

DEPARTMENT OF COMMERCE, COMMUNITY, AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING

BOARD OF PHARMACY

CONDENSED MINUTES OF THE MEETING HELD NOVEMBER 14, 2024

Date: November 14, 2024

Time: 09:00am – 05:00pm

Location: Atwood Building, Room 1535, Anchorage, AK and Online via Zoom™

Board Members: Ashley Schaber, Carla Hebert, Ramsey Bell, James Henderson, Sylvain Nouvion, and Dylan Sander.

Attending:

Staff: Michael Bowles, Carmen Pora, Holly Handley, Greg Gober, Lisa Sherrell and Melissa Dumas.

Absent: Sara Rasmussen

Agenda Item #1. Roll Call/Call to Order – Board and Staff Introductions

Roll Call:

Ashley Schaber - Present
Sara Rasmussen - Absent
James Henderson - Present
Carla Hebert - Present
Ramsey Bell – Present
Sylvain Nouvion – Present
Dylan Sanders - Present

On the record at 09:02am.

Quorum was met.

Board member introductions conducted.

Agenda Item #2 Ethics Disclosures

Brief Discussion: Ashley Schaber disclosed she is a member of the Alaska Pharmacists Association (AKPhA) Legislative Committee.

Agenda Item #3 Consent Agenda Items

Brief Discussion:

- Reviewed and approved changes to meeting agenda.
- Reviewed lost or stolen controlled substances/DEA 106s.

- Reviewed Well Being Indexes.
 - American Pharmacists Association’s (APhA) Well-Being Index for Pharmacy Personnel, August 2024 Edition
 - American Pharmacists Association’s (APhA) Well-Being Index for Pharmacy Personnel, September 2024 Edition

Motion: Carla Hebert moved to approve the consent agenda items as written and listed above, as well as the amended agenda. Seconded by Ashley Schaber.

Recorded Votes:

Roll Call:

Ashley Schaber - Yes

Sara Rasmussen -

James Henderson - Yes

Carla Hebert - Yes

Ramsey Bell – Yes

Sylvain Nouvion – Yes

Dylan Sanders - Yes

It was resolved to approve the consent agenda items as written and listed above, as well as the amended agenda.

Agenda Item #4 Investigations Review

Discussion:

- Investigators Holly Handley, Greg Gober, and Carmen Pora.
 - Investigative Report from August 06, 2024, through October 31, 2024
 - Open Cases: 62
 - Closed Cases: 63
 - License Actions: 6
 - License Denials: 4
 - The board conducted reviews of three open cases and one application.

Motion: Ashley Schaber motioned to approve the imposition of civil fine order as written for case # 2024-000433 and the consent agreements as written for cases 2023-001010 and 2023-000887 and asked for unanimous consent. Seconded by Carla Hebert.

Recorded Votes:

Unanimous consent

It was resolved to approve the imposition of civil fine order as written for case # 2024-000433 and the consent agreements as written for cases 2023-001010 and 2023-000887.

Motion: On a motion made by James Henderson in accordance with AS 44.62.310(c)(2) and seconded by Sylvain Nouvion, the board moved to enter executive session for the purpose of discussing subjects that tend to prejudice the reputation and character of any person, provided the person may request a public discussion. No request was made for public discussion. Board members James Henderson, Dylan Sanders, Sylvain Nouvion, Carla Hebert, Ramsey Bell, and staff members Michael Bowles, Greg Gober, Carmen Pora, and Holly Handley

were authorized to remain in the room. The application for Pharmacy Technician license number 227182 will be discussed. James Henderson requested unanimous consent.

Recorded Votes:

Unanimous Consent

It was resolved to enter executive session in accordance with AS 44.62.310(c)(2).

Off record for executive session at 9:25am

On record from executive session at 9:34am

No motions were made during the executive session.

Motion: James Henderson motioned to approve the application for Pharmacy Technician license number 227182. Seconded by Sylvain Nouvion.

Recorded Votes:

Ashley Schaber - Abstain

Sara Rasmussen -

James Henderson - Yes

Carla Hebert - Yes

Ramsey Bell – Yes

Sylvain Nouvion – Yes

Dylan Sanders - Yes

It was resolved to approve the application for Pharmacy Technician license number 227182.

Agenda Item #5 Division Updates

- Michael Bowles, Executive Administrator of the Board of Pharmacy
 - Michael Bowles discussed the function of NABP Verify and how it differs from a licensure compact.
 - Andrew Funk and Neal Watson, Member Relations/Government Affairs, NABP addressed the board and provided information on the NABP Verify program and the intended use of the program.
 - Ashley Schaber recommended the board hold on moving forward with pursuing NABP Verify and watch the work on a new NABP project that aims to increase interstate portability of licensed pharmacists.
 - Michael Bowles presented the board with an Alternative to Probation standard operating procedure (SOP) to assist the board with providing an outline on program requirements for licensees that self-disclose alcohol use or opioid use disorders (AUD/OD).
 - Carla Hebert had concerns about the AUD/OD assessment process and how accurate the process is.
 - Senior Investigator Billy Homestead discussed the SOP and how the nursing and medical boards have implemented similar SOPs to achieve the intent of the board.
 - Dylan Sanders asked if there is a referred program, how is it monitored from the outside? Are there potential patient safety issues with the employer?

- Ashley Schaber stated the program has been vetted by the department of law and is currently in use by other boards.
- Billy Homestead discussed how the monitoring is conducted through the division by the probation monitors/Investigator 2.
- Sylvain Nouvion asked who makes the determination if someone needs to be removed from the program.
- Billy Homestead discussed the probation monitor drafts the review memo with potential violations, a board member reviews and makes a recommendation.
- Carla Hebert asked if the closure comes back to the board if the licensee meets all requirements.
- Billy Homestead stated the probation monitor is the person that monitors the licensee during the duration of the program, and it is outlined in a consent agreement. Upon completion of the program the probation monitor closes out the program and the consent agreement if all requirements are met.
- James Henderson asked the board to discuss numbers 4 and 5 under the not eligible section to clarify if the board wants to consider providing a second chance to a licensee that has not successfully completed a program in the past and what happens if someone fails the program.
- Billy Homestead stated the same procedure as any disciplinary action would then occur and the board could consider suspension or revocation of licensure.
- Billy homestead clarified that ASAP does not always do an assessment, the board should consider this.
- Lisa Sherrell, Prescription Drug Monitoring Program (PDMP) Manager
 - PDMP Updates provided to the board
 - Seeing an uptick in testosterone and stimulants, consistent with national trends
 - No partner states added for data sharing
 - Lisa Sherrell discussed requirement to review PDMP. Recommended changing the requirement for registration based on the standard of care model.
 - Carla Hebert stated that applying standard of care to PDMP is an interesting idea. Thinks most pharmacists will check PDMP regardless of whether it is a requirement or not.
 - Ashley Schaber discussed an earlier recommendation of changing regulation to require all pharmacists register for PDMP. Interesting concept of integrating standard of care with PDMP review.

