**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 MEETING
**November 30 – December 1, 2017**

**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 was held via WebEx and at the State Office Building, Conference Room A in Juneau, Alaska on November 30 and December 1, 2017.**

**Agenda Item 1** **Call to Order/Roll Call** **Time: 9:02 a.m.**

The **November 30th, 2017** meeting day was called to order by Chair, Leif Holm at 9:02 a.m.

Board members present, constituting a quorum:

Leif Holm, PharmD #PHAP1606 – *Chair*
Richard Holt, PharmD #PHAP2008, MBA – *Vice Chair*
Phil Sanders, RPh #PHAP776
James Henderson, RPh #PHAP1683
Anne Gruening, Public Member
Lana Bell, RPh #PHAP893 (Absent)
Vacant, Public Member (Absent)

Division staff present:

Donna Bellino, Occupational Licensing Examiner
Laura Carrillo, Records & Licensing Supervisor
Sara Chambers, Deputy Director
Brian Howes, Investigator
Megyn Greider, Assistant Attorney General (assigned AAG)

Public members present:

Greg Estep (Pharmacist #PHAP2259, Walgreens)
Lis Houchen (NW Regional Director, National Association of Chain Drug Stores)
Lauri Wormsley (Pharmacist, Walgreens)
Molly Gray (Executive Director, Alaska Pharmacist Association)

Laurie Churns (Pharmacist, Albertsons)
Joseph "Bill" McLaughlin (Chief of Epidemiology, DHSS)
Regina McConkey (Substance Misuse Education Program Coordinator, DHSS)
Hunter Westcott (Pharmacy student, Albany College of Pharmacy – intern #125904)
Alex Perry-Ferrari (Pharmacy student, Albany College of Pharmacy – intern #126631)

**Agenda Item 2** **Review/Approve Agenda** **Time: 9:14 a.m.**

Chair Holm prompted the board to review the agenda. Vice Chair, Richard Holt commented that he'd like input from the Board as to what specific regulations the board would like him to speak about at the Alaska Pharmacists Association's 52nd Annual Convention and Trade Show in February. The board commented that this could be determined on Friday.

Records and Licensing Supervisor, Laura Carrillo added that employees from the Alaska Department of Health and Social Services (DHSS) would be calling during the public comment period, Agenda #13 or during the regulations discussion on 12 AAC 52.860, Agenda Item #s 9 and 18.

**On a motion duly made by James Henderson, seconded by Phil Sanders, and approved unanimously, it was**

> **RESOLVED to accept the November 30th and December 1st, 2017 agenda as amended.**

**Agenda Item 3** **Review/Approve Minutes** **Time: 9:19 a.m.**

The board addressed the meeting minutes from the July 25th, 2017 SB74 discussion meeting and the August 10-11, 2017 meeting, held via teleconference and in Anchorage, respectively. Dr. Holt commented that line 281 on page 31 from the August meeting needed to be corrected from Rich Holt to James Henderson.

**TASK**
Laura Carrillo will correct the August 10-11, 2017 meeting minutes in preparation for Chair Holm's signature.

**On a motion duly made by Rich Holt, seconded by Leif Holm and approved unanimously, it was:**

> **RESOLVED to approve the August 10-11, 2017 meeting minutes as amended and the July 25th, 2017 meeting minutes as written.**

*Brian Howes joined the room telephonically at 9:28 a.m.*

*Brian Howes left the room telephonically at 9:55 a.m.*

**Agenda Item 4 Ethics Disclosures Time: 9:28 a.m.**

Hearing nothing further on meeting minutes, Chair Holm prompted the board to disclose ethics issues. There were no ethics matters to disclose.

**Agenda Item 5 Investigative Report Time: 9:30 a.m.**

Investigator, Brian Howes provided his investigative report for the November 30 – December 1st meeting, which included the period of August 1, 2017 through November 15, 2017. Brian Howes informed the board that the division opened thirteen files and closed eight (8) matters, with eleven (11) cases still open as reflected on the investigative memorandum provided to the board. Brian Howes informed the board that there were a few matters to be discussed under executive session.

**On a motion duly made by Leif Holm, seconded by Rich Holt, and in accordance with AS 44.62.310(c)(2), 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.**

**The individuals in question did not request a public discussion. Staff members, Donna Bellino, Laura Carrillo, Sara Chambers, and Brian Howes were authorized to remain in the room.**

*Off record for executive session at 9:36 a.m.*
*On record for public discussion at 9:49 a.m.*

Upon return from executive session, a role call was made and all board members were present. Chair Holm clarified for the record that no votes were taken during executive session, but that the board was ready to vote on two open matters; case# 2017-00840 and case #2017-00919.

**On a motion duly made by Rich Holt, seconded by Leif Holm and approved unanimously, it was:**

> **RESOLVED to approve the consent agreement for case #2017-00840 involving individual, L.S. and in regards to an imposition of a civil fine.**

| | APPROVE | DENY | ABSTAIN | ABSENT |
|---|---|---|---|---|
| Leif Holm | x | | | |
| Richard Holt | x | | | |
| Phil Sanders | x | | | |
| James Henderson | x | | | |

| | | |
|---|---|---|
| Anne Gruening | x | |
| Lana Bell | | x |

**On a motion duly made by Rich Holt, seconded by Leif Holm and approved unanimously, it was:**

**RESOLVED to approve the consent agreement for case #2017-00919 involving a license surrender agreement for Z.S., PHAC2110.**

| | APPROVE | DENY | ABSTAIN | ABSENT |
|---|---|---|---|---|
| Leif Holm | x | | | |
| Richard Holt | x | | | |
| Phil Sanders | x | | | |
| James Henderson | x | | | |
| Anne Gruening | x | | | |
| Lana Bell | | | | x |

**Agenda Item 6 Legislative Audit Update Time: 9:56 a.m.**

*Sara Chambers joined the room at 9:54 a.m.*

Hearing nothing further on investigative or disciplinary matters, Chair Holm addressed the confidential legislative update.

**On a motion duly made by Leif Holm, seconded by Rich Holt, and in accordance with AS 44.62.310(c)(1), the board unanimously moved to enter executive session for the purpose of discussing matters, the immediate knowledge of which would clearly have an adverse effect upon the finances of the public entity.**

**Staff members, Donna Bellino, Laura Carrillo, and Sara Chambers, were authorized to remain in the room.**

*Off record for executive session at 9:55 a.m.*
*On record for public discussion at 10:23 a.m.*

Upon return from executive session, Chair Holm commented that no motions were made. Chair Holm called for a break.

*Off record for break at 10:24 a.m.*
*On record for public discussion at 10:03 a.m.*

**Agenda Item 7 Budget Report/Division Update Time: 10:03 a.m.**

Hearing nothing further on PDMP matters, the division's Deputy Director, Sara Chambers presented the budget report. Ms. Chambers stated that she would be reviewing the FY18 report first as it incorporates the FY17 information. The board was informed that their revenue is at $212,011 and their surplus is currently at $554,764. Ms. Chambers added that the number will be fairly low until later in the fiscal year at the time of renewal, at which time it is projected to be more similar to the FY16. Direct expenditures for personal services is at $215,674, contractual services is at $41,331, and total direct expenditures is $268,643. The board was then directed to refer to the object codes for personal services ("1,000 series"), which includes compensation, retirement benefits, and union dues. Ms. Chambers then commented that $292,481 in surplus is to be expected at the beginning of the new year.

