COMMONWEALTH OF PENNSYLVANIA

DEPARTMENT OF STATE

BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS

F I N A L M I N U T E S

MEETING OF:

STATE BOARD OF PHARMACY

TIME: 10:30 A.M.

Held at

PENNSYLVANIA DEPARTMENT OF STATE

2525 North 7th Street

CoPA HUB, Eaton Conference Room

Harrisburg, Pennsylvania 17110

as well as

VIA MICROSOFT TEAMS

April 29, 2025

State Board of Pharmacy
April 29, 2025

BOARD MEMBERS:

Christine Roussel, Pharm.D., BCOP, BCSCP, Chairperson
Arion R. Claggett, Acting Commissioner, Bureau of Professional and Occupational Affairs
Eric Esterbrook, R.Ph., Vice Chairperson
Janet Getzey Hart, R.Ph., Secretary
John R. Slagle, R.Ph.
James Reed Jr., R.Ph.
Ester Blair, Office of Attorney General

BUREAU PERSONNEL:

Sean C. Barrett, Esquire, Board Counsel
Nathan C. Giunta, Esquire, Board Prosecution Liaison
Caroline A. Bailey, Esquire, Board Prosecutor
Tyesha C. Miley, Esquire, Board Prosecutor
Ashley P. Murphy, Esquire, Board Prosecutor
Sara Trimmer, Pharm.D., R.Ph., Executive Secretary
Marc Farrell, Esquire, Regulatory Counsel, Office of Chief Counsel, Department of State
Cathy A. Tully, Esquire, Board Counsel, State Board of Massage Therapy
Elle Thompson, Law Clerk, PA Department of State
Kevin Knipe, MSW, LSW, CCDP Diplomate, Program Manager, Professional Health Monitoring
Jessica Zukoski, Senior Legal Analyst, Department of State
Willow Marsh, Legislative Aide, Department of State
Brooke Jones, Legal Extern, Department of State
Nichole Maloney, Administrative Officer 3
Thomas Leech II, Board Administrator
Corey Ulisse, Drug Program Specialist, Department of State
Robert Maloney, Drug Program Specialist, Department of State

ALSO PRESENT:

Daniel Longyhore, System Director, Knowledge Management for Pharmacy at Geisinger
Jill Rebuck, Executive Director, Pennsylvania Society of Health-System Pharmacists
Larry Jones, Pennsylvania Society of Health-System Pharmacists

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ALSO PRESENT: (cont.)

Jeffrey Krist, Senior Compliance Manager, Chewy Pharmacy
Amanda Abernathy, Director of Population Health and Quality at UNC Health Blue Ridge
Adam Womack, Pharmacist in Charge, LifeMD
Michelle Aytay, Manager, Pharmacy Affairs, Walgreens
Caitlin Collins, Pharm.D.
Charlotte Harris, Pharmacy Intern, Duquesne University
Sarah Everingham, MJ, CCEP, CPhT, Cardinal Health
Rebecca (Becky) Taylor, Pharm.D., MBA, BCPC, FASHP
Joshua Finger, Pharm.D., Enclara Pharmacia
Lauren Finoli, Pharm.D., BCPS, BCCCP, Manager of Pharmacy Clinical Services, Allegheny General Hospital
Jacquelyn Sassaman, Pentec Health
Jan Hernandez-Velazquez
Jennifer Hall, RPh
Jess Salus, Pharm.D.
Jessica Cole
Joe DuPrey, MS, RPh, PA Society of Health System Pharmacists
Judy Kutchman, RPh, AllianceRx, Walgreens Prime
Lucas W. Morgan, Esquire
Gerald McGrory, Director of Pharmacy Services
Katie Medei, Healthcare Specialty Supervisor, Walgreens Pharmacy
Michael Fleck
Michelle Omari-Okyere BS, Pharm.D., BCPS, BCGP, Lehigh Valley Health Network
Trisha Miller, Pharm.D., MPH, BCACP, Ambulatory Care & Public Health Pharmacist, University of Pittsburgh Medical Center
Joseph Millward, Pharmacy Quality and Accreditation, PANTHERx, Rare Pharmacy
Rachel Nixon
Misha Patel, M.D., Curriculum Education Assistant, Geisinger Commonwealth School of Medicine
Brett Rodgers, Senior Manager for Pharmacy Automation, University of Pittsburgh Medical Center
Laura Romeo, Pharmacist in Charge, ConnectiveRx Careform Pharmacy
Heather Sakely, Pharm.D., BCPS, BCGP, University of Pittsburgh

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ALSO PRESENT: (cont.)

