TEXAS STATE BOARD OF PHARMACY

TEXAS STATE BOARD OF PHARMACY
Health Professions Council Board Room
333 Guadalupe Street, Tower II, Suite 225
Austin, Texas

November 3, 2015

MINUTES[1]

Tuesday, November 3, 2015

President Jeanne D. Waggener, R.Ph., called the meeting to order at 9:03 a.m. Other Board Members present were Treasurer Buford T. Abeldt, Sr., R.Ph.; Dennis F. Wiesner, R.Ph.; Alice G. Mendoza, R.Ph.; L. Suzan Kedron; Phyllis A. Stine; Christopher M. Dembny, R.Ph.; Bradley A. Miller, Ph.T.R.; Jenny Downing Yoakum, R.Ph., Suzette Tijerina, R.Ph.; and Chip Thornsburg.

Staff present were Gay Dodson, R.Ph., Executive Director/Secretary; Cathy Stella, Director of Licensing and Administrative Services; Carol Fisher, R.Ph., M.P.A., Director of Enforcement; Allison Benz, R.Ph., M.S., Director of Professional Services; Kerstin Arnold, General Counsel; Steve Rapp, Director of Information Technology; Caroline Hotchkiss, Assistant General Counsel; Ben Santana, R.Ph., Chief of Compliance; Tyler Vance, Staff Attorney; Megan Holloway, Staff Attorney; Ginger Shuffer, Staff Attorney; Bj Slack, Prescription Monitoring Program Manager; and Becky Damon, Executive Assistant.

Also present was Legal Intern Mary Murphy.

[1]See agenda and corresponding attachments for supporting materials.

A. Announcements

- President Waggener made general announcements.

- Announcements were made concerning Board Members and staff. President Waggener welcomed new Board Members Chip Thornsburg; Suzette Tijerina, R.Ph.; and Jenny Downing Yoakum, R.Ph., to the meeting.

- Ms. Benz made an announcement concerning continuing education credit for attending the Board Meeting.

B. Discussion and Approval of Minutes of Previous Meetings (Tab 01)

Following discussion, the motion was made by Ms. Kedron to approve the minutes of the Board Business Meeting held August 4, 2015; the minutes of a Temporary Suspension Hearing held August 10, 2015, concerning Jesse Cornell Sanders II, R.Ph.; and the minutes of a Temporary Suspension Hearing held October 8, 2015, concerning Niko RX Pharmacy, Maria Cecilia Gutierrez, R.Ph., Sheila Zulema Gallegos, Pharmacy Technician, and Hanna Grace Gutierrez, Pharmacy Technician, as presented. The motion was seconded by Mr. Abeldt and passed unanimously.

C. Discussion of and Possible Action Regarding Rules

Final Adoption of Rules

- Rules Concerning Grounds for Discipline (§§281.7 and 281.9) (Tab 02)

  Ms. Benz explained that the Board voted to propose the amendments to §§281.7 and 281.9 during its August 4, 2015, meeting. The proposed amendments were published in the September 25, 2015, issue of the *Texas Register*, and no comments were received.

  Ms. Benz directed the Board's attention to amendments to §§281.7 and 281.9 and explained that the amendments update the grounds for discipline for pharmacists and pharmacy technicians to include abusive, intimidating, or threatening behavior toward a board employee during the performance of such employee's lawful duties; and adds failure to respond to a continuing education audit to the grounds for discipline for a pharmacy technician.

  Following discussion and review of the Preambles and Orders Adopting Rules, the motion was made by Ms. Stine to approve for adoption, by Board Order, amendments to §§281.7 and 281.9, as presented. The motion was seconded by Ms. Mendoza and passed unanimously.

- Rules Concerning Graduates from the Canadian Council for Accreditation of Pharmacy Programs (§283.2) (Tab 03)

  Ms. Benz explained that the Board voted to propose the amendments to §283.2 during its August 4, 2015, meeting. The proposed amendments were published in the September 25, 2015, issue of the *Texas Register*, and no comments were received.

  Ms. Benz directed the Board's attention to amendments to §283.2 and explained the amendments clarify that 1993-2004 graduates from a college/school of pharmacy whose professional degree program has been approved by the board and is accredited by the Canadian Council for Accreditation of Pharmacy Programs are not considered foreign graduates for the purpose of licensure; and update definitions regarding interns.

  Following discussion and review of the Preamble and Order Adopting Rules, the motion was made by Ms. Kedron to approve for adoption, by Board Order, amendments to §283.2, as presented. The motion was seconded by Mr. Dembny and passed unanimously.

- Rules Concerning Notification Requirements of Senate Bill 460 (§291.3) (Tab 04)

  Ms. Benz explained that the Board voted to propose the amendments to §291.3 during its August 4, 2015, meeting. The proposed amendments were published in the September 25, 2015, issue of the *Texas Register*, and no comments were received.

  Ms. Benz directed the Board's attention to amendments to §291.3 and explained that the amendments implement provisions of Senate Bill 460 requiring pharmacies to notify the board at least 30 days prior to changing location and allow pharmacies to notify consumers regarding complaints against the practice of pharmacy in an electronic messaging system; update the change of pharmacist employment requirements; and include the National Association of Board of Pharmacy Veterinary-Verified Pharmacy Practice Sites (Vet-VIPPS) and the e-Advertiser Approval Program as being in compliance with internet notifications.

  Following discussion and review of the Preamble and Order Adopting Rules, the motion was made by Mr. Miller to approve for adoption, by Board Order, amendments to §291.3, as presented. The motion was seconded by Ms. Mendoza and passed unanimously.

