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Reference No. 16A-549

Dear Eva,

After careful review, of the Pennsylvania Bulletin, Volume 31, Number 19, Saturday, May 12, 2001, Document Number 01-822, I would like to offer the following comments:

Section 27.20 (a) (2)

1. Section 27.20 (a) (2) The number **three** should replace the number **two**

Section 27.20 (a) (2) Would then read:

> **(2) There are three exceptions to the requirement that the pharmacist review the original of the prescription received on a facsimile machine before dispensing a schedule II controlled substance. A pharmacist may fill and dispense a prescription for a Schedule II controlled substance, which was received on a facsimile machine and may use the facsimile as the original pharmacy record of the following:**

Section 27.20 (a) (i)

The proposed Section 27.20 (a) (i), deals with the same issues as the Drug Enforcement Agency, Title 21, Code of Federal Regulations, Section 1306.11 (e)

> (e) A prescription prepared in accordance with Sec. 1306.05 written for a Schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be transmitted by the practitioner or the practitioner's agent to the pharmacy by facsimile. The facsimile serves as the original written prescription for purposes of this paragraph (e) and it shall be maintained in accordance with Sec. 1304.04(h) of this chapter.

Please note: This section allows the facsimile of prescriptions of this type for **ALL** patients regardless of their setting or membership in a hospice program.

The proposed section 27.20 (a) (2) (i) will read:

(i) A prescription for a Schedule II controlled narcotic substance which will be administered to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion in the patient's home **[or hospice]**.

2. Section 27.20 (a) (2) (i) The word narcotic should be removed.
   The use of the term narcotic may not always apply to all schedule II substances. The DEA will be modifying their regulations to allow this section to apply to newer non-narcotic Schedule II control substances.

If the intent is to leave the location of the patient in the state regulations, then the following recommendation would apply:

3. Section 27.20 (a) (2) (i) The words **or hospice** should be replace with **or for a patient belonging to a hospice program.** This language is consistent with the intent of the Federal Drug Enforcement Agency, Title 21, Code of Federal Regulations, Section 1306.11 (g).

4. Section 27.20 (a) (2) (i) The words **"which will be administered to"** should be replaced with the word **"for the direct administration"**.
   The issue of "administration by whom" may come into play. A patient might be taking the medication by himself or herself or the medication may be administered by another individual to the hospice patient. To avoid this dilemma the DEA has avoided this term in place of the phrase **for the direct the administration**. See CFR 1306.11 (e).

Section 27.20 (a) (2) (i) Would then read:

A prescription for a Schedule II controlled substance, for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion in the patient's home or for a patient belonging to a hospice program

OR

5. If the intent is to modify the state regulation to match the intent of the Drug Enforcement Agency CFR 1306.11(e), for **ALL** patients regardless of their setting or membership in a hospice program, then the regulation should read as:

   A prescription for a Schedule II controlled substance, for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion.

The proposed Section 27.20 (a) (i), deals with the same issues as the Drug Enforcement Agency, Title 21, Code of Federal Regulations, Section 1306.11 (g)

> g) A prescription prepared in accordance with Sec. 1306.05 written for a Schedule II narcotic substance for a patient enrolled in a hospice care program certified and/or paid for by Medicare under Title XVIII or a hospice program which is licensed by the state may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The practitioner or the practitioner's agent will note on the prescription that the patient is a hospice patient. The facsimile serves as the original written prescription for purposes of this paragraph (g) and it shall be maintained in accordance with § 1304.04(h) of this chapter.

Section 27.20 (a) (2) (iii)

The proposed section 27.20 (a) (2) (iii) will read:

(iii) A prescription for a Schedule II controlled narcotic substance which will be administered to a hospice patient.

6. Section 27.20 (a) (2) (iii) The word **narcotic** should be removed
   The use of the term narcotic may not always apply to all schedule II substances. The DEA has removed the word narcotic to allow the facsimile of non-narcotic Schedule II prescriptions for hospice patients.

7. Section 27.20 (a) (2) (iii) The words **which will be administered to** should be replaced with the word **"for"**.
   The issue administration by whom may come into play. A patient might be taking the medication by himself or herself. To avoid this dilemma the DEA has avoided this term in place of the word **for**.

