State of Alaska				
Department of Commerce, Community and Economic Development				
Division of Corporations, Business and Professional Licensing				
Alaska Board of Pharmacy				
DRAFT MINUTES OF THE EMERGENCY MEETING				
November 5 - 6, 2020 Videoconference				
By authority of AS 08.01.070(2), and in compliance with the provisions of AS 44. Article 6, a scheduled meeting of the Board of Pharmacy via videoconference of November 5 - 6, 2020. Due to the COVID-19 pandemic, in-person attendance who available.	n			
Agenda Item 1 Call to Order/Roll Call Time: 9:06 a.	m.			
The day 1, November 5, 2020 videoconference was called to order by Chair, Rich Holt at 9:0 a.m. Board members present, constituting a quorum: Richard Holt, PharmD #PHAP2008, MBA – Chair Leif Holm, PharmD #PHAP1606 – Vice Chair James Henderson, RPh #PHAP1683 Lana Bell, RPh #PHAP893 Tammy Lindemuth, Public Member Sharon Long, Public Member Justin Ruffridge, #PHAP1787				
Division staff present:				
Laura Carrillo, Executive Administrator				
Lisa Sherrell, PDMP Manager				
Heather Noe, Occupational Licensing Examiner (Board of Pharmacy)				
Ilsa Lund, Occupational Licensing Examiner (Board of Veterinary Examiners)				
Carl Jacobs, Investigator				
Harriet Dinegar-Milks (Department of Law)				
Mambara from the public present/resistand				
Members from the public present/registered:				

43	Kara King, ANMC
44	Coleman Cutchins, AK HSS
45	Erin Selby, NCPA
46	Charles Semling, DHSS
47	Michelle Hoyt
48	Ursula Iha, Bartlett Regional Hospital
49	Ashley Schaber, Alaska Pharmacists Association/ Alaska Native Tribal Health Consortium
50	Lorri Walmsley, Walgreens
51	Janelle Solbos
52	Ademola Are, National Community Pharmacist Association
53	Josh Fillible, Maniilaq Health Center
54	Dale Masten, Genoa Healthcare
55	Molly Gray, Alaska Pharmacists Association
56	Tom Wadsworth, UAA/ISU Doctor of Pharmacy Program
57	Erin Narus, SOA/HCS
58	Heather Heidorn, CRNA

Agenda Item 2 Review/Approve Agenda

The board reviewed the agenda for day 1. Tammy Lindemuth requested the CSAC update be moved earlier due to a scheduling conflict. Ms. Carrillo suggested moving it immediately after Agenda Item #5, the PDMP update, as a new subsection H since it relates to controlled substances.

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

RESOLVED to accept the November 5, 2020 meeting agenda as amended.

2	APPROVE	DENY	ABSTAIN	ABSENT
3 Leif Holm	X			
4 Richard Holt	X			
Justin Ruffridge	X			
6 Lana Bell	X			
7 Tammy Lindemu	ıth x			
James Henderson	n x			

The motion passed with no further discussion.

 \mathbf{X}

Agenda Item 3 Ethics

Sharon Long

Time: 9:12 a.m.

Time: 9:09 a.m.

For transparency, Chair Holt reminded the board and the public that he currently participates in the biweekly COVID-19 board chairs meeting as well as the biweekly PDMP board chairs meeting.

Dr. Ruffridge indicated he would abstain from voting on the collaborative practice agreement (CPA) application for Soldotna Specialty Pharmacy, for which he is the Director of Pharmacy Services.

Agenda Item 4 Review/Approve Meeting Minutes

The board reviewed the draft minutes from the August 27-28, 2020 meeting that was held via Zoom. Ms. Lindemuth noted that Katholyn Runnels' name was still spelled incorrectly on line 470.

Sharon Long commented that she was listed as absent early on in the meeting. Ms. Carrillo indicated she would double-check the minutes and make corrections as appropriate.

TASK 1

Ms. Carrillo will correct Kathlolyn Runnels' name in the August 27-28, 2020 meeting minutes. (Completed 11/07/2020.)

TASK 2

Ms. Carrillo reviewed the meeting minutes and audio recording; Ms. Long is listed as absent during the voting of the August 27, 2020 day 1 agenda, which began at 9:09 a.m. Ms. Long joined the room at 9:12 a.m. so was not present during this time. The minutes do not need to be corrected.

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 August 27 – 28, 2020 meeting minutes with the correction to Katholyn Runnels' name.

117		APPROVE	DENY	ABSTAIN	ABSENT	
118	Leif Holm	X				
119	Richard Holt	X				
120	Justin Ruffridge	X				
121	Lana Bell	X				
122	Tammy Lindemut	h x				
123	James Henderson	X				
124	Sharon Long	X				

The motion passed with no further discussion.

Time: 9:13 a.m.

<u>Registration and Use Summary</u>

Ms. Sherrell presented the board's November PDMP report, informing them that in the area of registration, the board will get a better sense of what compliance looks like after renewals from updated information from pharmacists on their dispensing status. Ms. Sherrell also informed the board that the license integration project was not successful, though it still is the intent to move forward with that feature. The report also indicates efforts with the PDMP's current vendor to turn on an automatic notification feature when a provider has missed a day of reporting. For the report period, there were more registered pharmacists than are dispensing, representing over a 100% registration compliance rate; however, this data is not to indicate there are no issues with non-compliance among licensees. Inflating compliance is the number of pharmacists who are registered but are not required to, as well as the population of pharmacists with active accounts but lapsed or expired licenses, which the license integration project would have deactivated had it launched successfully. Additionally, there are federal pharmacists who are registered but who are not required to under AS 08. A clearer picture of registration compliance will be provided in subsequent reports after the renewal season.

As other affected prescribing boards are currently in renewal, prescribers who are dispensing are going through the same process of being tracked for their compliance with reporting. Ms. Sherrell expressed concern over the number of prescribers who have indicated confusion over what it means to directly dispense.

