(Pub. L. 112–144, title X, § 1006, July 9, 2012, 126 Stat. 1105.)

Editorial Notes

REFERENCES IN TEXT

Section 1005 of this Act, referred to in par. (1), means section 1005 of Pub. L. 112–144, which amended section 826 of this title.

CODIFICATION

Section was enacted as part of the Food and Drug Administration Safety and Innovation Act, and not as part of the Controlled Substances Act which comprises this subchapter.

Statutory Notes and Related Subsidiaries

DEFINITION OF ''SECRETARY''

The term ''Secretary'' as meaning the Secretary of Health and Human Services, see section 1001(b) of Pub. L. 112–144, set out as an Effect of Notification note under section 356c of this title.

§ 827. Records and reports of registrants

(a) Inventory

Except as provided in subsection (c)—

(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) Periodic reports to Attorney General

(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(g) 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 re-

quire 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) Records and reports of registrants

(1) The Attorney General shall, not less frequently than quarterly, make the following information available to manufacturer and distributor registrants through the Automated Reports and Consolidated Orders System, or any subsequent automated system developed by the Drug Enforcement Administration to monitor selected controlled substances:

(A) The total number of distributor registrants that distribute controlled substances to a pharmacy or practitioner registrant, aggregated by the name and address of each pharmacy and practitioner registrant.

(B) The total quantity and type of opioids distributed, listed by Administration Controlled Substances Code Number, to each pharmacy and practitioner registrant described in subparagraph (A).

(2) The information required to be made available under paragraph (1) shall be made available not later than the 30th day of the first month following the quarter to which the information relates.

(3)(A) All registered manufacturers and distributors shall be responsible for reviewing the information made available by the Attorney General under this subsection.

(B) In determining whether to initiate proceedings under this subchapter against a registered manufacturer or distributor based on the failure of the registrant to maintain effective controls against diversion or otherwise comply with the requirements of this subchapter or the regulations issued thereunder, the Attorney General may take into account that the information made available under this subsection was available to the registrant.

(g) 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.

(h) 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.

(i) 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.

(j) Electronic reporting format

All of the reports required under this section shall be provided in an electronic format.

(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; Pub. L. 115–271, title III, § 3273(a), Oct. 24, 2018, 132 Stat. 3952; Pub. L. 117–215, title I, § 103(b)(1)(D), Dec. 2, 2022, 136 Stat. 2263.)

Editorial Notes

REFERENCES IN TEXT

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

AMENDMENTS

2022—Subsec. (d)(2). Pub. L. 117–215 substituted ''823(g)'' for ''823(f)'' in introductory provisions.

2018—Subsecs. (f) to (i). Pub. L. 115–271, § 3273(a)(1), (2), added subsec. (f) and redesignated former subsecs. (f) to (h) as (g) to (i), respectively.

Subsec. (j). Pub. L. 115–271, § 3273(a)(3), added subsec. (j).

2008—Subsec. (d). Pub. L. 110–425 designated existing provisions as par. (1) and added par. (2).

2000—Subsec. (h). Pub. L. 106–172 added subsec. (h).

1984—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'' 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''.

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 ''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—Subsec. (c). Pub. L. 95–633, § 110, inserted provision following par. (3) relating to the construction of the Convention on Psychotropic Substances.

Subsecs. (e), (f). Pub. L. 95–633 added subsec. (e) and redesignated former subsec. (e) as (f).

1974—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.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2008 AMENDMENT

Amendment by Pub. L. 110–425 effective 180 days after Oct. 15, 2008, except as otherwise provided, see section 3(j) of Pub. L. 110–425, set out as a note under section 802 of this title.

EFFECTIVE DATE OF 1978 AMENDMENT

Amendment by Pub. L. 95–633 effective on date the Convention on Psychotropic Substances enters into force in the United States [July 15, 1980], see section 112 of Pub. L. 95–633, set out as an Effective Date note under section 801a of this title.

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.

PURPOSE

Pub. L. 115–271, title III, § 3272, Oct. 24, 2018, 132 Stat. 3952, provided that:

''(a) IN GENERAL.—The purpose of this chapter [see section 3271 of Pub. L. 115–271, set out as a Short Title of 2018 Amendment note under section 801 of this title] is to provide drug manufacturers and distributors with access to anonymized information through the Automated Reports and Consolidated Orders System to help drug manufacturers and distributors identify, report, and stop suspicious orders of opioids and reduce diversion rates.

''(b) RULE OF CONSTRUCTION.—Nothing in this chapter should be construed to absolve a drug manufacturer, drug distributor, or other Drug Enforcement Administration registrant from the responsibility of the manufacturer, distributor, or other registrant to—

''(1) identify, stop, and report suspicious orders; or

''(2) maintain effective controls against diversion in accordance with section 303 of the Controlled Substances Act (21 U.S.C. 823) or any successor law or associated regulation.''

§ 828. Order forms

(a) Unlawful distribution of controlled substances

It shall be unlawful for any person to distribute a controlled substance in schedule I or II to another except in pursuance of a written order of the person to whom such substance is distributed, made on a form to be issued by the Attorney General in blank in accordance with subsection (d) and regulations prescribed by him pursuant to this section.

(b) Nonapplicability of provisions

Nothing in subsection (a) shall apply to—

(1) the exportation of such substances from the United States in conformity with subchapter II;

(2) the delivery of such a substance to or by a common or contract carrier for carriage in the lawful and usual course of its business, or to or by a warehouseman for storage in the lawful and usual course of its business; but where such carriage or storage is in connection with the distribution by the owner of the substance to a third person, this paragraph shall not relieve the distributor from compliance with subsection (a); or