

United States Code Annotated [Currentness](#)

Title 21. Food and Drugs ([Refs & Annos](#))

Chapter 13. Drug Abuse Prevention and Control ([Refs & Annos](#))

▣ [Subchapter I](#). Control and Enforcement

▣ [Part C](#). Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances

→ **§ 822. Persons required to register**

(a) Period of registration

(1) Every person who manufactures or distributes any controlled substance or list I chemical, or who proposes to engage in the manufacture or distribution of any controlled substance or list I chemical, shall obtain annually a registration issued by the Attorney General in accordance with the rules and regulations promulgated by him.

(2) Every person who dispenses, or who proposes to dispense, any controlled substance, shall obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by him. The Attorney General shall, by regulation, determine the period of such registrations. In no event, however, shall such registrations be issued for less than one year nor for more than three years.

(b) Authorized activities

Persons registered by the Attorney General under this subchapter to manufacture, distribute, or dispense controlled substances or list I chemicals are authorized to possess, manufacture, distribute, or dispense such substances or chemicals (including any such activity in the conduct of research) to the extent authorized by their registration and in conformity with the other provisions of this subchapter.

(c) Exceptions

The following persons shall not be required to register and may lawfully possess any controlled substance or list I chemical under this subchapter:

(1) An agent or employee of any registered manufacturer, distributor, or dispenser of any controlled substance or list I chemical if such agent or employee is acting in the usual course of his business or employment.

(2) A common or contract carrier or warehouseman, or an employee thereof, whose possession of the controlled substance or list I chemical is in the usual course of his business or employment.

(3) An ultimate user who possesses such substance for a purpose specified in [section 802\(25\)](#) of this title.

(d) Waiver

The Attorney General may, by regulation, waive the requirement for registration of certain manufacturers, distributors, or dispensers if he finds it consistent with the public health and safety.

(e) Separate registration

A separate registration shall be required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances or list I chemicals.

(f) Inspection

The Attorney General is authorized to inspect the establishment of a registrant or applicant for registration in accordance with the rules and regulations promulgated by him.

CREDIT(S)

(Pub.L. 91-513, Title II, § 302, Oct. 27, 1970, 84 Stat. 1253; [Pub.L. 98-473, Title II, § 510](#), Oct. 12, 1984, 98 Stat. 2072; [Pub.L. 103-200](#), § 3(b), Dec. 17, 1993, 107 Stat. 2336.)

HISTORICAL AND STATUTORY NOTES

Revision Notes and Legislative Reports

1970 Acts. House Report No. 91-1444 and Conference Report No. 91-1603, see 1970 U.S. Code Cong. and Adm. News, p. 4566.

1984 Acts. House Report No. 98-1030 and [House Conference Report No. 98-1159](#), see 1984 U.S. Code Cong. and Adm. News, p. 3182.

1993 Acts. House Report No. 103-379, see 1993 U.S. Code Cong. and Adm. News, p. 2983.

References in Text

“This subchapter”, referred to in subsecs. (b) and (c), was in the original “this title” which is 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 Short Title note set out under § 801 of this title and Tables.

Section 802(25) of this title, referred to in subsec. (c)(3) of this section, was redesignated 802(26) by Pub.L. 98-473, § 507(a), Oct. 12, 1984, 98 Stat. 2071, and was further redesignated 802(27) by Pub.L. 99-570, Title I, § 1003(b)(2), Oct. 27, 1986, 100 Stat. 3207-6, without amending this section to conform to the redesignations.

Amendments

1993 Amendments. Subsec. (a)(1). Pub.L. 103-200, § 3(b)(1), inserted “or list I chemical” following “controlled substance” wherever appearing.

Subsec. (b). Pub.L. 103-200, § 3(b)(2), inserted “or list I chemicals” following “controlled substances” and “or chemicals” following “such substances”.

Subsec. (c). Pub.L. 103-200, § 3(b)(3), inserted “or list I chemical” following “controlled substance” wherever appearing.

Subsec. (e). Pub.L. 103-200, § 3(b)(4), inserted “or list I chemicals” following “controlled substances”.

