Secretary, such information and assurances as
25 the Secretary determines necessary to assess wheth-

1 er the practitioner continues to meet the require-
2 ments for a waiver under this paragraph.”;

3 (B) in clause (ii), by striking “Upon re-
4 ceiving a notification under subparagraph (B)”
5 and inserting “Upon receiving a determination
6 from the Secretary under clause (iii) finding
7 that a practitioner meets all requirements for a
8 waiver under subparagraph (B)”;

9 (C) in clause (iii)—

10 (i) by inserting “and shall forward
11 such determination to the Attorney Gen-
12 eral” before the period at the end of the
13 first sentence; and

14 (ii) by striking “physician” and in-
15 serting “practitioner”;

16 (3) in subparagraph (G)—

17 (A) by amending clause (ii)(IV) to read as
18 follows:

19 “(IV) The physician has, with respect to
20 the treatment and management of opiate-de-
21 pendent patients, completed not less than 8
22 hours of training (through classroom situations,
23 seminars at professional society meetings, elec-
24 tronic communications, or otherwise) that is
25 provided by the American Society of Addiction

1 Medicine, the American Academy of Addiction
2 Psychiatry, the American Medical Association,
3 the American Osteopathic Association, the
4 American Psychiatric Association, or any other
5 organization that the Secretary determines is
6 appropriate for purposes of this subclause. Such
7 training shall address—

8 “(aa) opioid maintenance and detoxi-
9 fication;

10 “(bb) appropriate clinical use of all
11 drugs approved by the Food and Drug Ad-
12 ministration for the treatment of opioid
13 use disorder;

14 “(cc) initial and periodic patient as-
15 sessments (including substance use moni-
16 toring);

17 “(dd) individualized treatment plan-
18 ning; overdose reversal; relapse prevention;

19 “(ee) counseling and recovery support
20 services;

21 “(ff) staffing roles and considerations;

22 “(gg) diversion control; and

23 “(hh) other best practices, as identi-
24 fied by the Secretary.”; and

25 (B) by adding at the end the following:

1 “(iii) The term ‘qualifying practitioner’
2 means—

3 “(I) a qualifying physician, as defined in
4 clause (ii); or

5 “(II) during the period beginning on the
6 date of the enactment of the Opioid Use Dis-
7 order Treatment Expansion and Modernization
8 Act and ending on the date that is 3 years after
9 such date of enactment, a qualifying other prac-
10 titioner, as defined in clause (iv).

11 “(iv) The term ‘qualifying other practitioner’
12 means a nurse practitioner or physician assistant
13 who satisfies each of the following:

14 “(I) The nurse practitioner or physician
15 assistant is licensed under State law to pre-
16 scribe schedule III, IV, or V medications for the
17 treatment of pain.

18 “(II) The nurse practitioner or physician
19 assistant satisfies one or more of the following:

20 “(aa) Has completed not fewer than
21 24 hours of initial training addressing each
22 of the topics listed in clause (ii)(IV)
23 (through classroom situations, seminars at
24 professional society meetings, electronic
25 communications, or otherwise) provided by

1 the American Society of Addiction Medi-
2 cine, the American Academy of Addiction
3 Psychiatry, the American Medical Associa-
4 tion, the American Osteopathic Associa-
5 tion, the American Nurses Credentialing
6 Center, the American Psychiatric Associa-
7 tion, the American Association of Nurse
8 Practitioners, the American Academy of
9 Physician Assistants, or any other organi-
10 zation that the Secretary determines is ap-
11 propriate for purposes of this subclause.

12 “(bb) Has such other training or ex-
13 perience as the Secretary determines will
14 demonstrate the ability of the nurse practi-
15 tioner or physician assistant to treat and
16 manage opiate-dependent patients.

17 “(III) The nurse practitioner or physician
18 assistant is supervised by or works in collabora-
19 tion with a qualifying physician, if the nurse
20 practitioner or physician assistant is required
21 by State law to prescribe medications for the
22 treatment of opioid use disorder in collaboration
23 with or under the supervision of a physician.

1 The Secretary may review and update the require-
2 ments for being a qualifying other practitioner under
3 this clause.”; and

4 (4) in subparagraph (H)—

5 (A) in clause (i), by inserting after sub-
6 clause (II) the following:

7 “(III) Such other elements of the requirements
8 under this paragraph as the Secretary determines
9 necessary for purposes of implementing such re-
10 quirements.”; and

11 (B) by amending clause (ii) to read as fol-
12 lows:

13 “(ii) Not later than 1 year after the date of enact-
14 ment of the Opioid Use Disorder Treatment Expansion
15 and Modernization Act, the Secretary shall update the
16 treatment improvement protocol containing best practice
17 guidelines for the treatment of opioid-dependent patients
18 in office-based settings. The Secretary shall update such
19 protocol in consultation with experts in opioid use disorder
20 research and treatment.”.

21 (b) RECOMMENDATION OF REVOCATION OR SUSPEN-
22 SION OF REGISTRATION IN CASE OF SUBSTANTIAL NON-
23 COMPLIANCE.—The Secretary of Health and Human
24 Services may recommend to the Attorney General that the
25 registration of a practitioner be revoked or suspended if

1 the Secretary determines, according to such criteria as the
2 Secretary establishes by regulation, that a practitioner
3 who is registered under section 303(g)(2) of the Controlled
4 Substances Act (21 U.S.C. 823(g)(2)) is not in substantial
5 compliance with the requirements of such section, as
6 amended by this Act.

