United States Code Annotated Currentness
Title 21. Food and Drugs (Refs & Annos)
Chapter 13. Drug Abuse Prevention and Control (Refs & Annos)

§ 827. Records and reports of registrants

(a) Inventory

Except as provided in subsection (c) of this section--

(1) every registrant under this subchapter shall, on May 1, 1971, or as soon thereafter as such registrant first engages in the manufacture, distribution, or dispensing of controlled substances, and every second year thereafter, make a complete and accurate record of all stocks thereof on hand, except that the regulations prescribed under this section shall permit each such biennial inventory (following the initial inventory required by this paragraph) to be prepared on such registrant's regular general physical inventory date (if any) which is nearest to and does not vary by more than six months from the biennial date that would otherwise apply;

(2) on the effective date of each regulation of the Attorney General controlling a substance that immediately prior to such date was not a controlled substance, each registrant under this subchapter manufacturing, distributing, or dispensing such substance shall make a complete and accurate record of all stocks thereof on hand; and

(3) on and after May 1, 1971, every registrant under this subchapter manufacturing, distributing, or dispensing a controlled substance or substances shall maintain, on a current basis, a complete and accurate record of each such substance manufactured, received, sold, delivered, or otherwise disposed of by him, except that this paragraph shall not require the maintenance of a perpetual inventory.

(b) Availability of records

Every inventory or other record required under this section (1) shall be in accordance with, and contain such relevant information as may be required by, regulations of the Attorney General, (2) shall (A) be maintained separately from all other records of the registrant, or (B) alternatively, in the case of nonnarcotic controlled substances, be in such form that information required by the Attorney General is readily retrievable from the ordinary business records of the registrant, and (3) shall be kept and be available, for at least two years, for inspection and copying by officers or employees of the United States authorized by the Attorney General.

(c) Nonapplicability

The foregoing provisions of this section shall not apply--

(1)(A) to the prescribing of controlled substances in schedule II, III, IV, or V by practitioners acting in the lawful course of their professional practice unless such substance is prescribed in the course of maintenance or detoxification treatment of an individual; or

(B) to the administering of a controlled substance in schedule II, III, IV, or V unless the practitioner regularly engages in the dispensing or administering of controlled substances and charges his patients, either separately or together with charges for other professional services, for substances so dispensed or administered or unless such substance is administered in the course of maintenance treatment or detoxification treatment of an individual;

(2)(A) to the use of controlled substances, at establishments registered under this subchapter which keep records

with respect to such substances, in research conducted in conformity with an exemption granted under section 355(i) or 360b(j) of this title;

(B) to the use of controlled substances, at establishments registered under this subchapter which keep records with respect to such substances, in preclinical research or in teaching; or

(3) to the extent of any exemption granted to any person, with respect to all or part of such provisions, by the Attorney General by or pursuant to regulation on the basis of a finding that the application of such provisions (or part thereof) to such person is not necessary for carrying out the purposes of this subchapter.

Nothing in the Convention on Psychotropic Substances shall be construed as superseding or otherwise affecting the provisions of paragraph (1)(B), (2), or (3) of this subsection.

(d)(1) Every manufacturer registered under section 823 of this title shall, at such time or times and in such form as the Attorney General may require, make periodic reports to the Attorney General of every sale, delivery or other disposal by him of any controlled substance, and each distributor shall make such reports with respect to narcotic controlled substances, identifying by the registration number assigned under this subchapter the person or establishment (unless exempt from registration under section 822(d) of this title) to whom such sale, delivery, or other disposal was made.

(2) Each pharmacy with a modified registration under section 823(f) of this title that authorizes the dispensing of controlled substances by means of the Internet shall report to the Attorney General the controlled substances it dispenses, in the amount specified, and in such time and manner as the Attorney General by regulation shall require, except that the Attorney General, under this paragraph, may not require any pharmacy to report any information other than the total quantity of each controlled substance that the pharmacy has dispensed each month. For purposes of this paragraph, no reporting shall be required unless the pharmacy has met 1 of the following thresholds in the month for which the reporting is required:

(A) 100 or more prescriptions dispensed.

