Regulatory Analysis Form

(Completed by Promulgating Agency)

(All Comments submitted on this regulation will appear on IRRC's website)

INDEPENDENT REGULATORY REVIEW COMMISSION

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

(2) Agency Number: **16A**

Identification Number: **5428**

IRRC Number: 2949

(3) PA Code Cite: **49 Pa. Code §§ 27.18 and 27.201**

(4) Short Title: **Electronic Prescribing of Controlled Substances**

(5) Agency Contacts (List Telephone Number and Email Address):

Primary Contact: **Kerry Maloney, Counsel, State Board of Pharmacy, P.O. Box 2649, Harrisburg, PA 17105-2649; phone: 717-783-7200; fax: 717-787-0251; email: kmaloney@pa.gov.**

Secondary Contact: **Cynthia Montgomery, Regulatory Counsel, Department of State, P.O. Box 2649, Harrisburg, PA 17105-2649; phone: 717-783-7200; fax: 717- 787-0251; email: cymontgome@pa.gov.**

(6) Type of Rulemaking (check applicable box):

- ☐ Proposed Regulation
- ☐ Final Regulation
- X **FINAL OMITTED REGULATION**
- ☐ Emergency Certification Regulation;
- ☐ Certification by the Governor
- ☐ Certification by the Attorney General

(7) Briefly explain the regulation in clear and nontechnical language. (100 words or less)

Currently, Board regulations permit pharmacists to accept electronically transmitted prescriptions for any and all medications except Schedule II controlled substances. In March of 2010, the U.S. Drug Enforcement Administration (DEA) amended its regulations to permit the electronic prescribing of Schedule II controlled substances. DEA's regulations provide certain safeguards, such as the requirement that it certify any technical application selected by a pharmacy to receive these electronic prescriptions. The Pennsylvania Department of Health (DOH) regulates controlled substances in the Commonwealth. In December of 2010, DOH published a Notice in the Pennsylvania Bulletin (40 Pa.B. 7160), by which it sought to announce its interpretation of its regulations, so as to make them consistent with the new DEA regulations. By this rulemaking, the Board seeks to do the same, by amending its regulations in the most expeditious fashion.

(8) State the statutory authority for the regulation. Include specific statutory citation.

The amendments are authorized under section 6(k)(9) of the Pharmacy Act (act) (63 P.S. §§ 390-6(k)(9)).

(9) Is the regulation mandated by any federal or state law or court order, or federal regulation? Are there any relevant state or federal court decisions? If yes, cite the specific law, case or regulation as well as, any deadlines for action.

The proposed rulemaking is needed to conform to changes made to its regulations by the U.S. Drug Enforcement Agency (DEA) in March of 2010, as well as a Notice published in the *Pennsylvania Bulletin* (at 40 Pa.B. 7160) by the Pennsylvania Department of Health (DOH) regarding electronic prescribing of controlled substances generally and Schedule II controlled substances in particular.

(10) State why the regulation is needed. Explain the compelling public interest that justifies the regulation. 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 rulemaking because it will provide them with an more efficient, less paper-intensive, method by which it may fill prescriptions for Schedule II controlled substances. The public will benefit by more expeditious, yet also safe, access to properly prescribed medications. Everyone will benefit because these amendments will eliminate confusion among the regulated community as to whether Pennsylvania pharmacists are permitted to accept electronically transmitted prescriptions for Schedule II controlled substances.

(11) If data is the basis for this regulation, please provide a description of the data, explain in detail how the data was obtained, and how it meets the acceptability standard for empirical, replicable and testable data that is supported by documentation, statistics, reports, studies or research. Please submit data or supporting materials with the regulatory package. If the material exceeds 50 pages, please provide it in a searchable electronic format or provide a list of citations and internet links that, where possible, can be accessed in a searchable format in lieu of the actual material. If other data was considered but not used, please explain why that data was determined not to be acceptable.

No data was the basis for this regulation.

(12) Describe who and how many people will be adversely affected by the regulation. How are they affected?

The Board does not foresee any groups being adversely affected by the regulation.

(13) 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.

