

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing

Alaska Board of Pharmacy

MINUTES OF THE MEETING

May 20 - 21, 2021 Videoconference

By authority of AS 08.01.070(2), and in compliance with the provisions of AS 44.62, Article 6, a scheduled meeting of the Board of Pharmacy via videoconference on May 20-21, 2021. Due to the COVID-19 pandemic, in-person attendance was not available.

Agenda Item 1 Call to Order/Roll Call

Time: 9:04 a.m.

The day 1, **May 20, 2021** videoconference was called to order by Chair, Rich Holt at 9:04 a.m.

Board members present, constituting a quorum:

Richard Holt, PharmD #PHAP2008, MBA – *Chair*
Leif Holm, PharmD #PHAP1606 – *Vice Chair*
Lana Bell, RPh #PHAP893
Tammy Lindemuth, Public Member (joined at 2:15 p.m.)
James Henderson, RPh #PHAP1683 (joined at 9:25 a.m.)
Justin Ruffridge, #PHAP1787

Division staff present:

Laura Carrillo, Executive Administrator
Lisa Sherrell, PDMP Manager
Heather Noe, Occupational Licensing Examiner
Bethany Carlile, Occupational Licensing Examiner
Greg Francois, Chief Investigator
Sonia Lipker, Lead Investigator
Michael Bowles, Investigator III
Sharon Walsh, Deputy Director

Members from the public present/registered:

Jennifer Schneider, State License Servicing
Sam Curtis, DEA
Thomas Olsen, DEA
Dan Nelson
Lauren Paul, CVS Health
Charles Semling, DHSS
Ashley Schaber, Alaska Pharmacists Association/Alaska Native Medical Center
Lorri Walmsley, Walgreens
Caren Robinson, AkPhA
Jennifer Adams, ISU
Brenda Walker, VA
Molly Gray, Alaska Pharmacists Association
Loren Breen, APG
Cheryl Williams, UBC Pharmacy
Wilson Echin, SPP
Gail Elliott, Kaiser Permanente
Kendra Croker, Cardinal Health

Agenda Item 2 Review/Approve Agenda

Time: 9:05 a.m.

Chair Holt verbally reviewed the agenda for the board and public. Ms. Carrillo clarified that Marilyn Zimmerman, the division's paralegal, would be presenting a matter to the board during Agenda Item #6 after Investigator Bowles' update. Agent Olson would also be joining the board for the Drug Enforcement Administration (DEA) update under Agenda Item #7. Ms. Carrillo also added that the official letter from Dr. Schaber on behalf of the AKPhA regarding white bagging had also been received and added to the Onboard packet for Agenda Item #10, but was not reflected in the public version already published. A slide deck from Melissa DeNoon with the South Dakota PDMP was also added to correspondence for discussion around drug takeback programs.

On a motion duly made by Lana Bell to approve the meeting agenda, seconded by Justin Ruffridge, and approved unanimously, it was:

RESOLVED to accept the May 20, 2021 meeting agenda as written.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt	x			
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth				x
James Henderson				x

Sharon Long	x
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The motion passed with no further discussion.

Agenda Item 3 Ethics Time: 9:09 a.m.

There were no ethics to report; however, Chair Holt reminded the board and the public that he currently participates in the biweekly healthcare board chairs meeting as well as the biweekly PDMP board chairs meeting.

Agenda Item 4 Review/Approve Meeting Minutes Time: 9:10 a.m.

The board reviewed the February 18 and 19, 2021 draft meeting minutes.

Sonia Lipker joined the room at 9:10 a.m.

Greg Francois joined the room at 9:11 a.m.

On a motion duly made by Lana Bell to approve the meeting agenda, seconded by Justin, and approved unanimously, it was:

RESOLVED to approve the February 18 - 19 meeting minutes as written.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt	x			
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth				x
James Henderson				x
Sharon Long				x

The motion passed with no further discussion.

TASK 1

Ms. Carrillo will send the minutes to Chair Holt for signature and request they be published to the board's meeting page.

Agenda Item 6 PDMP Update Time: 9:14 a.m.

James Henderson entered the room at 9:25 a.m.

PDMP – Pharmacy Report

Ms. Sherrell provided the board's report. Updates included the new contract with Appriss Health starting on April 1st and the re-launch of the license integration project on June 15th. Ms. Sherrell stated updates to the user manual would be posted soon, which will include instructions on new features implemented as a result of the new contract. Ms. Sherrell reminded the board that the license integration project will assess for discrepancies between the licensing system and the PDMP platform, AWARe, and will deactivate accounts where there are discrepancies with license #s, license status, and name. New license types had been created during the pandemic, so the file transfer list needs to be updated accordingly. According to the list now, there are about 156 pharmacists that would be deactivated.

As of now, there are 1,082 licensed pharmacist, 736 are registered, and only 716 are directly dispensing. Ms. Sherrell explained the breakdown by role, e.g.: pharmacist, pharmacist-in-charge, IHS dispenser, and VA dispenser. Ms. Sherrell then provided an update on delinquent reporters. The April analysis revealed 17 pharmacies as being delinquent for the first time; letters were sent to all and 10 had returned responses.

Ms. Sherrell reviewed recommendations to prescribing boards, such as using delegates to maximize PDMP use and providing guidance to licensees on judicious prescribing practices and dangerous combinations. The annual Awareness and Feedback questionnaire will be launched this summer, which will help us understand apprehension of usage and provide insight into topics to include in education and outreach. Ms. Sherrell shared that she participated in training with a dentist who provided valuable feedback on their interactions with the PDMP; this provided an opportunity to educate the provider on how to submit a UCF report and how to submit zero reports. Ms. Sherrell stated that in-person education and outreach will start in Juneau with pharmacies and expand to other providers throughout Alaska. Chair Holt expressed that in-person is preferable and more effective, but that logistically, the state may not approve travel. Ms. Sherrell stated there are rollover funds from the previous year to use for education and outreach travel purposes.

Forthcoming updates to the system include a delinquent reporting communications module to notify providers when they had missed a reporting day. Dr. Holm asked about the timeline of the launch, expressing it will be helpful in reducing the number of missed days. Ms. Sherrell stated there are some issues with reporting submission settings that may create false alarm flags of delinquency. For example, a pharmacy may be reporting consistently at 10:00 p.m. and have a system update that causes the report to transmit at 10:15 p.m., which would trigger a delinquent notice. This was an issue with another rollout state that has since been corrected with another state, but there was another issue with delivery language in messaging.

It was also explained that clean-up with prescribing boards also needed to be done because prescribers indicated on their renewals that they were directly dispensing (and therefore required to report), when they weren't actually dispensing. The board of nursing sent a notice to its licensees to clarify dispensing status, and nearly half of them indicated it was an inadvertent

mistake. Time is needed to clean up our dispenser/reporter list so those who are not truly dispensing will not receive delinquent notices.

Ms. Gray expressed the report was informative and suggested similar reports be shared with other boards and associations to facilitate connectedness of information. Ms. Sherrell stated there are similar board reports issued to prescribing boards.

About the provider outlier module, Chair Holt inquired whether reports are sent to the provider or to the board, to which Ms. Sherrell clarified it is visible administratively for analysis only. The function will also include the ability to see distances traveled for medications, which may indicate doctor shopping.

Resources

Ms. Carrillo provided a refresher of resources found on the state website, pdmp.alaska.gov, including where to access the data dispensing submission form and a zero-reporting video. Ms. Carrillo reminded the board that zero reporting can only be done via ClearingHouse and stated the user manuals would be updated and posted soon to reflect add-ons as a result of the new contract.

Agenda Item 6 Investigative Update

Time: 9:42 a.m.

Investigator Bowles presented the board's report which included activity from February 5th through May 6th. There are 33 open cases and 4 have closed.

Investigator Bowles addressed the recusal document sent to board members and stated that in cases where the matter may advance to a hearing, the board needs to make sure there is no possibility of bias or sway by a reviewing board member for a proposed disciplinary action. Dr. Holm inquired whether board members are allowed to be present for discussion, to which Investigator Bowles affirmed. Chair Holt inquired whether it is an absolute requirement that reviewing board members must recuse themselves from voting because the document from Director Chambers states it is still possible to vote. Chair Holt's understanding is that the reviewing board member can put on record to request to recuse themselves, but that as Chair, he could decline the request. Investigator Bowles highly recommended recusals not be denied. Dr. Ruffridge agreed, stating reviewing board members should be able to vote on a matter if they are already providing a recommendation to the board.

On a motion duly made by Lana Bell in accordance with AS 44.62.310(c)(2), seconded by James Henderson and with unanimous approval, 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.
RESOLVED to enter into executive session in accordance with AS 44.62.310(c)(2).

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			

Richard Holt	x		
Justin Ruffridge	x		
Lana Bell	x		
Tammy Lindemuth			x
James Henderson	x		
Sharon Long			x

The motion passed with no further discussion.

Off record for executive session at 9: 57 a.m.

On record from executive session at 10:32 a.m.

