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?
X Proposed Rulemaking **__ 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 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 Pharmacy 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 Pharmacy 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 filling process.

Lastly, this rulemaking package amends the Pharmacy Board's regulations at 49 Pa. Code §27.204 by adding a section that sets forth standards for the use of automated medication systems. This section 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.

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(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 allowing a pharmacy to accept 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 record keeping 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.

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, environmental 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 record keeping, centralized prescription processing, and automated medication systems. Nonregulation will leave Pennsylvania at a competitive disadvantage to states that already have regulations similar to these in effect.

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(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.

(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.

Before submitting this proposed regulation the Board sought input from interested parties such as: Merk-Medco, TechRx Inc., David Schuetz, R.Ph., iScribe, Pennsylvania Pharmacists Association, Pennsylvania Society of Health-Systems Pharmacists, Williams Apothecary, Eckerd Corp., Pyxis Corp., express Scripts, National Association of Chain Drug Stores, PharMerica, UPMC Presbyterian, McKesson Automated Healthcare Inc., Syncor, Value drug Company, Andrea Centola, CVS, PACDS, PDX Inc., ScriptPro, FourHealth Technologies Inc., Cardinal Health, and Chartwell. The Board considered their input and incorporated their suggestions into the proposed rulemaking.

Regulatory Analysis Form

(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 is no cost/saving 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.

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	$1,110,142.10	$1,197,924.91	$1,244,104.47	$1,270,000.00

(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.

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.

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 may affect the Department of Health, which is the agency responsible for inspecting hospital pharmacies.

(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 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.

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.

If pharmacies choose to accept electronically transmitted prescriptions or use computerized record keeping 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 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 under Executive Order 1996-1.

CDL-1

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

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REVIEW COMMISSION

#2405 DO NOT WRITE IN THIS SPACE

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

BY: _____
(DEPUTY ATTORNEY GENERAL)

MAY 06 2004
DATE OF APPROVAL

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

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: Richard R. Smiga R.Ph.
Richard R. Smiga, R.Ph.

TITLE: Chairman
(EXECUTIVE OFFICER, CHAIRMAN OR SE

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

BY: _____

4/1/04
DATE OF APPROVAL

Asst.
~~(Deputy~~ General Counsel
(Strike inapplicable title)

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

PROPOSED 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) proposes to amend §§ 27.1 and 27.14 (relating to definitions; and supplies) and to add §§27.201- 27.204 (relating to electronically transmitted prescriptions and use of computer based technology), to read as set forth in Annex A.

Effective Date

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

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)).

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 regulations would allow the incorporation of this technology into the practice of pharmacy and bring Pennsylvania up to date with regulations of other states that currently regulate this technology. The purpose of the regulations 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 via telephone or facsimile under §§27.18(n) and 27.20. The proposed regulations would allow pharmacies to accept a prescription that was transmitted electronically, via 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 regulations would also allow pharmacies to maintain required records on a computer as opposed to keeping paper files. Pharmacies can then begin moving toward a paperless record keeping system.

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

Description of Proposed Amendments

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 from that section 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 amendment 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) would regulate prescriptions transmitted to a pharmacy by electronic means. Currently the regulations allow for a pharmacist to accept prescriptions transmitted via the telephone or a facsimile machine, but they do not address the acceptance of prescriptions transmitted via electronic means such as a computer or palm device. The proposal 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, he 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 regulations clarify that as an electronic transaction, the transmittal of a prescription via 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 regulation sets forth the information that must be retrievable. All information that is currently required to be on prescriptions under §27.18(b)(1) (relating to standards of practice) 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 regulation 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, that 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 found in §27.14(a) (relating to supplies).

Proposed §27.204 (relating to automated medication systems) would regulate 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 such a system. Automated medication systems may be used either in a licensed pharmacy or off-site as long as the operation of the automated medication system is supervised by a pharmacist. The regulation requires that automated medication systems be validated to accurately dispense medication prior to going into use. The regulation 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 regulation requires written policies and procedures of operation, quality assurance programs, plans for recovery from disaster, and preventative maintenance.

Compliance with Executive Order 1996-1

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

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 regulations would have no fiscal impact, nor would they impose any additional paperwork requirement on the Commonwealth. The regulations 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.*

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 – any 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. "Automated medication system" 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 shall mean the communication to the pharmacist via 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 his 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 the requirements of §27.18(b)(2) (relating to standards of practice), a pharmacist may accept an electronically transmitted prescription, from a prescriber or his 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 shall contain the signature or the electronic equivalent of a signature of the prescriber made in accordance with the requirements of the Electronic Transactions Act (73 P .S. §2260.101 – 2260.5101).

(2) The prescription includes all the following information:

(i) All 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 shall be electronically encrypted or transmitted by other technological means designed to protect and prevent access, alteration, manipulation, or use by any unauthorized person.

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

(5) An electronically transmitted prescription shall be processed in accordance with the requirements of the Act and Board regulations.

(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) Any 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 (via 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 shall 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 is 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 is filed according to §27.18(b) (relating to standards of practice).

(d) In the event that 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 shall include confidentiality of patient information.

(2) The prescription container:

(i) Is clearly labeled with all 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) The rules in this section establish standards applicable to all 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 on-site, 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.

(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. 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 such change shall be signed or initialed by the registered pharmacist in charge and shall include the date on which the registered pharmacist in charge approved the change.

(4) Set forth methods that shall 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 shall 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 shall 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 shall 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. Such 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 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.

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF PHARMACY
Post Office Box 2649
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June 8, 2004

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

Re: Proposed Regulation
State Board of Pharmacy
16A-5410: Technology And Automation

Dear Chairman McGinley:

Enclosed is a copy of a proposed 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., Chairperson
State Board of Pharmacy

MJR/CLC:lm
Enclosure
c: Basil L. Merenda, Commissioner
Bureau of Professional and Occupational Affairs
Linda C. Barrett, Chief Counsel
Department of State
Joyce McKeever, Deputy Chief Counsel
Department of State
Cynthia Montgomery, Regulatory Counsel
Department of State
Gerald S. Smith, Senior Counsel in Charge
Department of State
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:	Technology and Automation
AGENCY:	DEPARTMENT OF STATE #2405

TYPE OF REGULATION

X Proposed Regulation

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
6/8/04	Nancy Barnhart	HOUSE COMMITTEE ON PROFESSIONAL LICENSURE
6-8-04	Donna Herman	SENATE COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICENSURE
6/8/04	Gayle J. Huffman	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
6/8/04	C. Lee Brown	LEGISLATIVE REFERENCE BUREAU (for Proposed only)

May 14, 2004