RULES AND REGULATIONS

Title 49—PROFESSIONAL AND VOCATIONAL STANDARDS

STATE BOARD OF PHARMACY

[49 PA. CODE CH. 27]

Electronic Prescribing of Controlled Substances

[42 Pa.B. 5182]

[Saturday, August 11, 2012]

The State Board of Pharmacy (Board) amends §§ 27.18 and 27.201 (relating to standards of practice; and electronically transmitted prescriptions) to read as set forth in Annex A. This final-omitted rulemaking makes the Board's regulations consistent with Federal regulations published at 75 FR 16236 (March 31, 2010) by the Drug Enforcement Administration (DEA) of the United States Department of Justice, which became effective June 1, 2010, as well as the Department of Health (Department) notice published at 40 Pa.B. 7160 (December 11, 2010).

Background and Purpose

The DEA published at 75 FR 16236 revisions to the regulations which provide health care practitioners the option of transmitting prescriptions for controlled substances electronically. The revised regulations are in 21 CFR Parts 1300, 1304, 1306 and 1311.

The revised Federal regulations permit, but do not require, pharmacies to receive, dispense and archive electronic prescriptions. The electronic prescription and the application utilized by the pharmacy must meet DEA requirements. For example, the application being used to import, display and store electronic prescriptions must either be audited by a qualified third party or be certified by an approved certification body as in compliance with the DEA's requirements. The application provider shall provide a copy of the report of the auditor or certification body to pharmacies that use or are considering use of the pharmacy application.

Further, the DEA's revised regulations acknowledge that electronic prescriptions for controlled substances may be subject to state laws and regulations. If state requirements are more stringent than the DEA's regulations, the State requirements supersede less stringent DEA provisions. At the time of the publication of the DEA's revised regulations in 2010, the Board's regulations and those of the Department were more stringent than the DEA's revised regulations.

The Department has the authority to administer The Controlled Substance, Drug, Device and Cosmetic Act (DD&C Act) (35 P. S. §§ 780-101—780-144). This authority includes the promulgation of regulations regarding, among other things, the possession, distribution, sale, purchase or manufacture of controlled substances as may be necessary to aid in the enforcement of the DD&C Act. The Department published a notice entitled "electronically transmitted prescriptions" at 40 Pa.B. 7160. In that notice, the

Department clarified its position on whether the electronic transmission of prescriptions to a pharmacy is an acceptable practice for the medical and pharmaceutical communities under the DD&C Act and its regulations. Department regulations in 28 Pa. Code Chapter 25 (relating to controlled substances, drugs, devices, and cosmetics) provide that prescription orders may be written on prescriptions blanks or may be oral, if allowed by law, and that prescriptions for controlled substances shall be written in indelible ink, indelible pencil or typewriter and include certain information. The Department's notice clarifies its interpretation that a prescription transmitted electronically or by facsimile constitutes a "written order on a prescription blank" and that an electronically-transmitted prescription for a controlled substance is considered to be typewritten, provided that the transmission of the prescription otherwise complies with Federal and State laws and regulations, including the Board's regulations.

Thus, the Board's regulations remain as the last regulatory obstacle to the use of e-prescribing technology for the transmission of prescriptions for Schedule II controlled substances in this Commonwealth. The Pennsylvania Pharmacists Association has urged the Board to move as quickly as possible to effectuate these amendments because with the recent changes to the DEA regulations and publication of the Department's notice, many prescribers believe that the current restrictions have been lifted and will begin to submit electronic prescriptions for controlled substances, including Schedule II controlled substances, as soon as their software has been certified under the DEA regulations. However, pharmacies and pharmacists will have to reject these prescriptions or delay patient care until a handwritten prescription is obtained in compliance with the Board's existing regulations. Additionally, since the Federal law was revised, all of the contiguous states now permit the transmission of electronic prescriptions for Schedule II controlled substances in accordance with the DEA regulations.

Omission of Proposed Rulemaking

Under section 204 of the act of July 31, 1968 (P. L. 769, No. 240) (45 P. S. § 1204), known as the Commonwealth Documents Law (CDL), the Board is authorized to omit the procedures for proposed rulemaking in sections 201 and 202 of the CDL (45 P. S. §§ 1201 and 1202) if the Board finds that the specified procedures are impracticable, unnecessary or contrary to the public interest.