1984 Amendments. Subsec. (a)(1). Pub.L. 98-473, designated existing provisions as par. (1) and, as so designated, struck out provisions relating to dispensing controlled substances.

Subsec. (a)(2). Pub.L. 98-473, added subsec. (a)(2).

Effective and Applicability Provisions

1993 Acts. Amendment to this section by Pub.L. 103-200, to take effect on the date that is 120 days after the date of enactment of Pub.L. 103-200, which was approved Dec. 17, 1993, see section 11 of Pub.L. 103-200, set out as a note under section 802 of this title.

1970 Acts. Section effective the first day of the seventh calendar month that begins after the day immediately preceding Oct. 27, 1970, see § 704(a) of Pub.L. 91-513, set out as a note under § 801 of this title.

Provisional Registration

Section 703 of Pub.L. 91-513 provided that:

“(a)(1) Any person who--

“(A) is engaged in manufacturing, distributing, or dispensing any controlled substance on the day before the effective date of section 302 [this section], and

“(B) is registered on such day under section 510 of the Federal Food, Drug, and Cosmetic Act [section 360 of this title] or under section 4722 of the Internal Revenue Code of 1954 [former section 4722 of Title 26],

shall, with respect to each establishment for which such registration is in effect under any such section, be deemed to have a provisional registration under section 303 [section 823 of this title] for the manufacture, distribution, or dispensing (as the case may be) of controlled substances.

“(2) During the period his provisional registration is in effect under this section, the registration number assigned such person under such section 510 [section 360 of this title] or under such section 4722 [former section 4722 of Title 26] (as the case may be) shall be his registration number for purposes of section 303 of this title [section 823 of this title].

“(b) The provisions of section 304 [section 824 of this title], relating to suspension and revocation of registration, shall apply to a provisional registration under this section.

“(c) Unless sooner suspended or revoked under subsection (b), a provisional registration of a person under subsection (a)(1) of this section shall be in effect until--

“(1) the date on which such person has registered with the Attorney General under section 303 [section 823 of this title] or has had his registration denied under such section, or

“(2) such date as may be prescribed by the Attorney General for registration of manufacturers, distributors, or dispensers, as the case may be,

whichever occurs first.”

CROSS REFERENCES

Robberies or burglaries of controlled substances belonging to persons registered under this section, see [18 USCA § 2118](#).

CODE OF FEDERAL REGULATIONS

Administrative policies, practices, and procedures, see [21 CFR § 1316.01 et seq.](#)

Debarment and suspension, drug-free workplace, grants, see [21 CFR § 1404.100 et seq.](#)

General applicability, exceptions, etc., see [21 CFR § 1307.01 et seq.](#)

Mandatory declassification review program, see [21 CFR § 1402.1 et seq.](#)

Registration requirements, see [21 CFR § 1301.01 et seq.](#)

Uniform administrative requirements, grants and cooperative agreements, see [21 CFR § 1403.1 et seq.](#)

LIBRARY REFERENCES

American Digest System

Drugs and Narcotics 12.

RESEARCH REFERENCES

ALR Library

[33 ALR, Fed. 220](#), Federal Criminal Liability of Licensed Physician for Unlawfully Prescribing or Dispensing “Controlled Substance” or Drug in Violation of the Controlled Substances Act ([21 U.S.C.A. §§ 801 et seq.](#))...

[19 ALR, Fed. 736](#), Administrative Inspections and Warrants Under § 510 of Comprehensive Drug Abuse Prevention & Control Act of 1970 ([21 U.S.C.A. § 880](#)).

[51 ALR 4th 235](#), Liability of Hospital or Sanitarium for Negligence of Physician or Surgeon.

[174 ALR 549](#), Interest Necessary to Maintenance of Declaratory Determination of Validity of Statute or Ordinance.

[133 ALR 1140](#), Charge of Illegal Sale of Narcotics or Intoxicating Liquor Predicated Upon Defendant's Issuance of

Prescription Therefor Otherwise Than in the Course of His Professional Practice.

