

clude in the final order an explanation of why the public health benefits of increasing the quota clearly outweigh the consequences of having an increased volume of the covered controlled substance available for sale, and potential diversion, in the United States.

(B) Not later than 1 year after October 24, 2018, and every year thereafter, the Attorney General shall submit to the Committee on the Judiciary, the Committee on Health, Education, Labor, and Pensions, and the Committee on Appropriations of the Senate and the Committee on the Judiciary, the Committee on Energy and Commerce, and the Committee on Appropriations of the House of Representatives the following information with regard to each covered controlled substance:

(i) An anonymized count of the total number of manufacturers issued individual manufacturing quotas that year for the covered controlled substance.

(ii) An anonymized count of how many such manufacturers were issued an approved manufacturing quota that was higher than the quota issued to that manufacturer for the covered controlled substance in the previous year.

(3) Not later than 1 year after October 24, 2018, the Attorney General shall submit to Congress a report on how the Attorney General, when fixing and adjusting production and manufacturing quotas under this section for covered controlled substances, will—

(A) take into consideration changes in the accepted medical use of the covered controlled substances; and

(B) work with the Secretary of Health and Human Services on methods to appropriately and anonymously estimate the type and amount of covered controlled substances that are submitted for collection from approved drug collection receptacles, mail-back programs, and take-back events.

(Pub. L. 91–513, title II, §306, Oct. 27, 1970, 84 Stat. 1257; Pub. L. 94–273, §3(16), Apr. 21, 1976, 90 Stat. 377; Pub. L. 109–177, title VII, §713, Mar. 9, 2006, 120 Stat. 264; Pub. L. 112–144, title X, §1005, July 9, 2012, 126 Stat. 1105; Pub. L. 115–271, title III, §3282(a), Oct. 24, 2018, 132 Stat. 3954.)

REFERENCES IN TEXT

Schedules I and II, referred to in text, are set out in section 812(c) of this title.

AMENDMENTS

2018—Subsec. (a). Pub. L. 115–271, §3282(a)(1), designated existing provisions as par. (1), substituted “Except as provided in paragraph (2), production” for “Production” in second sentence, and added par. (2).

Subsec. (b). Pub. L. 115–271, §3282(a)(2), substituted “reduce individual manufacturing” for “reduce individual production”.

Subsec. (c). Pub. L. 115–271, §3282(a)(3), substituted “December” for “October”.

Subsec. (i). Pub. L. 115–271, §3282(a)(4), added subsec. (i).

2012—Subsec. (h). Pub. L. 112–144 added subsec. (h).

2006—Subsec. (a). Pub. L. 109–177, §713(1), inserted “and for ephedrine, pseudoephedrine, and phenylpropanolamine” after “for each basic class of controlled substance in schedules I and II”.

Subsec. (b). Pub. L. 109–177, §713(2), inserted “or for ephedrine, pseudoephedrine, or phenylpropanolamine”

after “for each basic class of controlled substance in schedule I or II”.

Subsec. (c). Pub. L. 109–177, §713(3), inserted “and for ephedrine, pseudoephedrine, and phenylpropanolamine” after “for the basic classes of controlled substances in schedules I and II”.

Subsec. (d). Pub. L. 109–177, §713(4), inserted “or ephedrine, pseudoephedrine, or phenylpropanolamine” after “that basic class of controlled substance”.

Subsec. (e). Pub. L. 109–177, §713(5), inserted “or for ephedrine, pseudoephedrine, or phenylpropanolamine” after “for a basic class of controlled substance in schedule I or II”.

Subsec. (f). Pub. L. 109–177, §713(6), inserted “or ephedrine, pseudoephedrine, or phenylpropanolamine” after “controlled substances in schedules I and II”, “or of ephedrine, pseudoephedrine, or phenylpropanolamine” after “the manufacture of a controlled substance”, and “or chemicals” after “such incidentally produced substances”.

Subsec. (g). Pub. L. 109–177, §713(7), added subsec. (g). 1976—Subsec. (c). Pub. L. 94–273 substituted “October” for “July”.

EFFECTIVE DATE

Section effective on first day of seventh calendar month that begins after Oct. 26, 1970, but with Attorney General authorized to postpone such effective date for such period as he might determine to be necessary for the efficient administration of this subchapter, see section 704(c) of Pub. L. 91–513, set out as a note under section 801 of this title.

CHANGE TO EDITORIAL HEADING IN UNITED STATES CODE

Pub. L. 115–271, title III, §3282(b), Oct. 24, 2018, 132 Stat. 3955, provided that: “The Law Revision Counsel is directed to amend the heading for subsection (b) of section 826 of title 21, United States Code, by striking ‘Production’ and inserting ‘Manufacturing’.”

COORDINATION WITH UNITED STATES TRADE REPRESENTATIVE

Pub. L. 109–177, title VII, §718, Mar. 9, 2006, 120 Stat. 267, provided that: “In implementing sections 713 through 717 and section 721 of this title [amending this section and sections 830, 842, 952, 960, and 971 of this title], the Attorney General shall consult with the United States Trade Representative to ensure implementation complies with all applicable international treaties and obligations of the United States.”

§ 826a. Attorney General report on drug shortages

Not later than 6 months after July 9, 2012, and annually thereafter, the Attorney General shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on the Judiciary of the Senate a report on drug shortages that—

(1) identifies the number of requests received under section 826(h) of this title (as added by section 1005 of this Act), the average review time for such requests, the number of requests granted and denied under such section, and, for each of the requests denied under such section, the basis for such denial;

(2) describes the coordination between the Drug Enforcement Administration and Food and Drug Administration on efforts to prevent or alleviate drug shortages; and

(3) identifies drugs containing a controlled substance subject to section 826 of this title when such a drug is determined by the Secretary to be in shortage.

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

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.

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(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.