(B) 5,000 or more dosage units of all controlled substances combined.

(e) Reporting and recordkeeping requirements of drug conventions

In addition to the reporting and recordkeeping requirements under any other provision of this subchapter, each manufacturer registered under section 823 of this title shall, with respect to narcotic and nonnarcotic controlled substances manufactured by it, make such reports to the Attorney General, and maintain such records, as the Attorney General may require to enable the United States to meet its obligations under articles 19 and 20 of the Single Convention on Narcotic Drugs and article 16 of the Convention on Psychotropic Substances. The Attorney General shall administer the requirements of this subsection in such a manner as to avoid the unnecessary imposition of duplicative requirements under this subchapter on manufacturers subject to the requirements of this subsection.

(f) Investigational uses of drugs; procedures

Regulations under sections 355(i) and 360(j) of this title, relating to investigational use of drugs, shall include such procedures as the Secretary, after consultation with the Attorney General, determines are necessary to insure the security and accountability of controlled substances used in research to which such regulations apply.

(g) Change of address

Every registrant under this subchapter shall be required to report any change of professional or business address in such manner as the Attorney General shall by regulation require.

(h) Reporting requirements for GHB

In the case of a drug product containing gamma hydroxybutyric acid for which an application has been approved under section 355 of this title, the Attorney General may, in addition to any other requirements that apply under this section with respect to such a drug product, establish any of the following as reporting requirements:

(1) That every person who is registered as a manufacturer of bulk or dosage form, as a packager, repackager, labeler, relabeler, or distributor shall report acquisition and distribution transactions quarterly, not later than the 15th day of the month succeeding the quarter for which the report is submitted, and annually report end-of-year inventories.

(2) That all annual inventory reports shall be filed no later than January 15 of the year following that for which the report is submitted and include data on the stocks of the drug product, drug substance, bulk drug, and dosage forms on hand as of the close of business December 31, indicating whether materials reported are in storage or in process of manufacturing.

(3) That every person who is registered as a manufacturer of bulk or dosage form shall report all manufacturing transactions both inventory increases, including purchases, transfers, and returns, and reductions from inventory, including sales, transfers, theft, destruction, and seizure, and shall provide data on material manufactured, manufactured from other material, use in manufacturing other material, and use in manufacturing dosage forms.

(4) That all reports under this section must include the registered person's registration number as well as the registration numbers, names, and other identifying information of vendors, suppliers, and customers, sufficient to allow the Attorney General to track the receipt and distribution of the drug.

(5) That each dispensing practitioner shall maintain for each prescription the name of the prescribing practitioner, the prescribing practitioner's Federal and State registration numbers, with the expiration dates of these registrations, verification that the prescribing practitioner possesses the appropriate registration to prescribe this controlled substance, the patient's name and address, the name of the patient's insurance provider and documentation by a medical practitioner licensed and registered to prescribe the drug of the patient's medical need for the drug. Such information shall be available for inspection and copying by the Attorney General.

(6) That section 830(b)(3) of this title (relating to mail order reporting) applies with respect to gamma hydroxybutyric acid to the same extent and in the same manner as such section applies with respect to the chemicals and drug products specified in subparagraph (A)(i) of such section.

CREDIT(S)

(Pub.L. 91-513, Title II, § 307, Oct. 27, 1970, 84 Stat. 1258; Pub.L. 93-281, § 5, May 14, 1974, 88 Stat. 125; Pub.L. 95-633, Title I, §§ 104, 110, Nov. 10, 1978, 92 Stat. 3772, 3773; Pub.L. 98-473, Title II, §§ 514, 515, Oct. 12, 1984, 98 Stat. 2074; Pub.L. 106-172, § 4, Feb. 18, 2000, 114 Stat. 9; Pub.L. 110-425, § 3(c), Oct. 15, 2008, 122 Stat. 4824.)

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.

1974 Acts. House Report No. 93-884, see 1974 U.S. Code Cong. and Adm. News, p. 3029.

1978 Acts. House Report No. 95-1193, see 1978 U.S. Code Cong. and Adm. News, p. 9496.

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.

