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 Medicine

(2) Agency Number: **16A**
Identification Number: **4933**

IRRC Number: 2931

(3) PA Code Cite: **49 Pa. Code § 16.92**

(4) Short Title: **Prescribing**

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

Primary Contact: **Teresa Lazo, Board Counsel, State Board of Medicine; (717)783-7200; P.O. Box 2649, Harrisburg, PA 17105-2649; (717)787-0251; tlazo@pa.gov**

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

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

☐ Proposed Regulation
X **Final Regulation**
☐ 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)

The rulemaking rewrites § 16.92 (related to prescribing, administering and dispensing controlled substances) for clarity and will expand the provisions of the current section to three non-controlled substances that are often abused or overused, and that can be dangerous or fatal.

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

This rulemaking is authorized by section 8 of the Medical Practice Act of 1985 (act) (63 P.S. § 422.8).

(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.
No. The rulemaking is not mandated by any other Federal or state law or court order or Federal regulation.

(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.

The rulemaking is necessary to protect the public from unscrupulous practitioners who would inappropriately prescribe and overprescribe drugs of abuse that are not 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.

In addition to the articles provided as attachments to the proposed rulemaking's regulatory analysis form, the article cited in the final rulemaking's preamble is attached.

(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 rulemaking.

(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 physicians licensed by the Board of Medicine and other practitioners licensed and authorized to prescribe drugs by the Board will be required to comply with the regulation.

(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.

The Board does not anticipate savings to the regulated community associated with compliance with the rulemaking. If Pennsylvania practitioners are prescribing these additional drugs of abuse without the necessary and prudent safeguards mandated by the rulemaking, these practitioners may experience some additional costs in performing the required examinations and reevaluations of patients to whom these additional three drugs are prescribed. The Board has no way to estimate or quantify any potential costs.

(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.

The Board does not anticipate either 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.

The Board anticipates some savings to state government may be associated with the implementation of the regulation. The savings will result from the decrease in traffic accidents and overdose fatalities associated with the three drugs being added to the Board's regulation. The Board does not anticipate any costs to state government associated with compliance with the 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
Pa. State Board of Medicine	**$5,790,741.22**	**$4,850,758.87**	**$5,571,463.51**	**$6,665,000.00**

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

Poisoning or overdose from prescription drugs claims the most lives from injury in the Commonwealth, and the most lives from all accidental death nationwide. The benefits of requiring minimal patient safety provisions prior to prescribing these three drugs of abuse outweigh any cost or adverse effect of the regulation.

(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.

The Board discussed the comments to the proposed rulemaking and the amendments to the proposed rulemaking at two public meetings. Aside from the comments received during the public comment period, no groups or individuals have corresponded with the Board regarding the rulemaking.

(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.

The Board carefully considered all of the comments made and finds the final rulemaking necessary for the protection of the public.

(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.

This rulemaking will be more stringent than Federal requirements. The Federation of State Medical Boards and National Association of Boards of Pharmacy have encouraged their member boards to develop regulations to monitor and restrict inappropriate prescribing and overprescribing. The regulation will bring Pennsylvania in line with the regulation of these drugs in many other states.

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

The regulation is consistent with regulations adopted in others state that restrict the prescription of drugs over the Internet in a variety of ways, including by requiring pre-prescription physical examination and prohibiting prescribing based on a questionnaire. The Board's proposal requires a physician to obtain objective data related to a patient's specific complaint. In this manner, it is narrowly tailored and will not provide a prohibitive restriction on legitimate uses of telemedicine technology in medical practice.

Delaware provides that a practitioner, whether acting within or outside Delaware, shall not issue a prescription drug order, by email or otherwise, to or on behalf of a Delaware patient through an internet pharmacy unless the person is a licensed practitioner who has a patient-practitioner relationship with the Delaware patient. "Patient-practitioner" relationship includes that the practitioner has conducted at least one in-person medical evaluation of the patient and performed a medical history and physical examination sufficient to establish a diagnosis and to identify underlying conditions of, or contraindications to, the treatment recommended or provided. 16 Del. Code § 4743(12) and 4744(c)(1).

