

PROPOSED RULEMAKING

DEPARTMENT OF STATE

[4 PA. CODE CH. 161]

Fees for Notary Services

The Department of State (Department) proposes to amend § 161.1 (relating to schedule of fees) by revising the fees that notaries public may charge for their services to read as set forth in Annex A.

A. *Effective Date*

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

B. *Statutory Authority*

The proposed rulemaking is authorized under section 21 of the Notary Public Law (act) (57 P. S. § 167), which requires that the fees of notaries public be fixed by the Secretary of the Commonwealth (Secretary) with the approval of the Attorney General. Although section 21 of the act does not require the Secretary to establish notary public fees through the regulatory process, the last notary public fee increase, which occurred on February 11, 1984, was brought about through the rulemaking process and the Secretary has determined that it is in the best interest of the public to also provide for public comment on this proposed rulemaking. Under section 16 of the act (57 P. S. § 162), as amended by the act of December 9, 2002 (P. L. 1269, No. 151) (Act 151) (effective July 1, 2003), notaries public shall in addition to their other powers have the power to administer verifications and therefore, the Secretary is proposing to add a fee for verifications.

C. *Background and Purpose*

As previously noted, the fees that notaries public may charge for their services have not been increased since February 11, 1984. (See 14 Pa.B. 431.) Yet, the costs that notaries public must now incur have increased substantially since 1984. For example, the minimum cost to become a notary public, including the Department's application fee, obtaining mandatory education under Act 151 at a minimum of \$35 per class, securing a bond, obtaining a rubber stamp seal and purchasing a register, has increased from about \$46.50 to approximately \$128 since 1984.

One of the major purposes of the proposed rulemaking, which increases fees from \$2 to \$5 for most services, is to help the fees of notaries public bear a closer correlation to increases in the Consumer Price Index, which according to the United States Department of Labor, Bureau of Labor Statistics, rose 85.7% between August 1984 and September 2003.

It is also the intent of the proposed rulemaking to help notaries public better absorb the increased costs they face for the notary public application process, supplies, recordkeeping and recording fees. For example, all Recorders of Deeds charge notaries public fees for recording their oath, commission and bond with the fees ranging from \$32.50 to \$70.50. In addition, the proposed rulemaking will assist applicants seeking initial appointment or reappointment as a notary public in meeting the costs of fulfilling the notary public education requirement

mandated by the most recent amendments to the act brought about by Act 151. Notaries public are typically paying at least \$45 for the 3-hour course and possibly as much as \$159 for the course offered by some providers.

Finally, another major purpose is to help ensure that notary public fees remain competitive with the fees that notaries public may charge in other states. In contrast to the \$2 that notaries public may charge for their services in this Commonwealth, a total of 19 other states, including Delaware, have set their fees at \$5 or higher.

D. *Fiscal Impact and Paperwork Requirements*

The proposed rulemaking will have no adverse fiscal impact on the Department, the Bureau of Commissions, Elections and Legislation (Bureau) or the notaries public it commissions. The proposed rulemaking will also have no adverse fiscal impact on the Commonwealth or its political subdivisions. In addition, the proposed rulemaking will not impose any additional paperwork requirements upon the Commonwealth, its political subdivisions or the private sector.

E. *Sunset Date*

The Secretary and the Department monitor the regulations of the Bureau on a continuing basis. Therefore, no sunset date has been assigned.

F. *Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on June 9, 2004, the Department 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 State Government Committee and the House State Government 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 Department, the General Assembly and the Governor of comments, recommendations or objections raised.

G. *Public Comment*

Interested persons are invited to submit written comments, recommendations or objections regarding this proposed rulemaking to Christal Pike-Nase, Counsel, Bureau of Commissions, Elections and Legislation, Notary Section, Office of Chief Counsel, Department of State, 302 North Office Building, Harrisburg, PA 17120 within 30 days following publication of this proposed rulemaking in the *Pennsylvania Bulletin*. Reference no. 16-33 (Fees for Notary Services) when submitting comments.

PEDRO A. CORTES,
Secretary of the Commonwealth

Fiscal Note: 16-33. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 4. ADMINISTRATION

PART VIII. BUREAU OF [LEGISLATION, COMMISSIONS AND ELECTIONS] COMMISSIONS, ELECTIONS AND LEGISLATION

Subpart C. COMMISSIONS

CHAPTER 161. FEES

§ 161.1. Schedule of fees.

The Bureau of Commissions, Elections and Legislation fee schedule shall conform with the following table:

<i>Description</i>	<i>Fees (in dollars)</i>
	* * * * *
NOTARY PUBLIC FEE SCHEDULE	
Executing affidavits (no matter how many signatures)	\$ [2] 5
Executing acknowledgments	\$ [2] 5
In executing acknowledgments, each additional name	\$ [1] 2
Executing certificates (per certified copy)	\$ [2] 5
Administering oaths (per individual taking an oath)	\$ [2] 5
Taking depositions, per page	\$ [2] 3
Executing verifications	\$ 5
[Making] Executing protests, per page	\$ [2] 3

[Pa.B. Doc. No. 04-1062. Filed for public inspection June 18, 2004, 9:00 a.m.]