Motion: Carla Hebert motioned to approve the standard operation procedure for the alternative to probation program as written, seconded by Sylvain Nouvion.

Recorded Votes:

Ashley Schaber - Yes
Sara Rasmussen -
James Henderson - Yes
Carla Hebert - Yes
Ramsey Bell – Yes
Sylvain Nouvion – Yes
Dylan Sanders – Yes

It was resolved to approve the standard operation procedure for the alternative to probation program as written.

Agenda Item #6 Public Comment Period

Discussion:

- No public comments received during this time.

Agenda Item #7 Board Business

- Controlled Substances Advisory Committee (CSAC)
 - Ashley Schaber addressed the requirement to continue addressing the CSAC. Sunset audit requires tracking of CSAC
 - The board discussed Gabapentin
 - Could be something the CSAC could address.
 - Not currently scheduled by the DEA nationally.
 - Some states have started to schedule.
 - Dylan Sanders stated there are potential cost issues, puts a burden on how to store; unit dose cups would ease the burden.
 - Carla Hebert stated huge drug of abuse in the corrections setting and scheduling would limit the use.
 - Ramsey Bell asked what factors are being considered to schedule, what is the DEA considering, what are other states considering?
 - Carla Hebert stated it is diverted.
 - Ashley Schaber stated the CSAC would broaden the view outside of the practice setting
 - James Henderson asked if there were any drugs that were scheduled specifically in Alaska?
 - Ashley Schaber stated not that she was aware of.
 - Lisa Sherrell stated there was a setting that needed to be corrected approximately 2 years ago in PDMP addressing gabapentin. The DEA is not looking into scheduling. Might be a good idea to invite the DEA to a meeting to discuss gabapentin.
 - Task for Michael Bowles to follow up on the CSAC and when they may be meeting.
 - Lisa Sherrell stated the last time CSAC met gabapentin was discussed and it is on their agenda.
 - Ashley Schaber discussed partnering with the Alaska Pharmacy Association (AKPhA) to address gabapentin education.
- Position Elections
 - Chairperson
 - Carla Hebert nominated Ashley Schaber to be the chairperson for the 2025 year, Sylvain Nouvion seconded.
 - Unanimous consent to approve Ashley Schaber as the chairperson for the 2025 year.
 - Vice Chairperson
 - Ashley Schaber asked the members if anyone was interested in serving as vice chairperson.
 - Carl Hebert volunteered to serve as the vice chairperson.
 - Carla Hebert nominated herself to be the vice chairperson for the 2025 year, Ashley Schaber seconded.
 - Unanimous consent to approve Carla Hebert as the chairperson for the 2025 year.
 - Secretary

- Ashley Schaber discussed the responsibilities of the secretary position, taking good notes, capturing motions.
- Sylvain Nouvion nominated himself to be the secretary for the 2025 year, James Henderson seconded.
- Unanimous consent to approve Sylvain Nouvion as the secretary for the 2025 year.
- These positions begin immediately.
- Newsletter Discussion – Utilizing Listserv
 - Ashley Schaber discussed the board’s goal to increase communication to all licensees. Good partnership with AKPhA providing information quarterly and annually, but this is only available to AKPhA members which only make up a portion of all licensees.
 - The board did discuss the possibility of partnering with NABP and putting out a newsletter through NABP but there were also questions concerning sharing email and external considerations such as cost to the board.
 - Discussed the executive administrator sending quarterly updates through listserv.
- Update on Information from the Med Spa Workgroup
 - Ashley Schaber discussed the structure of the workgroup and the areas of focus the workgroup is addressing.
- Update on Topics Discussed at Alaska Hospital & Healthcare Association (AHHA) Conference
 - James Henderson informed the board of the subjects covered.
- Update on Topics Discussed at AKPhA Conference
 - Carla Hebert informed the board of the subjects covered.
- NABP District Meeting Update
 - Ashley Schaber and Carla Hebert attended.
 - Carla Hebert discussed topics covered
 - Patients losing access to care
 - Wellbeing was discussed, losing pharmacists at the patient care level
 - Standard of Care, self-regulating, latitude to address issues
 - Continuous Quality Improvement
 - Importance of boards of pharmacy working with associations and schools

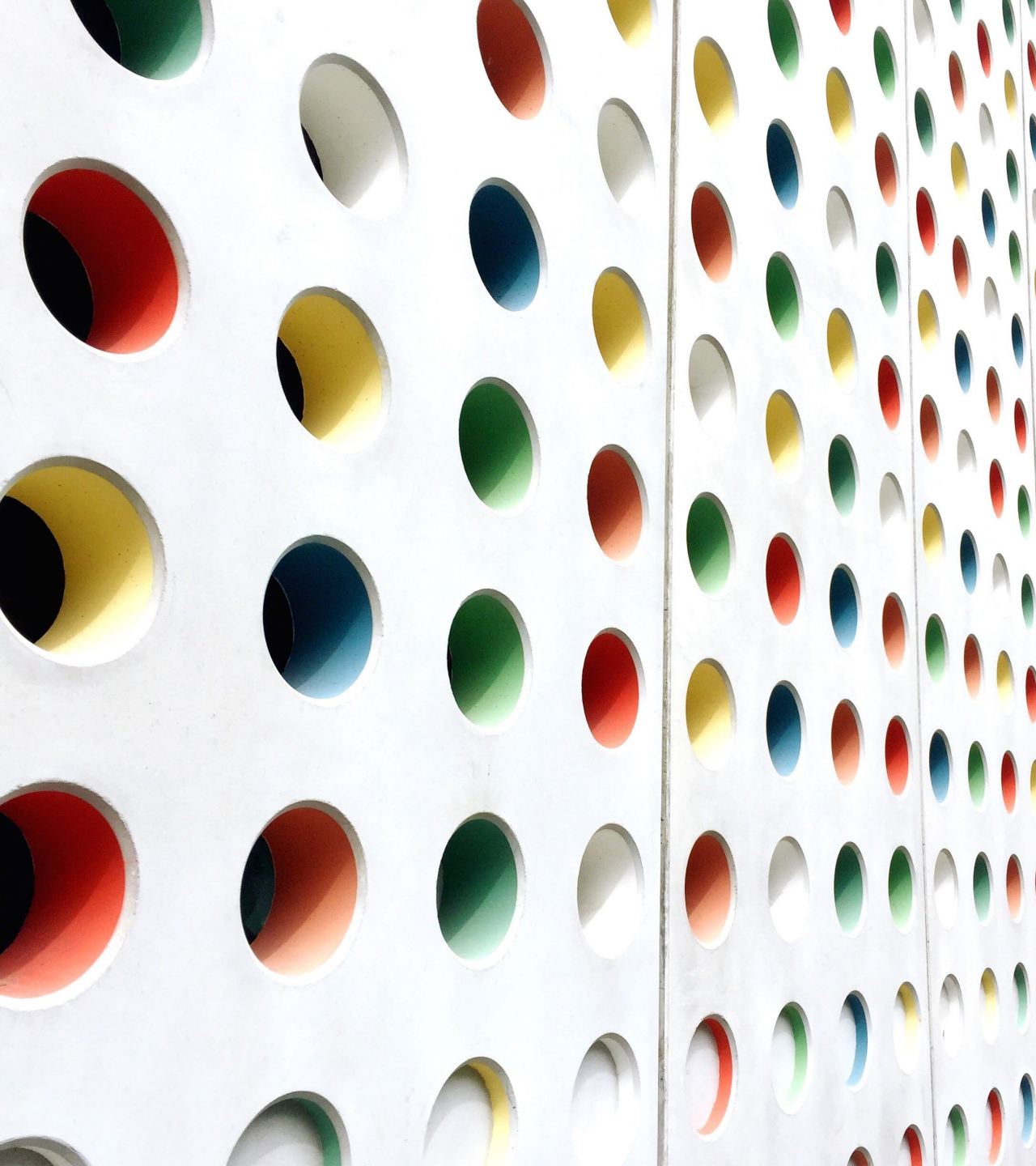
James Henderson requested a 10-minute break.