[108 ALR 331](#), Criminal Responsibility of One Who Furnishes Instrumentality of a Kind Ordinarily Used for Legitimate Purposes, With Knowledge that it is to be Used by Another for Criminal Purposes.

[54 ALR 730](#), Constitutionality of Statute Regulating Sale of Poisons, Drugs, or Medicines.

[39 ALR 236](#), Harrison Narcotic Act.

Encyclopedias

[Am. Jur. 2d Drugs and Controlled Substances § 62](#), Requirement, Generally.

[Am. Jur. 2d Drugs and Controlled Substances § 63](#), Who Must Register.

[Am. Jur. 2d Drugs and Controlled Substances § 67](#), Authority Conferred by Registration.

Forms

[Federal Procedural Forms § 31:248](#), Overview.

[Federal Procedural Forms § 31:253](#), When to Apply for Registration.

[Federal Procedural Forms § 31:265](#), Review and Inspection.

Treatises and Practice Aids

[Federal Procedure, Lawyers Edition § 35:667](#), Review and Inspection.

[Federal Procedure, Lawyers Edition § 35:839](#), Prohibited Acts--As Applied to Physicians.

NOTES OF DECISIONS

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[1](#). Prior law

Even when construed as making it unlawful for persons other than those required thereby to register and pay a

special tax to purchase the narcotic drugs therein specified in unstamped paper, Revenue Act 1914, § 1, was not unconstitutional. [U. S. v. Wong Sing, U.S.Utah 1922, 43 S.Ct. 7, 260 U.S. 18, 67 L.Ed. 105.](#)

Revenue Act 1914, § 1, was not limited to importers, manufacturers, dealers, etc., required thereby to register. [U. S. v. Wong Sing, U.S.Utah 1922, 43 S.Ct. 7, 260 U.S. 18, 67 L.Ed. 105.](#)

2. Constitutionality

Statute requiring that physician register separately at each physical location in which he administers controlled substances as a regular part of his professional practice was not unconstitutionally vague as applied to doctors who administered controlled substances at women's clinic; one doctor admitted that he worked approximately eight hours a week at that clinic, and another doctor conceded in deposition that in three of the last four years he earned between \$8,000 and \$11,000 a year from procedures performed in that clinic. [U.S. v. Clinical Leasing Service, Inc., C.A.5 \(La.\) 1991, 930 F.2d 394](#), certiorari denied [112 S.Ct. 188, 502 U.S. 864, 116 L.Ed.2d 149.](#)

Statute requiring registration, at "each principal place of business," of physicians who dispense controlled substances was not unconstitutionally vague by suggesting that physician was only required to register at primary place of business; physician of ordinary means and intelligence would understand that provision applied to each important or consequential place of business where physician distributed controlled substances. [U.S. v. Clinical Leasing Service, Inc., C.A.5 \(La.\) 1991, 925 F.2d 120](#), rehearing denied [930 F.2d 394](#), certiorari denied [112 S.Ct. 188, 502 U.S. 864, 116 L.Ed.2d 149.](#)

Provisions authorizing regulations including regulation limiting registration to persons legally qualified to engage in activities for which registration is sought under laws of jurisdiction in which operations are carried on is valid exercise of congressional power, meeting requirements of substantive due process. [U. S. v. Mosby, C.A.8 \(Mo.\) 1970, 422 F.2d 72](#), certiorari denied [90 S.Ct. 2217, 399 U.S. 914, 26 L.Ed.2d 571.](#)

Former proscription against trafficking, transportation or possession of narcotic drugs in case of failure to register did not violate [U.S.C.A.Const. Amend. 5. Palmer v. U. S., C.A.9 \(Or.\) 1964, 332 F.2d 788. Constitutional Law ↪ 4509\(9\); Internal Revenue ↪ 4241](#)

Controlled Substances Act (CSA) was not unconstitutionally vague as applied to owners and operators of company, who were non-registrants under the CSA, who allegedly used the Internet to sell prescription drugs without legitimate medical purposes and outside the usual course of professional practice; non-registrants had adequate notice of the proscribed conduct, and the CSA did not lend itself to arbitrary enforcement as to non-registrants. [U.S. v. Birbragher, N.D.Iowa 2008, 576 F.Supp.2d 1000. Constitutional Law ↪ 4509\(9\); Controlled Substances ↪ 6](#)