Ms. Sherrell then pointed to the MME chart, indicated that the last time this chart was presented, there were alarming statistics with dangerous combinations (October through March), but that now from June through October, there have been marked decreases, e.g.: 87% decrease among APRN licensees, for example. Ms. Sherrell then pointed to the alarming number of providers who reviewed zero patients, but noted it had improved since the previous report. In between these two reports, Ms. Sherrell informed the board the PDMP did launch Clinical Alerts, which may have contributed to the decrease. Dangerous concurrent prescribing of opioids and benzodiazepines has also gone down.

Chair Holt inquired as to whether providers who may be exempt from reviewing, such as emergency physicians, were included in the data of no reporting. Ms. Sherrell stated she filtered out oncology, surgery, and emergency care specialties.

Chair Holt also commented that while it is important to acknowledge dangerous combinations, which the CDC recommends as dangerous, there is no regulation prohibiting this. In 2016 after SB74 passed, there was a Joint Committee on Prescriptive Guidelines that convened and recommended a 120 MMEs/day limitation, though the legislature did not codify that. Ms. Sherrell clarified they set the MME threshold in Clinical Alerts to 50 MME because that's what the Medical Board has set in regulations. Ms. Sherrell also recognized there could be legitimate clinical

Time: 9:20 a.m.

reasons as to why a patient may be on dangerous concurrent prescriptions, though the data is to keep providers aware of when these combinations are present to assist in assessing risk.

Dr. Ruffridge commented on the registration numbers, requesting more clarification on there being 100% compliance when this is rarely the case. Ms. Sherrell acknowledged compliance is rarely at 100% but that on paper, the total numbers of registrations have exceeded the number who are required to register. Chair Holt commented that if the data is cleaned to remove those who aren't required to register, stale accounts, or filtered out by those who didn't register on time, compliance is not at 100%.

Dr. Holm inquired whether there was a way to filter out those pharmacists who are not in Alaska and therefore are not required to register, also commenting there seems to be a large percentage of pharmacists who are registered but do not dispense. Ms. Carrillo responded there are two ways we are doing this now: filtering out those pharmacists without Alaska addresses and filtering out pharmacists who do not have a dispensing designation tied to their license. Ms. Carrillo added that part of what is contributing to skewed data is that non-dispensing or out-of-state pharmacists are able to register if they want to, and many opted to only because it allowed them to renew their pharmacists license online versus on paper.

PDMP Recommendations

The report continues with a recommendations section, which is similarly provided in other board reports for the prescribing boards and include recommendations to increase use through delegate access and to ensure user roles are accurate as these affect the accuracy of prescriber report cards.

Grant Updates

Ms. Sherrell sharing the news that the division received two grants: one from the Bureau of Justice Assistance (BJA) and another for the Statewide Opioid Response (SOR). The BJA award

document has still not been released, so it is unclear which activities the funding will support;

however, the BJA grant is for enforcement purposes.

PDMP MOUs

Ms. Carrillo presented the intrastate and interstate datasharing update to the board, noting there were no new intrastate connections since the last report in August. There were new connections via PMP InterConnect "PMPi", which is a datasharing hub between states. Connecticut, Hawaii, and Wyoming have all integrated bidirectionally with the Alaska PDMP via PMPi, and Nebraska is pending with the BJA's/IJIS' datasharing hub, RxCheck. From August – October 2020, there was a 17% increase in the number of patient reviews performed through integrated states compared to the same timeframe in 2019. Ms. Carrillo also informed the board that the Military Health System, which launched their own PDMP in December 2018, has signed their part of the MOU, but is awaiting signatures on DCCED's end with execution expected to occur soon. The Veterans Health Administration (VHA) is also working with PDMP staff to integrate access.

RFP Update

- 212 Ms. Sherrell informed the board that the RFP was out and due for responses soon, and that
- because of this, integration and enhancement projects are being put on hold. We are expected to
- 214 have a vendor selected by the end of the year.

- Statewide Opioid Action Plan Review Summit 2020
- 217 Ms. Carrillo attended the 3-day opioid summit to contribute to goals and strategies around the
- state's opioid response. Ms. Carrillo was assigned to the prescribing practices committee, where
- 219 they focused on Goal 3, which aims to reduce the risks of substance misuse and addiction in
- Alaska. The group discussed prescriptive guidelines, which Chair Holt mentioned earlier (Joint
- 221 Committee on Prescriptive Guidelines), but those efforts weren't codified by the legislature. The
- group also talked about incorporating different datasets into the PDMP, including overdose and
- 223 MAT data to improve the clinical decision making of providers when reviewing patient
- prescription histories. The 2018 2022 Statewide Opioid Action Plan can be found here:
- 225 http://dhss.alaska.gov/osmap/Documents/Statewide-Opioid-Action-Plan-2018-2022.pdf

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PDMP Legislative Report

- 228 Ms. Carrillo reminded the board that the annual PDMP report to the legislature is due in
- February/March and inquired whether the board had any specific input on what to include this
- year. Chair Holt recommended including the extent of the Board of Pharmacy's education and
- outreach efforts as there have been a number of documents and resources put together to assist its
- licensees and licensees from other affected boards to better understand and comply with PDMP
- requirements. Chair Holt himself attended other boards' meetings to be a PDMP resource, such as
- for the Board of Veterinary Examiners, and has drafted a number of templates and guidance
- 235 documents to assist with compliance.

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- 237 Ms. Carrillo commented on the Awareness and Feedback Questionnaire, which Ms. Sherrell
- launched in February to gauge provider understanding of and challenges to PDMP use.
- Participants identified education and outreach as the lowest ranked barrier to using the PDMP,
- 240 which doesn't diminish the need for continued education and outreach, but highlights that
- providers generally understand how to use the PDMP, but using it may be hindered by other
- factors, such as time.

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Controlled Substances Advisory Subcommittee

- Tammy Lindemuth presented her update of the CSAC. Ms. Lindemuth informed the board the
- 246 CSAC last met on October 20th, where they continued discussing Kratom and moved forward as a
- board to put forth recommendations to the Governor to schedule mitragynine kratom and 7-
- 248 hydroxymitragynine as schedule 3A drugs, which the Alaska crime lab has the capabilities to
- 249 detect.