All pharmacists who choose to receive, process and fill electronic prescriptions of controlled substances would be required to comply with the provisions of this rulemaking. There are approximately 20,700 pharmacists currently registered with the Board.

(14) 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. Explain how the dollar estimates were derived.

There should be no additional costs to the regulated community associated with compliance with this rulemaking because the Board's regulations already provided for the use of electronic prescriptions. These amendments would permit the use of electronic prescriptions for another classification of controlled substances. Note: There are costs under the DEA regulations to those in the regulated community who opt to provide this service in terms of technological matters such as obtaining access to an audited and DEA-compliant application. However, as noted by the DEA, it is not mandated that pharmacists accept electronically transmitted prescriptions.

(15) 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. Explain how the dollar estimates were derived.

There are no costs or savings to local governments associated with compliance with the rulemaking.

(16) 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. Explain how the dollar estimates were derived.

There are no costs or savings to state government associated with implementation of the proposed rulemaking.

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

(17a) Provide the past three year expenditure history for programs affected by the regulation.

Program	FY -3	FY -2	FY -1	Current FY
State Board of Pharmacy	**$1,742,656**	**$1,695,150**	**$1,748,926**	**$2,226,000 (budgeted)**

(18) Explain how the benefits of the regulation outweigh any cost and adverse effects.

Because the acceptance of electronic prescriptions of Schedule II controlled substances is not mandatory, pharmacies will be able to decide via their own cost-benefits analysis whether to commence offering this service. The technology-based costs may be offset by the greater efficiency in processing and filling prescriptions. Many pharmacists have switched to utilizing computerized recordkeeping systems since the Board authorized this method along with electronic prescribing of medications other than Schedule II's in 2006 . Therefore, some, much or all of the technology for adapting to electronic prescribing of Schedule II's may already be in place in many pharmacies.

(19) Describe the communications with and input from the public and any advisory council/group in the development and drafting of the regulation. List the specific persons and/or groups who were involved.

In accordance with Executive Order 1996-1, in June 2011, the Board sent a draft of this rulemaking to pharmacy and professional associations, hospitals, pharmacy schools and other stakeholders that the Board has identified as having an interest in this rulemaking and solicited their comments. The Board considered these comments at the July 19, 2011, meeting and made revisions to the rulemaking as a result of those comments. Also based upon those comments, the Board voted at that meeting to approve this rulemaking as final, with proposed rulemaking omitted.

(20) Include a description of any alternative regulatory provisions which have been considered and rejected and a statement that the least burdensome acceptable alternative has been selected.

No alternative regulatory schemes were considered.

(21) 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 regulations.

The regulations in their existing form are more stringent than the federal standards recently adopted by DEA, as well as the Notice issued by the Pennsylvania Department of Health (DOH). The rulemaking is necessary to make the Board's regulations consistent with the Federal and DOH standards.

(22) How does this regulation compare with those of other states? How will this affect Pennsylvania's ability to compete with other states?

States have been proceeding at various paces to implement regulations on the subject of electronic prescribing of controlled substances. States that have a regulation in place for e-prescribing of controlled substances have a competitive advantage over states whose regulations remain more stringent than Federal regulations. DOH, which regulates controlled substances in the Commonwealth, has recognized this in issuing the Notice that clarifies its own regulations on this subject. The Board realizes it must expeditiously enact this rulemaking to remain consistent with, and keep pace with, developments in Federal and DOH regulations. A review of the regulations of surrounding states indicates that a majority permit electronic prescriptions of controlled substances, including Schedule II controlled substances. Ohio (Ohio Administrative Code 4729-5-21); West Virginia (WV Code of State Rules § 15-1-21); Virginia (Title 18 of the Virginia Admin. Code 110-20-255); New Jersey (NJ Admin. Code 13:39-7.11); Maryland (Code of Maryland Regulations 10.34.20.02 and .04); Delaware (24 Delaware Administrative Code 2500-5.1.13.6) and New York (NY Public Health Law § 3332) all permit electronic prescribing of Schedule II controlled substances in accordance with state and Federal law. The rulemaking will permit Pennsylvania to remain competitive with surrounding states.

