Regulatory Analysis Form

This space for use by IRRC

(1) Agency
Department of State, Bureau of Professional and Occupational Affairs, State Board of Pharmacy

(2) I.D. Number (Governor's Office Use)

16A-5410

IRRC Number: 2405

(3) Short Title
Technology and Automation Regulations

(4) PA Code Cite	(5) Agency Contacts & Telephone Numbers
49 Pa. Code §§ 27.1, 27.14 and 27.201 – 27.204	**Primary Contact: Carole L. 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)	(7) Is a 120-Day Emergency Certification Attached?
___ Proposed Rulemaking **_X_ Final Order Adopting Regulation** **___ Final Order, Proposed Rulemaking Omitted**	**_X_ No** **___ Yes: By the Attorney General** **___ Yes: By the Governor**

(8) Briefly explain the regulation in clear and non-technical language.

This rulemaking package amends the Pharmacy Board's (Board) regulations at 49 Pa. Code §27.1 to add definitions pertaining to the new sections added to the regulations.

This rulemaking package also amends the Board's regulations at 49 Pa. Code §27.14 to cross reference section 27.203(b), which creates an exception for the minimum drug inventory requirement.

This rulemaking package amends the Board's regulations at 49 Pa. Code §27.201 by adding a section that permits pharmacies to accept a prescription transmitted electronically by a prescriber. The patient may choose the pharmacy where the prescription is sent. The means via which the prescription is sent must be secure to prevent unauthorized access by an intervening person so that the prescription could be altered or manipulated in any way. The electronic prescription must be maintained for two years from the date of the most recent filling and must be readily retrievable in the form of an image or a hard copy.

This rulemaking package also amends the Board's regulations at 49 Pa. Code §27.202 by adding a section that permits computerized record keeping systems. This section sets forth the information

that must be maintained in the system, what must be done if the system experiences downtime, how long the information must be maintained, how the data must be accessible, and what safeguards must be in place to prevent unauthorized people from obtaining or manipulating information stored in the system.

This rulemaking package further amends the Board's regulations at 49 Pa. Code §27.203 by adding a section that sets forth the standards for centralized prescription processing. This section defines terms applicable to centralized prescription processing and details which pharmacy is responsible for each step in the prescription process.

Lastly, this rulemaking package amends the Board's regulations at 49 Pa. Code §27.204 by adding a section that prescribes the standards for procedures of operation, training of personnel, a quality assurance program, a written recovery plan, and a written program for preventative maintenance.

(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) (63 P.S. §§390-4(j), and 390-6(k((1) and (9)).

(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.

This regulation is not mandated by federal or state law or court order, or federal regulation.

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

Section 27.201 implements the use of technology in the practice of pharmacy by regulating a pharmacy's acceptance of a prescription that is transmitted electronically. Currently the Board's regulations allow for a prescription to be sent by facsimile or telephoned in to a pharmacy, in addition to the patient bringing in a written prescription. The regulation recognizes that there are other ways a prescription may be delivered to a pharmacy while ensuring its authenticity and accuracy.

Section 27.202 also recognizes the use of technology in the practice of pharmacy by setting forth the standards that must be used in maintaining patient records on a computer. Currently the Board's regulations allow the patient profile and prescription records to be maintained electronically, but do not set the standards for what information must be maintained. The public is served because the use of the computerized recordkeeping system allows information to be at a pharmacist's fingertips to more easily identify potential drug interactions or reactions. Setting uniform standards for computerized record keeping is also in the public interest.

Section 27.203 serves the public by allowing pharmacies to utilize centralized prescription processing centers to fill prescriptions. This allows the pharmacist to spend more time on the clinical aspects of pharmacy rather than manually filling prescriptions.

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Section 27.204 serves the public by allowing pharmacies to use automated medication systems. Like §27.203, this allows the pharmacist to spend more time on the clinical aspects of pharmacy and relieves some of the pharmacist's workload by assuming the duty of counting pills and filling and labeling the bottles. The public benefits because the regulation protects the public through the effective control and regulation of the use of automation in pharmacies.

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

Nonregulation will unnecessarily restrict the ways that a prescription can be transmitted to a pharmacy. It will also fail to provide standards for computerized recordkeeping, centralized prescription processing, and automated medical systems. Nonregulation will leave Pennsylvania at a competitive disadvantage to states that already have regulations similar to these in effect.

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

Pharmacists will benefit from the regulations because they will be able to spend more time concentrating on the clinical aspects of the practice of pharmacy. The public will benefit because the centralized filling and automated medication systems will relieve some of the workload on pharmacists who are overworked due to a pharmacist shortage. The public will also benefit because uniform standards will be in place for the use of technology.

(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 that accept electronically transmitted prescriptions or use computerized recordkeeping systems, centralized prescription processing or automated medication systems; pharmacists who fill electronically transmitted prescriptions; doctors who will electronically transmit prescriptions to pharmacies. It is unknown at this time how may individuals will fall into this category.

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(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.

A notice of the proposed rulemaking was published at 34 Pa.B. 3146 (June 19, 2004) and was submitted to the House Professional Licensure Committee and the Senate Consumer Protection and Professional Licensure Committee as well as IRRC. The Board also received comments from members of the public. In preparing the final rulemaking, the Board considered the comments received from the House Professional Licensure Committee, IRRC and the public. The Senate Consumer Protection and Professional Licensure Committee did not comment on the proposed regulation.

(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.

If a pharmacy chooses to use either electronically transmitted prescriptions, computerized recordkeeping, centralized prescription processing or automated medication systems there may be costs incurred in acquiring the software or technology necessary to utilize these. However, the regulations are not imposing the use of any of this technology therefore it is difficult to estimate the specific costs or potential savings.

(18) Provide a specific estimate of the costs and/or savings to local governments associated with compliance, including any legal, accounting or consulting procedures, which 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 are no costs and/ or savings to the Board associated with the implementation of the regulation.

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(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 +1	FY +2	FY +3	FY +4	FY +5
SAVINGS:	**$**	**$**	**$**	**$**	**$**	**$**
Regulated Community	N/A	N/A	N/A	N/A	N/A	N/A
Local Government						
State Government						
Total Savings						
COSTS:	**$**	**$**	**$**	**$**	**$**	**$**
Regulated Community	N/A	N/A	N/A	N/A	N/A	N/A
Local Government						
State Government						
Total Costs						
REVENUE LOSSES:	**$**	**$**	**$**	**$**	**$**	**$**
Regulated Community	N/A	N/A	N/A	N/A	N/A	N/A
Local Government						
State Government						
Total Revenue Losses						

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

It is difficult to estimate the costs involved with the regulation as it is not known how many pharmacies will choose to use the technology that is available.

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(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	**$1,213,162.22**	**$1,389,369.42**	**$1,588,828.54**	**$1,655,000.00**

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

The benefits of the regulations outweigh any adverse effects and costs because pharmacies have a choice whether or not to use any of the technology involved. Pharmacists will benefit because the technology will allow them to focus more on the clinical aspects of their jobs by taking away the pill counting aspect of it.

(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 these regulations are necessary to implement the technology involved and set standards for its use.

(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.

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(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.

Currently there are no federal regulations pertaining to the topics addressed in these regulations.

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

For each section the Board looked to model acts and what other states have promulgated in their regulations. Currently, New York, New Jersey, Delaware, Maryland and Ohio have regulations pertaining to the electronic transmission of prescriptions. Enacting this section will put Pennsylvania on track with what other states are already doing. The text of §27.201 section is similar to the regulations of the surrounding states mentioned.

New York, New Jersey, Delaware, Maryland, and Ohio currently have regulations pertaining to computerized recordkeeping. Section 27.202 is similar to other states' regulations that set forth the standards for computerized record keeping.

Currently Maryland is the only state that has specific regulations pertaining to centralized prescription processing. Ohio has regulations that allow prescriptions to be filled by a "board approved central-filling operation" but the regulations do not list the standards for the central-filling operation. Section 27.203 will not put Pennsylvania at a competitive disadvantage with other states.