GAME COMMISSION

[58 PA. CODE CH. 135]

Lands and Buildings

To effectively manage the wildlife resources of this Commonwealth, the Game Commission (Commission), at its April 20, 2004, meeting, proposed the following rule-making:

Amend § 135.48 (relating to State game lands roads open to vehicular traffic for disabled persons) to permit the Director to designate State game lands (SGLs) roads open to vehicular traffic for disabled persons.

The proposed rulemaking will have no adverse impact on the wildlife resources of this Commonwealth.

The authority for the proposed rulemaking is 34 Pa.C.S. (relating to Game and Wildlife Code) (code).

The proposed rulemaking was made public at the April 20, 2004, meeting of the Commission. Comments can be sent until June 25, 2004, to the Director, Information and Education, Game Commission, 2001 Elmerton Avenue, Harrisburg, PA 17110-9797.

1. Introduction

The Commission is proposing to amend § 135.48 to permit the Director to designate SGLs roads open to vehicular traffic for disabled persons.

2. Purpose and Authority

At the April 2002 Commission meeting, the Commissioners voted to authorize the Executive Director and staff to decide on all future trail designations needed to administer Chapter 135 (relating to lands and buildings) and seasonal openings and closings of SGLs administrative roads. The Commission proposes that the same authorization be given to SGLs roads open to vehicular traffic for disabled persons.

Section 721(a) of the code (relating to control of property) provides "The administration of all lands and waters owned, leased or otherwise controlled by the commission shall be under the sole control of the Director, and the commission shall promulgate regulations . . . for its use and protection as necessary to properly manage these lands or waters." The amendment to § 135.48 is proposed under this authority.

3. Regulatory Requirements

The proposed rulemaking amends § 135.48 to permit the Director to designate SGLs roads open to vehicular traffic for disabled persons.

4. Persons Affected

Disabled persons wishing to hunt or trap in this Commonwealth will be affected by the proposed rulemaking.

5. Cost and Paperwork Requirements

The proposed rulemaking will result in very limited additional cost and paperwork related to providing a list of open roads available to disabled persons.

6. Effective Date

The proposed rulemaking will be effective upon final-form publication in the *Pennsylvania Bulletin* and will remain in effect until changed by the Commission.

7. Contact Person

For further information regarding the proposed rulemaking, contact Michael A. Dubaich, Director, Bureau of Law Enforcement, 2001 Elmerton Avenue, Harrisburg, PA 17110-9797, (717) 783-6526.

VERNON R. ROSS,
Executive Director

Fiscal Note: 48-191. No fiscal impact; (8) recommends adoption.

Annex A
TITLE 58. RECREATION
PART III. GAME COMMISSION
CHAPTER 135. LANDS AND BUILDINGS
Subchapter C. STATE GAME LANDS

§ 135.48. State game lands roads open to vehicular traffic for disabled persons.

(a) *Vehicular traffic permitted.* Vehicular traffic will be permitted on designated roads on State game lands for persons issued a Disabled Persons Permit under section 2923(a) of the act (relating to disabled person permits). **State game lands roads open to vehicular traffic for disabled persons will be designated by the Director. The Commission will make a list of these open roads available to the permittee.**

* * * * *

(b) *[Designated roads on State game lands.*

(1) **State Game Lands No. 110—Berks and Schuylkill Counties—Game lands road beginning at State Route 183 to a parking lot located on Township Road T-720, north of Shartlesville, Pennsylvania, a distance of approximately 7.6 miles.**

(2) **State Game Lands No. 117—Washington County—game lands road beginning 5 miles north of Burgettstown Community Park along State Route 4007 to the intersection of State Route 18, a distance of approximately 2.5 miles.**

(3) **State Game Lands No. 12—Bradford and Sullivan Counties—Game lands road beginning at village of Wheelerville, Pennsylvania, along State Route 154 to the intersection of Township Road T-359 south of the town of Laquin, a distance of approximately 8.5 miles.**

(4) **State Game Lands No. 49—Bedford and Fulton Counties—Game lands road beginning 1.5 miles east of Robinsonville, Pennsylvania, along State Route 2006 to a parking lot located on Township Road T-316, a distance of approximately 3.8 miles.**

(5) **State Game Lands No. 244—Jefferson County—Game lands road beginning 3.5 miles east of Knox Dale, Pennsylvania, along State Route 2025 to a parking lot located on this game land, a distance of approximately 3 miles.**

(6) **State Game Lands No. 134—Lycoming and Sullivan Counties—Game lands road beginning 2.5 miles west of Hillsgrove, Pennsylvania, along State Route 4010 to the intersection of State Route 1005, a distance of approximately 6 miles.**

(7) **State Game Lands No. 210—Dauphin County—Game lands road (Lukes Trail) beginning at western game lands boundary to the intersection of State Route 4013, a distance of approximately 1.4 miles.**

(8) **State Game Lands No. 59—McKean and Potter Counties—Game lands road beginning at northern game lands boundary on Township Route T-342 to the intersection of State Route 4001, a distance of approximately 2.4 miles.**

(9) **State Game Lands No. 37—Tioga County—Game lands road beginning at northern game lands boundary on Stephenhouse Run Road to Rarick Fire Tower and intersection of Township Route T-710, a distance of approximately 2.1 miles.]**

Additional reference. See § 135.2 (relating to unlawful acts).

