Regulatory Analysis Form

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2001 DEC -6 AM 11:05

(1) Agency

Department of State, Bureau of Professional and Occupational Affairs, State Board of Pharmacy

(2) I.D. Number (Governor's Office Use)
16A-549

IRRC Number: 2197

(3) Short Title
Reference Library and Facsimile Machines

(4) PA Code Cite

49 Pa. Code §§ 27.14, 27.20

(5) Agency Contacts & Telephone Numbers

Primary Contact: Carole Clarke, Counsel, State Board of Pharmacy 783-7200
Secondary Contact: Joyce McKeever, Deputy Chief Counsel, Department of State 783-7200

(6) Type of Rulemaking (check one)

___ Proposed Rulemaking
_X_ Final Order Adopting Regulation
___ Final Order, Proposed Rulemaking Omitted

(7) Is a 120-Day Emergency Certification Attached?

_X_ No
___ Yes: By the Attorney General
___ Yes: By the Governor

(8) Briefly explain the regulation in clear and nontechnical language.

This rulemaking package amends the Pharmacy Board's regulations at 49 Pa. Code § 27.14(c)(14) which currently requires a pharmacy to have an adequate reference library including two of the latest editions of references specifically listed in the regulation. The proposed regulation would amend this section by eliminating the specific list of references and replacing it with language that would allow a pharmacy to maintain references more appropriate to that pharmacy's area of practice.

This rulemaking package would also amend the Pharmacy Board's regulations at 49 Pa. Code § 27.20 to allow a pharmacist to fill prescriptions for all Schedule II controlled substances for hospice patients which are received on a facsimile machine without reviewing the original of the prescription before dispensing the Schedule II controlled substance. Currently this section only allows a facsimile prescription for injectable Schedule II controlled substances for hospice patients. The rulemaking package would amend the current Board regulation §27.20 to make it consistent with federal law.

(9) State the statutory authority for the regulation and any relevant state or federal court decisions.

The regulation is authorized under Sections 4(j) and 6(k)(1) and (9) of the Pharmacy Act (Act), Act of September 27, 1961, P.L. 1700, as amended, 63 P.S. §§ 390-4(j), 6(k) (1) and (9).

Regulatory Analysis Form

(10) Is the regulation mandated by any federal or state law or court order, or federal regulation? If yes, cite the specific law, case or regulation, and any deadlines for action.

Yes. Section 6(k)(1) and (9) of the Act, empowers the Board to promulgate regulations as may be necessary to carry into effect the provisions of the Act.

(11) Explain the compelling public interest that justifies the regulation. What is the problem it addresses?

Under current Section 47.14(c)(14), a pharmacy must maintain two references specifically listed in that section. However, there are many references available which are not listed in the regulation which are more pertinent to current pharmacy practice or more appropriate to a pharmacy's particular area of practice. It is not uncommon that pharmacies maintain the two specified 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 regulation 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.

Section 47.20 is consistent with Federal law regarding the "injectable only" facsimile 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 patients residing in a hospice. Federal law allows facsimile prescriptions as the original prescription for all Schedule II controlled substances for patients in hospice facilities; the Board regulation only allows facsimile prescriptions for "injectable" Schedule II controlled substances for hospice patients. This rulemaking package would amend Section 47.20 to allow facsimile prescriptions as original prescriptions for all Schedule II controlled substances for all hospice patients, making it consistent with Federal law.

Hospice patients are often homebound and it may be difficult for them or their caregivers to obtain a written prescription. If the faxed copy of hospice patient's 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.

(12) State the public health, safety, environmental or general welfare risks associated with nonregulation.

Nonregulation will continue the unnecessary burden on pharmacies to maintain expensive references that are not relevant to their area of practice while incurring expenses for additional references that are more appropriate to their practice. It will also discourage pharmacies from obtaining more current, up-to-date references that are more attuned to modern pharmacy practice.

