

“(2) other health care practitioners and the public on a pharmacist’s ability to decline to fill prescriptions in certain circumstances and a description of those circumstances (as described in the materials developed under subsection (a)(1)).

“(c) STAKEHOLDER INPUT.—In developing the programs and materials required under subsection (a), the Secretary of Health and Human Services shall seek input from relevant national, State, and local associations, boards of pharmacy, medical societies, licensing boards, health care practitioners, and patients, including individuals with chronic pain.”

EFFECT OF SCHEDULING ON PRESCRIPTIONS

Pub. L. 101-647, title XIX, §1902(c), Nov. 29, 1990, 104 Stat. 4852, provided that any prescription for anabolic steroids subject to refill on or after Nov. 29, 1990, could be refilled without restriction under subsec. (a) of this section.

§ 829a. Delivery of a controlled substance by a pharmacy to an administering practitioner

(a) In general

Notwithstanding section 802(10) of this title, a pharmacy may deliver a controlled substance to a practitioner in accordance with a prescription that meets the requirements of this subchapter and the regulations issued by the Attorney General under this subchapter, for the purpose of administering the controlled substance by the practitioner if—

(1) the controlled substance is delivered by the pharmacy to the prescribing practitioner or the practitioner administering the controlled substance, as applicable, at the location listed on the practitioner’s certificate of registration issued under this subchapter;

(2) the controlled substance is to be administered for the purpose of maintenance or detoxification treatment under section 823(g)(2) of this title and—

(A) the practitioner who issued the prescription is a qualifying practitioner authorized under, and acting within the scope of that section; and

(B) the controlled substance is to be administered by injection or implantation;

(3) the pharmacy and the practitioner are authorized to conduct the activities specified in this section under the law of the State in which such activities take place;

(4) the prescription is not issued to supply any practitioner with a stock of controlled substances for the purpose of general dispensing to patients;

(5) except as provided in subsection (b), the controlled substance is to be administered only to the patient named on the prescription not later than 14 days after the date of receipt of the controlled substance by the practitioner; and

(6) notwithstanding any exceptions under section 827 of this title, the prescribing practitioner, and the practitioner administering the controlled substance, as applicable, maintain complete and accurate records of all controlled substances delivered, received, administered, or otherwise disposed of under this section, including the persons to whom controlled substances were delivered and such other information as may be required by regulations of the Attorney General.

(b) Modification of number of days before which controlled substance shall be administered

(1) Initial 2-year period

During the 2-year period beginning on October 24, 2018, the Attorney General, in coordination with the Secretary, may reduce the number of days described in subsection (a)(5) if the Attorney General determines that such reduction will—

(A) reduce the risk of diversion; or

(B) protect the public health.

(2) Modifications after submission of report

After the date on which the report described in section 3204(b) of the SUPPORT for Patients and Communities Act is submitted, the Attorney General, in coordination with the Secretary, may modify the number of days described in subsection (a)(5).

(3) Minimum number of days

Any modification under this subsection shall be for a period of not less than 7 days.

(Pub. L. 91-513, title II, §309A, as added Pub. L. 115-271, title III, §3204(a), Oct. 24, 2018, 132 Stat. 3945.)

Editorial Notes

REFERENCES IN TEXT

Section 3204(b) of the SUPPORT for Patients and Communities Act, referred to in subsec. (b)(2), is section 3204(b) of Pub. L. 115-271, title III, Oct. 24, 2018, 132 Stat. 3946, which is not classified to the Code.

§ 830. Regulation of listed chemicals and certain machines

(a) Record of regulated transactions

(1) Each regulated person who engages in a regulated transaction involving a listed chemical, a tableting machine, or an encapsulating machine shall keep a record of the transaction for two years after the date of the transaction.

(2) A record under this subsection shall be retrievable and shall include the date of the regulated transaction, the identity of each party to the regulated transaction, a statement of the quantity and form of the listed chemical, a description of the tableting machine or encapsulating machine, and a description of the method of transfer. Such record shall be available for inspection and copying by the Attorney General.