New Jersey has a regulation pertaining to automated medication systems. The Board drew heavily from New Jersey's regulation in drafting §27.204. Ohio and Delaware have regulations pertaining to the use of automated devices but they are not along the same lines as New Jersey. This section will put Pennsylvania on track with some of the most progressive states in this area including Nevada and New Jersey.

(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 regulations will expand on §§ 27.14 and 27.19, which allow for computerized recordkeeping of telephone prescriptions, refills, counseling and the patient profile.

The regulations will affect §25.53, relating to prescriptions orders, 28 Pa. Code §25.53. These Department of Health regulations pertain to generic substitution. However, the Electronic Transactions Act will render these regulations unenforceable with regard to electronic prescriptions.

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

The Board reviews its regulatory proposals at regularly scheduled public meetings. The Board meets each month at 2601 N. Third Street, Harrisburg, and the meeting schedule can be obtained from the Department of State's website at www.dos.state.pa.us/bpoa.

(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.

If pharmacies choose to accept electronically transmitted prescriptions or use computerized recordkeeping systems they will have less paperwork and paper records to maintain. If pharmacies choose to use centralized prescription processing or automated medication systems they will have to maintain the required audit trails, written policies and procedures of operation, personnel training, written program for quality assurance, written plan for recovery, and written program for preventative maintenance.

(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.

There are no perceived special groups of affected people.

(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 as an Order of Final Rulemaking in the Pennsylvania Bulletin. Compliance will be required as of that date.

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

The Board reviews the effectiveness of its regulations on a regular basis under Executive Order 1996-1.

(3) The name of the program.

(4) The provider's name.

(5) The number of clock hours of continuing education credit.

(6) The course approval number or an indication of the provider's status as a preapproved provider.

§ 45.507. Disciplinary action authorized.

(a) A licensed speech-language pathologist, audiologist or teacher of the hearing impaired who submits fraudulent continuing education records may be subject to discipline under section 10 of the act (63 P. S. § 1710).

(b) A licensed speech-language pathologist, audiologist or teacher of the hearing impaired who fails to complete the required continuing education requirement within any biennial renewal period may be subject to discipline.

(c) The falsification of a continuing education record by a program provider may result in revocation of approval by the Board for further program offerings by that provider.

(d) The Board may revoke the approval of a provider based on any appropriate grounds, including failure of the provider to comply with § 45.506 (relating to provider responsibilities).

[Pa.B. Doc. No. 04-1065. Filed for public inspection June 18, 2004, 9:00 a.m.]

STATE BOARD OF PHARMACY

[49 PA. CODE CH. 27]

Technology and Automation

The State Board of Pharmacy (Board) proposes to amend §§ 27.1 and 27.14 (relating to definitions; and supplies) and to add §§ 27.201—27.204 (relating to technology and automation) to read as set forth in Annex A.

Effective Date

The proposed rulemaking will be effective upon final-form publication in the *Pennsylvania Bulletin*.

Statutory Authority

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

Background and Purpose

The use of computer-based information and communications systems are now prevalent in the fields of medicine and pharmacy. Current regulations of the Board do not reflect nor regulate the use of this technology. The proposed rulemaking allows the incorporation of this technology into the practice of pharmacy and brings the Commonwealth up to date with regulations of other states that currently regulate this technology. The purpose of the proposed rulemaking is to set standards for the use of this technology.

Currently, the Board's regulations do not govern whether pharmacies may accept the transmission of prescriptions of a lawful prescriber by electronic means. Prescriptions may be sent to the pharmacy by telephone or facsimile under §§ 27.18(n) and 27.20 (relating to standards of practice; and facsimile machines). The proposed rulemaking allows pharmacies to accept a prescription that was transmitted electronically through the Internet or intranet. Pharmacies would also be permitted to maintain the prescription electronically, thus eliminating a need to maintain an original paper prescription. The proposed rulemaking also allows pharmacies to maintain required records on a computer as opposed to keeping paper files. Pharmacies can then begin moving toward a paperless recordkeeping system.

The proposed rulemaking also provides for the use of centralized prescription processing and automated medication systems. By implementing these innovations into the practice of pharmacy, a pharmacist may spend more time dealing with the clinical aspects of the practice of pharmacy.

Description of the Proposed Rulemaking

Section 27.14(c)(11) permits the use of a computerized recordkeeping system in a pharmacy and lists two standards for the use of a computerized recordkeeping system. Proposed § 27.202 (relating to computerized recordkeeping systems) provides a more comprehensive set of standards for a pharmacy's use of a computerized recordkeeping system. Therefore, the proposed amendment to § 27.14(c)(11) removes standards for computerized recordkeeping to the extent they are under proposed § 27.202 and instead cross references § 27.202. The Board also proposes to amend § 27.14 to remove the direct reference to 21 CFR 1304.04(h) (relating to maintenance of records and inventories) and replace that language with a broader reference to State and Federal laws and regulations. The Board recognizes that 21 CFR 1304.04(h) is not the only law or regulation that governs controlled substance prescription records. The proposed rulemaking is more accurate with regard to the duty of a pharmacy to maintain records in accordance with both State and Federal law.

Proposed § 27.201 (relating to electronically transmitted prescriptions) regulates prescriptions transmitted to a pharmacy by electronic means. Currently, the regulations allow for a pharmacist to accept prescriptions transmitted through the telephone or a facsimile machine, but they do not address the acceptance of prescriptions transmitted through electronic means such as a computer or palm device. The proposed rulemaking sets forth the requirements of the electronic prescription that a pharmacist may accept. To protect the prescription from being altered, it must be electronically encrypted or protected by some other means to prevent access, alteration, manipulation or use by an unauthorized person. The patient is able to choose the pharmacy where the prescription will be transmitted. If a pharmacist believes that the prescription does not comply with State and Federal Law, the pharmacist may choose not to fill the prescription. This section also sets forth the recordkeeping requirements for electronic prescriptions. The regulation requires that either a hard copy or a readily retrievable image must be kept for at least 2 years from the date of the most recent filling of the prescription. This 2-year time frame mirrors the length of time that paper prescriptions are required to be kept on file. Like the existing regulations dealing with facsimile machines, this section prohibits any pharmacy or pharmacist from supplying electronic equipment to any prescriber for transmitting prescriptions. Additionally, the proposed rulemaking clarifies that as an electronic transaction, the transmittal of a prescription through electronic means would also be governed by the Electronic Transactions Act (73 P. S. §§ 2260.101—2260.5101).

Proposed § 27.202 provides standards for maintaining records on a computer as opposed to keeping paper files. The records must be immediately retrievable for prescriptions filled within the previous 12 months or retrievable within 3 working days for prescriptions filled within the previous 24 months. The Board feels that these timeframes are reasonable and will not adversely affect patient care. The proposed rulemaking sets forth the information that must be retrievable. Information that is currently required to be on prescriptions under § 27.18(b)(1), as well as identification of the pharmacist responsible for prescription information entered into the computer system, must be retrievable. This section also provides the procedures to be followed when the system experiences down time. To ensure patient safety, prescription information must be entered into the computerized recordkeeping system as soon as it is available for use. Furthermore, when the information from the computerized recordkeeping system is not available, prescriptions may only be refilled if the number of refills authorized by the prescriber has not been exceeded. Finally, safeguards must be in place to prevent access by unauthorized individuals and to identify any modification or manipulation of information in the system.

