## GEORGIA BOARD OF PHARMACY Conference Call 2 Peachtree Street, NW, 6<sup>th</sup> Floor Atlanta, GA 30303 September 30, 2019 1:00 p.m.

The following Board members were present:

Bill Prather, President Vicki Arnold

Michael Brinson Hal Henderson

Dean Stone

Staff present:

Tanja Battle, Executive Director Dennis Troughton, Director, GDNA

Michael Karnbach, Deputy Director, GDNA Max Changus, Assistant Attorney General

Kimberly Emm, Attorney

## **Open Session**

President Prather established that a quorum was present and called the meeting to order at 1:01 p.m.

**USP 800 Enforcement:** President Prather stated that USP has postponed enforcement of the new chapters. He stated that due to the staff office and GDNA receiving numerous calls regarding this matter, it was decided that the Board needed to issue a statement.

Vicki Arnold made a motion to adopt the following statement. Dean Stone seconded and the Board voted unanimously in favor of the motion. The statement reads as follows:

IMPORTANT INFORMATION CONCERNING UNITED STATES PHARMACOPEIA'S ANNOUNCEMENT POSTPONING THE EFFECTIVE DATE OF REVISED CHAPTERS <795> AND <797> AND THE GA BOARD'S/GDNA'S ENFORCEMENT OF CHAPTER <800>.

The United States Pharmacopeia ("USP") announced on September 23, 2019, that – as required by USP by-laws – it is postponing the official dates of the revised USP chapters <795> and <797> and new chapter <825> while appeals for review of these chapters are resolved. These chapters were previously scheduled to go into effect on December 1, 2019.

Existing USP chapters <795> and <797> will continue to be enforced. The GA Drugs & Narcotics Agency (GDNA) will continue to use the inspection forms and tools to existing USP chapter <795> and <797> requirements. As pharmacists know, under GA Law, 26-4-86, and GA Board of Pharmacy Rule, 480-11-.02, compounding activities must comply with USP-NF standards. This includes chapters <795> and <797>. The revised chapters as well as the new chapter <825> will be enforced when they go into effect. USP did not set a new effective date in its announcement.

Since USP has announced that as of December 1, 2019, chapter <800> is to be simply informational and <u>not</u> [compendially] applicable, GDNA will not be inspecting for compliance with chapter <800>, until such time that the revised versions of chapters <795> and <797> are made effective by USP.

Again, USP did not set a new effective date in its announcement. Pharmacies working toward chapter <800> compliance are strongly encouraged to take the time afforded by this delay to finalize those preparations.

\*\*A link to the 09/23/19 USP announcement is provided here: https://www.uspnf.com/notices/compounding-chapters-postponement

There being no further business to discuss, the meeting was adjourned at 1:06 p.m.

The next meeting of the Georgia Board of Pharmacy is scheduled for Wednesday, October 16, 2019 at 9:00 a.m., at the Department of Community Health's office located at 2 Peachtree Street, N.W., 5<sup>th</sup> Floor, Atlanta, GA 30303.

Minutes recorded by Kimberly Emm, Attorney Minutes edited by Tanja D. Battle, Executive Director