Hearing nothing further on the budget report, the board's new Records & Licensing Supervisor, Laura Carrillo introduced herself and directed the board to her position description, which was included in the board's packet. Sara Chambers added that Ms. Carrillo will be a good fit for the position as she is currently working on her master's degree in public health. In addition to being the board's supervisor, Ms. Carrillo is the new point of contact for the Prescription Drug Monitoring Program (PDMP), for which Brian Howes had previously taken on in addition to his role as the board's assigned investigator. Ms. Carrillo stated that Brian is continuing to assist with administrative matters during this transition, and directed the board to the packet as there were several items related to the PDMP for discussion.

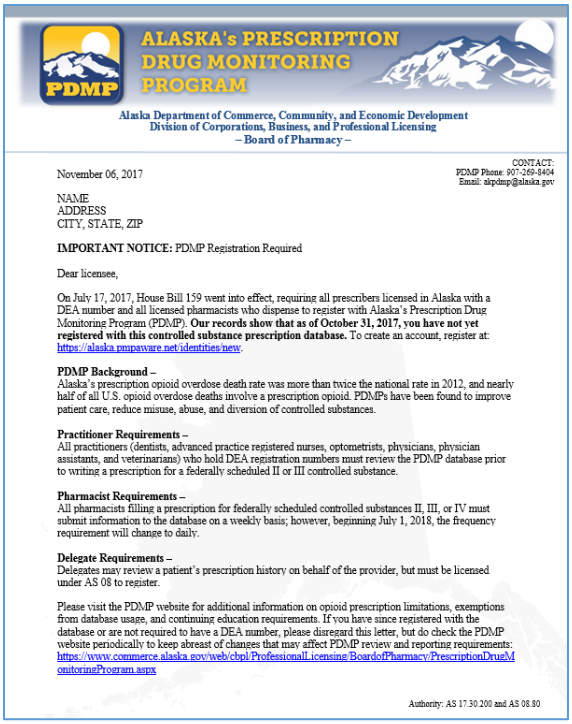
*PDMP Website*

Ms. Carrillo addressed the board's current PDMP website, commenting that there were a few changes to be made to improve user friendliness and formatting. Ms. Carrillo stated that the links and resources would be clarified with additional language and descriptions. Additionally, new instructions for registering on the PDMP would be added as a new version for delegate registration was recently created. Ms. Carrillo then addressed the controlled substance legislative update dated August 2017 and the letter from Chair Holm dated September 19, 2017. Chair Holm commented that the intent of the letter was to clarify responsibilities for pharmacies and pharmacists.

*Data Driven Prevention Initiative (DDPI) Grant*

Ms. Carrillo then commented on the DDPI grant activities, which are required as a condition for receiving funding from the Centers for Disease Control and Prevention (CDC). Chair Holm inquired to the division what the estimated annual cost is of the PDMP. Deputy Director, Sara Chambers stated that the exact cost is unknown, but that the DDPI grant was to fund PDMP functions for 5 years and had initially been for the amount of $42,000 but increased to $52,000. The grant was to fund PDMP functions for 5 years, with which the board is currently in their second year. Chair Holm asked how long the length of the grant is for, to which Sara stated there are three more years for the DDPI grant. The board was informed that the new PDMP manager position requires the collaboration with stakeholders, including staff from DHSS to complete a set of activities that will be evaluated by an external evaluator.

- *DDPI Activity 1.2: identify and contact dispensers and non-enrolled prescribers* –
  - Ms. Carrillo informed the board that this activity was initiated on November 6th, with a mass mail-out sent to non-enrolled prescribers on November 17th reminding individuals of the mandated registration with the PDMP following HB 159 (Figure 1). It was added that the division received a number of inquiries from individuals who had already registered with the PDMP but received the letter. Paramedics also inadvertently received the notice. Ms. Carrillo commented that the cause of this was that middle initials were auto-populating into first-name columns, which was the result of the data migration from the program's previous vendor—this ultimately skewed the list of non-registered users. Ms. Carrillo added that there is currently not a way to extract non-registered individuals using license numbers as the program does not have the license integration feature; the current system relies solely on exact name matches between what is entered in the individual's professional license and what is entered at the time of PDMP registration. Ms. Carrillo stated she would post a notice to the PDMP website clarifying the importance of this. Ms. Carrillo stated that although several registered users received the notice, it is better to cast a wider net, but that she would be more cognizant of any inadvertent name errors before mailing out subsequent notices. Ms. Carrillo then stated that it's not possible to keep track of each licensee's work status, e.g.: whether they are not working but keep their license in active status, are out of state but maintain their Alaska license, etc., but that sending out a notice on a continuous basis can help prompt individuals to register if their work status has since changed. Chair Holm commented that this reminder notice should be sent annually.



ALASKA's PRESCRIPTION DRUG MONITORING PROGRAM

PDMP

Alaska Department of Commerce, Community, and Economic Development
Division of Corporations, Business, and Professional Licensing
– Board of Pharmacy –

November 06, 2017

CONTACT:
PDMP Phone: 907-269-8404
Email: akpdmp@alaska.gov

NAME
ADDRESS
CITY, STATE, ZIP

**IMPORTANT NOTICE:** PDMP Registration Required

Dear licensee,

On July 17, 2017, House Bill 159 went into effect, requiring all prescribers licensed in Alaska with a DEA number and all licensed pharmacists who dispense to register with Alaska's Prescription Drug Monitoring Program (PDMP). **Our records show that as of October 31, 2017, you have not yet registered with this controlled substance prescription database.** To create an account, register at: https://alaska.pmpaware.net/identities/new.

**PDMP Background –**
Alaska's prescription opioid overdose death rate was more than twice the national rate in 2012, and nearly half of all U.S. opioid overdose deaths involve a prescription opioid. PDMPs have been found to improve patient care, reduce misuse, abuse, and diversion of controlled substances.

**Practitioner Requirements –**
All practitioners (dentists, advanced practice registered nurses, optometrists, physicians, physician assistants, and veterinarians) who hold DEA registration numbers must review the PDMP database prior to writing a prescription for a federally scheduled II or III controlled substance.

**Pharmacist Requirements –**
All pharmacists filling a prescription for federally scheduled controlled substances II, III, or IV must submit information to the database on a weekly basis; however, beginning July 1, 2018, the frequency requirement will change to daily.

**Delegate Requirements –**
Delegates may review a patient's prescription history on behalf of the provider, but must be licensed under AS 08 to register.

