

Calendar No. **740**

106TH CONGRESS
2^D SESSION

H. R. 2634

IN THE SENATE OF THE UNITED STATES

JULY 27, 2000

Received; read twice and placed on the calendar

AN ACT

To amend the Controlled Substances Act with respect to registration requirements for practitioners who dispense narcotic drugs in schedule III, IV, or V for maintenance treatment or detoxification 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 “Drug Addiction Treat-
3 ment Act of 2000”.

4 **SEC. 2. AMENDMENT TO CONTROLLED SUBSTANCES ACT.**

5 (a) IN GENERAL.—Section 303(g) of the Controlled
6 Substances Act (21 U.S.C. 823(g)) is amended—

7 (1) in paragraph (2), by striking “(A) security”
8 and inserting “(i) security”, and by striking “(B)
9 the maintenance” and inserting “(ii) the mainte-
10 nance”;

11 (2) by redesignating paragraphs (1) through
12 (3) as subparagraphs (A) through (C), respectively;

13 (3) by inserting “(1)” after “(g)”;

14 (4) by striking “Practitioners who dispense”
15 and inserting “Except as provided in paragraph (2),
16 practitioners who dispense”; and

17 (5) by adding at the end the following para-
18 graph:

19 “(2)(A) Subject to subparagraphs (D) and (J), the
20 requirements of paragraph (1) are waived in the case of
21 the dispensing (including the prescribing), by a practi-
22 tioner, of narcotic drugs in schedule III, IV, or V or com-
23 binations of such drugs if the practitioner meets the condi-
24 tions specified in subparagraph (B) and the narcotic drugs
25 or combinations of such drugs meet the conditions speci-
26 fied in subparagraph (C).

1 “(B) For purposes of subparagraph (A), the condi-
2 tions specified in this subparagraph with respect to a prac-
3 titioner are that, before the initial dispensing of narcotic
4 drugs in schedule III, IV, or V or combinations of such
5 drugs to patients for maintenance or detoxification treat-
6 ment, the practitioner submit to the Secretary a notifica-
7 tion of the intent of the practitioner to begin dispensing
8 the drugs or combinations for such purpose, and that the
9 notification contain the following certifications by the
10 practitioner:

11 “(i) The practitioner is a qualifying physician
12 (as defined in subparagraph (G)).

13 “(ii) With respect to patients to whom the prac-
14 titioner will provide such drugs or combinations of
15 drugs, the practitioner has the capacity to refer the
16 patients for appropriate counseling and other appro-
17 priate ancillary services.

18 “(iii) In any case in which the practitioner is
19 not in a group practice, the total number of such pa-
20 tients of the practitioner at any one time will not ex-
21 ceed the applicable number. For purposes of this
22 clause, the applicable number is 30, except that the
23 Secretary may by regulation change such total num-
24 ber.

1 “(iv) In any case in which the practitioner is in
2 a group practice, the total number of such patients
3 of the group practice at any one time will not exceed
4 the applicable number. For purposes of this clause,
5 the applicable number is 30, except that the Sec-
6 retary may by regulation change such total number,
7 and the Secretary for such purposes may by regula-
8 tion establish different categories on the basis of the
9 number of practitioners in a group practice and es-
10 tablish for the various categories different numerical
11 limitations on the number of such patients that the
12 group practice may have.

13 “(C) For purposes of subparagraph (A), the condi-
14 tions specified in this subparagraph with respect to nar-
15 cotic drugs in schedule III, IV, or V or combinations of
16 such drugs are as follows:

17 “(i) The drugs or combinations of drugs have,
18 under the Federal Food, Drug, and Cosmetic Act or
19 section 351 of the Public Health Service Act, been
20 approved for use in maintenance or detoxification
21 treatment.