(3) It is the duty of each regulated person who engages in a regulated transaction to identify each other party to the transaction. It is the duty of such other party to present proof of identity to the regulated person. The Attorney General shall specify by regulation the types of documents and other evidence that constitute proof of identity for purposes of this paragraph.

(b) Reports to Attorney General

(1) Each regulated person shall report to the Attorney General, in such form and manner as the Attorney General shall prescribe by regulation—

(A) any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed

chemical will be used in violation of this subchapter;

(B) any proposed regulated transaction with a person whose description or other identifying characteristic the Attorney General furnishes in advance to the regulated person;

(C) any unusual or excessive loss or disappearance of a listed chemical under the control of the regulated person; and

(D) any regulated transaction in a tableting machine or an encapsulating machine.

Each report under subparagraph (A) shall be made at the earliest practicable opportunity after the regulated person becomes aware of the circumstance involved. A regulated person may not complete a transaction with a person whose description or identifying characteristic is furnished to the regulated person under subparagraph (B) unless the transaction is approved by the Attorney General. The Attorney General shall make available to regulated persons guidance documents describing transactions and circumstances for which reports are required under subparagraph (A) and subparagraph (C).

(2) A regulated person that manufactures a listed chemical shall report annually to the Attorney General, in such form and manner and containing such specific data as the Attorney General shall prescribe by regulation, information concerning listed chemicals manufactured by the person. The requirement of the preceding sentence shall not apply to the manufacture of a drug product that is exempted under section 802(39)(A)(iv) of this title.

(3) MAIL ORDER REPORTING.—(A) As used in this paragraph:

(i) The term “drug product” means an active ingredient in dosage form that has been approved or otherwise may be lawfully marketed under the Food, Drug, and Cosmetic Act¹ [21 U.S.C. 301 et seq.] for distribution in the United States.

(ii) The term “valid prescription” means a prescription which is issued for a legitimate medical purpose by an individual practitioner licensed by law to administer and prescribe the drugs concerned and acting in the usual course of the practitioner’s professional practice.

(B) Each regulated person who engages in a transaction with a nonregulated person or who engages in an export transaction which—

(i) involves ephedrine, pseudoephedrine, or phenylpropanolamine (including drug products containing these chemicals); and

(ii) uses or attempts to use the Postal Service or any private or commercial carrier;

shall, on a monthly basis, submit a report of each such transaction conducted during the previous month to the Attorney General in such form, containing such data, and at such times as the Attorney General shall establish by regulation.

(C) The data required for such reports shall include—

(i) the name of the purchaser;

(ii) the quantity and form of the ephedrine, pseudoephedrine, or phenylpropanolamine purchased; and

(iii) the address to which such ephedrine, pseudoephedrine, or phenylpropanolamine was sent.

(D) Except as provided in subparagraph (E), the following distributions to a nonregulated person, and the following export transactions, shall not be subject to the reporting requirement in subparagraph (B):

(i) Distributions of sample packages of drug products when such packages contain not more than two solid dosage units or the equivalent of two dosage units in liquid form, not to exceed 10 milliliters of liquid per package, and not more than one package is distributed to an individual or residential address in any 30-day period.

(ii) Distributions of drug products by retail distributors that may not include face-to-face transactions to the extent that such distributions are consistent with the activities authorized for a retail distributor as specified in section 802(49) of this title, except that this clause does not apply to sales of scheduled listed chemical products at retail.

(iii) Distributions of drug products to a resident of a long term care facility (as that term is defined in regulations prescribed by the Attorney General) or distributions of drug products to a long term care facility for dispensing to or for use by a resident of that facility.

(iv) Distributions of drug products pursuant to a valid prescription.

(v) Exports which have been reported to the Attorney General pursuant to section 954 or 971 of this title or which are subject to a waiver granted under section 971(f)(2) of this title.

(vi) Any quantity, method, or type of distribution or any quantity, method, or type of distribution of a specific listed chemical (including specific formulations or drug products) or of a group of listed chemicals (including specific formulations or drug products) which the Attorney General has excluded by regulation from such reporting requirement on the basis that such reporting is not necessary for the enforcement of this subchapter or subchapter II.