Section 27.20 (a) (2) (iii) Would then read:

> **A prescription for a Schedule II controlled substance for a hospice patient.**

Thank you, again for allowing me to offer these comments.

Sincerely,

Hospice Pharmacia
a division of excelleRx, Inc.

Richard B. Greene, R.Ph.
Director of Regulatory Affairs and Contracts

PROPOSED RULEMAKING

STATE BOARD OF PHARMACY

[49 PA. CODE CH. 27]

Reference Libraries; Facsimile Machines

[31 Pa.B. 2480]

The State Board of Pharmacy (Board) proposes to amend §§ 27.14 and 27.20 (relating to supplies; and facsimile machines) to read as set forth in Annex A.

Effective Date

The amendments will be effective upon publication of the final-form regulations in the *Pennsylvania Bulletin.*

Statutory Authority

The proposed amendments are authorized under sections 4(j) and 6(k)(1) and (9) of the Pharmacy Act (act) (63 P. S. §§ 390-4(j) and 390-6(k)(1)--(9)).

Background and Purpose

Section 27.14(c)(14) currently requires a pharmacy to have an adequate reference library including two or more of the latest editions of references specifically listed in the section. The proposed rulemaking would amend this section by eliminating the specific list of references and replacing it with language that would allow a pharmacy to maintain references which are more appropriate and necessary to that pharmacy's area of practice.

Section 27.20 allows a pharmacist to fill a prescription for a Schedule II controlled substance that is received on a facsimile machine under certain conditions. The Board regulation is consistent with Federal law with one exception. Federal law allows a pharmacist to use the facsimile prescription as the original prescription for all Schedule II controlled substances for hospice patients, while the Board regulation only allows a facsimile prescription as the original prescription for "injectable" Schedule II controlled substances for hospice patients. This rulemaking package is the Board's attempt to make its regulation consistent with Federal law.

Description of Proposed Amendments

Proposed § 47.14(c)(14) would remove a list of 13 references from which the current regulation now requires the pharmacy to maintain the latest editions of at least two references. The proposal recognizes that many references are not listed in the regulation which are more comprehensive or pertinent, or both, to current pharmacy practice or more appropriate to a pharmacy's particular area of practice. It is not uncommon that pharmacies

maintain the two required references which then sit on the shelf unused because the pharmacy actually uses other references that are more applicable to current pharmacy practice as well as more consistent with that pharmacy's scope of practice. The proposed rulemaking would eliminate the unnecessary cost of maintaining required, yet unused, references while allowing and encouraging pharmacies to maintain references more pertinent to their area of practice.

Current § 27.20 allows a pharmacist to fill a prescription for a Schedule II controlled substance received on a facsimile machine if the original prescription signed by the medical practitioner is presented to the pharmacist for review prior to the actual dispensing of the controlled substance. There are two exceptions to the requirement that the original prescription be presented prior to dispensing; 1) prescriptions for "injectable" Schedule II controlled substances which will be administered in a patient's home or hospice; and 2) prescriptions for Schedule II controlled substances for residents of a long-term care facility.

The Board regulation is consistent with Federal law regarding the "injectable only" prescriptions for Schedule II controlled substances administered in a patient's home, and prescriptions for Schedule II controlled substances for residents of long-term care facilities. It is inconsistent with Federal law regarding hospice patients. Federal law allows facsimile prescriptions as the original prescription for all Schedule II controlled substances for patients in hospice facilities. On July 25, 2000, the Drug Enforcement Agency published an Interim Rule in the *Federal Register* that interprets the Federal regulation's language regarding "patients residing in a hospice facility" to include all hospice patients regardless of the setting. The Board regulation only allows facsimile prescriptions for "injectable" Schedule II controlled substances for patients in a hospice.

The Board's rulemaking package would amend the Board regulation to allow facsimile prescriptions as original prescriptions for all Schedule II controlled substances for all hospice patients, making it consistent with Federal law and the Drug Enforcement Administration Interim Rule.

Hospice patients are often homebound and it may be difficult for them or their caregivers to obtain a written prescription. At this time, a faxed prescription for an injectable Schedule II controlled substance may serve as the original pharmacy record. However, a faxed prescription for an oral or topical Schedule II controlled substance for a hospice patient can be dispensed to the hospice patient only after the original prescription is presented to the pharmacist for review. If the faxed copy of hospice patients' oral and topical Schedule II controlled substance prescriptions could serve as the original pharmacy record, the burden on hospice patients and their care-givers would be reduced by eliminating the need to first obtain a written prescription from the medical practitioner for the oral and topical Schedule II controlled substances. Increased access for hospice patients to oral and topical Schedule II medications, especially during emergencies, allows for faster pain relief and an increase in the quality of life.