Upon return from the executive session, Chair Holt clarified no motions were made under executive session.

On a motion duly made by Lana Bell to approve the imposition of civil fine in the amount of \$1,000.00 for case #2020-000886, seconded by Justin Ruffridge and approved by the board with one recusal, it was:

RESOLVED to approve the imposition of civil fine for case #2020-000886.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt	x			
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth				x
James Henderson			x	
Sharon Long				x

The motion passed with no further discussion.

On a motion duly made by Lana Bell to approve the voluntary pharmacy technician license surrender for case #2021-000085, seconded by Justin Ruffridge and approved unanimously, it was:

RESOLVED to accept the voluntary pharmacy technician license surrender for case #2021-000085.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			

Richard Holt	x	
Justin Ruffridge	x	
Lana Bell	x	
Tammy Lindemuth		x
James Henderson	x	
Sharon Long		x

The motion passed with no further discussion.

On a motion duly made by Lana Bell to approve the imposition of civil fine in the amount of \$250.00 for case #2020-000360, seconded by Justin Ruffridge and approved by the board with one recusal, it was:

RESOLVED to approve the imposition of civil fine for case #2020-000360.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt			x	
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth				x
James Henderson	x			
Sharon Long				x

The motion passed with no further discussion.

On a motion duly made by Lana Bell to approve the imposition of civil fine in the amount of \$500.00 for case #2020-001064, seconded by Justin Ruffridge and approved by the board with one recusal, it was:

RESOLVED to approve the imposition of civil fine for case #2020-001064.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm			x	
Richard Holt	x			
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth				x
James Henderson	x			
Sharon Long				x

The motion passed with no further discussion.

On a motion duly made by Lana Bell to approve the imposition of civil fine in the amount of \$250.00 for case #2020-000359, seconded by Justin Ruffridge and approved by the board with one recusal, it was:

RESOLVED to approve the imposition of civil fine for case #2020-001064.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm			x	
Richard Holt	x			
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth				x
James Henderson	x			
Sharon Long				x

The motion passed with no further discussion.

On a motion duly made by Rich Holt to approve the imposition of civil fine in the amount of \$250.00 for case #2020-000602, seconded by Lana Bell and approved by the board with one recusal, it was:

RESOLVED to approve the imposition of civil fine for case #2020-001064.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt	x			
Justin Ruffridge			x	
Lana Bell	x			
Tammy Lindemuth				x
James Henderson	x			
Sharon Long				x

The motion passed with no further discussion.

TASK 2

Ms. Carrillo will send the signed imposition of civil fine and voluntary license surrender documents to Chair Holt for his signature then forward the signed documents to Investigator Bowles.

Agenda Item 7 DEA Update

Time: 10:45 a.m.

Ms. Carrillo welcomed the DEA officials, Thomas Olsen, tactical diversion group supervisor and Samuel Curtis, Investigative Analyst. Agent Olsen stated agent Pitt was unable to make the meeting.

Agent Olson shared that the Tactical Diversion Squad, which has been in place since 2016, is identifying problematic prescribing practices in a collaborative effort with the PDMP and division investigators to combat the opioid epidemic. Over the years, the team has identified offenders prescribing high amounts of opioids resulting in adverse outcomes within communities.

Samuel Curtis highlighted that in analyzing mechanisms by which practitioners write prescriptions, they noticed a trend two years ago where doctors and nurses were writing large amounts of prescriptions for 28 to 30-days at one time, sometimes for a 30 day-supply in 3 separate prescriptions written in 90-day intervals, 4 times per year. More recently; however, Mr. Curtis stated the trend has shifted: prescribers are moving away from high daily limits to smaller prescriptions that pharmacies are comfortable filling. In many cases, practitioners are taking what used to be 30-day prescriptions for oxycodone to now prescribing 40 days-supply within a 7-day period. Now, prescriptions are often being filled 2 days early, for example, 7-day prescriptions are being filled after 5 days.

Mr. Curtis also shared that in reviewing the patterns from PDMP data, they are seeing prescriptions written for varying quantities of days, e.g.: every 28 days, then 23, then 26, then 29, then 30; quantities are continuously. The DEA notes that looking at the quantity of pills is not as valuable anymore as providers seem to be doing the math on prescription days to add more prescriptions. The DEA is also seeing more variation in personal details given, for example, variations of different names and different zip codes to receive oxycodone and methadone. Mr. Curtis expounded on this, offering the example that a prescriber will write a prescription for methadone to Sam Curtis at Walmart using a street address and then write another prescription for oxycodone for Samuel Curtis using the PO box address, which creates a channel for same-day prescribing and patient pick-up before reporting systems are able to update these transactions for visibility into the PDMP until the following day. These smaller prescriptions are ones that pharmacists are comfortable filling without realizing there are more opioid pills being dispensed over the course of a month.

Dr. Holm commented he hadn't filled a methadone prescription in a long time and inquired when this co-prescribing trend started. Mr. Curtis stated this has been an existing trend for some time, that it used to be geographically concentrated in one area of Alaska but it is now more spread out. Chair Holt inquired whether the DEA has presented similar updates to the practitioner boards, to which Mr. Curtis stated they have been. Mr. Curtis stated the trend of breaking up prescriptions into smaller day amounts to give patients higher quantities of opioids for a month is a more recent trend seen in the last two months. Agent Olson stated that as they have had success intervening with the most egregious prescribers, other prescribers engaging in problematic behaviors have

become more sophisticated; it seems there has been communication between the egregious prescribers with other prescribers on how to continue these practices. Agent Olson stated some prescriptions are being consumed and some are being sold on the street.

Dr. Ruffridge stated he has observed a more recent trend of the 7-day fill becoming a requirement from insurance payers or they will not pay for a larger quantity without a prior authorization. Dr. Ruffridge is concerned providers are writing 7-day fills to avoid prior authorization. Prior authorization allows for review of medications commonly abused and the 7-day supply may avoid this. From the payer perspective, Dr. Ruffridge stated that while the intent may be to help, payers may not realize the burden being placed on the enforcement end and on the pharmacists attempting to notice whether this is contributing to a concerning trend. Mr. Curtis stated this trend isn't specific to one insurance program; it is seen across private payers, military, veteran, and CMS programs. Regardless of practitioner or payer type, Mr. Curtis stated across programs, the DEA is estimating that 30-day prescriptions every 28 days amounts to 13 months of prescriptions. The DEA further estimates that up to 22-months of supply days are put into the hands of patients each year with 7 days prescriptions being filled every 5 days.

Chair Holt also suggested to the DEA that they share updates with the AKPhA. Agent Olson shared that they held a program, Practitioner Diversion Awareness Conference (PDAC) to educate pharmacists on DEA trends in the past. The DEA plans to continue to provide this opportunity to providers. Ms. Gray shared that the AKPhA's next annual conference will be held on February 11-13, 2022, which would be a great opportunity to host a PDAC as the association has hosted this program before.

Ms. Carrillo inquired whether these trends are reflective of what the DEA is seeing nationally or if it is specific to Alaska. Mr. Curtis stated the trends are more specific to Alaska, both the co-prescribing of oxycodone and methadone and the shortening of supply days. Data is showing the DEA that these practices are originating from specific geographic locations and are radiating out from there to other providers. Mr. Curtis added these are providers that have been practicing in the state for 20 or more years, so it is believed these practices are purposeful.

Ms. Carrillo also inquired whether the practices are intentionally done with a nefarious motive, or if the issue is more on the patient drug seeking end. Agent Olson stated that based on the level of awareness of the opioid epidemic, it is hard to imagine providers altering their prescribing practices, including creating separate profiles, out of ignorance, that it is intentional. Mr. Curtis added that there seems to be conversations between patients and providers leading to mutual decisions to receiving more prescriptions.

Dr. Holm stated he had to step out at 11:30 a.m.

Agenda Item 8 Public Comment #1

Time: 11:15 a.m.

There was nobody on the record for public comment.

Agenda Item 10 Board Business

Time: 11:21 a.m.

With no public comment, the board moved to discussing board business.

Disciplinary matrix

Ms. Carrillo pointed to the disciplinary matrix precedence document put together by the Board of Barbers and Hairdressers as a reference example for the board. Mr. Henderson had requested the board discuss development of a matrix to help guide appropriate decision making for disciplinary actions. As part of this request, Investigator Bowles provided to Ms. Carrillo a copy of more recent disciplinary actions the board has taken. The board reviewed the precedence list.

Chair Holt agreed a disciplinary matrix would be useful, though recommended the board take a little more time to review the decisions that were made. As there were different disciplinary actions taken for the same violations, Chair Holt expressed a need to do a deeper dive into the precedence list to understand the nuances of the cases as there appeared to be varying levels of egregiousness.

Chair Holt recommended that the board members review the precedence list and be prepared to discuss what actions the board may want to add to the disciplinary matrix. Ms. Carrillo stated she would compile a chart and tally the types of actions/reprimands most commonly issued. Chair Hold noted the board had already established a matrix for PDMP-related violations and at some point had established a standard violation for issues related to continuing education. Mr. Henderson recalled this discussion, stating it was a dollar amount per hour of missed continuing education activity.