Maryland allows a physician to prescribe medication after conducting a patient evaluation, and provides that if the evaluation does not include a face-to-face interaction with the patient, the physician must incorporate real-time auditory communications or real-time visual and auditory communications with the patient. Code of Maryland Regulations 10.32.05.05.

New Jersey requires that a physician must perform a physical examination of a patient before issuing prescriptions. New Jersey does not specify the character of the physical examination. N.J. Admin. Code tit. 13, 13:35-7.1A.

New York provides that a physician must conduct a physical examination before prescribing controlled substances and has specifically stated that online questionnaires are not a sufficient substitute for a physical examination. 10 NYCRR 80.63

Regulations of the Ohio Board of Medicine prohibit a physician from prescribing any dangerous drug to a person the physician has not personally examined. Ohio Code of Regulations 4731-11-09.

In Virginia, a physician may prescribe medications only if there is a bona-fide physician-patient relationship. To have this relationship, the physician must conduct a physical examination, which can take place "physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically." Va. Code Ann. § 54.1-33.3.

By definition, West Virginia deems it unprofessional for a physician to issue a prescription via electronic or other means without establishing an on-going physician-patient relationship. W. Va. Code St. R. § 11-1A-12.

(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 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.

This rulemaking will not require any legal, accounting or consulting procedures or any additional recordkeeping or other paperwork.

Physicians will, of course, be required to document the findings of their patient examinations in patient medical records.

(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 determined that there are no special needs of any subset of its applicants or licensees for whom special accommodations should be made.

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

A. The date by which the agency must receive public comments:	**April 4, 2012**
B. The date or dates on which public meetings or hearings will be held:	**The Board meets public session on the 4th Tuesday of each month.**
C. The expected date of promulgation of the proposed regulation as a final-form regulation:	**Fall 2012**
D. The expected effective date of the final-form regulation:	**Upon final promulgation**
E. The date by which compliance with the final-form regulation will be required:	**Upon the effective date**
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. The Board reviews its regulatory proposals at regularly scheduled public meetings, generally the fourth Tuesday of each month. More information can be found on the Board's website (www.dos.state.pa.us/med).

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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 Medicine
(AGENCY)

DOCUMENT/FISCAL NOTE NO. 16A-4933

_____
DATE OF ADOPTION:

BY: _____
~~James W. Freeman, MD~~

TITLE: Chairman
(EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)

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

BY: SHAWN E. SMITH

MAR 08 2013
DATE OF APPROVAL

(Deputy General Counsel
(~~Chief Counsel~~,
~~Independent Agency~~
(Strike inapplicable title)

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

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

FINAL RULEMAKING

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF MEDICINE

49 Pa. Code §§ 16.92

PRESCRIBING, ADMINISTERING AND DISPENSING

The State Board of Medicine (Board) hereby amends § 16.92 (relating to prescribing, administering and dispensing) to read as set forth in Annex A.

Effective date

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

Statutory Authority

The amendments are authorized under section 8 of the Medical Practice Act of 1985 (act) (63 P.S. § 422.8).

Background and Purpose

Poisoning is the leading cause of accidental death in the United States, and 9 out of 10 poisoning deaths are related to prescription drug overuse or abuse. See, Margaret Warner et al., Drug poisoning deaths in the United States, 1980–2008, NCHS data brief, no. 81 (Hyattsville, MD: National Center for Health Statistics, 2011). In Pennsylvania and 29 other states, poisoning is the leading cause of injury death. There can be no doubt that all states must take steps to reverse this preventable cause of death.