22 “(ii) The drugs or combinations of drugs have
23 not been the subject of an adverse determination.
24 For purposes of this clause, an adverse determina-
25 tion is a determination published in the Federal

1 Register and made by the Secretary, after consulta-
2 tion with the Attorney General, that the use of the
3 drugs or combinations of drugs for maintenance or
4 detoxification treatment requires additional stand-
5 ards respecting the qualifications of practitioners to
6 provide such treatment, or requires standards re-
7 specting the quantities of the drugs that may be pro-
8 vided for unsupervised use.

9 “(D)(i) A waiver under subparagraph (A) with re-
10 spect to a practitioner is not in effect unless (in addition
11 to conditions under subparagraphs (B) and (C)) the fol-
12 lowing conditions are met:

13 “(I) The notification under subparagraph (B) is
14 in writing and states the name of the practitioner.

15 “(II) The notification identifies the registration
16 issued for the practitioner pursuant to subsection
17 (f).

18 “(III) If the practitioner is a member of a
19 group practice, the notification states the names of
20 the other practitioners in the practice and identifies
21 the registrations issued for the other practitioners
22 pursuant to subsection (f).

23 “(ii) Upon receiving a notification under subpara-
24 graph (B), the Attorney General shall assign the practi-
25 tioner involved an identification number under this para-

1 graph for inclusion with the registration issued for the
2 practitioner pursuant to subsection (f). The identification
3 number so assigned clause shall be appropriate to preserve
4 the confidentiality of patients for whom the practitioner
5 has dispensed narcotic drugs under a waiver under sub-
6 paragraph (A).

7 “(iii) Not later than 45 days after the date on which
8 the Secretary receives a notification under subparagraph
9 (B), the Secretary shall make a determination of whether
10 the practitioner involved meets all requirements for a
11 waiver under subparagraph (B). If the Secretary fails to
12 make such determination by the end of the such 45-day
13 period, the Attorney General shall assign the physician an
14 identification number described in clause (ii) at the end
15 of such period.

16 “(E)(i) If a practitioner is not registered under para-
17 graph (1) and, in violation of the conditions specified in
18 subparagraphs (B) through (D), dispenses narcotic drugs
19 in schedule III, IV, or V or combinations of such drugs
20 for maintenance treatment or detoxification treatment, the
21 Attorney General may, for purposes of section 304(a)(4),
22 consider the practitioner to have committed an act that
23 renders the registration of the practitioner pursuant to
24 subsection (f) to be inconsistent with the public interest.

1 “(ii)(I) A practitioner who in good faith submits a
2 notification under subparagraph (B) and reasonably be-
3 lieves that the conditions specified in subparagraphs (B)
4 through (D) have been met shall, in dispensing narcotic
5 drugs in schedule III, IV, or V or combinations of such
6 drugs for maintenance treatment or detoxification treat-
7 ment, be considered to have a waiver under subparagraph
8 (A) until notified otherwise by the Secretary.

9 “(II) For purposes of subclause (I), the publication
10 in the Federal Register of an adverse determination by
11 the Secretary pursuant to subparagraph (C)(ii) shall (with
12 respect to the narcotic drug or combination involved) be
13 considered to be a notification provided by the Secretary
14 to practitioners, effective upon the expiration of the 30-
15 day period beginning on the date on which the adverse
16 determination is so published.

17 “(F)(i) With respect to the dispensing of narcotic
18 drugs in schedule III, IV, or V or combinations of such
19 drugs to patients for maintenance or detoxification treat-
20 ment, a practitioner may, in his or her discretion, dispense
21 such drugs or combinations for such treatment under a
22 registration under paragraph (1) or a waiver under sub-
23 paragraph (A) (subject to meeting the applicable condi-
24 tions).

1 “(ii) This paragraph may not be construed as having
2 any legal effect on the conditions for obtaining a registra-
3 tion under paragraph (1), including with respect to the
4 number of patients who may be served under such a reg-
5 istration.

6 “(G) For purposes of this paragraph:

7 “(i) The term ‘group practice’ has the meaning
8 given such term in section 1877(h)(4) of the Social
9 Security Act.