Nonregulation will also continue the present a burden for hospice patients and their care-givers by requiring a hospice patient to first obtain a written prescription from a medical practitioner for oral and topical Schedule II medications and present it to the pharmacist prior to dispensing, even though the pharmacist has a facsimile prescription for the medication. This burden, especially during emergencies, prevents the hospice patient from obtaining fast pain relief and decreases his/her quality of life.

Regulatory Analysis Form

(13) Describe who will benefit from the regulation. (Quantify the benefits as completely as possible and approximate the number of people who will benefit.)

Pharmacies as well as consumers will benefit if pharmacies are allowed to maintain references more adequately addressing current pharmacy practice and areas specific to a pharmacy's area of practice. Hospice patients benefit from this regulation. The regulation amends the current Board regulation and allows a pharmacist to fill a facsimile prescription for an oral or topical Schedule II controlled substance for hospice patients without first obtaining a written prescription. 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.

(14) Describe who will be adversely affected by the regulation. (Quantify the adverse effects as completely as possible and approximate the number of people who will be adversely affected.)

There are no perceived people or groups of people who will be adversely affected by the proposed regulation.

(15) List the persons, groups or entities that will be required to comply with the regulation. (Approximate the number of people who will be required to comply.)

Pharmacies, pharmacists who are filling facsimile prescriptions; doctors who are sending facsimile prescriptions to pharmacies for their hospice patients; and hospice patients. It is unknown at this time how many individuals will fall into this category.

(16) Describe the communications with and input from the public in the development and drafting of the regulation. List the persons and/or groups who were involved, if applicable.

Both prior to publication and during the public comment period following publication of proposed rulemaking in the Pennsylvania Bulletin, the Board obtained input from professional organizations, such as the Pennsylvania Pharmacists Association, the Pennsylvania Society of Health-Systems Pharmacists, and the Pennsylvania Hospice Network, individuals, the House Professional Licensure Committee and IRRC. The Board has considered and incorporated their suggestions in final rulemaking as noted in the Preamble thereto.

(17) Provide a specific estimate of the costs and/or savings to the regulated community associated with compliance, including any legal, accounting or consulting procedures, which may be required.

It is not uncommon that pharmacies maintain the two required references which then sit on the shelf unused because the pharmacy actually purchases and 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 regulation would eliminate the unnecessary cost of maintaining required, yet unused references while allowing and encouraging pharmacies to purchase those references more pertinent to their area of practice.

Regulatory Analysis Form

(18) Provide a specific estimate of the costs and/or savings to local governments associated with compliance, including any legal, accounting or consulting procedures that may be required.

This regulation does not affect local governments.

(19) Provide a specific estimate of the costs and/or savings to state government associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required.

There is no cost/saving to the Board associated with implementation of this regulation.

Regulatory Analysis Form

(20) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

	Current FY	FY +1	FY +2	FY +3	FY +4	FY +5
SAVINGS:	$	$	$	$	$	$
Regulated Community	NA	NA	NA	NA	NA	NA
Local Government						
State Government						
Total Savings						
COSTS:						
Regulated Community	NA	NA	NA	NA	NA	NA
Local Government						
State Government						
Total Costs						
REVENUE LOSSES:						
Regulated Community	NA	NA	NA	NA	NA	NA
Local Government						
State Government						
Total Revenue Losses						

(20a) Explain how the cost estimates listed above were derived.

There are no costs associated with this regulation. There may, however, be some savings. Currently a pharmacy maintains the required references and references not included on the current list of required references which are more comprehensive and/or specific to its pharmacy practice. The regulated community may actually save money because a pharmacy will not be mandated to purchase and maintain unused required references. However, those savings, if any, is not known at this time.

Regulatory Analysis Form

(20b) Provide the past three year expenditure history for programs affected by the regulation.

Program	FY -3	FY -2	FY -1	Current FY
Pharmacy Board	$1,174,069.18	$1,171,442.25	$1,173,738.10	$1,168,000.00

(21) Using the cost-benefit information provided above, explain how the benefits of the regulation outweigh the adverse effects and costs.