Proposed § 27.203 (relating to centralized prescription processing) sets forth the standards applicable to centralized prescription processing. Centralized prescription processing is a process where a prescription is tendered to one pharmacy (the proposed rulemaking calls it the "originating pharmacy"), then transmitted to a central fill pharmacy where the prescription is filled or refilled. Generally, given the volume of prescriptions that it fills, the central fill pharmacy uses an automated medication system to fill prescriptions. The filled prescription is then transferred to the delivering pharmacy where the filled prescription is ultimately delivered to the patient. This section sets forth definitions for each pharmacy involved in centralized prescription processing and specifies which pharmacy is responsible for each step in the prescription filling process. The Board has determined that because a central processing center may be considered the "originating pharmacy" as defined by this section, the central processing center must also be a licensed pharmacy. Because the Board understands that the primary focus of the central processing center will be to process prescriptions and not actually dispense them, the Board has decided to exempt the central processing center from the requirement to maintain $5,000 worth of nonproprietary drugs and devices in § 27.14(a).

Proposed § 27.204 (relating to automated medication systems) regulates the use of automated medication systems to fill prescriptions. This section defines an automated medication system and sets forth the requirements and safeguards that must be in place to use a system such as this. Automated medication systems may be used either in a licensed pharmacy or offsite as long as the operation of the automated medication system is supervised by a pharmacist. The proposed rulemaking requires that automated medication systems be validated to accurately dispense medication prior to going into use. The proposed rulemaking also requires an audit trail of the activity of each pharmacist, technician or other authorized personnel working on the automated medication system. The Board may inspect the system to further validate the accuracy of the system. This section sets forth a comprehensive list of requirements pertaining to policies and procedures in operating these systems, conducting maintenance and in the case of disaster. The proposed rulemaking requires written policies and procedures of operation, quality assurance programs, plans for recovery from disaster and preventative maintenance.

Fiscal Impact and Paperwork Requirements

The proposed rulemaking has no fiscal impact, nor would it impose any additional paperwork requirement on the Commonwealth. The proposed rulemaking should alleviate some paperwork 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 June 8, 2004, the Board submitted a copy of this proposed 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 and the House Professional Licensure Committee. A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, IRRC may convey any comments, recommendations or objections to the proposed rulemaking within 30 days of the close of the public comment period. The comments, recommendations or objections shall specify the regulatory review criteria which have not been met. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the rulemaking, by the Board, the General Assembly and the Governor of comments, recommendations or objections raised.

Public Comment

Interested persons are invited to submit written comments, suggestions or objections regarding this proposed rulemaking to Melanie Zimmerman, State Board of Pharmacy, P. O. Box 2649, Harrisburg, PA 17105-2649 within 30 days following publication of this proposed rulemaking in the *Pennsylvania Bulletin*.

RICHARD R. SIGMA, R.Ph.,
Chairperson

Fiscal Note: 16A-5410. 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

GENERAL PROVISIONS

§ 27.1. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

* * * * *

Automated medication system—

(i) A process that performs operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing or

distribution of medications, and which collects, controls and maintains all transaction information.

(ii) The term does not mean an automatic counting device.

* * * * *

***Central fill pharmacy*—A pharmacy engaging in centralized prescription processing by filling and refilling prescriptions, which includes the preparation and packaging of the medication.**

***Centralized prescription processing*—The processing, under the direction of a pharmacist, of a request to fill or refill a prescription, to perform functions such as refill authorizations, interventions or other matters related to the practice of pharmacy for subsequent delivery to the delivering pharmacy.**

***Central processing center*—A pharmacy operated under the direction of a pharmacist that engages solely in centralized prescription processing.**

* * * * *

***Delivering pharmacy*—The pharmacy that receives the processed prescription or the filled or refilled prescription for delivering to the patient or the patient's authorized representative.**

* * * * *

***Originating pharmacy*—The pharmacy that receives the patient's or prescribing practitioner's request to fill or refill a prescription and performs functions such as the prospective drug review. The central processing center or the central fill pharmacy may be considered the originating pharmacy if the prescription was transmitted by the prescriber directly to the centralized pharmacy or if the patient requested the refill from that pharmacy.**

* * * * *

STANDARDS

§ 27.14. Supplies.

* * * * *

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

* * * * *

(11) Prescription files for keeping prescriptions of nonproprietary drugs in accordance with the act and, for controlled substance prescriptions, **[the regulations of the DEA in 21 CFR 1304.04(h) (relating to maintenance of records and inventories)]** State and Federal laws and regulations. The original prescription **or image of the original prescription** shall be retained for 2 years **from the date of the most recent filling.** A pharmacy may make use of a computerized recordkeeping system for keeping track of telephone prescriptions, refills, counseling, and the like**[, if the system has safeguards to prevent accidental erasure and the information can be transferred to hard copy within 72 hours]** in accordance with § 27.202 (relating to computerized recordkeeping systems).

* * * * *

TECHNOLOGY AND AUTOMATION

§ 27.201. Electronically transmitted prescriptions.

(a) For the purposes of this section, an electronically transmitted prescription means the communication to the pharmacist by means of data base exchange or e-mail (which does not include telephone or facsimile machine) of original prescriptions or refill authorizations, which have been sent directly from an authorized licensed prescriber or an authorized agent to the pharmacy of the patient's choice and which have not been altered, accessed, viewed, screened or manipulated by an intervening entity or person unless authorized by law.

(b) Except for Schedule II controlled substances which must conform to § 27.18(b)(2) (relating to standards of practice), a pharmacist may accept an electronically transmitted prescription, from a prescriber or a designated agent which has been sent directly to a pharmacy of the patient's choice if 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 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 must be stored for at least 2 years from the date of the most recent filling.

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

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

§ 27.202. Computerized recordkeeping systems.

(a) A computerized system used by a pharmacy for recording and maintaining information concerning prescriptions under State and Federal laws must be designed so that it is capable of providing immediate retrieval (by means of monitor, hard-copy printout or other transfer medium) of patient information for all prescriptions filled within the previous 12 months and retrieval within 3 working days of all prescriptions dispensed within the previous 24 months from the last activity date. This information must include the following data:

(1) The information required to be on prescriptions under § 27.18(b)(1) (relating to standards of practice).

(2) Identification of the pharmacist responsible for prescription information entered into the computer system.

(b) The system must be able to transfer all patient information to hard copy within 3 working days.

(c) Prescriptions entered into a computer system but not immediately dispensed must meet the following conditions:

(1) The complete prescription information must be entered in the computer system.

(2) The information must appear in the patient's profile.

(3) There must be positive identification, in the computer system or on the hard-copy prescription, of the pharmacist who is responsible for entry of the prescription information into the system.

(4) The original prescription must be filed according to § 27.18(b).

(d) If the computerized recordkeeping system experiences down time, the prescription information must be entered into the computerized recordkeeping system as soon as it is available for use. During the time the computerized recordkeeping system is not available, prescriptions may be refilled only if the number of refills authorized by the prescriber has not been exceeded.

(e) The system must have adequate safeguards to:

(1) Prevent access by any person who is not authorized to obtain information from the system.

(2) Identify any modification or manipulation of information concerning a prescription.

(3) Prevent accidental erasure of information.

§ 27.203. Centralized prescription processing.

(a) *Centralized prescription processing.* A central fill pharmacy or central processing center may fulfill a request for the processing, filling or refilling of a prescription from either the originating pharmacy or from the patient or the prescriber and may deliver the processed, filled or refilled prescription to a delivering pharmacy provided:

(1) The central fill pharmacy or the central processing center that is to process, fill or refill the prescription has a contract with or has the same owner as the originating pharmacy and the delivering pharmacy. Contractual provisions must include confidentiality of patient information.

(2) The prescription container:

(i) Is clearly labeled with the information required by Federal and State laws and regulations.

(ii) Clearly shows the name, address, telephone number and DEA number of the delivering pharmacy.

(3) Pharmacies that either utilize or act as central fill pharmacies or central processing centers shall have policies and procedures in place that include an audit trail that records and documents the central prescription process and the individuals accountable at each step in the process for complying with Federal and State laws and regulations including recordkeeping.

(4) Pharmacies that engage in centralized prescription processing share a common electronic file.