Prior to making the determination to adopt this final-omitted rulemaking, the Board sent a draft of the rulemaking in proposed form to the regulated community and other affected or interested parties on June 29, 2011. The Board held public discussion regarding the final-omitted rulemaking at its July 19, 2011, meeting. Commentators who responded in writing to support the final-omitted rulemaking include the National Association of Chain Drug Stores and Pennsylvania Association of Chain Drug Stores, the Pennsylvania Pharmacists Association, the Pennsylvania Medical Society and the Montgomery County Pharmacy Association.

Given that the Department issued a notice in response to the DEA's amendment of its regulations, and with the support of the regulated community, the Board believes that it is in the best interests of the regulated community, as well as prescribers and patients, to bring its regulations into consistency with those of the applicable Federal and State agencies to permit the transmission of electronic prescriptions for Schedule II controlled substances. The Board finds for good cause that publication of this rulemaking as proposed is unnecessary.

Under section 204(3) of the CDL, notice of proposed rulemaking has been omitted as unnecessary because the rulemaking is merely incorporating the regulatory changes made by the DEA to Federal regulations and the notice published by the Department at 40 Pa.B. 7160 regarding its interpretation of existing regulations to permit the electronic prescribing of controlled substances.

Accordingly, the Board adopts this rulemaking without notice of proposed rulemaking. Comments on the final-omitted rulemaking may be submitted within 30 days of publication to the following Board contact person.

Description of the Amendments

Under former § 27.18(b)(2), prescriptions for Schedule II controlled substances must be written with ink, indelible pencil, typewriter, word processor or computer printer and manually signed by the prescriber. Former § 27.201(b) provided that, with the specific exception of Schedule II controlled substances, a pharmacist may accept an electronically transmitted

prescription from an authorized licensed prescriber or an authorized designated agent that was sent directly to a pharmacy of the patient's choice if the requirements in this section were met.

This final-omitted rulemaking adds electronic means to the methods in which a prescription for a Schedule II controlled substance may be written and provides an exception to the manual signature requirement by providing that electronic prescriptions shall be electronically signed by the prescriber. This final-omitted rulemaking also adds § 27.201(b)(5), which provides that the electronic transmission of a prescription for a Schedule II, III, IV or V controlled substance is considered a written prescription order on a prescription blank and may be accepted by a pharmacist provided that the transmission complies with this chapter and other requirements under Federal or other State laws or regulations. Paragraph (5) lists some of the applicable State and Federal laws and regulations. Paragraph (5) purposely uses the terms "written," "prescription order" and "prescription blank" to be consistent with the Department's interpretation of 28 Pa. Code Chapter 25.

Statutory Authority

This final-omitted rulemaking is authorized under section 6(k)(9) of the Pharmacy Act (act) (63 P. S. § 390-6(k)(9)).

Fiscal Impact and Paperwork Requirements

This final-omitted rulemaking will not have adverse fiscal impact on the Commonwealth or its political subdivisions. This final-omitted rulemaking will not impose additional paperwork requirements upon the Board. The inherent goal of the final-omitted rulemaking is to decrease paperwork in the form of the prescriptions and related recordkeeping, which is consistent with § 27.201 and § 27.202 (relating to computerized recordkeeping systems).

It is the intention of this final-omitted rulemaking to make the Board's regulations consistent with recent Federal and State regulatory changes. Those changes recognize pharmacists' needs to avail themselves of technological developments to better serve their patients. There may be costs to pharmacists/pharmacies involved in upgrading their technology or obtaining an application for the submission of electronic prescriptions that meets the requirements of the DEA's regulations. However, because the acceptance of electronic prescriptions of Schedule II controlled substances is not mandatory, pharmacies will be able to decide by means of their own cost-benefit analyses whether to accept these prescriptions electronically. Many pharmacies began to utilize computerized recordkeeping systems when the Board authorized this method, along with electronic prescribing of medications (other than Schedule II controlled substances), in 2006. Therefore, some of the technology for adapting to electronic prescribing of Schedule II controlled substances may already be in place.