- Rules Concerning Inventory Requirements (§291.17) (Tab 05)

  Ms. Benz explained that the Board voted to propose the amendments to §291.17 during its August 4, 2015, meeting. The proposed amendments were published in the September 25, 2015, issue of the *Texas Register*, and no comments were received.

  Ms. Benz directed the Board's attention to amendments to §291.17 and explained that the amendments update the inventory requirements; clarify the recordkeeping regarding the time inventory shall be taken; and add Class A-S and Class C-S to the inventory requirements.

  Following discussion and review of the Preamble and Order Adopting Rules, the motion was made by Ms. Stine to approve for adoption, by Board Order, amendments to §291.17, as presented. The motion was seconded by Mr. Miller and passed unanimously.

- Rules Concerning Pharmacist-in-Charge (§§291.32, 291.53 and 291.73) (Tab 06)

  Ms. Benz explained that the Board voted to propose the amendments to §§291.32, 291.53 and 291.73 during its August 4, 2015, meeting. The proposed amendments were published in the September 25, 2015, issue of the *Texas Register*, and comments were received from the National Association of Drugs Stores and CVS Health.

  Ms. Benz directed the Board's attention to amendments to §§291.32, 291.53 and 291.73 and explained that the amendments clarify that pharmacists may not serve as the pharmacist-in-charge of other pharmacies if the pharmacist is required to be a full time pharmacist; eliminate references to sterile compounding; add transferring or receiving a prescription to the list of pharmacist duties; and correct grammar.

  Following discussion of the rules, the Board recommended revisions to the proposed amendments to §291.73, and postponed action on these rules until later in the meeting.

  Following discussion of the rules, the Board postponed action on the proposed amendments to §291.32, until later in the meeting.

  Following discussion and review of the Preamble and Order Adopting Rules, the motion was made by Mr. Dembny to approve for adoption, by Board Order, amendments to §291.53, as presented. The motion was seconded by Ms. Mendoza and passed unanimously.

- Rules Concerning Prescription Transfer Requirements (§291.34) (Tab 07)

  Ms. Benz explained that the Board voted to propose the amendments to §291.34 during its August 4, 2015, meeting. The proposed amendments were published in the September 25, 2015, issue of the *Texas Register*, and comments were received from the National Association of Drugs Stores; Jim Martin, R.Ph.; Bobby Muniz, Pharm.D., R.Ph.; the Alliance of Independent Pharmacists of Texas; Nario Rene Cantu, R.Ph.; Carlos Solis, R.Ph.; and CVS Health.

  Ms. Benz directed the Board's attention to amendments to §291.34 and explained that the amendments clarify that prescriptions must be transferred within four business hours; and update the rules regarding distributions to include dangerous drugs.

  President Waggener recognized the following persons who presented oral remarks to the Board:

  Rene Garza, Pharm.D.,R.Ph., representing the Texas Pharmacy Association
  John Rocchio, Pharm.D., R.Ph., representing CVS Health
  David Dubose, R.Ph.

  Following discussion and review of comments received, the motion was made by Ms. Stine to withdraw from consideration for final adoption the proposed amendments to §291.34. The motion was seconded by Ms. Mendoza and passed unanimously.

- Rules Concerning Military Service Members, Military Veterans, and Military Spouses (§§283.12 and 297.10) (Tab 08)

  Ms. Benz explained that the Board voted to propose the amendments to §§283.12 and 297.10 during its August 4, 2015, meeting. The proposed amendments were published in the September 25, 2015, issue of the *Texas Register*, and no comments were received.

  Ms. Benz directed the Board's attention to amendments to §§283.12 and 297.10 and explained that the amendments implement provisions of Senate Bill 807 and Senate Bill 1307 regarding military service members, military veterans, and military spouses.

  Following discussion and review of the Preambles and Orders Adopting Rules, the motion was made by Ms. Mendoza to approve for adoption, by Board Order, amendments to §§283.12 and 297.10, as presented. The motion was seconded by Mr. Wiesner and passed unanimously.

- Rules Concerning Procedures Relating to Immunizations and Hand Sanitizing (§295.15) (Tab 09)

  Ms. Benz explained that the Board voted to propose the amendments to §295.15 during its August 4, 2015, meeting. The proposed amendments were published in the September 25, 2015, issue of the *Texas Register*, and no comments were received.

  Ms. Benz directed the Board's attention to amendments to §295.15 and explained that the amendments add requirements regarding hand sanitation for pharmacists administering immunizations.

  President Waggener recognized Rene Garza, Pharm.D.,R.Ph., with the Texas Pharmacy Association, who presented oral remarks to the Board.

  Following discussion and review of the Preamble and Order Adopting Rules, the motion was made by Mr. Dembny to approve for adoption, by Board Order, amendments to §295.15, as presented. The motion was seconded by Mr. Thornsburg and passed unanimously.

- Rules Concerning Administration of Epinephrine by a Pharmacist (§295.16) (Tab 10)

  Ms. Benz explained that the Board voted to propose new rule §295.16 during its August 4, 2015, meeting. The proposed new rule was published in the September 25, 2015, issue of the *Texas Register*, and comments were received from the Texas Medical Association.

  Ms. Benz directed the Board's attention to new rule §295.16 and explained that the new rule implements the provisions of House Bill 1550 passed during the 84th Legislative Session regarding the administration of epinephrine by a pharmacist. Ms. Benz explained the proposed new rule had been revised to change the definition of anaphylaxis to be consistent with Senate Bill 66 passed during the 84th Legislative Session.

  Following discussion and review of the Preamble and Order Adopting Rules, the motion was made by Mr. Abeldt to approve for adoption, by Board Order, new rule §295.16, as revised. The motion was seconded by Mr. Dembny and passed unanimously.