(5) Each pharmacy engaging in centralized prescription processing shall be jointly responsible for properly filling the prescription.

(6) The delivering pharmacy is responsible for making the offer to counsel to the patient under § 27.19(e) (relating to prospective drug review and patient counseling).

(b) *Exemption.* The central processing center is exempt from maintaining an inventory of at least $5,000 worth of nonproprietary drugs and devices under § 27.14(a) (relating to supplies).

§ 27.204. Automated medication systems.

(a) This section establishes standards applicable to licensed pharmacies that utilize automated medication systems which may be used to store, package, dispense or distribute prescriptions.

(b) A pharmacy may use an automated medication system to fill prescriptions or medication orders provided that:

(1) The pharmacist manager, or the pharmacist under contract with a long-term care facility responsible for the dispensing of medications if an automated medication system is utilized at a location which does not have a pharmacy onsite, is responsible for the supervision of the operation of the system.

(2) The automated medication system has been tested and validated by the pharmacy and found to dispense accurately prior to the implementation of the system. The pharmacy shall make the results of the testing available to the Board upon request.

(3) The pharmacy shall make the automated medication system available to the Board for the purpose of inspection, whereby the Board may validate the accuracy of the system.

(4) The automated medication system shall electronically record the activity of each pharmacist, technician or other authorized personnel with the time, date and initials or other identifier in a manner that a clear, readily retrievable audit trail is established. It is the intent of this section to hold responsible each pharmacist for the transaction performed by that pharmacist, precluding the need for a final check of a prescription by one individual pharmacist prior to delivery.

(c) The pharmacist manager or the pharmacist under contract with a long-term care facility responsible for the delivery of medications shall be responsible for the following:

(1) Reviewing and approving the policies and procedures for system operation, safety, security, accuracy, access and patient confidentiality.

(2) Ensuring that medications in the automated medication system are inspected, at least monthly, for expiration date, misbranding and physical integrity, and ensuring that the automated medication system is inspected, at least monthly, for security and accountability.

(3) Assigning, discontinuing or changing personnel access to the automated medication system.

(4) Ensuring that the automated medication system is stocked accurately and an accountability record is maintained in accordance with the written policies and procedures of operation.

(5) Ensuring compliance with applicable provisions of State and Federal law.

(d) When an automated medication system is used to fill prescriptions or medication orders, it must be operated according to written policies and procedures of operation. The policies and procedures of operation must:

(1) Include a table of contents.

(2) Include a description of all procedures of operation.

(3) Set forth methods that shall ensure retention of each amendment, addition, deletion or other change to the policies and procedures of operation for at least 2 years after the change is made. Each change shall be signed or initialed by the registered pharmacist in charge

and include the date on which the registered pharmacist in charge approved the change.

(4) Set forth methods that ensure that a pharmacist currently licensed in the transmitting jurisdiction reviews and approves the transmission of each original or new prescription or medication order to the automated medication system before the transmission is made.

(5) Set forth methods that ensure that access to the records of medications and other medical information of the patients maintained by the pharmacy is limited to licensed practitioners or personnel approved to have access to the records.

(6) Set forth methods that ensure that access to the automated medication system for stocking and removal of medications is limited to licensed pharmacists or qualified support personnel acting under the supervision of a licensed pharmacist. An accountability record which documents all transactions relative to stocking and removing medications from the automated medication system must be maintained.

(7) Identify the circumstances under which medications may be removed from the automated medication system by a licensed medical practitioner for distribution to a patient without prior order review by a licensed pharmacist.

(e) A pharmacy that uses an automated medication system to fill prescriptions or medication orders shall, at least annually, review its written policies and procedures of operation and revise them, if necessary.

(f) A copy of the written policies and procedures of operation adopted under this section shall be retained at the pharmacy and at the long-term care facility where the automated medication system is utilized. Upon request, the pharmacy shall provide to the Board a copy of the written policies and procedures of operation for inspection and review.

(g) The pharmacist manager shall be responsible for ensuring that, prior to performing any services in connection with an automated medication system, all licensed practitioners and supportive personnel are trained in the pharmacy's standard operating procedures with regard to automated medication systems as set forth in the written policies and procedures. The training shall be documented and available for inspection.

(h) A pharmacy that uses an automated medication system to fill prescriptions or medication orders shall operate according to a written program for quality assurance of the automated medication system which:

(1) Requires monitoring of the automated medication system.

(2) Establishes mechanisms and procedures to test the accuracy of the automated medication system at least every 6 months and whenever any upgrade or change is made to the system.

(3) Requires the pharmacy to maintain all documentation relating to the written program for quality assurance for at least 2 years. Upon reasonable notice from the Board, the pharmacy shall provide information to the Board regarding the quality assurance program for automated medication systems.

(i) A pharmacy that uses an automated medication system to fill prescriptions or medication orders shall maintain a written plan for recovery from a disaster that interrupts the ability of the pharmacy to provide services. The written plan for recovery must include:

(1) Planning and preparation for a disaster.

(2) Procedures for response to a disaster.

(3) Procedures for the maintenance and testing of the written plan for recovery.

(j) A pharmacy that uses an automated medication system to fill prescriptions or medication orders shall maintain a written program for preventative maintenance of the system. Documentation of completion of all maintenance shall be kept on file in the pharmacy for a minimum of 2 years.

[Pa.B. Doc. No. 04-1066. Filed for public inspection June 18, 2004, 9:00 a.m.]

CDL-1

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

2405

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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-5410

DATE OF ADOPTION: _____

BY: Michael J. Romano

TITLE: Chairperson
(EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)

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

BY: DAVID C. CURTIS

11.01.05
DATE OF APPROVAL

EXECUTIVE
(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
Technology and Automation

The State Board of Pharmacy (Board) amends §§ 27.1, 27.14 and 27.16 (relating to definitions, supplies, and construction and equipment requirements) and adds §§ 27.201 – 27.204 (relating to technology and automation) to read as set forth in Annex A. The rulemaking adds definitions, updates §§ 27.14 and 27.16 and adds new sections for electronically transmitted prescriptions, computerized recordkeeping systems, central fill pharmacies, and automated medication systems.

Notice of Proposed Rulemaking was published at 34 Pa.B. 3146 (June 19, 2004). Publication was followed by a 30-day public comment period. The Board received comments from the Pennsylvania Department of Health (DOH), Cardinal Health, Diamond Pharmacy Services, WebMD, Rx.com, Neighbor Care and the Pennsylvania Society of Health-System Pharmacists (PSHP). The House Professional Licensure Committee (HPLC) submitted seven comments to the proposed rulemaking. The Senate Consumer Protection and Professional Licensure Committee made no comments. The Independent Regulatory Review Commission (IRRC) submitted seven comments to the proposed rulemaking. The Board discussed the comments at its August 17, 2004, and September 21, 2004 public meetings.

Summary of Comments and Responses to Proposed Rulemaking

Section 27.1 Definitions.

HPLC recommended revision of the definition of "automated medication system" and suggested alternate language. The Board has amended the definition accordingly. IRRC recommended adding a definition of the term "automatic counting device" to the final-form regulation. The Board has added a definition of "automatic counting device" as IRRC suggested. PSHP and IRRC queried whether the definition of "automated medication system" would prohibit the use of automated compounding systems from a central location to fill or prepare intravenous medications, or the batching of products for use in a centralized pharmacy. An automated compounding system is not included in the definition of "automated medication system" therefore the definition would not prohibit the use of automated compounding systems.

HPLC and IRRC recommended rewriting the definition of "originating pharmacy" so that a licensee can clearly determine when a central fill pharmacy or a central processing center is an "originating pharmacy". The Board has amended the final-form definition accordingly and has also amended the definitions of "central fill pharmacy" and "delivering pharmacy" to obviate any confusion between the terms used to describe pharmacies in the centralized prescription processing regulation.

IRRC commented that the definition of "prescription" should be amended to include electronic orders. The Board has amended the final-form regulation accordingly.

