Comments of the Independent Regulatory Review Commission

State Board of Pharmacy Regulation #16A-5425 (IRRC #3006)

Collaborative Management of Drug Therapy

July 3, 2013

We submit for your consideration the following comments on the proposed rulemaking published in the May 4, 2013 *Pennsylvania Bulletin*. Our comments are based on criteria in Section 5.2 of the Regulatory Review Act (RRA) (71 P.S. § 745.5b). Section 5.1(a) of the RRA (71 P.S. § 745.5a(a)) directs the State Board of Pharmacy (Board) to respond to all comments received from us or any other source.

1. Section 27.1. Definitions. – Clarity.

Section 27.302 (relating to collaborative agreement for management of drug therapy in a non-institutional setting) uses the undefined term *non-institutional setting*. While we recognize that the term *institutions* is defined in existing Section 27.1 and includes in (iii) what the term does not include, the proposed regulation is unclear as to what settings qualify as non-institutional. In the final-form regulation, we ask the Board to clarify for the regulated community what constitutes a non-institutional setting by explicitly defining this term. The Board may also consider revising the definition of *institutions* if necessary to provide additional clarity between the two terms.

2. Section 27.301. Written protocol for the management of drug therapy in an institutional setting. – Clarity; Implementation procedures.

Comments submitted by the House Professional Licensure Committee (Committee) point out that Section 9.1(e)(10) of the Pharmacy Act specifies that written agreements or protocols must be filed with the Board and the State Board of Medicine and/or the State Board of Osteopathic Medicine, and that Section 9.3(k)(2) requires a collaborative agreement to comply with the requirements of Section 9.1(e). The Committee recommends, and we agree, that the Board clarify in Section 27.301(d) that the written protocol must be filed with the appropriate boards.

Likewise, we agree with the Committee's recommendation that the Board add a similar requirement to Section 27.302 for written collaborative agreements.

3. Section 27.302. Collaborative agreement for management of drug therapy in a non-institutional setting. – Protection of the public health, safety and welfare; Clarity; Implementation Procedures.

The Pennsylvania Medical Society commented that the regulation does not provide for physicians to have access to pharmacist records for regular review. Paragraph (f)(6) does require the collaborative agreement to contain a method for documenting decisions made and a plan for communication or feedback. Would adding a provision that explicitly provides physician access to pharmacist records provide clarity regarding the intent of the regulation, as well as greater protection of the public health, safety and welfare of patients? We ask the Board to consider this suggestion and explain why such a provision is or is not needed in the final rulemaking.