Scott Young
Chelsey Walker, Pharmacy Manager, Meadville Medical Center
Steven Zahn, Pharmacy Inspector, Bureau of Enforcement and Investigation, Department of State
Katrina Lepro, Pharmacy Fellow, PANTHERx, Rare Pharmacy
Nicole Fidler, Associate, Malady & Wooten
Kate McCale, Vice President, Compliance & Regulatory Affairs, Hospital and Healthsystem Associastion of Pennsylvania
Steven L. Sheaffer, Pharm.D., FASHP, Pennsylvania Society of Health-System Pharmacists
Megan Ammon, Pharm.D., BCMTMS, Clinical Program Coordinator at Weis Markets
Martin James Farrell, RPh
Christopher Miller, Pharm.D., Giant Eagle
Allen Solomon, Pharm.D.
Sheetal Kamath, MPharm, RPh, University of Pittsburgh Medical Center Presbyterian Shadyside
Rachel Wilbur-Adams, Sargent's Court Reporting Service, Inc.
Grace Sesi, Executive Director, Regulatory Affairs, CVS Health, Chairperson, Michigan Bureau of Pharmacy
Matthew Schonder, RPh, MBA, Director of Pharmacy, University of Pittsburgh Medical Center McKeesport
Christy Sims
Jill McCormack
Mikala Conatser
Call-In 1-215-340-1983
Call-In 1-412-359-3595
Call-In 1-412-327-7856
Call-In 1-717-503-2061
Erin Badstuebner, Sargent's Court Reporting Service, Inc.

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State Board of Pharmacy

April 29, 2025

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[Pursuant to Section 708(a)(5) of the Sunshine Act, at 9:00 a.m., the Board entered into Executive Session with Sean C. Barrett, Esquire, Board Counsel, for the purpose of conducting quasi-judicial deliberations and to receive the advice of Board Counsel. The Board returned to open session at 10:30 a.m.]

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The regularly scheduled meeting of the State Board of Pharmacy was held on Monday, March 3, 2025. Christine Roussel, Pharm.D., BCOP, BCSCP, Chairperson, called the meeting to order at 10:30 a.m.

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Introduction of Board Members/Attendees

[Christine Roussel, Pharm.D., BCOP, BCSCP, Chairperson, requested an introduction of Board members and attendees.]

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[Sean C. Barrett, Esquire, Board Counsel, noted the the meeting was being recorded, and those who

continued to participate were giving their consent to be recorded.

Mr. Barrett also noted the Board entered into Executive Session for the purpose of conducting quasi-judicial deliberations on a number of matters that are currently pending before the Board and to receive the advice of counsel.]

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Approval of the Agenda for the March 03, 2025 meeting

CHAIR ROUSSEL:

All right. Let’s get started with the approval of the Agenda. Would anybody like to make a motion to approve the agenda as written or any amendments?

MR. SLAGLE:

I'll make that motion.

CHAIR ROUSSEL:

Anybody want to second that?

MR. ESTERBROOK:

Second.

CHAIR ROUSSEL:

Let’s call the vote for the Agenda.

Reed, aye; Slagle, aye; Esterbrook, aye; Claggett, aye; Hart, aye; Blair, abstain;

Roussel, aye.

[The motion carried. Ester Blair was abstained from the motion.]

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Approval of the Minutes for the March 03, 2025 meeting

CHAIR ROUSSEL:

Let’s do an approval of the minutes. Are there any edits or amendments to the meeting? Minutes from the last meeting, March 03, 2025? All right. Hearing no need for amendments. A motion to approve the amendments?

MR. SLAGLE:

Motion.

CHAIR ROUSSEL:

Second?

MR. ESTERBROOK:

Second.

CHAIR ROUSSEL:

Let’s call the vote.

Reed, aye; Slagle, aye; Esterbrook, aye; Claggett, aye; Hart, aye; Blair, abstain; Roussel, aye.

[The motion carried. Ester Blair was abstained from the motion.]

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Report of Board Prosecution

[Caroline A. Bailey, Esquire, Board Prosecutor, presented the Consent Agreements for Items 2 through 4, Case Nos. 24-54-005287, 24-54-007162, and 24-54-007707.]

MR BARRETT:

Based on the presentation of Board Prosecution, does any member of the Board wish to return to Executive session for further deliberations?

Okay. Hearing none, based on Executive Session deliberations, I believe the Board Chair would approve a motion to approve the Consent Agreements at Item 2, Case No. 24-54-005287; at Item 3, Case No. 24-54-007162; and at Item No. 4, Case No. 24-54-007707.

MR. SLAGLE:

So moved.

MR. ESTERBROOK:

Second.

CHAIR ROUSSEL:

All right, any further discussion? Let's call the vote.

Reed, aye; Slagle, aye; Esterbrook, aye; Claggett, aye; Hart, aye; Blair, aye; Roussel, aye.

[The motion carried unanimously. The Respondent for Item 2 is Stroud Compounding & Wellness Drugstore; Item 3, Saumilbhai Patel, RPh; and Item 4, Front St. Pharmacy.]

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[Tyesha C. Miley, Esquire, Board Prosecutor, presented the Consent Agreements for Items 5 and 6, Case Nos. 24-54-006441 and 24-54-009370.]

MR BARRETT:

And based upon the presentation of Board prosecution, does any member of the Board wish to return to Executive Session for further deliberations?

Hearing none, before I do the motion, I'll just note for the record that Board member Esterbrook recused himself from any deliberations in this matter on both of these matters, No. 5 and 6.

