''(ii) submit a report to the Congress on the findings and conclusions of such review.

''(B) CONTENTS.—Each report under subparagraph (A) shall include an assessment of—

''(i) compliance with the requirements of [former] section 303(g)(2) of the Controlled Substances Act (21 U.S.C. 823(g)(2)) [former 21 U.S.C. 823(h)(2)], as amended by this section;

''(ii) the measures taken by the Secretary of Health and Human Services to ensure such compliance;

''(iii) whether there is further need to increase or decrease the number of patients a practitioner, pursuant to a waiver under [former] section 303(g)(2) of the Controlled Substances Act (21 U.S.C. 823(g)(2)) [former 21 U.S.C. 823(h)(2)], is permitted to treat;

''(iv) the extent to which, and proportions with which, the full range of Food and Drug Administration-approved treatments for opioid use disorder are used in routine health care settings and specialty substance use disorder treatment settings;

''(v) access to, and use of, counseling and recovery support services, including the percentage of patients receiving such services;

''(vi) changes in State or local policies and legislation relating to opioid use disorder treatment;

''(vii) the use of prescription drug monitoring programs by practitioners who are permitted to dispense narcotic drugs to individuals pursuant to a waiver described in clause (iii);

''(viii) the findings resulting from inspections by the Drug Enforcement Administration of practitioners described in clause (vii); and

''(ix) the effectiveness of cross-agency collaboration between [the] Department of Health and Human Services and the Drug Enforcement Administration for expanding effective opioid use disorder treatment.''

PROVISIONAL REGISTRATION

For provisional registration of persons engaged in manufacturing, distributing, or dispensing of controlled substances on the day before the effective date of section 822 of this title who are registered on such date under section 360 of this title or section 4722 of Title 26, Internal Revenue Code, see section 703 of Pub. L. 91–513, set out as a note under section 822 of this title.

§ 824. Denial, revocation, or suspension of registration

(a) Grounds

A registration pursuant to section 823 of this title to manufacture, distribute, or dispense a controlled substance or a list I chemical may be suspended or revoked by the Attorney General upon a finding that the registrant—

(1) has materially falsified any application filed pursuant to or required by this subchapter or subchapter II;

(2) has been convicted of a felony under this subchapter or subchapter II or any other law of the United States, or of any State, relating to any substance defined in this subchapter as a controlled substance or a list I chemical;

(3) has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances or list I chemicals or has had the suspension, revocation, or denial of his registration recommended by competent State authority;

(4) has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section; or

(5) has been excluded (or directed to be excluded) from participation in a program pursuant to section 1320a–7(a) of title 42.

A registration pursuant to section 823(h)(1)[1] of this title to dispense a narcotic drug for maintenance treatment or detoxification treatment may be suspended or revoked by the Attorney General upon a finding that the registrant has failed to comply with any standard referred to in section 823(h)(1)[1] of this title.

(b) Limits of revocation or suspension

The Attorney General may limit revocation or suspension of a registration to the particular controlled substance or list I chemical with respect to which grounds for revocation or suspension exist.

(c) Service of show cause order; proceedings

(1) Before taking action pursuant to this section, or pursuant to a denial of registration under section 823 of this title, the Attorney General shall serve upon the applicant or registrant an order to show cause why registration should not be denied, revoked, or suspended.

(2) An order to show cause under paragraph (1) shall—

(A) contain a statement of the basis for the denial, revocation, or suspension, including specific citations to any laws or regulations alleged to be violated by the applicant or registrant;

(B) direct the applicant or registrant to appear before the Attorney General at a time and place stated in the order, but not less than 30 days after the date of receipt of the order; and

(C) notify the applicant or registrant of the opportunity to submit a corrective action plan on or before the date of appearance.

(3) Upon review of any corrective action plan submitted by an applicant or registrant pursuant to paragraph (2), the Attorney General shall determine whether denial, revocation, or suspension proceedings should be discontinued, or deferred for the purposes of modification, amendment, or clarification to such plan.

(4) Proceedings to deny, revoke, or suspend shall be conducted pursuant to this section in accordance with subchapter II of chapter 5 of title 5. Such proceedings shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under this subchapter or any other law of the United States.