IRRC next questioned what a central processing center does. A central processing center is not a fully functional pharmacy in that it is not a place where drugs are dispensed. A central processing center is a facility that performs the refill authorizations, counseling, interventions, billing or other functions related to the practice of pharmacy. This facility would generally consist of an office and a computer and would only perform cognitive functions, not filling and labeling. It is important to license this facility as a pharmacy to give the Board jurisdiction over the facility itself, as the functions performed at the facility are integral to the practice of pharmacy.

PSHP asked whether the central pharmacy and a satellite pharmacy in an institution would be designated as one of the defined pharmacy terms for centralized prescription processing. The pharmacy terms (originating pharmacy, central fill pharmacy, central processing center, and delivering pharmacy) only pertain to centralized filling of prescriptions. Since institutions generally fill drug orders for patients of the institution, these are not contemplated as coming under the central fill regulation. However, the terms would apply to an institution's outpatient pharmacy that fills prescriptions using a centralized filling process. By definition, satellite pharmacies do not fill outpatient prescriptions and would not come into play in the centralized prescription filling process.

Section 27.14. Supplies.

HPLC recommended that §27.14 (relating to supplies) contain language that makes it clear that an exception to the inventory requirements is found in §27.203(b) (relating to centralized prescription processing). IRRC also commented on the need to cross-reference this section with §27.203(b). The Board has amended the final-form regulation accordingly. The Board also amended this section to allow central processing centers to maintain equipment, supplies and a reference library necessary to engage in centralized prescription processing.

Section 27.16. Construction and equipment requirements.

The Board amended the final-form regulation to add provisions that were overlooked in the proposed regulation. The amendments create an exception to the minimum size requirements of the prescription area and the requirement to have a sink use solely for pharmaceutical purposes. Central processing centers will instead need only adequate space to perform the functions taking place at that pharmacy.

Section 27.201. Electronically transmitted prescriptions.

HPLC commented that subsection (a) should be rewritten without parentheses. The Board has amended the final-form regulation accordingly. IRRC recommended that the definition of

"electronically transmitted prescription" be amended to allow any method of electronic communication that can reliably provide the information required by §27.201(b) and the Board has done so. IRRC commented that §27.201(a) was difficult to comprehend. With the amendments to this section the Board believes the final-form regulation is clear as to the Board's intent and is comprehendible to pharmacists and information technologists who are subject to the regulations. WebMD commented that §27.201(a) excluded computer-to-facsimile machine electronic prescriptions. The Board agrees and has amended the section with language suggested by WebMD.

IRRC commented that subsection (b) does not address § 3(a) of the act of November 24, 1976, commonly known as the Generic Substitution Law (35 P.S. §960.3(a)) (relating to generic equivalent drugs) and recommended that the Board address the requirements of 35 P.S. §960.3(a) in the final-form regulation. WebMD also requested that the Board include guidance as to how a prescriber's generic substitution instructions would be communicated in electronically transmitted prescriptions. The generic substitution law instructs prescribers what must be imprinted on a prescription blank and what must be written to indicate that the brand medication should be dispensed. The Board cannot change the final-form regulations to address the generic substitution laws because the Board does not have the authority to impose an affirmative duty on a professional not licensed by the Board. The Board believes it does not have the statutory or regulatory authority to place requirements on prescribers.

WebMD commented that the regulations would prohibit prescribers' use of electronic data interchange (EDI) networks to deliver electronically transmitted prescriptions to the pharmacy of the patient's choice. EDI networks access an electronically transmitted prescription to route the prescription between prescribers and pharmacies. An EDI network scans the prescription to ensure that information required by law has been entered into the appropriate data field. EDI networks decrypt the prescription's content and convert it to a format that can be received via a point-to-point transmission over telephone lines and printed at the pharmacy's facsimile machine. The EDI network does not actually read the prescription, nor substantively alter the prescription information. WebMD suggested alternate language to §27.201(a) to allow EDI networks to deliver electronically transmitted prescriptions between prescribers and pharmacies. The Board agrees and has amended the final-form regulation with the language suggested by WebMD.

IRRC commented that given the importance of the Electronic Transactions Act (ETA)(73 P.S. §§ 2260.101 et seq.) to this regulation, it would be appropriate to address electronic prescription requirements in a separate subsection. The Board believes that references to the ETA are clear and the requirements of an electronic prescription are clearly stated in subsection (b). The Board cannot possibly cover every detail of electronic prescriptions. This technology is already in use at many pharmacies, however until now it has not had specific regulations to govern its use. Pharmacies were left to apply this technology within the requirements of the regulations pertaining to paper prescriptions. The regulations are intended to provide minimum standards to protect the public by the use of this technology. Finally, the Board notes that developing further regulations at this time

may be counter productive. The Board suggests pharmacists working with the new regulations will provide the genesis for further rulemaking in the areas of automation and computer based technology.

IRRC commented that subparagraph (b)(5) should be a separate subsection. The Board has amended the final-form regulation accordingly.

PSHP queried whether the term "prescription" as used in §27.201 included orders or drug orders as defined in the Board regulations. The terms "prescription" and "drug order" are separately defined in §27.1 (relating to definitions) and as such a drug order is not included under the term "prescription".

Section 27.202. Computerized recordkeeping systems.

HPLC commented that subsection (a) should be rewritten without parentheses. The Board has amended the final-form regulation accordingly. IRRC inquired why the Board is not requiring backup of computerized recordkeeping systems in this section. First, the Board notes that subsection (e) requires the computerized recordkeeping system to have adequate safeguards to prevent accidental erasure of information, which would accomplish the same goal as backing up the system. The Board is not using specific language such as "backing up the system" because newer technology negates the need to do this. New technology uses mirror drives and other means to ensure the safety of information without the need for back up of the system.

In subsection (d) IRRC and PSHP questioned how the number of refills could be verified unless the patient brings the original prescription vial/container with them to the pharmacy, or if the patient is phoning in their refill. Upon further review of subsection (d) the Board removed that language in the final-form regulation. It deems the language unnecessary as pharmacists may use professional judgment in filling or refilling prescriptions regardless of the type of recordkeeping system in use.

PSHP asked if the Board has considered requiring minimum contingency plans in case of a system failure. In the draft stage of the regulations, similar provisions were included, but after careful thought were removed by the Board. These provisions can be too restrictive and would not apply to all systems. Furthermore, technological changes could render any minimum contingency plans obsolete and require frequent updating of the regulations.

Section 27.203. Centralized prescription processing.

HPLC recommended that in subsection (a) the word "provided" be replaced with "if the following requirements are met". The Board has amended the final-form regulation accordingly.

Rx.com commented that other states have added language to their central fill rules that explicitly allow home delivery by central fill pharmacies. The Board notes that if the central fill pharmacy is delivering the filled prescription then it would also be the delivering pharmacy as defined by §27.1 (relating to definitions). The Board amended the definitions for central fill pharmacy, delivering pharmacy and originating pharmacy to clarify its intent. Because the Board's current regulations already allow for home delivery of medications by pharmacies, it is unnecessary to add specific language to the central fill regulations to allow home delivery.

In the final-form regulation the Board added exemptions that were overlooked during the proposed stage of the regulation. A central processing pharmacy is exempt from the minimum size requirement for a prescription area as well as the requirement to have a sink used solely for pharmaceutical purposes. These exemptions are cross-referenced in §27.16(b) (relating to construction and equipment requirements).

Section 27.204. Automated medication systems.

HPLC noted that the regulations required pharmacies to have policies and procedures in place, to have policies of operation, and to operate according to a written program, but there was no duty imposed on pharmacies to actually create these policies or programs. In response, the Board modified the appropriate sections to create a duty to write or adopt these policies or programs. IRRC asked who has the responsibility to write the policies and procedures. The responsibility is on the pharmacy to maintain these policies and procedures. Therefore, the owner of the pharmacy permit should have these as part of the supplies in the pharmacy and it would be up to each pharmacy how to create these. These policies could be created by any number of people. For example, the permit owner or pharmacist manager could write the policies and procedures or pharmacies could adopt policies and procedures prepared by the manufacturer of the automated medication systems.