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

This rulemaking will maintain consistency with Federal and DOH regulations relating to electronic prescribing of controlled substances and would not affect other regulations of the Board or other state agencies.

(24) Submit a statement of legal, accounting or consulting procedures and additional reporting, recordkeeping or other paperwork, including copies of forms or reports, which will be required for implementation of the regulation and an explanation of measures which have been taken to minimize these requirements.

No legal, accounting or consulting procedures or additional reporting, recordkeeping or other paperwork are required for the implementation of this rulemaking.

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

The Board has not identified any particular groups or persons requiring special provisions.

(26) Include a schedule for review of the regulation including:

A. The date by which the agency must receive public comments: **N/A**

B. The date or dates on which public meetings or hearings will be held: **The Board meets in public session monthly, generally the 3rd Tuesday of the month, at which time it discusses the Board's regulatory agenda.**

C. The expected date of promulgation of the final-form regulation: **Winter 2011/2012**

D. The expected effective date of the final-form regulation: **Upon publication in the Pa. Bulletin as final.**

E. The date by which compliance with the final-form regulation will be required: **On the effective date (publication in the Pa. Bulletin).**

F. The date by which required permits, licenses or other approvals must be obtained: **N/A**

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

The Board continually reviews the efficacy of its regulations, as part of its annual review process under Executive Order 1996-1. The Board reviews its regulatory proposals at regularly scheduled public meetings, generally the 3rd Tuesday of each month. More information can be found on the Department's website (www.dos.state.pa.us).

CDL-1

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FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

DO NOT WRITE IN THIS SPACE

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

BY: _____
(DEPUTY ATTORNEY GENERAL)

_____
DATE OF APPROVAL

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

State Board of Pharmacy
(AGENCY)

DOCUMENT/FISCAL NOTE NO. 16A-5428

DATE OF ADOPTION: _____

BY: _____
Edward J. Bechtel

TITLE: Chairman
(EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)

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

Megan L. Consedine

Megan L. Consedine

MAY 18 2012
DATE OF APPROVAL

~~Executive~~ Deputy General Counsel
(Strike inapplicable title)

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

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

FINAL RULEMAKING (WITH NOTICE OF PROPOSED RULEMAKING OMITTED)

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF PHARMACY
49 PA. CODE, CHAPTER 27

§§ 27.18 and 27.201

ELECTRONIC PRESCRIBING OF CONTROLLED SUBSTANCES

The State Board of Pharmacy (Board) hereby amends §§ 27.18 and 27.201 (relating to to standards of practice; and electronically transmitted prescriptions), to read as set forth in Annex A. The intent of this rulemaking is to make the Board's regulations consistent with Federal regulations enacted on March 31, 2010, by the Drug Enforcement Administration (DEA) of the United States Department of Justice, which became effective June 1, 2010, as well as the Notice of the Pennsylvania Department of Health (DOH) published in the *Pennsylvania Bulletin* on December 11, 2010.

Background and Purpose

On March 31, 2010, DEA published in the *Federal Register* at 75 F.R. 16235-16319 revisions to its regulations which provide health care practitioners the option of transmitting prescriptions for controlled substances electronically, effective June 1, 2010. The revised regulations are located in the Code of Federal Regulations at 21 CFR Parts 1300, 1304, 1306 and 1311.

The revised Federal regulations permit, but do not require, pharmacies to receive, dispense and archive these electronic prescriptions. The electronic prescription and the application utilized by the pharmacy must meet DEA requirements. For example, the application being used to import, display and store electronic prescriptions must either be audited by a qualified third party or be certified by an approved certification body as in compliance with the DEA's requirements. The application provider must provide a copy of the report of the auditor or certification body to any pharmacies that use or are considering use of the pharmacy application.

Further, DEA's revised regulations acknowledge that electronic prescriptions for controlled substances may be subject to State laws and regulations. If State requirements are more stringent than DEA's regulations, the State requirements would supersede any less stringent DEA provision. At the time of the passage of DEA's revised regulations in 2010, both the Board's regulations and those of DOH were more stringent than DEA's revised regulations.