While the Board already had in place a regulation to provide safeguards for physicians prescribing, administering and dispensing controlled substances, the Board had previously failed to address and provide similar safeguards related to non-controlled prescription drugs. Requiring the same safeguards for all non-controlled prescription drugs would be unnecessary and overly burdensome because most non-controlled prescription drugs, such as antibiotics, are used very safely and are not either drugs of abuse themselves or used in association with drugs of abuse. As more fully set forth in the notice of proposed rulemaking, the Board has identified three non-controlled drugs with sufficiently similar propensities for abuse or use in combination with drugs of abuse to controlled substances, and for which there are numerous cases reported of fatal overdose, to warrant placing additional requirements on physicians who prescribe, administer and dispense these drugs.

Summary of Comments and Responses to Proposed Rulemaking

Comments from the Public

Notice of the proposed rulemaking was published at 42 Pa.B. 1122 (March 3, 2012). The Board received comments from the Pennsylvania Pharmacists Association; JNESCO District Council 1, IUOE/AFL-CIO; the Pennsylvania Medical Society; and the law firm of Kalogredis, Sansweet, Dearden and Burke, Ltd. on behalf of their client Troy Pharmacy in Pittsburgh. In addition, the Board received comments from the House Professional Licensure Committee (HPLC) and the Independent Regulatory Review Commission (IRRC).

The Pennsylvania Pharmacists Association stated that it supports the proposed regulation as written. JNESCO, on behalf of 5,000 nurses and health care workers, wrote in support of the Board's proposal, noting that "it is vital to monitor those substances that have the potential to be improperly prescribed" and that healthcare workers have a "moral, ethical and legal obligation to ensure the safety and well-being of the patients we serve." JNESCO noted that Pennsylvania would be the 17th state to further regulate these drugs. The Board appreciates the support of these groups.

The Pennsylvania Medical Society, representing about 17,000 physicians, residents and medical students, wrote in support of the rulemaking and applauded the Board for introducing the regulation as a means to tackle prescription drug abuse and diversion. The Medical Society agreed that butalbital, carisoprodol and tramadol hydrochloride are all medications with the potential for overuse or abuse with potential fatal side effects. The Medical Society also noted with approval the Board's emphasis on ensuring that the doctor-patient relationship is paramount prior to prescribing medications. The Board appreciates the support of the Medical Society.

The law firm of Kalogredis, Sansweet, Dearden and Burke, Ltd. on behalf of their client Troy Pharmacy in Pittsburgh, wrote in opposition to the proposal. The firm viewed the proposal as an attempt to classify the three drugs as controlled substances, which it viewed as the proper role of the Federal Drug Enforcement Agency (DEA), and stated that the Board was attempting to by-pass the DEA drug review system for adding or deleting controlled substances.

The Board's rulemaking does not attempt to reclassify the three drugs. As noted by the firm, at the Federal level, the DEA is involved in the classification of drugs as controlled substances. In fact, on December 12, 2011, the Administrator of the DEA issued final rulemaking placing carisoprodol into Schedule IV on the Federal list of controlled substances. See 76 FR 77330; 21 CFR 1308.

At the state level, the Pennsylvania Controlled Substance, Drug, Device and Cosmetic Act (35 Pa.C.S. 780-101 – 780-144) contains the listing of substances controlled in this Commonwealth and vests authority to control substances listed in the statutory schedules with the Secretary of Health. The Board is not seeking to amend the Pennsylvania Controlled Substance, Drug, Device and Cosmetic Act. Rather, the Board is regulating the practice of medicine within the Commonwealth.

The firm also suggested that the Board's proposal violated the Commerce Clause of the United States Constitution, because it would "force non PA licensed medical practitioners to follow onerous 'controlled drug' procedures to prescribe these drugs, rather than prescribing them as non controlled drugs which is permitted in their home state" thereby discriminating "against out of state licensed physicians prescriptions being dispensed by a PA licensed pharmacy." The Board disagrees with the firm's statement that Board regulations must be followed by physicians who are not licensed in the Commonwealth and who are not practicing in the Commonwealth. Physicians are required to follow the law and regulations of the state in which they are practicing.