There are no adverse effects and costs associated with this regulation. Pharmacies will benefit because they will no longer be required to maintain reference books which they do not use in addition to the reference books they maintain that they do use, thus resulting in a possible savings. Hospice patients will benefit because pharmacists can dispense the patient's Schedule II Controlled narcotic medications upon receipt of a facsimile prescription, without waiting until the original prescription is submitted to the pharmacist.

(22) Describe the nonregulatory alternatives considered and the costs associated with those alternatives. Provide the reasons for their dismissal.

Nonregulatory alternatives were not considered because this regulation is necessary to carry into effect the provisions of the Act. Sections 4(j) and 6(k)(1) and (9) of the Act empower the Board to promulgate regulations as may be necessary to carry into effect the provisions of the Act.

(23) Describe alternative regulatory schemes considered and the costs associated with those schemes. Provide the reasons for their dismissal.

No alternative regulatory schemes were considered. See 22 above.

Regulatory Analysis Form

(24) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulation.

The current Board regulation § 27.20 is more stringent than federal law. The rulemaking package would make the current Board regulation consistent with federal law.

(25) How does this regulation compare with those of other states? Will the regulation put Pennsylvania at a competitive disadvantage with other states?

The reference library section of the regulation is consistent with other states, including, Maryland, New Jersey, Ohio, and New York. The language for the regulation was adopted in part from Maryland's regulations.

A comparison with those states bordering Pennsylvania was done regarding the facsimile section of the regulation. Ohio has a similar regulation enacted in 2001. Maryland and Delaware have less stringent general regulations governing facsimile transmissions. New Jersey and New York do not have similar regulations. It should be noted that no state, other than Ohio, has amended its regulations since the change was made to the federal law in 2000. The comparison was also made to federal law because this is where the inconsistency and subsequent disadvantage originate. This regulation will make Pennsylvania consistent with federal law.

(26) Will the regulation affect existing or proposed regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

The regulation amends current Sections 27.14 and 27.20.

(27) Will any public hearings or informational meetings be scheduled? Please provide the dates, times, and locations, if available.

The Board reviews its regulatory proposals at regularly scheduled public meetings. The Board meets each month at116 Pine Street, Harrisburg and the meeting schedule can be obtained from the Department of State's website at www.dos.state.pa.us.

Regulatory Analysis Form

(28) Will the regulation change existing reporting, record keeping, or other paperwork requirements? Describe the changes and attach copies of forms or reports which will be required as a result of implementation, if available.

No.

(29) Please list any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, elderly, small businesses, and farmers.

The regulation addresses the particular needs of hospice patients. The regulation amends the current Board regulation and allows a pharmacist to fill a facsimile prescription for an oral or topical Schedule II controlled substance for hospice patients without first obtaining a written prescription. 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.

(30) What is the anticipated effective date of the regulation; the date by which compliance with the regulation will be required; and the date by which any required permits, licenses or other approvals must be obtained?

The regulation will be effective upon publication in the Pennsylvania Bulletin as final rulemaking.

(31) Provide the schedule for continual review of the regulation.

The Board reviews the effectiveness of its regulations on a regular basis.

CAL-1

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

2197 DO NOT WRITE IN THIS SPACE

Copy below is hereby approved as to form and legality. Attorney General

BY: _____
(DEPUTY ATTORNEY GENERAL)

_____
DATE OF APPROVAL

Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by:

State Board of Pharmacy
(AGENCY)

DOCUMENT/FISCAL NOTE NO. 16A-549

DATE OF ADOPTION: _____

BY: M A. Podgurski
Michael A. Podgurski, R.Ph.

TITLE: Chairman
(EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)

Copy below is approved as to form and legality. Executive or Independent Agencies.