IRRC next commented that subsection (b) uses the term "other identifier" and questions what the Board would consider an adequate method of electronically recording the activity of each pharmacist, technician or other authorized personnel. The Board notes that this term is already used in §27.18(b)(1) (relating to standards of practice) in reference to prescribers and is not a new term. There are several means to identify a pharmacist other than initials such as an employee number or name or by recording the information through biometrics, retina scans or bar code scans.

HPLC commented that the Board should rewrite the language in subsection (b)(4) so that the language clearly and accurately reflects the Board's policy. IRRC also commented that paragraph (4) was not clear. The regulation requires an audit trail to be established so that each pharmacist, technician or other authorized personnel who works on the automated medication system is identified. The Board has amended this subsection with language that clearly states that each pharmacist who works on the automated medication system will be held responsible for the transaction performed by that pharmacist. The pharmacist will also be responsible for transactions

performed by personnel under the supervision of the pharmacist. Because the system has been validated, a final check of the filled prescription is unnecessary. (In a regular retail pharmacy situation, a pharmacist is required to check the filled prescription before it is dispensed. This pharmacist's initials are usually listed on the prescription label.) The last sentence of paragraph (4) indicates that the Board will hold each pharmacist who worked with the automated medication system responsible for the pharmacist's actions and the actions of the technicians and other authorized personnel working under the pharmacist's supervision.

IRRC questioned whom the Board meant by "qualified support personnel" in subsection (d)(6). Cardinal Health also commented that subsection (d)(6) would limit access to an automated medication system to only pharmacists and qualified support personnel under the supervision of a licensed pharmacist and would prevent other healthcare professionals legally authorized to administer drugs from accessing the system. To clarify the issue expressed by Cardinal Health, the Board amended the definition of "automated medication system" in the final-form rulemaking to clarify that automated medication system does not refer to machines such as a unit based dispensing cabinet and amended the language of §27.204(d)(6) to remove the term "qualified support personnel" and add the term "the pharmacist's designee" to allow the pharmacist operating the automated medication system greater latitude to designate who can access the system. The Board also notes in response to Cardinal Health's concerns that subsection (d)(7) specifically allows pharmacists to identify circumstances under which a licensed medical practitioner could remove medications from the automated medication system for distribution to a patient.

General Comments

DOH commented that the regulations might conflict with certain sections of the Pennsylvania Code. In particular, 28 Pa. Code §25.53(b) (relating to prescription orders,) requires prescribers to handwrite "brand necessary" or "brand medically necessary", and subsection (d) requires controlled substance prescriptions to be written in indelible ink, indelible pencil or typewriter. The Board notes that section 303 of the ETA (73 P.S. §2260.303) would make these provisions unenforceable with regard to electronic prescriptions. DOH further commented that 28 Pa. Code §25.56 (a) and (b) (relating to prescription record keeping) require prescription records of controlled substances in schedules I and II to be maintained separately and controlled substances III through V to be marked with a red letter "C". Pharmacies still have to comply with all applicable State and Federal regulations, so any pharmacy that stores prescription records on a computer will still have to adhere to this regulation. The Board's regulations do not supercede this requirement. The Board notes, that where other laws or regulations prohibit the use of electronic prescriptions, these regulations would not apply. The Board urges DOH to update its regulations to take into consideration electronic prescriptions and computerized recordkeeping.

PSHP asks whether the Board plans to reference the requirements of patient confidentiality contained in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (42 U.S.C.A.

§§300gg - 300gg-92) in these regulations. The Board does not intend to specifically reference HIPAA's confidentiality provisions. Confidentiality is already addressed in §27.19(i) (relating to prospective drug review and patient counseling) and requires pharmacists to regard all information obtained as confidential unless State or Federal law or regulations require or authorize the disclosure.

HPLC and IRRC requested that the Board consult DOH regarding its concerns before final regulations are submitted. The Board has consulted with DOH and has addressed the DOH's concerns in this Preamble.

IRRC noted that several sections require compliance with "State and Federal laws and regulations" and commented that the Board should replace this language with specific citations to the applicable laws or regulations. The Board chose this language for two reasons: 1) several different State and Federal laws apply to the practice of pharmacy, it would be cumbersome to list each specific law and regulation and 2) the specific area of law involving technology and automation is still evolving and there are regulations that have yet to be promulgated that would pertain to the Board's regulations. For example, the Federal Drug Enforcement Administration is in the process of promulgating Federal regulations pertaining to electronic prescribing of controlled substances. In other places in the act and regulations there are general references to State and Federal laws (See section 8(11) of the act and §§27.14(b)(2), 27.18(p)(3), 27.20(i)(2)(iii) relating to supplies; standards of practice; and facsimile machines), therefore the Board declines to make this change.

Statutory Authority

The 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) and (9)).

Fiscal Impact and Paperwork Requirements

The Board had identified no fiscal impact or paperwork requirements to state or local governments associated with the final rulemaking.

Compliance with Executive Order 1996-1

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. This final-form rulemaking addresses a compelling public interest and otherwise complies with Executive Order 1996-1.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a), on June 8, 2004, the Board submitted a copy of the notice of proposed rulemaking, published at 34 Pa.B. 3146, to IRRC and the Chairpersons of the House Professional Licensure Committee (HPLC) and the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC) for review and comment.

Under section 5(c) of the Regulatory Review Act, IRRC, the HPLC and the SCP/PLC were provided with copies of the comments received during the public comment period, as well as other documents when requested. In preparing the final-form rulemaking, the Board has considered all comments from IRRC, the HPLC, the SCP/PLC and the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P. S. § 745.5a(j.2)), on _____, the final-form rulemaking was (deemed) approved by the HPLC. On _____, the final-form rulemaking was (deemed) approved by the SCP/PLC. Under section 5.1(e) of the Regulatory Review Act, IRRC met on _____, and (deemed) approved the final-form rulemaking.

Additional Information

Individuals who need information about the regulation may contact Melanie Zimmerman, R.Ph., Executive Secretary, State Board of Pharmacy, P.O. Box 2649, Harrisburg, PA 17105-2649.

Findings

The State Board of Pharmacy finds that:

(1) Public notice of intention to adopt a regulation at 49 Pa.Code, Chapter 27, 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 under those sections 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) This final rulemaking is necessary and appropriate for the administration of the Pharmacy Act.

(4) The amendments to this final rulemaking do not enlarge the original purpose of the proposed regulation published at 34 Pa.B. 3146 (June 19, 2004).

Order

The Board therefore ORDERS that:

(A) The regulations of the Board, 49 Pa.Code Chapter 27, are amended to read as set forth in Annex A.

(B) The Board shall submit this Order and a copy of Annex A to the Office of Attorney General and the Office of General Counsel for approval as required by law.

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

(D) This Order shall take effect upon publication in the Pennsylvania Bulletin.

Michael J. Romano, R.Ph.
Chairman, State Board of Pharmacy

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

GENERAL PROVISIONS

§27.1. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

* * *

Automated medication system –

(i) A process that performs operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing ~~or~~ AND distribution of medications, and which collects, controls and maintains all transaction information.

(ii) The term does not ~~mean~~ INCLUDE an automatic counting device OR UNIT BASED DISPENSING CABINET.

AUTOMATIC COUNTING DEVICE – A DEVICE USED IN A PHARMACY TO AUTOMATICALLY COUNT MEDICATION FOR DISPENSING.

* * *

Central fill pharmacy – A pharmacy engaging in centralized prescription processing by filling and refilling prescriptions, which includes the preparation and packaging of the medication. A CENTRAL FILL PHARMACY MAY ALSO BE THE ORIGINATING OR DELIVERING PHARMACY.