- Ms. Lindemuth shared the CSAC also discussed spice and looked at Texas' statute that addresses
- 252 synthetic cannabinoids and how implementation of the laws have been affecting their
- communities. The group also discussed gabapentin in Western Alaska, where it is highly abused. It

was ultimately decided to recommend to the Governor it be scheduled as a 5A drug. The CSAC is also further exploring definitions of marijuana, including CBD oil.

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Chair Holt inquired as to whether the CSAC considered reporting requirements since schedule Vs aren't required to be reviewed in or reported to the PDMP, or what other considerations were made in the recommendations. Ms. Lindemuth indicated that recommending scheduling has more to do with the prosecutorial aspect and the ability to have jurisdiction over gabapentin related crimes. Dr. Holm expressed concern over the prosecutorial approach, commenting the focus should be on identifying the misuse and abuse so it can be curtailed and identifying agents that contributes to illicit use. Dr. Holm referenced Portalnd, Oregon, which has decriminalizing heroin and cocaine. Ruffridge agreed, indicated that pregabalin, or Lyrica, which is a schedule V, is used in a similar fashion as gabapentin and can be combined with opiates. Dr. Ruffridge commented there needs to be a way to get this data into the PDMP and not be used punitively.

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Ms. Carrillo commented that schedule Vs used to be in the PDMP but was repealed in 2017 because of the lower potential for abuse. Ms. Carrillo inquired whether there is a shift in use, in combination with illicit drugs. Ms. Lindemuth indicated it wasn't occurring on a large scale within the state but is more in Western Alaska. It was added that due to the pandemic and limited ability to import illicit substances, the availability of heroin has gone down, so people are able to order gabapentin at a cheap price and have it delivered via the postal service. Dr. Ruffridge's understanding is that the goal of scheduling gabapentin is to curtail it being used as a combo agent to extend or enhance their high when used in combination with opiates and gabapentin, which is contributing to massive increase in overdoses. Dr. Ruffridge indicated the benefit of being in PDMP is it would allow providers to see what is being prescribed and to help reduce diversion and misuse.

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Chair Holt informed the board that in order for gabapentin or Kratom to be reported to the PDMP, it would have to be scheduled federally. Ms. Carrillo commented that while schedule Vs aren't required to be reported, some providers report all prescriptions, including this schedule. It could be recommended that providers review schedule Vs even though it cannot be mandated.

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The board returned to discussing Kratom. Ms. Lindemuth shared that Kratom is a natural substance that mimics opioids as it acts on the opioid receptor. Dr. Holm commented it is being advertised in Fairbanks and can be easily purchased. Mr. Henderson stated that every federally scheduled drug is approved by the FDA, so it would seem to be a moot point to schedule Kratom.

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The board continued to address gabapentin, Kratom, and scheduling.

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Link to CSAC site: http://www.law.state.ak.us/department/criminal/csac.html

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Agenda Item 6 <u>Investigative Report</u>

Time: 10:18 a.m.

Investigator Jacobs joined the board to present their investigative report, which includes activity from August 18, 2020 and October 27, 2020. There were 43 matters opened and 11 cases closed during this time. There were no new probation matters to report. Investigator Jacobs indicated they've seen an influx in cases due to the board being in renewal. There were also two matters reopened from 2017 related to actions taking by the board during their August meeting related to renewal and reinstatement. There is also an enforcement action to address for case #2019-000720.

Dr. Ruffridge inquired whether pharmacist applications go against a background check or whether the self-certification on the professional fitness section is adequate. From investigative perspective, Investigator Jacobs indicated they do their due diligence, but noted that with renewals, the referred matters are typically related to license issues as opposed to criminal activity history. Failure to disclose previous actions. To Dr. Ruffridges' concern over cross checking responses to selfcertification of no adverse history, Dr. Holt added there isn't a way to validate to make sure that pharmacists was truthful in answering "no" to the professional fitness section.

Consent Agreements

 The board acknowledged they had a consent agreement matter, case #2019-000720, to discuss confidentially.

On a motion duly made by Lana Bell in accordance with AS 44.62.310(c)(2), and seconded by James Henderson, the board unanimously 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	n x			
James Henderson	X			
Sharon Long	X			

The motion passed with no further discussion.

Staff members, Laura Carrillo and Carl Jacobs were authorized to remain in the room.

339 Off record at 10:37 a.m.340 On record at 10:47 a.m.

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

On a motion duly made by Lana Bell in accordance with AS 44.62.310(c)(2), and seconded by Justin Ruffridge, to accept the consent agreement for case #2019-000720, it was:

RESOLVED to accept the consent agreement in case # 2019-000720.

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

The motion passed with no further discussion.

TASK 3

Ms. Carrillo will obtain the signed consent agreement for case #2019-000720 and forward to Investigator Jacobs along with a copy of the board's motion.

364 (Completed 11/09/2020.)

Agenda Item 7 <u>Board Business</u>

Investigator Jacobs informed the board there were two additional matters to address that were initially opened in 2017, case #s 2017-00092 and 2017-000557. Due to the nature of the matters, Investigator Jacobs recommended discussing these in executive session. Ms. Carrillo informed the board the individual involved in case #2017-000557 was present and had requested a discussion with the board.

On a motion duly made by Lana Bell in accordance with AS 44.62.310(c)(2), and seconded by Justin Ruffridge, the board unanimously 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).

 Time: 11:02 a.m.

381		APPROVE	DENY	ABSTAIN	ABSENT
382	Leif Holm	X			
383	Richard Holt	X			
384	Justin Ruffridge	X			
385	Lana Bell	X			
386	Tammy Lindemuth	n x			
387	James Henderson	X			
388	Sharon Long	X			

The motion passed with no further discussion.

Staff members, Laura Carrillo and Carl Jacobs were authorized to remain in the room.

Off record at 11:08 a.m. On record at 12:22 p.m.