[Pa.B. Doc. No. 04-1063. Filed for public inspection June 18, 2004, 9:00 a.m.]

PENNSYLVANIA PUBLIC UTILITY COMMISSION

[52 PA. CODE CH. 101]

[L-00040166]

Public Utility Security Planning and Readiness

The Pennsylvania Public Utility Commission, on March 18, 2004, adopted at proposed rulemaking order requiring all jurisdictional utilities to develop and maintain written physical, cyber security, emergency response and business continuity plans.

Executive Summary

Pursuant to 66 Pa.C.S. § 1501, every public utility must furnish and maintain adequate, efficient, safe, and reasonable service and facilities, and make changes, alterations, and improvements in or to such service and facilities as shall be necessary for the accommodation, convenience, and safety of its patrons, employees, and the public.

The proposed regulations require jurisdictional utilities to develop and maintain written physical security, cyber security, emergency response, and business continuity plans. In addition, jurisdictional utilities must file a Self Certification Form with the Commission documenting compliance with the above mentioned plans.

These proposed regulations will ensure that jurisdictional utilities are effectively equipped and prepared to provide safe and reliable utility service when faced with security concerns. In addition, jurisdictional utilities will be required to review and exercise their ability to detect, prevent, respond to and recover from abnormal operating conditions on an annual basis.

The contact persons are Kimberly Joyce, Law Bureau (legal), 717-705-3819 and Darren Gill, Bureau of Fixed Utility Services (technical), 717-783-5244.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on June 3, 2004, the Commission 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 House and Senate Committees. 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 Commission, the General Assembly and the Governor of comments, recommendations or objections raised.

Public Meeting held
March 18, 2004

Commissioners Present: Terrance J. Fitzpatrick, Chairperson; Robert K. Bloom, Vice Chairperson; Glen R. Thomas; Kim Pizzingrilli; Wendell F. Holland

Public Utility Security Planning and Readiness; Doc. No. L-00040166

Proposed Rulemaking Order

By the Commission:

This proposed rulemaking requires all jurisdictional utilities to develop and maintain written physical, cyber security, emergency response and business continuity plans to protect the Commonwealth's infrastructure and ensure safe, continuous and reliable utility service. In accordance with the proposed regulations, jurisdictional utilities will submit a Physical and Cyber Security Planning Self Certification Form (Self Certification Form) to the Commission documenting compliance with these four plans.

Background

In the past several years, the Pennsylvania Public Utility Commission (Commission) has ardently worked with its jurisdictional utilities to ensure the safe and reliable delivery of utility services to citizens in the Commonwealth and to refine the emergency management and response processes.

Beginning in 1998, the Commission instituted a Year 2000 technology (Y2K) readiness formal investigation which examined the readiness of approximately 750 public utilities and conducted an assessment of Y2K readiness for twenty-three jurisdictional companies. The attacks of September 11, 2001 dramatically underscored the importance of safeguarding public utility assets. As a result, the Commission immediately surveyed its jurisdictional companies, the PJM Interconnection, and the Pennsylvania Rural Electric Association (PREA). Rail safety inspectors, gas safety inspectors and telecommunications staff were also contacted to assess their industry.

In addition, the Commission began coordinating its security efforts with the state Office of Homeland Security and submitted several comprehensive reports to the House of Representatives and the state Office of Homeland Security. Through this process, the Commission developed a security self certification process for all Commission jurisdictional utilities. The Commission directed that a Physical and Cyber Security Planning Self Certification Form be submitted to the Commission yearly as part of each utility's Annual Financial or Annual Assessment Report.

Procedural History

The Physical and Cyber Security Program Self Certification Requirements for Public Utilities were issued by the Commission in a Tentative Order¹ entered on August 5, 2003 and published in the *Pennsylvania Bulletin* on August 16, 2003. Comments to the Tentative Order were due on September 5, 2003.

Comments were filed by the Pennsylvania Telephone Association (PTA), the Energy Association of Pennsylvania (EAP), Pennsylvania-American Water Company (PA-American) and The Peoples Natural Gas Company d/b/a Dominion Peoples (Dominion Peoples). Columbia Gas of Pennsylvania, Inc. (Columbia) provided late comments on September 8, 2003.

At the Public Meeting of December 4, 2003, the Commission responded to the filed comments and determined that a self certification process for utility security programs should be instituted for the current and anticipated security compliance of all jurisdictional utilities. The Commission ordered that jurisdictional utilities complete and file with the Commission the Physical and Cyber Security Planning Self Certification Form. See Appendix A. Utilities under the reporting requirements of 52 Pa. Code §§ 27.10, 61.28, 63.36, 65.19, 59.48 and 57.47 must file the Self Certification Form at Docket No. M-00031717, at the time each Annual Financial Report is filed, beginning on or after January 1, 2004.² Utilities not subject to the reporting requirements above, but subject to the reporting requirements of 52 Pa. Code §§ 29.43, 31.10 and 33.103 must file the Self Certification Form at Docket No. M-00031717, at the time each Annual Assessment Report is filed, beginning on or after January 1, 2004.³

In the Order entered on December 9, 2003, the Commission further ordered the Law Bureau, in conjunction with the Bureau of Fixed Utility Services and the Bureau of Transportation and Safety, to initiate a rulemaking to include the requirement for jurisdictional utilities to develop and maintain appropriate written physical and cyber security plans, emergency response plans and business continuity plans as part of the Commission's regulations. This rulemaking includes the requirement that jurisdictional utilities submit the Self Certification Form to the Commission.