(E) The Attorney General may revoke any or all of the exemptions listed in subparagraph (D) for an individual regulated person if he finds that drug products distributed by the regulated person are being used in violation of this subchapter or subchapter II. The regulated person shall be notified of the revocation, which will be effective upon receipt by the person of such notice, as provided in section 971(c)(1) of this title, and shall have the right to an expedited hearing as provided in section 971(c)(2) of this title.

(c) Confidentiality of information obtained by Attorney General; non-disclosure; exceptions

(1) Except as provided in paragraph (2), any information obtained by the Attorney General under this section which is exempt from disclosure under section 552(a) of title 5, by reason of section 552(b)(4) of such title, is confidential and may not be disclosed to any person.

(2) Information referred to in paragraph (1) may be disclosed only—

(A) to an officer or employee of the United States engaged in carrying out this subchapter, subchapter II, or the customs laws;

¹ See References in Text note below.

(B) when relevant in any investigation or proceeding for the enforcement of this subchapter, subchapter II, or the customs laws;

(C) when necessary to comply with an obligation of the United States under a treaty or other international agreement; or

(D) to a State or local official or employee in conjunction with the enforcement of controlled substances laws or chemical control laws.

(3) The Attorney General shall—

(A) take such action as may be necessary to prevent unauthorized disclosure of information by any person to whom such information is disclosed under paragraph (2); and

(B) issue guidelines that limit, to the maximum extent feasible, the disclosure of proprietary business information, including the names or identities of United States exporters of listed chemicals, to any person to whom such information is disclosed under paragraph (2).

(4) Any person who is aggrieved by a disclosure of information in violation of this section may bring a civil action against the violator for appropriate relief.

(5) Notwithstanding paragraph (4), a civil action may not be brought under such paragraph against investigative or law enforcement personnel of the Drug Enforcement Administration.

(d) Scheduled listed chemicals; restrictions on sales quantity; requirements regarding non-liquid forms

With respect to ephedrine base, pseudoephedrine base, or phenylpropanolamine base in a scheduled listed chemical product—

(1) the quantity of such base sold at retail in such a product by a regulated seller, or a distributor required to submit reports by subsection (b)(3) may not, for any purchaser, exceed a daily amount of 3.6 grams, without regard to the number of transactions; and

(2) such a seller or distributor may not sell such a product in nonliquid form (including gel caps) at retail unless the product is packaged in blister packs, each blister containing not more than 2 dosage units, or where the use of blister packs is technically infeasible, the product is packaged in unit dose packets or pouches.

(e) Scheduled listed chemicals; behind-the-counter access; logbook requirement; training of sales personnel; privacy protections

(1) Requirements regarding retail transactions

(A) In general

Each regulated seller shall ensure that, subject to subparagraph (F), sales by such seller of a scheduled listed chemical product at retail are made in accordance with the following:

(i) In offering the product for sale, the seller places the product such that customers do not have direct access to the product before the sale is made (in this paragraph referred to as “behind-the-counter” placement). For purposes of this paragraph, a behind-the-counter placement of a product includes circumstances

in which the product is stored in a locked cabinet that is located in an area of the facility involved to which customers do have direct access.

(ii) The seller delivers the product directly into the custody of the purchaser.

(iii) The seller maintains, in accordance with criteria issued by the Attorney General, a written or electronic list of such sales that identifies the products by name, the quantity sold, the names and addresses of purchasers, and the dates and times of the sales (which list is referred to in this subsection as the “logbook”), except that such requirement does not apply to any purchase by an individual of a single sales package if that package contains not more than 60 milligrams of pseudoephedrine.

