

**ALABAMA STATE BOARD OF PHARMACY
BUSINESS MEETING MINUTES
September 15, 2021**

President Brenda Denson called the September 15, 2021, meeting of the Alabama State Board of Pharmacy to order at 9:07 a.m. to conduct necessary business and determined a quorum was present.

The following Board members were present:

Brenda R. Denson	President
Chris Phung	Vice President
Rob Colburn	Treasurer
Christy K. Garmon	Member
Gary Mount	Member
Jim Ward	Attorney

Other Alabama Board of Pharmacy staff members present via WebEx teleconference or in person were:

Donna C. Yeatman, Executive Secretary	Sean Malloy, Drug Investigator
Susan Alverson, Ph.D., Dir. of Legislative Affairs	Wendy Passmore, Operations Manager
Edward R. Braden, Chief Drug Investigator	Rhonda Coker, Technician Licensing Manager
Cristal Anderson, Director of Compliance	Anne Marie Nolen, Pharmacist Licensing Mgr.
Glenn Wells, Drug Investigator	Terry Lawrence, IT/Licensing Manager
Casey Shaw, Drug Investigator	

Members of the public present via WebEx teleconference or in person were:

Jim Driskell	Clemice Hurst	Mary McKnight
Zuri Foster	Julie Jordan	Louise Jones
Greg Peden	Julie Lasseigne	Aaron Lopez
Robert Dyar	Kelli Littlejohn	Shandra Wright
Melissa Pharo	Laura Matthews	Jeff Church
Tommy Cobb	Paula Hudson	Bart Bamberg
Bart Bamberg	Kimberly Witt	Jessica Higginbotham
Rachel Weaver	Roland Naseman	Alex Jenkins
Leah Croft	Sarah Cantrell	Corie Hawks
Allen Broome	Mike Juliano	Stephen Brown
Stephen McCormick	Rachel Kiefer	Eddie Vanderver
Laura Churns	Caitlin Robbins	

1. MOTION TO ADOPT AGENDA

President Denson called for a motion to adopt the agenda. A motion to adopt the agenda was made by Mr. Colburn and seconded by Dr. Garmon. A vote was taken and the motion to adopt the agenda passed with aye votes from Mr. Phung, Mr. Colburn, Dr. Garmon, and Dr. Mount.

2. PRESENTATIONS

- Greg Peden with the Boykin Community Center, an interdisciplinary clinic in an underserved area of Auburn, gave a presentation requesting approval for Boykin Pharmacy to operate less than 20 hours per week. A motion was made by Dr. Garmon and seconded by Mr. Phung to approve the request to operate less than 20 hours per week. A vote was taken and the motion to operate less than 20 hours per week passed unanimously.

3. TREASURER'S REPORT:

Treasurer Rob Colburn presented the treasurer's report for October 2020 through August of 2021. Total revenues for the year were 115.41 percent of the annual budget. Total expenses for the year were 81.80 percent of annual budget through 91.67 percent of the fiscal year. Licensing fee revenues were 111.05 percent of the annual budget projection with almost every category above 100 percent except technician registration fees. Total expenses are tracking about 18.2 percent below budget with one month remaining in the fiscal year. Miscellaneous professional services is above budget due to the expense of creating a new website.

A motion to approve the treasurer's report was made by Dr. Garmon and seconded by Mr. Phung. A vote was taken and the motion to approve the treasurer's report passed unanimously.

4. WELLNESS COMMITTEE REPORT

Eddie Braden, Chief Drug Investigator, gave the report of Dr. Garver as follows:

There are currently 114 people in the screening program with signed contracts or orders. There are presently two pharmacists in residential treatment. There is one pharmacist having a hearing that Dr. Garver has worked with but refuses to comply stating other medical issues. There is one pharmacist who has left treatment against medical advice, revoking releases, and not returning calls. The investigators have been made aware of this individual. The total number of pharmacy professionals identified and worked with in 2021 is 35.

All licensees have responded well to the virtual observation collections and more collection sites are returning to their normal routines. Dr. Garver thanked the staff for their assistance and the Board members for their support and fairness in discipline and generosity and mercy.