The various security issues facing our utilities present questions that are fundamental to the public health, safety and convenience of Pennsylvanians. Consequently, each of our jurisdictional utilities must be prepared to demonstrate that it is adequately addressing the security issue so as to enable it to furnish and maintain adequate, efficient, safe and reasonable service. 66 Pa.C.S. § 1501. Therefore, the development, maintenance, exercising and implementation of physical security, cyber security, emergency response, and business continuity plans are necessary to ensure that our jurisdictional utilities are effectively equipped to furnish and maintain adequate, efficient, safe and reasonable service.

As referenced above, the Commission has explicit statutory authority to institute these reporting requirements and to carry out and enforce the purposes of the Public Utility Code in the public interest. 66 Pa.C.S. §§ 501, 504 and 1501. The subject matter that the Commission may examine includes issues of security, which if ignored, could pose a serious threat to the utilities' responsible for providing safe and reliable utility service. Thus, the intent of this rulemaking is to create a minimum set of requirements that can be consistently implemented with sufficient flexibility to account for differences in the types of utilities under the Commission's jurisdiction.

Through this rulemaking, we underscore our commitment to ensure the safe and reliable delivery of utility service in the Commonwealth by promulgating regulations that require each jurisdictional utility to develop and maintain written physical security plans, cyber security plans, emergency response plans and business continuity plans. In addition, each utility will review and exercise its ability to detect, prevent, respond to and recover from abnormal operating conditions. Compliance

² This group includes common carriers of passengers and/or household goods and jurisdictional telecommunications, electric, gas, steam heating and water/wastewater utilities.

³ This group includes common carriers and forwarders of property and railroad carriers.

¹ Docket No. M-00031717.

with the proposed regulations also requires that each jurisdictional utility file the Self Certification Form.

The Commission believes that the adoption of the self certification process will aid the safeguarding of public utility assets, but at the same time, recognizes the sensitive nature of the information that each utility must provide us in the Self Certification Form. Disclosure of a Self Certification Form to the public could be used for criminal or terroristic purposes, jeopardize security or cause substantial harm to the entity filing the Self Certification Form. The potential harm from release of a completed form outweighs the public's interest in accessing this information. Therefore, great care will be taken to protect the confidentiality of information contained in the Self Certification Form, commensurate with its extraordinary sensitivity. As such, the Self Certification Form is deemed confidential and access to it will be restricted.⁴

We further acknowledge that protecting the Commonwealth's infrastructure and key assets necessitates a cooperative paradigm. Homeland security requires coordinated action on the part of federal, state, and local government; the private sector; and concerned citizens. Many other government entities have become actively involved with critical infrastructure protection. For example, the National Electric Reliability Council established security guidelines for physical and cyber security. The Environmental Protection Agency established requirements for emergency plans, vulnerability analysis and corrective measure implementation. The Department of Transportation Office of Pipeline Safety established regulations for security programs and the Pipeline Safety Act was reauthorized to provide for expanded security certification of personnel operating on pipelines. The Federal Railway Administration has established similar protocols.

We do not wish to replicate rules and regulations that are already in place. However, it is our duty to identify and secure the critical infrastructure and key assets within the Commonwealth under our jurisdiction. Therefore, the Self Certification Form is drafted so that any overlapping reporting duties or regulations by other state or federal agencies will not overly burden utilities under our jurisdiction and plans under this rulemaking may satisfy more than one agency or department.

Accordingly, under sections 501, 504 and 1501 of the Public Utility Code, 66 Pa.C.S. §§ 501, 504 and 1501; sections 201 and 202 of the Act of July 31, 1968, P. L. 769 No. 240, 45 P. S. §§ 1201—1202, and the regulations promulgated thereunder at 1 Pa. Code §§ 7.1, 7.2 and 7.5; section 204(b) of the Commonwealth Attorneys Act, 71 P. S. § 732.204(b); section 745.5 of the Regulatory Review Act, 71 P. S. § 745.5; and section 612 of The Administrative Code of 1929, 71 P. S. § 232, and the regulations promulgated thereunder at 4 Pa. Code §§ 7.231—7.234, we are considering adopting the proposed regulations set forth in Annex A; *Therefore,*

It Is Ordered That:

1. The proposed rulemaking be opened to consider the regulations set forth in Annex A.

2. The Secretary submit this Order, Appendix A and Annex A to the Office of Attorney General for review as to form and legality and to the Governor's Budget Office for review of fiscal impact.

⁴ Self Certification forms must be filed under separate cover with the Secretary at Docket M-00031717.