TASK 3

Ms. Carrillo will create a draft matrix charting the most common types of reprimands on the different types of violations for further discussion at the September meeting.

TASK 4

Ms. Carrillo will look for the decision on fine amounts per hour of missed continuing education and will add it to the September meeting agenda.

Agenda Item 9 Lunch

Time: 11:31 a.m.

Off record for lunch at 11:31 a.m.

On record at 12:19 p.m.

Board members present, constituting a quorum:

Richard Holt, PharmD #PHAP2008, MBA – *Chair*

Leif Holm, PharmD #PHAP1606 – *Vice Chair* (joined at 2:07 p.m.)

Lana Bell, RPh #PHAP893

Tammy Lindemuth, Public Member (joined at 2:15 p.m.)
James Henderson, RPh #PHAP1683 (joined at 9:25 a.m.)
Justin Ruffridge, #PHAP1787

Upon return from lunch, Chair Holt shared the update that Ms. Noe was able to find the August 2017 meeting minutes reflecting the discussion of the fine amounts per missed hour of continuing education.

Agenda Item 10 Board Business

Time: 12:20 p.m.

Disciplinary matrix

Upon return from lunch, Chair Holt shared the update that Ms. Noe was able to find the August 2017 meeting minutes reflecting the discussion of the fine amounts per missed hour of continuing education. Mr. Henderson inquired about the medical board and nursing board's matrices. Chair Holt stated he was aware the medical board did have a PDMP and general practice matrix.

TASK 5

Ms. Carrillo will retrieve a copy of the Medical Board's matrix and will provide it to the board at their next meeting in September.

Chair Holt shared that the New York licensing boards provide a website for the public to search for disciplinary actions and asked the board if they were aware of any other states that publish these. Ms. Carrillo screen shared how to access the disciplinary actions page, which isn't specific to the Board of Pharmacy but includes any disciplinary actions searchable by quarter. Ms. Carrillo noted the New York search is interactive whereas the CBPL action page is not.

Inspections

Included in the OnBoard packet were items requested from the November, 2020 meeting. Chair Holt recalled for the board that the investigative unit had stated few inspections per year is reasonable cost-wise. The board reviewed the sample letter to pharmacies from the investigative unit notifying them of the status of their inspection. A copy of the inspection template used to assess compliance with established standards and protocols was also included in the packet for review. Chair Holt advised that the board should discuss what aspects the board wants the investigator to focus on.

Mr. Henderson inquired who the investigator would be assigned to perform inspections. Chair Holt asked for a volunteer from the board to partner with Investigator Bowles to engage in training on inspection needs. Ms. Bell offered to train Mr. Bowles.

Chair Holt stated he had provided markups on the inspection template.

TASK 6

Ms. Bell will touch base with Investigator Bowles to review the inspection process.

TASK 7

Ms. Carrillo will locate the inspection template markups from Chair Holt and will incorporate it into the September meeting materials.

TASK 8

All board members will be prepared to provide input on inspection report by the September meeting.

On a motion duly made by Lana Bell in accordance with AS 44.62.310(c)(2), seconded by James Henderson and with unanimous approval, 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.

RESOLVED to enter into executive session in accordance with AS 44.62.310(c)(2).

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt	x			
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth				x
James Henderson	x			
Sharon Long				x

The motion passed with no further discussion. Board staff were authorized to remain in the room.

Off record for executive session at 12:37 p.m.

On record from executive session at 1:44 p.m.

Upon return to the record, Chair Holt clarified that no motions were made during executive session.

Application Review

Ms. Carrillo noted to the board that an applicant requested discussion of their application in executive session. Dr. Ruffridge stated he would recuse from voting due to the applicant being a current employee.

On a motion duly made by Lana Bell in accordance with AS 44.62.310(c)(2), seconded by James Henderson and with unanimous approval, 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.

RESOLVED to enter into executive session in accordance with AS 44.62.310(c)(2).

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt	x			
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth				x
James Henderson	x			
Sharon Long				x

The motion passed with no further discussion. Board staff were authorized to remain in the room.

Off record for executive session at 1:47 p.m.

On record from executive session at 2:07 p.m.

Leif Holm joined the board at 2:08 p.m.

Upon return to the record, Chair Holt Clarified that no motions were made in executive session. Dr. Holm stated he would recuse due to not having been present for the application review.

On a motion duly made by Justin Ruffridge to approve the wholesale drug distributor application for Blessings International, #169542, seconded by Lana Bell and approved by the board with one recusal, it was:

RESOLVED to approve the license application for Blessings International, #169542.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm			x	
Richard Holt	x			
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth				x
James Henderson	x			
Sharon Long				x

The motion passed with no further discussion.

TASK 9

Ms. Carrillo will provide the motion minutes to Ms. Noe for issuance of the wholesale drug distributor license for Blessings International, in-process #169542.

For the next application review of pharmacy technician in-process license #164543, Dr. Ruffridge declared a conflict as the applicant is a current employee. Dr. Holm also requested recusal due to not being present for application review. Chair Holt approved these recusals.

On a motion duly made by Richard Holt to approve the pharmacy technician license for, #164543, seconded by James Henderson and approved by the board with one recusal, it was:

RESOLVED to approve the license application for #164543.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm			x	
Richard Holt	x			
Justin Ruffridge			x	
Lana Bell	x			
Tammy Lindemuth				x
James Henderson	x			
Sharon Long				x

The motion passed with no further discussion.

TASK 10

Ms. Carrillo will provide the motion minutes to Ms. Carlile for issuance of the pharmacy technician license for in-process #164543.

Tammy Lindemuth joined the room at 2:15 p.m.

On a motion duly made by Justin Ruffridge to table the in-process pharmacist application for #147445 pending receipt of a completed application, seconded by Richard Holt and approved unanimously, it was:

RESOLVED to table the license application for #147445.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt	x			
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth	x			
James Henderson	x			
Sharon Long				x

The motion passed with no further discussion.

TASK 11

Ms. Carrillo will follow-up with the applicant for in-process #147445 requesting documents required to complete the application. The application will be placed on the September agenda.

On a motion duly made by Justin Ruffridge to table the reinstatement application for pharmacist, #PHAP1602 pending receipt of a completed application, seconded by James Henderson and approved unanimously, it was:

RESOLVED to table the pharmacist reinstatement application for #PHAP1602.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt	x			
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth	x			
James Henderson	x			
Sharon Long				x

The motion passed with no further discussion.

TASK 12

Ms. Carrillo will follow-up with #PHAP1602 to communicate applicable timelines to proceed with the application. The application will be placed on the September agenda.

Agenda Item 12 Industry/Profession Updates

Time: 2:24 p.m.

AKPhA

Dr. Schaber and Ms. Gray, executive director of the AKPhA were present for an update on upcoming events and status of legislation. Lobbyist, Caren Robinson, was also available to provide updates:

Ms. Gray informed the board there was an inaugural leadership development event scheduled for September 24th at the BP Energy Center and an AKPhA academy of health system pharmacy seminar on September 25th. Ms. Gray added the association is currently accepting proposals for presentations. Ms. Gray then addressed HB 145, which proposed to expand pharmacy practice authority will be rolled over to next session, though it was starting to be looked at as vehicle for other legislation, primarily regarding COVID-19, so was stalled in house rules.

Ms. Robinson expressed optimism for the expansion bill but reiterated that COVID-19 provisions related to mandatory testing and vaccine passports were discussed and potentially weighed down the bill.

Dr. Schaber introduced the issue of white bagging, which she indicated was brought to her attention through ANMC as they were receiving requests from insurance companies to use this process to purchase infusion medications. AKPhA has looked into this and realizes it is a more widespread problem. White bagging is a process where an insurance company doesn't pay a provider or insurance provider but uses a specialty pharmacy. Dr. Schaber highlighted the problems this poses, including the inability of the patient's pharmacy to ensure adequate storage and chain of custody to meet the FDA's Drug Supply Chain Security Act (DSCSA) and negative financial impacts to facilities. Another problematic process is with brown bagging where a patient brings the medication to the infusion center for administration. A third issue, clear bagging is when the health system's own specialty pharmacy delivers the medications directly to the clinic. Chair Holt advised the board that if it wishes to seek changes statutorily, the board should be prepared to make the recommendation. Dr. Schaber pointed out there are examples of recent state legislation, which Ms. Carrillo had included in the board's packet.

DHSS - Medicaid

Ms. Carrillo noted to the board that Dr. Erin Narus wasn't able to make the meeting but provided an update by email:

- This upcoming Monday, May 24 at 1pm, the Division of Health Care Services will be hosting a public scoping meeting related to regulations for the Medicaid Pharmacy Services program.
- Dr. Charles Semling was also on the line to reiterate the importance of attending this meeting.

Agenda Item 13 Budget Report/Division Update

Time: 2:34 p.m.

Deputy Director, Sharon Walsh, joined the room at 2:30 p.m.