BY: Steven V. Tan

DATE OF APPROVAL
10/24/01
(Deputy General Counsel (~~Chief Counsel, Independent~~ Agency (Strike inapplicable title)

[ ] Check if applicable
Copy not approved.
Objections attached.

[ ] Check if applicable. No Attorney General approval or objection within 30 day after submission.

FINAL RULEMAKING

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF PHARMACY
49 Pa. Code, Chapter 27
Reference Library and Facsimile Machines

The State Board of Pharmacy (Board) hereby amends its regulations at 49 Pa. Code, Chapter 27, by amending Sections 27.14 and 27.20 as set forth in Annex A.

A. Effective Date

The amendment will be effective upon publication of the final form regulation in the Pennsylvania Bulletin.

B. Statutory Authority

The amendment is authorized under Sections 4(j) and 6(k)(1) and (9) of the Pharmacy Act (Act), Act of September 27, 1961, P.L. 1700, as amended, 63 P.S. §§ 390-(4)(j), 6(k)(1) and (9).

C. Background and Purpose

Section Code 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 rulemaking amends this section by eliminating the specific list of references and replacing it with language that allows a pharmacy to maintain references which are more appropriate and necessary to that pharmacy's area of practice.

Pharmacy Board regulation at 49 Pa. Code 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 narcotic 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 amends this regulation and makes it consistent with federal law.

D. Summary of Comments and Responses on Proposed Rulemaking

Notice of the proposed rulemaking was published at 31 Pa.B. 2480 (May 12, 2001). Publication was followed by a 30 day public comment period during which the Board received one public comment. Following the close of the public comment period the Board received comments from the House Professional Licensure Committee (HPLC) and the Independent Regulatory Review Commission (IRRC). The Senate Consumer Protection and Professional Licensure Committee (SCP/PLC) did not comment. The following is a response to the comments.

Section 24.14. Supplies

IRRC recommended that the Board consider deleting repeated references to the phrase "an adequate reference library" in this section for greater readability and less repetition. The Board agrees and has amended this section accordingly.

IRRC also commented that the phrase "safe and effective manner" used in Subsection (c)(14)(iii) (A) was unclear and recommended that the Board include examples of what it considers "a safe and effective manner." The intention underlying this rulemaking was to ensure that pharmacists had reference materials that are applicable to their type of pharmacy practice (e.g., nuclear pharmacy vs. family pharmacy). Therefore, the Board determined not to cite specific referenced volumes. To accommodate IRRC's concern, however, the Board has amended the language in an attempt to clarify what it meant with regard to this particular standard.

Section 27.20. Facsimile Machines.

There were three comments to this Section. First, HPLC, IRRC and Mr. Greene questioned the use of the phrase "which will be administered to..." in subsections (a)(2)(i) and (a)(2)(iii). IRRC questioned whether the Board intended to exclude self-administered medications, and if not, recommended that the Board replace the phrase with the phrase "for the direct administration" used in the federal regulations. HPLC noted Mr. Greene's comment that patients often self-administer their medications. Mr. Greene recommended eliminating the phrase "which will be administered to" and replacing it with the word "for." The Board did not intend to exclude self-administration for hospice patients. Its intent is only to be consistent with federal law. IRRC is correct that federal law uses the phrase "for the direct administration" but this is in regard to prescriptions written for a Schedule II narcotic substance for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion (21 C.F.R. 1306.11(e) (2000)). Subsection 27.20 (a)(2)(i) follows this federal regulation and the Board has amended this Subsection by deleting the phrase "which will be administered to" and replacing it with "to be compounded for the direct administration" so that it will now be consistent with the most current version of the federal law. However this phrase is not used with regard to prescriptions written for Schedule II narcotic substances for patients in a hospice program. Rather, 21 C.F.R. 1306.11(g) (2000) uses the language recommended by Mr. Greene. Therefore, the Board has amended Subsection 27.20(a)(2)(iii) eliminating the phrase "which will be administered to" and replacing it with the word "for." Again, the Board's intent is to have the language in its regulation follow that of the federal law.