3. The Secretary certify this Order, Appendix A and Annex A and deposit them with the Legislative Reference Bureau to be published in the *Pennsylvania Bulletin*.

4. An original and 15 copies of any comments referencing the docket number of the proposed regulations be submitted within 30 days of publication in the *Pennsylvania Bulletin* to the Pennsylvania Public Utility Commission, Attention: Secretary, P. O. Box 3265, Harrisburg, PA 17105-3265. When preparing comments, parties should consider this Order in conjunction with the Tentative Order and Order in Docket No. M-00031717.

5. A copy of any comments be filed electronically to Kimberly A. Joyce, kjoyce@state.pa.us.

6. The contact persons for this rulemaking are (technical) Darren Gill, (717) 783-5244 and (legal) Kimberly A. Joyce, Law Bureau, (717) 705-3819.

7. A copy of this Order, Appendix A and Annex A be filed at Docket No. M-00031717.

8. A copy of this Order, Appendix A and Annex A be served upon the Pennsylvania Emergency Management Agency, the Pennsylvania Office of Homeland Security, the Department of Environmental Protection, the Energy Association of Pennsylvania, the Pennsylvania Telephone Association, the Pennsylvania Motor Truck Association, the Pennsylvania Bus Association, the Pennsylvania Taxicab and Paratransit Association, Pennsylvania Moving and Storage Association, the Pennsylvania Limousine Association, the Pennsylvania Chapter of the National Association of Water Companies, the Pennsylvania Section of the American Water Works Association, the Pennsylvania Rural Water Association, Pennsylvania League of Cities and Municipalities, Pennsylvania State Association of Boroughs, Pennsylvania Local Government Commission, Pennsylvania State Association of Township Supervisors and the PUC jurisdictional respondents to House Resolution 361.

9. All jurisdictional utilities operating within the Commonwealth are directed to file the Physical and Cyber Security Planning Self Certification Form consistent with our previous order at Docket No. M-00031717.

JAMES J. MCNULTY,
Secretary

Fiscal Note: 57-234. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 52. PUBLIC UTILITIES

PART I. PUBLIC UTILITY COMMISSION

Subpart E. PUBLIC UTILITY SECURITY PLANNING AND READINESS

CHAPTER 101. PUBLIC UTILITY PREPAREDNESS THROUGH SELF CERTIFICATION

Sec.	Purpose.
101.1.	Purpose.
101.2.	Definitions.
101.3.	Plan requirements.
101.4.	Reporting requirements.
101.5.	Confidentiality of self certification form.
101.6.	Compliance.

§ 101.1. Purpose.

This chapter requires a jurisdictional utility to develop and maintain appropriate written physical security, cyber security, emergency response and business continuity plans to protect this Commonwealth's infrastructure and ensure safe, continuous and reliable utility service. A jurisdictional utility shall submit a Physical and Cyber

Security Planning Self Certification Form (Self Certification Form) to the Commission documenting compliance with this chapter.

§ 101.2. Definitions.

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

Abnormal operating condition—A condition possibly showing a malfunction of a component or deviation from normal operations that may:

- (i) Indicate a condition exceeding design limits.
- (ii) Result in a hazard to person, property or the environment.

Business continuity plan—A written plan that will ensure the continuity or uninterrupted provision of operations and services through arrangements and procedures that enable a utility to respond to an event that could occur by change or unforeseen circumstances. The business continuity plan must:

- (i) Provide guidance on the system restoration for emergencies, disasters and mobilization.
- (ii) Establish a comprehensive process addressing business recovery, business resumption and contingency planning.

Business recovery—The process of planning for and implementing expanded operations to address less time-sensitive business operations immediately following an interruption or disaster.

Business resumption—The process of planning for and implementing the restarting of defined business operations following an interruption or disaster, usually beginning with the most critical or time-sensitive functions and continuing along a planned sequence to address all identified areas required by the business.

Contingency planning—Process of developing advance arrangements and procedures that enable a jurisdictional utility to respond to an event that could occur by change or unforeseen circumstances.

Critical functions—Business activities or information that cannot be interrupted or unavailable for several business days without significantly jeopardizing operations of the organization.

Cyber security—The measures designed to protect computers, software and communications networks that support, operate or otherwise interact with the company's operations.

Cyber security plan—A written plan that delineates a jurisdictional utility's information technology disaster plan. This plan must include:

- (i) Critical functions requiring automated processing.
- (ii) Appropriate backup for application software and data.
- (iii) Alternative methods for meeting critical functional responsibilities in the absence of information technology capabilities.
- (iv) A recognition of the critical time period for each information system before the utility could no longer continue to operate.

Emergency response plan—A written plan describing the actions a jurisdictional utility will take if an abnormal operating condition exists, whether due to natural causes or sabotage. Actions include:

(i) Identifying and assessing the problem.

(ii) Mitigating the problem in a coordinated, timely and effective manner.

(iii) Notifying the emergency management system.

Mission critical—A term used to describe essential equipment or facilities to the organization's ability to perform necessary business functions.

Physical security—The physical (material) measures designed to safeguard personnel, property and information.

Physical security plan—

(i) A written plan that delineates the response to security concerns at mission critical equipment or facilities.

