

106TH CONGRESS  
1ST SESSION

# S. 324

To amend the Controlled Substances Act with respect to registration requirements for practitioners who dispense narcotic drugs in schedule IV or V for maintenance treatment or detoxification treatment.

---

## IN THE SENATE OF THE UNITED STATES

JANUARY 28, 1999

Mr. HATCH (for himself, Mr. LEVIN, and Mr. MOYNIHAN) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

---

## A BILL

To amend the Controlled Substances Act with respect to registration requirements for practitioners who dispense narcotic drugs in schedule 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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Drug Addiction Treat-  
5 ment Act of 1999”.

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

7 Section 303(g) of the Controlled Substances Act (21  
8 U.S.C. 823(g)) is amended—

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

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

7 (3) by inserting “(1)” after “(g)”;

8 (4) by striking “Practitioners who dispense”  
 9 and inserting “Except as provided in paragraph (2),  
 10 practitioners who dispense”; and

11 (5) by adding at the end the following:

12 “(2)(A) Subject to subparagraphs (D) and (G),  
 13 the requirements of paragraph (1) are waived in the  
 14 case of the dispensing, by a practitioner, of narcotic  
 15 drugs in schedule IV or V or combinations of such  
 16 drugs if the practitioner meets the conditions speci-  
 17 fied in subparagraph (B) and the narcotic drugs or  
 18 combinations of such drugs meet the conditions  
 19 specified in subparagraph (C).

20 “(B) For purposes of subparagraph (A), the  
 21 conditions specified in this subparagraph with re-  
 22 spect to a practitioner are that, before dispensing  
 23 narcotic drugs in schedule IV or V, or combinations  
 24 of such drugs, to patients for maintenance or detoxi-  
 25 fication treatment, the practitioner submit to the

1 Secretary a notification of the intent of the practi-  
2 tioner to begin dispensing the drugs or combinations  
3 for such purpose, and that the notification contain  
4 the following certifications by the practitioner:

5 “(i) The practitioner is a physician li-  
6 censed under State law, and the practitioner  
7 has, by training or experience, the ability to  
8 treat and manage opiate-dependent patients.

9 “(ii) With respect to patients to whom the  
10 practitioner will provide such drugs or combina-  
11 tions of drugs, the practitioner has the capacity  
12 to refer the patients for appropriate counseling  
13 and other appropriate ancillary services.

14 “(iii) In any case in which the practitioner  
15 is not in a group practice, the total number of  
16 such patients of the practitioner at any one  
17 time will not exceed the applicable number. For  
18 purposes of this clause, the applicable number  
19 is 20, except that the Secretary may by regula-  
20 tion change such total number.

21 “(iv) In any case in which the practitioner  
22 is in a group practice, the total number of such  
23 patients of the group practice at any one time  
24 will not exceed the applicable number. For pur-  
25 poses of this clause, the applicable number is

20, except that the Secretary may by regulation change such total number, and the Secretary for such purposes may by regulation establish different categories on the basis of the number of practitioners in a group practice and establish for the various categories different numerical limitations on the number of such patients that the group practice may have.

“(C) For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to narcotic drugs in schedule IV or V or combinations of such drugs are as follows:

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

“(ii) The drugs or combinations of drugs have not been the subject of an adverse determination. For purposes of this clause, an adverse determination is a determination published in the Federal Register and made by the Secretary, after consultation with the Attorney General, that the use of the drugs or combinations of drugs for maintenance or detoxification

1 treatment requires additional standards respect-  
2 ing the qualifications of practitioners to provide  
3 such treatment, or requires standards respect-  
4 ing the quantities of the drugs that may be pro-  
5 vided for unsupervised use.

6 “(D)(i) A waiver under subparagraph (A) with  
7 respect to a practitioner is not in effect unless (in  
8 addition to conditions under subparagraphs (B) and  
9 (C)) the following conditions are met:

10 “(I) The notification under subparagraph  
11 (B) is in writing and states the name of the  
12 practitioner.

13 “(II) The notification identifies the reg-  
14 istration issued for the practitioner pursuant to  
15 subsection (f).

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

21 “(IV) A period of 30 days has elapsed  
22 after the date on which the notification was  
23 submitted, and during such period the practi-  
24 tioner does not receive from the Secretary a  
25 written notice that one or more of the condi-

1           tions specified in subparagraph (B), subpara-  
2           graph (C), or this subparagraph, have not been  
3           met.