Please visit the PDMP website for additional information on opioid prescription limitations, exemptions from database usage, and continuing education requirements. If you have since registered with the database or are not required to have a DEA number, please disregard this letter, but do check the PDMP website periodically to keep abreast of changes that may affect PDMP review and reporting requirements: https://www.commerce.alaska.gov/web/cbpl/ProfessionalLicensing/BoardofPharmacy/PrescriptionDrugMonitoringProgram.aspx

Authority: AS 17.30.200 and AS 08.80

Figure 1. Mail-out to non-registered users.

- *DDPI Activity 2.1: identify barriers and limitations associated with the use of the PDMP–*
    - This activity requires the PDMP manager, in collaboration with other stakeholders, to 1.) develop a questionnaire to solicit awareness levels, identify database limitations, and areas of improvement and 2.) an online survey to gather input on database utilization satisfaction. The board was informed that DHSS conducted a sample survey (Hays Report) including 30 key informants (licensed prescribers and registered users) that solicited feedback on the user friendliness, challenges, barriers, and benefits of the database. Ms. Carrillo commented that the Hays Survey would serve as a good platform to scale up and meet the requirements of this activity. Ms. Carrillo stated she was collaborating with Elana Habib and Regina McConkey at HSS who have expertise in survey design and epidemiological studies, adding that the Arizona administrator had provided their annual survey and results as a reference tool to help develop this. It was stated that Ms. Carrillo would continue to meet with DHSS team members to develop the survey in the coming weeks.

**TASK**
Laura Carrillo will post a notice to the website informing individuals that they must register with the PDMP using the exact name and spelling as how it appears on their professional license.

**TASK**
Laura Carrillo will mail out the PDMP registration reminder notice on an annual basis, being sure to include language clarifying any nuances in work or license status that may not require registration.

**TASK**
Laura Carrillo will continue to work with DHSS team members on PDMP activities for the DDPI grant.

*NASCA Conference Update*
Ms. Carrillo gave a brief update on her participation at the National Association of State Controlled Substances Authorities (NASCA) conference held in San Antonio, TX from October 17 – 20, 2017. A summary of the topics were provided in the board packet and included discussions on drug take-back programs, abuse deterrent drugs, and state PDMPs.

*Prescriber Reports*
Ms. Carrillo then gave the board an update on prescriber reports (report cards), which allows the board to issue unsolicited reports to registered licensees and is authorized under AS 17.30.200(t) as a result of HB 159. Funding for prescriber reports will be covered by a Bureau of Justice Administration (BJA) PDMP enhancement grant that DHSS applied for on behalf of the division, which was awarded in the fall of 2017 for an amount slightly over $255,000. Ms. Carrillo stated that the division is just waiting on the RSA to implement the report. Ms. Carrillo inquired to Chair Holm when the board would like these reports to go live, to which he stated that they should be implemented as the RSA is received.

Ms. Carrillo stated that the report cards will show an individual's prescribing trends in relation to trends of others within the same profession and specialty. The report cards will provide information on the top three prescriptions given, the number of opioids prescribed, and total MMEs for opioids including Oxycodone and hydrocodone products. Rich Holt inquired as to whether the reports will also show information on anxiolytic, sedative, and hypnotic prescriptions, to which Ms. Carrillo confirmed. It was added that the number of patient report requests, excess multiple provider thresholds, and dangerous combination therapy information will be shown. Ms. Carrillo also stated that measurements are provided in monthly averages and that an audit trail of all requests will be generated automatically.

*Prescribing Guidelines*

Laura asked if the board had any questions regarding the DDPI grant activities, to which Rich Holt commented that pharmacists and prescribers are under the impression that the board holds the ultimate responsibility to alleviate the opioid crisis. Deputy Director, Sara Chambers acknowledged that while the PDMP is under the purview of the board, other PDMP boards and stakeholders hold a level of responsibility for education, outreach, and prescriptive discretion. Rich Holt commented that he has spoken with pharmacists about the board's goals to decrease opioid prescriptions, adding that when he talks to these individuals, they aren't aware that the division came out with prescribing guidelines on morphine milligram equivalents (MMEs). Ms. Chambers clarified that the division has not adopted prescribing guidelines, commenting that the public is misinformed. Ms. Chambers expounded upon this, stating that all the boards with PDMP requirements got together and made a collaborative recommendation to the legislature, but there has not been prescribing guidelines formally adopted for the state of Alaska. Ms. Chambers asserted that one aspect the board may want to do is to continue promoting the Health and Social Services website, which augments into the bigger opioid crisis. Ms. Chambers reiterated that the board cannot absorb all of the responsibility for the opioid crisis, but that resources and contact information linking inquirers to stakeholder websites can be incorporated into the PDMP website.

Chair Holm inquired to Ms. Chambers as to whether there was going to be further action with prescription guidelines. Ms. Chambers responded that there are a have a few options to implement these guidelines: one option is to seek this explicit authority through legislation and another option is for the board to develop a task force to convene on this issue. Chair Holm inquired if the board is able to establish guidelines without having explicit statutory authority, to which Ms. Chambers commented that it is her understanding that all PDMP boards with prescribing authority have the ability to adopt prescribing guidelines in regulation. Ms. Chambers added that it would behoove the board and the PDMP for the involved boards to come up with standard language for these guidelines.

Rich Holt commented that he recalled an educational component. Ms. Carrillo referred to the legislative update on initial and continuing education requirements, commenting that some boards and individuals may be interpreting the minimum requirement to participate in two hours of pain management, opioid misuse, and opioid abuse as a total of six (6) hours; however, the legislative intent is that the two hour minimum is for all topics. Ms. Carrillo stated that PDMP boards are

handling this education requirement differently; the medical board, for example, determined that the two required hours will be inclusive in their existing 50 hours required for renewal, but that the hours still have to meet the accreditation requirements. Ms. Carrillo added that it is ultimately up to the boards to determine whether they want to create new sections in their regulations or have the requirements inclusive into their existing hourly requirements.

The board and Ms. Chambers continued to discuss the board's statutory obligations of demonstrable actions that will affect change in the opioid crisis. Ms. Chambers commented that it would be a good idea for one board member to collaborate with other PDMP stakeholders so updates can be provided to show how the board is meeting their educational and collaborative PDMP efforts. Ms. Chambers suggested that Rich Holt may be a good lead as he has experience with being the point of contact for legislative matters.

**TASK**
Laura Carrillo will add DHSS links to the PDMP website.

**TASK**
Laura Carrillo will add takeback programs to the agenda for the February Meeting and include the information prepared by Rich Holt in the board packet.

**Agenda Item 8 Lunch** **Time: 12:05 p.m.**

Chair Holm called for lunch.