(iv) In the case of a sale to which the requirement of clause (iii) applies, the seller does not sell such a product unless the sale is made in accordance with the following:

(I) The prospective purchaser—

(aa) presents an identification card that provides a photograph and is issued by a State or the Federal Government, or a document that, with respect to identification, is considered acceptable for purposes of sections 274a.2(b)(1)(v)(A) and 274a.2(b)(1)(v)(B) of title 8, Code of Federal Regulations (as in effect on or after March 9, 2006); and

(bb) signs the written logbook and enters in the logbook his or her name, address, and the date and time of the sale, or for transactions involving an electronic logbook, the purchaser provides a signature using one of the following means:

(AA) Signing a device presented by the seller that captures signatures in an electronic format. Such device shall display the notice described in clause (v). Any device used shall preserve each signature in a manner that clearly links that signature to the other electronically-captured logbook information relating to the prospective purchaser providing that signature.

(BB) Signing a bound paper book. Such bound paper book shall include, for such purchaser, either (aaa) a printed sticker affixed to the bound paper book at the time of sale which either displays the name of each product sold, the quantity sold, the name and address of the purchaser, and the date and time of the sale, or a unique identifier which can be linked to that electronic information, or (bbb) a unique identifier which can be linked to that information and which is written into the book by the seller at the time of sale. The purchaser shall sign adjacent to the printed sticker or written unique identifier related to that sale. Such bound paper book shall display the notice described in clause (v).

(CC) Signing a printed document that includes, for such purchaser, the name of each product sold, the quantity sold, the name and address of the purchaser, and the date and time of the sale. Such document shall be printed by the seller at the time of the sale. Such document shall contain a clearly identified signature line for a purchaser to sign. Such printed document shall display the notice described in clause (v). Each signed document shall be inserted into a binder or other secure means of document storage immediately after the purchaser signs the document.

(II) The seller enters in the logbook the name of the product and the quantity sold. Such information may be captured through electronic means, including through electronic data capture through bar code reader or similar technology.

(III) The logbook maintained by the seller includes the prospective purchaser's name, address, and the date and time of the sale, as follows:

(aa) If the purchaser enters the information, the seller must determine that the name entered in the logbook corresponds to the name provided on such identification and that the date and time entered are correct.

(bb) If the seller enters the information, the prospective purchaser must verify that the information is correct.

(cc) Such information may be captured through electronic means, including through electronic data capture through bar code reader or similar technology.

(v) The written or electronic logbook includes, in accordance with criteria of the Attorney General, a notice to purchasers that entering false statements or misrepresentations in the logbook, or supplying false information or identification that results in the entry of false statements or misrepresentations, may subject the purchasers to criminal penalties under section 1001 of title 18, which notice specifies the maximum fine and term of imprisonment under such section.

(vi) Regardless of whether the logbook entry is written or electronic, the seller maintains each entry in the logbook for not fewer than 2 years after the date on which the entry is made.

(vii) In the case of individuals who are responsible for delivering such products into the custody of purchasers or who deal directly with purchasers by obtaining payments for the products, the seller has submitted to the Attorney General a self-certification that all such individuals have, in accordance with criteria under subparagraph (B)(ii), undergone training provided by the seller to ensure that the individuals understand the requirements that apply under this subsection and subsection (d).

(viii) The seller maintains a copy of such certification and records demonstrating that individuals referred to in clause (vii) have undergone the training.

(ix) If the seller is a mobile retail vendor:

(I) The seller complies with clause (i) by placing the product in a locked cabinet.

(II) The seller does not sell more than 7.5 grams of ephedrine base, pseudoephedrine base, or phenylpropanolamine base in such products per customer during a 30-day period.

(B) Additional provisions regarding certifications and training

(i) In general

A regulated seller may not sell any scheduled listed chemical product at retail unless the seller has submitted to the Attorney General the self-certification referred to in subparagraph (A)(vii). The certification is not effective for purposes of the preceding sentence unless, in addition to provisions regarding the training of individuals referred to in such subparagraph, the certification includes a statement that the seller understands each of the requirements that apply under this paragraph and under subsection (d) and agrees to comply with the requirements.

(ii) Issuance of criteria; self-certification

The Attorney General shall by regulation establish criteria for certifications under this paragraph. The criteria shall—

(I) provide that the certifications are self-certifications provided through the program under clause (iii);

(II) provide that a separate certification is required for each place of business at which a regulated seller sells scheduled listed chemical products at retail; and

(III) include criteria for training under subparagraph (A)(vii).