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

 On a motion duly made by Rich Holt for case #2017-000057, with conditions for licensure due to violations to 12 AAC 52.920(a)(4), AS 08.80.261(a2), (a9),a(11), and a(14), it was proposed to remove the condition of no access to controlled substances while in the workplace, given the applicant has successfully demonstrated professional behavior in his current treatment programs with the PA board of pharmacy over the past three years and to reduce drug testing and urine analysis to two years. With the condition that if after one (1) year, there are no issues related to the testing and analysis, the board will accept the license as successful, and seconded by Lana Bell, it was:

RESOLVED to accept the consent agreement in case #2017-00057 as amended to remove the condition of no access to controlled substances in the workplace and to reduce drug testing and urine analysis to two years.

413		APPROVE	DENY	ABSTAIN	ABSENT
414	Leif Holm	X			
415	Richard Holt	X			
416	Justin Ruffridge	X			
417	Lana Bell	X			
418	Tammy Lindemuth	n x			
419	James Henderson	X			
420	Sharon Long	X			

- Discussion: Chair Holt commented that the applicant has professionally demonstrated over the 422
- 423 past three years that a license is not needed because he is actively practicing under another license.
- 424 Chair Holt expressed that the applicant's presence and time with the board today demonstrates his
- professionalism, and in the board's due diligence to protect the public while continuing to be a 425
- resource to applicants, he is comfortable with the amended terms of the agreement. 426

- 428 TASK 4
- 429 Ms. Carrillo will send the board's motion wording for case #2017-00057 to Investigator Jacobs.
- 430 (Completed 12/02/2020.)

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432 The application for Wedgewood Village Pharmacy, which was on the agenda for review/approval, 433 will be reviewed and voted on via OnBoard.

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- 435 TASK 5
- Ms. Noe will upload the Wedgewood Village Pharmacy application for voting in OnBoard 436 (Completed; quorum established and license issued on 11/09/2020.)

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Agenda Item 9 Time: 12:28 p.m. Lunch

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441 Upon return to the record for lunch, Chair Holt opened up presentations for association and profession updates. 442

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Agenda Item 11 <u>Industry/Profession Updates</u> Time: 1:10 p.m.

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Alaska Pharmacists Association

Molly Gray let the board know they are looking forward to receiving award nominations for 447 recognition and that there are open positions for the board of directors, with December 1st being 448 449 the deadline for each. Ms. The AKPhA will also be launching their immunization certificate program on November 22nd. Ms. Gray stated that both technicians and pharmacists may attend 450 451 and that it is a fully ACPE- accredited certificate program. Ms. Gray has reached out to PTCB, and while that course isn't specifically accredited to technicians, techs can have up to 5 hours of 452 453 pharmacy CE now applicable to their certificate via that board. They are looking at a technician-454 specific program to be available soon through APhA and Idaho State University

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Ms. Gray thanked the board for their prompt response to DHSS' mandate on allowing technicians to provide immunizations, citing that other boards of pharmacies scrambled to get guidance together for their licensees. The board's guidance was sent through its ListServ.

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- 460 Dr. Schaber also thanked the board for their responses and guidance through the pandemic before 461 turning to the legislative proposal that was put together by the association's legislative committee,
- 462 UAA, and Idaho State University. Dr. Schaber requested to the board that they review their
- 463 practice modernization act proposal, make amendments as appropriate, and introduce this to the
- legislature. The goal of the proposal is for pharmacists to continue to provide clinical services that 464

they're already providing that are essential to the healthcare system both during the pandemic and beyond. Changes would be to title 21 to include pharmacists in the list of protected providers, update practice of pharmacy but stipulating medical services Alaska pharmacists already provide, and to update the scope of practice of pharmacy technicians to include vaccines. Ms. Schraber continued to explain that the amendments are intended to align contemporary compensation models with the range of patient health care services that Alaska pharmacists already provide.

Alaska Department of Health and Social Services - Medicaid

Dr. Narus informed the board that the enrollment in Medicaid for pharmacy professional groups is very slow and is hoping that through the board or through other means, knowing that COVID is on its way, that there's encouragement for pharmacies and pharmacists to enroll in the Medicaid program, so that DHSS can get them processed through the various checks and make sure they are being reimbursed for their professional services. Dr. Ruffridge inquired how slow it was going, to which Dr. Narus indicated it was only one pharmacy and less than 25 pharmacists as of today, November 5. Dr. Narus indicated that some of the challenges are at the corporate level, but commented that if there was a way to expedite the application by going through the pharmacist-incharge to get that application in; consult the NPI and licensure databases, it could help recoup administration costs for the vaccine. Chair Holt stated from his personal perspective, he has reached out to his corporation to progress on this, but there are conflicting priorities. Chait Holt indicated he would follow-up. Ms. Gray commented the AKPhA is providing a workshop, which could be a helpful push.

Ms. Long inquired about the tiered system for COVID-19 vaccines; from the federal level, there are three phases for the vaccine rollout: Phase 1b is CMS-certified longterm; Phase 2 is community role out to high-risk populations/availability at pharmacies; and Phase 3 is for the general population. Smaller pharmacies not serviced in this rollout can receive immunizations through their state immunization program. Dr. Narus added that pharmacists must be enrolled in the Medicaid program in order to order vaccines.

Agenda Item 12 Public Comment

Dr. Cutchins encouraged the board to think flexibly in being able to provide services during the pandemic; adding that after speaking with federal leadership, is anticipating we will begin using monoclonal antibodies for treatment of COVID-19 cases in ambulatory care and possibly for post-exposure prophylaxis. Dr. Cutchins stated there will be many challenges, but honed in on IV infusions; they will be a single-stick for immediate use, so don't have to be in sterile setting. Drugs would have to be given within 3 days of a positive test, so time will be of the essence in reducing barriers. Dr. Cutchins encouraged the board to think about collaborative practice agreement changes and prescriptive authority.

Chair Holt reminded the board about our limitations with allowing a pharmacist to prescribe and the barriers with collaborative practice approvals; a letter was written to the medical board in August of 2019 requesting they repeal the requirement for the agreements to be approved by the

Time: 2:13 p.m.

board of pharmacy. Chair Holt is actively working with Dr. Wein from the medical on efforts to repeal this regulatory barrier.