*Off record for lunch at 12:05 p.m.*
*On record for public discussion at 1:16 p.m.*

**Agenda Item 9 Regulations** **Time: 1:16 p.m.**

*Megyn Greider, Assistant Attorney General joined the room at 1:16 p.m.*
*Bill McLaughlin, DHSS joined the room at 1:37 p.m.*
*Regina McConkey, DHSS joined the room at 1:37 p.m.*

*SB 74 Regulations: 12 AAC 52.855, 12 AAC 52.865, 12 AAC 52.870, 12 AAC 52.885, 12 AAC 52.880, 12 AAC 52.890, 12 AAC 52.920, 12 AAC 52.995*
Upon return from lunch, Chair Holm addressed the pending regulations project. Rich Holt informed the board that the board-approved draft was reviewed by division staff and Assistant Attorney General, Megyn Greider, which resulted in several comments and suggested revisions. As there were a number of draft versions between October and November, Rich Holt informed the board that he had decided not to go forward with initiating a public comment period on this draft.

- *12 AAC 52.855 – Registration with the PDMP Controlled Substance Database*

- The Board reviewed the proposed language to this section. AAG Greider commented that the board is opting to require that pharmacists who dispense II, III, or IV drugs register with the PDMP
- Leif Holm asked if the Board should not mention other professions, to which Megyn clarified they should mention specific providers.
- Megyn then moved onto the section onto section, (d) of the proposed regulation, in which she indicated that the language stating that the practitioner could use his or her own credentials in an emergency room department conflicts with the intended language associated PDMP access in emergency room departments. Chair Holm asked for additional information on this, to which Sara Chambers commented that this will be discussed on December 1st for the EDIE presentation, which may be a more appropriate time to discuss it.
- For a registration recap: individuals who must register include all licensees who have access, including a pharmacist-in-charge who dispenses a controlled II, III, or IV controlled substance; pharmacists who dispenses a controlled II, III, or IV controlled substance; and practitioners who prescribes, administers, or directly dispenses a schedule II, III, or IV controlled substance; as well as any licensee with a DEA number
- For a reporting recap: individuals who must report include a pharmacist-in-charge of each licensed or registered pharmacy unless exempt by AS 17.30.200(u); any pharmacist unless exempt by AS 17.30.200(u); any practitioner who directly dispenses a schedule II, III, or IV controlled substance, unless exempt by AS 17.30.200(u)
- For a review recap: individuals required to review the database include a practitioner dispensing, prescribing, or administering a schedule II or III controlled substance, unless exempt by AS 17.30.200(k)(4)(A)-(B)

- *12 AAC 52.860 – Access to and Conditions for Use of the PDMP*
  - The board reviewed this section, focusing first on delegate access. AAG Greider commented that individuals delegating the authority should hold the ultimate responsibility for activity conducted by their delegates, to which the board agreed.
  - Megyn then turned to the proposed subsection on authorized employees of the Alaska Department of Health and Social Services. The proposed language states that an authorized individual means an employee of the department for whom the commissioner or commissioner's designee has requested access. Megyn informed the board that the proposed section on requiring registration for practitioners employed by a native/tribal health organization or United States Public health Service (USPHS) is being struck since they are not required to be licensed. Megyn commented that the board is not able to make requirements for federally regulated health organizations. Instead, access for practitioners under such organizations would be set out in a memorandum of agreement with the state at the department level. Ms. Chambers added that the memorandum of agreement would refer to their existing employment with blanket access rather than that being a new document

that would have to be developed. Megyn asked what the memorandum of agreement was, to which Ms. Chambers clarified that it would be between the clinical staff and the health organization. Megyn commented that we may have to go back to HSS to ask them what sort of MOU they have.

- *12 AAC 52.865 – Reporting and Reviewing PDMP Information*
    - Megyn commented that there is a disconnect here between SB74 and HB159 with the reporting requirement going from weekly to daily, which won't go into effect until July 2018. Megyn suggested inserting a phrase that would indicate when the daily requirement would take effect, e.g.: "the reporting requirement will be weekly until July 1st, 2018, after which reporting will switch to daily."
    - Turning to section (e) on correcting errors within 24 hours, Chair Holm commented that as a pharmacist, when he receives an error, it is done so electronically. This can pose unreasonable time constraints if errors need to be corrected on a weekend.
    - James Henderson presented a scenario in which pharmacists submit data on Friday with businesses not opening until Monday morning, prompting clarification on whether the 24 hours means 24 business hours. AAG Greider referred to the time computation in 12 AAC 02.920(1)(b), which clarifies that these are business days. As such, AAG Greider stated that the board could add "within 24 hours as calculated under 12 AAC 02.920." to this section.
    - The board then addressed subsection (g) of the proposed language. The board wanted to eliminate misinterpretation that pharmacists must review the information in the database to check a patient's prescription records before dispensing, prescribing, or administering a schedule II or III controlled substance under federal law. Megyn commented that in the bill, pharmacists are included in the definition of "practitioner", however, Leif commented that this does not include pharmacists, which is why the letter September 19th, 2017 letter from Chair Holm was posted to the website. This clarified that pharmacists have no statutory or regulatory requirement to fulfill in regards to evaluating the initial quantity of opioids written under limitations imposed by HB159. Megyn asked the board where the language was that excluded "pharmacists" from the definition of "practitioner", to which Ms. Chambers stated that was included in HB159 in the legislative intent. Ms. Chambers referred to legal clarification on this, which stated in essence that although pharmacists are included in the definition of practitioner under AS 11.71.900, the specific context there is that pharmacists are practitioners required to register due to distributing or dispensing controlled substances. Pharmacists aren't, however, practitioners in the context of having to meet specific requirements when *engaging* with the PDMP. Ultimately, the definition of a practitioner includes pharmacists only with regards to their scope of work, but not with regards to the administration of the database because of the fact that the definition in AS 11.71.900 only applies if the language in the PDMP statutes provides different definition or context. The role

of pharmacists are already clearly defined in PDMP statutes, such that it isn't necessary to adding to the definition or redefining it.

- Returning to discussion on reporting and 24-hour requirements, Chair Holm reiterated that the 24 hours is defined as within one business day since the language states that it has to be daily as of the previous submission date. Phil Sanders commented that is problematic for pharmacies that operate 7 days per week, such as his. The board ultimately decided that 72 hours is more reasonable.
- Rich Holt asked Megyn if pharmacist's delegates can submit the data. Megyn stated that the statute says pharmacist-in-charge (PIC), but if the PIC isn't available, it must just be a pharmacist. Megyn inquired as to whether anyone recalled discussions as to how the data would actually be transmitted. Ms. Chambers commented that she had attended the hearings but that this wasn't addressed, adding that the way in which data is transmitted is the technology aspect. Megyn stated that the responsibility to report falls on the individuals who the board regulates, meaning that pharmacists required to report that are licensed under the board are ultimately held responsible, rather than IT staff who are a part of that technological transmission of information.

- *12 AAC 52.870 – Waiver of Electronic Submission Requirement*
  - AAG Greider commented that in the existing regulations, the board is relying on the universal claims form of the National Council for Prescription Drug Programs. She inquired as to whether this form meets the requirements of AS 17.20.300(b).