So, based upon Executive Session

deliberations, I believe the Board Chair would entertain a motion to approve the Consent Agreements at Item No. 5, Case No. 24-54-006441, and at Item 6, Case No. 24-54-009370.

MR. SLAGLE:

So moved.

CHAIR ROUSSEL:

Second?

MR. REED:

Second.

CHAIR ROUSSEL:

Excellent, any further discussion? Let's call the vote.

Reed, aye; Slagle, aye; Esterbrook, recused; Claggett, aye; Hart, aye; Blair, aye; Roussel, aye.

[The motion carried. Eric Esterbrook recused from deliberations and voting on the motion. The Respondent for Item 5, is Professional Pharmacy; and Item 6, Professional Pharmacy Inc.]

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[Nathan C. Giunta, Esquire, Board Prosecution Liaison, presented the Consent Agreement for Item 7,

Case No. 21-54-019593; Item 8, Case Nos. 22-54-002556 and 22-54-002557; and Items 9 through 13, Case Nos. 22-54-013804, 24-54-009601, 24-54-017144, 25-54-001299, and 25-54-002378.]

MR BARRETT:

Okay. Based on the presentation of Board Prosecution, does any member of the Board wish to reenter Executive Session for further deliberations?

Hearing none, so, based on Executive Session deliberations, I believe the Board Chair would entertain a motion to reject the Consent Agreement at Item No. 9, Case No. 22-54-013804, as too lenient.

MR. SLAGLE:

So moved.

MR. REED:

Second.

CHAIR ROUSSEL:

Any discussion? Then let’s call the vote.

Reed, aye; Slagle, aye; Esterbrook, aye; Claggett, aye; Hart, aye; Blair, aye; Roussel, aye.

[The motion carried unanimously.]

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MR BARRETT:

Okay. And we'll do No. 12 next. And just for the record, Board member James Reed recused himself from any deliberations or consideration in Item No. 12. Based on Executive Session deliberations, I believe the Board Chair would entertain a motion to approve the Consent Agreement at Item 12, Case No. 25-54-001299.

MR. SLAGLE:

So moved.

CHAIR ROUSSEL:

Second?

MR. ESTERBROOK:

Second.

CHAIR ROUSSEL:

Any discussion? Then let's call the vote.

Reed, recused; Slagle, aye; Esterbrook, aye; Claggett, aye; Hart, aye; Blair, aye; Roussel, aye.

[The motion carried. James Reed recused from deliberations and voting on the motion. The Respondent's name is Walgreens #02445.]

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MR BARRETT:

Okay. And based on Executive Session deliberations, I believe the Board Chair would entertain a motion to adopt the Consent, approve the Consent Agreements at Item No. 7, Case No. 21-54-019593; at Item No. 8, Case Nos. 22-54-002556 and 22-54-002557; Item 10, Case No. 24-54-009601; Item No. 11, Case No. 24-54-017144; and Item No. 13, Case No. 25-54-002370.

MR. SLAGLE:

So moved on all of those.

CHAIR ROUSSEL:

Second?

MR. ESTERBROOK:

Second.

CHAIR ROUSSEL:

Any discussion? Then let's call the vote.

Reed, aye; Slagle, aye; Esterbrook, aye; Claggett, aye; Hart, aye; Blair, aye; Roussel, aye.

[The motion carried unanimously. The Respondent's name for Item 7, is Couzins Enterprises, LLC d/b/a Patriot Pharmacy; Item 8, The New Pharmacy & Adebayo Adeniran; Item 10, Paula M. Hughes, RPh; Item 11, Martin James Farrell, RPh; and Item 13, Northeast Discount Pharmacy.]

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[Ray Michalowski, Esquire, Senior Board Prosecutor, presented Item 14, Case No. 25-54-000258.]

MR BARRETT:

Okay. And we do have to vote on the VRP Agreement, so, I'll do that quick. Based on Executive Session deliberations, I believe the Board Chair would entertain a motion to adopt the VRP Agreement at Case No. 25-54-000258

MR. SLAGLE:

So moved.

MR. ESTERBROOK:

Second.

CHAIR ROUSSEL:

Any discussion? Then let's call the

vote.

Reed, aye; Slagle, aye; Esterbrook, aye; Claggett, aye; Hart, aye; Blair, aye; Roussel, aye.

[The motion carried unanimously.]

***

Report of Board Counsel – Legislative Update

[Sean C. Barrett, Esquire, Board Counsel, informed the Board that a number of new and recurring bills impacting the Board of Pharmacy had recently been introduced in the legislature. He noted that copies of these bills were uploaded to the Board's OneDrive and were also accessible through the General Assembly's website. He emphasized that no detailed discussion was needed at the time, but he wanted the Board to be aware, adding that any feedback from the regulated community should be directed to the General Assembly, as the proposals originated there.

Mr. Barrett outlined several specific bills, including House Bill 60 of 2025, which would allow the transfer of Schedule II controlled substances between pharmacies, and House Bill 69 of 2025, which would broaden the cancer drug repository program into a more inclusive prescription drug repository

program. He also mentioned House Bill 442 of 2025, focusing on pharmaceutical collection sites and educational initiatives, and House Bill 446 of 2025, which would require hospitals to offer unused medication to patients when medically appropriate. Lastly, he highlighted Senate Bill 301 of 2025, a price disclosure measure requiring pharmacies to provide certain pricing information.]

