**(FINAL/APPROVED)**

# VIRGINIA BOARD OF PHARMACY
# MINUTES OF AD HOC COMMITTEE MEETING REGARDING ROUTINE PHARMACY INSPECTION PROCESS

June 20, 2018
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 1:05 pm

PRESIDING: Jody H. Allen, Chairman

MEMBERS PRESENT:
Cynthia Warriner
Melvin L. Boone, Sr.
Ryan K. Logan
Sheila K. W. Elliott

STAFF PRESENT:
Caroline D. Juran, Executive Director
J. Samuel Johnson, Deputy Executive Director
Ellen Shinaberry, Deputy Executive Director
Beth O'Halloran, Deputy Executive Director
Melody Morton, Inspections Manager for Enforcement
Maria Damico, Pharmacy Inspector for Enforcement
Tim Reilly, Pharmacy Inspector for Enforcement

APPROVAL OF AGENDA:

**MOTION:** **The committee voted unanimously to approve the agenda as presented. (motion by Warriner, second by Logan)**

PUBLIC COMMENT: Christina Barrille, Executive Director for the Virginia Pharmacists Association thanked the Board for reviewing the inspection report and considering changes to the inspection deficiency guide. While overall the association approved of the proposed changes such as warnings for first time deficiencies, several members expressed a general concern with the inspection of USP <800> and requested clarity from the Board with regard to the inspection process for USP <800>.

- Overview of Revised Inspection Report: Ms. Juran provided an overview of why the ad hoc committee was convened. During the December 2017 full board meeting, it was agreed that an ad hoc committee should be formed to review the current inspection report and Guidance Document 110-9. It had been seven years since the current inspection program was implemented and Guidance Document 110-9 had become lengthy as more deficiencies were added throughout the years. Ms. Juran thanked Mr. Johnson and Melody Morton (Inspections Manager for Enforcement) for their hard work on

this project, along with Ms. Michelle Schmitz (Executive Director of Enforcement), and Pam Twombly (Deputy Executive Director of Enforcement). She shared that staff from the Board of Pharmacy and Enforcement, to include all pharmacy inspectors, met on April 26, 2018 to discuss the pros and cons with the current inspection process and report. Staff reached the following consensus regarding revisions to the current inspection reported: the report should remain as an Excel document; language from the former inspection report should be used in lieu of the current language; the report should be shortened to focus exclusively on items Virginia is interested in reviewing; and, the sterile compounding portion of the inspection report should be used for all pharmacies performing sterile compounding. Ms. Juran reminded the board that Virginia is a blueprint state for NABP and has agreed to use the sterile compounding portion of the universal inspection report for pharmacies that ship sterile compounded drugs into other states. Additionally she referenced the language on the revised inspection report regarding USP Chapter <800> that the inspectors will use when educating pharmacists on the new standards as requested by the board. She reminded the board that USP <800> cannot be enforced until the chapter has taken effect in December 2019 and that this portion of the inspection report is for educational purposes only.

Mr. Johnson stated that the report has been divided into multiple tabs. The inspector will only use the tabs relevant to the practice setting. He stated the length of the average pharmacy inspection report would likely be approximately 23 pages which is significantly shorter than the current version. When comparing the use of a shorter checklist inspection report format verses a lengthier format full of text referencing the relevant laws and regulations, there was consensus that the lengthier format assisted the inspectors and aided in educating the licensees more than the shorter checklist format. He then provided a detailed review of each section of the revised inspection report. Revisions and committee suggestions included:

- Removing areas of demographic information from the general inspection portion as well as the "areas reviewed";
- Adding "educational purposes only" or "deficiencies will not be cited" on the USP <800> portion;
- Removing "compounding of inordinate amounts" from page 21;
- Removing pages 27-37 within the non-sterile compounding portion as these items do not coincide with a Virginia deficiency listed in Guidance Document 110-9;
- Adding a heading to the sterile compounding portion;
- Rewording a few items to ensure the use of "compliant" or "non-compliant" clearly represents the issue;
- Clarify headings for the central or remote processing portion to distinguish between community/retail and hospital.

There was consensus that the inspectors should being using the revised inspection report on July 2, 2018 as presented and amended.

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| **ACTION ITEMS:** | **Board staff will include on a subsequent meeting agenda: Consideration for renaming Guidance Document 110-36 since the current title is limited to compounding and yet USP Chapter <800> appears to be broader than just compounding; Adoption of guidance to clarify the requirement for a pharmacist-in-charge to be "fully engaged" at the pharmacy; and, Adoption of guidance to clarify what constitutes a remodel of a pharmacy for which a remodel application and fee must be submitted.** |
| Review of Guidance Document 110-9 | Mr. Johnson provided a review of the proposed changes to Guidance Document 110-9. Effective July 1, 2018, the proposed changes identify certain deficiencies for which the board would cite a deficiency on the inspection summary when a violation is observed during a routine inspection, but would not impose a monetary penalty through the issuance of a pre-hearing consent order for the first documented occurrence of the violation. If the same violation is observed during the next subsequent routine or focused inspection, then the board will cite the deficiency and impose the recommended monetary penalty. The committee was referred to the last page of Guidance Document 110-9 for examples further explaining the concept. The committee then reviewed each of the proposed changes to Guidance Document 110-9. |
| **MOTION:** | **The committee voted unanimously to recommend to the full board to amend Guidance Document 110-9 as presented and amended as follows:**<br>• **Change all draft references of "first citation" to "first documented occurrence";**<br>• **Deficiency 12: strike the draft language "first citation and no drug loss = no penalty; drug loss or repeat = $ penalty";**<br>• **Deficiency 12a: insert "of Schedule II" following "first documented occurrence and no drug loss";**<br>• **Deficiency 14: insert "per occurrence" as a condition for when it should be cited and strike the draft language "over 5 days late and first citation = no penalty; repeat = $ penalty";**<br>• **Deficiency 15: strike draft language "expired drugs not included and first citation = no penalty; repeat = $ penalty"; and,**<br>• **Deficiency 20b: strike draft language "1000 per compounded sterile product, up to maximum of 5000". (motion by S. Elliott, second by Boone).** |
| ADJOURN: | With all business concluded, the meeting adjourned at approximately 4:30 pm. |

Jodi H. Allen, Chairman

Caroline D. Juran, Executive Director

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