Comments from HPLC and IRRC

HPLC submitted comments to the Board on April 4, 2012. HPLC first suggested that § 16.92(b)(2) (related to reevaluations) may need to be clarified as to who does the reevaluation and that the reevaluation should become part of the medical record or that (b)(2) should be moved to (b)(4)(ii) so it becomes part of the written medical record. Reevaluations may be done by the same practitioners that can perform an initial evaluation. As is set forth in § 16.92(b), a licensed physician or physician assistant shall carry out or cause to be carried out the functions listed in § 16.92(b)(1) – (8). Reevaluations must be recorded in the medical record for several reasons. First, § 16.92(b)(4) states that accurate and complete medical records shall document the evaluation and care received by patients. Second, § 16.95(a) (relating to medical records) provides that a physician shall maintain medical records which accurately, legibly and completely reflect the evaluation and treatment of the patient. Reevaluation is, of course, a subset of evaluation. For these reasons, the Board does not believe § 16.92(b)(2) requires clarification.

Similarly, HPLC next suggested that § 16.92(b)(3) (related to patient counseling) may need to be clarified in regards to who does the counseling. As noted above, all of the provisions of § 16.92(b) must be carried out by or be caused to be carried out by a licensed physician or physician assistant. The Board does not believe it is necessary to repeat the provisions of subsection (b) in each of the paragraphs under subsection (b).

Third, HPLC recommended that the Board use the term "licensed health care provider" consistently throughout the regulation. The Board agrees and has added the word "licensed" to § 16.92(b)(4)(i)(A) and (b)(8).

IRRC questioned the Board's assertion in the proposed rulemaking that there would not be any additional costs or any additional recordkeeping associated with the regulation, noting that it appeared that the more stringent requirements for evaluations, which necessitate recording those evaluations, would likely impact the regulated community in both additional costs and recordkeeping requirements. The Board has amended the fiscal costs statement and the regulatory analysis to acknowledge those potential costs to the regulated community as suggested.

IRRC questioned whether the phrase "or cause to be carried out" might be exploited by unscrupulous practitioners to circumvent the intent of the rulemaking, and suggested the Board consider clarifying the phrase. Of the two groups of its licensees to which the regulation applies, physicians and physician assistants, only physicians are authorized to delegate the performance of medical services. The Board is confident that physicians know to whom they are permitted to delegate particular tasks and understand that the terminology "or cause to be carried out," which has been in the Board's regulation for many years, makes the physician responsible for any task delegated to another. Therefore, the Board declines to add additional language related to the phrase.

IRRC noted that, although an initial medical history and physical examination are required, the medical records are not required to include documentation of the initial medical

history and physical examination of a patient. The Board disagrees. The Board's recordkeeping regulation, § 16.95, requires a physician to maintain medical records for patients which accurately, legibly and completely reflect the evaluation and treatment of the patient, which would include the initial medical history and results of any physical examination. In addition, § 16.92(b)(4) states the following: "Accurate and complete medical records shall document the evaluation and care received by patients." As amended in the final-form rulemaking, § 16.92(b)(4)(ii) requires documentation of the name, strength and quantity of a drug, and the date on which a drug was prescribed, administered or dispensed, as well as any change in the patient's symptoms, diagnosis or directions for drug use.

IRRC also suggested that paragraph (b)(4) be amended to require documentation in the medical record of the periodic reevaluations required by paragraph (b)(2). The Board believes that its medical record regulation, § 16.95, and § 16.92(b)(4), already require documentation of reevaluations. Nevertheless, the Board has amended § 16.92(b)(4)(ii)(B) to more specifically require recording information obtained on reevaluation.