- Rules Concerning House Bill 751 Interchangeable Biological Products (§§309.1-309.8, 291.33, 291.34, and 291.104) (Tab 11)

  Ms. Benz explained that the Board voted to propose new rule §309.5, and the amendments to §§291.33, 291.34, 291.104, 309.1-309.4 and 309.6-309.8 during its August 4, 2015, meeting. The proposed new rule and amendments were published in the September 25, 2015, issue of the *Texas Register*, and comments were received from Biotechnology Industry Organization, and America's Health Insurance Plans.

  Ms. Benz directed the Board's attention to new rule §309.5, and the amendments to §§291.33, 291.34, 291.104, 309.1-309.4 and 309.6-309.8 and explained the new rule and the amendments implement the provisions of House Bill 751 passed during the 84th Legislative Session regarding interchangeable biological products.

  Following discussion of the rules and review of comments received the Board recommended revisions to the proposed new rule §309.5, and the amendments to §§291.34, 309.1-309.4 and 309.6-309.8 and postponed action until later in the meeting.

  Following discussion of the rules, the Board postponed action on the proposed amendments to §§291.33 and 291.104 until later in the meeting.

- Rules Concerning Class C Pharmacies Located in Freestanding Ambulatory Surgical Centers and Class F Pharmacies Located in Freestanding Emergency Medical Care Centers (§§291.76 and 291.151) (Tab 12)

  Ms. Benz explained that the Board voted to propose the amendments to §§291.76 and 291.151 during its August 4, 2015, meeting. The proposed amendments were published in the September 25, 2015, issue of the *Texas Register*, and comments were received from the Texas Medical Association.

  Ms. Benz directed the Board's attention to amendments to §§291.76 and 291.151 and explained that the amendments update the rules for pharmacies in Freestanding Ambulatory Surgical Centers to be consistent with other sections; eliminate language that is no longer necessary; and correct grammar. The amendments updated the rules for pharmacies in Freestanding Emergency Medical Care Centers to be consistent with other sections; eliminate language that is no longer necessary; and correct grammar.

  Following discussion of the rules and review of comments received the Board recommended revisions to the proposed amendments, and postponed action until later in the meeting.

- Rules Concerning the Pharmacist-in-Charge of Class E Pharmacies (§291.103) (Tab 13)

  Ms. Benz explained that the Board voted to propose the amendments to §291.103 during its August 4, 2015, meeting. The proposed amendments were published in the September 25, 2015, issue of the *Texas Register*, and comments were received from Express Scripts, Inc.; CVS Health; and Prime Therapeutics.

  Ms. Benz directed the Board's attention to amendments to §291.103 and explained the amendments require the pharmacist-in-charge of a non-resident pharmacy (Class E) to be licensed in Texas.

  Following discussion and review of the Preamble and Order Adopting Rules, the motion was made by Mr. Abeldt to approve for adoption, by Board Order, amendments to §291.103, as presented. The motion was seconded by Mr. Dembny and passed unanimously.

President Waggener recessed the meeting at 10:18 a.m.

President Waggener reconvened the meeting at 10:33 a.m.

<u>Proposal of Rules</u>

- Rules Concerning Grounds for Discipline for a Pharmacy License (§281.8) (Tab 14)

  Ms. Benz directed the Board's attention to suggested amendments to rule language concerning the grounds for discipline for a pharmacy license. She explained the amendments add abusive, intimidating, or threatening behavior toward a board member or employee during the performance of such member's or employee's lawful duties by the owner, managing officer(s), or other pharmacy employee(s) as grounds for discipline of a pharmacy license.

  Following discussion, the motion was made by Mr. Dembny to approve for proposal amendments to §281.8, as presented. The motion was seconded by Ms. Stine and passed unanimously.

- Rules Concerning the Definition of a Healthcare Professional (§283.2) (Tab 15)

  Ms. Benz directed the Board's attention to suggested amendments to rule language concerning the definition of a healthcare professional. She explained the amendments to update the definition of a healthcare professional preceptor to include dentists, veterinarians, advanced practice registered nurses, and physician assistants.

Ms. Benz explained to the Board that rules concerning the Definition of a Healthcare Professional (§283.2) (Tab 15) and rules concerning the Duties of a Pharmacist-Intern (§283.5) (Tab 16) were related and recommended the Board consider them at the same time.

- Rules Concerning the Duties of a Pharmacist-Intern (§283.5) (Tab 16)

  Ms. Benz directed the Board's attention to suggested amendments to rule language concerning the duties of a pharmacist-intern. She explained the amendments allow intern-trainees to perform the duties of a pharmacist while under the supervision of a pharmacist preceptor at a site assigned by the college/school of pharmacy.

  Following discussion, the motion was made by Ms. Mendoza to approve for proposal amendments to §§283.2 and 283.5, as presented. The motion was seconded by Mr. Abeldt and passed unanimously.

- Rules Concerning Inspection Reports for Non-Resident Pharmacies (Class E) (§291.104) (Tab 17)

  Ms. Benz directed the Board's attention to suggested amendments to rule language concerning the inspection reports for non-resident pharmacies (Class E). She explained the amendments update the rules to require non-resident (Class E) pharmacies to submit an inspection conducted within the last two years as part of the pharmacy application. The proposed change makes the requirement consistent with other sections of the rules.

  Following discussion, the motion was made by Mr. Dembny to approve for proposal amendments to §291.104, with recommended changes. The motion was seconded by Mr. Miller and passed unanimously.

- Rules Concerning Pharmacies Compounding Sterile Preparations (§291.133) (Tab 18) and Discussion Concerning Recordkeeping for Sterile Compounding in Hospitals (Tab 31)

  Ms. Benz directed the Board's attention to suggested amendments to rule language concerning pharmacies compounding sterile preparations. She explained the amendments clarify end process checking requirements to be consistent with other sections of the rules; clarify sterility testing requirements to be consistent with USP 797; and clarify requirements for blood products in nuclear pharmacies.