Off record at 11:31am

On record at 11:42am

Agenda Item #8 Industry Updates

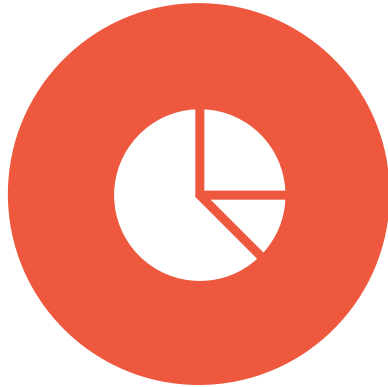
- Brandy Seignemartin, PharmD, AKPhA Executive Director
 - Provided the board with a presentation on the AKPhA areas of focus for the upcoming year.



Industry Update

ALASKA PHARMACY ASSOCIATION

Industry Update



SHOTS GRANT



HB 226 & MARKET INSIGHTS



REGULATION OF PSYCHEDELIC
MEDICINES WORKGROUP

Increasing Access to Care at Pharmacies with SHOTS

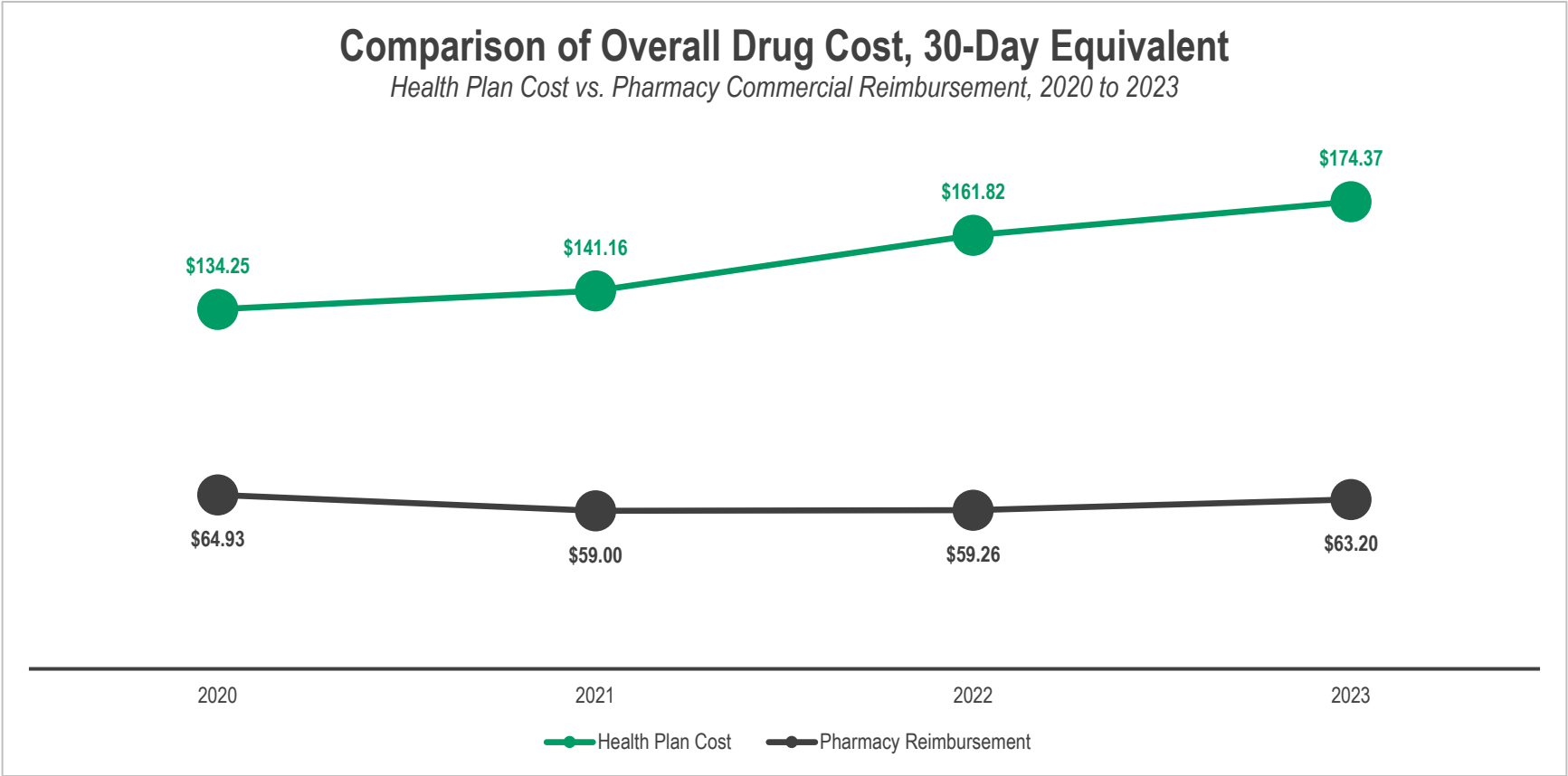
- Supported Immunizations, Healthcare Delivery, On-Site Training and Services - SHOTS Grant
- Support pharmacies in increasing services and improving patient access to care
- Partner with UAA / ISU Doctor of Pharmacy Program
- Many training and partnership opportunities for Alaska pharmacy professionals

HB 226 & Market Insights

- HB 226 covers commercial market (Approximately 15%)
 - What's left?
 - Medicare = Approx. 15%
 - Medicaid = Approx. 33%
 - All self insured plans = Approx. 37%
- Data review: [Understanding Drug Pricing from Divergent Perspectives](#)