IRRC questioned the exemption of a patient in an inpatient care setting from counseling regarding possible side effects. IRRC suggested adding "possible side effects" to the counseling requirements in the first sentence of paragraph (b)(3) and removing "possible side effects" from the exemption in the second sentence of paragraph (b)(3). The first sentence of paragraph (b)(3) is a general statement requiring all patients to be counseled regarding the condition diagnosed and the drug prescribed, administered or dispensed. This general statement would not benefit from adding one particular aspect of counseling, that is, counseling about possible side effects. The second sentence of paragraph (b)(3) serves two purposes: first, it elaborates on the content of the counseling generally required and second, it exempts a patient in an inpatient care setting from the counseling requirement. Generally, patients treated in an outpatient setting are counseled on the drug, dosage, duration and other instructions for use because they are expected to administer the prescribed drugs to themselves. In an inpatient setting, it is usually the medical/nursing staff of the facility that will be administering the drugs and monitoring the patient for possible side effects. Additionally, a patient in an inpatient care setting may be unconscious, under anesthesia, or otherwise incapable of counseling. A patient in an inpatient care setting may be in cardiac arrest or other emergent condition, such as in an emergency room or intensive care unit, where delaying the prescription and administration of a drug until the patient can be counseled could cause patient death. The patient counseling provision in this rulemaking is identical to the patient counseling provision in the existing regulation and no problems with the provision have been brought to the Board's attention over the years that the existing regulation has included this language. The Board therefore declines the suggested edit to paragraph (b)(3).

Next, IRRC suggested that the information in subparagraphs (b)(4)(i) and (ii) should both be specifically required to be recorded in the medical record on and after the initial occasion when a drug is prescribed. The Board agrees and has amended the regulation accordingly.

IRRC raised several additional issues related to clarity of the rulemaking. First, IRRC suggested that the Board consider including a reference to the appropriate section of the Medical Practice Act regarding penalties for non-compliance with the proposed rulemaking. None of the

other provisions in Subchapter F (relating to minimum standards of practice) include such a reference and it is understood that failure to comply may result in disciplinary action. The Board declines to add such a reference to these provisions.

IRRC suggested that the Board use the term "licensed health care provider" consistently in the regulation. The Board has made amendments to do so.

IRRC asked if a prescription relayed electronically to a pharmacist meets the requirement in paragraph 5(b) that an emergency oral prescription be covered by a written prescription delivered to the pharmacist within 72 hours. This requirement is virtually identical to the Department of Health regulations at 28 Pa. Code § 25.45 (relating to emergency oral prescriptions). On March 31, 2010, the Federal Drug Enforcement Agency 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. On December 11, 2010, the Pennsylvania Department of Health 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 Drug Device and Cosmetic Act and its regulations. The 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. Additionally, on August 11, 2012, the State Board of Pharmacy promulgated amended regulations at § 27.201(b)(5) (relating to electronically transmitted prescriptions) which provide that "the electronic transmission of a prescription...is considered a written prescription order." The Board believes the regulated community understands that a "written prescription" may now be transmitted electronically, so long as the licensed health care practitioner complies with the applicable Federal and State laws and regulations.

Fiscal Impact and Paperwork Requirements

The amendments will have no adverse fiscal impact and will impose no additional paperwork requirements on the Commonwealth or its political subdivisions. Physicians prescribing, administering or dispensing the three additional drugs will need to ensure proper examinations of patients to assess the appropriateness of prescribing these three drugs and keep medical records that accurately reflect the care provided to patients. If there are any physicians who are not already examining patients to assess the appropriateness of prescribing these three drugs, these physicians will need to conform to the regulation. Because of the high potential for abuse, misuse, dependency and possible death associated with these three drugs, the Board speculates that few physicians are currently prescribing these drugs without first carrying out, or causing to be carried out, an examination of the patient and appropriate documentation in the medical record.

Sunset Date

The Board continuously monitors the 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 February 22, 2012, the Board submitted a copy of the proposed rulemaking, published at 42 Pa.B. 1122 and a copy of a Regulatory Analysis Form 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) for review and comment.