  Ms. Benz presented written comments received from the Texas Society of Health-System Pharmacist (TSHP).

President Waggener recognized the following persons who presented oral remarks to the Board:

Sidney Phillips, R.Ph., representing TSHP
Jeff Wagner, R.Ph., representing TSHP
Brian Cohen, R.Ph., representing the UT Southwestern Medical Center
Don Warner, R.Ph., representing GE Healthcare
Lucinda Van Anglen, R.Ph., representing Healix

Following discussion of the suggested rule amendments concerning pharmacies compounding sterile preparations the Board directed staff to bring additional rule language to a future Board meeting.

- New Rules Concerning Controlled Substances (§§315.1-315.15) (Tab 19)

  Ms. Benz directed the Board's attention to suggested new rules which would implement the provisions of Senate Bill 195 passed during the 84th Legislative Session.

  Following discussion, the motion was made by Mr. Thornsburg to approve for proposal new rules §§315.1-315.15, as presented. The motion was seconded by Mr. Wiesner and passed unanimously.

Rule Review

- For Proposal

  Ms. Benz directed the Board's attention to the TSBP Rule Review Plan for FY2014-2017 (Tab 20)

  - Chapter 291 Concerning Pharmacies (Community Pharmacy (Class A)) (§§291.31-291.35) (Tab 21)

  - Chapter 283 Concerning Licensing Requirements for Pharmacist (§§283.1-283.12) (Tab 22)

  Following discussion, in accordance with Government Code §2001.039, the motion was made by Mr. Dembny to approve for proposal as presented, the review of Chapter 291 (§§291.31-291.35); and Chapter 283 (§§283.1-283.12). The motion was seconded by Mr. Abeldt and passed unanimously.

President Waggener recessed the meeting at 11:42 a.m.

President Waggener reconvened the meeting at 12:30 p.m.

Ms. Kedron left the meeting during the recess.

D. <u>Discussion of and Possible Action Concerning the Following Reports and Discussions</u>

- Discussion Concerning a Log of Initials or Codes that Identify Individuals Involved in the Data Entry of a Prescription (Tab 33)

  Mr. Wiesner stated that current rules require a permanent log of the initials or identification codes that identify individuals involved in the data entry of a prescription. He suggested amending the rules to a time limit that would correspond with the time limit for the filing of a complaint.

  Following discussion, the Board directed staff to bring back suggested rule language for the Board's consideration at its February Board Meeting.

- Discussion Concerning Pharmacy Automation Rules (Tab 32)

  Mr. Wiesner stated that new dispensing technology provides improvements in both patient safety and documentation. He explained that the new technology does not necessarily fit into the current pharmacy rules as the automated methods of dispensing are so improved. He suggested that dispensing technology may need to stand alone and unique within the pharmacy rules.

  Following discussion the Board directed the Executive Director to work with experts in the field of dispensing technology to develop suggested rule language which would reflect advances in the dispensing of prescription medication.

- Professional Recovery Network

  - Ms. Fisher discussed performance measures regarding the number of individuals participating in the peer assistance program for the past three fiscal years (FY2013-2015) as well as the quarterly report on the number of pharmacists participating in the program during FY2015 (September 1, 2014 – August 31, 2015). (Tab 26)

  - President Waggener recognized Courtney Hulbert with the Professional Recovery Network (PRN). Ms. Hulbert directed the Board's attention to the PRN budget report for FY2015 (September 1, 2014 – August 31, 2015). Ms. Hulbert reviewed current PRN activities for the Board. (Tab 27)

  - Ms. Hulbert directed the Board's attention to the Professional Recovery Network Program Audit for program year ended August 31, 2015, and noted that there were no exceptions noted in the audit. (Tab 28)

Following review of the audit by the Board, the motion was made by Mr. Dembny to approve the Professional Recovery Network Program Audit for the program year ended August 31, 2015, as presented. The motion was seconded by Ms. Mendoza and passed unanimously.

- Financial Update

  - Review of FY2015 Operating Budget (Tab 23)

    Ms. Stella reviewed the expenditures for all four quarters of FY2015 (September 1, 2014 - through August 31, 2015) for the Board.

    Following discussion the motion was made by Mr. Dembny to approve the FY2015 expenditures as presented. The motion was seconded by Mr. Abeldt and passed unanimously.

  - Review of Board Member Travel Budget (Tab 24)

    Ms. Stella reviewed the Board Member FY2015 Travel Budget and reviewed the Board Member Travel Budget for FY2016.

  - Consideration of Material Changes to Contracts for Goods and Services Awarded Under Chapter 2155 of Texas Government Code (Tab 25)

    Ms. Stella presented a report on material changes to TSBP contracts for goods and services for the fourth quarter of FY2015 (June 1, 2015 – August 31, 2015). The report listed contracts that exceeded either the original cost estimate or the original term date.

    Following consideration, in accordance with Section §2155.088 of the Texas Government Code, the motion was made by Mr. Abeldt to approve the material changes to the contracts for goods and services as reported. The motion was seconded by Ms. Stine and passed unanimously.

C. <u>Discussion of and Possible Action Regarding Rules</u> (cont'd)

<u>Final Adoption of Rules</u> (cont'd)

- Rules Concerning Pharmacist-in-Charge (§291.32) (Tab 06) (cont'd) and Rules Concerning House Bill 751 Interchangeable Biological Products (§291.33) (Tab 11) (cont'd))

Ms. Benz explained that the Board reviewed the proposed amendments to §§291.32 and 291.33 earlier in the meeting. She directed the Board's attention to the proposed amendments concerning Pharmacist-in-Charge and interchangeable biological products.