5. APPROVAL OF MINUTES

A motion was made by Dr. Mount and seconded by Mr. Colburn to approve the Board business meeting minutes from the August 18, 2021, business meeting. A vote was taken and the motion to approve the August 18, 2021, Board business meeting minutes passed with aye votes from Mr. Phung, Mr. Colburn, Dr. Garmon, and Dr. Mount.

A motion was made by Dr. Mount and seconded by Mr. Colburn to approve the Board interview minutes from the August 18, 2021, interviews. A vote was taken and the motion to approve the August 18, 2021, Board interview minutes passed unanimously.

6. INVESTIGATOR'S REPORT

Chief Investigator Eddie Braden was called upon to give his report. The investigation and inspection statistics for the month are listed in the Dropbox. He will also have items for executive session.

7. SECRETARY'S REPORT

Donna Yeatman gave the Executive Secretary's report, which consisted of the following:

- Ms. Yeatman is continuing to work with LSA to refine language on the changes approved by the Board to the intern/extern statute. Dr. Nolen and Ms. Yeatman met with Auburn University and Samford University and discussed the proposed changes to the statute. Both schools were supportive of the changes and made comments and suggestions.
- The FDA has extended the period for states to sign the MOU. The Board received a response from the FDA to their request just a few days ago, so that will be reviewed by Ms. Yeatman and Mr. Ward in the next week.
- No further off-site order entry requests have been received since the last Board meeting, so no approvals have been granted.
- The annual review and self-assessment process of Board staff is complete. Ms. Yeatman thanked Rhonda Coker and Eddie Braden for their review of staff and the staff for completing all required elements of the review process timely. All individual performance reviews will be communicated with the staff by the end of September.
- The Alabama Department of Public Health released a guidance for monoclonal antibody subcutaneous administration on September 1, 2021. However, on September 10, 2021, the Ninth Amendment to the PREP Act was introduced, which specifies requirements for administration of the monoclonal antibodies and other future COVID therapeutics for pharmacists, pharmacy interns, and qualified technicians. ADPH then issued a new guidance to reflect those PREP Act requirements. Some of those requirements require ACPE training for anyone giving the antibodies, which must include hands-on technique; a clinical evaluation of indications and contraindications of COVID-19 therapeutics; the recognition and treatment of emergency reaction to COVID-19 therapeutics; and additional training required in the FDA approval authorization clearance or licensing. Pharmacy personnel must also possess a current basic CPR certification.
- Ms. Yeatman thanked Scott Daniel and Anne Marie Nolen for working with her to complete the MPJE review encompassing approximately 2,500 questions.
- Dr. Nolen and Ms. Yeatman spoke to the first-year class at Samford University on August 26.
- Rhonda Coker, Twalia King, Eddie Braden, Scott Daniel, and Ms. Yeatman met with representatives of the Alabama Department of Health to discuss opportunities to improve communication and information to provide better utilization of PDMP. ADPH requested assistance identifying incorrect DEA numbers that are being submitted into the database. ADPH also requested the pharmacy have the correct contact person on file with ADPH should anyone need to communicate with a pharmacy.
- ADPH has been sending information to all pharmacies that the ASAP version 4.2B must be in place in all pharmacies by December 1, 2021. Any data submitted that does not meet this version will be returned as an error after that date.

- Governor Kay Ivey issued a proclamation adding a pharmacist's ability to increase the days supply of emergency refills from 72 hours to 30 days due to Hurricane Ida.
- Individuals are still not notifying the Board of changes as a supervising pharmacist within ten days of a change. Any pharmacist changing positions as a supervising pharmacist, either assuming the role or leaving the role, is required to notify the Board of the change within ten days. Failure to notify the Board of a change could result in disciplinary action to the pharmacist and/or the permit holder.
- Effective January 1, 2020, all newly registered technicians are required to complete a Board-approved training program within six months of registration. Failure of a technician to complete the required training within the specified time period may result in disciplinary action for the technician, as well as the supervising pharmacist and the permit holder. Any technician required to complete training that has not done so will not be allowed to renew their technician registration online.
- Renewal notices have been mailed to all facilities and technicians. Online renewals opened September 1, 2021. The Board will process renewals as timely as possible, but to ensure registrations and permits do not lapse, please submit renewals as early as possible.
- The Board heard or settled 17 cases this month. There are 26 cases scheduled for October; 48 scheduled for November; ten scheduled for December; and 16 waiting to be scheduled. There are now 157 cases in progress, up from 130 last month. There are 112 cases being actively worked by investigators, which is up from 89, and eight complaints are pending resolution.
- Ms. Yeatman thanked all pharmacy professionals who work hard every day to care for the citizens of Alabama.

