In accordance with the Administrative Procedures Act, R.I. Gen. Laws § 42-35-2.6, the following is a concise explanatory statement:

AGENCY: Rhode Island Department of Health

DIVISION: N/A

RULE IDENTIFIER: 216-RICR-40-05-1

RULE TITLE: Licensure and Discipline of Physicians

REASON FOR RULEMAKING: This rule is being amended to incorporate materials, add the definitions of: compounding, compounding sterile preparations, prescriber, and telemedicine; remove prohibition on volunteer licenses for academic physicians; permit prescribing a 30-day supply of non-controlled substances for family members; prohibit accepting of gifts greater than $100; requires conforming to compounding standards; permits the Board to issue fines; and require 90-day notice to patients when a physician closes his or her practice; and revises the collaborative pharmacy procedures.

ANY FINDINGS REQUIRED BY LAW AS A PREEQUISITE TO THE EFFECTIVENESS OF THE RULE: N/A

TESTIMONY AND COMMENTS:

A comment was received objecting to the inclusion of the definitions “compounding” and “compounding sterile preparations” and that these definitions be removed from the Regulation. The comment objects to such inclusion as a physician would be able to prescribe, prepare and administer medications and raises concerns for medication safety as physicians are not trained in the practice of compounding. Physicians are already authorized to compound medications under 21 U.S.C. § 503A. The inclusion of the definitions and the use of the definitions requires Rhode Island physician’s who choose to compound to follow the Department’s regulations on compounding found in Pharmacists, Pharmacies, and Manufactures, Wholesalers and Distributors (216-RICR-40-15-1) and the United States Pharmacopeia (USP). These requirements will ensure that physicians follow the same standards required of compounding pharmacists. This comment will not be accepted at this time.

CHANGES TO THE TEXT OF THE RULE:

No changes to the text of the regulation.

REGULATORY ANALYSIS:

In development of this rule, consideration was given to:

1) Alternative approaches;
2) Overlap or duplication with other statutory and regulatory provisions; and

3) Significant economic impact on small business

No alternative approach, duplication or overlap was identified based on available information. RIDOH has determined that the benefits of the rule justify its costs.