- *12 AAC 52.885 – Purge of Database Records*
  - Megyn asked the board why the information included in the purge since the statute obligates the board to require that prescription information in the database be purged and that the information doesn't limit that information to only patient-specific information. Rich commented that the statute states AS 17.20.300(k)(1) states that there is the limit of two years, adding that health and social services would like to have data going further back to more properly monitor data trends. Sara stated that whether the board could attempt to adopt a regulation that word purge the deidentified information but retain the non-deidentified information. Megyn asked if the legislative intent was whether DHHS could have specific information. Bill McLaughlin, Chief of Epidemiology stated that AS 17.30.200(d)(10) authorizes DHSS to get de-identified information, adding that when DHHS conducts surveillance and generates reports, there is no need to have identifying information, but that there may be certain linkages that could be helpful to better characterize decedents and their potential history of drug abuse in an epidemiological study.
  - Referring to the draft language regarding DHSS access, Dr. McLaughlin commented that he was in support of the language stating that those authorized to access PDMP information should be named by the commissioner.

- Dr. McLaughlin commented that his understanding is that database records need to be purged after two years, but that it only pertains to identifying data, such that de-identified data does *not* need to be purged. Megyn Greider clarified that the proposed language is limited as there is no statutory authority for this provision. Sara commented that she doesn't believe the legislature specifically addressed the details of purging information, adding that legislative auditors interpreted the purge as meaning all data, including de-identified data *and* identifiable data.
- AAG Greider advised the board to put out the proposed language in 12 AAC 52.885(1)-(8) so that DHSS can weigh in as to why or why not certain data should be included, adding that this would be a good opportunity to capture feedback and will help to inform the direction of the language that best suits the board and DHSS.
- Dr. McGlaughlin stated that DHSS could house the data as long as they could be authorized to do so, adding they are very much accustomed to doing that and would be willing to do so if given explicit statutory authority. AAG Greider advised that DHSS consult with their attorney. As the board of pharmacy is concerned, the board does not have a time limitation on how long DHHS can maintain data.

- *12 AAC 52.890* Grounds for Discipline
  - Ms. Carrillo commented that the board of pharmacy can discipline their own licensees but only the appropriate boards under which an individual is license has the authority to delegate licensees that they directly regulate.

**TASK**
Megyn will email Sara and Stacy Kraly about MOUs.

**TASK**
Rich Holt will check whether the claims form meetings the current statutory requirements.

**TASK**
The board will include 12 AAC 52.885(1)-(8) to go out for public comment

Chair Holm for break at 3:06 p.m.

*Off record for lunch at 3:06 p.m.*
*On record for public discussion at 3:19 p.m.*

**Agenda Item 15 <u>New/Old Business</u> Time: 3:19 p.m.**

*<u>Veterinary Board Questions for PDMP</u>*
Although the board planned to discuss questions for the board of Veterinary Examiners in relation to PDMP on December 1st, the board felt it was a fortuitous time to discuss the questions as AAG Greider was available to provide feedback. The board acknowledged the unique position

of the veterinary board in relation to the PDMP, as their client base are non-humans. Acknowledging Rich Holt's attempt to provide clarification, Megyn comment that there were some areas of correction and clarification. AAG Greider first clarified that "health care facility" in the context of a veterinarian clinic isn't clear as there is not a definition on what a healthcare facility is.

- Question #4 regarding requirement to research an owner –
    - AAG Greider suggested to require at least one owner to be listed for every animal patient. Chair Holm commented that owners aren't listed, that animal first names are listed with the owner's last name. Greg Estep added that the PDMP requires the partial spelling of one's last name but that the system requires the DOB. Mr. Estep also added that pharmacies may input different birth dates for that animal, which would create some gaps and loop holes in the data. Chair Holm commented that it's not practical to enter a date of birth for the animal.
    - Ms. Carrillo inquired as to whether veterinarians are required to obtain a DEA if they are prescribing or dispensing, to which Megyn stated that veterinarians do need to obtain a personal DEA number rather than use the veterinary clinic DEA#. Ms. Carrillo added that in the PDMP, there is no user role for veterinary clinics; there is an individual user role for veterinarians who must provide a personal DEA number.
    - Chair Holm commented that the board is not aware of regulations that prohibit veterinary clinic DEA numbers.

- Question #5 regarding Fentanyl Transdermal Patch –
    - James Henderson commented that it needs to be reported under the intended use, not what it is expected.

The Board continued to discuss the questions provided by the Veterinary Board and the feedback provided by Megyn Greider.

**TASK**
Laura will retrieve the updated veterinarian draft FAQs from Rich Holt.

**Agenda Item 9** **<u>Regulations</u>** **Time: 1:16 p.m.**

Chair Holm then prompted the board to move to the other set of regulations that the board had approved in May, including affidavit of good moral character for interns and inspection reports for out-of-state pharmacies. The board also discussed registration versus licensing of out-of-state pharmacies.

*<u>Out-of-state pharmacy inspection reports</u>*
The board addressed out-of-state pharmacy inspection reports. Donna Bellino commented that an inspection report was developed at some point by the board or division and is currently posted to the website. Rich Holt asked what the legality of this form is if out-of-state pharmacies are

registered rather than licensed, to which Megyn stated that they would have a good argument that their registration cannot be denied in the absence of such a report. Ms. Bellino stated that the Alaska self-inspection report (form #08-4607) is needed only if the out-of-state pharmacy has not had an in-state inspection report completed within the last two years. It was also added that for initial licensure, self-inspection reports are not required but are only if their home state inspection report is older than two years and if the pharmacy will be going through a change in ownership Ms. Bellino added that all out-of-state pharmacies need to submit the self-inspection report at the time of renewal, but pharmacies that do sterile and non-sterile compounding can provide "not applicable" responses to questions pertaining to compounding.

*Out-of-state pharmacy registration versus licensing*

The board continued to further discuss registration versus licensing of out-of-state pharmacies. Rich Holt commented that the board *registers* out of state pharmacies, which indicates that a registration is a type of license, but it doesn't require registrants to follow its state licensure requirements. AAG Greider added that registrations doesn't allow as extensive oversight as does a license type, citing legislative testimony from 1992 and 1996 that explained the board's regulatory powers over this type of registration. In regards to potential disciplinary actions, it was added that out-of-state pharmacies registered in multiple states only must follow the licensing requirements under which are established in their *home* state; that making any requirements for out-of-state pharmacies violates interstate commerce laws. Chair Holm inquired to AAG Greider as to whether the Alaska board would have the authority to deny an out of state license registration application if they did have disciplinary or other adverse action in any jurisdiction in which they're doing business. Chair Holm commented that the board has set a precedence of allowing registration of out-of-state pharmacies and inquired as to whether moving forward, they are obligated to continue this precedence or can deny a license based on certain criteria. AAG Greider clarified that the board can only deny applications for which there hasn't been a precedence of denying a registration based on the same type of violation. Donna commented that a lot of time is spent reviewing disciplinary actions on out-of-state pharmacy application, adding that the board had been previously advised that they can't put more onus on an out-of-state pharmacy than an in-state pharmacy. When reviewing professional fitness sections of out-of-state pharmacy applications, it was suggested that staff can continue requesting pertinent documentation surrounding "yes" responses to such activity, but that these documents are for record keeping purpose rather than for gathering information to support disciplinary action. Ultimately, the board does not have the authority to require out-of-state pharmacies to submit a self-inspection or any type of report, and cannot impose redundant discipline on or action against out-of-state pharmacies.