DOH has the authority to administer the provisions of the Controlled Substance, Drug, Device and Cosmetic Act (DD&C Act) (35 P.S. §§ 780-101 – 780-144). This authority includes the promulgation of regulations regarding, among other things, the possession, distribution, sale, purchase or manufacture of controlled substances as may be necessary to aid in the enforcement of the DD&C Act. On December 11, 2010, DOH published in the *Pennsylvania Bulletin* (40 Pa.B. 7160) a Notice entitled "Electronically Transmitted Prescriptions." In that Notice, the Department of Health clarified its position on whether the electronic transmission of prescriptions to a pharmacy is an acceptable practice for the medical and pharmaceutical communities under the DD&C Act and its regulations. DOH regulations provide that prescription orders may be written on prescriptions blanks or may be oral, if allowed by law; and that prescriptions for controlled substances shall be written in indelible ink, indelible pencil or typewriter and shall include certain information. DOH's notice clarifies its interpretation that a prescription transmitted electronically or by facsimile constitutes a "written order on a prescription blank" and that an electronically-transmitted prescription for a controlled substance is considered to be typewritten, provided that the transmission of the prescription otherwise complies with Federal and State laws and regulations, including the

Board's regulations.

Thus, the Board's regulations remain as the last regulatory obstacle to the use of e-prescribing technology for the transmission of prescriptions for Schedule II controlled substances in Pennsylvania. The Pennsylvania Pharmacists Association has urged the Board to move as quickly as possible to effectuate these amendments because with the recent changes to the DEA regulations and publication of DOH's notice, many prescribers believe that the current restrictions have been lifted and will begin to submit electronic prescriptions for controlled substances, including Schedule II controlled substances, as soon as their software has been certified under the DEA regulations. However, pharmacies and pharmacists will have to reject these prescriptions or delay patient care until a handwritten prescription is obtained in compliance with the Board's existing regulations. Additionally, since the Federal law was revised, all of the contiguous states now permit the transmission of electronic prescriptions for Schedule II controlled substances, in accordance with the DEA regulations.

Omission of Proposed Rulemaking

Under section 204 of the Act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. § 1204), known as the Commonwealth Documents Law (CDL), the Board is authorized to omit the procedures for proposed rulemaking in sections 201 and 202 of the CDL (45 P.S. §§ 1201 and 1202) if the Board finds that the specified procedures are impracticable, unnecessary or contrary to the public interest.

Prior to making the determination to adopt this amendment without prior notice of proposed rulemaking, the Board sent a draft of the rulemaking in proposed form to the regulated community and other affected or interested parties on June 29, 2011, in accordance with Executive Order 1996-1. The Board held public discussion regarding the rulemaking at its meeting of July 19, 2011. Commentators who responded in writing to support the rulemaking included: National Association of Chain Drug Stores and Pennsylvania Association of Chain Drug Stores (NACDS/PACDS); Pennsylvania Pharmacists Association (PPA); Pennsylvania Medical Society (PMS); and the Montgomery County Pharmacy Association.

Given that DOH has issued its Notice in response to the DEA's amendment of its regulations, and with the support of the regulated community, the Board believes that it is in the best interests of the regulated community, as well as prescribers and patients alike, to bring its regulations into consistency with those of the applicable Federal and State agencies to permit the transmission of electronic prescriptions for Schedule II controlled substances. The Board finds for good cause that publication of this rulemaking as proposed is unnecessary.

Under authority of section 204(3) of the CDL (45 P.S. § 1204(3)), proposed rulemaking has been omitted as unnecessary because the rulemaking is merely incorporating the regulatory changes made by the Federal regulations enacted on March 31, 2010, and which became effective June 1, 2010, and the Notice published by DOH in the *Pennsylvania Bulletin* on December 11, 2010, regarding its interpretation of existing regulations to permit the electronic prescribing of controlled substances.

Accordingly, the Board adopts this amendment without prior notice of proposed rulemaking. Comments on the amendment may, however, be submitted within 30 days of publication to the contact person for the Board indicated below.