3. Law governing

Whether osteopaths in Georgia are entitled to register and to distribute or administer narcotic, drugs is controlled by applicable Georgia statutes regulating the sale and purchase of narcotic drugs, and, in absence of a decision of the question by the highest judicial tribunal of Georgia, the court of appeals would apply the law as it understood it to be in Georgia. [Georgia Ass'n of Osteopathic Physicians & Surgeons v. Allen, C.C.A.5 \(Ga.\) 1940, 112 F.2d 52.](#)

4. Power of Congress

It is quite reasonable for Congress to authorize only certain persons as handlers of narcotic drugs, and regulation of

drug handling by addicts or former addicts is proper. [U. S. v. Mosby, C.A.8 \(Mo.\) 1970, 422 F.2d 72](#), certiorari denied [90 S.Ct. 2217, 399 U.S. 914, 26 L.Ed.2d 571](#).

5. Dealers

In prosecution for selling narcotics without having registered, fact that defendant was charged under four counts with making four separate sales did not give rise to inference that he was a dealer and therefore required to register. [Walker v. U.S., C.A.9 \(Cal.\) 1949, 176 F.2d 796](#).

6. Osteopaths and physicians


Registration with Attorney General is required for physician to be eligible for medical exception to § 841(a)(1) of this title proscribing distribution, dispensation or possession with intent to distribute or dispense, controlled substance. [U. S. v. King, C.A.9 \(Mont.\) 1978, 587 F.2d 956](#).

Physicians who are registrants under this chapter, and who are guilty of technical violations in their day-to-day dealings with controlled substances in accordance with their professional responsibilities are liable only for penalties provided for in § 842 and 843 of this chapter, but physicians who act without any legitimate medical purpose and beyond course of professional practice are subject to penalties provided by § 841 of this chapter. [U. S. v. Green, C.A.7 \(Ill.\) 1975, 511 F.2d 1062](#), certiorari denied [96 S.Ct. 561, 423 U.S. 1031, 46 L.Ed.2d 404](#), certiorari denied [96 S.Ct. 562, 423 U.S. 1031, 46 L.Ed.2d 405](#).

Michigan chiropractors, who did not have state license to use narcotic drugs, were not entitled to registration. [Kavanagh v. Fowler, C.C.A.6 \(Mich.\) 1945, 146 F.2d 961](#).

Under Ga.Code Ann. § 84-906, classifying “osteopathy” as a nondrug-giving school of medical practice, and construing “practice of medicine” as used in Ga.Code 1933, § 84-901, regulating sale of narcotics, to be limited to prescribing or administering some drug or medicinal substance, or those means of treatment for prevention of disease taught in medical colleges and practiced by medical practitioners, osteopaths in Georgia were not entitled to register with the Collector under § 3220 et seq. of Title 26 [I.R.C.1939]. [Georgia Ass'n of Osteopathic Physicians & Surgeons v. Allen, C.C.A.5 \(Ga.\) 1940, 112 F.2d 52](#).

The Kansas provisions relating to the dispensing of narcotics and to the practice of medicine, surgery, and osteopathy, as construed by the Kansas Supreme Court, prohibit the use, sale, or distribution of narcotic drugs for any purpose by an osteopathic physician, and therefore, it was proper to refuse to recognize osteopathic physicians as “physicians” and to issue licenses to distribute, dispense, give away, or administer narcotic drugs to osteopathic physicians. [Burke v. Kansas State Osteopathic Ass'n, C.C.A.10 \(Kan.\) 1940, 111 F.2d 250](#).