Ms. Carrillo asked if the board could issue a position statement, which Leif Holm referred to as a clean state. AAG Greider stated that the board cannot issue a position statement or change the regulations. Donna inquired as to whether it would be possible through legislative action to license rather than register, to which Megyn commented that such a bill would likely not pass. James Henderson commented that the board should go back to the legislature and ask for more authority to regulate out-of-state pharmacies, to which Anne Gruening agreed. AAG Greider

inquired as to whether there was a universal inspection form, to which Donna stated there is an inspection provided by the NABP, where the report can be several hundred pages.

The board continued to discuss the topic of registering versus licensing out-of-state pharmacies before adjourning for the day.

**On a motion duly made by Anne Gruening, seconded by James Henderson and approved unanimously, it was:**

**RESOLVED to recess the meeting at 5:05 p.m. until December 1, 2017 at 9:00 a.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
**November 30 – December 1, 2017**

**Agenda Item 11** **Call to Order/Roll Call** **Time: 9:09 a.m.**

The **December 1, 2017** meeting day was called to order by Chair, Leif Holm at 9:02 a.m.

Board members present, constituting a quorum:

Leif Holm, PharmD #PHAP1606 – *Chair*
Richard Holt, PharmD #PHAP2008, MBA – *Vice Chair*
Phil Sanders, RPh #PHAP776
James Henderson, RPh #PHAP1683
Anne Gruening, Public Member
Lana Bell, RPh #PHAP893 (Absent)
Vacant, Public Member (Absent)

Division staff present:

Donna Bellino, Occupational Licensing Examiner
Laura Carrillo, Records & Licensing Supervisor
Sara Chambers, Deputy Director
Megyn Greider, Assistant Attorney General (assigned attorney)
Marilyn Zimmerman, Paralegal
Beth Parsons, Paralegal

Public members present:

Greg Estep (Pharmacist #PHAP2259, Walgreens)
Lis Houchen (NW Regional Director, National Association of Chain Drug Stores)
Lauri Wormsley (Pharmacist, Walgreens)
Molly Gray (Executive Director, Alaska Pharmacist Association)
Laurie Churns (Pharmacist, Albertsons)
Anne Zink (Medical Director for Mat-Su Regional Medical Center)
Connie Beemer (Alaska State Hospital and Nursing Home Association)
Justin Keller (Collective Medical Technologies)

Hunter Westcott (Pharmacy student, Albany College of Pharmacy – intern #125904)
Alex Perry-Ferrari (Pharmacy student, Albany College of Pharmacy – intern #126631)

**Agenda Item 13 Public Comment Time: 9:15 a.m.**

The board was a few minutes behind schedule, but Chair Holm called for public comment that had been scheduled for 9:10 a.m.

Greg Estep was on the line telephonically and indicated that although he is a pharmacist for Walgreens, he is representing himself and not his employer during this public comment period. Mr. Estep expressed his concerns for the lack of guidance on technician-to-pharmacist ratios. Mr. Estep commented that if there was such a ratio, there would be more flexibility with staff duties. Mr. Estep inquired as to whether such a ratio could be established on an individual basis via the pharmacist-in-charge and encouraged the board to make a more formal determination for an appropriate ratio—adding that this would address safety concerns.

Rich Holt asked to clarify Greg's comment, stating that the board addressed this issue about a year ago, but that the board didn't implement such a ratio. Rich Holt inquired to Mr. Estep to clarify whether he is advocating for this to be included in a regulations project. The board continued to discuss this issue.

There were no additional public comments.

**Agenda Item 12 Review/Approve Agenda Time: 9:19 a.m.**

Hearing nothing further on public comment, Chair Holm prompted the board to provide a motion to approve the agenda for the second day of the meeting.

Anne Gruening first commented that the board would not be discussing the Controlled Substance Advisory Council (CSAC) update from Lana Bell due to her absence, and that the veterinary questions discussion scheduled for today would not be discussed as they were addressed on the previous day.

**On a motion duly made by Anne Gruening, seconded by Leif Holm, and approved unanimously, it was**

**RESOLVED to accept the December 1st, 2017 agenda as amended.**

**Agenda Item 14 PDMP/EDIE via Gateway Time: 9:21 a.m.**

Ms. Carrillo informed the board that Connie Beemer from the Alaska State Hospital and Nursing Home Association (ASHNA) and Justin Keller from Collective Medical Technologies (CMT) would be joining the board to present information on PDMP gateway access for emergency

departments. Connie Beemer added that Anne Zink, Medical Director for Mat-Su Regional Medical Center would also be present for this discussion. These individuals are part of the Alaska ED Care Coordination Project and were present to discuss the importance of receiving PDMP information at the point of care in the emergency department setting. There currently is not clear language outlining or authorizing the transmission of data through a patient's electronic health record, of which is important for the Board of Pharmacy to weigh-in on and provide feedback. The program is referred to as EDIE (Emergency Department Information Exchange) and its ultimate goal is to improve patient care and reduce overall health care costs by minimizing redundancy and improving care through coordination in the emergency department.

Anne Zink introduced herself to the board, expressing her optimism on adopting an electronic medical records system for care coordination. Dr. Zink added that this system has been successful in several states, including Washington. Dr. Zink highlighted Washington's success, stating that there has been a 9.9% reduction in overall ED Medicaid visits, a 10.7% reduction among frequent E.D. patients, a 14.2% reduction of low-acuity visits, and a 24% reduction in narcotic prescriptions.

Justin Keller with CMT, the chosen vendor for gateway access provided background information on EDIE, including that it started in Salt Lake City where it was first implemented in Washington, and is now operating in 13 states. Mr. Keller informed the board that this is essentially an electronic health exchange system that collects information from disparate health systems and provides real-time information to emergency departments (Figure 2). Mr. Keller further explained that the pre-managed system is risk-based and provides alerts when patients are at risk for drug abuse or diversion. EDIE collates all health care information and uses that information to generate a flag when a patient meets the established risk criteria (Figure 3). It was further explained that when a patient registers at an emergency department, the department receives information from the electronic medical record, which the PDMP queries.