(iii) Program for regulated sellers

The Attorney General shall establish a program regarding such certifications and training in accordance with the following:

(I) The program shall be carried out through an Internet site of the Department of Justice and such other means as the Attorney General determines to be appropriate.

(II) The program shall inform regulated sellers that section 1001 of title 18 applies to such certifications.

(III) The program shall make available to such sellers an explanation of the criteria under clause (ii).

(IV) The program shall be designed to permit the submission of the certifications through such Internet site.

(V) The program shall be designed to automatically provide the explanation referred to in subclause (III), and an acknowledgement that the Department has received a certification, without requiring direct interactions of regulated sell-

ers with staff of the Department (other than the provision of technical assistance, as appropriate).

(iv) Availability of certification to State and local officials

Promptly after receiving a certification under subparagraph (A)(vii), the Attorney General shall make available a copy of the certification to the appropriate State and local officials.

(v) Publication of list of self-certified persons

The Attorney General shall develop and make available a list of all persons who are currently self-certified in accordance with this section. This list shall be made publicly available on the website of the Drug Enforcement Administration in an electronically downloadable format.

(C) Privacy protections

In order to protect the privacy of individuals who purchase scheduled listed chemical products, the Attorney General shall by regulation establish restrictions on disclosure of information in logbooks under subparagraph (A)(iii). Such regulations shall—

(i) provide for the disclosure of the information as appropriate to the Attorney General and to State and local law enforcement agencies; and

(ii) prohibit accessing, using, or sharing information in the logbooks for any purpose other than to ensure compliance with this subchapter or to facilitate a product recall to protect public health and safety.

(D) False statements or misrepresentations by purchasers

For purposes of section 1001 of title 18, entering information in the logbook under subparagraph (A)(iii) shall be considered a matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States.

(E) Good faith protection

A regulated seller who in good faith releases information in a logbook under subparagraph (A)(iii) to Federal, State, or local law enforcement authorities is immune from civil liability for such release unless the release constitutes gross negligence or intentional, wanton, or willful misconduct.

(F) Inapplicability of requirements to certain sales

Subparagraph (A) does not apply to the sale at retail of a scheduled listed chemical product if a report on the sales transaction is required to be submitted to the Attorney General under subsection (b)(3).

(G) Certain measures regarding theft and diversion

A regulated seller may take reasonable measures to guard against employing individuals who may present a risk with respect to the theft and diversion of scheduled listed chemical products, which may include, notwithstanding State law, asking applicants

for employment whether they have been convicted of any crime involving or related to such products or controlled substances.

(2) Mail-order reporting; verification of identity of purchaser; 30-day restriction on quantities for individual purchasers

Each regulated person who makes a sale at retail of a scheduled listed chemical product and is required under subsection (b)(3) to submit a report of the sales transaction to the Attorney General is subject to the following:

(A) The person shall, prior to shipping the product, confirm the identity of the purchaser in accordance with procedures established by the Attorney General. The Attorney General shall by regulation establish such procedures.

(B) The person may not sell more than 7.5 grams of ephedrine base, pseudoephedrine base, or phenylpropanolamine base in such products per customer during a 30-day period.

(C) Each regulated person who makes a sale at retail of a scheduled listed chemical product and is required under subsection (b)(3) to submit a report of the sales transaction to the Attorney General may not sell any scheduled listed chemical product at retail unless such regulated person has submitted to the Attorney General a self-certification including a statement that the seller understands each of the requirements that apply under this paragraph and under subsection (d) and agrees to comply with the requirements. The Attorney General shall by regulation establish criteria for certifications of mail-order distributors that are consistent with the criteria established for the certifications of regulated sellers under paragraph (1)(B).

(3) Exemptions for certain products

Upon the application of a manufacturer of a scheduled listed chemical product, the Attorney General may by regulation provide that the product is exempt from the provisions of subsection (d) and paragraphs (1) and (2) of this subsection if the Attorney General determines that the product cannot be used in the illicit manufacture of methamphetamine.