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Report of Board Counsel - Matters for Deliberation

[Sean C. Barrett, Esquire, Board Counsel, Item 25, Case No. 24-54-015788, was tabled.]

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Review of Applications

MR BARRETT:

So, based on Executive Session deliberations, I believe the Board Chair would entertain a motion to provisionally deny the new non-resident pharmacy of New Solutions Functional Wellness Pharmacy.

MR. SLAGLE:

So moved.

MR. ESTERBROOK:

Second.

CHAIR ROUSSEL:

Any discussion? Then let's call the vote.

Reed, aye; Slagle, aye; Esterbrook, aye; Claggett, aye; Hart, aye; Blair, aye; Roussel, aye.

[The motion carried unanimously.]

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MR BARRETT:

Okay. And Item No. 27, based on Executive Session deliberations, I believe the Board Chair would entertain a motion to approve the New Nonresident Pharmacy Application of Southwood Pharmacy.

MR. SLAGLE:

So moved.

MR. ESTERBROOK:

Second.

CHAIR ROUSSEL:

Any discussion? Then let's call the vote.

Reed, aye; Slagle, aye; Esterbrook, aye; Claggett, aye; Hart, aye; Blair, aye;

Roussel, aye.

[The motion carried unanimously.]

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Report of Board Chair

[Christine Roussel, Pharm.D., BCOP, BCSCP, Chairperson, shared that a new guideline titled Pharmacy Access to Resources and Medication for Opioid Use Disorder had been published as a joint consensus document by the National Association of Boards of Pharmacy and the National Community Pharmacists Association. She noted that the document was available for those interested and highlighted its relevance, especially in light of previous discussions with the Department of Health regarding the dispensing of medications like buprenorphine for opioid use disorder (OUD).

Chair Roussel explained that the guideline includes an executive summary and detailed recommendations on maintenance therapy with buprenorphine, handling early refills, interpreting prescription data, and using telemedicine to optimize safety and effectiveness. She emphasized the guideline's broad applicability across pharmacy practice settings, including both community and hospital environments, due to the serious nature of

OUD. She thanked the Pennsylvania Pharmacists Association for bringing attention to the document and then invited Board members to share any additional updates.]

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Report of Board Members

[Eric Esterbrook, R.Ph., Vice Chairperson, shared that his observations from the ACPE Reaccreditation of the University of Pittsburgh School of Pharmacy. He approves of the current status of the school.]

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Report of Acting Commissioner

[Arion R. Claggett, Acting Commissioner, Bureau of Professional and Occupational Affairs, noted that the Board is still on schedule to replace the PALS Licensure System with the new model called, Evoke. It is currently on schedule to replace PALS at the beginning of 2026.]

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Report of Executive Secretary

[Sara Trimmer, Pharm.D., R.Ph., Executive Secretary, reported that the Board was actively processing a large volume of Applications and college verification forms in preparation for graduation season. She acknowledged the fast pace of incoming materials and

expressed appreciation for everyone's patience as evaluators reviewed documents and determined graduates' eligibility for testing.

Chair Roussel expressed her gratitude, sharing that pharmacists in the community had reached out to commend the Board of Pharmacy staff for their helpfulness and professionalism during phone interactions. She thanked the team for their outstanding work and noted that the meeting was moving into the public questions segment, with upcoming meeting dates also listed for reference.]

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Report of Board Counsel (Cont.) – 16A-5430

[Sean C. Barrett, Esquire, Board Counsel, provided an update on regulation number 16A-5430 concerning child abuse reporting requirements. This proposed rulemaking package had previously been approved by the Board and had progressed through the internal departmental approvals in March.

Mr. Barrett stated the package had since received approval from the Governor's Office of General Counsel, the Budget Office, and the Governor's Policy Office earlier in the month. It was then submitted to the Attorney General's Office on April 14th for statutory review, which is expected to be completed

within 30 days. If approved, the next steps would involve delivering the proposal to the Independent Regulatory Review Commission (IRRC), the professional licensure committees of the House and Senate, and the Legislative Reference Bureau (LRB). Upon LRB's publication in the Pennsylvania Bulletin, a 30-day public comment period would begin, followed by a 30-day period for IRRC comments.]

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Report of Board Counsel (Cont.) – 16A-5432 & 16A-5433

[Sean C. Barrett, Esquire, Board Counsel, provided an update on regulation 16A-5432 regarding licensure by endorsement, noting that Mark was continuing to work on it in the background. He stated the regulation was expected to undergo internal review soon before moving forward for the necessary approvals.

Mr. Barrett also reported on regulation 16A-5433, the pharmacy technician regulation package, which had been delivered to the Independent Regulatory Review Commission (IRRC) on March 20, and was scheduled for review at IRRC's public meeting on May 15. He encouraged those interested to attend or watch the livestream via the IRRC website (irrc.state.pa.us). If approved by IRRC, the regulation would be sent to the Attorney General's Office for a final 30-day

review.