Second, HPLC noted Mr. Greene's comment that the term "narcotic" should be removed from subsections (a)(2)(i) and (a)(2)(iii) because corresponding DEA regulations will be applicable to new, non-narcotic Schedule II controlled substances. However, the Board is not aware of any Drug Enforcement Administration (DEA) regulations eliminating the word narcotic. Rather, the most current version of 21 C.F.R. 1306.11(e) and (g) (2000) still includes the word narcotic. The Board will not remove the word narcotic from these subsections until, and if, the federal law removes it.

Finally, HPLC, IRRC and Mr. Greene recommended that the Board replace "hospice patient" in Subsection (a)(2)(iii) with "patient enrolled in a hospice care program" to be consistent with the language in the federal regulations. The Board agrees with this recommendation and has amended this subsection accordingly.

E. Compliance with Executive Order 1996-1, Regulatory Review and Promulgation

The Board reviewed this rulemaking and considered its purpose and likely impact on the public and the regulated population under the directives of Executive Order 1996-1. The final-form regulation addresses a compelling public interest as described in this Preamble and otherwise complies with Executive Order 1996-1.

F. Fiscal Impact and Paperwork Requirements

This regulation will have no fiscal impact or impose any additional paperwork requirements on the Commonwealth or its political subdivisions. Additionally, the proposed amendment should not necessitate any legal, accounting or reporting requirements on the regulated community.

G. Sunset Date

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

H. Regulatory Review

Under Section 5(a) of the Regulatory Review Act (71 P.S. §745.5(a)) the Board submitted a copy of the Notice of Proposed Rulemaking, published at 31 Pa.B. 2480, on May 12, 2001, to the IRRC and the Chairperson of the HPLC and the SCP/PLC for review and comment.

In compliance with section 5(b.1) of the Regulatory Review Act (71 P.S. § 745.5(b.1)), the Board also provided IRRC, SCP/PLC, and HPLC with copies of comments received as well as other documents. In preparing the final-form regulation, the Board has considered the comments received from IRRC, SCP/PLC, HPLC, and the public.

Under section 5.1(d) of the Regulatory Review Act (71 P.S. § 745.5a(d)), this final-form regulation was (deemed) approved by the HPLC on _____, ____ 200__, and (deemed) approved by SCP/PLC on _____, ____ 200__. Under section 5.1(e) of the Regulatory Review Act (71 P.S. § 745.5a(e)), IRRC met on _____, ____ 200__, and (deemed) the final-form regulation approved.

I. Contact Person

Further information may be obtained by contacting Melanie Zimmerman, Executive Secretary, State Board Pharmacy, P.O. Box 2649, Harrisburg, Pennsylvania 17105-2649, (717) 783-7156, www.dos.state.pa.us.

J. Findings

The Board Finds that:

(1) Public notice of proposed rulemaking was given under sections 201 and 202 of the act of July 31, 1968, P.L. 769, No. 240 (45 P.S. §§ 1201 and 1202) and the regulations promulgated thereunder at 1 Pa. Code §§ 7.1 and 7.2.

(2) A public comment period was provided as required by law and all comments were considered.

(3) These amendments do not enlarge the purpose of proposed rulemaking published at 29 Pa.B. 1088.

(4) These amendments are necessary and appropriate for administration and enforcement of the authorizing acts identified in Part B of this Preamble.

K. Order

The State Board of Pharmacy, acting under its authorizing statutes, orders that:

(a) The regulations of the Board, 49 Pa. Code Chapter 27, are amended by amending Sections 27.14 and 27.20.

(b) The Board shall submit this order and Annex A to the Office of General Counsel and to the Office of Attorney General 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 on publication in the Pennsylvania Bulletin.

hard-bound publications received from sources other than the original source, may be damaged or removed where inspection of the cover is deemed necessary and no reasonably available alternative form of inspection is adequate. Magazines and newspapers must be mailed directly from the original source. Small letter-sized pamphlets may be received in regular correspondence from family members, friends or religious advisors. Publications which are sent directly from a publisher, bookstore, distributor or department store will usually be deemed to have come from the original source.