10 “(ii) The term ‘qualifying physician’ means a
11 physician who is licensed under State law and who
12 meets one or more of the following conditions:

13 “(I) The physician holds a subspecialty
14 board certification in addiction psychiatry from
15 the American Board of Medical Specialties.

16 “(II) The physician holds an addiction cer-
17 tification from the American Society of Addic-
18 tion Medicine.

19 “(III) The physician holds a subspecialty
20 board certification in addiction medicine from
21 the American Osteopathic Association.

22 “(IV) The physician has, with respect to
23 the treatment and management of opiate-de-
24 pendent patients, completed not less than eight
25 hours of training (through classroom situations,

1 seminars at professional society meetings, elec-
2 tronic communications, or otherwise) that is
3 provided by the American Society of Addiction
4 Medicine, the American Academy of Addiction
5 Psychiatry, the American Medical Association,
6 the American Osteopathic Association, the
7 American Psychiatric Association, or any other
8 organization that the Secretary determines is
9 appropriate for purposes of this subclause.

10 “(V) The physician has participated as an
11 investigator in one or more clinical trials lead-
12 ing to the approval of a narcotic drug in sched-
13 ule III, IV, or V for maintenance or detoxifica-
14 tion treatment, as demonstrated by a statement
15 submitted to the Secretary by the sponsor of
16 such approved drug.

17 “(VI) The physician has such other train-
18 ing or experience as the State medical licensing
19 board (of the State in which the physician will
20 provide maintenance or detoxification treat-
21 ment) considers to demonstrate the ability of
22 the physician to treat and manage opiate-de-
23 pendent patients.

24 “(VII) The physician has such other train-
25 ing or experience as the Secretary considers to

1 demonstrate the ability of the physician to treat
2 and manage opiate-dependent patients. Any cri-
3 teria of the Secretary under this subclause shall
4 be established by regulation. Any such criteria
5 are effective only for 3 years after the date on
6 which the criteria are promulgated, but may be
7 extended for such additional discrete 3-year pe-
8 riods as the Secretary considers appropriate for
9 purposes of this subclause. Such an extension of
10 criteria may only be effectuated through a
11 statement published in the Federal Register by
12 the Secretary during the 30-day period pre-
13 ceding the end of the 3-year period involved.

14 “(H)(i) In consultation with the Administrator of the
15 Drug Enforcement Administration, the Administrator of
16 the Substance Abuse and Mental Health Services Admin-
17 istration, the Director of the Center for Substance Abuse
18 Treatment, the Director of the National Institute on Drug
19 Abuse, and the Commissioner of Food and Drugs, the Sec-
20 retary shall issue regulations (through notice and com-
21 ment rulemaking) or issue practice guidelines to address
22 the following:

23 “(I) Approval of additional credentialing bodies
24 and the responsibilities of additional credentialing
25 bodies.

1 “(II) Additional exemptions from the require-
2 ments of this paragraph and any regulations under
3 this paragraph.

4 Nothing in such regulations or practice guidelines may au-
5 thorize any Federal official or employee to exercise super-
6 vision or control over the practice of medicine or the man-
7 ner in which medical services are provided.

8 “(ii) Not later than 120 days after the date of the
9 enactment of the Drug Addiction Treatment Act of 2000,
10 the Secretary shall issue a treatment improvement pro-
11 tocol containing best practice guidelines for the treatment
12 and maintenance of opiate-dependent patients. The Sec-
13 retary shall develop the protocol in consultation with the
14 Director of the National Institute on Drug Abuse, the Di-
15 rector of the Center for Substance Abuse Treatment, the
16 Administrator of the Drug Enforcement Administration,
17 the Commissioner of Food and Drugs, the Administrator
18 of the Substance Abuse and Mental Health Services Ad-
19 ministration, and other substance abuse disorder profes-
20 sionals. The protocol shall be guided by science.

