PROPOSED RULEMAKING

STATE BOARD OF MEDICINE

[49 PA. CODE CH. 16]

Prescribing

The State Board of Medicine (Board) proposes to amend § 16.92 (relating to prescribing, administering and dispensing) 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 8 of the Medical Practice Act of 1985 (act) (63 P. S. § 422.8).

Background and Need for the Amendment

The problems caused by inappropriate prescribing and overprescribing have been compounded in recent years by rogue online pharmacies. Because of the severity of these problems, most states and the Federal government have promulgated regulations to place reasonable restrictions on prescribing drugs that will protect the public from unscrupulous practitioners. Nevertheless, instances of a single practitioner and single pharmacy dispensing hundreds of thousands of doses of dangerous drugs to patients virtually unknown to the practitioner or pharmacist persist. The Commonwealth's regulations must be reformed to address this threat to public health and safety.

Some of the attempts at regulation include the following. In 2006, the United States Department of Justice's Drug Enforcement Administration required practitioners to register in every state in which they prescribe to monitor and reduce inappropriate prescribing and overprescribing of controlled substances. In 2008, the United States Congress passed the Ryan Haight Online Pharmacy Consumer Protection Act (Pub. L. No. 110-425), which amended the Drug Abuse Prevention and Control Act (21 U.S.C.A. §§ 801—971) to address the alarming growth in prescription drug abuse by minors purchasing drugs over the Internet. It requires online pharmacies to have a valid prescription, preceded by a physical examination, to dispense controlled substances. However, this law failed to address drugs of abuse that are not listed as Federally-controlled substances. Rogue online pharmacies coupled with unscrupulous prescribers have turned to drugs of abuse that are not on the Federal controlled substance list.

The Federation of State Medical Boards and the National Association of Boards of Pharmacy have encouraged their member boards to develop regulations to monitor and restrict inappropriate prescribing and overprescribing. Most states have done so; however, the Commonwealth lags behind the rest of the Nation in regulating this area and has become one of the largest providers of prescription drugs of abuse to individuals in states across the United States. The Board, which already regulates physician prescribing of controlled substances, had not updated its prescribing regulations since 1998 and currently does not directly address the standards for prescribing drugs that are not controlled substances. Under the current regulations, to hold a physician licensee accountable for inappropriate prescribing or overprescribing of a drug that is not a controlled substance, the Commonwealth must allege and prove that a practitioner's prescribing deviated from the standard of care. To demonstrate the inappropriate prescribing or overprescribing, the Commonwealth must have access to the medical records of thousands of patients spread across the United States as well as the records of pharmacies that are frequently located offshore. Using the tools currently available under the Board's regulations, it is extremely difficult to hold unscrupulous physicians accountable for inappropriate prescribing or overprescribing of drugs that are not controlled substances.

Three drugs that are not controlled substances, but which share serious potential for addiction and abuse (butalbital, carisoprodol and tramadol hydrochloride), are being prescribed by Pennsylvania-licensed physicians and sold by rogue pharmacies at alarming rates in this Commonwealth. The Board therefore proposes to expand its regulation of prescribing, administering and dispensing of controlled substance to include these three drugs. The Board drafted a proposed revision of § 16.92 which would have applied to all drugs and provided its stakeholders with a draft of the draft proposal. The Board received many comments opining that its draft was overly inclusive and would have a negative impact on accessible health care. The Board revised the draft to its current form which is narrowly focused to address these three drugs which are not controlled substances, but which are currently being inappropriately prescribed and overprescribed. The Board spoke with representatives of its stakeholders regarding this proposed rulemaking. The proposed rulemaking met with unanimous approval.

The Board proposes to rewrite, simplify and update § 16.92 to expand it to include the following additional drugs that are not controlled substances in this Commonwealth: butalbital, carisoprodol and tramadol hydrochloride, including agents in which these drugs are an active ingredient. Butalbital is a barbiturate that is known to have addictive and abuse potential and is prone to overuse by the consumer. See, for example, Charles E. Romero, M.D., Joshua D. Baron, M.D., Antony P. Knox, M.D., PhD, Judy A. Hinchey, M.D., Allan H. Ropper, M.D. "Barbituate Withdrawal Following Internet Purchase of Fioricet." *Archives of Neurology*, 2004; 61: 1111-1112.