Regulatory Review

Under section 5.1(c) of the Regulatory Review Act (71 P. S. § 745.5a(c)), on May 30, 2012, the Board submitted a copy of the final-omitted rulemaking and a copy of a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC) and the House Professional Licensure Committee (HPLC). On the same date, the regulations were submitted to the Office of Attorney General for review and approval under the Commonwealth Attorneys Act (71 P. S. §§ 732-101—732-506).

Under section 5.1(j.2) of the Regulatory Review Act, on June 13, 2012, the final-omitted rulemaking was approved by the HPLC. On July 18, 2012, the final-omitted rulemaking was deemed approved by the SCP/PLC. Under section 5.1(e) of the Regulatory Review Act, IRRC met on July 19, 2012, and approved the final-omitted rulemaking.

Additional Information

For additional information about the final-omitted rulemaking, submit inquiries to Kerry Maloney, Counsel, State Board of Pharmacy, P. O. Box 2649, Harrisburg, PA 17105-2649, (717) 783-7200.

Findings

The Board finds that:

(1) Public notice of the Board's intention to amend its regulations under the procedures in sections 201 and 202 of the CDL has been omitted under the authority of section 204 of the CDL because public comment is

unnecessary in that the amendment adopted by this order adopts the changes made to applicable corresponding Federal and State regulations.

(2) The amendment of the Board's regulation in the manner provided in this order is necessary and appropriate for the administration of the act.

Order

The Board, acting under its authorizing statute, orders that:

(a) The regulations of the Board, 49 Pa. Code Chapter 27, are amended amending §§ 27.18 and 27.201 to read as set forth in Annex A, with ellipses referring to the existing text of the regulations.

(b) The Board shall submit this order and Annex A to the Office of General Counsel and the Office of Attorney General for approval as to form and legality as required by law.

(c) The Board shall certify this order and Annex A and deposit them with the Legislative Reference Bureau as required by law.

(d) This order shall take effect upon publication in the Pennsylvania Bulletin.

EDWARD J. BECHTEL, R.Ph.,

Chairperson

(Editor's Note: For the text of the order of the Independent Regulatory Review Commission relating to this document, see 42 Pa.B. 4992 (August 4, 2012).)

Fiscal Note: 16A-5428. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 27. STATE BOARD OF PHARMACY

STANDARDS

§ 27.18. Standards of practice.

* * * * *

(b) Prescriptions kept on file in the pharmacy must meet the following requirements:

(1) Prescriptions on file must show the name and address of the patient; the name and address or other identifier of the prescriber; the date the prescription was issued, if the prescription is for a controlled substance or if it was written with a PRN or ad lib refill designation; the name and quantity of the drug prescribed; directions for its use; cautions communicated to the ultimate consumer by means of auxiliary labels or other means when dispensed to the ultimate consumer; the date the prescription was compounded and dispensed; and the name or initials of the dispensing pharmacist.

(2) Prescriptions for controlled substances must show the DEA number of the prescriber. Prescriptions for Schedule II controlled substances must be written with ink, indelible pencil, typewriter, word processor, computer printer or by electronic means and shall be manually signed by the prescriber, except that prescriptions written by electronic means shall be electronically signed by the prescriber. Electronic prescriptions of Schedule II controlled substances must comply with § 27.201(b) (relating to electronically transmitted prescriptions). The pharmacist is responsible for compounding and dispensing nonproprietary drugs consistent with the Federal Controlled Substances Act (21 U.S.C.A. §§ 801—904), The Controlled Substance, Drug, Device and Cosmetic Act (35 P. S. §§ 780-101—

780-144) and the regulations promulgated under these acts.

(3) If a prescription for a nonproprietary drug is refilled, a record of the refill must show the date of the refill, the name or initials of the dispensing pharmacist and the quantity dispensed. If the pharmacist dispenses a quantity different from that of the original prescription, the pharmacist shall indicate the changes on the back of the original prescription or must enter the changes in the computerized files of the pharmacy.

(4) Original prescriptions or readily retrievable images of the original prescriptions shall be kept for 2 years from the date of the most recent filling.

(5) In an institution, Schedule II controlled substances which the pharmacy dispensed and which were ultimately received by the patient shall be recorded and the record kept for 2 years.

* * * * *

TECHNOLOGY AND AUTOMATION

§ 27.201. Electronically transmitted prescriptions.

