

missioner of Food and Drugs, Director of the Centers for Disease Control and Prevention, and Assistant Secretary for Mental Health and Substance Use, shall develop and disseminate not later than 1 year after the date of enactment of the Restoring Hope for Mental Health and Well-Being Act of 2022 [Dec. 29, 2022], and update periodically thereafter, as appropriate, materials for pharmacists, health care providers, and patients on—

“(1) circumstances under which a pharmacist may, consistent with section 309 of the Controlled Substances Act (21 U.S.C. 829) and regulations thereunder, including section 1306.04 of title 21, Code of Federal Regulations, decline to fill a prescription for a controlled substance because the pharmacist suspects the prescription is fraudulent, forged, or of doubtful, questionable, or suspicious origin; and

“(2) other Federal requirements pertaining to declining to fill a prescription under such circumstances, including the partial fill of prescriptions for certain controlled substances.

“(b) MATERIALS INCLUDED.—In developing materials under subsection (a), the Secretary of Health and Human Services shall include information for—

“(1) pharmacists on how to verify the identity of the patient;

“(2) pharmacists on how to decline to fill a prescription and actions to take after declining to fill a prescription; and

“(3) 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.

“(d) MATERIALS FOR TRAINING ON VERIFICATION OF IDENTITY.—Not later than 1 year after the date of enactment of this subsection [Dec. 29, 2022], the Secretary of Health and Human Services, after seeking stakeholder input in accordance with subsection (c), shall—

“(1) update the materials developed under subsection (a) to include information for pharmacists on how to verify the identity of the patient; and

“(2) disseminate, as appropriate, the updated materials.”

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 a narcotic drug in schedule III, IV, or V to be adminis-

tered for the purpose of maintenance or detoxification treatment and 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 45 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; amended Pub. L. 117-215, title I, §103(b)(1)(E), Dec. 2, 2022, 136 Stat. 2263; Pub. L. 117-328, div. FF, title I, §§1262(b)(2), 1264, Dec. 29, 2022, 136 Stat. 5682, 5685.)

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.

AMENDMENTS

2022—Subsec. (a)(2). Pub. L. 117-328, §1262(b)(2), which directed substitution of “the controlled substance is a narcotic drug in schedule III, IV, or V to be administered for the purpose of maintenance or detoxification

treatment and is to be administered by injection or implantation;" for "the controlled substance is to be administered for the purpose of maintenance or detoxification treatment under section 823(g)(2) 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;"

was executed by making the substitution for "the controlled substance is to be administered for the purpose of maintenance or detoxification treatment under section 823(h)(2) and—" and subpars. (A) and (B), to reflect the probable intent of Congress and the intervening amendment by Pub. L. 117-215. See Amendment note below.

Pub. L. 117-215 substituted "823(h)(2)" for "823(g)(2)" in introductory provisions.

Subsec. (a)(5). Pub. L. 117-328, §1264, substituted "45 days" for "14 days".

§ 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

¹ See References in Text note below.