Dr. Ruffridge inquired about delegating board decision making to Ms. Carrillo on collaborative practice agreements. Chair Holt stated that the collaborative practice agreement regulations explicitly state they will be approved by the board. Ms. Carrillo added that we would have to have the medical board repeal the part about approval, then the board would seek a regulation change to add approval of collaborative practice agreements as a duty under the EA regulations.

Agenda Item 11 <u>Industry/Profession Updates</u> Time: 2:24 p.m.

Following public comment, the board returned to industry updates.

District 7 Resolution

Dr. Ruffridge provided a summary of the NABP's resolution to be heard at their next meeting in May. The NABP is wanting to establish a task force to establish a member board to transition to a "just culture regulatory approach". This resolution is to discuss whether or not it is appropriate for boards of pharmacies to institute a fine, penalty, or some other action to individual practitioners or pharmacists who encounter medication errors and to help resolve those issues without punitive action. Dr. Ruffridge indicated it was a new concept to him and was surprised to learn other boards of pharmacies had already addressed this issue in their regulations. Chair Holt indicated from his perspective that he is very familiar with "just culture", because the company he works for is federally classified as a patient safety organization. A couple of years ago when he was looking through regulation, it always bothered him that they required a continuous quality improvement aspect of shared pharmacy services licenses, but not for other license types

The meeting ended abruptly due to a Juneau-wide power outage. Agenda items not discussed on Day 1 were moved to Day 2.

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552	Department of Commerce, Community and Economic Develo	pment
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568		me: 9:07 a.m.
569	8 ————	
570		h Holt at 9:07
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573	Board members present, constituting a quorum:	
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593	<u>Iembers from the public present/registered:</u>					
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595	Angela Wampler, Walgreens					
596	Dale Masten, Genoa Healthcare					
597	Lauren Paul, CVS Health					
598	Michelle Hoyt					
599	Jessica Adams, TelePharm a Cardinal Health Company					
600	Molly Gray, Alaska Pharmacists Association					
601	Ashley Schaber, Alaska Pharmacists Association/Alaska Native Tribal Health Consortium					
602	Lorri Walmsley, Walgreens					
603	Adam Chesler, Cardinal Health					
604	Erin Narus, SOA/HCS					
605	Heather Heidorn Copper River Native Association Pharmacy					
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Agenda Item 2 Review/Approve Agenda

The board reviewed the agenda for day 2. Due to the power outage affecting the Juneau area, the meeting abruptly ended shortly before 3:00 p.m. Chair Holt reviewed the agenda items that were not addressed the previous day:

- Application review
 - o 3 CPAs
- Review thefts and Loss
- Positive Statements
- FAQ review

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- Professional fitness questions
- Correspondence
- Work group updates
 - Administrative business

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623 It was proposed to move position statements to the regulations discussion at 9:00 a.m.

On a motion duly made by Tammy Lindemuth to approve the meeting agenda as amended to include items from Day 1 missed due to the power outage, seconded by Justin Ruffridge, and approved unanimously, it was:

RESOLVED to accept the November 6, 2020 meeting agenda as amended.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm				X
Richard Holt	X			
Justin Ruffridge	X			

Time: 9:08 a.m.

635	Lana Bell	x
636	Tammy Lindemuth	X
637	James Henderson	x
638	Sharon Long	x

The motion passed with no further discussion.

Agenda Item 3 Ethics

There were no ethics disclosures to report.

Agenda Item 4 Regulations Overview

Leif Holm joined the room at 9:23 a.m.

Position Statements

Chair Holt referred to the examples provided in the board packet and explained to the board that they are ideal informational documents because of the ability to provide more background and context than what is typically provided in FAQs. Chair Holt stated that it could be helpful for the issue around delivery drivers as there are still gray areas around what they can and can't do; it would be useful to use as template to clarify what the board's intent is. The board considered removing FAQs and replacing the with position statements. Dr. Ruffridge commented it can sometimes be difficult to navigate a specific subject in the FAQs. Ms. Long commented that the public should keep the FAQs since it's a recognized term.

Ms. Carrillo added that position statements don't have the force of law, do not create new laws, and do not repeal them; they provide clarification to licensees on the public on matters that are already within the scope of practice.

Regulations: Delivery driver

Chair Holt commented that the language for pharmacy technicians likely came from NABP model act language, so it doesn't give very clear, concise details as to what they can and can't do. Chair Holt pointed to 12 AAC 52.230(a)(1), specifically to the terms "manipulative", "nondiscretionary" and "supportive staff", which are vague terms. Chair Holt indicated he researched the definition of dispense: "dispense" or "dispensing" is defined in AS 08.80.480(8) and means the preparation and delivery of a drug or device to a patient or patient's agent under a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to, or use by, a patient.

 Chair Holt posed that since the board got rid of cashier and bookkeeper as functions requiring a technician license, does it really remove the requirement to have a license because they are working in the dispensing area? Dr. Ruffridge asked whether a cashier could grab a prepared prescription, ring it up, and give it to the patient without being a licensed technician? Chair Holt

Time: 9:14 a.m.

Time: 9:08 a.m.

indicated that is the question; at present if you look at the definition of "delivery" and "dispensing", does the board consider preparation (grabbing the bag) and delivery (giving prescription to patient) functions requiring a license? Dr. Ruffridge asked, by removing cashier from sentence maybe didn't do anything if the definition of delivery is to give the product to the individual, so it seems like all an unlicensed cashier can do is ring up the patient, and somebody else who is licensed would have to give that prescription to the patient.

Dr. Holm stated that his question was not about bookkeeper or cashier, but that a pharmacy wanted to use the store employee, one who was not necessarily employed by the pharmacy, to stock, order, provide supportive assistance but not handle part of the prescription process. Chair Holt stated his recollection was that the board didn't want to list or limit what is included in "dispensing area." Dr. Holm agreed they should have stated, "excluded cashier and bookkeeper." Dr. Ruffridge stated that even if the word "excluded" was used, it wouldn't change the statutory definition of "deliver". Chair Holt responded that it would still provide clarity as to what could be done.