Deputy Director, Sharon Walsh, joined the board to present their Quarter 3 budget report. As of March 31st, the board's total revenue was at \$996,647; non-investigative expenditures were at \$231,870, investigative expenditures were at \$304,019; indirect expenditures (internal costs, departmental costs, statewide costs such as IT) was \$192,331; with the board's ending surplus of \$719,527. For the PDMP, Deputy Director Walsh shared that there were \$166,915 in non-investigative expenditures with an ending cumulative surplus of \$226,768. Chair Holt thanked Deputy Director Walsh for the update and affirmed to the board they are on track financially.

Ms. Carrillo reminded the board that the fingerprint fee will be looked at during the board's next fee analysis as this fee wasn't figured into fee changes when the new facility license types were effective in October 2019.

TASK 13

Ms. Carrillo will follow-up on the fingerprint fees for wholesale drug distributors, outsourcing facilities, and third-party logistics providers.

Deputy Director Walsh also provided an update on HB 145 and the PDMP exemption bill, HB91. HB 145 was in the House Rules Committee and HB 91 didn't get referred out of House Labor and Commerce. As session has ended and special session is beginning, it is the expectation these bills will be rolled over into the second session.

Agenda Item 10 Board Business

Time: 2:45 p.m.

Hearing nothing further on division updates, Chair Holt prompted the board to return to the board business agenda item.

Review Lost/Stolen Rx

The board reviewed the reports from Safeway Pharmacy #18118 and Safeway Pharmacy #1821.

Strategic Plan

Ms. Carrillo informed the board that she had taken Ms. Bell's draft document on guiding principles, goals, and strategies and formatted it into a final version for 2021. Ms. Carrillo asked the board for feedback and suggested edits, for which there were none. Ms. Carrillo stated there would be a new 2022 strategic plan for the board to review at their September meeting.

TASK 14

Ms. Carrillo will request a new page for the board's Strategic Plan to be created with the 2021 plan uploaded to it.

TASK 15

Ms. Carrillo will work on the draft 2022 plan for review and discussion at the board's September meeting.

Annual Report

Ms. Carrillo provided the board with a draft of its 2021 Annual Report, due June 30th. Ms. Carrillo pointed out new updates to the report, including SWOTs (strengths, opportunities, weaknesses, and threats) created for licensing and PDMP purposes to help illustrate barriers to progress in achieving goals and objectives in these areas.

Ms. Carrillo stated the report was near done, with only the budgetary recommendations (travel) left. Ms. Carrillo recalled in the 2020 report, travel was included for two board members to attend a compounding conference, so stated she would pencil this into the report. Chair Holt also requested to add budget recommendations for inspections as the board had determined, with guidance from Chief Francois, that 15-20 inspections could be performed every two years. Dr. Ruffridge recommended the NABP Annual Conference in Arizona from May 19 – 22, 2022 be

included. Ms. Carrillo also indicated she would pencil in a board member to attend the National Drug Abuse and Heroin Summit “Rx Summit” from April 18 – 21, 2022. Ms. Sherrell also plans to attend this summit with Ms. Carrillo using grant-funds as it is a federally-required deliverable.

TASK 16

Ms. Carrillo will add in budgetary recommendations to the 2021 Annual Report for conference travel and training, including the NABP annual report and district meetings, MPJE workshops, compounding conferences, and the Rx Summit.

TASK 17

Ms. Carrillo will finalize the 2021 Annual Report and submit it to the board for review and approval.

Board of Nursing Letter Update

Ms. Carrillo informed the board that the Board of Nursing met in the beginning of May but was not able to review the board’s letter addressing 12 AAC 44.440(c)(2). The Board of Nursing plans to review this at their next meeting scheduled for August. Chair Holt commented that if the Board of Nursing wishes to maintain the regulation, that the Board of Pharmacy may want to consider regulation changes to clarify how pharmacists can manage identifier requirements on prescription labels, for example, adding language stating APRN-issued prescriptions are valid as long as the proper credentials are listed.

TASK 18

Ms. Carrillo will follow-up with the Board of Nursing on their plan to address the board’s letter at their next meeting in August.

Correspondence

The board reviewed a vaccine safety document from the FDA and correspondence from the NABP on its Model Act, 503B survey, request for information to Vermont. Ms. Carrillo informed the board she provided a response to the Vermont inquiry, sharing the Alaska Board of Pharmacy does not require pharmacy technicians to be registered to work in 503B facilities. Additional correspondence for review included a slide deck from Melissa DeNoon with the South Dakota PDMP. Ms. Carrillo explained she met with Ms. DeNoon and members of DHSS OSMAP to discuss involvement in a comprehensive drug takeback program. Ms. Carrillo shared that the SD PDMP wrote into their BJA grant application funds to cover drug takeback activities. The Alaska PDMP applied for the same grant, but did not request funds specifically to support this activity; however, Ms. Carrillo explained OSMAP has separate funds to assist with this project. Ms. Carrillo’s understanding is the board doesn’t have specific statutory authority to regulate this, but that pharmacies wanting to become designated takeback sites would amend their existing DEA registration to seek “Collector” status and follow the DEA’s regulations and guidelines. Ms. Carrillo asked for interest from the board and whether there were concerns about liability, since the responsibility of these receptacles would fall to the pharmacist-in-charge.

Ms. Carrillo also noted that in this meeting, it was the request of DHSS to gauge interest from pharmacies through its ListServ. Chair Holt suggested first getting feedback from the department of law as to whether the board can establish an approved mechanism for pharmacies to at least notify the board they are engaging in takeback programs. Chair Holt believes it may be reasonable that authority exists for the board to create a notification requirement through AS 08.80.030(d). Dr. Ruffridge commented he has researched this extensively and that because it can be a complex process, a good approach is to partner with local law enforcement agencies because their rules aren't the same as pharmacies. Ms. Carrillo added that the law enforcement collaboration was also suggested by Ms. DeNoon.

TASK 19

Ms. Carrillo will request legal guidance on whether the board can require pharmacies to notify them if they are engaged in drug takeback programs.

Board nominations

Chair Holt then moved to nominations, reminding the board that his last on the board will be on June 30th. Dr. Holm offered his vote of confidence for Dr. Ruffridge to take on the roll of board chair.

On a motion duly made by Lana Bell to nominate Justin Ruffridge as board chair and approved unanimously, it was:

RESOLVED to nominate Justin Ruffridge as the board chair.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt	x			
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth	x			
James Henderson	x			
Sharon Long				x

The motion passed with no further discussion.

Dr. Holm, Ms. Bell, and Ms. Lindemuth would remain as vice chair, secretary, and chair of the CSAC, respectively.

Agenda Item 11 Work Groups/Subcommittee Updates

Time: 3:28 p.m.

COVID-19 board chairs

Chair Holt reminded the board the COVID-19 chairs meeting is continuing to occur biweekly, though it has become more of a general meeting for board chairs during legislative session. Ms. Carrillo provided an update of the most recent board chairs meeting, which included topics around legislative updates, including military and military spouse licensure; the time and effort it takes to be a board member, and professions seeking to expand their practice authority.

CSAC

Ms. Lindemuth stated the CSAC's next meeting will be held in the beginning of June. Ms. Carrillo inquired when a copy of the meeting minutes would be posted as the last published meeting minutes are from 2018. Ms. Lindemuth stated she wrote the minutes and inquired how to post them. Ms. Carrillo recalled that the legislation changing the chair of the CSAC being a Department of Law designee to the Board of Pharmacy's chair or chair's designee was the only change; any administrative duties, including writing meeting minutes, is to be retained within DOL.

TASK 20

Ms. Carrillo will follow-up on expectations for CSAC administrative duties.

Compounding

Dr. Holm stated he and Dr. Ruffridge have not been able to meet.

PDMP board chairs

Chairs from the boards with PDMP requirements continue to meet biweekly. During these meetings, board representatives provide updates and solutions are shared on how to educate licensees about the requirements.

Agenda Item 14 Administrative Business

Time: 3:40 p.m.

License statistics

Ms. Carrillo provided the following license statistics as of mid-May:

Pharmacists = 1,057
Interns = 475
Techs = 1,257
In-state pharmacies = 132
Drug rooms = 40
Remote pharmacies = 1
OOS pharmacies = 641
In-state wholesalers = 16
OOS wholesalers = 626
Outsourcing = 32
3PL = 175
Courtesy pharmacists = 12
Courtesy interns = 0

Courtesy techs = 6
Emergency pharmacists = 10
Emergency interns = 0
Emergency techs = 0

Ms. Carrillo then displayed the board's Authorized Emergency Courtesy License Activities document, inquiring whether the board wished to enter an end date to the authorized reason for obtaining a courtesy license. At present, the only authorized reason is for the purpose of providing COVID-19 immunizations, which went into effect on November 6, 2020. Ms. Carrillo clarified that these aren't tied to an emergency declaration as it is in the board's emergency preparedness regulations. Dr. Ruffridge recommended rounding it out at the end of the fiscal year. Mr. Henderson inquired how many licenses were used for this purpose, to which Ms. Carrillo stated there were 12 issued to pharmacists and 6 to technicians, but whether they were actually used is unknown.

