

**DIVISION OF HEALTH SERVICES REGULATION
RHODE ISLAND BOARD OF PHARMACY
Sub-Committee Meeting
Compounding Regulations Update**

**3 CAPITOL HILL
CONFERENCE ROOM 205
PROVIDENCE, RHODE ISLAND**

2/23/2016

8:30 AM

PUBLIC MEETING MINUTES

BOARD MEMBERS IN ATTENDANCE

Annamarie Arvanites, RPh., Leo Lariviere, RPh., Lorraine Quirk, RPh.

STAFF IN ATTENDANCE

**Peter Ragosta, RPh, Executive Director, Chief Administrative Officer
Scott Campbell, RPh, Chief Compliance Officer**

OTHERS IN ATTENDANCE

**Shannon Baker, Jennifer Beough, Jaqueline Costantino, Jim Glass,
Anthony Harrison, Heather Larch, Elaine Wojcik**

PURPOSE OF SUB-COMMITTEE MEETING

A public meeting for the sub-committee formed at the request of the RI Board of Pharmacy to review and update the current pharmacy compounding regulations was held on 2/23/2016 at the Rhode Island Department of Health, Conference Room #205, 3 Capitol Hill, Providence, RI 02908.

CALL TO ORDER

The meeting was called to order at 8:30am by Annmarie Arvanites (Sub-Committee Chairperson). Peter Ragosta (Chief Administrative Officer),

directed the attention of attendees to the process of reviewing and suggesting changes and updates to each sub-section of section 19.0 Compounding of Pharmaceuticals contained in the RULES AND REGULATIONS PERTAINING TO PHARMACISTS, PHARMACIES AND MANUFACTURERS, WHOLESALERS AND DISTRIBUTORS [R5-19.1-PHAR].

DISCUSSION

After reviewing each sub-section of section 19.0, the sub-committee agreed to make revisions to sub-sections 19.9, 19.10, 19.11, 19.12, 19.13, 19.14, 19.15.1, 19.18, 19.19, 19.20, 19.21, 19.22, 19.23, and the addition of sub-section 19.28.1 to 19.28.

It was agreed upon by the sub-committee that the basis for majority of changes to the regulations is to bring state regulations into

accordance with federal regulations that refer to the United States Pharmacopeia (USP) requirements. The sub-committee further agreed to refer to current USP requirements as a broader term to be included in the regulations rather than point to specific chapters such as 795, 797, and 800 which are constantly updated.

It was agreed upon by the sub-committee to accept the recommendation of the Department for the addition of sub-section 19.28.1 which will require sterile compounding pharmacies (which includes hospital pharmacies) to submit a quarterly viable sampling report to the Chief Compliance Officer for the Board of Pharmacy. In addition to this quarterly report, the sub-committee agreed that sterile compounding pharmacies (which includes hospital pharmacies) shall submit notifications to the Chief Compliance Officer when above action level results for viable sampling occur. The sub-committee agreed that the timeframe for reporting such occurrences shall be as soon as they are discovered, or a reasonable timeframe as determined by the Board of Pharmacy.

CONCLUSION

Revisions to the aforementioned regulations will be drafted based on the recommendations of the sub-committee and submitted by the Department for public comment, community review, public hearing and all necessary processes prior to promulgation.

Respectfully submitted,

Peter Ragosta, RPh