A metabolite of carisporodol is meprobamate, which is a controlled substance. Roy R. Reeves, DO, PhD, Jeffery S. Hammer, M.D. and Richard O. Pendarvis, PhD. "Is the Frequency of Carisoprodoal Withdrawal Syndrome Increasing?" *Pharmacotherapy*, 2007; 27 (10): 1462-1466. Cases of dependence, withdrawal and abuse have also been reported with carisoprodol. Roy R. Reves, DO, PhD and Randy S. Burke, PhD. "Is it Time for Carisoprodol to Become a Controlled Substance at the Federal Level?" *Southern Medical Journal*, 2008; 101 (2): 127-128. The United States Department of Justice, Drug Enforcement Administration, Office of Diversion Control lists carisoprodol as a "drug of concern" and notes that carisoprodol has been consistently listed in the top 25 most frequently identified drugs by state and local forensic laboratories since 2000, and that Florida reported a 100% increase in carisoprodol/meprobamate related deaths from 208 in 2003 to 415 in 2008, surpassing opioids such as heroin, fentanyl and hydromorphone. The drug has been added to the state controlled substances lists in Alabama, Arizona, Arkansas, Florida, Georgia,

Hawaii, Indiana, Kentucky, Louisiana, Massachusetts, Minnesota, Nevada, New Mexico, Oklahoma, Oregon, Texas and West Virginia.

Tramadol is used to treat moderate to moderately severe pain and may induce psychic and physical dependence of the morphine-type; dependence and abuse, including drug-seeking behavior and taking illicit actions to obtain the drug; and withdrawal symptoms. Drug Enforcement Administration, Office of Diversion Control, Drug and Chemical Evaluation Section, "Tramadol," February 2011. Tramadol related incidents have dramatically increased by 165% from 1995 to 2002 in the Federal Drug Abuse Warning Network. "What is the addiction risk associated with tramadol?" *The Journal of Family Practice*, 2005, 54 (1): 72-73. Additional evidence that tramadol is a drug of abuse has led Arkansas and Kentucky to designate it a controlled substance under state law and Louisiana to list it as a drug of abuse. Anecdotal evidence from this Commonwealth suggests that tramadol is one of the most inappropriately and overprescribed drugs.

Description of the Proposed Amendments

The Board proposes to amend § 16.92 to expand its application to carisoprodol, butalbital and tramadol hydrocholoride, and agents in which these drugs are an active ingredient. The Board proposes to rewrite the section for clarity; however, other substantive amendments are not proposed.

Fiscal Impact and Paperwork Requirements

The proposed rulemaking will not have adverse fiscal impact on the Commonwealth or its political subdivisions. The proposed rulemaking will not impose additional paperwork requirements upon the Commonwealth or its political subdivisions. Because the Board believes that the standard of medical care in this Commonwealth already requires an objective examination before prescribing the three additional drugs, practitioners who are already compliant with the standard of care will not be affected by the proposed rulemaking.

Sunset Date

The Board continuously monitors the effectiveness of its regulations. Therefore, a sunset date has not 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 this proposed rulemaking and a copy of a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the House Professional Licensure Committee and the Senate Consumer Protection and 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 comments, recommendations or objections to the proposed rulemaking within 30 days of the close of the public comment period. The comments, recommendations or objections must 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 Teresa Lazo, Assistant Counsel, Department of State, P. O. Box 2649, Harrisburg, PA 17105-2649, st-medicine@state.pa.us within 30 days following publication of this proposed rulemaking in the *Pennsylvania Bulletin*. Reference No. 16A-4933 (Prescribing) when submitting comments.

JAMES W. FREEMAN, M.D.,
Chairperson

Fiscal Note: 16A-4933. 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 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 evaluations 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 dispensed. 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 dispensed, 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 and 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 under 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 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.

(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) Changes to the information recorded under subparagraph (i).

(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 Department 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 exceed the requirements of this section.

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