(ii) The plan must include specific features of a mission critical equipment or facility protection program and company procedures to follow based upon changing threat conditions or situations.

Responsible entity—Person or organization within a jurisdictional utility designated as the security or emergency response liaison to the Commission.

§ 101.3. Plan requirements.

(a) A jurisdictional utility shall develop and maintain written physical and cyber security, emergency response and business continuity plans.

(b) A jurisdictional utility shall review and update these plans annually.

(c) A jurisdictional utility shall maintain a testing schedule of these plans.

(d) A jurisdictional utility shall demonstrate compliance with subsections (a)—(c), through submittal of a Self Certification Form which is available at the Secretary's Bureau and on the Commission's website.

(d) A plan shall define roles and responsibilities by individual or job function.

(e) The responsible entity shall maintain a document defining the action plans and procedures used in subsection (a).

§ 101.4. Reporting requirements.

(a) A utility under the reporting requirements of §§ 27.10, 57.47, 59.48, 61.28, 63.36 and 65.19 shall file the Self Certification Form at the time each Annual Financial Report is filed, under separate cover at Docket No. M-00031717.

(b) A utility not subject to the financial reporting requirements in subsection (a), but subject to the reporting requirements of §§ 29.43, 31.10 and 33.103 (relating to assessment reports; assessment reports; and reports) shall file the Self Certification Form at the time each Annual Assessment Report is filed, under separate cover at Docket No. M-00031717.

§ 101.5. Confidentiality of self certification form.

A Physical and Cyber Security Self Certification Form filed at the Commission is not a public document or record and is deemed confidential and proprietary.

§ 101.6. Compliance.

(a) The Commission will review a Self Certification Form filed under § 101.4 (relating to reporting requirements).

(b) The Commission may review a utility's cyber security plan, physical security plan, emergency response plan and business continuity plan under 66 Pa.C.S. §§ 504—506 (relating to reports by public utility; duty to furnish information to commission; cooperation in valuing property; and inspection of facilities and records).

(c) The Commission may inspect a utility's facility to assess performance of its compliance monitoring under 66 Pa.C.S. §§ 504—506.

(d) A utility that has developed and maintained a substantially similar cyber security, physical security, emergency response or business continuity plan under the directive of another state or Federal entity may utilize that substantially similar plan for compliance with this subpart, upon the condition that a Commission representative be permitted to review the cyber security, physical security, emergency response or business continuity plan. A company that is utilizing a substantially similar plan shall briefly describe the alternative plan and identify the authority that requires the alternative plan along with the Self Certification Form filed with the Commission.

Appendix A

PHYSICAL AND CYBER SECURITY PLANNING SELF CERTIFICATION

Company Name: Utility/Industry Type:		Year Ended
CONFIDENTIAL		
Physical and Cyber Security Planning Self Certification		
Docket No. M-00031717F0004		
(Do Not Submit Actual Physical, Cyber, Emergency Response or Business Continuity Plans)		
Item No.	Classification	Response (Yes - No - N/A*)
1	Does your company have a physical security plan?	
2	Has your physical security plan been reviewed and updated in the past year?	
3	Is your physical security plan tested annually?	
4	Does your company have a cyber security plan?	
5	Has your cyber security plan been reviewed and updated in the past year?	
6	Is your cyber security plan tested annually?	
7	Has your company performed a vulnerability or risk assessment analysis as it relates to physical and/or cyber security?	
8	Does your company have an emergency response plan?	
9	Has your emergency response plan been reviewed and updated in the past year?	
10	Is your emergency response plan tested annually?	
11	Does your company have a business continuity plan?	
12	Has your business continuity plan been reviewed and updated in the past year?	
13	Is your business continuity plan tested annually?	

* Attach a sheet with a brief explanation if N/A is supplied as a response to a question.

The foregoing certification must be verified by the officer having control of the security planning for the respondent.

I am authorized to complete this form on behalf of _____ [name of corporation/partnership/ proprietorship] being the _____ [position] of this corporation/partnership/proprietorship and verify that the facts set forth above are true and correct to the best of my knowledge, information and belief. This verification is made pursuant to 52 Pa. Code § 1.36 and that statements herein are made subject to the penalties of 18 Pa.C.S. § 4904 (relating to unsworn falsification to authorities).

Name of Officer: _____

Signature of Officer: _____

Phone Number of Officer: _____

Email Address of Officer: _____

[Pa.B. Doc. No. 04-1064. Filed for public inspection June 18, 2004, 9:00 a.m.]

STATE BOARD OF EXAMINERS IN SPEECH-LANGUAGE AND HEARING

[49 PA. CODE CH. 45]
Continuing Education

The State Board of Examiners in Speech-Language and Hearing (Board) proposes to amend §§ 45.1, 45.2 and 45.13 (relating to fees; definitions; and renewal; inactive status) and to add Subchapter G (relating to continuing education) 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 section 5(7) of the Speech-Language and Hearing Licensure Act (act) (63 P. S. § 1705(7)).

Background and Need for the Proposed Rulemaking

The act of October 18, 2000 (P. L. 536, No. 71) authorizes the Board to establish by regulation a continuing education requirement for biennial renewal of licenses of speech-language and hearing professionals.