(a) For the purposes of this section, an electronically transmitted prescription means the communication of an original prescription or refill authorization by electronic means, to include computer-to-computer, computer-to-facsimile machine or e-mail transmission which contains the same information it contained when the authorized prescriber transmitted it. The term does not include a prescription or refill authorization transmitted by telephone or facsimile machine.

(b) A pharmacist may accept an electronically transmitted prescription from an authorized licensed prescriber or an authorized designated agent which has been sent directly to a pharmacy of the patient's choice if all the following requirements are met:

(1) The prescription must contain the signature or the electronic equivalent of a signature of the prescriber made in accordance with the requirements of the Electronic Transactions Act (73 P. S. §§ 2260.101—2260.5101).

(2) The prescription must include the following information:

(i) The information that is required to be contained on a prescription under State and Federal law.

(ii) The prescriber's telephone number.

(iii) The date of the transmission.

(iv) The name of the pharmacy intended to receive the transmission.

(3) The prescription must be electronically encrypted or transmitted by other technological means designed to protect and prevent access, alteration, manipulation or use by any unauthorized person.

(4) A hard copy or a readily retrievable image of the prescription information that is transmitted shall be stored for at least 2 years from the date of the most recent filling.

(5) The electronic transmission of a prescription for a Schedule II, III, IV or V controlled substance is considered a written prescription order on a prescription blank and may be accepted by a pharmacist provided that the transmission complies with this chapter and other requirements under Federal or other State laws or regulations, including The Controlled Substance, Drug, Device and Cosmetic Act (35 P. S. §§ 780-101—780-144), Department of Health regulations in 28 Pa. Code §§ 25.1—25.131 and Federal rules established by the United States Drug Enforcement Administration in 21 CFR Part 1311 (relating to requirements for electronic orders and prescriptions).

(c) An electronically transmitted prescription shall be processed in accordance with the act and this chapter.

(d) The pharmacist and pharmacy may not provide electronic equipment to a prescriber for the purpose of transmitting prescriptions.

[Pa.B. Doc. No. 12-1508. Filed for public inspection August 10, 2012, 9:00 a.m.]

Twitter Provides New Way to Fight Pharmacy Crime

RxPATROL® Tweets Crimes, Rewards and Valuable Tips*

Pharmacy staff, law enforcement officials and loss prevention personnel can now follow updates about pharmacy robberies, burglaries and potential threats in their area and nationwide at Twitter.com/rxpatrol. The tweets, or twitter messages, provide safety and security tips for pharmacy staff that may help protect customers and their businesses.

Tweets contain specific information on robberies and burglaries, including the exact location of the incident, description of the suspect and any pertinent information that could lead to the capture of a suspect. All information is verified with local law enforcement before it is released. All tweets direct followers to the RxPATROL database for additional information, including pictures and video of suspects.

Purdue Pharma, L.P. developed RxPATROL (Rx Pattern Analysis Tracking Robberies & Other Losses) in 2003 as a collaborative effort between industry, pharmacists and law enforcement to collect, collate, analyze and disseminate information on pharmacy theft in the United States and posts important crime-related information at RxPATROL.org. The program also issues alerts and updates via email to registered users in the pharmacy and law enforcement communities. However, since many pharmacy staff members do not have Internet access during work hours, and instead have access to cell phones, RxPATROL® is now using Twitter to instantly deliver pharmacy crime updates to followers via their cell phones.

Twitter can provide followers with timely pharmacy crime information, and offer access to information that is not often reported by the media. Twitter followers also receive notices for reward offers that are funded through Purdue's partnership with CrimeStoppers and other local anti-crime organizations.

"Pharmacy crime is a problem in many communities," said Capt. Richard Conklin, RxPATROL Program Analyst. "RxPATROL is using new communication vehicles to help pharmacy staff and law enforcement fight pharmacy crime."

Conklin monitors daily pharmacy crime reports from police departments across the U.S. and posts important crime related information on the RxPATROL website. Please visit www.rxpatrol.org for more information and start following RxPATROL by visiting Twitter.com/rxpatrol.

Submitted by Ann Rule, director and medical liaison of Purdue Pharma, L.P. *The Pennsylvania State Board of Pharmacy cannot verify the accuracy of the information contained within, and provides this information solely as a possible source of information to aid practicing pharmacists. Any questions or concerns about the use of RxPATROL should be directed to Purdue Pharma, L.P.*