(c) The Publications Review Committee will determine whether written or printed material is a publication and will rule on publications within 10 days after the material is received. Property will be forwarded to the property officer for processing. The committee will communicate its decision to the inmate, with reasons if a publication is disapproved.

(d) Receipt of publications may be disapproved when the publications contain the following:

(1) Information regarding the manufacture of explosives, incendiaries, weapons, escape devices or other contraband.

(2) Instructions regarding the ingredients or manufacture of poisons, drugs or intoxicating beverages.

(3) Writings which advocate violence, insurrection or guerrilla warfare against the government or any of its institutions or which create a clear and present danger within the context of the correctional institution.

(4) Materials which portray, depict or expressly encourage violent or assaultive sexual conduct or involuntary deviant sexual conduct.

(5) Writings which advocate, assist or are evidence of criminal activity or institution misconduct.

(e) A publication will not be prohibited solely on the basis that the publication is critical of penal institutions in general, of a particular institution, of a particular institutional staff member, of an official of the Department of Corrections, or of a correctional or penological practice in this or any other jurisdiction.

(f) The criteria set forth in subsection (d) should not be interpreted so broadly as to require disapproval of recognized textbooks in chemistry, physics or the social sciences.

(g) An inmate may receive more than one copy of a publication only with special approval of the Publications Review Committee.]

§ 93.6. Religious activities.

* * * * *

(c) [*Recognition*] *Accommodation of faiths.* Requests for [recognition by] accommodation of faiths [that are not well known] will be handled as follows:

* * * * *

(2) Information material will be forwarded to the Director of Chaplaincy Services for the Department [of Corrections who will determine the authenticity and religious needs of the group] for evaluation.

§ 93.7. Telephone calls.

(a) Inmates may make [collect] phone calls [to persons who are willing to accept the charges subject to institution rules and procedures] in accordance with applicable law. All phone calls, except confidential communications between attorneys and inmates shall be subject to monitoring in accordance with 18 Pa.C.S. Chapter 57 (relating to wiretapping and electronic surveillance).

(b) Phone calls to inmates will be permitted only if approved in advance by the [Superintendent] facility manager or [his] a designee.

§ 93.11. Housing.

(a) [No] An inmate [shall] does not have a right to be housed in a particular [institution] facility or in a particular area within [an institution] a facility.

* * * * *

[Pa.B. Doc. No. 01-821. Filed for public inspection May 11, 2001, 9:00 a.m.]

STATE BOARD OF PHARMACY

[49 PA. CODE CH. 27]

Reference Libraries; Facsimile Machines

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 con-

trolled 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 30

days 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.

(iii) A pharmacy shall maintain a library containing reference sources that:

(A) Enable the pharmacist to compound medications in a safe and effective manner.

(B) List the possible drug interactions and possible adverse effects of medications dispensed by the pharmacy.

(C) List the therapeutic equivalents for medications.

(D) List the therapeutic usage and dosages of medications dispensed by the pharmacy.

(E) Provide guidelines for the counseling of patients.

(iv) A pharmacy that specializes in nuclear or parenteral prescriptions may limit the library it maintains under subparagraph (ii) relating to the pharmacy's own specialization.

(v) A pharmacy shall maintain the latest editions including current supplements of each of its reference sources.

§ 27.20. Facsimile machines.

(a) *Schedule II controlled substances.*

* * * * *

(2) There are **[** two **]** **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:

(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]**.

* * * * *

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

* * * * *

[Pa.B. Doc. No. 01-822. Filed for public inspection May 11, 2001, 9:00 a.m.]

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

§ 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) ENABLES 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~~ INCLUDES 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.