(Pub. L. 91-513, title II, §310, as added Pub. L. 95-633, title II, §202(a), Nov. 10, 1978, 92 Stat. 3774; amended Pub. L. 100-690, title VI, §6052(a), Nov. 18, 1988, 102 Stat. 4312; Pub. L. 103-200, §§2(c), 10, Dec. 17, 1993, 107 Stat. 2336, 2341; Pub. L. 104-237, title II, §208, title IV, §402, Oct. 3, 1996, 110 Stat. 3104, 3111; Pub. L. 106-310, div. B, title XXXVI, §3652, Oct. 17, 2000, 114 Stat. 1239; Pub. L. 109-177, title VII, §§711(a)(2)(B), (b)(1), (c)(1), (2), (d), 716(b)(2), Mar. 9, 2006, 120 Stat. 257, 261, 267; Pub. L. 110-415, §2, Oct. 14, 2008, 122 Stat. 4349; Pub. L. 111-268, §§2, 3, Oct. 12, 2010, 124 Stat. 2847.)

Editorial Notes

REFERENCES IN TEXT

The Food, Drug, and Cosmetic Act, referred to in subsection (b)(3)(A)(i), probably means the Federal Food, Drug, and Cosmetic Act, act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§301 et seq.) of this title. For complete classification of

this Act to the Code, see section 301 of this title and Tables.

This subchapter, referred to in subsecs. (b)(3)(D)(vi), (E) and (e)(1)(C)(ii), 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. (b)(3)(D)(iv), (E) and (c)(2)(A), (B), 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

2010—Subsec. (e)(1)(B)(v). Pub. L. 111-268, §3, added cl. (v).

Subsec. (e)(2)(C). Pub. L. 111-268, §2, added subpar. (C).

2008—Subsec. (e)(1)(A)(iv) to (vi). Pub. L. 110-415 added cls. (iv) to (vi) and struck out former cls. (iv) to (vi) which related to procedures for sales subject to the logbook requirement.

2006—Subsec. (b)(3)(D)(ii). Pub. L. 109-177, §711(c)(2), inserted “, except that this clause does not apply to sales of scheduled listed chemical products at retail” before period at end.

Pub. L. 109-177, §711(a)(2)(B), substituted “section 802(49)” for “section 802(46)”.

Subsec. (b)(3)(D)(v). Pub. L. 109-177, §716(b)(2), substituted “section 971(f)(2)” for “section 971(e)(2)”.

Subsec. (d). Pub. L. 109-177, §711(b)(1), added subsec. (d).

Subsec. (e)(1). Pub. L. 109-177, §711(b)(1), added subsec. heading and par. (1).

Subsec. (e)(2). Pub. L. 109-177, §711(c)(1), added par. (2).

Subsec. (e)(3). Pub. L. 109-177, §711(d), added par. (3).

2000—Subsec. (b)(3). Pub. L. 106-310 added subpars. (A), (D), and (E), redesignated former subpars. (A) and (B) as (B) and (C), respectively, and inserted “or who engages in an export transaction” after “nonregulated person” in introductory provisions of subpar. (B).

1996—Subsec. (a)(1). Pub. L. 104-237, §208, substituted “for two years after the date of the transaction.” for the dash after “record of the transaction” and struck out subpars. (A) and (B) which read as follows:

“(A) for 4 years after the date of the transaction, if the listed chemical is a list I chemical or if the transaction involves a tableting machine or an encapsulating machine; and

“(B) for 2 years after the date of the transaction, if the listed chemical is a list II chemical.”

Subsec. (b)(3). Pub. L. 104-237, §402, added par. (3).

1993—Subsec. (a)(1). Pub. L. 103-200, §2(c)(1), substituted “list I chemical” for “precursor chemical” in subpar. (A) and “a list II chemical” for “an essential chemical” in subpar. (B).

Subsec. (b). Pub. L. 103-200, §10, designated existing provisions as par. (1), redesignated former pars. (1) to (4) as subpars. (A) to (D), respectively, in concluding provisions, substituted “subparagraph (A)” for “paragraph (1)” in two places, “subparagraph (B)” for “paragraph (2)”, and “subparagraph (C)” for “paragraph (3)”, and added par. (2).