Following discussion and review of the Preambles and Orders Adopting Rules, the motion was made by Mr. Dembny to approve for adoption, by Board Order, amendments to §§291.32 and 291.33, as presented. The motion was seconded by Ms. Mendoza and passed unanimously.

- Rules Concerning Pharmacist-in-Charge (§291.73) (Tab 06) (cont'd) and Rules Concerning Class C Pharmacies Located in Freestanding Ambulatory Surgical Centers and Class F Pharmacies Located in Freestanding Emergency Medical Centers (§291.76) (Tab 12) (cont'd)

  Ms. Benz explained that the Board reviewed the proposed amendments to §§291.73 and 291.76 earlier in the meeting and had directed staff to make revisions to the proposed amendments. She directed the Board's attention to the revised amendments concerning Pharmacist-in-Charge and Class C Pharmacies located in Freestanding Ambulatory Surgical Centers.

  Following discussion and review of the Preambles and Orders Adopting Rules, the motion was made by Mr. Miller to approve for adoption, by Board Order, amendments to §§291.73 and 291.76, as revised. The motion was seconded by Ms. Mendoza and passed unanimously.

- Rules Concerning House Bill 751 Interchangeable Biological Products (§291.104) (Tab 11) (cont'd)

  Ms. Benz explained that the Board reviewed the proposed amendments to §291.104 earlier in the meeting. She directed the Board's attention to the amendments concerning interchangeable biological products.

  Following discussion and review of the Preamble and Order Adopting Rules, the motion was made by Mr. Dembny to approve for adoption, by Board Order, amendments to §291.104, as presented. The motion was seconded by Ms. Stine and passed unanimously.

- Rules Concerning Class C Pharmacies Located in Freestanding Ambulatory Surgical Centers and Class F Pharmacies Located in Freestanding Emergency Medical Care Centers (§291.151) (Tab 12) (cont'd)

  Ms. Benz explained that the Board reviewed the proposed amendments to §291.151 earlier in the meeting and had directed staff to make revisions to the proposed amendments. She directed the Board's attention to the

revised amendments concerning Class F Pharmacies Located in Freestanding Emergency Medical Care Centers.

Following discussion and review of the Preamble and Order Adopting Rules, the motion was made by Mr. Dembny to approve for adoption, by Board Order, amendments to §291.151, as revised. The motion was seconded by Mr. Abeldt and passed unanimously.

- Rules Concerning House Bill 751 Interchangeable Biological Products (§§309.1-309.8) (Tab 11) (cont'd)

  Ms. Benz explained that the Board reviewed proposed new rule §309.5 and the proposed amendments to §§309.1-309.4 and 309.6-309.8 earlier in the meeting and had directed staff to make revisions to the proposed new rule and proposed amendments. She directed the Board's attention to the revised new rule and revised amendments concerning interchangeable biological products.

  Following discussion and review of the Preambles and Orders Adopting Rule, the motion was made by Ms. Mendoza to approve for adoption, by Board Order, new rule §309.5 and amendments to §§309.1-309.4 and 309.6-309.8, as revised. The motion was seconded by Mr. Abeldt and passed unanimously.

Mr. Wiesner left the meeting at 1:24 p.m.

D. <u>Discussion of and Possible Action Concerning the Following Reports and Discussions</u> (cont'd)

- Discussion Concerning TSBP FY2017-2021 Strategic Plan (Tab 29)

  Ms. Dodson directed the Board's attention to comments concerning the *TSBP FY2017-2021 Strategic Plan* received from the Texas Federation of Drug Stores and National Association of Chain Drug Stores; the American Association of Pharmacy Technicians; AARP Texas; the Texas Department of State Health Services; and the Texas Society of Health-System Pharmacists.

  Ms. Dodson reviewed issues from the *TSBP FY2015-2019 Strategic Plan* and asked Board Members for their recommendations concerning the FY2017-2021 Strategic Plan.

  Ms. Dodson explained that the Board staff would review the issues and present a draft of the *TSBP FY2017-2021 Strategic Plan* at the February Board meeting.

- Discussion Concerning Nasal Sprays and Whether They Should be Compounded in a Sterile Environment (Tab 30)

  Ms. Fisher presented information on recommendations concerning whether or not nasal sprays should be compounded in a sterile environment. She explained that comments were received from Gigi Davidson, BSPh. DICVP, Chair, USP Compounding Expert Committee, and Audra L. Conwell, CAE, Executive Director/CEO of the Alliance of Independent Pharmacist of Texas, and noted that the comments received from both Ms. Davidson and Ms. Conwell stated that the Federal Drug Administration and the USP 797 guidelines do not require nasal sprays be compounded as sterile preparations.

  Ms. Fisher also presented a report from Loyd V. Allen, Jr., Ph.D., FACA, FAPhA, in which he asserted that nasal sprays should be compounded as sterile preparations.

  Ms. Fisher explained that to date TSBP has taken a conservative approach and required nasal sprays be prepared in a sterile environment.

  President Waggener recognized John Boliver, PCCA, who presented oral remarks to the Board.

  Following discussion the motion was made by Ms. Yoakum that the Board not consider nasal sprays a sterile product and not require nasal sprays be compounded in a sterile environment. The motion was seconded by Mr. Abeldt and passed 7-0-1, with Ms. Stine abstaining.

President Waggener recessed the meeting at 2:25 p.m.

President Waggener reconvened the meeting at 2:34 p.m.

- Discussion Concerning Medical Board Rules Regarding Telemedicine (Tab 34)

  Ms. Arnold presented information concerning the Medical Board's rules regarding telemedicine.