(5) The requirements of this subsection shall not apply to the issuance of an immediate suspension order under subsection (d).

(d) Suspension of registration in cases of imminent danger

(1) The Attorney General may, in his discretion, suspend any registration simultaneously with the institution of proceedings under this section, in cases where he finds that there is an imminent danger to the public health or safety. A failure to comply with a standard referred to in section 823(h)(1)[1] of this title may be treated under this subsection as grounds for immediate suspension of a registration granted under such

[1] See References in Text note below.

section. A suspension under this subsection shall continue in effect until the conclusion of such proceedings, including judicial review thereof, unless sooner withdrawn by the Attorney General or dissolved by a court of competent jurisdiction.

(2) In this subsection, the phrase ''imminent danger to the public health or safety'' means that, due to the failure of the registrant to maintain effective controls against diversion or otherwise comply with the obligations of a registrant under this subchapter or subchapter II, there is a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur in the absence of an immediate suspension of the registration.

(e) Suspension and revocation of quotas

The suspension or revocation of a registration under this section shall operate to suspend or revoke any quota applicable under section 826 of this title.

(f) Disposition of controlled substances or list I chemicals

In the event the Attorney General suspends or revokes a registration granted under section 823 of this title, all controlled substances or list I chemicals owned or possessed by the registrant pursuant to such registration at the time of suspension or the effective date of the revocation order, as the case may be, may, in the discretion of the Attorney General, be placed under seal. No disposition may be made of any controlled substances or list I chemicals under seal until the time for taking an appeal has elapsed or until all appeals have been concluded except that a court, upon application therefor, may at any time order the sale of perishable controlled substances or list I chemicals. Any such order shall require the deposit of the proceeds of the sale with the court. Upon a revocation order becoming final, all such controlled substances or list I chemicals (or proceeds of sale deposited in court) shall be forfeited to the United States; and the Attorney General shall dispose of such controlled substances or list I chemicals in accordance with section 881(e) of this title. All right, title, and interest in such controlled substances or list I chemicals shall vest in the United States upon a revocation order becoming final.

(g) Seizure or placement under seal of controlled substances or list I chemicals

The Attorney General may, in his discretion, seize or place under seal any controlled substances or list I chemicals owned or possessed by a registrant whose registration has expired or who has ceased to practice or do business in the manner contemplated by his registration. Such controlled substances or list I chemicals shall be held for the benefit of the registrant, or his successor in interest. The Attorney General shall notify a registrant, or his successor in interest, who has any controlled substance or list I chemical seized or placed under seal of the procedures to be followed to secure the return of the controlled substance or list I chemical and the conditions under which it will be returned. The Attorney General may not dispose of any controlled substance or list I chemical seized or placed under seal under this subsection until the expiration of one hundred and eighty days from the date such substance or chemical was seized or placed under seal.

(h) Order to prohibit registration based on prior history

The Attorney General may issue an order to prohibit, conditionally or unconditionally, and permanently or for such period as the Attorney General may determine, any person from being registered under this subchapter to manufacture, distribute, or dispense a controlled substance or a list I chemical, if the Attorney General finds that—

(1) such person meets or has met any of the conditions for suspension or revocation of registration under subsection (a); and

(2) such person has a history of prior suspensions or revocations of registration.

(Pub. L. 91–513, title II, §304, Oct. 27, 1970, 84 Stat. 1255; Pub. L. 93–281, §4, May 14, 1974, 88 Stat. 125; Pub. L. 98–473, title II, §§304, 512, 513, Oct. 12, 1984, 98 Stat. 2050, 2073; Pub. L. 100–93, §8(j), Aug. 18, 1987, 101 Stat. 695; Pub. L. 103–200, §3(d), Dec. 17, 1993, 107 Stat. 2337; Pub. L. 103–322, title XXXIII, §330024(e), Sept. 13, 1994, 108 Stat. 2151; Pub. L. 106–310, div. B, title XXXV, §3502(b), Oct. 17, 2000, 114 Stat. 1227; Pub. L. 114–145, §2(a)(2), (b), Apr. 19, 2016, 130 Stat. 354; Pub. L. 117–36, §2, Aug. 6, 2021, 135 Stat. 328; Pub. L. 117–215, title I, §103(b)(1)(C), Dec. 2, 2022, 136 Stat. 2263; Pub. L. 117–328, div. FF, title I, §1262(b)(1), Dec. 29, 2022, 136 Stat. 5682.)