Harriet Dinegar-Milks joined the room 9:52 a.m.

Chair Holt commented to AAG Dinegar-Milks: when we look at statutory definition of "dispensing" under a prescription drug order, it includes preparation and delivery, so in any pharmacy where there is preparation and delivery, which is also defined in statute, by removing and eliminating the casher and bookkeeper perspective, it is creating gray area as to whether a cashier still falls in the statutory definition because they are looking in the delivery area. AAG Dinegar-Milks stated that any whomever has access to the prescription, that person is acting to deliver the drug under a lawful prescription. Dr. Ruffridge commented that the board should have just removed all of (2), to which AAG Milks agreed; a cashier or bookkeeper is a supportive staff member. Chair Holt stated that (a)(1) and (a)(2) are tied together as an "and". AAG Dinegar-Milks stated she believes a cashier or bookkeeper would not need a technician license because they are not performing functions associated with a pharmacy.

Ms. Long expressed concern about the assumption that cashiers are not in the dispensing area of the pharmacist; if they not are supervised by the pharmacist, then who are they supervised by? AAG Dinegar-Milks: if you want to exclude them from having a license, the board could state, "this does not include employees who perform administrative functions, such as a cashier or bookkeeper." AAG Dinegar-Milks further suggested:

- 12 AAC 52.230
- 715 (a)(1) written as is
- 716 (a)(2) but does not include employees performing purely administrative functions, such as bookkeeping and cashier duties.

From a legal perspective, AAG Dinegar-Milks stated there is no problem excluding delivery drivers. Dr. Ruffridge commented that he doesn't understand the purpose of line 2 to begin with;

if this is already a statutory definition of a pharmacy technician, which is a support staff member working under the supervision of the pharmacist. The problem with the wording is the word "dispensing". Dr. Ruffridge asked if the board would have zero problem allowing cashiers to work in the pharmacy without a license. AAG Milks also commented she wasn't sure what "manipulative" function means; it could be taking a bottle and putting it in a bag. Chair Holt stated he couldn't find a legal interpretation, but was not able to find in his research what this was defined as. The board discussed non-discretionary duties. Dr. Ruffridge stated the key in the sentence is "practice of pharmacy" which is defined in statute, so we're not so much focused on "non-discretionary", because it is not defined.

Chair Holt inquired whether the board could proceed with an official position statement, to which AAG Dinegar-Milks reiterated that a position statement doesn't have the force of law, and so if the board wanted to clarify this, they should change 12 AAC 52.230, including removing "manipulative" and "nondiscretionary functions" since these are not defined.

Regulations: Facility Licenses, Change of Name, Emergency permit, Other

The board then referred to the draft regulations document provided in the packet beginning on page 45, including reviewing each comment provided on the draft:

https://www.commerce.alaska.gov/web/Portals/5/pub/PHAboardpkt_2020_11_Day2.pdf

Referencing the emergency permit regulations, 12 AAC 52.110, Chair Holt informed the board this section can be expanded to interns and technicians. A certified true copy is not valuable to the application assessment and is recommended to be removed, especially during the pandemic when notaries aren't available. Ms. Carrillo commented that many licensees misunderstand what a certified true copy is, instead submitting a verification of license.

Chair Holt then addressed the length of time for a permit. AAG Dinegar-Milks stated other boards have taken a hard look at the emergency and how it's going to come to a close or whether it will become endemic. AAG Dinegar-Milks added it is a good idea to have an end date to the permit so there aren't licensees taking advantage of this permit long-term, bypassing other requirements, such as examinations. AAG Dinegar-Milks further suggested the board allow the emergency permits be renewed. Chair Holt acknowledged renewing would make sense as it takes a long time to go through the NABP examination process.

AAG Dinegar-Milks reminded the board that for emergency regulations, the board would need to make a decision within 10 days whether they board will adopt the emergency regulations as permanent. Chair Holt expressed adopting as permanent to which there was no opposition. AAG Dinegar-Milks stated the board would have to articulate a finding of an emergency and how this regulatory response might relate to that emergency. Chair Holt commented that interns and techs immunizing, so the board will need to contemplate how that exposure might affect the licensure fluctuations. Ms. Long stated that because in an emergency right now, it is better to be in front of the power curve than behind it. Dr. Ruffridge agreed. Ms. Long recalled Dr. Narus'

discussion on the rollout of vaccines and the anticipation of being in phase 2 by January or February. Chair Holt added that when you think about how DHSS has continuously added to what pharmacists, techs, and interns can do with ordering and administering, and with what Dr. Cutchins said about upcoming therapy, I don't think it is the end of pharmacists being asked to respond to COVID. Dr. Ruffridge expressed support in adopting emergency regulations.

Ms. Bell inquired whether there was a limit as to how long the board could allow an emergency license. AAG Milks stated one can't have an emergency to extend indefinitely because it becomes a new normal situation; we don't' like to see emergency situations used functionally because it skips over the public comment process; we try to use emergency regulations sparingly; as far as the emergency provisions that came out of an emergency declaration made by the governor, that goes away on November 15. Ms. Bell contemplated staff and processing time, recommending validity of permits to be for 180 days, to which AAG Dinegar-Milks indicated was doable.

AAG Dinegegar-Milks suggested the board create a new section called courtesy license: applicants can get a license renewable for 90 days. The reason for the AAG's suggestion is because the existing subsection 12 AAC 52.110, it is unlikely the emergency situation will persist for more than 60 days, so the way it is worded makes sense; perhaps what is needed is an emergency courtesy permit. AS 08.01.062 allows any program to issue courtesy licenses to individuals out of state. Ms. Bell agreed on a section just dealing with courtesy licenses per AS 08.01.062, which only applies to non-residents.