2008 Acts. House Report No. 110-869(Part I), see 2008 U.S. Code Cong. and Adm. News, p. 2130.

References in Text

"This subchapter", referred to in subsecs. (a), (c)(2), (3), (d) and (e), 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 volume.

Schedules II, III, IV, and V, referred to in subsec. (c)(1), are set out in § 812(c) of this title.

Amendments

2008 Amendments. Subsec. (d)(1). Pub.L. 110-425, § 3(c)(1), struck "**(d)** Every" and inserted **(d)(1)** Every".

Subsec. (d)(2). Pub.L. 110-425, § 3(c)(2), added par. (2).

2000 Amendments. Subsec. (h). Pub.L. 106-172, § 4, added subsec. (h).

1984 Amendments. Subsec. (c)(1)(A). Pub.L. 98-473, § 514(a), substituted "to the prescribing of controlled substances in schedule II, III, IV, or V by practitioners acting in the lawful course of their professional practice unless such substance is prescribed in the course of maintenance or detoxification treatment of an individual; or" for "with respect to any narcotic controlled substance in schedule II, III, IV, or V, to the prescribing or administering of such substance by a practitioner in the lawful course of his professional practice unless such substance was prescribed or administered in the course of maintenance treatment or detoxification treatment of an individual; or".

Subsec. (c)(1)(B). Pub.L. 98-473, § 514(b), substituted "to the administering of a controlled substance in schedule II, III, IV, or V unless the practitioner regularly engages in the dispensing or administering of controlled substances and charges his patients, either separately or together with charges for other professional services, for substances so dispensed or administered or unless such substance is administered in the course of maintenance treatment or detoxification treatment of an individual;" for "(B) with respect to nonnarcotic controlled substances in schedule II, III, IV, or V, to any practitioner who dispenses such substances to his patients, unless the practitioner is regularly engaged in charging his patients, either separately or together with charges for other professional services, for substances so dispensed;".

Subsec. (g). Pub.L. 98-473, § 515, added subsec. (g).

1978 Amendments. Subsec. (c). Pub.L. 95-633, § 110, added provision following par. (3) relating to the construction of the Convention on Psychotropic Substances.

Subsec. (e). Pub.L. 95-633 § 104, added subsec. (e). Former subsec. (e) redesignated (f).

Subsec. (f). Pub.L. 95-633 § 104, redesignated former subsec. (e) as (f).

1974 Amendments. Subsec. (c)(1)(A). Pub.L. 93-281 substituted "any narcotic controlled substance" for "narcotic controlled substances" and made section applicable to any narcotic controlled substance prescribed or administered in the course of maintenance treatment or detoxification treatment of an individual.

Effective and Applicability Provisions

2008 Acts. Except as otherwise provided, amendments by Pub.L. 110-425 effective 180 days after Oct. 15, 2008, and for provisions relating to definitions and temporary phase-in of regulations of practice of telemedicine, see Pub.L. 110- 425, § 3(j), set out as a note under 21 U.S.C.A. § 802.

1978 Acts. Amendment by Pub.L. 95-633 effective on the date the Convention on Psychotropic Substances enters into force in the United States [July 15, 1980], see § 112 of Pub.L. 95-633, set out as a note under § 801a 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.

Guidelines and Regulations for Pub.L. 110-425

The Attorney General may promulgate and enforce any rules, regulations, and procedures necessary and appropriate for efficient execution of functions under Pub.L. 110-425 or the amendments made by that Act, and, with the concurrence of the Secretary of Health and Human Services, may promulgate interim rules necessary for implementation of Pub.L. 110-425 prior to its effective date, see Pub.L. 110-425, § 3(k), set out as a note under 21 U.S.C.A. § 802.

Rule of Construction of Pub.L. 110-425 Amendments

Nothing in Pub.L. 110-425 or the amendments made by that Act shall be construed as authorizing, prohibiting, or limiting the use of electronic prescriptions for controlled substances, see Pub.L. 110-425, § 4, set out as a note under 21 U.S.C.A. § 802.

21 U.S.C.A. § 827, 21 USCA § 827

Current through P.L. 111-144 approved 3-2-10