8. ATTORNEY REPORT

Mr. Ward only has matters to discuss in executive session.

9. OLD BUSINESS

- Proposed New Rule 680-X-2-.47, Off Site Vaccine Order Entry Processing. This new rule will provide standards for off-site vaccine order entry processing for immunizations by any pharmacy. The comment period is September 1, 2021, through October 8, 2021. The public hearing will be October 13, 2021.
- Amended Rule 680-X-2-.40, Non-Disciplinary Penalty for Late Renewal of License, Permit, Registration, Certification, or any Similar Document Issued. The amended rule will add clarity to the entities eligible for the nondisciplinary penalty. The comment period is September 1, 2021, through October 8, 2021. The public hearing will be October 13, 2021.
- Anne Marie Nolen has received several requests to change and/or add to the collaborative practice agreement standard formulary and protocol. After a discussion of the changes, a motion was made by Mr. Colburn and seconded by Dr. Mount and Dr. Garmon to approve

the changes to the collaborative practice agreement standard formulary and protocol. A vote was taken and the motion passed unanimously.

10. NEW BUSINESS

- Ms. Yeatman received a request from Corie Hawks with Political Capital, LLC, requesting the Board's stance on 503B products in connection with veterinary medicine. Dr. Alverson stated based on her understanding there is no 503B allowed for veterinary compounding. After a discussion, it was recommended that Ms. Hawks would need to come to a Board meeting and give a presentation regarding this request.
- Ms. Yeatman announced earlier but again stated there had been an amendment to the PREP Act.
- Mr. Braden stated that he, along with Ms. Yeatman, Dr. Nolen, and Scott Daniel received training with PDMP concerning error audits. Beginning Monday, September 20, 2021, when the Board receives complaints, which could encompass PDMP, random audits will be held.

11. EXECUTIVE SESSION

A motion was made by Dr. Garmon and seconded by Dr. Mount to retire into executive session. An individual voice vote was taken and the motion passed unanimously.

12. RECESS

A recess was held for executive session from 9:54 a.m. to 11:09 a.m.

13. MOTIONS ON CASES

A motion was made by Dr. Garmon and seconded by Mr. Phung to allow withdrawal in case number 21-L-0127. A vote was taken and the motion to allow withdrawal passed unanimously.

A motion was made by Dr. Garmon and seconded by Mr. Phung in case numbers 21-L-0146, 21-L-0186, 17-0065, and 17-0076 to take no action. A vote was taken and the motion to take no action passed with aye votes from Dr. Denson, Mr. Colburn, Dr. Garmon, and Dr. Mount.

A motion was made by Dr. Garmon and seconded by Mr. Phung to take no further action in case number 21-0039. A vote was taken and the motion to take no further action passed unanimously.

A motion was made by Dr. Garmon and seconded by Mr. Phung of no violation in the following case numbers: 21-0094, 21-0121, 21-0122, 21-0125, 21-0128, 21-0130, 21-0132, 21-0138, and 21-0149. A vote was taken and the motion of no violation passed with aye votes from Mr. Phung, Mr. Colburn, Dr. Garmon, and Dr. Mount.

A motion was made by Dr. Garmon and seconded by Mr. Phung to issue letters of concern in case number 21-0137. A vote was taken and the motion to issue letters of concern passed unanimously.

14. ADJOURN

The meeting was adjourned at 11:12 a.m.


Brenda Denson, President


Donna C. Yeatman, Executive Secretary


Date