Description of the Proposed Rulemaking

The proposed rulemaking will require licensed speech-language and hearing professionals to successfully complete 20 clock hours of continuing education as a condition for each biennial renewal period. The continuing education requirement will be implemented after providing written notice to all licensees in accordance with section 5(7) of the act. The applicable biennial period will be inserted in the final-form rulemaking based on the effective date of the rulemaking. Upon application for renewal, each licensee will provide verification of successful completion of the required continuing education. The Board shall require documentary proof of successful completion from the licensees selected for audit. All licensees shall maintain proof of completion of continuing education credits for 4 years. The Board will not renew the license of a licensee who did not complete the required continuing education prior to the renewal date. Upon completion of continuing education, the Board may then renew that license.

In addition, the proposed rulemaking provides standards by which the Board may approve providers of courses of continuing education and responsibilities of the providers. The Board will be deemed to have approved any course previously approved or sponsored by the American Speech-Language and Hearing Association, the American Academy of Audiology and courses offered by academic programs in speech-language pathology, audiol-

ogy or teaching of the hearing impaired associated with institutions of higher education accredited by any state's department of education or a regional commission on institutions of higher education. Other providers may apply for approval of individual courses at least 90 days prior to the scheduled course date. The application fee for individual course approval will be \$40. The Board may deny approval of any course for which the identified faculty is not qualified, the course is in office management, the method for certifying attendance is not verifiable or the provider has made material misstatements in the application. Each provider will be required: to disclose to prospective attendees in advance the objective, content, teaching method and number of hours of continuing education credit; to open the course to licensees; to provide adequate physical facilities; to provide appropriate instructional materials; to employ qualified instructors; and to evaluate the program. Each provider will also be required to provide to each attendee a record of the continuing education, including the participant's name, the dates of the program, the name of the program, the provider's name and the number of continuing education credits. The provider must also be able to provide the Board with verification of a licensee's participation in a continuing education program, including the date of the approval of the program and the name of the entity that approved the program for continuing education credit.

Finally, the proposed rulemaking will authorize disciplinary action against licensees who fail to complete the required continuing education or who submit fraudulent records. Under the same section, providers are subject to the revocation of course approval for appropriate grounds.

Fiscal Impact and Paperwork Requirements

The proposed rulemaking will have a limited fiscal impact on the Commonwealth or its political subdivisions. The proposed rulemaking requires the Board to review all applications for compliance with the continuing education requirement and additional costs will be incurred during the audit process. Ten percent of all licenses will be selected for audit of the continuing education following each biennial renewal period. The costs incurred in the audit will include the cost of postage for inquiry letters, the administrative costs of reviewing the responses and any additional disciplinary action to be taken against licensees who have not complied with the continuing education requirement. It is impossible to estimate the number of licensees who might not comply with the required amount of continuing education. Therefore, the Board cannot estimate any increased enforcement costs at this time. There are no other costs or savings to State government associated with implementation of the proposed rulemaking.

Sunset Date

The Board continuously monitors the cost effectiveness of its regulations. 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, recommendations or objections regarding this proposed rulemaking to Sandra Matter, Administrative Assistant, State Board of Examiners in Speech-Language and Hearing, P. O. Box 2649, Harrisburg, PA 17105-2649 within 30 days following publication of this proposed rulemaking in the *Pennsylvania Bulletin*.

SONYA M. WILT, Chairperson

Fiscal Note: 16A-6802. 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 45. STATE BOARD OF EXAMINERS IN SPEECH-LANGUAGE AND HEARING

Subchapter A. GENERAL PROVISIONS

§ 45.1. Fees.

(a) The following are the fees set by the State Board of Examiners in Speech-Language and Hearing:

* * * * *

(5) Application for continuing education course approval \$40

* * * * *

§ 45.2. Definitions.

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

* * * * *

Biennial renewal period—The period from August 1 of an even-numbered year to July 31 of the next even-numbered year.

* * * * *

Clock hour—Consists of 50 to 60 minutes of instruction or participation in an approved continuing education course or program.

Continuing education record—Report provided to a participant in a continuing education course or program by the provider which indicates the name

of the participant, the dates of the program, the name of the program, the provider's name and the number of clock hours of continuing education credit.

* * * * *

Inactive license—A license status in which the licensee notifies the Board that the licensee no longer requires an active license to practice.

Lapsed license—A license status in which the license has not been currently renewed.

* * * * *

Provider—An agency, organization, institution, association or center approved by the Board to offer an organized continuing education course or program.

* * * * *

Subchapter B. LICENSURE

§ 45.13. Renewal; inactive status; required continuing education.

* * * * *

(g) Beginning with the renewal period following _____ (Editor's Note: The blank refers to the effective date of the adoption of this proposed rulemaking.), an application for renewal of a speech-language pathologist, audiologist or teacher of the hearing impaired license will not be granted unless the licensee has certified that the licensee has completed the required continuing education hours under § 45.501 (relating to credit hour requirements). If requested by the Board, an application for renewal must also include the documentation required by § 45.504 (relating to reporting of completion of continuing education).