On a motion duly made by Justin Ruffridge to cease courtesy license application approvals related to COVID-19 immunizations beginning June 30, 2021, seconded by Tammy Lindemuth and approved unanimously, it was:

RESOLVED to end issuance of courtesy licenses for the purpose of providing COVID-19 vaccinations on June 30, 2021.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt	x			
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth	x			
James Henderson	x			
Sharon Long				x

The motion passed with no further discussion.

TASK 21

Ms. Carrillo will update the board's Authorized Emergency Courtesy License Activities document to provide an end date and will request to take down the courtesy license application on June 30.

Task list review

The board reviewed the task list. Dr. Ruffridge stated he is about a quarter of the way through looking at the board's FAQs to determine which need to be removed and which can be made into position statements.

A brief discussion was had between Chair Holt and Dr. Ruffridge on drafting regulation changes. Chair Holt shared it is helpful to draft regulations in a format as close to drafting format as possible. Ms. Carrillo stated it has been past practice to append agreed upon regulatory changes to the minutes. Dr. Ruffridge inquired whether it's possible to append markups to the most current version of the published statutes and regulations booklet.

TASK 22

Ms. Carrillo will inquire with the regulations specialist whether it is possible to include most recent regulatory markups in published statutes and regulations.

Upcoming travel/conference/workshops

The following events are upcoming:

MPJE Review Committee (not state-specific) – June 1 – 11, 2021

Program Review and Training (staff only) – June 15, 2021

Task 23

Ms. Carrillo will plan to attend the staff NABP training on June 15th.

Agenda Item 15 Public Comment #2

Time: 4:00 p.m.

Ms. Sherrell inquired about the use of medication disposal bags in the PDMP education and outreach plan, asking for input on whether it would be helpful to send bags to pharmacies for distribution to their patients and if there was a specific brand that was most effective. Chair Holt agreed it would be useful, adding that if there was a bag available for every prescription, he would provide one. Chair Holt suggested either Detterra or DisposeRx. Dr. Ruffridge added that he received a grant for 1,500 Mallinckrodt disposal bags several years ago and it was well received in the community. Pharmacist, Dan Nelson shared that Alaska Native Medical Center (ANMC) previously received a large stock of Deterra disposal bags, which were handed out for some time and especially helpful in rural areas. Dr. Nelson added that when clinics were in need of more, they could reach out to ask.

Lorri Walsmley from Walgreens shared an invite to the meeting for districts 6, 7, and 8 from August 29 to 31st in Phoenix. Ms. Walsmley added she could send out the attendance link and agenda.

Pharmacist, Jordan Hussey inquired about the process for being selected as a board member. Chair Holt described the process of applying, sending resumes, participating in interviews, sending the list to the Governor's Chief of Staff, then going through the legislative confirmation office to confirm.

Agenda Item 16 Adjourn

Time: 4:15 p.m.

The board recessed at 4:15 p.m.

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing

Alaska Board of Pharmacy

MINUTES OF THE MEETING

May 20 - 21, 2021 Videoconference

By authority of AS 08.01.070(2), and in compliance with the provisions of AS 44.62, Article 6, a scheduled meeting of the Board of Pharmacy via videoconference on May 20-21, 2021. Due to the COVID-19 pandemic, in-person attendance was not available.

Agenda Item 1 Call to Order/Roll Call

Time: 9:03 a.m.

The day 2, **May 21, 2021** videoconference was called to order by Chair, Rich Holt at 9:03 a.m.

Board members present, constituting a quorum:

Richard Holt, PharmD #PHAP2008, MBA – *Chair*
Lana Bell, RPh #PHAP893
Tammy Lindemuth, Public Member
James Henderson, RPh #PHAP1683
Justin Ruffridge, #PHAP1787

Division staff present:

Laura Carrillo, Executive Administrator
Lisa Sherrell, PDMP Manager
Heather Noe, Occupational Licensing Examiner
Bethany Carlile, Occupational Licensing Examiner

Members from the public present/registered:

AAG Megyn Weigand, Department of Law
Ashley Schaber, Alaska Pharmacists Association/Alaska Native Medical Center
Lorri Walmsley, Walgreens
Molly Gray, Alaska Pharmacists Association

Agenda Item 2 Review/Approve Agenda

Time: 9:04 a.m.

Chair Holt reviewed the agenda. Ms. Carrillo added that AAG Megyn Weigand would be present to discuss the negative implication canon at 9:30 a.m. under Agenda Item #5 as a follow-up from the board's February meeting. Ms. Carrillo also recommended to add the discussion of PDMP reporting compliance recommendations and the board's disciplinary matrix under Agenda Item #8. Chair Holt clarified the discussion of white bagging would be statute related discussed under Agenda Item #9.

On a motion duly made by Lana Bell to approve the meeting agenda, seconded by Justin Ruffridge, and approved unanimously, it was:

RESOLVED to accept the May 21, 2021 meeting agenda as amended.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt	x			
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth	x			
James Henderson	x			
Sharon Long				x

The motion passed with no further discussion.

Agenda Item 3 Ethics

Time: 9:09 a.m.

There were no ethics to report.

Agenda Item 4 Public Comment #3

Time: 9:15 a.m.

Ms. Gray inquired whether she should announce there will be a board member position open in light of Chair Holt leaving at the end of June. Chair Holt believes it's appropriate to inform AKPhA members a position would be available soon. Dr. Ruffridge stated he submitted his application when membership was full but was still able to proceed with the process and recommended interested applicants apply now as there will be additional openings in the near future.

Dr. Schaber inquired about automated dispensing kiosks and the required placement of them in relation to a pharmacy, citing discussion around the 10 feet rule. Chair Holt clarified that the board's inquiry into whether regulating automated dispensing kiosks was within their authority resulted in guidance from the Department of Law to include distance requirements for installing

these. The board has not implemented a 10 foot rule as of yet but automated dispensing kiosks regulations are in draft form and will be discussed in the future.

Agenda Item 5 Legal Opinion Updates

Time: 9:26 a.m.

AAG Weigand joined the room at 9:32 a.m.

Expedited partner therapy

The board reviewed guidance on issuing expedited partner therapy. Ultimately, pharmacists are still required to obtain the patient's information prior to dispensing medication, which would include partners; without this information, the prescription order cannot legally be filled. DOL suggests the board amend 12 AAC 52.460 to exempt partner information from being obtained for partner therapies. Dr. Ruffridge expressed concern about patient safety and instead suggested a new regulation section on partner therapy so the board can address allergies, contraindications, and other verbiage to address standards for patient safety.

Negative implication canon

This topic is in follow-up to the board's February meeting. Dr. Ruffridge inquired how applicable this canon is in all measures of statute and regulation projects because it doesn't seem most people are aware of this and that there are significant implications. In testimony for HB 145, for example, medical providers felt strongly that language was added to ensure limitations were placed on pharmacist prescribing, though Dr. Ruffridge's opinion is that it's not necessary to specify what is limited. AAG Weigand stated the canon is always applicable; when statements are affirmatively provided in a list, this means other areas not included in the list are automatically excluded. AAG Weigand added that one way we can avoid implications of this canon are to make a non-inclusive list, e.g.: "including", which already means including but not limited to; they are only providing examples.

Medication management of out-of-state pharmacies

The board reviewed the guidance from DOL, which provides that out-of-state pharmacies cannot engage in telepharmacy services because a telepharmacy system can only be used by central and remote pharmacies under direct supervision of a pharmacist located in Alaska. Chair Holt recommended that statutory changes be made to regulate telepharmacies, much in the same way the board would need to seek legislative change to know what Internet pharmacies are providing services to Alaska. Chair Holt reminded the board that Alaska only registers non-resident pharmacies, which limits the board's ability to enforce and discipline. It has been the board's interest to seek legislative change to license rather than register these pharmacies.

Chair Holt also recommended clarifying in statute or regulation what activities constitute telepharmacy services. Mr. Henderson agreed with these changes as it would provide much needed clarity to the board. Ms. Lindemuth also expressed that legislative change would be ideal; with tele-services growing, the board should be statutorily prepared to address concerns and avoid any loopholes that might otherwise be present. Ms. Carrillo suggested these items could possibly be

1097 rolled into HB 145 for second session. Ms. Gray commented there is a telehealth bill, SB78, which
1098 could also include telepharmacy services next session. Ms. Gary also informed the board of
1099 Governor-introduced SB93 and HB13 for a payer healthcare database under the Division of
1100 Insurance, adding these may also be vehicles to introduce telepharmacy legislation.

1101
1102 Chair Holt stated if it is the will of the board to seek changes through a Governor's bill, language
1103 would need to be prepared by July. Chair Holt added that it would be timely to also update the
1104 definition of "drug" to include compressed gasses and blood banks through legislative change.