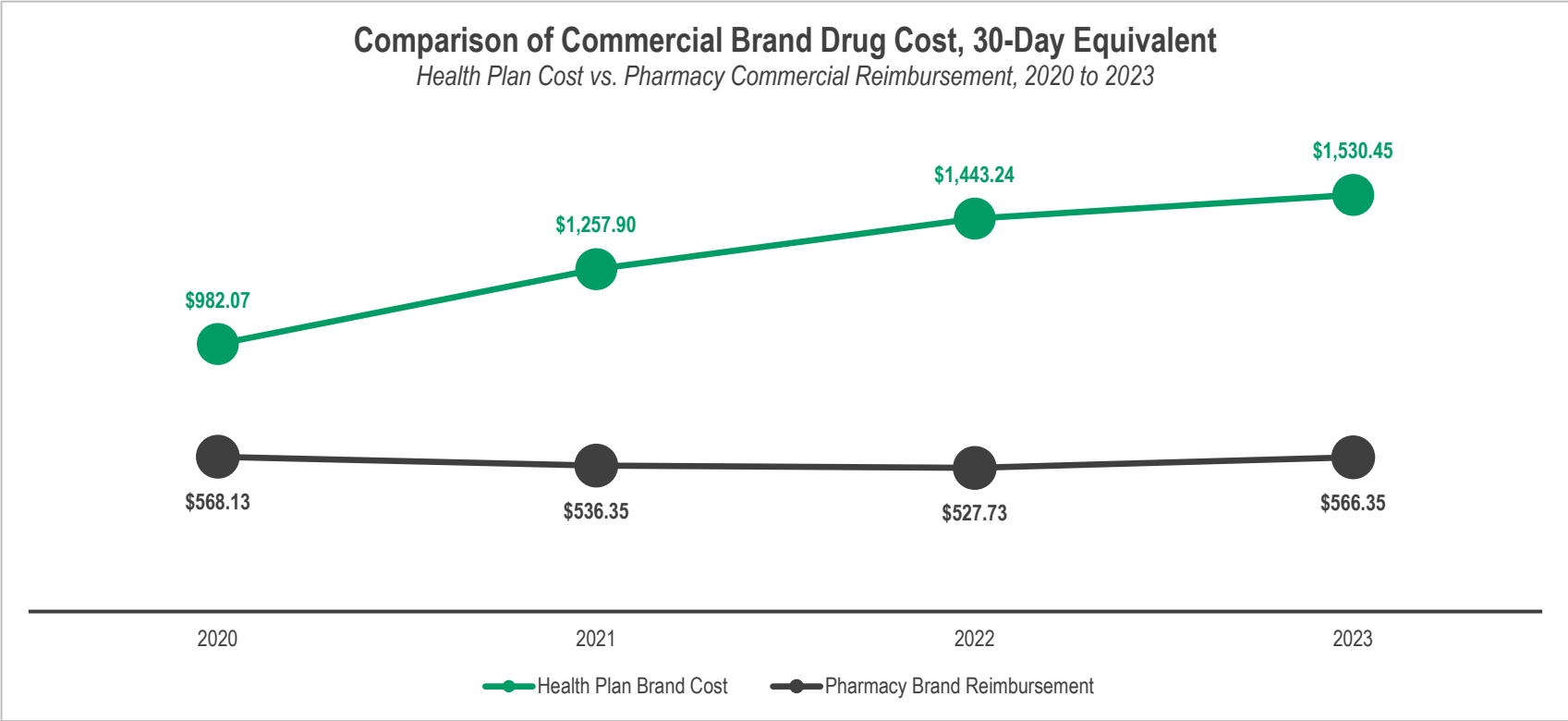
Overall commercial cost trends

- ▶ Plan sponsor costs increased 30% over the four-year period.
- ▶ Pharmacy reimbursement decreased by 3% over the same timeframe.



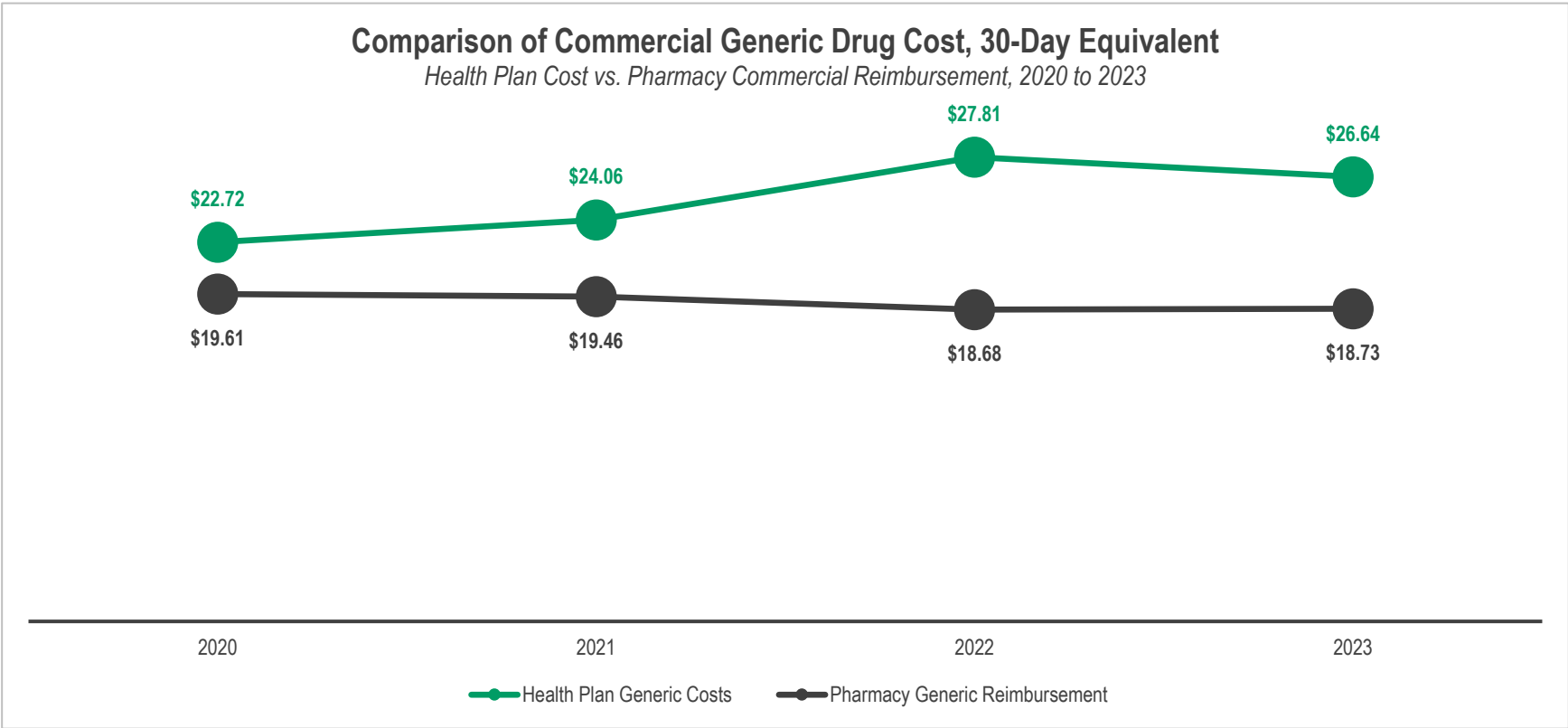
Comparison of Washington commercial brand drug costs, 2020-2023