Mr. Barrett explained that, following the Attorney General's approval, the regulation would be sent to the Legislative Reference Bureau (LRB) for publication in the Pennsylvania Bulletin. He estimated that final publication—and thus the regulation's effective date—would likely occur within 45 to 60 days after the IRRC meeting.]

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Report of Board Counsel (Cont.) - 16A-5434 & 16A-5435

[Sean C. Barrett, Esquire, Board Counsel stated two additional regulations—16A-5434 concerning COVID-19 immunizations and 16A-5435 titled ABC Map, Opioid Education and Prescribing—were still in progress behind the scenes. He acknowledged that the regulatory workload was currently heavy but assured the Board that these Items remained on the radar and would continue to be updated as they advanced through the process.]

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Report of Board Counsel (Cont.) - General Revisions

[Sean C. Barrett, Esquire, Board Counsel, explained that the Board had previously worked through part two of the general revisions and was now reviewing pages 57 through 81. He noted that there had been prior

discussion about the timing of the North American Pharmacist Licensure Examination – Jurisprudence (NPJE), particularly whether it should occur before graduation. Although ideas had been exchanged, no final language had been decided. He encouraged Board members to prepare for a more detailed discussion at the next meeting, specifically regarding section 27.21, and mentioned he would coordinate further with Mark on how to handle the matter.

Chair Roussel added that the Board welcomes proposed language submissions in advance, especially concerning section 27.21. She noted that Mark particularly appreciates receiving input beforehand and mentioned that other states are also active in this area, indicating broader relevance.

Mr. Barrett introduced section 27.205 on Remote Automated Medication Systems, asking if there were any issues and confirming that the Board was working off the most current version of the document. He stated there had been no new language changes since the last update, though Mark was working on revisions discussed previously.

Jill Rebuck, Executive Director, Pennsylvania Society of Health-System Pharmacists, shared that suggested wording related to pharmacy technicians and

automation had been submitted in writing through the pharmacy website for Mark's consideration.

Mr. Barrett acknowledged the submission and suggested that the Board go through the sections together for discussion, emphasizing that decisions should be made by the Board as a whole, not just by him and Mark.

Ms. Rebuck clarified that there would be no further comments submitted on satellite pharmacies. After group discussions, it was determined that addressing satellite pharmacy regulations would require more time and deliberation than the current timeline allowed. She offered to read the submitted suggestions or adjust based on the Board’s preference, aiming to be efficient with the discussion.

Chair Roussel affirmed that the six suggestions submitted were thoughtful and relevant. She asked Ms. Rebuck to identify specific sections so the Board could follow along, noting that although some suggestions referred to earlier pages (52-53), they overlapped with topics starting on page 57 and were therefore appropriate for the current discussion.

Ms. Rebuck proposed revisions to section 27.204 on page 52 regarding automated medication systems

within or on the same premises as a pharmacy. Representing PSHP, she recommended changing the last sentence of subsection (a) to include automatic counting devices and unit-based dispensing cabinets in the definition of automated medication systems. She also suggested updating the language to require identification of the manufacturer's model and name, as well as a description of how the system is used. Additionally, she proposed removing the requirement for testing and validation results to be available to the Board.

Chair Roussel sought clarification on Ms. Rebuck's intent, pointing out that the current language explicitly excludes automatic counting devices and unit-based dispensing cabinets from the definition. She confirmed that the proposed change would shift the language from exclusion to inclusion, and questioned whether that exclusion might have been intentional to avoid unnecessary regulation.

Ms. Rebuck confirmed that PSHP believed the exclusion might have been an error. She explained that, in their view, unit-based dispensing cabinets and similar systems should fall under the definition of automated medication systems, especially when used within or near a pharmacy.

Mr. Esterbrook recalled that the exclusion had likely been added to reduce confusion in the field between complex automated medication systems and simpler devices. The goal was to differentiate systems requiring regulation from those that did not.

Chair Roussel agreed, explaining that the intent was likely to avoid overregulating basic devices like pill counters while maintaining oversight over larger, more integrated systems. She acknowledged that unit-based dispensing cabinets could be part of broader systems but reiterated the importance of drawing a regulatory line between complex systems and simpler devices.

Mr. Barrett supported this interpretation, stating that the original language was likely designed to limit regulatory scope and prevent unnecessary oversight of devices that serve a basic counting function.

Chair Roussel elaborated by questioning the necessity of requiring validation for simple counting devices, noting that most are not subject to routine testing or formal validation processes. She reflected on common practice, where these devices might not be revalidated over time, and asked others if such practices were followed in their facilities.

Mr. Barrett described the system used in his setting, which takes pictures of each counted pill for verification. He noted that such devices offer visual confirmation and suggested that systems like theirs differ from traditional counting machines in how they support accuracy and oversight.

Chair Roussel stated she viewed systems taking images for verification as true automated medication systems, distinguishing them from simple pill counters. She emphasized that the ability to visually confirm contents through a screen supported the definition of an automated system, which may have been the original intent behind the regulatory language.