Editorial Notes

REFERENCES IN TEXT

Section 823(h) of this title, referred to in subsecs. (a) and (d)(1), originally consisted of pars. (1) and (2). Par. (1) was redesignated as the entire subsec. (h), with its subpars. (A) to (C) redesignated pars. (1) to (3), and former par. (2) was struck out by Pub. L. 117–328, div. FF, title I, §1262(a), Dec. 29, 2022, 136 Stat. 5681.

This subchapter, referred to in subsecs. (a)(1), (2), (c)(4), (d)(2), and (h), was in the original ''this title'', meaning title II of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1242, and is popularly known as the ''Controlled Substances Act''. For complete classification of title II to the Code, see second paragraph of Short Title note set out under section 801 of this title and Tables.

Subchapter II, referred to in subsecs. (a)(1), (2) and (d)(2), was in the original ''title III'', meaning title III of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1285. Part A of title III comprises subchapter II of this chapter. For classification of Part B, consisting of sections 1101 to 1105 of title III, see Tables.

AMENDMENTS

2022—Subsec. (a). Pub. L. 117–328, §1262(b)(1), which directed substitution of ''823(g)'' for ''823(g)(1)'' in two places in concluding provisions, could not be executed because of the intervening amendment by Pub. L. 117–215, §103(b)(1)(C). See Amendment note below.

Pub. L. 117–215, in concluding provisions, substituted ''823(h)(1)'' for ''823(g)(1)'' in two places.

Subsec. (d)(1). Pub. L. 117–328, §1262(b)(1), which directed substitution of ''823(g)'' for ''823(g)(1)'', could not be executed because of the intervening amendment by Pub. L. 117–215, §103(b)(1)(C). See Amendment note below.

Pub. L. 117–215 substituted ''823(h)(1)'' for ''823(g)(1)''.

2021—Subsec. (h). Pub. L. 117–36 added subsec. (h).

2016—Subsec. (c). Pub. L. 114–145, §2(b), struck out ''The order to show cause shall contain a statement of

the basis thereof and shall call upon the applicant or registrant to appear before the Attorney General at a time and place stated in the order, but in no event less than thirty days after the date of receipt of the order. Proceedings to deny, revoke, or suspend shall be conducted pursuant to this section in accordance with subchapter II of chapter 5 of title 5. Such proceedings shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under this subchapter or any other law of the United States.'' after ''denied, revoked, or suspended.'', designated existing provisions as par. (1), and added pars. (2) to (5).

Subsec. (d). Pub. L. 114–145, § 2(a)(2), designated existing provisions as par. (1) and added par. (2).

2000—Subsec. (a). Pub. L. 106–310, § 3502(b)(1), substituted ''section 823(g)(1) of this title'' for ''section 823(g) of this title'' in two places in concluding provisions.

Subsec. (d). Pub. L. 106–310, § 3502(b)(2), substituted ''section 823(g)(1) of this title'' for ''section 823(g) of this title''.

1994—Subsec. (g). Pub. L. 103–322 inserted ''or chemical'' after ''such substance'' in last sentence.

1993—Subsec. (a). Pub. L. 103–200, § 3(d)(1), inserted ''or a list I chemical'' after ''controlled substance'' in introductory provisions and par. (2) and inserted ''or list I chemicals'' after ''controlled substances'' in par. (3).

Subsec. (b). Pub. L. 103–200, § 3(d)(2), inserted ''or list I chemical'' after ''controlled substance''.

Subsec. (f). Pub. L. 103–200, § 3(d)(3), inserted ''or list I chemicals'' after ''controlled substances'' wherever appearing.