- ▶ Health plan sponsors saw a \$548.38 increase in brand drug costs (55% increase)
- ▶ Meanwhile, pharmacies received \$1.78 less for brand drugs (0% decrease)



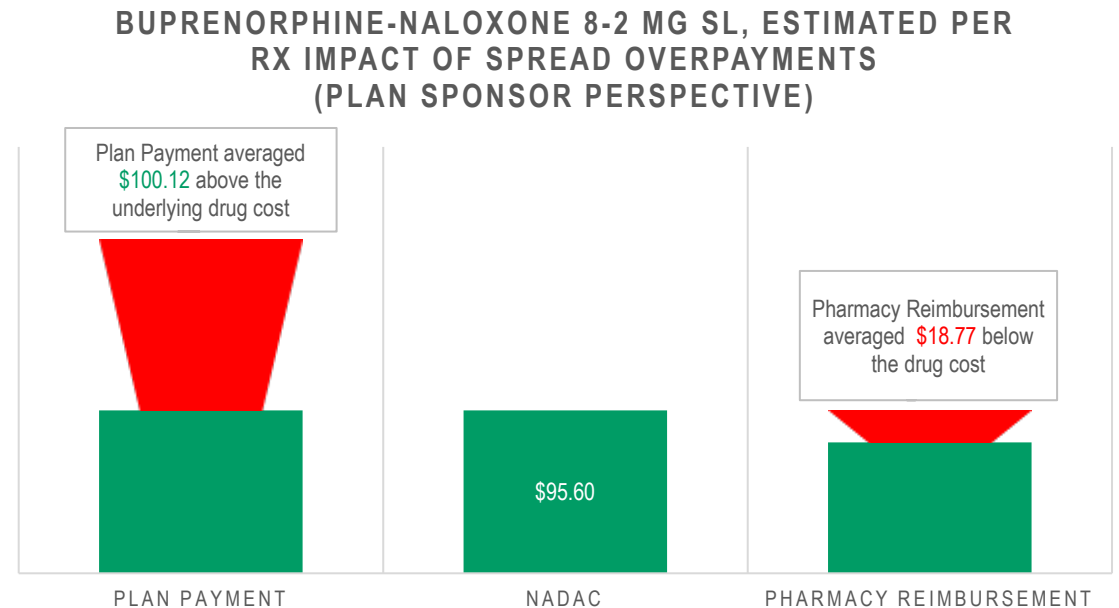
Comparison of Washington commercial generic drug costs, 2020-2023

- ▶ Health plan sponsors saw a \$3.92 increase in generic drug costs (17% increase)
- ▶ Meanwhile, pharmacies received \$0.88 less for generic drugs (4% decrease)



Spread pricing sub-analysis: Buprenorphine-naloxone estimated spread per Rx

- ▶ Certain health plan sponsors were billed \$195.73 per generic Suboxone (buprenorphine-naloxone) 8-2 MG SL prescription, equivalent to a \$100.12 health plan cost over NADAC, but adjudicated rates from matched billings from the pharmacy claims data suggest pharmacies are receiving on average of \$76.84 in reimbursement per prescription for the same claim (or -\$18.77 below NADAC).



HB 228: Task Force for the Regulation of Psychedelic Medicines

- Law named AKPhA Board to select a pharmacist representative

Agenda Item #9 Division Updates Continued

- Melissa Dumas, Administrative Operations Manager
 - Budget Report for 4th Quarter Fiscal Year 2024 was provided to the board.
 - The fee change process was explained to the board.
 - Melissa Dumas stated the public comment process is where the board can provide input on proposed fee changes.
 - Michael Bowles stated fee changes fall under the division director and not the board according to the centralized licensing regulations.

Agenda Item #10 Adjourn for Lunch (off record at 12:25pm)

Ashley Schaber made a motion to adjourn for lunch and asked for unanimous consent.

Recorded Votes:

Unanimous consent.

It was resolved to adjourn for lunch.

Agenda Item #11 Roll Call/Call to Order (on record at 1:01pm)

Roll Call:

Ashley Schaber - Present
Sara Rasmussen - Absent
James Henderson - Present
Carla Hebert - Present
Ramsey Bell – Present
Sylvain Nouvion – Present
Dylan Sanders – Present

Quorum was met.

Agenda Item #12 Statutes Discussion

- Ashley Schaber discussed the current statute change concepts the board is pursuing during the upcoming legislative session.
- Ashley Schaber stated she is working with the legislature to find a sponsor for a legislative bill. Representative Justin Ruffridge who was previously a member of the board is in support of the statute change concepts.
- Ashley Schaber asked the board if there was any opposition to her working with other boards. No opposition.
- The concept of addressing sterile compounding came from the Med Spa Workgroup.
- James Henderson stated the discussion for the board is built around the IV hydration clinics that are providing on demand services. The discussion centers around keeping that industry safe and regulating “immediate use” products came into discussion. The current definitions in statute are not sufficient in addressing immediate use products such as IV bags.
- Ashley Schaber asked if the goal was to provide definition for other boards or the board of pharmacy.
- James Henderson and Dylan Sanders stated the goal is to achieve guidance for other boards.
- Ashley Schaber stated the board of pharmacy has recently made regulations changes to address sterile compounding in terms of standard of care.

Agenda Item #13 Public Comment Period

Discussion:

- No public comments received during this time.

Agenda Item #14 Board Business Continued

- Upcoming Conference Attendee Discussion
 - NABP Member Forum, Mount Prospect, Il - December 04-05, 2024
 - Attending Member – Ramsey Bell
 - AKPhA Annual Meeting, Anchorage, AK – February 14-16, 2025
 - Executive Administrator – Michael Bowles
 - Attending Member – Carla Hebert
 - Board of Pharmacy presentation will be provided by Carla Hebert.
 - NABP Committee on Law Enforcement/Legislation, Mount Prospect, Il – March 03-04, 2025
 - Executive Administrator – Michael Bowles
 - Rx and Illicit Drug Summit – Nashville, TN- April 21-24, 2025
 - PDMP Manager – Lisa Sherrell
 - Chief Investigator – Erika Prieksat
 - Executive Administrator – Michael Bowles
 - NABP Annual Meeting, Ft. Lauderdale, FL – May 13-16, 2025
 - Executive Administrator – Michael Bowles
 - Attending Member – Sylvain Nouvion
- Review Strategic Plan and Discuss Prioritization Matrix
 - Ashley Schaber stated the board should filter all decisions through the strategic plan and think about changes members would like to see.
 - February or April meeting will be the update to the 2025 strategic plan.
 - Ashley Schaber discussed the “priority matrix” received at the board chairperson meeting held by Sara Chambers.
 - Ashley Schaber asked the board to review the 2024 annual report and consider areas in the section “New/Continued Initiatives”.
 - The board reviewed the ongoing tasks list.
 - Michael Bowles discussed the meeting he had with the investigations team and the conclusion that there is nothing in regulation that outlines what an effective Continuous Quality Improvement (CQI) program is.
 - Carla Hebert discussed the CQI FAQs she created for the board and how they can be used in the regulatory process.