(h) An application for reactivation of an inactive or lapsed speech-language pathologist, audiologist or teacher of the hearing impaired license must also include the documentation required by § 45.504 for the preceding biennial period.

Subchapter G. CONTINUING EDUCATION

§ 45.501. Credit hour requirements.

(a) Each speech-language pathologist, audiologist or teacher of the hearing impaired shall complete 20 clock hours of continuing education during each biennial renewal period, beginning with the renewal period following _____ (Editor's Note: The blank refers to the effective date of the adoption of this proposed rulemaking.)

(b) Up to 10 clock hours of approved continuing education credit per biennial renewal period may be granted on a case-by-case basis for services as a lecturer or speaker, and for publication of articles, books and research relating to the practice of speech-language pathology, audiology or teaching of the hearing impaired. A licensee seeking continuing education credit under this subsection shall submit a written request with a copy of the lecture, presentation, article, book or research. The request shall be submitted 180 days prior to the expiration of the biennial renewal period for which the licensee is seeking credit.

(c) Unless granted a waiver under § 45.502 (relating to exemption and waiver), the Board will not renew or reactivate any speech-language pathologist, audiologist or teacher of the hearing impaired license until the continu-

ing education required prior to the current biennial renewal period has been completed.

§ 45.502. Exemption and waiver.

(a) An individual applying for initial licensure shall be exempted from the continuing education requirement for the biennial period in which the license is granted.

(b) The Board may waive all or part of the continuing education requirement for a biennial renewal period upon request of a licensee. The request must be made in writing, with supporting documentation, and include a description of circumstances sufficient to show why compliance is impossible. Waiver requests will be evaluated by the Board on a case-by-case basis. Waivers may be granted for serious illness, military service or other demonstrated hardship. The Board will send written notification of its approval or denial of a waiver request.

§ 45.503. Continuing education requirement for biennial renewal of inactive and lapsed licenses.

A licensee seeking to reinstate an inactive or lapsed license shall show proof of compliance with the continuing education requirement for the preceding biennial period.

§ 45.504. Reporting completion of continuing education.

(a) Applicants at the time of license renewal shall provide, on forms provided by the Board, a signed statement certifying that the continuing education requirement has been met.

(b) The Board will utilize a random audit of renewals to determine compliance with the continuing education requirement. Applicants selected for audit shall provide the Board the certified continuing education record, as described in § 45.506(b) (relating to provider responsibilities), for each continuing education program completed to prove compliance with the continuing education requirement.

(c) Individuals shall retain the certified continuing education records for courses completed for a minimum of 4 years.

§ 45.505. Approval of continuing education programs.

(a) Credit for continuing education may be obtained for any program approved in advance by the Board. Preapproval is contingent upon compliance with § 45.506 (relating to provider responsibilities).

(b) Anyone, to include colleges, universities, associations, professional societies and organizations, seeking approval to offer programs of continuing education shall:

(1) Apply for approval of the program on forms provided by the Board.

(2) File the application at least 90 days prior to the first scheduled date of the program.

(c) An application must contain:

(1) The full name and address of the provider.

(2) The title of the program.

(3) Faculty names and credentials, and, if requested by the Board, curriculum vitae.

(4) A schedule of the program, including the title and description of each subject, the name of the lecturers and the time allotted.

(5) The total number of clock hours of credit to be awarded.

(6) A method of certifying participation.

(7) The program coordinator who is responsible for certifying participation and compiling an official list of Pennsylvania licensees in attendance at the continuing education program.

(8) A fee as required by § 45.1 (relating to fees).

(d) The Board may deny approval of a program of continuing education based on any appropriate grounds, including the following:

(1) The provider failed to comply with § 45.506 for other programs.

(2) The provider made one or more false or misleading material statements on the application.

(3) The identified faculty is deemed not qualified to present the program.

(4) The course content is in office management or practice building.

(5) The method of certifying participation is not verifiable.

(e) The following programs are deemed approved for continuing education credit:

(1) Continuing education programs approved or sponsored by the American Speech-Language and Hearing Association.

(2) Continuing education programs approved or sponsored by the American Academy of Audiology.

(3) Courses and programs offered by academic programs in speech-language pathology, audiology or teaching of the hearing impaired associated with institutions accredited by any state's department of education or a regional commission on institutions of higher education.

§ 45.506. Provider responsibilities.

(a) For each program, the provider shall:

(1) Disclose to prospective participants in advance the objectives, content, teaching method and number of hours of continuing education credit.

(2) Open each course to licensees.

(3) Provide adequate facilities for the number of anticipated participants and the teaching methods to be used.

(4) Provide appropriate instructional materials.

(5) Utilize a verifiable method of certifying participation.

(6) Employ qualified instructors who are knowledgeable in the subject matter.

(7) Evaluate the program through the use of questionnaires of the participants.

(8) Issue a certified continuing education record to each participant.

(9) Retain participation records, written outlines and a summary of evaluations for 5 years.

(10) Provide the Board, upon request, verification of licensee's participation in a continuing education program, including the date of approval of the program and the name of the entity that approved the program for continuing education credit.

(b) Each continuing education record must include at a minimum:

(1) The name of the participant.

(2) The dates of participation in the program.

- (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 proce-

dures 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.

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