The Controlled Substances Act imposed no duty on pharmaceutical companies that manufactured OxyContin to report physician, who was allegedly inappropriately prescribing OxyContin, to either the police or to licensing authorities. [Labzda v. Purdue Pharma, L.P., S.D.Fla.2003, 292 F.Supp.2d 1346](#). [Products Liability](#)  [46.2](#)

Evidence showed that physicians were regularly engaged in dispensing or administering controlled substances at clinic, and, thus, although physicians were registered to dispense substances at other locations, they violated registration requirements since they were not registered to dispense substances at clinic. [U.S. v. Clinical Leasing Service, Inc., E.D.La.1990, 759 F.Supp. 310](#), affirmed [925 F.2d 120](#), rehearing denied [930 F.2d 394](#), certiorari denied [112 S.Ct. 188, 502 U.S. 864, 116 L.Ed.2d 149](#).

7. Prisoners

Prisoner who had not been licensed or otherwise legally qualified to engage in sale and distribution of narcotics would not have been permitted to register in accordance with provisions requiring registration of those engaged in distribution of narcotics. [Harris v. U. S., S.D.N.Y.1969, 299 F.Supp. 382.](#)

8. Intent

A person who concededly manufactures, or attempts to manufacture, controlled substance without intent to distribute but solely to use as intermediate step in chemical process which contemplates destruction of all illicit substance upon completion of process is subject to punishment if person is not registered by Attorney General for the controlled substance. [U.S. v. Lendmann, C.A.7 \(Ill.\) 1985, 757 F.2d 916.](#)

9. Self-incrimination

Amendments in 1965 to the Federal Food, Drug, and Cosmetic Act, § 301 et seq. of this title, were not unconstitutional because of registration requirements; no element of self-incrimination was involved in legislative abjuration of manufacture or of possession with intent to sell of depressant or stimulant drugs by unregistered person. [U. S. v. Shipstead, C.A.9 \(Or.\) 1970, 433 F.2d 368.](#)

Prior provisions under the internal revenue laws requiring declaration, registration, and invoicing for legal possession of marihuana did not violate constitutional privilege against self-incrimination. [U. S. v. Avey, C.A.9 \(Ariz.\) 1970, 428 F.2d 1159](#), certiorari denied [91 S.Ct. 140, 400 U.S. 903, 27 L.Ed.2d 139.](#)

Former § 360a and § 331 of this title for control of LSD manufacturing did not wrongfully force self-incrimination of defendants who were prosecuted for illegally manufacturing LSD notwithstanding their contention that direct consequence of federal registration would have been that federal agents would inform state law officers of defendants' activities and state would initiate prosecutions, where defendants' failure to register did not subject them to penalty or lead to their arrest on the manufacturing charges. [U. S. v. Stanley, C.A.9 \(Cal.\) 1970, 427 F.2d 1066](#), certiorari granted in part , vacated in part [91 S.Ct. 234, 400 U.S. 936, 27 L.Ed.2d 242](#), on remand [446 F.2d 374.](#)

As an illicit consumer of marijuana, defendant, charged with conspiracy was not entitled to register and, thus, could not be incriminated by a disclosure obligation which did not apply to him. [U. S. v. Young, C.A.8 \(Minn.\) 1970, 422 F.2d 302](#), certiorari denied [90 S.Ct. 1718, 398 U.S. 914, 26 L.Ed.2d 78.](#)

Even if those involved in illicit marijuana activity could register, registration would not necessarily be incriminating since there can be and are legitimate registrants, such as physicians, veterinarians, research personnel, and certain importers. [U. S. v. Young, C.A.8 \(Minn.\) 1970, 422 F.2d 302](#), certiorari denied [90 S.Ct. 1718, 398 U.S. 914, 26 L.Ed.2d 78.](#)

Fact that act of declaring marijuana and registering might subject importer to prosecution by state for possession of marijuana in that part of state between border and customs office and that importer who imported marijuana for a legal use would be furnishing evidence to be used in event he should use marijuana for purposes not licensed under state law was not sufficient to create rights under [U.S.C.A.Const. Amend. 5](#) and deprive United States of its right to know what crosses border or to impose conditions upon admission to United States of foreign goods. [U. S. v. King, S.D.Cal.1969, 307 F.Supp. 217](#), affirmed [430 F.2d 1177](#), certiorari denied [91 S.Ct. 972, 401 U.S. 962, 28 L.Ed.2d](#)

[247.](#)

21 U.S.C.A. § 822, 21 USCA § 822

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