Centralized prescription processing – The processing, under the direction of a pharmacist, of a request to fill or refill a prescription, to perform functions such as refill authorizations, interventions or other matters related to the practice of pharmacy for subsequent delivery to the delivering pharmacy.

Central processing center – A pharmacy operated under the direction of a pharmacist that engages solely in centralized prescription processing.

* * *

Delivering pharmacy – The pharmacy that receives the processed prescription or the filled or refilled prescription for delivering to the patient or the patient's authorized representative. A DELIVERING PHARMACY MAY ALSO BE AN ORIGINATING OR CENTRAL FILL PHARMACY.

* * *

Originating pharmacy – The pharmacy that receives the patient's or prescribing practitioner's request to fill or refill a prescription and performs functions such as the prospective drug review. The TERM INCLUDES A central processing center or ~~the~~ A central fill pharmacy ~~may be considered the originating pharmacy~~ if the prescription was transmitted by the prescriber directly to the CENTRAL PROCESSING CENTER OR CENTRAL FILL ~~centralized~~ pharmacy or if the patient requested the refill from that pharmacy.

***

Prescription – A written, ELECTRONIC or oral order issued by a licensed medical practitioner in the course of professional practice for a controlled substance, other drug or device or medication which is dispensed for use by a consumer.

* * *

STANDARDS

§27.14. Supplies.

(a) A pharmacy shall maintain a supply of drugs and devices adequate to meet the needs of the health professions and the patients it is intended to serve. The applicant for a pharmacy permit shall show proof by affidavit that the applicant has ordered or possesses and shall continue to maintain an inventory of nonproprietary drugs, devices and equipment appropriate to the practice of that pharmacy. The inventory shall include at least $5,000 worth of nonproprietary drugs and devices, at cost, from a licensed wholesaler or manufacturer. The inventory may not go below this figure at any time. A CENTRAL PROCESSING CENTER IS NOT REQUIRED TO MAINTAIN $5,000 WORTH OF NONPROPRIETARY DRUGS AND DEVICES UNDER §27.203(B) (RELATING TO CENTRALIZED PRESCRIPTION PROCESSING).

* * *

(c) EXCEPT FOR A PHARMACY LICENSED AS A CENTRAL PROCESSING CENTER, A pharmacy shall maintain at least the following equipment and supplies:

* * *

(11) Prescription files for keeping prescriptions of nonproprietary drugs in accordance with the act and, for controlled substance prescriptions, [the regulations of the DEA in 21

CFR 1304.04(h) (relating to maintenance of records and inventories)] State and Federal laws and regulations. The original prescription or image of the original prescription shall be retained for 2 years from the date of the most recent filling. A pharmacy may make use of a computerized recordkeeping system for keeping track of telephone prescriptions, refills, counseling, and the like[, if the system has safeguards to prevent accidental erasure and the information can be transferred to hard copy within 72 hours]in accordance with §27.202 (relating to computerized recordkeeping systems).

(D) A PHARMACY LICENSED AS A CENTRAL PROCESSING CENTER SHALL MAINTAIN EQUIPMENT, SUPPLIES AND AN ADEQUATE REFERENCE LIBRARY NECESSARY TO ENGAGE IN CENTRALIZED PRESCRIPTION PROCESSING.

* * *

§27.16. Construction and equipment requirements.

* * *

(b) *Building standards.* The following apply to building standards.

(1) *Minimum size.*

(i) The minimum size of the prescription area shall be at least 250 square feet, and shall be large enough, considering the level of activity, to carry on the practice of pharmacy in a manner that protects the health and safety of professionals, employes and the public. Within the prescription area, there shall be a prescription working counter of at least 10 linear feet in length and 2 linear feet in width. If more than two pharmacists are on duty simultaneously, the

minimum counter length shall be increased by 5 linear feet for an additional pharmacist. Institutions with special considerations may apply to the Board for a waiver.

(ii) A PHARMACY LICENSED AS A CENTRAL PROCESSING CENTER NEED NOT CONFORM TO THE MINIMUM SPACE REQUIREMENTS IN SUBPARAGRAPH (I), BUT SHALL HAVE ADEQUATE SPACE TO PERFORM THE FUNCTIONS TAKING PLACE AT THAT PHARMACY.

* * *

(5) *Sanitary facilities.* EXCEPT FOR PHARMACIES LICENSED AS CENTRAL PROCESSING CENTERS, Pharmacies shall be equipped with a sink within the prescription area to be used solely for pharmaceutical purposes. The sink shall measure at least 200 square inches exclusive of drainboard area. The sink shall be connected properly to supply hot and cold water. Restroom facilities for employes of the pharmacy shall be provided reasonably close to, but outside of the prescription area.

* * *

TECHNOLOGY AND AUTOMATION

§27.201. Electronically transmitted prescriptions.

(a) For the purposes of this section, an electronically transmitted prescription means the communication ~~to the pharmacist by means of data base exchange or e-mail (which does not include telephone or facsimile machine) of original prescriptions or refill authorizations, which have been sent directly from an authorized licensed~~

~~prescriber or an authorized agent to the pharmacy of the patient's choice and which have not been altered, accessed, viewed, screened, or manipulated by an intervening entity or person unless authorized by law~~ 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) Except for Schedule II controlled substances which must conform to the requirements of §27.18(b)(2) (relating to standards of practice), a pharmacist may accept an electronically transmitted prescription~~,~~ from a AN AUTHORIZED LICENSED prescriber or ~~a~~ 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 SECTIONS 103 AND 301 OF the Electronic Transactions Act (73 P .S. ~~§§2260.101-2260.5101~~ 2260.103 AND 2260.301).

(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 must be stored for at least 2 years from the date of the most recent filling.

~~(5)~~ (C) An electronically transmitted prescription must be processed in accordance with the act and this chapter.

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

§27.202. Computerized recordkeeping systems.

(a) A computerized system used by a pharmacy for recording and maintaining information concerning prescriptions under State and Federal laws must be designed so that it is capable of providing immediate retrieval, ~~(~~by means of monitor, hard-copy printout or other transfer medium~~)~~, of patient information for all prescriptions filled within the previous 12 months and retrieval within 3 working days of all prescriptions dispensed within the previous 24 months from the last activity date. This information must include the following data:

(1) The information required to be on prescriptions under §27.18(b)(1) (relating to standards of practice).

(2) Identification of the pharmacist responsible for prescription information entered into the computer system.

(b) The system must be able to transfer all patient information to hard copy within 3 working days.

(c) Prescriptions entered into a computer system but not immediately dispensed must meet all of the following conditions:

(1) The complete prescription information must be entered in the computer system.

(2) The information must appear in the patient's profile.

(3) There must be positive identification, in the computer system or on the hard-copy prescription, of the pharmacist who is responsible for entry of the prescription information into the system.

(4) The original prescription must be filed according to §27.18(b).

(d) If the computerized recordkeeping system experiences down time, the prescription information must be entered into the computerized recordkeeping system as soon as it is available for use. ~~During the time the computerized recordkeeping system is not available, prescriptions may be refilled only if the number of refills authorized by the prescriber has not been exceeded.~~

(e) The system must have adequate safeguards to:

(1) Prevent access by any person who is not authorized to obtain information from the system.

(2) Identify any modification or manipulation of information concerning a prescription.

(3) Prevent accidental erasure of information.

§27.203. Centralized prescription processing.

(a) *Centralized prescription processing.* A central fill pharmacy or central processing center may fulfill a request for the processing, filling or refilling of a prescription from either the originating pharmacy or from the patient or the prescriber and may deliver the processed, filled or refilled prescription to a delivering pharmacy ~~provided~~ IF THE FOLLOWING REQUIREMENTS ARE MET:

(1) The central fill pharmacy or the central processing center that is to process, fill or refill the prescription has a contract with or has the same owner as the originating pharmacy and the delivering pharmacy. Contractual provisions must include confidentiality of patient information.