Mr. Jones explained that the regulations were originally written in an era dominated by simpler machines like Kirby Lesters and Brewer counters, which lacked advanced features like lasers or specific gravity sensors. At the time, the only recommendation, originating from the DEA—was to double count-controlled substances. The exclusion of basic counting devices was intentional, given their limitations, and automated dispensing machines (ADMs) were understood to be more complex systems requiring centralized brains, which are addressed elsewhere in

the regulation.

Chair Roussel asked the group whether they were comfortable retaining the phrase does not include in the current regulatory definition.

Dr. Trimmer responded that she supported keeping the exclusion in place, agreeing that it helped avoid overregulating pharmacies. She also expressed appreciation for the historical and technical context that had been provided.

Dr. Trimmer recommended revising section 27.204B on page 52 by changing the language to state that the automated medication system should include the manufacturer’s name and model, if applicable, along with a description of how the system is used. She proposed removing the requirement for testing and validation results to be made available to the Board, explaining that such data is typically not provided by vendors due to the human element involved. While some level of independent validation, such as barcode verification, can be performed, comprehensive validation results are not realistically available.

Chair Roussel agreed with the recommendation, emphasizing that the term validation has a specific, rigorous meaning in pharmacy, especially in sterile compounding. She noted that the way it was being

used in the regulation felt imprecise and burdensome, lacking a standard method for testing as found in more formal validations like USP sterility testing. She supported removing the term from this context to avoid setting unrealistic expectations and to preserve the meaning of validation for scenarios where it truly applies.

Mr. Barrett, questioned whether any form of accuracy testing was performed before automated systems were installed. He clarified that the regulation did not seem to be asking for scientific validation, but that the language might misleadingly suggest that level of rigor.

Chair Roussel clarified that automated medication systems function more like drug vending machines, with designated drawers for each medication. She stressed that accuracy relies largely on human input, such as correctly stocking the machine, and that there is no true way to validate the system beyond monitoring for human error. She described how errors, like a wrong drug in a pocket, trigger reporting and review processes, reinforcing that this does not meet the formal definition of validation. She expressed support for the proposed language emphasizing system description and manufacturer

details instead.

Chair Roussel reiterated that the proposed wording was more accurate and avoided diluting the meaning of validation, which has significant implications elsewhere in pharmacy practice. She asked the group if they supported adopting this more practical language.

Mr. Barrett followed up by asking whether general policies might be required—suggesting that pharmacies should maintain policies on system use that could be available to the Board rather than requiring formal validation.

Chair Roussel provided context on the standard practices. She explained that medications are loaded into machines using barcode scanning, and similarly scanned upon removal. She added that machines are checked monthly for expiration dates and proper stocking, and logs are kept to document these checks. She concluded that referencing compliance with internal policies and procedures would be a more realistic and effective regulatory approach.

Dr. Trimmer recommended revising page 53, section 27.204(B)(3), to state that pharmacies should make automated medication system records and/or electronic data from other automated pharmacy systems readily

available to the Board for inspection purposes. She proposed removing the previous language about independent validation by the Board, aligning this suggestion with prior discussions about the impracticality of such validations. She clarified the revision would effectively end the sentence at the comma, replacing it with a period.

Chair Roussel agreed, noting that the Board did not intend to independently validate systems that even operators themselves could not formally validate. She confirmed the proposed punctuation change, supporting the practical simplification of the language.

Mr. Barrett asked whether the existing regulation had caused any issues in practice and if the regulated community had experienced problems with its current form.

Chair Roussel responded that the issue likely had not surfaced because inspectors were not actively inspecting hospitals, which might otherwise raise complications if they had to comply with the original language.

Mr. Jones suggested that, in addition to system records, hospitals should also be prepared to provide corresponding policies during inspections, further

reinforcing proper system use rather than direct testing.

Mr. Barrett noted that the intent seemed to be shifting from inspecting the machines themselves to ensuring appropriate usage through policies and documentation, as direct technical validation of the machines was neither feasible nor practical.

Mr. Jones confirmed that during inspections, the focus was typically on reviewing records, manufacturer certifications, and facility documentation. While a few states might conduct direct testing, this was not standard practice. Instead, Pennsylvania's approach centered on ensuring regulatory compliance rather than technical validation.

Dr. Trimmer proposed a revision to page 56, section 27.204(H)(2), suggesting the removal of the requirement to test the system's accuracy every six months. Instead, she recommended language requiring pharmacies to establish mechanisms and procedures to regularly ensure the equipment is working within vendor-specified operations, including whenever any upgrade or related change is made to the system. She explained that this revised wording better reflected best practices and what facilities could

realistically provide to the Board during inspections.

Chair Roussel asked whether, from an inspector's perspective, this language would capture data such as how often the wrong drug ended up in the wrong pocket—something typically tracked by hospitals. She questioned whether such occurrences would fall under the scope of vendor-specified operations, as this information would likely be useful during inspections.