7 (c) OPIOID DEFINED.—Section 102(18) of the Con-
8 trolled Substances Act (21 U.S.C. 802(18)) is amended
9 by inserting “or ‘opioid’ ” after “The term ‘opiate’ ”.

10 (d) REPORTS TO CONGRESS.—

11 (1) IN GENERAL.—Not later than 2 years after
12 the date of enactment of this Act and not less than
13 over every 5 years thereafter, the Secretary of
14 Health and Human Services, in consultation with
15 the Drug Enforcement Administration and experts
16 in opioid use disorder research and treatment,
17 shall—

18 (A) perform a thorough review of the pro-
19 vision of opioid use disorder treatment services
20 in the United States, including services pro-
21 vided in opioid treatment programs and other
22 specialty and nonspecialty settings; and

23 (B) submit a report to the Congress on the
24 findings and conclusions of such review.

1 (2) CONTENTS.—Each report under paragraph
2 (1) shall include an assessment of—

3 (A) compliance with the requirements of
4 section 303(g)(2) of the Controlled Substances
5 Act (21 U.S.C. 823(g)(2)), as amended by this
6 Act;

7 (B) the measures taken by the Secretary of
8 Health and Human Services to ensure such
9 compliance;

10 (C) whether there is further need to in-
11 crease or decrease the number of patients a
12 waived practitioner is permitted to treat, as
13 provided for by the amendment made by sub-
14 section (a)(1);

15 (D) the extent to which, and proportions
16 with which, the full range of Food and Drug
17 Administration-approved treatments for opioid
18 use disorder are used in routine health care set-
19 tings and specialty substance use disorder treat-
20 ment settings;

21 (E) access to, and use of, counseling and
22 recovery support services, including the percent-
23 age of patients receiving such services;

1 (F) changes in State or local policies and
2 legislation relating to opioid use disorder treat-
3 ment;

4 (G) the use of prescription drug moni-
5 toring programs by practitioners who are per-
6 mitted to dispense narcotic drugs to individuals
7 pursuant to a waiver under section 303(g)(2) of
8 the Controlled Substances Act (21 U.S.C.
9 823(g)(2));

10 (H) the findings resulting from inspections
11 by the Drug Enforcement Administration of
12 practitioners described in subparagraph (G);
13 and

14 (I) the effectiveness of cross-agency col-
15 laboration between Department of Health and
16 Human Services and the Drug Enforcement
17 Administration for expanding effective opioid
18 use disorder treatment.

19 **SEC. 4. SENSE OF CONGRESS.**

20 It is the Sense of Congress that, with respect to the
21 total number of patients that a qualifying physician (as
22 defined in subparagraph (G)(iii) of section 303(g)(2) of
23 the Controlled Substances Act (21 U.S.C. 823(g)(2)) can
24 treat at any one time pursuant to such section, the Sec-
25 retary of Health and Human Services should consider

1 raising such total number to 250 patients following a third
 2 notification to the Secretary of the need and intent of the
 3 physician to treat up to 250 patients that is submitted
 4 to the Secretary not sooner than 1 year after the date
 5 on which the physician submitted to the Secretary a sec-
 6 ond notification to treat up to 100 patients.

7 **SEC. 5. PARTIAL FILLS OF SCHEDULE II CONTROLLED SUB-**
 8 **STANCES.**

9 (a) IN GENERAL.—Section 309 of the Controlled
 10 Substances Act (21 U.S.C. 829) is amended by adding at
 11 the end the following:

12 “(f) PARTIAL FILLS OF SCHEDULE II CONTROLLED
 13 SUBSTANCES.—

14 “(1) PARTIAL FILLS.—

15 “(A) IN GENERAL.—A prescription for a
 16 controlled substance in schedule II may be par-
 17 tially filled if—

18 “(i) it is not prohibited by State law;

19 “(ii) the prescription is written and
 20 filled in accordance with the Controlled
 21 Substances Act (21 U.S.C. 801 et seq.),
 22 regulations prescribed by the Attorney
 23 General, and State law;

1 “(iii) the partial fill is requested by
2 the patient or the practitioner that wrote
3 the prescription; and

4 “(iv) the total quantity dispensed in
5 all partial fillings does not exceed the total
6 quantity prescribed.

7 “(B) OTHER CIRCUMSTANCES.—A pre-
8 scription for a controlled substance in schedule
9 II may be partially filled in accordance with
10 section 1306.13 of title 21, Code of Federal
11 Regulations (as in effect on the date of enact-
12 ment of the Reducing Unused Medications Act
13 of 2016).

14 “(2) REMAINING PORTIONS.—

15 “(A) IN GENERAL.—Except as provided in
16 subparagraph (B), remaining portions of a par-
17 tially filled prescription for a controlled sub-
18 stance in schedule II—

19 “(i) may be filled; and

20 “(ii) shall be filled not later than 30
21 days after the date on which the prescrip-
22 tion is written.

23 “(B) EMERGENCY SITUATIONS.—In emer-
24 gency situations, as described in subsection (a),
25 the remaining portions of a partially filled pre-

1 scription for a controlled substance in schedule

2 II—

3 “(i) may be filled; and

4 “(ii) shall be filled not later than 72

5 hours after the prescription is issued.”.

6 (b) RULE OF CONSTRUCTION.—Nothing in this sec-
7 tion shall be construed to affect the authority of the Attor-
8 ney General to allow a prescription for a controlled sub-
9 stance in schedule III, IV, or V of section 202(c) of the
10 Controlled Substances Act (21 U.S.C. 812(c)) to be par-
11 tially filled.

 Passed the House of Representatives May 11, 2016.

Attest:

KAREN L. HAAS,

Clerk.