Subsec. (c)(2)(D). Pub. L. 103-200, §2(c)(2), substituted “chemical control laws” for “precursor chemical laws”.

1988—Pub. L. 100-690 amended section generally, substituting provisions relating to regulation of listed chemicals and certain machines for provisions relating to reporting by any person who distributes, sells, or imports any piperidine.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2010 AMENDMENT

Pub. L. 111-268, §6(a), Oct. 12, 2010, 124 Stat. 2848, provided that: “This Act [amending this section and sec-

tion 842 of this title and enacting provisions set out as notes under this section and section 801 of this title] and the amendments made by this Act shall take effect 180 days after the date of enactment of this Act [Oct. 12, 2010].”

EFFECTIVE DATE OF 2006 AMENDMENT

Pub. L. 109-177, title VII, §711(b)(2), Mar. 9, 2006, 120 Stat. 261, provided that: “With respect to subsections (d) and (e)(1) of section 310 of the Controlled Substances Act [21 U.S.C. 830(d), (e)(1)], as added by paragraph (1) of this subsection:

“(A) Such subsection (d) applies on and after the expiration of the 30-day period beginning on the date of the enactment of this Act [Mar. 9, 2006].

“(B) Such subsection (e)(1) applies on and after September 30, 2006.”

Pub. L. 109-177, title VII, §711(c)(3), Mar. 9, 2006, 120 Stat. 261, provided that: “The amendments made by paragraphs (1) and (2) [amending this section] apply on and after the expiration of the 30-day period beginning on the date of the enactment of this Act [Mar. 9, 2006].”

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 1988 AMENDMENT

Amendment by Pub. L. 100-690 effective 120 days after Nov. 18, 1988, see section 6061 of Pub. L. 100-690, set out as a note under section 802 of this title.

EFFECTIVE DATE; TIME TO SUBMIT PIPERIDINE REPORT; REQUIRED INFORMATION

Pub. L. 95-633, title II, §203(a), Nov. 10, 1978, 92 Stat. 3776, provided that:

“(1) Except as provided under paragraph (2), the amendments made by this title [enacting this section and amending sections 841 to 843 of this title] shall take effect on the date of the enactment of this Act [Nov. 10, 1978].

“(2) Any person required to submit a report under section 310(a)(1) of the Controlled Substances Act [subsec. (a)(1) of this section] respecting a distribution, sale, or importation of piperidine during the 90 days after the date of the enactment of this Act [Nov. 10, 1978] may submit such report any time up to 97 days after such date of enactment.

“(3) Until otherwise provided by the Attorney General by regulation, the information required to be reported by a person under section 310(a)(1) of the Controlled Substances Act (as added by section 202(a)(2) of this title) [subsec. (a)(1) of this section] with respect to the person’s distribution, sale, or importation of piperidine shall—

“(A) be the information described in subparagraphs (A) and (B) of such section, and

“(B) except as provided in paragraph (2) of this subsection, be reported not later than seven days after the date of such distribution, sale, or importation.”

REPEALS

Pub. L. 96-359, §8(b), Sept. 26, 1980, 94 Stat. 1194, repealed section 203(d) of Pub. L. 95-633, which had provided for the repeal of this section effective Jan. 1, 1981.

REGULATIONS

Pub. L. 111-268, §6(b), Oct. 12, 2010, 124 Stat. 2848, provided that: “In promulgating the regulations authorized by section 2 [amending this section], the Attorney General may issue regulations on an interim basis as necessary to ensure the implementation of this Act by the effective date [see Effective Date of 2010 Amendment note above].”

Pub. L. 95-633, title II, §203(b), Nov. 10, 1978, 92 Stat. 3777, required the Attorney General to publish proposed interim regulations for piperidine reporting under sec-

tion 830(a) of this title not later than 30 days after enactment, and final interim regulations not later than 75 days after enactment, such final interim regulations to be effective on and after the ninety-first day after enactment.