- Report on Appeals from State Office of Administrative Hearing Cases (Tab 35)

  Ms. Arnold presented information concerning the appeal of cases from the State Office of Administrative Hearing.

- Report on Interagency Prescription Monitoring Program Work Group (Tab 36)

  Ms. Benz presented information concerning the Prescription Monitoring Program. She reminded the Board that earlier in the meeting they had approved for proposal new rules which would implement Senate Bill 195. She explained that the Pharmacy Board will be responsible for both the monitoring of controlled substances and the official prescription forms.

  Ms. Dodson explained that after working with the Department of Public Safety and reviewing their current software program it was determined the Board would need to implement a new software program and TSBP staff were working on the specifications for a Request for Proposal from software venders.

- Report on Sunset Review (Tab 37)

  Ms. Dodson presented information on the Sunset Commission's Review of the Board. She explained that the Sunset Commission staff were currently evaluating the Texas State Board of Pharmacy and they will issue a report in April 2016.

- Update on Legislation Filed During the 84th Texas Legislative Session that has an Impact on TSBP and/or the Practice of Pharmacy (Tab 38)

  Ms. Dodson directed the Board's attention to an action chart concerning legislation that was passed during the 84th Session of the Texas Legislature that has an impact on TSBP and/or the practice of pharmacy. The chart contains the bill number, action required of TSBP, the effective date of the bill, TSBP's internal deadline, and the current status of TSBP's implementation of the bill.

F. **<u>Disciplinary Orders</u>**

- Consideration of Proposals for Decision (Tab 39)

  - No Proposals for Decision were presented.

Ms. Arnold directed the Board's attention to reports concerning disciplinary orders for pharmacy technicians and pharmacy technician trainees, pharmacies, and pharmacists.

- Report on Agreed Board Orders Entered by Executive Director (Tab 40)

  - The Board reviewed 45 Agreed Board Orders concerning pharmacy technicians and pharmacy technician trainees that had been entered by the Executive Director on behalf of the Board, in

accordance with the Board's directives, during the period from August 6, 2015, through October 27, 2015.

- ○ The Board reviewed 19 Agreed Board Orders concerning pharmacies and pharmacists, that had been entered by the Executive Director on behalf of the Board, in accordance with the Board's directives, during the period from August 20, 2015, through October 26, 2015, and one Confidential Agreed Board Order entered on August 31, 2015.

- Discussion of and Action on Proposed Agreed Board Orders and Proposed Default Board Orders (Tab 41)

  - ○ The Board reviewed the alleged violations, as well as the recommended sanctions for each of the following: 20 proposed Agreed Board Orders concerning pharmacy technicians and pharmacy technician trainees who appeared for an Informal Conference; and 11 proposed Default Board Orders concerning pharmacy technicians and pharmacy technician trainees who did not appear for an Informal Conference.

Agreed Board Orders (Technicians and Technician Trainees)
(Following an Informal Conference)

1.	Bianca Rojo	ABO #T-15-212
2.	Vanessa Valdez	ABO #T-15-187
3.	Eric Gordon Bloom	ABO #T-15-270
4.	Delicia Gambrell	ABO #T-15-228-N
5.	Brittney Marie Knowles	ABO #T-15-181-N
6.	Valencia D. Mapp	ABO #T-15-225
7.	Gabriella Newton	ABO #T-15-231
8.	Linda Kay Pierce	ABO #T-14-493
9.	Randee Chantelle Tingle	ABO #T-14-479
10.	Victor Anthony Avina	ABO #T-15-244-N
11.	Xinia Eliza Caro	ABO #T-15-315-N
12.	Tegra Tyana Chism	ABO #T-15-331-N
13.	Crystal Lynne Faulk	ABO #T-15-299
14.	Malcolm Ashanti Frisby	ABO #T-16-009
15.	Stephen Walter Krueger	ABO #T-15-347-N
16.	Elizabeth R. Lopez	ABO #T-15-313-N
17.	Frances McShan	ABO #T-15-274-N
18.	Jonathan Jerry Mitchell	ABO #T-15-177-N
19.	Kristy Lynn Trevino	ABO #T-15-178
20.	Annabell Vallejo	ABO #T-15-348

Default Board Orders (Technicians and Technician Trainees)
(Did not appear for an Informal Conference)

21.	Donetta Alexander	BO #T-15-257

22.	Susana Cadenas	BO #T-15-233-N
23.	Kanyon Coppenbarger	BO #T-15-232-N
24.	Emily Anne Dingman	BO #T-14-480
25.	Joshua Sebastian Lerma	BO #T-14-478-N
26.	Jacob Scott McKenzie	BO #T-15-075
27.	Jessica Pirkle Miller	BO #T-15-227
28.	Layla Rincones	BO #T-15-194-N
29.	Emily Browning	BO #T-15-213
30.	Quoc-Vu Cao	BO #T-15-234
31.	Angelique Quintanilla	BO #T-15-344

The motion was made by Mr. Dembny to approve the 20 proposed Agreed Board Orders concerning pharmacy technicians and pharmacy technician trainees who appeared for an Informal Conference; and 11 proposed Default Board Orders concerning pharmacy technicians and pharmacy technician trainees who did not appear for an Informal Conference.

The motion was seconded by Ms. Yoakum and passed as follows.