Ashley Schaber requested a 10-minute break.

Off record at 2:20pm


On record at 2:35pm

- Standard of Care Model Presentation
 - Guest Speaker, Jennifer Adams, PharmD, Idaho State University
 - Provided her background and experience with standard of care regulatory models.
 - Provided the board with a presentation on standard of care.

How to Implement a Standard of Care Regulatory Model



Jennifer L. Adams, PharmD, EdD, FAPhA, FNAP
Associate Dean for Academic Affairs,
Associate Professor
Idaho State University/ University of Alaska Anchorage
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Executive Director
Alaska Pharmacy Association

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Recent Rule Changes for AK

OPTION B

Article 11 General Provisions

12 AAC 52. 995 DEFINITIONS

(44) “standard of care” means care provided by a licensee that is within the accepted standard of care that would be provided in a similar setting by a reasonable and prudent licensee or registrant with similar education, training, and experience.



Recent Rule Changes for AK

Article 10 Alaska Disciplinary Guidelines

12 AAC 52.920 Disciplinary Guidelines

~~(15) failing to use reasonable knowledge, skills or judgment in the practice of pharmacy~~

Acts or omissions within the practice of pharmacy which fail to meet the standard of care;



Recent Rule Changes for AK

12 AAC 52. 205 GENERAL STANDARDS OF PHARMACY PRACTICE

(a) To determine whether a specific act is within the scope of pharmacy practice in or into the state, or whether an act can be delegated to other individuals under a licensee's supervision, the licensee must independently determine whether the act is:

(1) expressly prohibited by:

A. this chapter; or

b. any applicable state or federal laws;

(2) consistent with licensee or registrant's education, training, and experience; and

(3) within the accepted standard of care that would be provided in a similar setting by a reasonable and prudent licensee or registrant with similar education, training, and experience.

(b) The pharmacist-in-charge shall make necessary changes or improvements to ensure patient safety and employee wellness in a pharmacy, as part of a continuous quality improvement program for pharmacy services.



How to Adopt a Standard of Care Regulatory Model

- ✓ Define standard of care in regulation
 - ✓ Add standard of care to unprofessional conduct in regulation
 - ✓ Adopt a general approach to the practice of pharmacy that allows for delegation based on standard of care
-
- Can be done in regulation because boards have authority to discipline
 - Can also be done in statute (or later moved to statute)



How to Implement a Standard of Care Regulatory Model

1

Adopt a Broad Definition of "Practice of Pharmacy"

2

Allow Elasticity for Scope of Practice Advancement Over Time

3

Decide Which Limited Instances Still Necessitate Prescriptive Regulation

4

Eliminate All Remaining Unnecessary Regulations

5

Strengthen Accountability Mechanisms and Oversight




1. Adopt a Broad Definition of “Practice of Pharmacy”

- Every state has a definition, typically in the “Pharmacy Practice Act”
- It is imperative that this definition be broad and allow for full scope of practice including medication administration, prescribing, laboratory tests, and disease management.
- Idaho has, over time, refined its definition to:
54.1705(46) “Practice of pharmacy” means the safe interpretation, evaluation, compounding, administration, and dispensing of prescription drug orders, patient counseling, collaborative pharmacy practice, provision of pharmaceutical care services, proper storage of drugs and devices, and prescribing of drugs and devices as may be further defined in this chapter.
- This definition is the necessary precursor to pharmacists being able to practice at the top of their education and training, not at the bottom of what their license allows.
- **AK next step suggestions:** New beginning of Article 5? Expand on the general approach?



2. Allow Elasticity for Scope Advancement Over Time

- To provide flexibility for pharmacy practice advancements, a board of pharmacy must establish laws allowing the individual licensee to determine if a specific act is within the defined scope of pharmacy practice.
 1. Is the act expressly prohibited?
 2. Is the act consistent with licensee education, training, and experience?
 3. Does performing this act fall within the accepted standard of care that would be provided in a similar setting by another licensed individual with the same education, training, and experience?
- The elastic clause also applies to which tasks can be delegated to other individuals, such as pharmacy interns or pharmacy technicians.
- **AK next step suggestions:** 



3. Decide Instances that Require Prescriptive Regulation

- While it is essential to identify instances where prescriptive regulations are still necessary, the inclusion of waivers in law provide a mechanism to bypass certain regulations, fostering innovation without compromising public safety.
- **AK next step suggestions:** review any specific training requirements for advanced scope activities for removal, review facility requirements to see what can be general and what might need specifics




4. Eliminate Unnecessary Regulation

- Eliminating unnecessary regulations or those incompatible with a standard of care regulatory model allows for streamlining tasks.
- If the purpose behind a regulation is unclear and its purpose cannot be readily described, it should be deemed unnecessary until proven otherwise.
- **AK next step suggestions:** consider a full statute and regulation review using these criteria



5. Strengthen Accountability Mechanisms & Oversight

- Though implementation of this model enables the utilization of pharmacists to enhance public health without constant legislative battles, regulations regarding unprofessional conduct are necessary to bring discipline against any licensee for violating the standard of care.
 - IDAPA 24.36.01.104.16 Standard of Care. Acts of omissions within the practice of pharmacy which fail to meet the standard provided by other qualified licensees or registrants in the same or similar setting.
 - **AK next step suggestions:** 



5. Strengthen Accountability Mechanisms & Oversight

- **AK next step suggestions:** Are there general guidelines for advanced scope of practice activities that might be helpful?

IDAPA 24.36.01.350 PHARMACIST PRESCRIBING: GENERAL REQUIREMENTS.

01. Education....

02. Patient-Prescriber Relationship.....

03. Patient Assessment....

04. Collaboration with Other Health Care Professionals....

05. Documentation.....

06. Prescribing Exemption....



Conclusion

- A standard of care regulatory model empowers pharmacists by regulating them similarly to other health professions such as nursing and medicine, providing regulatory consistency across the health care system.
- The incorporation of a standard of care regulatory model into pharmacy practice regulation presents an exciting opportunity to leverage pharmacists' clinical ability in safeguarding public health through patient access to quality care.