Under section 5(c) of the Regulatory Review Act (71 P.S. § 745.5(c)), IRRC, the SCP/PLC and the HPLC were provided with copies of the comments received during the public comment period as well as other information when requested. In preparing for the final-form rulemaking, the Board has considered all comments from the IRRC, the HPLC and the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P.S. § 745.5a(j.2), on _____, 2012, the final-form rulemaking was approved by the HPLC. On _____, 2012, the final-form rulemaking was deemed approved by SCP/PLC. Under section 5.1(e) of the Regulatory Review Act, IRRC met on _____, 2012, and approved the final-form rulemaking.

Contact Person

Interested persons may obtain information regarding the final-form rulemaking by writing to Teresa Lazo, Board Counsel, State Board of Medicine, P.O. Box 2649, Harrisburg, PA 17105-2649, or by e-mail at tlazo@pa.gov.

Findings

The Board finds that:

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

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

(3) The amendments to the final-form rulemaking do not enlarge the purpose of the proposed rulemaking published at 42 Pa.B. 1122.

(4) This final-form rulemaking is necessary and appropriate for administration and enforcement of the authorizing acts identified in this Preamble.

Order

The Board orders that:

(a) The Regulations of the Board at 49 Pa. Code Chapter 16 are amended by amending § 16.92 (relating to prescribing, administering and dispensing) 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 to the Office of Attorney General as required by law.

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

(d) This order shall take effect on publication in the Pennsylvania Bulletin.

COMMENTATORS LIST FOR REG. 16A-4933

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ANNEX A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 16. STATE BOARD OF MEDICINE—

GENERAL PROVISIONS

Subchapter F. MINIMUM STANDARDS OF PRACTICE

§ 16.92. Prescribing, administering and dispensing [controlled substances].

[(a) A person licensed to practice medicine and surgery in this Commonwealth or otherwise licensed or regulated by the Board, when prescribing, administering or dispensing controlled substances , shall carry out, or cause to be carried out, the following minimum standards:

(1) *Initial medical history and physical examination.* In a health care facility regulated by the Department of Health, the Department of Public Welfare or the Federal government, an initial medical history shall be taken and an initial physical examination shall be conducted to the extent required by the Department of Health in 28 Pa. Code (relating to health and safety) or Department of Public Welfare in 55 Pa. Code (relating to public welfare) or the Federal government in appropriate Federal regulations, whichever is applicable, and bylaws of the health care facility and its medical staff. In other practice settings, before commencing treatment that involves prescribing, administering or dispensing a controlled substance, an initial medical history shall be taken and an initial physical examination shall be conducted unless emergency circumstances justify

otherwise. Alternatively, medical history and physical examination information recorded by another health care provider may be considered if the medical history was taken and the physical examination was conducted within the immediately preceding 30 days. The physical examination shall include an evaluation of the heart, lungs, blood pressure and body functions that relate to the patient's specific complaint.

(2) *Reevaluations.* Among the factors to be considered in determining the number and frequency of follow-up evaluation that should be recommended to the patient are the condition diagnosed, the controlled substance involved, expected results and possible side effects. For chronic conditions, periodic follow-up evaluations shall be recommended to monitor the effectiveness of the controlled substance in achieving the intended results.

(3) *Patient counseling.* Appropriate counseling shall be given to the patient regarding the condition diagnosed and the controlled substance prescribed, administered or dispensed. Unless the patient is in an inpatient care setting, the patient shall be specifically counseled about dosage levels, instructions for use, frequency and duration of use and possible side effects.

(4) *Medical records.* In a health care facility regulated by the Department of Health, the Department of Public Welfare or the Federal government, information pertaining to the prescription, administration or dispensation of a controlled substance shall be entered in the medical records of the patient and the health care facility under 28 Pa. Code or 55 Pa. Code or appropriate Federal regulations, whichever is applicable, and bylaws of the health care facility and its medical

staff. In other practice settings, certain information shall be recorded in the patient's medical record on each occasion when a controlled substance is prescribed, administered or dispensed. This information shall include the name of the controlled substance, its strength, the quantity and the date it was prescribed, administered or dispense. On the initial occasion when a controlled substance is prescribed, administered or dispensed to a patient, the medical record shall also include a specification of the symptoms observed and reported, the diagnosis of the condition for which the controlled substance is being given and the directions given to the patient for the use of the controlled substance. If the same controlled substance continues to be prescribed, administered or dispense, the medical record shall reflect changes in the symptoms observed and reported, in the diagnosis of the condition for which the controlled substance is being given and in the directions given to the patient.