1105
1106 Medicolegal investigative access

1107 Ms. Carrillo addressed medical/coroner's access to PDMP information. Guidance was previously
1108 provided clarifying medicolegal investigators within the M/CO office can also have access to the
1109 data. At present, access is through direct login credentials. The basis of the follow-up on this
1110 guidance is to determine whether a subpoena is required since other investigator, for example,
1111 CBPL and DEA investigators, must submit a subpoena.

1112
1113 Chair Holt called for a brief break.

1114
1115 Off record at 10:55 a.m.

1116 On record at 11:08 a.m.

1117
1118 Upon return from record, it was clarified Ms. Lindemuth would be out for the rest of the meeting.

1119
1120 Collaborative practice agreements

1121 The board reviewed the guidance on approval of collaborative practice agreements through the
1122 board's executive administrator (EA). As written, 12 AAC 52.240 doesn't allow the EA to approve
1123 these; however, if this section was amended to create a checklist of required items and if the EA
1124 regulation, 12 AAC 52.993, was amended to add approval of these agreements, the board's
1125 preference to administratively approve these would be met, rather than requiring full board
1126 approval as per the State Medical Board's corresponding regulations in 12 AAC 40.983(k). Ms.
1127 Carrillo added that later on in the agenda, there will be further discussion on a proposed
1128 collaborative agreement join approval process with the Medical Board.

1129
1130 **Agenda Item 6 Regulations Update**

Time: 11:02 a.m.

- 1131
1132 • 12 AAC 52.990 - Display of licenses – The board discussed this and landed on the
1133 following amendment: "A licensee shall retain all licenses, certifications, registrations, or
1134 permits in the practice site. This documentation shall be made available to the board, law
1135 enforcement, or inspector upon request. The division's licensing website printout
1136 confirming active credentials is acceptable in lieu of a printed document."
1137 • 12 AAC 52 (new) - Drug and device expiration date on labels - Chair Holt inquired if the
1138 board would be interested in mandating expiration dates are on labels, which Dr. Ruffridge
1139 agreed would be beneficial for patient safety. Mr. Henderson's thought was that most

pharmacies already indicate the expiration date on their label, to which Chair Holt stated was standard practice for some pharmacies but not might be for all. Chair Holt confirmed it is standard in some pharmacies but can't speak to all others. Dr. Ruffridge stated the FDA's 1979 law sets expiration dates and recommended the board could consider adding a separate expiration dates for unit dosed medication packs, which should have a much shorter expiration date than the one year.

TASK 24

Chair Holt will put language together addressing expiration dates into 12 AAC 52.480 for the board's consideration at their next meeting in September.

- 12 AAC 52 (New) - Facility standards for equipment and supplies - "all pharmacies have in their possession the equipment and supplies necessary to engage in the practice of pharmacy relevant to the pharmacy services offered. The equipment is in good repair and is available in sufficient quantity to meet the needs of the practice of pharmacy conducted therein.
- 12 AAC 52 (New) – Inspections – the board reviewed Chair Holt's suggested language for inspections, which included language requiring that for pharmacies in which findings are discovered during the inspection process, the discrepancies will need to be addressed within a certain timeframe. Ms. Bell suggested suggesting giving pharmacies and facilities 90 days to correct the issues or submit a corrective action plan. Mr. Henderson inquired whether this would be enough time and recommended the plan be approved by the board.

To clarify this applies to pharmacies and facilities located in the state and authorized CBPL investigators to perform inspections, Ms. Carrillo suggested amending this to read, "A wholesale drug distributor, pharmacy, drug room, or remote pharmacy located in this state shall permit an authorized investigator assigned to the board, who shows proper identification, to enter and inspect the facility at reasonable times and in a reasonable manner, and to inspect the pharmacy or facility's record and written operating procedures. Ms. Carrillo inquired about the chain of events, for example, whether the inspection report with findings needs to be reviewed by the board before being notified they must address the discrepancies or if the pharmacy/facility can simply receive the findings, correct them, then notify the board or investigator that they have been corrected. Ms. Bell envisioned the investigator would identify the discrepancies and the pharmacy/facility would submit a correct action plan. Ms. Bell inquired whether there should be a penalty for discrepancies.

Mr. Henderson also inquired whether the inspector would then need to go out and verify the pharmacy/facility did in fact correct the discrepancies, suggesting we may need to institute a fee if the investigator is expected to perform a subsequent review. Dr. Ruffridge believes 30 days is more appropriate and that the inspector should not go back out a 2nd time for the pharmacy/facility to prove that corrections were made. Instead, Dr. Ruffridge states simply acknowledging that corrections is needed would be sufficient, but that if pharmacies/facilities show up as deficient multiple times, the board could assess a fine.

Chair Holt suggested requiring a notification form so there is a record of acknowledging the discrepancy.

Dr. Ruffridge believes the board is financially solvent to provide inspection services using its surplus without implementing a separate inspection fee, but agreed an analysis would be useful. Chair Holt recalled investigations had indicated 10 – 15 inspections per year was doable, adding previous investigator, Mr. Howes had been doing these. Ms. Carrillo inquired whether inspections were done in the Anchorage and surrounding areas or if travel was involved, which might increase the cost.

TASK 25

Ms. Carrillo will create a draft notification form acknowledging discrepancies of an inspection and will present it to the board at their September meeting.

TASK 26

Ms. Carrillo will look into the cost of the inspections if the board were to do 10-15 inspections and will add this into the board's annual report.

Agenda Item 7 Lunch

Time: 12:01 p.m.

Chair Holt called for lunch at 12:01p.m.

Back on record at 1:04 p.m.

Board members present, constituting a quorum:

Richard Holt, PharmD #PHAP2008, MBA – *Chair*

Lana Bell, RPh #PHAP893

James Henderson, RPh #PHAP1683

Justin Ruffridge, #PHAP1787

Division staff present:

Laura Carrillo, Executive Administrator

Lisa Sherrell, PDMP Manager

Heather Noe, Occupational Licensing Examiner

Bethany Carlile, Occupational Licensing Examiner

Agenda Item 8 PDMP Regulations

Time: 1:06 p.m.

Registration (May 6, 2021)

Ms. Carrillo reviewed the changes to 12 AAC 52.855 regarding registration, which went into effect on May 6th and now requires providers to register with the PDMP within 30 days of meeting the mandatory registration requirement. The amendment also includes a requirement for non-

dispensing pharmacists to submit a dispensation exemption form within 30 days of licensure if the pharmacist does not plan to dispense controlled substances in the state. update to the registration regulations, which went into effect on May 6th for all licensees required to register with the PDMP. Add to disciplinary matrix.

Renewal and notifications

The board previously discussed additional changes to PDMP regulations during its February meeting and had left off on discussing language related to the registration process. The board discussed use of secure email accounts and ultimately landed on “non-shared email address” to align with existing the existing end user language agreement (EULA). The board also previously addressed the need to include language regarding delegates and renewal, as both exist but are not codified.

Ms. Carrillo provided draft language, including a section on notifying the board within 10 days of a change in dispensing or distributing status by pharmacies and pharmacists. Chair Holt inquired whether the intent is to assist in reporting compliance clean-up. Ms. Carrillo recalled that during the previous meeting, Ms. Bell inquired whether pharmacies can report when they are no longer dispensing or distributing controlled substances. Presently, the main opportunity is every two years at renewal, though licensees could notify us in writing at any time. Ms. Carrillo added that when pharmacy reporting analyses started in January and Ms. Sherrell was following up with pharmacies receiving a notice of delinquency, several pharmacies had responded they were dispensing/distributing at the time of their renewal but had since stopped. This notification would assist in timely and more accurate status capture of dispensing/distributing and avoid sending notices to licensees where reporting doesn’t apply. Ms. Carrillo added that the 10 days was suggested because there is also a 10-day PIC change timeframe.

Chair Holt further inquired whether receipt of these notices will prompt removal of the licensee from the PDMP. Ms. Carrillo stated pharmacists would be removed if they are no longer dispensing. Ms. Sherrell clarified we would also manually remove pharmacies from Compliance Reporting in AWA^Rx^E as license integration won’t automatically deactivate these accounts. Ms. Carrillo commented that if a similar integration project between the compliance function in AWA^Rx^E and the dispensing/DEA designations in Portal was implemented, it would be helpful and worth pursuing in the future.

Regarding delegate access, Chair Holt inquired about the process for this and whether a form is required. Ms. Sherrell clarified that delegates aren’t required to pay or submit a form; as long as the delegate is regulated under AS 08 and at least one supervising provider has approved their account, admin will approve the delegate to have access. Mr. Henderson inquired whether the board wished to clarify the role of delegates among all provider types, including veterinarians, nurses, doctors, etc. Ms. Carrillo suggested a separate regulations section on delegates might be appropriate; providers have expressed a desire to appoint a delegate for the purpose of that delegate reviewing how a provider’s treatment practices aligns with their institutional prescribing practices; however, quality review isn’t the intent of delegate access. Ms. Carrillo stated the intent

is for delegates to review and report for patients they are involved in a treating relationship with under the supervision of their practitioner. Dr. Ruffridge commented a new section may not be necessary since delegates are able to have the same abilities as the supervising provider. It was ultimately decided not to create a separate section for delegate access at this time.