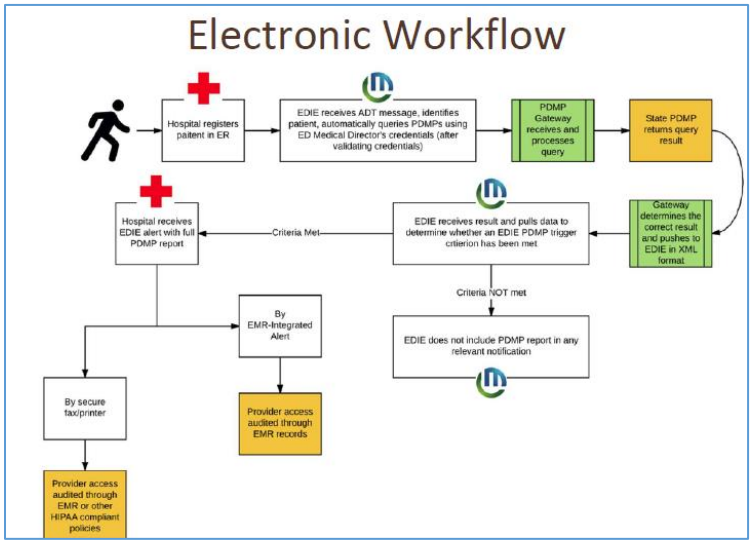



Figure 2. EDIE workflow

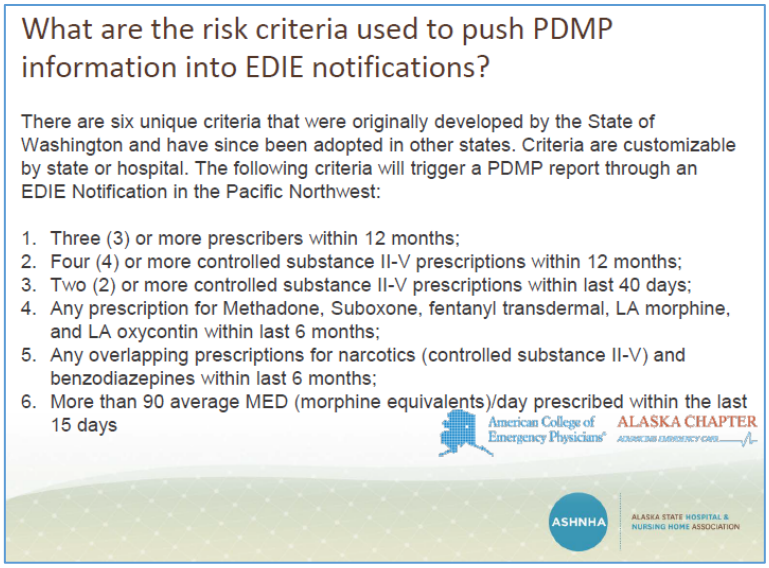



Figure 3. EDIE risk criteria.

Mr. Keller clarified that EDIE does not store PDMP information; the only record that is maintained is the notification that is sent to the provider. Mr. Keller also commented that the medical director's credentials are used because in the EDIE setting, it is not possible to know which provider is going to see the patient.

Chair Holm asked if board has authority to implement this, to which Connie Beemer stated that electronic health information exchange specifically states that the notification needs to include information from the state's prescription drug monitoring program. Deputy Director, Sara Chambers commented that the division has been engaged in collaborative learning about the project and recognizes the importance for emergency room staff. Ms. Chambers, emphasized the importance of addressing the concern of producing an audit trail of people who are accessing the information. As explained previously and alluded to by AAG Greider, the system relies upon the credentials of the medical director who will be vouching for the entire facility through which all employees will be accessing the PDMP information.

Chair Holm expressed concern about privacy issues if there is blanket access is through one account. Mr. Keller clarified that the medical director is not in charge of the access, but her/his credentials is used to query information, adding that the audit trail will clarify which specific provider actually reviewed that patient's history. With registration requirements, whoever is accessing the database will always be someone with an authorized PDMP account. Phil Sanders asked if there were specific action that the board is needing to take on this EDIE system. Ms. Chambers commented that the division wanted Connie and her coordination team to be aware of this significant project that is authorized under SB 74 and is under the authority of the board. Rich Holt referred back to AAG Greider's comments regarding user IDs and passwords, stating that the current regulations in 12 AAC 52.855(d) is in conflict with what the CMT system is trying to achieve; the language indicates that the pharmacist or practitioner must register with the PDMP

and must access the information using their own user account, login name, and password issued by the department. Ms. Chambers suggested adding an additional section (e) that could address a caveat for emergency departments.

**Agenda Item 15 New/Old Business Time: 10:01 a.m.**

*Marilyn Zimmerman and Beth Parsons entered the room at 10:16 a.m.*

*Board member seats*

Hearing nothing further on the EDIE coordination project, Chair Holm moved to determining board seats. Chair Holm commented that he is hesitant about continuing on as chair but that he does appreciate and enjoy the profession. Anne Gruening inquired to Rich Holt if he would be interested in becoming chair. Phil Sanders inquired to Leif if he would be interested in becoming vice chair, to which he stated that he would be interested. Rich Holt also inquired as to whether Phil Sanders would be willing to be the secretary, however, it was ultimately determined that the secretary seat would be discussed at a later date.

Donna Bellino commented that the new seats have historically been elected during the 4th quarter meeting, with new seats taking effect for the FY18 first quarter, at which time the board has historically met in February.

**On a motion duly made by Anne Gruening, seconded by James Henderson, and approved unanimously, it was**

> **RESOLVED to elect Richard Holt as Chair and Leif Holm as the Vice Chair to take effect on March 2, 2018.**

*Consent agreements*

Marilyn Zimmerman and Beth Parsons entered the room to provide discussions on consent agreements and audit concerns.

**On a motion duly made by Anne Gruening, seconded by Leif Holm, and in accordance with AS 44.62.310(c)(2), 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.**

**Staff members, Donna Bellino and Laura Carrillo were authorized to remain in the room.**

*Off Record for executive session at 10:30 a.m.*
*On Record for public discussion at 11:05 a.m.*

Upon return from executive session, Chair Holm commented that no motions were made.

**On a motion duly made by Anne Gruening, seconded by James Henderson and approved unanimously, it was:**

**RESOLVED to approve the consent agreement for Odilio Kong, #PHAC3011.**

| | APPROVE | DENY | ABSTAIN | ABSENT |
|---|---|---|---|---|
| Leif Holm | x | | | |
| Richard Holt | x | | | |
| Phil Sanders | x | | | |
| James Henderson | x | | | |
| Anne Gruening | x | | | |
| Lana Bell | | | | x |

**On a motion duly made by Anne Gruening, seconded by Leif Holm and approved unanimously, it was:**

**RESOLVED to approve the license surrender for Lisa Gore, #PHAP1100.**

| | APPROVE | DENY | ABSTAIN | ABSENT |
|---|---|---|---|---|
| Leif Holm | x | | | |
| Richard Holt | x | | | |
| Phil Sanders | x | | | |
| James Henderson | x | | | |
| Anne Gruening | x | | | |
| Lana Bell | | | | x |

**On a motion duly made by Anne Gruening, seconded by Rich Holt and approved unanimously, it was:**

**RESOLVED to approve the pharmacy technician license for Kathleen Soria, #127780.**

| | APPROVE | DENY | ABSTAIN | ABSENT |
|---|---|---|---|---|
| Leif Holm | x | | | |
| Richard Holt | x | | | |
| Phil Sanders | x | | | |
| James Henderson | x | | | |
| Anne Gruening | x | | | |
| Lana Bell | | | | x |

**On a motion duly made by Anne Gruening, seconded by Phil Saners and approved unanimously, it was:**

**RESOLVED to approve the pharmacy technician application for Ryan Thompson, #125715.**

| | APPROVE | DENY | ABSTAIN | ABSENT |
|---|---|---|---|---|
| Leif Holm | x | | | |
| Richard Holt | x | | | |
| Phil Sanders | x | | | |
| James Henderson | x | | | |
| Anne Gruening | x | | | |
| Lana Bell | | | | x |

*Off record for break at 11:09 a.m.*
*On record for public discussion at 11:22 a.m.*

**Agenda Item 18** **Regulation Review/Discussion** **Time: 11:22 a.m.**

Returning from break, Chair Holm addressed regulations as a carry-over from the previous day, starting with the topic of the Universal Claims Form for the waiver of electronic submission requirements under 12 AAC 52.865 and 12 AAC 52.870 for dispensers. Rich Holt commented that the form was available in many versions on the NABP site, but suggested to the board for a specific form to be created that aligns with the regulatory requirements.