(5) *Emergency prescriptions.* In the case of an emergency phone call by a known patient, a prudent, short-term prescription for a controlled substance may be issued. Neither a refill nor a consecutive issuance of this emergency prescription may be given unless a physical examination and evaluation of the patient are first conducted. The results of this examination and evaluation shall be set forth in the patient's medical record together with the diagnosis of the condition for which the controlled substance is being prescribed. An emergency oral prescription for a Schedule II controlled substance shall be covered by a written prescription delivered to the pharmacist within 72 hours. In certain health care facilities regulated by the Department of Health, the Department of Public Welfare or the

Federal government, orders for the immediate, direct administration of a Schedule II controlled substance to a patient are not considered prescriptions and are, therefore, not subject to the requirements in this paragraph. Further information regarding this exclusion can be found in The Controlled Substance, Drug, Device and Cosmetic Act (35 P.S. §§ 780-101—780-144) and 28 Pa. Code Chapter 25 (relating to controlled substances, drugs, devices and cosmetics).

(b) This section establishes minimum standards for the prescription, administration and dispensation of controlled substances by persons licensed to practice medicine and surgery in this Commonwealth or otherwise licensed or regulated by the Board. This section does not restrict or limit the application of The Controlled Substance, Drug, Device and Cosmetic Act or of another statute or regulation, and does not relieve a person from complying with more stringent standards that may be imposed by another statute or regulation.

(c) Compliance with this section will not be treated as compliance with the standards of acceptable and prevailing medical practice when medical circumstances require that the practitioner exceed the requirements of this section.]

(a) For purposes of this section, "drug" includes the following:

(1) Controlled substances under The Controlled Substance, Drug, Device and Cosmetic Act (35 P.S. §§ 780-101—780-144) or substances that are controlled substances under Federal law.

(2) Carisoprodol or agents in which carisoprodol is an active ingredient.

(3) Butalbital or agents in which butalbital is an active ingredient.

(4) Tramadol hydrochloride or agents in which tramadol hydrochloride is an active ingredient.

(b) When prescribing, administering or dispensing drugs regulated by this section, a person licensed to practice medicine and surgery in this Commonwealth or otherwise licensed or regulated by the Board shall carry out, or cause to be carried out, the following minimum standards:

(1) *Initial medical history and physical examination.* An initial medical history shall be taken and an initial physical examination shall be conducted unless emergency circumstances justify otherwise. Medical history and physical examination information recorded by another licensed health care provider may be considered if the medical history was taken and the physical examination was conducted within the immediately preceding 30 days. The physical examination shall include an objective evaluation of the heart, lungs, blood pressure and body functions that relate to the patient's specific complaint.

(2) *Reevaluations.* Reevaluations of the patient's condition and efficacy of the drug therapy shall be made consistent with the condition diagnosed, the drug or drugs involved, expected results and possible side effects.

(3) *Patient counseling.* The patient shall be counseled regarding the condition diagnosed and the drug prescribed, administered or dispensed. Unless the patient is in an inpatient care setting, the patient shall be specifically counseled about dosage levels, instructions for use, frequency and duration of use and possible side effects.

(4) *Medical records.* Accurate and complete medical records must document the evaluation and care received by patients.

(i) On the initial occasion when a drug is prescribed, administered or dispensed to a patient, the medical record must include the following:

(A) A specification of the symptoms observed by the LICENSED health care provider and reported by the patient.

(B) The diagnosis of the condition for which the drug is being given.