Regulations: Length/validity of controlled substance prescriptions

Dr. Ruffridge expressed his opinion that this is a non-issue as pharmacist uses their discretion to determine how long that prescription should be valid for. Chair Holt stated the time limit on schedule II controlled substance in NY used to be 14 days and is 3 days in HI. Mr. Henderson supported a time limit. Dr. Holm stated the federal government has already put a time limit and doesn't believe someone who is abusing is holding on to an old prescription. Dr. Ruffridge stated he doesn't believe there should be a limitation on it and doesn't believe it would be a deterrent.

The board decided they would not pursue a regulation and would instead defer to federal law.

Regulations: Age limit for controlled substance prescription pick-up

Dr. Holm stated he could see why a regulation would be appropriate because pharmacists are scared to make a discretionary call and get in trouble for it. The board did not decide to pursue limits in regulation.

Agenda Item 7 <u>Lunch</u> Time: 12:05 p.m.

Off record for lunch at 12:05 p.m. Back on record at 1:04 p.m.

Agenda Item 8 <u>Budget Report/Division Update</u>

Melissa Dumas joined the room to present the board's FY20 4th quarter report. Ms. Dumas commented that the revenue appears to be down significantly in FY20, but a good chunk was brought in at the end of the fiscal year from June to September due to the delayed renewal. Ms. Dumas assured the board this isn't something to be concerned about if you're looking at FY18 to FY19 revenue. Ms. Dumas continued to provide her report, indicating that the total direct expenditures was at \$219,230.

Moving onto the report for the PDMP, PDMP personal services for was at \$41,343 and the ending cumulative surplus was at \$62,567. Ms. Carrillo inquired whether she knew of projected revenue, to which Ms. Dumas estimated to be at least \$100,000. Chair Holt reviewed the expenditures on fingerprinting, expressing surprise over the financial impact. Ms. Noe informed the board the fingerprinting cost to DPS is \$35 and over 500 applications were processed.

Agenda Item 9 Return to Regulations

 AAG Dinegar-Milks worked with regulations specialist, Jun Maiquis, on drafting language for the emergency permit and courtesy license regulations in 12 AAC 52/110. AAG Dinegar-Milks stated that the first subsection, (a), incorporates the changes the board discussed previously. Subsection (b) is changed from 60 to 90 days, calling it an emergency permit, even though the title is emergency licensure. In a new subsection (c), there is a new circumstance, where in a pandemic situation, the board could issue a courtesy license for pharmacists, interns, or techs to practice and who meets a requirement of the rest of the section. AAG Dinegar-Milks indicated the board may restrict the license to only those services required to respond to the urgent situation. Chair Holt liked this section, commented it makes sense to not require a renew.

 Ms. Carrillo inquired whether we should remove the fee. Dr. Ruffridge inquired as to what the fee is, which Chair Holt indicated is \$90. AAG Dinegar-Milks stated other boards do charge a fee (d); Add back in the fee in 12 AAC 02.310. Ms. Carrillo inquired about subsection (c) and whether it applies to non-residents only, to which AAG Milks indicated it does. In follow-up, Ms. Carrillo commented it could limit in-state techs and interns from applying.

Chair Holt also inquired as to whether there is a way expand the courtesy permit to resident pharmacists, which AAG Dinegar-Milks indicated is possible. The continued to review the draft of the emergency regulations.

Based on the finding that: pharmacists are using emergency permits to assist in the state of Alaska COVID-19 emergency response; 2.) there is a complexity of obtaining licensure; and 3.) a large-scale vaccination release related to COVID-19 is upcoming, Chair Holt motioned to amend 12 AAC 52.110 in order to facilitate licensees being able to further assist Alaskans in the ongoing emergency response, seconded by Tammy Lindemuth. It was:

Time: 1:06 p.m.

Time: 1:35 p.m.

850 851 852	RESOLVED to amend 12 AAC 52.110 to read 12 AAC 52.110. Emergency licensure to practice as a pharmacist, pharmacy intern, or pharmacy
853	technician [PHARMACIST PERMIT]. (a) If the board determines that an emergency exists requiring
854	the provision of licensed coverage in a pharmacy [THE BOARD WILL ISSUE AN EMERGENCY
855	PHARMACIST PERMIT FOR THE PURPOSE OF PROVIDING COVERAGE IN A PHARMACY] that is
856	temporarily without the services of a pharmacist due to death, illness, or other emergency
857	circumstances, the board may issue an emergency pharmacist, pharmacy intern, or pharmacy
858	technician permit to an applicant who
859	(1) submits a completed application on a form provided by the department [FOR A
860	PHARMACIST LICENSE];
861	(2) pays the emergency permit fee required in 12 AAC 02.310;
862	(3) submits verification on a form provided by the department that the applicant is
863	currently licensed [CERTIFIED TRUE COPY OF A CURRENT PHARMACIST LICENSE IN GOOD STANDING
864	in another licensing jurisdiction and the applicant's license in the other jurisdiction is not
865	suspended, revoked, or otherwise restricted except for failure to apply for renewal or failure to
866	obtain the required continuing education requirements [STATE];
867	(4) repealed 10/31/2019; and
868	(5) has not been convicted of a felony or another crime that affects the applicant's
869	ability to practice pharmacy competently and safely.
870	(b) An emergency permit <u>under (a) of this section is nonrenewable, and</u> is valid for <u>90</u> [60]
871	days or until the emergency circumstances no longer exist, whichever is shorter.