21 “(I) During the 3-year period beginning on the date
22 of the enactment of the Drug Addiction Treatment Act
23 of 2000, a State may not preclude a practitioner from dis-
24 pensing or prescribing drugs in schedule III, IV, or V, or
25 combinations of such drugs, to patients for maintenance

1 of detoxification treatment in accordance with this para-
2 graph unless, before the expiration of that 3-year period,
3 the State enacts a law prohibiting a practitioner from dis-
4 pensing such drugs or combinations of drug.

5 “(J)(i) This paragraph takes effect on the date of the
6 enactment of the Drug Addiction Treatment Act of 2000,
7 and remains in effect thereafter except as provided in
8 clause (iii) (relating to a decision by the Secretary or the
9 Attorney General that this paragraph should not remain
10 in effect).

11 “(ii) For purposes relating to clause (iii), the Sec-
12 retary and the Attorney General may, during the 3-year
13 period beginning on the date of the enactment of the Drug
14 Addiction Treatment Act of 2000, make determinations
15 in accordance with the following:

16 “(I) The Secretary may make a determination
17 of whether treatments provided under waivers under
18 subparagraph (A) have been effective forms of main-
19 tenance treatment and detoxification treatment in
20 clinical settings; may make a determination of
21 whether such waivers have significantly increased
22 (relative to the beginning of such period) the avail-
23 ability of maintenance treatment and detoxification
24 treatment; and may make a determination of wheth-

1 er such waivers have adverse consequences for the
2 public health.

3 “(II) The Attorney General may make a deter-
4 mination of the extent to which there have been vio-
5 lations of the numerical limitations established
6 under subparagraph (B) for the number of individ-
7 uals to whom a practitioner may provide treatment;
8 may make a determination of whether waivers under
9 subparagraph (A) have increased (relative to the be-
10 ginning of such period) the extent to which narcotic
11 drugs in schedule III, IV, or V or combinations of
12 such drugs are being dispensed or possessed in viola-
13 tion of this Act; and may make a determination of
14 whether such waivers have adverse consequences for
15 the public health.

16 “(iii) If, before the expiration of the period specified
17 in clause (ii), the Secretary or the Attorney General pub-
18 lishes in the Federal Register a decision, made on the
19 basis of determinations under such clause, that this para-
20 graph should not remain in effect, this paragraph ceases
21 to be in effect 60 days after the date on which the decision
22 is so published. The Secretary shall in making any such
23 decision consult with the Attorney General, and shall in
24 publishing the decision in the Federal Register include any
25 comments received from the Attorney General for inclu-

1 sion in the publication. The Attorney General shall in
 2 making any such decision consult with the Secretary, and
 3 shall in publishing the decision in the Federal Register
 4 include any comments received from the Secretary for in-
 5 clusion in the publication.”.

6 (b) CONFORMING AMENDMENTS.—Section 304 of the
 7 Controlled Substances Act (21 U.S.C. 824) is amended—

8 (1) in subsection (a), in the matter after and
 9 below paragraph (5), by striking “section 303(g)”
 10 each place such term appears and inserting “section
 11 303(g)(1)”; and

12 (2) in subsection (d), by striking “section
 13 303(g)” and inserting “section 303(g)(1)”.

14 **SEC. 3. ADDITIONAL AUTHORIZATION OF APPROPRIATIONS**

15 **REGARDING DEPARTMENT OF HEALTH AND**
 16 **HUMAN SERVICES.**

17 For the purpose of assisting the Secretary of Health
 18 and Human Services with the additional duties established
 19 for the Secretary pursuant to the amendments made by
 20 section 2, there are authorized to be appropriated, in addi-
 21 tion to other authorizations of appropriations that are
 22 available for such purpose, such sums as may be necessary
 23 for fiscal year 2000 and each subsequent fiscal year.

Passed the House of Representatives July 19, 2000.

Attest: JEFF TRANDAHL,
Clerk.

Calendar No. 740

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