Supply day exemptions to reviewing and reporting

Ms. Carrillo addressed AS 17.30.200(k)(A), inquiring whether it is the intent for any supply day to be exempt from being reviewed in these scenarios as these are not tied specifically to any supply day as is (B). Chair Holt stated it would be appropriate to defer to prescribing boards as to what supply days don't have to be reviewed. Ms. Sherrell added that we have in the past referred licensees to their prescribing boards, but the boards did not know either. Ms. Carrillo added that (B) implies any non-refillable prescription intended to last more than 3 days must be reviewed.

Ms. Carrillo addressed AS 17.30.200(t), also inquiring whether a (1)(A)(B) constitutes exempted reporting for any supply day. Ms. Carrillo also asked the board if their understanding of (2)(A)(B) means that providers working in inpatient pharmacies or emergency departments must comply with the reporting requirement if the outpatient supply is for more than 24 hours. Dr. Ruffridge stated there typically aren't instances where inpatient pharmacies dispense more than a 24-hour supply because they are prepackaged. The board agreed emergency providers issuing any prescription more than a 24-hour supply is to be reported.

TASK 27

Ms. Carrillo will clarify with the prescribing board chairs that AS 17.30.200(t) requires prescriptions written for more than a 24-hour supply to be reported.

On a motion duly made by Justin Ruffridge to approve the PDMP regulations as discussed for cursory review by the Department of Law, seconded by Rich Holt, and approved unanimously, it was:

RESOLVED to accept the proposed PDMP regulation amendments for cursory review by the Department of Law.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt	x			
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth				x
James Henderson	x			
Sharon Long				x

The motion passed with no further discussion.

1311 **12 AAC 52.855. Registration with the prescription drug monitoring program controlled substance**
1312 **prescription database.** (a) A prescriber shall register with the prescription drug monitoring program's
1313 controlled substance prescription database (PDMP) not later than 30 days after the date of initial
1314 licensure or the date of registration with the federal Drug Enforcement Administration (DEA),
1315 whichever is later.

1316 (b) A licensed pharmacist practicing in this state shall register with the PDMP. Registration
1317 must be completed not later than 30 days after initial licensure if the pharmacist's practice is
1318 expected to involve dispensing a schedule II, III, or IV controlled substance under federal law. If not
1319 dispensing in this state, a pharmacist shall submit, not later than 30 days after initial licensure, a
1320 PDMP dispensation exemption form provided by the board. A pharmacist who submitted a
1321 dispensation exemption form shall register with the PDMP before dispensing a schedule II, III, or IV
1322 controlled substance under federal law in this state.

1323 (c) Except as provided in (a) of this section, before dispensing, prescribing, or administering a
1324 schedule II, III, or IV controlled substance under federal law, a pharmacist or practitioner required to
1325 register with the PDMP must

1326 (1) register online on the PDMP [WEBSITE; AND] by **providing**

1327 **A. a non-shared email address;**

1328 **B. password;**

1329 **C. user role;**

1330 **D. healthcare specialty;**

1331 **E. the drug enforcement administration (DEA) number issued to the**

1332 **prescriber, or if a pharmacist, the employer's DEA; and**

1333 (2) pay the fee established in 12 AAC 02.107.

1334 (d) After completing the registration requirements, a pharmacist or practitioner required to
1335 register with the PDMP will be issued a [USER ACCOUNT, LOGIN NAME, AND PASSWORD BY THE
1336 DEPARTMENT] **registration number**.

1337 (e) A pharmacist or practitioner required to register with the PDMP must access information
1338 in the PDMP using the [USER ACCOUNT, LOGIN NAME, AND PASSWORD ISSUED BY THE
1339 DEPARTMENT] **credentials created in (c)(1)(A)(B) of this section**.

1340 (f) A pharmacist or practitioner required to register with the PDMP may access information in
1341 the PDMP using another registrant's credentials only as authorized by a contract executed by the
1342 department for the purposes of AS 47.05.270. (Eff. 12/29/2011, Register 200; am 6/7/2018, Register
1343 226; am ____/____/_____, Register ____)

1344 **Authority:** AS 08.80.005 AS 08.80.030 AS 17.30.200

1345
1346 12 AAC 52.____ PDMP Registration Renewal (NEW) (a) A registration will expire on the same date as
1347 the pharmacist's or practitioner's corresponding professional license.

1348 (b) To renew a registration, a licensee required to register must submit the fee established in 12 AAC
1349 02.107 on or before the expiration date.

1350
1351 12 AAC 52.____ Change in Dispensing or Distributing of Controlled Substances (NEW) (a) a pharmacist
1352 registered with the PDMP under 12 AAC 52.855 must notify the board on a form provided by the
1353 department when the pharmacist no longer dispenses controlled substances in the state within 10
1354 days of the change in dispensing status.

1355 (b) a pharmacist who submitted the dispensation exemption form in 12 AAC 52.855(b) who begins
1356 dispensing controlled substances in the state must notify the board on a form provided by the
1357 department and register with the PDMP within 10 days of the change in dispensing status.

1358 (c) a pharmacy required to report to the PDMP that no longer dispenses or distributes controlled
1359 substances in or to the state must notify the board on a form provided by the department within 10
1360 days of the change in dispensing or distributing status.

1361 (d) a pharmacy that obtains a DEA registration after its license or registration is initially granted by
1362 the board and intends to dispense or distribute controlled substances in the state must notify the
1363 board on a form provided by the department within 10 days of the change in dispensing or
1364 distributing status.

1365

1366 **12 AAC 52.____ PDMP Registration Renewal (NEW) (a) A registration will expire on the same date**
1367 **as the pharmacist's or practitioner's corresponding professional license.**

1368 **(b) To renew a registration, a licensee required to register must submit the fee established in 12**
1369 **AAC 02.107 on or before the expiration date.**

1370

1371 **12 AAC 52.____ Change in Dispensing or Distributing of Controlled Substances (NEW) (a) a**
1372 **pharmacist registered with the PDMP under 12 AAC 52.855 must notify the board on a form**
1373 **provided by the department when the pharmacist no longer dispenses controlled substances in the**
1374 **state within 10 days of the change in dispensing status.**

1375 **(b) a pharmacist who submitted the dispensation exemption form in 12 AAC 52.855(b) who begins**
1376 **dispensing controlled substances in the state must comply with the requirements in 12 AAC**
1377 **52.855(c) within 10 days of the change in dispensing status.**

1378 **(c) a pharmacy required to report to the PDMP that no longer dispenses or distributes controlled**
1379 **substances in or to the state must notify the board on a form provided by the department within**
1380 **10 days of the change in dispensing or distributing status.**

1381 **(d) a pharmacy that obtains a DEA registration after its license or registration is initially granted by**
1382 **the board and intends to dispense or distribute controlled substances in the state must notify the**
1383 **board on a form provided by the department within 10 days of the change in dispensing or**
1384 **distributing status.**

1385 **TASK 28**

1386 Ms. Carrillo will forward the approved PDMP regulation amendments to the regulations specialist
1387 to request cursory review by the Department of Law and will append the changes to the minutes.

1388
1389 Reporting limitations and recommendations

1390 Ms. Carrillo and Ms. Sherrell drafted a process summary of challenges to monitoring PDMP
1391 reporting compliance and recommendations for how to improve this. As a recap, the board
1392 previously defined “continuous delinquency” as pharmacies appearing in subsequent quarterly
1393 delinquent pharmacy analysis lists as well as pharmacies who have been notified of their
1394 delinquencies but have not attempted to respond to the notice or attempted to correct the data.

1395
1396 It was recommended the board revisit their compliance analysis as the primary limitations are that
1397 analytics functions only display a 30-day lookback period and the system doesn’t display when a
1398 pharmacy has since submitted missed data or corrected errored data. Another issue discovered is
1399 that the system only allows admin to enter a static date for running delinquency reports; it was
1400 previously believed that the date entered would display all the pharmacies flagged as delinquent for
1401 every day up until that date; however, the results actually display pharmacies that were delinquent
1402 on a specific date. PDMP staff have asked Appriss to add the ability to enter dynamic timeframes
1403 as opposed to one single date.

1404
1405 Ms. Sherrell stated that in most cases, pharmacies don’t just appear on the list once; pharmacies
1406 typically are delinquent for many days. Ms. Sherrell added that the communications reporting
1407 module will likely resolve delinquencies, to which Dr. Holm agreed.