872	(c) In an urgent situation, the board may issue an emergency courtesy license to practice as
873	a pharmacist, pharmacy intern, or pharmacy technician to an applicant who meets the
874	requirements of this section. The board may restrict the license to only those services required to
875	respond to the urgent situation. The licensee may not practice as a pharmacist, pharmacy intern, or
876	pharmacy technician outside the scope of the limited purpose for which the emergency courtesy
877	license is issued.
878	(d) An applicant for an emergency courtesy license under this section must submit to the
879	department a completed application on a form provided by the department. A complete
880	application includes the applicable application and licensing fees established in 12 AAC 02.310.
881	(e) An emergency courtesy license issued under this section is valid for the period specified
882	by the board and may not exceed 120 consecutive days. An emergency courtesy license may be
883	renewed for one additional period specified by the board, not to exceed 120 consecutive days.
884	(f) The board will not issue, and an emergency courtesy license holder may not use, an
885	emergency courtesy license as a substitute for a temporary license or other license required under
886	AS 08.80.
887	(g) While practicing under an emergency courtesy license issued under this section, the
888	holder of the emergency courtesy license must comply with the standards of practice set out in AS
889	08.80 and this chapter.
890	(h) The board may refuse to issue an emergency courtesy license for the same reasons that
891	it may deny, suspend, or revoke a license under AS 08.80.261.
892	(i) In this section, "urgent situation" means a health crisis requiring an increased availability
893	of pharmacists, pharmacy interns, or pharmacy technicians. (Eff. 1/16/98, Register 145; am

894	1/1//2007, R	Register 181; am 8/1	2/2007, Register 183; a	am 10/31/2019, Registe	er 232; am
895	//_	, Register)		
896	Authority:	AS 08.80.005	AS 08.80.030	AS 08.80.155	

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

The motion passed with no further discussion.

TASK 6

910 Ms. Carrillo will send the draft regulations and motion to Mr. Maiquis along with the emergency911 FAOs.

(Completed on 11/09/2020.)

Agenda Item 8 (from Day 1) Correspondence

AKPhA

Chair Holt read the letter from the AKPhA regarding a change to title 21 to include "pharmacist" to the list of protected health care providers in the unfair discrimination subsection; Title 8 definitions and article 3 and articles. Chair Holt called for Ashley Schaber or Molly to go through their Modernization Act: Ms. Gray stated Kara Robinson is also on the line to assist if needed. The first section, AS 21.36.090, is to add pharmacists to the unfair discrimination act. Chair Holt provided comments to this draft relating to modernizing other areas, e.g.: prescriptive authority. Dr. Schaber commented it would make sense to allow independent prescribing as well as dosage form, which could help decrease ER/doctor visits.

Section 2: removing the term "pharmaceutical" Rich indicated you need to also remove "and"; Dr. Ruffridge inquired whether it is truly a modernization act or whether there are other priorities included. Dr. Schaber stated it includes changes that absolutely need to be changed. Ms. Gray added it is a timely change; per the board's guidance, once the DHSS mandate is lifted, technicians will not have the authority to administer COVID vaccinations.

 Time: 1:35 p.m.

Dr. Ruffridge recommended changing it to "pharmacist mobilization act"; we can work on 932 933 modernization after we mobilize. Chair Holt inquired as to what the mindset around removing the 934 term "pharmaceutical" was? Dr. Schaber stated it relates back to payors in terms of pharmaceutical 935 versus medical care, that there is some misalignment there.

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Chair Holt asked for clarification on what is being changed; what is changing to AS 08.80.030, powers and duties of the board, that needs to be addressed? The board discussed establishing a subcommittee to discuss statute changes as well as steps to support this legislation, possibly through the Governor's support.

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TASK 7

943 Dr. Holt, Dr. Ruffridge, and Ms. Lindemuth will establish a subcommittee to discuss statute 944 changes.

(Met on 11/18/2020.)

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The board reviewed the other correspondence included in the board packet.

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Agenda Item 13 (from Day 1) Administrative Business

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Renewal/Audit

Ms. Carrillo provided the board with a status update on renewal: 74% of licensees had renewed and that 82 technicians and pharmacists had been randomly selected for an audit of their continuing education activities. Ms. Carrillo shared renewal observations and recommended amendments to reduce barriers to renewal, including removing certain submission requirements, such as certified true copies of licenses and inspection reports.

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<u>Upcoming travel/conferences</u>

Upcoming conferences include the AKPhA – Annual Conference from February 12 – 14, 2021 and the 3rd Annual Compounding Pharmacy Compliance Conference on November 16 – 19, which Dr. Holt plans to participate in virtually. Dr. Ruffridge plans to attend the AKPhA conference.

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Task List

Chair Holt addressed Internet pharmacy licensing and shared that in his research, Florida does require Internet pharmacies to be licensed. Chair Holt asked the board to think about whether this was a statute change they wanted to pursue, but noted that regardless of what type of pharmacy they are, they need to register with the board before shipping to the state.

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PDMP Disciplinary Matrix

971 Ms. Sherrell drafted the disciplinary matrix per the board's discussion during their previous 972 meeting:

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Time: 4:10 p.m.

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Proposed Disciplinary Matrix			
Complaint	Proposed Sanctions		
Registration (AS 17.30.200(e)(n), 12 AAC 52.855):	(Notice sent on July 7, 2020 via board letter to all pharmacists with		
 No registration Delayed registration – not registered within 30 days 	Alaska addresses). \$250 civil fine beginning on October 1, 2020 (or after 30 days of initial licensure or after beginning to dispense schedule II, III, or IV federally controlled substances) and an additional \$25 per day until registration is completed.		
Delinquent Reporting (AS 17.30.200(b)(e), 12 AAC 52.865): • Daily reporting (12 AAC 52.865)(b))	[Wa ming issued September 16, 2020 via board letter to all licensees As of January 1, 2021 quarterly compliance audits will track delinquent submissions of data to the PDMP. First reprimand: \$5,000 civil fine for continued submission delinquendes Continued submission delinquencies may result in license suspension		

On a motion duly made by Justin Ruffridge to accept the disciplinary matrix as presented, seconded by Tammy Lindemuth, and approved unanimously, it was:

RESOLVED to accept the disciplinary matrix as presented.

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

 $Discussion: the \ board \ will \ continue \ to \ discuss \ the \ matrix \ for \ unauthorized \ access \ at \ the \ December \ meeting$

Agenda Item 9 Adjourn

On a motion duly made by Tammy Lindemuth, seconded by Lana Bell, and approved unanimously to adjourn the meeting, the meeting was adjourned at 4:42 p.m.

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1011	Laura Carrillo	02-22-2021
1012	Laura Carrillo, Executive Administrator	Date
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1015	Vichard Atbut	
1016	Richard Holt, Chair	Date

Time: 3:08 p.m.