Agreed Board Orders (Technicians and Technician Trainees)
(Following an Informal Conference)

1. 7-0-1 Mr. Miller abstained
2. 8-0-0
3. 8-0-0
4. 8-0-0
5. 8-0-0
6. 8-0-0
7. 8-0-0
8. 8-0-0
9. 8-0-0
10. 7-0-1 Mr. Miller abstained
11. 7-0-1 Mr. Miller abstained
12. 7-0-1 Mr. Miller abstained
13. 7-0-1 Mr. Miller abstained
14. 7-0-1 Mr. Miller abstained
15. 7-0-1 Mr. Miller abstained
16. 7-0-1 Mr. Miller abstained
17. 7-0-1 Mr. Miller abstained
18. 7-0-1 Mr. Miller abstained
19. 7-0-1 Mr. Miller abstained
20. 7-0-1 Mr. Miller abstained

Default Board Orders (Technicians and Technician Trainees)
(Did not appear for an Informal Conference)

21. 8-0-0

22. 8-0-0
23. 8-0-0
24. 8-0-0
25. 8-0-0
26. 8-0-0
27. 8-0-0
28. 8-0-0
29. 7-0-1 Mr. Miller abstained
30. 7-0-1 Mr. Miller abstained
31. 7-0-1 Mr. Miller abstained

- The Board reviewed the alleged violations, as well as the recommended sanctions for each of the following: 11 proposed Agreed Board Orders (Alternative Resolutions); 37 proposed Agreed Board Orders concerning pharmacies, pharmacists and technicians following an Informal Conference; one Default Board Order concerning a pharmacist who did not appear for an Informal Conference.

Agreed Board Orders (Pharmacies and Pharmacists)
(Alternative Resolutions)

1.	CVS/pharmacy #6721	ABO #C-15-012-B
2.	Jason Lee	ABO #C-15-012-A
3.	CVS/pharmacy #6945	ABO #H-15-013-B
4.	Kimberly Irby	ABO #H-15-013-A
5.	H.E.B. Pharmacy #014	ABO #H-15-021
6.	LDI Pharmacy	ABO #L-15-012
7.	Harsh Vardhan	ABO #H-15-041-A
8.	Walgreens #7061	ABO #H-15-024-B
9.	Walgreens #9143	ABO #H-15-023-B
10.	Walgreens #11749	ABO #H-15-028
11.	Walgreens Mail Service, Inc.	ABO #J-15-006

Agreed Board Orders (Pharmacies and Pharmacist)
(Following an Informal Conference)

12.	Always Care Pharmacy -1	ABO #L-15-022
13.	Avita Drugs	ABO #C-15-019
14.	Better Living Medical Equipment & Services, Ltd.	ABO #K-15-011-B
15.	Wallace Randal Robin	ABO #K-15-011-A
16.	Biofusion	ABO #L-15-003
17.	Castle Hills Pharmacy, LLC	ABO #C-15-006-B
18.	Michael Lawrence Ward	ABO #C-15-006-A
19.	CVS/pharmacy #4109	ABO #C-15-005-B
20.	Utpal Shah	ABO #C-15-005-A
21.	Lori Ann Dolley	ABO #T-15-216
22.	ECompounding Pharmacy	ABO #L-15-011

23.	James Michael Jones	ABO #B-12-013-A
24.	Lea Joo	ABO #H-14-048-A
25.	Emmanuel Kanu	ABO #R-15-005
26.	Legends Pharmacy	ABO #K-15-010-B
27.	Grace Anne Parma Howard	ABO #K-15-010-A
28.	New Day Pharmacy	ABO #B-15-003-B
29.	Adriena Zena Shelton	ABO #B-15-003-A
30.	Pinecroft Pharmacy	ABO #K-14-008-B
31.	Marline Atehsiri Asongwe	ABO #K-14-008-A
32.	Rood and Riddle Veterinary Pharmacy	ABO #L-15-019
33.	Stonegate Pharmacy	ABO #H-15-001-B
34.	Justin Timothy Swanberg	ABO #K-15-015
35.	Quang-Hai Martin Tran	ABO #F-15-011
36.	Trident Pharmacy	ABO #C-15-023-B
37.	Kingsley Chinonye Okafor	ABO #C-15-023-A
38.	Hetty Osaro Umeh	ABO #M-15-012
39.	University General Hospital	ABO #K-15-018-B
40.	Maureen E. Price	ABO #K-15-018-A
41.	Walgreens #6435	ABO #C-15-017-B
42.	Maria Concepcion Montenegro	ABO #C-15-017-A
43.	Jon B. Williamson	ABO #T-15-214
44.	Walgreens #6619	ABO #H-15-020-B
45.	Wendell Payne	ABO #H-15-020-A
46.	Walgreens #03660	ABO #H-13-065-B
47.	Walgreens #10846	ABO #H-14-015-B
48.	Walgreens #12715	ABO #H-15-003

Default Board Order (Pharmacist)
(Did not appear for an Informal Conference**)**

49.	Trent Steven Griffin	BO #F-15-007

The motion was made by Mr. Dembny to approve the 11 proposed Agreed Board Orders (Alternative Resolutions); 37 proposed Agreed Board Orders concerning pharmacies; pharmacists; pharmacist-interns; and technicians following an Informal Conference; and one proposed Board Order concerning a pharmacist who did not appear for an Informal Hearing.

The motion was seconded by Ms. Yoakum and passed as follows.