References

1. Adams JL, O'Connor S, Seignemartin B, Shipman AJ, McConnell W, Dudman A, Akers J, Vernon V. Battling professional self-sabotage: Embracing standard of care as the future of pharmacy regulation. *J Am Pharm Assoc.* 2023. DOI: <https://doi.org/10.1016/j.japh.2023.08.015>.
2. Adams, AJ. 2019. Transitioning pharmacy to “standard of care” regulation: Analyzing how pharmacy regulates relative to medicine and nursing. *Res Social Adm Pharm.*
<https://www.sciencedirect.com/science/article/abs/pii/S155174111830562X?via%3Dihub>
3. Adams AJ, Chopski NL, Adams JL. How to implement a standard of care regulatory model for pharmacists. *J Am Pharm Assoc.* 2024. DOI: <https://doi.org/10.1016/j.japh.2024.02.007>.
4. Cornell Law School Legal Information Institute https://www.law.cornell.edu/wex/bright-line_rule
5. Burns A. 2018. What is the Pharmacists Patient Care Process and why is it important? *Pharmacy Today.*
[https://www.pharmacytoday.org/article/S1042-0991\(18\)30492-4/fulltext](https://www.pharmacytoday.org/article/S1042-0991(18)30492-4/fulltext)
6. Adams AJ, Weaver KK. 2019. Pharmacists’ Patient Care Process: A State “Scope of Practice” Perspective. *Innovations in pharmacy*, Vol. 10, No. 2. <https://pubs.lib.umn.edu/index.php/innovations/article/view/1389/1485>
7. Adams AJ, Weaver KK, Adams JL. 2023. Revisiting the Continuum of Pharmacist Prescriptive Authority. *JAPhA.* 63(2023) 1508-1514 [https://www.japha.org/article/S1544-3191\(23\)00238-8/fulltext](https://www.japha.org/article/S1544-3191(23)00238-8/fulltext)
8. Adams, AJ., Frost TP, and Weaver KK. 2021. Pharmacy Regulatory Innovation Index: Benchmarking the regulatory environment in 10 western states. *Journal of the American Pharmacists Association*
<https://www.sciencedirect.com/science/article/abs/pii/S1544319121001850>
9. Shakya, Shishir and Plemmons, Alicia and Bae, Kihwan and Timmons, Edward, The Pharmacist Will See You Now: Pharmacist Prescriptive Authority and Access to Care in Idaho (December 6, 2022). Available at SSRN: <https://ssrn.com/abstract=4294905> or <http://dx.doi.org/10.2139/ssrn.4294905>
10. Carmichael JM, et al. Collaborative Drug Therapy Management by Pharmacists. *Pharmacotherapy.* 1997;17(5):1050-1061.

How to Implement a Standard of Care Regulatory Model



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Standard of Care – Implementing, Inspecting & Investigating

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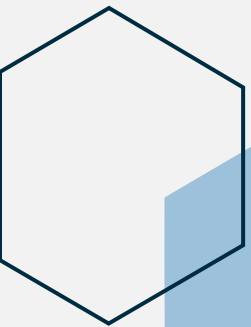


Objectives

Describe roles of the pharmacist that evolved from the switch to standard of care model of regulation.

Examine the impact of standard of care model on the inspection process

Discuss the investigation process under the model of standard of care



Established Pharmacist Services

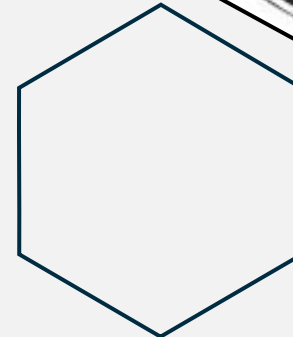
Settings Include:

Telehealth

Community

Primary care

Health System



Case 1: Telehealth Clinic

A 37-year-old female patient

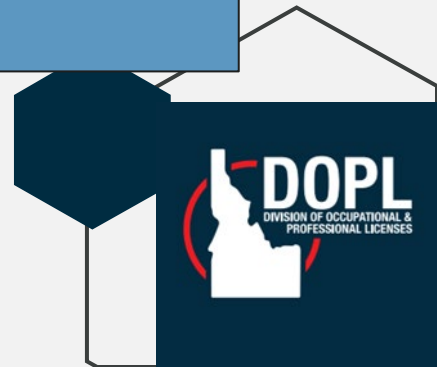
PMHx: significant for primary hypothyroidism and major depression

CC: Visiting Idaho with her spouse for a concert and forgot her regular medications at home.

Med List: Usual regimen levothyroxine 88 mcg QAM, and Bupropion SR 150 mg BID. Her last dose of each medication was this morning.

Her regular pharmacy is an independent pharmacy in her home state that does not have a location in Idaho and is closed for the day. The patient schedules a virtual visit with an independent Idaho licensed pharmacist who operates a telehealth practice. The pharmacist conducts a real time telephone visit with the patient including a clinical interview.

After assessing the patient, the pharmacist determines that there are no contraindications to continuing therapy and prescribes a 1-month refill of each medication without dose change and instructs the patient to follow up with their primary team. The pharmacist has practice experience and education with both disease states. The practice does not have a drug outlet license.



Case 1: Telehealth Clinic

Which of the following is true?

- A. The pharmacist cannot provide pharmaceutical care services outside of a licensed drug outlet
- B. The pharmacist cannot prescribe a medicine based off of a telehealth encounter
- C. The pharmacist cannot treat a patient who does not live in Idaho
- D. The pharmacist established a patient practitioner relationship appropriate for issuing a one-time refill via telehealth.



Case 2: Community Pharmacy

- A patient presents to their community pharmacy and asks the pharmacist if phenazopyridine will interact with their regular medications.
- The pharmacy provides some acute care services, including treating simple urinary tract infections, and the pharmacist offers to conduct a medical visit with the patient. Upon patient consent and confirmation of insurance, the pharmacist conducts a clinical interview and a limited exam and a CLIA waived urine dipstick and assesses the patient as having a simple UTI without contraindication for treatment with standard of care nitrofurantoin.
- The pharmacist prescribes a 5 day course of nitrofurantoin macrocrystals 100 mg BID x 5 days and provides instructions on the safe use of phenazopyridine OTC as well as monitoring and follow-up instructions.
- The pharmacy has a CLIA waiver and an Idaho drug outlet license, and the pharmacist is licensed in Idaho.

Case 2: Community Pharmacy

- Which of the following is true?
 - A. The pharmacist can only prescribe the nitrofurantoin after a non-pharmacist provider diagnoses the patient with a UTI
 - B. The pharmacist may only prescribe the nitrofurantoin if assessment and treatment of UTIs is within their individual education, training and experience and they are following the community standard of care.
 - C. The pharmacist can not prescribe nitrofurantoin unless they have completed at least a PGY-1 residency or are a Board Certified Ambulatory Care Pharmacist.
 - D. The pharmacist can not order perform and interpret a urine dipstick test

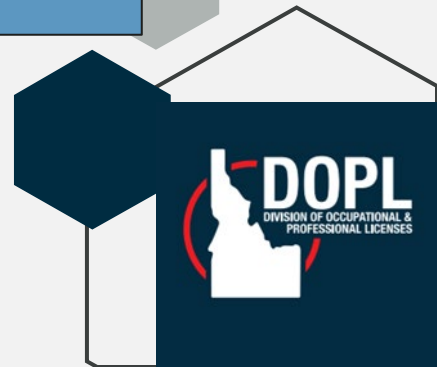
Case 3: Primary Care Clinic

A primary care clinic embedded clinical pharmacist provides post diagnostic care for common primary care medical conditions as part of a multidisciplinary care team.