Subsec. (g). Pub. L. 103–200, § 3(d)(4), inserted ''or list I chemicals'' after ''controlled substances'' in two places and ''or list I chemical'' after ''controlled substance'' wherever appearing.

1987—Subsec. (a)(5). Pub. L. 100–93 added par. (5).

1984—Subsec. (a)(3). Pub. L. 98–473, § 512(1), inserted provisions relating to suspension, etc., recommended by competent State authority.

Subsec. (a)(4). Pub. L. 98–473, § 512(2), added par. (4).

Subsec. (f). Pub. L. 98–473, § 304, inserted provisions relating to vesting of right, title, and interest in the United States.

Subsec. (g). Pub. L. 98–473, § 513, added subsec. (g).

1974—Subsec. (a). Pub. L. 93–281, § 4(a), provided for revocation or suspension of a registration pursuant to section 823(g) of this title for failure of a registrant to comply with standards referred to in such section 823(g).

Subsec. (d). Pub. L. 93–281, § 4(b), substituted ''A suspension under this subsection'' for ''Such suspension'' in third sentence.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103–322 effective 120 days after Dec. 17, 1993, see section 330024(f) of Pub. L. 103–322, set out as a note under section 802 of this title.

EFFECTIVE DATE OF 1993 AMENDMENT

Amendment by Pub. L. 103–200 effective on date that is 120 days after Dec. 17, 1993, see section 11 of Pub. L. 103–200, set out as a note under section 802 of this title.

EFFECTIVE DATE OF 1987 AMENDMENT

Amendment by Pub. L. 100–93 effective at end of fourteen-day period beginning Aug. 18, 1987, and inapplicable to administrative proceedings commenced before end of such period, see section 15(a) of Pub. L. 100–93, set out as a note under section 1320a–7 of Title 42, The Public Health and Welfare.

EFFECTIVE DATE

Section effective on first day of seventh calendar month that begins after Oct. 26, 1970, see section 704 of Pub. L. 91–513, set out as a note under section 801 of this title.

PROVISIONAL REGISTRATION

Applicability of this section to provisional registrations, see section 703 of Pub. L. 91–513, set out as a note under section 822 of this title.

§ 825. Labeling and packaging

(a) Symbol

It shall be unlawful to distribute a controlled substance in a commercial container unless such container, when and as required by regulations of the Attorney General, bears a label (as defined in section 321(k) of this title) containing an identifying symbol for such substance in accordance with such regulations. A different symbol shall be required for each schedule of controlled substances.

(b) Unlawful distribution without identifying symbol

It shall be unlawful for the manufacturer of any controlled substance to distribute such substance unless the labeling (as defined in section 321(m) of this title) of such substance contains, when and as required by regulations of the Attorney General, the identifying symbol required under subsection (a).

(c) Warning on label

The Secretary shall prescribe regulations under section 353(b) of this title which shall provide that the label of a drug listed in schedule II, III, or IV shall, when dispensed to or for a patient, contain a clear, concise warning that it is a crime to transfer the drug to any person other than the patient.

(d) Containers to be securely sealed

It shall be unlawful to distribute controlled substances in schedule I or II, and narcotic drugs in schedule III or IV, unless the bottle or other container, stopper, covering, or wrapper thereof is securely sealed as required by regulations of the Attorney General.

(e) False labeling of anabolic steroids

(1) It shall be unlawful to import, export, manufacture, distribute, dispense, or possess with intent to manufacture, distribute, or dispense, an anabolic steroid or product containing an anabolic steroid, unless the steroid or product bears a label clearly identifying an anabolic steroid or product containing an anabolic steroid by the nomenclature used by the International Union of Pure and Applied Chemistry (IUPAC).

(2)(A) A product described in subparagraph (B) is exempt from the International Union of Pure and Applied Chemistry nomenclature requirement of this subsection if such product is labeled in the manner required under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.].

(B) A product is described in this subparagraph if the product—

(i) is the subject of an approved application as described in section 505(b) or (j) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(b), (j)]; or

(ii) is exempt from the provisions of section 505 of such Act relating to new drugs because—

(I) it is intended solely for investigational use as described in section 505(i) of such Act; and