Description of the Amendments

Under current § 27.18(b)(2) (relating to standards of practice), prescriptions for Schedule II controlled substances must be written with ink, indelible pencil, typewriter, word processor or computer printer and must be manually signed by the prescriber. The current Board regulations at § 27.201(b) (relating to electronically transmitted prescriptions), provide that, with the specific exception of Schedule II controlled substances, a pharmacist may accept an electronically transmitted prescription from an authorized licensed prescriber or an authorized designated agent which has been sent directly to a pharmacy of the patient's choice if all of the requirements enumerated in the section are met.

These amendments add electronic means to the methods in which a prescription for a Schedule II controlled substance may be written, and provides an exception to the manual signature requirement, by providing that electronic prescriptions must be electronically signed by the prescriber. The amendments also add paragraph (5), which provides that the electronic transmission of a prescription for a Schedule II, III, IV, or V controlled substance is considered a written prescription order on a prescription blank and may be accepted by a pharmacist, provided that the transmission complies with this chapter and any other requirements under Federal or other State laws or regulations. The new paragraph lists some of the applicable State and Federal laws and regulations. The new paragraph purposely uses the terms "written," "prescription order," and "prescription blank," in order to be consistent with the Department of Health's interpretation of its regulations at 28 Pa. Code, Chapter 25 (relating to controlled substances, drugs, devices and cosmetics).

Statutory Authority

The amendments are authorized under section 6(k)(9) of the Pharmacy Act (act) (63 P.S. § 390-6(k)(9)).

Fiscal Impact and Paperwork Requirements

The proposed rulemaking will have no adverse fiscal impact on the Commonwealth or its political subdivisions. The rulemaking will impose no additional paperwork requirements upon the Board. The inherent goal of the regulation is to decrease paperwork in the form of the prescriptions and related recordkeeping, which is consistent with the Board's prior enactment of §§ 27.201 and 27.202 (relating to electronically transmitted prescriptions; and computerized recordkeeping systems). It is the intention of the rulemaking to make the Board's regulations consistent with recent

Federal and State regulatory changes. Those changes recognize pharmacists' need to avail themselves of technological developments to better serve their patients. There may be costs to pharmacists/pharmacies involved in upgrading their technology or obtaining an application for the submission of electronic prescriptions that meets the requirements of the DEA's regulations. However, because the acceptance of electronic prescriptions of Schedule II controlled substances is not mandatory, pharmacies will be able to decide via their own cost-benefit analysis whether to accept these prescriptions electronically. Many pharmacies began to utilize computerized recordkeeping systems when the Board authorized this method, along with electronic prescribing of medications (other than Schedule II controlled substances) in 2006. Therefore, some of the technology for adapting to electronic prescribing of Schedule II controlled substances may already be in place.

Regulatory Review

Under section 5(c) of the Regulatory Review Act (RRA) (71 P.S. § 745.5(c)), on May 30, 2012, the Board submitted copies of the final rulemaking, with proposed rulemaking omitted, to the Independent Regulatory Review Commission (IRRC), and the Chairpersons of the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC) and the House Professional Licensure Committee (HPLC). On the same date, the Board submitted a copy of the regulations to the Office of the Attorney General under the Commonwealth Attorneys Act (71 P.S. §§ 732-101 – 732-506).

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

Additional Information

For additional information about the final rulemaking, submit inquiries to Kerry Maloney, Counsel, State Board of Pharmacy, by mail at P.O. Box 2649, Harrisburg, PA 17105-2649, or by telephone at (717) 783-7200.

Findings

The Board finds that:

(1) Public notice of the Board's intention to amend its regulations under the procedures in sections 201 and 202 of the CDL (45 P.S. §§ 1201 and 1202) has been omitted under the authority of section 204 of the CDL (45 P.S. §1204), because public comment is unnecessary in that the amendment adopted by this order adopts the changes made to applicable corresponding Federal and State regulations.

(2) The amendment of the Board's regulation in the manner provided in this order is necessary and appropriate for the administration of the Act.

Order

The Board, acting under its authorizing statute, orders that:

(a) The regulations of the Board, 49 Pa. Code, Chapter 27, are amended by amending §§ 27.18 and 27.201 to read as set forth in Annex A.