1408 Ms. Carrillo stated that in light of the new information on limitations with monitoring and not
1409 knowing whether any data has since been corrected, she did not yet forward the 50 or so potential
1410 delinquent pharmacies to the Investigations Unit during the April analysis. The 17 pharmacies
1411 who appeared as delinquent for the first time were notified and Ms. Sherrell has been in follow-up.
1412 Ms. Sherrell reiterated that the problem isn't that we can't forward potential non-compliance
1413 matters to Investigations, it's that PDMP staff wouldn't be able to confirm whether any of the
1414 pharmacies had since corrected the data without allocating a significant amount of datamining
1415 work. Notices that missing data has since been submitted is not a feature of the current system;
1416 there is no automation to inform staff of when the data has been corrected. Chair Holt and Dr.
1417 Ruffridge expressed frustration and disbelief in these limitations. Ms. Carrillo shared Appriss is
1418 aware of the limitations and are finding ways to strategize solutions. Dr. Ruffridge stated there
1419 should be a way for pharmacies to easily login and see a green checkmark when a submission has
1420 been successfully reported.

1421
1422 Ms. Carrillo commented the board may need to amend its disciplinary matrix if it is agreed that
1423 analysis of compliance should change from quarterly to monthly. As included in the
1424 recommendations document, Ms. Carrillo shared that simplifying the non-compliance criteria by
1425 grouping licensees into dichotomous categories (was a report submitted? yes/no) would help align
1426 with system capabilities, though it may be unpopular because this approach doesn't take into
1427 account the egregiousness of the missing data; rather, it categorizes pharmacies into a box of
1428 whether or not they missed one day of reporting, regardless of how many prescriptions were not
1429 reported, what types of drugs were not reported, and what the schedules were.

1430
1431 The board continued to discuss the issues. Ms. Sherrell suggested the reports would need to be
1432 run daily and then on a monthly basis, all the pharmacies who ever appeared as delinquent on at
1433 least one day would be forwarded to the Investigative Unit. Mr. Henderson inquired if it would
1434 matter if the pharmacy fixed the data the next day, to which Ms. Sherrell stated they would still be
1435 non-compliant for missing the reporting day. Dr. Ruffridge added that within the disciplinary
1436 matrix, the part about responding to the notice—whether through contacting the office or
1437 correcting the data—would need to be removed. Chair Holt suggested requesting guidance from
1438 DOL on whether we can require pharmacies to respond to notices of delinquency. Ms. Carrillo
1439 stated a certified mail letter is an official way to provide notice to licensees.

1440
1441 Ms. Bell inquired about what other boards have done to address reporting non-compliance. Ms.
1442 Carrillo explained they are beginning to track licensees required to report but have not yet defined
1443 non-compliance parameters. Ms. Carrillo commented that as the board of pharmacy smooths out
1444 their process, it can be shared with the prescribing boards. Dr. Ruffridge asked if other prescribing
1445 boards have to analyze their data, to which Ms. Sherrell and Ms. Carrillo stated they don't; it is just
1446 them, but that the bulk of the work will be upfront and it should get smoother as more providers
1447 become compliant and boards establish their own processes. The board discussed when to start
1448 the new daily running of reports for monthly referrals. Ms. Carrillo stated that since licensees were
1449 made aware of the board's quarterly analysis plan in September, a similar notice should be sent
1450 informing licensees of the new process. Ms. Sherrell suggested a do-over would be appropriate if

new criteria for delinquency is being established. Chair Holt recommended that for the first month, licensees are notified they are missing data, and that in subsequent months, licensees will be referred to the investigative unit. The board discussed that the fine would be imposed only in subsequent appearances as a delinquent reporter.

TASK 29

Ms. Carrillo will update the board's PDMP disciplinary matrix to reflect daily tracking of reporting compliance for monthly referrals to the Investigative Unit.

TASK 30

Laura will draft letter of new plan and will send the notice to the board for review/approval with the aim to mail it out on June 1st.

Agenda Item 9 Potential Statute Changes

Time: 3:30 p.m.

White bagging

The board returned to discussion of white bagging, which was a topic presented by Dr. Schaber on day 1. Chair Holt clarified it would require a statute change. Ms. Carrillo commented it may be a legislative change with division of insurance under Title 21. Chair Holt encouraged the board to think about the different avenues of pursuing this: seeking support in the next 2 months for a proposal as a Governor's bill; to work with the association to add onto HB145 in the second session; or to act independently as a board to find its own sponsors. Chair Holt stated that if it is the will of the board to try to seek the Governor's support, that a meeting within the next 30-45 days would be ideal.

Ms. Carrillo asked for clarification on brown bagging, to which Dr. Schaber stated is when medication is shipped to the patient, and the patient then goes to the hospital to have prescription administered there. Dr. Schaber added that this is commonly seen in infusion pharmacies. Mr. Henderson inquired whether white bagging and brown bagging is the same. Dr. Schaber clarified that this is when a payer requires the hospital to purchase from a specific specialty pharmacy and then ships that to the hospital for administration to the patient. White bagging is distinguished from brown bagging in that only the latter involves direct shipment to the patient.

Chair Holt recommended the board review other state's legislation. Included in the board's packet were an ASHP slide deck from April 2021 including examples of state legislation. Dr. Schaber stated Texas and Virginia had passed legislation, so it would be most useful to look at their language.

Outstanding statute project

Chair Holt reviewed the board's pending legislative changes the board has previously discussed but as potential amendments but not yet officially approved to move forward. Among these topics are requirements related to affidavits of moral character, licensing versus registration of out-of-

state pharmacies, prohibiting the use of the term “apothecary” by unlicensed pharmacies, and automated dispensing machines.

Agenda Item 6 Regulations Update

Time: 3:58 p.m.

Ms. Carrillo reviewed the cooperative practice improvement plan she developed with Natalie Norberg, EA for the State Medical Board. The board of pharmacy had developed its own process for reviewing and approving these applications because the medical board hadn’t been approving them; however, the Medical Board recently revisited this topic and wishes to become more involved. The improvement plan outlines how cooperative practice agreements relates to HB 145 and a plan for next administrative steps. As part of next steps, Ms. Carrillo provided a markup of the board’s collaborative practice regulations in 12 AAC 52.240, which strikes most of the language because it is not necessary to verbatim have what the Medical Board has in their cooperative practice agreement regulations in 12 AAC 40.983. Ms. Carrillo also created form markups to merge the board of pharmacy’s form and the medical board’s form.

Ms. Carrillo explained that the idea is the State Medical Board would have primary approval of the cooperative practice agreement application, and once approved, it would be forwarded to the board of pharmacy to be endorsed by the EA. The hope is that this would also be another avenue to avoid full-board approval as previously described in day 1.

Chair Holt cautioned that the language may only relate to medical board licensees, but that most of the agreement applications are coming from Board of Nursing licensees. Ms. Carrillo acknowledged this, stating she recently reignited cooperative/collaborative practice agreements with the prescribing boards since the language states it involves providers with the authority to prescribe rather than specifying the type of healthcare provider.

Ms. Bell inquired whether pharmacists from IHS facilities can participate in collaborative relationships without seeking board approval. Ms. Bell was asked by an IHS-employed pharmacist about this and didn’t believe approval was required. Chair Holt recalled previous discussions on what requirements the board could hold licensees to who were employed by the HIS.

TASK 31

Ms. Carrillo will follow up with EA Norberg on the Medical Board’s discussion of the joint cooperative practice agreement plan.

TASK 32

Ms. Carrillo will follow-up with the Board of Nursing, Board of Dental Examiners, and Board of Examiners in Optometry on their intent to pursue similar cooperative practice agreement regulations. Ms. Carrillo will provide an update at the September meeting.

TASK 33

Ms. Bell will provide language to Ms. Carrillo on a potential request to DOL regarding IHS pharmacists and collaborative practice agreements.

Agenda Item 13 Public Comment #4

Time: 4:00 p.m.

Lorri Walmsley inquired on what the board's legislative priorities are, and if it includes technician immunizations. Chair Holt stated these were addressed via emergency preparedness regulations.

Agenda Item 11 Farewell Chair Holt/Upcoming Meetings

Time: 4:10 p.m.

Farewell Dr. Holt

Day 2 of this meeting marks Chair Holt's last meeting day after several productive years on the board. Ms. Carrillo thanked Dr. Holt for his commitment to the board and expressed gratitude for how knowledgeable, accessible, dedicated, and proactive he has been for the board and pharmacy profession. Ms. Bell, Mr. Henderson, and Dr. Ruffridge expressed their thanks with similar sentiments that he has been an exceptional chair and will be sorely missed.

Chair Holt expressed his gratitude for the opportunity to serve on the board, adding it has been a wonderful experience. Chair Holt expressed he would still participate when he can through providing comment on regulations, maybe eventually returning to Alaska.

Next meeting dates

September 23 – 24th – Anchorage

November 18 – 19th – Anchorage

February 17-18 – Juneau

TASK 34

Ms. Carrillo will submit travel requests for the September and November meetings in Anchorage and February 2022 meeting in Juneau.

Agenda Item 9 Adjourn

Time: 4:28 p.m.

On a motion duly made by Lana Bell, seconded by James Henderson, and approved unanimously to adjourn the meeting, the meeting was adjourned at 4:28 p.m.

Laura Carrillo

09/27/2021

Laura Carrillo, Executive Administrator

Date

Justin Ruffridge

9/28/2021

Justin Ruffridge, Chair

Date