Dr. Trimmer responded affirmatively, noting that facilities routinely track this type of data and could provide it at the time of inspection, as it relates to ensuring proper functioning of the system.

Mr. Jones clarified that errors can occur either at the floor level—where automated dispensing machines (ADMs) are used—or upstream, where robots or carousels in the central pharmacy load the initial medication. He emphasized that properly sequencing the entire process in the pharmacy is essential to prevent downstream errors.

Mr. Barrett questioned whether the proposed revision implied that mechanisms for accuracy checks would only be required during system upgrades or changes, potentially eliminating routine verification

requirements for longstanding systems. He suggested considering language that might trigger action during inspections.

Dr. Trimmer clarified that the proposed language did not limit obligations to upgrades only. It required mechanisms and procedures to regularly ensure equipment functionality at all times, with upgrades being one specific trigger—highlighted, but not exclusive.

Chair Roussel added that monthly inspections were standard practice in many facilities. These inspections involved checking each drug pocket for correct contents and expiration dates, in line with internal policies and procedures. She noted that these routine processes served as the operational mechanism to confirm the equipment was functioning properly.

Mr. Jones explained that manufacturer and vendor standards are typically incorporated into pharmacy policies, emphasizing that these standards are essential because vendors validate the systems and update their recommendations over time as needed.

Mr. Barrett expressed concern about the use of the word regularly in regulations, stating that as a lawyer, vague terms like that can be problematic

because they lack specific, enforceable meaning.

Mr. Jones added that aligning regulations with evolving industry and vendor standards helps ensure they remain current and enforceable, rather than outdated soon after publication.

Rebecca Taylor, UPMC, Pharm.D., MBA, BCPC, FASHP, provided an example, noting that even an upgrade to Microsoft software can impact automated dispensing machine (ADM) performance and interfacing with electronic medical records. She emphasized the need for post-upgrade monitoring to detect and escalate system malfunctions, citing real-world experiences.

Chair Roussel supported the suggested language change, saying it was consistent with other quality assurance requirements found elsewhere in the document, such as those on page 60. She pointed out that monthly on-site inspections already include checks for expiration dates, drug integrity, and machine functionality, showing alignment between the new proposal and existing expectations.

Chair Roussel further asked for Board consensus on whether the proposed language change in Item four was acceptable. She felt it was a reasonable and streamlined revision and asked if others agreed with that assessment.

Mr. Barrett questioned whether a packaging robot containing many drugs—like those with 200 canisters should also be considered an automated medication system. He expressed concern about ensuring the software and functioning of such complex machines were addressed in the regulations, not just point-of-care dispensing units like Pyxis.

Chair Roussel confirmed that such packaging robots are indeed covered under the definition of automated medication systems. She noted that pharmacists typically check each unit-dose packet visually, and issues like incorrect drops trigger immediate intervention and vendor notification. She argued that these real-time checks make periodic accuracy testing redundant and that the proposed changes more accurately reflect actual practice, where systems are constantly monitored during use.

Ms. Taylor noted that the language in section 10 was relevant to automated dispensing systems, which were already being discussed, suggesting it might be appropriate to consider it now.

Chair Roussel acknowledged that section 10 related to automated dispensing cabinets and agreed to address it during the current discussion since it aligned with the ongoing topic.

Ms. Taylor proposed adding language to section 27.12(b)(1) on page 10 to exempt medications that are not patient-specific and dispensed through automated dispensing cabinets or centralized automation from the requirement that pharmacists review every prescription or drug order. She referenced language starting at the bottom of page 9 and explained the addition would acknowledge existing decentralized models where medications, like vancomycin, are pre-reviewed, barcoded, and dispensed directly to nurses without pharmacist re-verification at the point of withdrawal.

Chair Roussel questioned the implication of the proposed change, expressing concern that it might suggest a pharmacist does not need to inspect medications before they are stocked into automated dispensing cabinets. She clarified that under current practice, pharmacists do inspect medications prior to stocking and that verification occurs within standard workflow, without needing this additional regulatory language. She noted the proposed wording might unintentionally suggest eliminating pharmacist oversight.

Ms. Taylor pointed to the language on page 55, which permits automated verification of final

products dispensed from the system without pharmacist intervention, stating that their proposal was intended to support that clause. However, she acknowledged that if the Board believed the language was unnecessary, she was open to removing it.

Chair Roussel reiterated that current practice already covers pharmacist verification before stocking and that the proposal seemed redundant or possibly misleading.]

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[Christine Roussel, Pharm.D., BCOP, BCSCP, Chairperson, noted that pages 10 through 24 would be discussed at a later date. She prompted further discussion regarding pages 57 through 81.

Mr. Jones brought up language on the bottom of page 70, referencing a previous meeting where he had tried to address the same issue. He stated he had also submitted related materials to Mark and Sean, though they indicated they might not have received them.

Mr. Jones explained that when pharmacists are authorized to administer immunizations within hospitals, the Department of Health (DOH) oversees all medication administration within those facilities. He highlighted existing Pharmacy Board

regulations requiring compliance with DOH and Department of Public Welfare rules. He proposed adding a new section F to clarify that pharmacist-administered services must be approved by medical staff through the pharmacy committee, helping avoid confusion during inspections and ensuring hospital-affiliated retail pharmacies are not penalized for providing immunizations without prior submission to medical staff.