A female patient of reproductive age who was referred to the pharmacist for diabetes management mentions during an encounter that they are concerned about potential unintended pregnancy while struggling to control their blood sugar levels.

After discussing the risks and benefits of available options, the patient opts for medroxyprogesterone injections. The pharmacist orders a pregnancy test that is performed by clinic laboratory staff, and upon negative results, orders and personally administers medroxyprogesterone from the clinic supply.

The pharmacist is licensed in Idaho and the clinic does not have a drug outlet license. The clinic's lab services fall under the supervision of the Medical Director and are properly licensed and registered.



Case 3: Primary Care Clinic

Which of the following is true?

- A. The pharmacist can order medroxyprogesterone if permitted by clinic policy and privileging but may not administer the medroxyprogesterone in a clinic without a drug outlet license.
- B. The pharmacist can both order and administer a medication in the clinic if permitted by clinic policy and privileging
- C. The pharmacist cannot order a laboratory test that is performed by non-pharmacy staff
- D. The pharmacist can neither order nor administer medroxyprogesterone in a clinic without a drug outlet license



Inspections:

- Data collectors guided by statute and regulation
- Pictures say a thousand words
- Consistent approach
- Supervisor/Chief Investigator reviews inspections
- Board has final determination of violation and subsequent sanction



DRUG OUTLETS: MINIMUM FACILITY STANDARDS

- A resident drug outlet that dispenses prescription drugs to patients in Idaho must meet the following minimum requirements:
 - **01. Security and Privacy.** A drug outlet must be constructed and equipped with adequate security to protect its equipment, records and supply of drugs, devices and other restricted sale items from unauthorized access, acquisition or use. All protected health information must be stored and maintained in accordance with HIPAA.
 - **02. Controlled Substance Storage.** Drug outlets must store controlled substances in accordance with federal law.
 - **03. Authorized Access to the Restricted Drug Storage Area.** Access to the restricted drug storage area must be limited to authorized personnel.
 - **04. Staffing.** A drug outlet must be staffed sufficiently to allow for appropriate supervision, to otherwise operate safely and, if applicable, to remain open during the hours posted as open to the public for business.

Investigations:

- Complaint Based
- Data collectors guided by statute and regulation
- Consistent approach
- Supervisor/Chief Investigator reviews investigations
- Board has final determination of violation and subsequent sanction



Case 1: Community Pharmacy Prescribing

- Complaint: Pharmacist did not meet the standard of care in treating a patient for influenza
- Investigation found:
 - No assessment completed (no documented flu test)
 - No documentation (prescription record, PCP notification, or follow-up)
 - No label on medication
 - No payment

PHARMACIST PRESCRIBING: GENERAL REQUIREMENTS (IDAPA 24.36.01.350)

- **01. Education.** Only prescribe drugs or devices for conditions for which the pharmacist is educationally prepared and for which competence has been achieved and maintained.
- **02. Patient-Prescriber Relationship.** Only issue a prescription for a legitimate medical purpose arising from a patient-prescriber relationship as defined in Section 54-1733, Idaho Code.
- **03. Patient Assessment.** Obtain adequate information about the patient's health status to make appropriate decisions based on the applicable standard of care and the best available evidence.
- **04. Collaboration with Other Health Care Professionals.** Recognize the limits of the pharmacist's own knowledge and experience and consult with and refer to other health care professionals as appropriate.
- **05. Documentation.** Maintain documentation adequate to justify the care provided including, but not limited to, the information collected as part of the patient assessment, the prescription record, provider notification, and the follow-up care plan.

Case 2: Clinic Prescribing

- Complaint: Pt wife alleges provider did not manage her husband's prescription in a safe manner.
- Investigation found:
 - Respondent had seen patient three times between 2014-16
 - Respondent prescribed Ambien once in 2014 & Norco once in 2016
 - Patient sees another community provider for pain management
 - Respondent explained progress notes are typed from his handwritten notes due to difficult to read handwriting
 - Progress notes were initialed by respondent

BOM Standard of Care (Idaho Code 54-1814(7)):

- It is **grounds for medical discipline for a physician or physician assistant to provide health care that fails to meet the standard of health care** provided by other qualified physicians or physician assistants **in the same community** or similar communities....



Thank You!

What questions do you have for me?

Nicki Chopski, PharmD, ANP

(208) 803-5982

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- Guest Speaker, Nicki Chopski, PharmD, Idaho Board of Pharmacy
 - Provided her background and experience with standard of care regulatory models.
 - Provided the board with a presentation on standard of care.
- Task for Michael Bowles to reach out to the Executive Administrators for the board of nursing and medical board and discuss standard of care model regulatory guidelines.
- Regulations Discussion
 - Ashley Schaber discussed the items covered at the statute and regulation committee meeting conducted on October 10, 2024.
 - PDMP registration was discussed by the board and whether it should be approached through a standard of care perspective.
 - Task for Michael Bowles to meet with Lisa Sherrell and discuss the board's perspective of looking at PDMP from a standard of care model and provide guidance on regulation changes that may be needed.
- Tasks List Review and Update
 - Task created for Michael Bowles to post the CQI FAQs to the website.
 - Task created for Michael Bowles to write draft language to address license requirement for changes to ownership, and physical location.
 - Task created for all board members to review the statute and regulations to work on standard of care regulatory language changes.

Motion: Ashley Schaber moved to repeal 12 AAC 52.100(a)(6), seconded by Carla Hebert.

Recorded Votes:

Ashley Schaber - Yes

Sara Rasmussen -

James Henderson - Yes

Carla Hebert - Yes

Ramsey Bell – Yes

Sylvain Nouvion – Yes

Dylan Sanders – Yes

It was resolved to repeal 12 AAC 52.100(a)(6).

Motion: Carla Hebert moved to repeal 12 AAC 52.100(a)(4), seconded by James Henderson. Carla Hebert requested unanimous consent.

Recorded Votes:

Unanimous consent.

It was resolved to repeal 12 AAC 52.100(a)(4).

Motion: James Henderson moved to approve the regulation change concept of requiring an updated home license along with written notifications of changes to physical address, name, and ownership, seconded by Ashley Schaber. James Henderson requested unanimous consent.

Recorded Votes:

Unanimous consent.

It was resolved to approve the regulation change concept of requiring an updated home license along with written notifications of changes to physical address, name, and ownership.

Agenda Item #15 Chair Final Comments

Discussion:

- Next Quarterly Meeting – February 20, 2025
- May 22, 2025, is the following meeting
- Ashley Schaber requested members complete meeting evaluations and provide feedback.

Agenda Item #16 Adjourn

Ashley Schaber moved to adjourn the meeting, asked for unanimous consent. Seconded by Carla Hebert.

Recorded Votes:

Unanimous consent.

It was resolved to adjourn at 5:00pm.