(C) The directions given to the patient for the use of the drug.

(D) THE NAME, STRENGTH AND QUANTITY OF THE DRUG, AND THE DATE ON WHICH THE DRUG WAS PRESCRIBED, ADMINISTERED OR DISPENSED.

(ii) After the initial occasion when a drug is prescribed, administered or dispensed, ~~the following information shall be recorded in the patient's medical record:~~

~~(A) The name of the drug.~~

~~(B) The strength of the drug.~~

~~(C) The quantity of the drug.~~

~~(D) The date the drug was prescribed, administered or dispensed.~~

~~(E) Any~~ THE MEDICAL RECORD MUST INCLUDE THE INFORMATION REQUIRED IN CLAUSE (b)(4)(i)(D) AND ANY

changes OR ADDITIONS to the information recorded under ~~subparagraph~~ CLAUSES (b)(4)(i)(A-C).

(5) *Emergency prescriptions.* In the case of an emergency contact from a known patient, a prudent, short-term prescription for a drug may be issued. Neither a refill nor a consecutive issuance of this emergency prescription may be given unless a physical examination and evaluation of the patient is first conducted by a licensed health care provider. The results of this examination and evaluation shall be recorded in the patient's medical record together with the diagnosis of the condition for which the drug is being prescribed. An emergency oral prescription for a Schedule II controlled substance shall be covered by a written prescription delivered to the pharmacist within 72 hours.

(6) *Compliance with other laws.*

(i) This section may not be construed as restricting or limiting the application of The Controlled Substance, Drug, Device and Cosmetic Act or statutes or regulations of the Pennsylvania Departments of Health and the Department of Public Welfare that govern the prescription, administration and dispensation of drugs and medical recordkeeping in certain health care facilities.

(ii) This section may not be construed as restricting or limiting the application of Federal laws or regulations that govern the prescription, administration and dispensation of drugs and medical recordkeeping in certain health care facilities.

(iii) This section does not relieve a person from complying with more stringent standards that may be imposed by another statute or regulation.

(7) *Compliance with facility policy.* This section does not relieve a person from complying with more stringent standards that may be imposed by the health care facility in which the person practices or by the person's employer.

(8) *Adherence to standards of practice.* Compliance with this section will not be treated as compliance with the standards of acceptable and prevailing medical practice when medical circumstances require that the ~~practitioner~~ LICENSED HEALTH CARE PROVIDER exceed the requirements of this section.

* * * * *

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF MEDICINE
Post Office Box 2649
Harrisburg, Pennsylvania 17105-2649
(717) 783-1400

March 21, 2013

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

Re: Final Regulation
State Board of Medicine
16A-4933: PRESCRIBING, ADMINISTERING AND DISPENSING

Dear Chairman Lutkewitte:

Enclosed is a copy of a final rulemaking package of the State Board of Medicine pertaining to Prescribing, Administering and Dispensing.

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

Sincerely,

Andrew J. Behnke, MD, Chairperson
State Board of Medicine

AJB/TL: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
Teresa Lazo, Counsel
State Board of Medicine
State Board of Medicine

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER: 16A-4933

SUBJECT: PRESCRIBING, ADMINISTERING AND DISPENSING

AGENCY: DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF MEDICINE

TYPE OF REGULATION

Proposed Regulation

X Final Regulation

Final Regulation with Notice of Proposed Rulemaking Omitted

120-day Emergency Certification of the Attorney General

120-day Emergency Certification of the Governor

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

RECEIVED
IRRC
2013 MAR 21 AM 11: 14

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
		HOUSE COMMITTEE ON PROFESSIONAL LICENSURE
3/21/13	Michele Warren	MAJORITY CHAIR Julie Harhart
		SENATE COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICENSURE
3-21-13		MAJORITY CHAIR Robt. M. Tomlinson
3/21/13	K Cooper	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
		LEGISLATIVE REFERENCE BUREAU (for Proposed only)

March 8, 2013