Chair Roussel responded that she found Jones' language thoughtful and clarifying but expressed hesitation about stepping into DOH's regulatory domain.

Mr. Barrett echoed Roussel's concerns, pointing out the potential overlap between DOH and Board of Pharmacy authority. He acknowledged that while pharmacists are authorized under the practice act to give immunizations, conflicts may still arise with DOH regulations.

Mr. Jones clarified that his proposal did not seek to override DOH authority but to integrate their own language directly into pharmacy regulations. He emphasized that the current ambiguity left retail pharmacies vulnerable during inspections and that his changes would resolve that uncertainty.

Mr. Barrett acknowledged the importance of the issue and committed to reviewing the relevant DOH language more thoroughly before providing a final opinion. He apologized for not doing so earlier and promised to follow up.

Mr. Jones concluded by stressing the urgency of the situation, noting that several pharmacies were left in limbo because of inconsistent regulatory interpretation by individual inspectors.]

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[Christine Roussel, Pharm.D., BCOP, BCSCP, Chairperson, directed the Board's attention to comments on page 80, regarding the review of compounding regulations. She explained that the original intent behind the language was to keep it simple, acknowledging the constantly evolving nature of compounding standards from the FDA and USP, including references to USP chapters 795, 797, and 800. She praised the current wording for its brevity and flexibility, stating that it allowed inspectors to apply updated federal standards without requiring frequent revisions to state regulations.

Mr. Michalowski pointed out that the regulations had previously incorporated broad language referencing all applicable laws, which allowed for

inclusion of current FDA guidance. He supported the idea of maintaining flexible, high-level references to regulatory standards rather than specifying details that might become outdated.

Chair Roussel agreed with Michalowski, reaffirming her preference for minimal, general language in the regulation. She emphasized that fewer words often result in stronger policy, especially for complex topics like compounding, and voiced support for leaving the existing language untouched.

Mr. Barrett concurred with the approach, noting that overly specific language could cause issues when new FDA guidance is issued. He emphasized that broadly worded regulations allow for adaptability and avoid the risk of becoming obsolete with each new update.

Mr. Michalowski added that this same principle could apply to other parts of the regulations, such as immunization-related language on page 70, where current rules reference specific age minimums. He warned that if statutory age limits change, detailed regulatory language could quickly become outdated.

Mr. Barrett explained that recent legislative changes moved immunization language out of the

Pharmacy Act and into the insurance code, noting it as an unusual decision.

Jeff Krist, representing Chewy, agreed with the prior discussion on keeping regulations simple. He emphasized that FDA and USP standards, especially those for veterinary compounding, are already very complex. Given that his company operates across all 50 states, he noted that states with their own compounding regulations—rather than deferring to USP—often create significant operational and accreditation challenges, making it harder for businesses to operate due to inconsistent inspection standards.

Mr. Barrett asked whether most states generally defer to the FDA on compounding regulations.

Mr. Krist confirmed that most do, though some states like Texas and Kentucky maintain their own regulations, which complicate compliance. He added that federal standards are easier to follow due to expert panels and structured guidance.

Chair Roussel added that multi-state facilities often default to the most stringent regulatory standard across all jurisdictions for consistency and legal protection. She acknowledged that while USP is not perfect, its transparent and thoughtful peer

review process is beneficial. She then directed the group to move on to page 81 and asked if there were any final suggestions, noting that unresolved comments from PSHP might be revisited later if not addressed now.

Chair Roussel reminded the group that section 27.21, found on page 29, would be discussed at the June 17th meeting. Mr. Barrett added that the plan was for Mark to prepare a full draft of the proposed changes. He noted that if adjustments to section 27.21 were necessary, they could be made at that time, with the broader goal of advancing the regulatory package to the next stage. This would allow the required 30-day review periods to begin and the group's work to take effect.]

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Adjournment

CHAIR ROUSSEL:

Motion to close. All those in favor?

MR. ESTERBROOK:

So moved.

MR. SLAGLE:

Second.

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[There being no further business, the State Board of

Pharmacy Meeting adjourned at 12:06 p.m.]

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CERTIFICATE

I hereby certify that the foregoing summary minutes of the State Board of Pharmacy meeting, was reduced to writing by me or under my supervision and the minutes accurately summarize the substance of the State Board of Pharmacy meeting.

Erin Badstuebner,
Minute Clerk
Sargent's Court Reporting
Service, Inc.

STATE BOARD OF PHARMACY
REFERENCE INDEX

April 29, 2025

TIME	AGENDA
9:00	Executive Session
10:30	Return to Open Session
10:30	Official Call to Order
10:31	Introduction of Board Members/Attendees
10:33	Approval of Minutes
10:37	Report of Board Prosecution
11:15	Report of Board Chair
11:16	Report of Committees
11:17	Report of Acting Commissioner
11:19	Report of Regulatory Counsel
12:06	Adjournment