~~(iii) A pharmacy shall maintain a library containing reference sources that:~~

~~(a)~~ (iii) ~~Enable~~ ENABLES the pharmacist to compound medications in a safe and effective manner CONSISTENT WITH ACCEPTED STANDARDS OF PHARMACY PRACTICE;

~~(b)~~ (iv) ~~List~~ LISTS the possible drug interactions and possible adverse effects of medications dispensed by the pharmacy;

~~(c)~~ (v) ~~List~~ LISTS the therapeutic equivalents for medications;

~~(d)~~ (vi) ~~List~~ LISTS the therapeutic usage and dosages of medications dispensed by the pharmacy; ~~and~~

~~(e)~~ (vii) ~~Provide~~ PROVIDES guidelines for the counseling of patients.

~~(iv)~~ (viii) A pharmacy that specializes in nuclear or parenteral prescriptions may limit the library it maintains pursuant to (ii) of this section relating to the pharmacy's own specialization.

~~(v)~~ (ix) ~~A pharmacy shall maintain~~ MAINTAINS the latest editions including current supplements of each of its reference sources.

27.20 Facsimile machines

(a) Schedule II controlled substances.

(1) A pharmacist may fill a prescription for a Schedule II controlled substance which was 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. The original prescription shall be maintained as the original pharmacy record.

(2) There are [two] 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:

(i) A prescription for a Schedule II controlled narcotic substance ~~which will be administered~~ to BE COMPOUNDED FOR THE DIRECT ADMINISTRATION TO a patient by parenteral, intravenous, intramuscular, subcutaneous

or intraspinal infusion in the patient's home [or hospice].

(ii) A prescription for a Schedule II controlled substance for a resident of a long term care facility.

(iii) A prescription for a Schedule II controlled narcotic substance ~~which will be administered to~~ FOR a ~~hospice~~ patient ENROLLED IN A HOSPICE CARE PROGRAM.

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF PHARMACY
Post Office Box 2649
Harrisburg, Pennsylvania 17105-2649
(717) 783-7156

December 6, 2001

The Honorable John R. McGinley, Jr., Chairman
INDEPENDENT REGULATORY REVIEW COMMISSION
14th Floor, Harristown 2, 333 Market Street
Harrisburg, Pennsylvania 17101

Re: Final Regulation
State Board of Pharmacy
Reference Library and Facsimile Machines: 16A-549

Dear Chairman McGinley:

Enclosed is a copy of a final rulemaking package of the State Board of Pharmacy pertaining to Reference Library and Facsimile Machines.

The Board will be pleased to provide whatever information the Commission may require during the course of its review of the rulemaking.

Sincerely,

Michael A. Podgurski, R. Ph., Chairperson
State Board of Pharmacy

MAP/CLC:lm
Enclosure
c: John T. Henderson, Jr., Chief Counsel
Department of State
Albert H. Masland, Commissioner
Bureau of Professional and Occupational Affairs
Joyce McKeever, Deputy Chief Counsel
Department of State
Philip Zarone, Regulatory Counsel
Bureau of Professional and Occupational Affairs
Gerald S. Smith, Senior Counsel in Charge
Bureau of Professional and Occupational Affairs
Carole L. Clarke, Counsel
State Board of Pharmacy
State Board of Pharmacy

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER:	16A-549
SUBJECT:	State Board of Pharmacy - Reference Library and Facsimile Machines
AGENCY:	DEPARTMENT OF STATE

TYPE OF REGULATION

Proposed Regulation

X Final Regulation

Final Regulation with Notice of Proposed Rulemaking Omitted

120-day Emergency Certification of the Attorney General

120-day Emergency Certification of the Governor

Delivery of Tolled Regulation
a. With Revisions b. Without Revisions

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
12-6-01		HOUSE COMMITTEE ON PROFESSIONAL LICENSURE
DEC 06 2001		SENATE COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICENSURE
Dec. 4, 2001		INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL
		LEGISLATIVE REFERENCE BUREAU

October 24, 2001