4           “(ii) The Secretary shall provide to the Attor-  
5           ney General such information contained in notifica-  
6           tions under subparagraph (B) as the Attorney Gen-  
7           eral may request.

8           “(E) If in violation of subparagraph (A) a prac-  
9           titioner dispenses narcotic drugs in schedule IV or V  
10          or combinations of such drugs for maintenance  
11          treatment or detoxification treatment, the Attorney  
12          General may, for purposes of section 304(a)(4), con-  
13          sider the practitioner to have committed an act that  
14          renders the registration of the practitioner pursuant  
15          to subsection (f) to be inconsistent with the public  
16          interest.

17          “(F) In this paragraph, the term ‘group prac-  
18          tice’ has the meaning given such term in section  
19          1877(h)(4) of the Social Security Act.

20          “(G)(i) This paragraph takes effect on the date  
21          of enactment of the Drug Addiction Treatment Act  
22          of 1999, and remains in effect thereafter except as  
23          provided in clause (iii) (relating to a decision by the  
24          Secretary or the Attorney General that this para-  
25          graph should not remain in effect).

1           “(ii) For the purposes relating to clause (iii),  
2           the Secretary and the Attorney General shall, during  
3           the 3-year period beginning on the date of enact-  
4           ment of the Drug Addiction Treatment Act of 1999,  
5           make determinations in accordance with the follow-  
6           ing:

7                   “(I)(aa) The Secretary shall—

8                           “(aaa) make a determination of  
9                           whether treatments provided under waivers  
10                          under subparagraph (A) have been effec-  
11                          tive forms of maintenance treatment and  
12                          detoxification treatment in clinical settings;

13                           “(bbb) make a determination regard-  
14                          ing whether such waivers have significantly  
15                          increased (relative to the beginning of such  
16                          period) the availability of maintenance  
17                          treatment and detoxification treatment;  
18                          and

19                           “(ccc) make a determination regard-  
20                          ing whether such waivers have adverse con-  
21                          sequences for the public health.

22                          “(bb) In making determinations under this  
23                          subclause, the Secretary—

1 “(aa) may collect data from the prac-  
 2 titioners for whom waivers under subpara-  
 3 graph (A) are in effect;

4 “(bb) shall promulgate regulations (in  
 5 accordance with procedures for substantive  
 6 rules under section 553 of title 5, United  
 7 States Code) specifying the scope of the  
 8 data that will be required to be provided  
 9 under this subclause and the means  
 10 through which the data will be collected;  
 11 and

12 “(cc) shall, with respect to collecting  
 13 such data, comply with applicable provi-  
 14 sions of chapter 6 of title 5, United States  
 15 Code (relating to a regulatory flexibility  
 16 analysis) and of chapter 8 of such title (re-  
 17 lating to congressional review of agency  
 18 rulemaking).

19 “(II) The Attorney General shall—

20 “(aa) make a determination of the ex-  
 21 tent to which there have been violations of  
 22 the numerical limitations established under  
 23 subparagraph (B) for the number of indi-  
 24 viduals to whom a practitioner may provide  
 25 treatment;



1 “(bb) make a determination regarding  
2 whether waivers under subparagraph (A)  
3 have increased (relative to the beginning of  
4 such period) the extent to which narcotic  
5 drugs in schedule IV or V or combinations  
6 of such drugs are being dispensed or pos-  
7 sessed in violation of this Act; and

8 “(cc) make a determination regarding  
9 whether such waivers have adverse con-  
10 sequences for the public health.

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

1       ceived from the Secretary for inclusion in the publi-  
2       cation.

3               “(H) During the 3-year period beginning on the  
4       date of enactment of the Drug Addiction Treatment  
5       Act of 1999, a State may not preclude a practitioner  
6       from dispensing narcotic drugs in schedule IV or V,  
7       or combinations of such drugs, to patients for  
8       maintenance or detoxification treatment in accord-  
9       ance with the Drug Addiction Treatment Act of  
10      1999, unless, before the expiration of that 3-year pe-  
11      riod, the State enacts a law prohibiting a practi-  
12      tioner from dispensing such drugs or combination of  
13      drugs.”.

14      (e) CONFORMING AMENDMENT.—Section 304 of the  
15      Controlled Substances Act (21 U.S.C. 824) is amended—

16              (1) in subsection (a), in the matter following  
17      paragraph (5), by striking “section 303(g)” each  
18      place the term appears and inserting “section  
19      303(g)(1)”; and

20              (2) in subsection (d), by striking “section  
21      303(g)” and inserting “section 303(g)(1)”.

○