FINAL/APPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF AD HOC INSPECTION COMMITTEE

June 4, 2014
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 3:40pm.

PRESIDING: Ellen Shinaberry, Committee Chairman

MEMBERS PRESENT:
R. Crady Adams
Jody H. Allen
Cynthia Warriner
Ryan K. Logan

STAFF PRESENT:
Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Heather W. Hurley, Administrative Assistant

APPROVAL OF AGENDA: An amended agenda was provided to the board. With no further changes made to the agenda, the amended agenda was approved as presented.

PUBLIC COMMENT: The Committee received public comment from Joe Cabaleiro, Pharmacist and Associate Director of Pharmacy for the Accreditation Commission for Health Care (ACHC). Mr. Cabaleiro requested the Committee's consideration to allow the ACHC certification program to be accepted as an alternative to the required inspection report performed by the resident state regulatory or licensing body. It was referenced that the board has agreed within Guidance Document 110-38 to accept the Verified Pharmacy Provider inspection report from the National Association of Boards of Pharmacy (NABP) for non-resident pharmacies. He stated that the ACHC surveyors are trained and that their certification program focuses on USP-NF standards for 795 and 797. Mr. Cabaleiro reviewed the accreditation process with the Committee by presenting a power point program. The presentation consisted of the following; personnel competency interviews, having a scoring system for their surveys, plan of corrective action, and having a review plan of corrective action. If the pharmacy has met all requirements, then an accreditation or certification certificate is issued. Louis S. Diorio, Pharmacist, FAPhA, Principal for LDT Health Solutions, Inc., requested that the Committee give consideration for their gap analysis tool being accepted in lieu of an inspection report as required in Virginia law and outlined in Guidance Document 110-38. Mr. Diorio stated that the audit conducted uses self-assessments and they have used the gap analysis tool thus far in New Jersey, New York and South Carolina.

DISCUSSION: The Committee discussed the requests from ACHC and LDT Health Solutions. While the Committee saw value in the information provided and showed appreciation for their request, the following concerns were expressed: the ACHC certification program is very new and there is little

experience with the program thus far; the ACHC certification program does not review for compliance of general pharmacy practice requirements; NABP appears to be meeting the inspection needs as it recently indicated to the board that it had succeeded at inspecting all the nonresident pharmacies by mid-April that applied for inspection prior to the deadline of January 31, 2014 as noted in the letters sent to all nonresident pharmacies; and, that it may be premature at this time to make other adjustments to this complex subject which requires critical oversight.

MOTION:

The Committee voted unanimously not to take any action at this time on the requests from ACHC and LDT Health Solutions to accept their certification/surveys in lieu of an inspection performed by the resident state regulatory or licensing board and therefore, no recommendation for amending Guidance Document 110-38 was made. (motion by Warriner, second by Logan)

CONSIDERATION OF AMENDING GUIDANCE DOCUMENT 110-9 TO INCLUDE A DEFICIENCY REGARDING NON-COMPLIANCE WITH GLOVED FINGERTIP SAMPLING:

The Committee discussed the amending of Guidance Document 110-9 to include a deficiency regarding non-compliance with gloved fingertip sampling. There was discussion as to whether there should be a delay in implementing the deficiency. The committee concluded that pharmacists should already be performing gloved finger tip testing as this is not a new requirement of USP chapter <797> and Inspector Tim Reilly confirmed that it is his observation that most pharmacists are performing gloved finger tip testing presently. Staff indicated they would provide information on the subject in the next board e-newsletter to be published in July.

MOTION:

The Committee voted unanimously to recommend to the full board that it amend Guidance Document 110-9 by inserting "or gloved finger tip testing" following the words "media-fill testing" in Major Deficiency 26 and in Major Deficiency 25a. (motion by Warriner, second by Munden)

ADJOURN:

With all business concluded, the meeting adjourned at 5:04pm.

Ellen B. Shinaberry

Ellen Shinaberry, Committee Chairman

September 9, 2014

Date

Caroline D. Juran, Executive Director

September 9, 2014

Date