(b) The Board shall submit this order and Annex A to the Office of General Counsel and the Office of Attorney General for approval as to form and legality as required by law.

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

(d) This order shall take effect upon publication 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

* * * * *

STANDARDS

* * * * *

§ 27.18. Standards of practice.

* * * * *

(b) Prescriptions kept on file in the pharmacy must meet the following requirements:

* * * * *

(2) Prescriptions for controlled substances must show the DEA number of the prescriber. Prescriptions for Schedule II controlled substances must be written with ink, indelible pencil, typewriter, word processor, [or] computer printer or by electronic means and must be manually signed by the prescriber, except that prescriptions written by electronic means must be electronically signed by the prescriber. Electronic prescriptions of Schedule II controlled substances must comply with the requirements of § 27.201(b) (relating to electronically transmitted prescriptions). The Pharmacist is responsible for compounding and dispensing nonproprietary drugs consistent with the Federal Controlled Substances Act (21 U.S.C.A. §§ 801 – 904), The Controlled Substance, Drug, Device and Cosmetic Act (35 P.S. §§ 780-101 – 780-144) and the regulations promulgated under these acts.

* * * * *

TECHNOLOGY AND AUTOMATION

§ 27.201. Electronically transmitted prescriptions.

* * * * *

(b) [Except for Schedule II controlled substances which must conform to the requirements of § 27.18(b)(2)(relating to standards of practice), a] A pharmacist may accept an electronically transmitted prescription from an authorized licensed prescriber or an authorized designated agent which has been sent directly to a pharmacy of the patient's choice if all the following requirements are met:

* * * * *

(5) The electronic transmission of a prescription for a Schedule II, III, IV, or V controlled substance is considered a written prescription order on a prescription blank and may be accepted by a pharmacist, provided that the transmission complies with this chapter and any other requirements under Federal or other State laws or regulations, including, but not limited to, the Controlled Substance, Drug, Device and Cosmetic Act (35 P.S. §§ 780-101 – 780-144), the regulations promulgated by the Department of Health at 28 Pa. Code §§ 25.1 – 25.131 (relating to controlled substances, drugs, devices and cosmetics) and Federal rules established by the United States Drug Enforcement Administration at 21 CFR Part 1311 (relating to requirements for electronic orders and prescriptions).

* * * * *

COMMENTATOR' S LIST

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

May 30, 2012

The Honorable Silvan B. Lutkewitte, III, Chairman
INDEPENDENT REGULATORY REVIEW COMMISSION
14th Floor, Harristown 2, 333 Market Street
Harrisburg, Pennsylvania 17101

Re: Final Omitted Regulation
State Board of Pharmacy
16A-5428: ELECTRONIC PRESCRIBING OF CONTROLLED SUBSTANCES

Dear Chairman Lutkewitte:

Enclosed is a copy of a Final Omitted rulemaking package of the State Board of Pharmacy pertaining to Electronic Prescribing of Controlled Substances.

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

Sincerely,

Edward J. Bechtel, RPh, Chairperson
State Board of Pharmacy

EJB/KEM:rs
Enclosure
cc: Katie True, Commissioner
Bureau of Professional and Occupational Affairs
Rebecca Oyler, Director of Policy, Department of State
Steven V. Turner, Chief Counsel
Department of State
Cynthia Montgomery, Regulatory Counsel
Department of State
Kerry E. Maloney, Counsel
State Board of Pharmacy
State Board of Pharmacy

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER: 16A-5428

SUBJECT: ELECTRONIC PRESCRIBING OF CONTROLLED SUBSTANCES

AGENCY: DEPARTMENT OF STATE
STATE BOARD OF PHARMACY

TYPE OF REGULATION

Proposed Regulation

Final Regulation

X 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

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FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
		HOUSE COMMITTEE ON PROFESSIONAL LICENSURE
5/30/12	Michele Warren	MAJORITY CHAIR Julie Harhart
5/30/12	Mary Walmer	SENATE COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICENSURE
		MAJORITY CHAIR Robt. M. Tomlinson
5/30/12	K Cooper	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
		LEGISLATIVE REFERENCE BUREAU (for Proposed only)