FINAL/APPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF REGULATION COMMITTEE

December 11, 2012
Second Floor
Training Room 1

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 3:12PM.

PRESIDING: Ellen B. Shinaberry, Committee Chairman

MEMBERS PRESENT:
R. Crady Adams
Empsy Munden
Robert M. Rhodes
Cynthia Warriner

STAFF PRESENT:
Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Howard M. Casway, Senior Assistant Attorney General
Elaine J. Yeatts, Senior Policy Analyst, DHP

APPROVAL OF AGENDA: With no changes made to the agenda, the agenda was approved as presented (motion by Warriner, second by Munden).

The Regulation Committee met to discuss adoption of the proposed Regulations for Continuous Quality Improvement Programs and proposed Regulations for Working Conditions for Pharmacists. Additionally, the Committee discussed proposed changes to the Regulations for Practitioners of the Healing Arts to Sell Controlled Substances, Regulations Governing Wholesale Distributors, Manufacturers, and Warehousers, and Regulations for Collaborative Practice Agreements.

CONTINUOUS QUALITY IMPROVEMENT REGULATIONS

The Committee discussed adoption of the proposed regulations for Continuous Quality Improvement Programs to replace the Emergency Regulations that are in effect from October 1, 2012 until September 30, 2013. The public comment period had closed on November 7, 2012. Ms. Yeatts provided a summary of the one public comment received. The committee discussed and recommended changes to the definition of "dispensing error".

MOTION:

The Committee voted unanimously to recommend to the full Board on December 12, 2012, adoption of the proposed Continuous Quality Improvement regulations with the following changes to the definition of "dispensing error": addition of the word "known" at the beginning of section (2)(a), (2)(b), (2)(c), and (20)(e) and removal of the words "if known" from (2)(b) and (2)(c) (motion by Wariner, second by Adams).

WORKING CONDITIONS FOR PHARMACISTS

The Committee discussed the adoption of proposed regulations for Working Conditions for Pharmacists. The public comment period had closed on October 10, 2012. Ms. Yeatts provided a summary of the approximately fourteen public comments received. A motion to withdraw the NOIRA was not carried. (motion by Munden, second by Warriner, opposed Adams, Rhodes, Shinnaberry). A motion to withdraw the NOIRA with a recommendation that the Regulation Committee be tasked with developing a guidance document to address working conditions was not carried (motion by Warriner, second by Munden, opposed Adams, Rhodes, Shinnaberry).

MOTION:

The Committee voted to recommend to the full Board on December 12, 2012, proposed regulations for Working Conditions for Pharmacists adding a new section B to Regulation 18VAC110-20-110 which states: Except in an emergency, a permit holder shall not require a pharmacist to work longer than 12 continuous hours in any work day without being allowed at least 6 hours of off time between consecutive shifts. A pharmacist working longer than 6 continuous hours shall be allowed to take a 30 minute break. (motion by Adams, second by Rhodes, opposed Warriner).

REGULATIONS FOR PRACTITIONERS OF THE HEALING ARTS TO SELL CONTROLLED SUBSTANCES

The Committee reviewed proposed changes to the Regulations for Practitioners of the Healing Arts to Sell Controlled Substances presented by Board staff.

- 18VAC110-30-20 – amendment suggested to conform language to Code
- 18VAC110-30-90, 18VAC110-30-100, and 18VAC110-30-130 – amendments suggested for consistency with regulations for pharmacies and to recognize allowances which are currently approved under a limited-use license

MOTION:

The Committee voted unanimously to recommend to the full Board on December 12, 2012, adoption of the proposed changes to the Regulations for Practitioners of the Healing Arts to Sell Controlled Substances (motion by Warriner, second by Rhodes).

REGULATIONS GOVERNING WHOLESALE DISTRIBUTORS, MANUFACTURERS, AND WAREHOUSERS

The Committee reviewed proposed changes to the Regulations Governing Wholesale Distributors, Manufacturers, and Warehousers presented by Board staff.

- 18VAC110-50-70 – amendment suggested to clarify who must provide a social security number or control number as currently indicated in Guidance Document 110-34
- 18VAC110-50-40 and 18VAC110-50-80 – amendments to clarify intent of regulations

MOTION:

The Committee voted unanimously to recommend to the full Board on December 12, 2012, adoption of the proposed Regulations Governing Wholesale Distributors, Manufacturers, and Warehousers (motion by Warriner, second by Adams).

REGULATIONS FOR COLLABORATIVE PRACTICE AGREEMENTS

The Committee reviewed proposed changes to the Regulations for Collaborative Practice Agreements presented by Board staff.

- 18VAC110-40-10 - consistent with the definition of "collaborative agreement" in §54.1-3300, a definition of "alternate practitioner" is suggested to clarify that a licensed nurse practitioner or physician assistant who is authorized in a practice agreement with a Virginia-licensed doctor of medicine, osteopathy, or podiatry may participate in a collaborative practice agreement

MOTION:

The Committee voted unanimously to recommend to the full Board on December 12, 2012, adoption of the proposed Regulations for Collaborative Practice Agreements (motion by Rhodes, second by Munden).

ADJOURN:

With all business concluded, the meeting adjourned at 6:35PM.

Ellen B. Shinaberry

Ellen Shinaberry, Committee Chairman

3/12/13

Date

Caroline D. Juran

Caroline D. Juran, Executive Director

3/12/2013

Date