Comments of the Independent Regulatory Review Commission

State Board of Medicine Regulation #16A-4933 (IRRC #2931)

Prescribing

May 2, 2012

We submit for your consideration the following comments on the proposed rulemaking published in the March 3, 2012 *Pennsylvania Bulletin*. Our comments are based on criteria in Section 5.2 of the Regulatory Review Act (71 P.S. § 745.5b). Section 5.1(a) of the Regulatory Review Act (71 P.S. § 745.5a(a)) directs the State Board of Medicine (Board) to respond to all comments received from us or any other source.

1. Economic impact of the regulation.

The Board proposes to add three drugs to the more stringent evaluation and recordkeeping requirements of Section 16.92. The Board states in the Preamble and in responses in the Regulatory Analysis Form (RAF) that compliance with the proposed rulemaking will not result in additional costs and will not require any additional recordkeeping. However, it appears that requiring more stringent evaluations and recordkeeping would likely impact the regulated community in one or both of these areas. Therefore, the Board should either amend the information provided on the RAF regarding economic impact (RAF #14) and recordkeeping (RAF #24), or further explain why the Board does not anticipate either savings or costs, or additional paperwork, associated with compliance with the rulemaking.

2. Section 16.92. Prescribing, administering and dispensing. – Protection of the public health, safety and welfare; Clarity.

"Or cause to be carried out"

Subsection (b) requires licensed health care providers to carry out, "or cause to be carried out," the minimum standards specified in the regulation. In the Preamble, the Board states that the proposed rulemaking is necessary to protect the public from unscrupulous practitioners who inappropriately prescribe or overprescribe drugs of abuse that are not controlled substances. The Board also states that the problems caused by inappropriate prescribing and overprescribing have been compounded in recent years by rogue online pharmacies. The phrase "or cause to be carried out" might be exploited by unscrupulous practitioners to circumvent the intent of the proposed rulemaking. For these reasons, the Board should clarify the phrase "or cause to be carried out" in Subsection (b).

Initial medical history and physical examination

Paragraph (b)(1) requires an initial medical history and physical examination. However, the medical records required by Paragraph (b)(4) do not require documentation of the initial medical history and physical examination. We suggest adding this documentation to the medical records required by Paragraph (b)(4).

Reevaluations

Paragraph (b)(2) requires periodic reevaluations of the patient's condition and efficacy of the drug therapy. We suggest adding documentation of reevaluations to the medical records required by Paragraph (b)(4).

Patient counseling

Under Paragraph (b)(3), we question the exemption of a patient in an inpatient care setting from counseling regarding possible side effects. A patient in a hospital, for example, may notice the occurrence of side effects well before a health care professional might observe them. We suggest 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) so that patient counseling on possible side effects will occur regardless of the care setting.

Medical records

Subparagraph (b)(4)(ii) lists the information, such as the name and strength of a drug, that must be recorded in a patient's medical record after the initial occasion when a drug is prescribed, administered or dispensed. The Board should consider requiring the same information on the initial occasion under Subparagraph (b)(4)(i).

3. Miscellaneous clarity.

- The Board should consider including a reference to the appropriate section of the Medical Practice Act regarding penalties for non-compliance with this proposed rulemaking.

- For consistency, the Board should use the term "licensed health care provider" throughout the proposed regulation. Specifically, "licensed" should be added to "health care provider" in Clause (b)(4)(i)(A) and "practitioner" should be replaced with "licensed health care provider" in Paragraph (b)(8).

- We recognize the phrase "written prescription" is used in existing regulation in Paragraph (a)(5), which is repeated in the new language of Paragraph (b)(5). The requirement for "written" prescriptions may be outdated because many prescriptions are relayed to pharmacies electronically. Would a prescription relayed electronically to a pharmacist meet the requirement in Paragraph (b)(5) that an emergency oral prescription "shall be covered by

a written prescription delivered to the pharmacist within 72 hours"? If so, the final-form regulation should include this clarification.