Agreed Board Orders (Pharmacies & Pharmacists)
(Alternative Resolutions)

1. 8-0-0
2. 8-0-0
3. 8-0-0
4. 8-0-0
5. 8-0-0

6. 8-0-0
7. 8-0-0
8. 8-0-0
9. 8-0-0
10. 8-0-0
11. 8-0-0

Agreed Board Orders (Pharmacies & Pharmacists)
(Following an Informal Conference)

12. 7-0-1 Ms. Stine abstained
13. 7-0-1 Ms. Stine abstained
14. 8-0-0
15. 8-0-0
16. 8-0-0
17. 8-0-0
18. 8-0-0
19 8-0-0
20. 8-0-0
21. 8-0-0
22. 8-0-0
23. 7-0-1 Mr. Abeldt abstained
24. 7-0-1 Mr. Miller abstained
25. 7-0-1 Ms. Stine abstained
26. 8-0-0
27. 8-0-0
28. 7-0-1 Ms. Stine abstained
29. 7-0-1 Ms. Stine abstained
30. 8-0-0
31. 8-0-0
32. 7-0-1 Ms. Stine abstained
33. 8-0-0
34. 8-0-0
35. 7-0-1 Ms. Stine abstained
36. 8-0-0
37. 8-0-0
38. 7-0-1 Ms. Stine abstained
39. 8-0-0
40. 8-0-0
41. 8-0-0
42. 8-0-0
43. 8-0-0
44. 7-0-1 Ms. Stine abstained
45. 7-0-1 Ms. Stine abstained
46. 7-0-1 Ms. Stine abstained
47. 8-0-0
48. 7-0-1 Ms. Stine abstained

Default Board Order (Pharmacist)
(Did not appear for an Informal Conference)

49. 7-0-1 Mr. Miller abstained

- The Board reviewed the alleged violations and the Temporary Suspension Orders entered for the following pharmacy, pharmacist and pharmacy technicians following Temporary Suspension Hearings.

1.	Jesse Cornell Sanders II	A-15-025-AS2
2.	Niko RX Pharmacy	C-15-038-BS1
3.	Sheila Zulema Gallegos	T-15-392-NS1
4.	Hanna Grace Gutierrez	T-15-393-NS1

- Confidential Agreed Board Orders (Tab 42)

  - The Board reviewed the alleged violations, as well as the recommended sanctions for each of the following seven proposed Confidential Agreed Board Orders following an Informal Conference and one proposed Confidential Board Order concerning a pharmacist who did not appear for an Informal Hearing.

Agreed Board Orders (Pharmacy and Pharmacists)
(Following an Informal Conference)

1. ABO #R-15-008
2. ABO #G-15-008
3. ABO #N-15-021
4. ABO #M-15-010
5. ABO #R-15-004
6. ABO #M-15-007-B
7. ABO #M-14-007-A

Board Order (Pharmacist)
(Did not appear for an Informal Conference)

8. BO #G-15-016

The motion was made by Ms. Stine to approve the seven proposed Confidential Agreed Board Orders following an Informal Conference, and one proposed Confidential Board Order concerning a pharmacist who did not appear for an Informal Hearing.

The motion was seconded by Mr. Miller and passed as follows:

Agreed Board Orders (Pharmacy and Pharmacists)
(Following an Informal Conference)

1. 7-0-1 Ms. Stine abstained
2. 7-0-1 Mr. Miller abstained
3. 7-0-1 Ms. Stine abstained
4. 7-0-1 Ms. Stine abstained
5. 8-0-0
6. 8-0-0
7. 8-0-0

Default Board Order (Pharmacist)
(Did not appear for an Informal Conference)

8. 8-0-0

- Discussion of and Action on Proposed Remedial Plans (Tab 43)

  - The Board reviewed the alleged violations, as well as the recommended sanctions for each of the following: two proposed Remedial Plans (Alternative Resolutions); and one proposed Remedial Plan, following an Informal Conference.

Remedial Plans (Alternative Resolutions)

1. Alesha Christine Erickson #H-15-034-A
2. Kimberly Ann Warner Klotz #H-15-024-A

Remedial Plans (Following an Informal Conference)

3. Stacy Collin Kurmel #H-15-001-A

The motion was made by Mr. Dembny to approve the two proposed Remedial Plans (Alternative Resolutions); and one proposed Remedial Plan following an Informal Conference.

The motion was seconded by Ms. Yoakum and passed as follows.

Remedial Plans (Alternative Resolutions)

1. 8-0-0
2. 8-0-0

Remedial Plans (Following an Informal Conference)

3. 8-0-0

F. Consideration of and Possible Action Concerning Enforcement Reports

- Report on Complaints Closed and Dismissed During the Previous Quarter (Tab 44)

  The Board received a report on complaints dismissed and closed during FY2015 (September 1, 2014 – August 31, 2015). The report also included quarterly averages for FY2014 as compared to FY2015, as well as percentage change from FY2014 to FY2015.

  Ms. Fisher reviewed the report for the Board.

- Report on Status of Active/Pending Complaints (Tab 45)

  The Board received the *Report on Status of Active/Pending Complaints*.

  Ms. Fisher reviewed the report for the Board.

G. Miscellaneous

- Items to be Placed on Agenda for November Board Meeting (Tab 46)

  - Amendments concerning prescription transfer requirements.
  - Amendments concerning compounding sterile preparations.
  - Amendments concerning log of initials or codes that identify individuals involved in the data entry of a prescription.
  - TSBP FY2017-2021 Strategic Plan.

- Discussion of and Possible Action on Recent Conferences and Events

  The Board discussed Board Member and Executive Director attendance at recent conferences and events.

- Discussion of and Possible Action on Upcoming Conferences and Events

  The Board discussed Board Member and Executive Director attendance at upcoming conferences and events.

- Election of Officers (Tab 47)

  President Waggener called for nominations for the office of Vice President that was vacant because Joyce Tipton, R.Ph., was not re-appointed to the Board.

  Mr. Abeldt nominated Mr. Dembny for the office of Vice President. The nomination was seconded by Ms. Yoakum and passed unanimously.

President Waggener adjourned the meeting at 3:27 p.m.

APPROVED:

_____
Jeanne D. Waggener, R.Ph.
President

_____
Gay Dodson, R.Ph.
Executive Director/Secretary

February 2, 2016