REPORT TO PRESIDENT AND CONGRESS ON
EFFECTIVENESS OF TITLE II OF PUB. L. 95-633

Pub. L. 95-633, title II, §203(c), Nov. 10, 1978, 92 Stat. 3777, required the Attorney General to analyze and evaluate the impact and effectiveness of the amendments made by title II of Pub. L. 95-633, and report to the President and Congress not later than Mar. 1, 1980.

§ 831. Additional requirements relating to online pharmacies and telemedicine

(a) In general

An online pharmacy shall display in a visible and clear manner on its homepage a statement that it complies with the requirements of this section with respect to the delivery or sale or offer for sale of controlled substances and shall at all times display on the homepage of its Internet site a declaration of compliance in accordance with this section.

(b) Licensure

Each online pharmacy shall comply with the requirements of State law concerning the licensure of pharmacies in each State from which it, and in each State to which it, delivers, distributes, or dispenses or offers to deliver, distribute, or dispense controlled substances by means of the Internet, pursuant to applicable licensure requirements, as determined by each such State.

(c) Internet pharmacy site disclosure information

Each online pharmacy shall post in a visible and clear manner on the homepage of each Internet site it operates, or on a page directly linked thereto in which the hyperlink is also visible and clear on the homepage, the following information for each pharmacy that delivers, distributes, or dispenses controlled substances pursuant to orders made on, through, or on behalf of, that website:

(1) The name and address of the pharmacy as it appears on the pharmacy's Drug Enforcement Administration certificate of registration.

(2) The pharmacy's telephone number and email address.

(3) The name, professional degree, and States of licensure of the pharmacist-in-charge, and a telephone number at which the pharmacist-in-charge can be contacted.

(4) A list of the States in which the pharmacy is licensed to dispense controlled substances.

(5) A certification that the pharmacy is registered under this part to deliver, distribute, or dispense by means of the Internet controlled substances.

(6) The name, address, telephone number, professional degree, and States of licensure of any practitioner who has a contractual relationship to provide medical evaluations or issue prescriptions for controlled substances, through referrals from the website or at the request of the owner or operator of the website, or any employee or agent thereof.

(7) The following statement, unless revised by the Attorney General by regulation: "This online pharmacy will only dispense a controlled substance to a person who has a valid prescription issued for a legitimate medical purpose based upon a medical relationship with a prescribing practitioner. This includes at least one prior in-person medical evaluation or medical evaluation via telemedicine in accordance with applicable requirements of section 309."

(d) Notification

(1) In general

Thirty days prior to offering a controlled substance for sale, delivery, distribution, or dispensing, the online pharmacy shall notify the Attorney General, in such form and manner as the Attorney General shall determine, and the State boards of pharmacy in any States in which the online pharmacy offers to sell, deliver, distribute, or dispense controlled substances.

(2) Contents

The notification required under paragraph (1) shall include—

(A) the information required to be posted on the online pharmacy's Internet site under subsection (c) and shall notify the Attorney General and the applicable State boards of pharmacy, under penalty of perjury, that the information disclosed on its Internet site under subsection (c) is true and accurate;

(B) the online pharmacy's Internet site address and a certification that the online pharmacy shall notify the Attorney General of any change in the address at least 30 days in advance; and

(C) the Drug Enforcement Administration registration numbers of any pharmacies and practitioners referred to in subsection (c), as applicable.

(3) Existing online pharmacies

An online pharmacy that is already operational as of the effective date of this section, shall notify the Attorney General and applicable State boards of pharmacy in accordance with this subsection not later than 30 days after such date.

(e) Declaration of compliance

On and after the date on which it makes the notification under subsection (d), each online pharmacy shall display on the homepage of its Internet site, in such form as the Attorney General shall by regulation require, a declaration that it has made such notification to the Attorney General.

(f) Reports

Any statement, declaration, notification, or disclosure required under this section shall be considered a report required to be kept under this part.

(g) Notice and designations concerning Indian tribes

(1) In general

For purposes of sections 802(52) and 882(c)(6)(B) of this title, the Secretary shall