(2) The prescription container:

(i) Is clearly labeled with the information required by Federal and State laws and regulations.

(ii) Clearly shows the name, address, telephone number and DEA number of the delivering pharmacy.

(3) Pharmacies that either utilize or act as central fill pharmacies or central processing centers shall ~~have~~ CREATE OPERATING policies and procedures. ~~in place that~~ THE POLICIES AND PROCEDURES MUST include an audit trail that records and documents the central prescription process and the individuals

accountable at each step in the process for complying with Federal and State laws and regulations including recordkeeping.

(4) Pharmacies that engage in centralized prescription processing share a common electronic file.

(5) Each pharmacy engaging in centralized prescription processing shall be jointly responsible for properly filling the prescription.

(6) The delivering pharmacy is responsible for making the offer to counsel to the patient under §27.19(e) (relating to prospective drug review and patient counseling).

(b) *ExemptionS.* The central processing center is exempt from:

(1) ~~maintaining~~ MAINTAINING an inventory of at least $5,000 worth of nonproprietary drugs and devices under §27.14(a) (relating to supplies).

(2) THE MINIMUM SIZE REQUIREMENTS OF §27.16(B)(1) (RELATING TO CONSTRUCTION AND EQUIPMENT REQUIREMENTS).

(3) THE REQUIREMENT TO HAVE A SINK USED SOLELY FOR PHARMACEUTICAL PURPOSES OF §27.16(B)(5).

§27.204. Automated medication systems.

(a) This section establishes standards applicable to licensed pharmacies that utilize automated medication systems which may be used to store, package, dispense or distribute prescriptions.

(b) A pharmacy may use an automated medication system to fill prescriptions or medication orders provided that:

(1) The pharmacist manager, or the pharmacist under contract with a long-term care facility responsible for the dispensing of medications if an automated medication system is utilized at a location which does not have a pharmacy onsite, is responsible for the supervision of the operation of the system.

(2) The automated medication system has been tested and validated by the pharmacy and found to dispense accurately prior to the implementation of the system. The pharmacy shall make the results of such testing available to the Board upon request.

(3) The pharmacy shall make the automated medication system available to the Board for the purpose of inspection, whereby the Board may validate the accuracy of the system.

(4) The automated medication system shall electronically record the activity of each pharmacist, technician or other authorized personnel with the time, date and initials or other identifier in such a manner that a clear, readily retrievable audit trail is established. ~~It is the intent of this section to hold responsible each pharmacist for the transaction performed by that pharmacist, precluding the need for a final check of a prescription by one individual pharmacist prior to delivery.~~ A PHARMACIST WILL BE HELD RESPONSIBLE FOR TRANSACTIONS PERFORMED BY THAT PHARMACIST OR UNDER THE SUPERVISION OF THAT PHARMACIST.

(c) The pharmacist manager or the pharmacist under contract with a long-term care facility responsible for the delivery of medications shall be responsible for the following:

(1) Reviewing and approving all policies and procedures for system operation, safety, security, accuracy, access and patient confidentiality.

(2) Ensuring that medications in the automated medication system are inspected, at least monthly, for expiration date, misbranding and physical integrity, and ensuring that the automated medication system is inspected, at least monthly, for security and accountability.

(3) Assigning, discontinuing or changing personnel access to the automated medication system.

(4) Ensuring that the automated medication system is stocked accurately and an accountability record is maintained in accordance with the written policies and procedures of operation.

(5) Ensuring compliance with all applicable provisions of State and Federal law.

(d) When an automated medication system is used to fill prescriptions or medication orders, it shall be operated according to written policies and procedures of operation CREATED OR ADOPTED BY THE PHARMACY. The policies and procedures of operation shall:

(1) Include a table of contents.

(2) Include a description of all procedures of operation.

(3) Set forth methods that shall ensure retention of each amendment, addition, deletion or other change to the policies and procedures of operation for at least 2 years after the change is made. Each change shall be signed or initialed by the registered pharmacist ~~in charge~~ MANAGER and include the date on which the registered pharmacist ~~in charge~~ MANAGER approved the change.

(4) Set forth methods that ensure that a pharmacist currently licensed in the transmitting jurisdiction reviews and approves the transmission of each original or new prescription or medication order to the automated medication system before the transmission is made.

(5) Set forth methods that ensure that access to the records of medications and other medical information of the patients maintained by the pharmacy is limited to licensed practitioners or personnel approved to have access to the records.

(6) Set forth methods that ensure that access to the automated medication system for stocking and removal of medications is limited to licensed pharmacists or ~~qualified support personnel~~ THE PHARMACIST'S DESIGNEE acting under the supervision of a licensed pharmacist. An accountability record which documents all transactions relative to stocking and removing medications from the automated medication system must be maintained.

(7) Identify the circumstances under which medications may be removed from the automated medication system by a licensed medical practitioner for distribution to a patient without prior order review by a licensed pharmacist.

(e) A pharmacy that uses an automated medication system to fill prescriptions or medication orders shall, at least annually, review its written policies and procedures of operation and revise them, if necessary.

(f) A copy of the written policies and procedures of operation adopted under this section shall be retained at the pharmacy and at the long-term care facility where the automated medication system is utilized. Upon request, the pharmacy shall provide to the Board a copy of the written policies and procedures of operation for inspection and review.

(g) The pharmacist manager shall be responsible for ensuring that, prior to performing any services in connection with an automated medication system, all licensed practitioners and supportive personnel are trained in the pharmacy's standard operating procedures with regard to automated medication systems as set forth in the written policies and procedures. The training shall be documented and available for inspection.

(h) A pharmacy that uses an automated medication system to fill prescriptions or medication orders shall CREATE AND operate according to a written program for quality assurance of the automated medication system which:

(1) Requires monitoring of the automated medication system.

(2) Establishes mechanisms and procedures to test the accuracy of the automated medication system at least every 6 months and whenever any upgrade or change is made to the system.

(3) Requires the pharmacy to maintain all documentation relating to the written program for quality assurance for at least 2 years. Upon reasonable

notice from the Board, the pharmacy shall provide information to the Board regarding the quality assurance program for automated medication systems.

(i) A pharmacy that uses an automated medication system to fill prescriptions or medication orders shall maintain a written plan for recovery from a disaster that interrupts the ability of the pharmacy to provide services. The written plan for recovery shall include:

(1) Planning and preparation for a disaster.

(2) Procedures for response to a disaster.

(3) Procedures for the maintenance and testing of the written plan for recovery.

(j) A pharmacy that uses an automated medication system to fill prescriptions or medication orders shall maintain a written program for preventative maintenance of the system. Documentation of completion of all maintenance shall be kept on file in the pharmacy for a minimum of 2 years.

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November 28, 2005

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
16A-5410: Technology And Automation

Dear Chairman McGinley:

Enclosed is a copy of a final rulemaking package of the State Board of Pharmacy pertaining to Technology and Automation.

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

Sincerely,

Michael J. Romano, R.Ph.

Michael J. Romano, R.Ph., Chairperson
State Board of Pharmacy

MJR/CLC:apm
Enclosure
c: Basil L. Merenda, Commissioner
Bureau of Professional and Occupational Affairs
Albert Masland, Chief Counsel
Department of State
Joyce McKeever, Deputy Chief Counsel
Department of State
Cynthia Montgomery, Regulatory Counsel
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Gerald S. Smith, Senior Counsel in Charge
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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-5410
SUBJECT:	State Board of Pharmacy: Technology and Automation
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
11/28/05	Nancy Ahearn	HOUSE COMMITTEE ON PROFESSIONAL LICENSURE
11/28/05	Mary Walmer	SENATE COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICENSURE
11/28/05	J. Gilbert	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
		LEGISLATIVE REFERENCE BUREAU (for Proposed only)

November 1, 2005