Compliance with Executive Order 1996-1

In compliance with Executive Order 1996-1, the Board extended the invitation to the following boards, associations and interested licensees and educators to preliminarily review and comment on the Board's draft regulatory proposal:

Lonna H. Donaghue, Executive Director, Pennsylvania Hospice Network; Joan Harrold, MD, Medical Director, Hospice of Lancaster County; Coleen Kayden, R.Ph., Lancaster, PA; Denise Harris, Director, Pinnacle Health Hospice; Richard B. Greene, R.Ph., Hospice

Pharmacia; Michael P. Cinque, R.Ph.; Terri Bostick, iScribe; Pennsylvania Pharmacists Association; Pennsylvania Society of Health-Systems Pharmacists.

The Board reviewed and considered all comments and suggestions received by these and other interested parties during the regulatory development process.

Fiscal Impact and Paperwork Requirements

These proposed amendments would have no fiscal impact or additional paperwork requirements on the Commonwealth. Additionally, the proposed amendments should not necessitate any legal, accounting or reporting requirements on the regulated community.

Sunset Date

The Board reviews the effectiveness of its regulations on an ongoing basis. Therefore, no sunset date has been assigned.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on May 2, 2001, the Board submitted a copy of proposed amendments to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the House of Professional Licensure Committee and the Senate Consumer Protection and Licensure Committee. In addition to submitting the proposed amendments, the Board has provided IRRC and the Committees with a detailed regulatory analysis form prepared by the agency in compliance with Executive Order 1996-1 "Regulatory Review and Promulgation." A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, if IRRC has objections to any portion of the proposed amendments, it will notify the Board within 10 days after the close of the Committees' review. The notification shall specify that regulatory review criteria which have not been met by the portion. The Regulatory Review Act specifies detailed procedures for review prior to publication of the regulations by the Board, the General Assembly and the Governor of objections raised.

Public Comment

Interested persons are invited to submit written comments, suggestions or objections regarding the proposed amendments to Eva Cheney, State Board of Pharmacy, P. O. Box 2649, Harrisburg, PA 17105-2649, within 30days of publication of this proposed rulemaking. Please reference No. 16A-549 when submitting comments.

MICHAEL A. PODGURSKI,
Chairperson

Fiscal Note: 16A-549. 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 PHARMACY

§ 27.14. Supplies.

* * * * *

(c) A pharmacy shall maintain at least the following equipment and supplies:

* * * * *

(14) **[An adequate reference library including two or more of the latest editions of the following, including current supplements:**

(i) The United States Pharmacopeia, *The National Formulary.*

(ii) *Physicians Desk Reference.*

(iii) *Drug Facts and Comparisons.*

(iv) *Remington's Pharmaceutical Sciences.*

(v) *The United States Dispensatory.*

(vi) *Physicians' Generix.*

(vii) *USPDI* (United States Pharmacopeia Dispensing Information).

(viii) *American Drug Index.*

(ix) Goodman and Gilman's *Pharmacological Basis of Therapeutics.*

(x) *AHFS Drug Information.*

(xi) *Radiological Health Handbook.*

(xii) *The Merk Index: An Encyclopedia of Chemicals, Drugs, and Biologicals.*

(xiii) *Martindale: The Extra Pharmacopeia.*]

An adequate reference library which meets the following standards:

(i) A pharmacy shall maintain an adequate reference library to enable it to prepare and dispense prescriptions properly, consistent with its scope of practice.

(ii) A pharmacy shall maintain a library of reference sources appropriate to the type of pharmacy practice at that particular location. A pharmacy shall include in the pharmacy's library current material regarding the technical, clinical and professional aspects of practice with emphasis in the area in which the pharmacy specializes.

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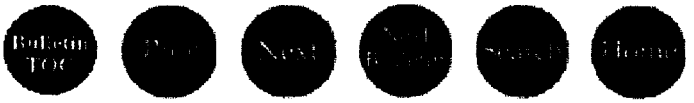

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