The board then moved on to discussing the topic of providing satisfactory proof of record keeping, required for out-of-state pharmacies under 12 AAC 52.130(c). AAG Greider commented that the board already has the language that allows the board to clarify what is meant by "proof satisfactory". The board continued to discuss this with AAG Greider and assigned staff until it was ultimately determined that satisfactory proof could be demonstrated by submitting a statement along with a summary of the policies and procedures or a copy of such documentation.

Moving onto the proposed language in 12 AAC 52.855 for PDMP registration requirements, Rich Holt asked AAG Greider whether the language is confusing to state "on a form provided by the board" when registering is done via an online registration. AAG Greider agreed and commented that this language may inadvertently miscommunicate to licensees that a paper registration is available. The board continued to discuss alternative language to clarify that registration will be done online. Ms. Carrillo then commented on the proposed language to implement a registration fee, adding that tracking of this payment is more compatible with an online registration as payments relative to receiving payment separately from a paper application, which could consequently delay the registration process. Ms. Bellino agreed, stating that it is more efficient to receive both the payment and registration at the same time.

The board also discussed 12 AAC 52.200(c), 12 AAC 52.240(a), 12 AAC 52.470 regarding refills, 12 AAC 52.480 regarding labeling, and draft regulations from the August meeting. Other topics included regulation changes for pharmacy technicians, collaborative practice agreements, and drug-takeback programs. The board also discussed including the intern jurisprudence exam within the application to improve efficiency. The board agreed the exam could be added as it is an open-book exam.

**TASK**
Laura to create an administrative form for the proof satisfactory draft and will bring it to the next meeting tentative scheduled for February 28 – March 1, 2018.

**TASK**
Laura to incorporate jurisprudence test for pharmacist interns into initial application packet.

*Off record for break at 1:07 p.m.*
*On record for public discussion at 1:15 p.m.*

Upon return from break, the board was ready to make a motion to approve the regulation drafts (included in these minutes following the motions).

**On a motion duly made by Rich Holt, seconded by Anne Gruening, and approved unanimously, it was**

> **RESOLVED to approve the draft language from the Department of Law titled, "SB74, HB159 regs 12.1.17" and "PHA-08/17 12/01/17".**

**On a motion duly made by Rich Holt, seconded by Leif Holm, and approved unanimously, it was**

> **RESOLVED to approve the regulation draft prepared by the division's regulations specialist dated 10/03/17 be sent to the Department of Law for cursory review.**

> REGULATION DRAFTS:

**Chapter 52. Board of Pharmacy.**

(Words in **boldface and underlined** indicate language being added; words [CAPITALIZED AND BRACKETED] indicate language being deleted. Complete new sections are not in boldface or underlined.)

12 AAC 52.855 is repealed and readopted to read:

**12 AAC 52.855. Registration with the Prescription Drug Monitoring Program controlled substance prescription database.** (a) A licensed pharmacist shall register with the Prescription Drug Monitoring Program's controlled substance prescription database (PDMP) before dispensing a schedule II, III, or IV controlled substance under federal law. .

(b) Before dispensing, prescribing, or administering a schedule II, III, or IV controlled substance under federal law, a pharmacist or practitioner required to register with the PDMP must

(1) register online on the PDMP website; and

(2) pay the fee established in 12 AAC 02.310.

(c) After completing the registration requirements, a pharmacist or practitioner required to register with the PDMP will be issued a user account, login name, and password by the department.

(d) A pharmacist or practitioner required to register with the PDMP must access information in the PDMP using the user account, login name, and password issued by the department.

(e) A pharmacist or practitioner required to register with the PDMP may access information in the PDMP using another registrant's credentials only as authorized by a contract executed by the department for the purposes of AS 47.07.038. (Eff. 12/29/2011, Register 200; am ___/___/____, Register ____)

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

12 AAC 52.860 is repealed and readopted to read:

**12 AAC 52.860. Access to and conditions for use of the Prescription Drug Monitoring Program database.** (a) Access to the PDMP is limited as described in AS 17.30.200(d).(b) For the purposes of AS 17.30.200(d)(1):

(i)."personnel of this board" means employees of the Department of Commerce, Community, and Economic Development assigned to the Board of Pharmacy, and

(ii). "personnel of another board or agency" means an employee of the state of Alaska assigned to a board that requires licensees to register with the PDMP or an agency identified in a search warrant, subpoena, or order issued by an administrative law judge or a court. .

(b) For the purposes of AS 17.30.200(d)(2), "authorized board personnel or contractors" means:

(i). employees of the Department of Commerce, Community, and Economic Development assigned to the Board of Pharmacy , or

(ii). employees of a state contractor providing PDMP data storage or data management services.

(c) For the purposes of AS 17.30.200(d)(3) and (4), a licensed practitioner or licensed or registered pharmacist authorizing an "agent or employee" to access the PDMP is responsible for maintaining and terminating the agent or employee's access to the PDMP.

(d) For the purposes of AS 17.30.200(d)(8) and (10), "authorized employee of the Department of Health and Social Services" means an employee of the Department of Health and Social Services (DHSS) for whom the DHSS commissioner or commissioner's official designee has requested access in writing to the board prior to the release of information. (Eff. 12/29/2011, Register 200; am ___/___/____, Register ____)

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

12 AAC 52.865 is repealed and readopted to read:

**12 AAC 52.865. Reporting and reviewing PDMP information.** (a) Unless excused from reporting under AS 17.30.200(u), information required under AS 17.30.200(b) must be submitted by a pharmacist, if the pharmacist-in-charge is not present.

(b) Unless excused from reporting under AS 17.30.200(u), a pharmacist or practitioner required to submit information under AS 17.30.200(b) must submit the information to the Alaska Prescription Drug Monitoring Program (PDMP) daily as of the previous submission date..

(c) The time computation under 12 AAC 02.920(b) applies to a submission of information under AS 17.30.200(b) and this section. (d) For the purposes of AS 17.30.200(b)(8), "other appropriate identifier" and "other appropriate identifying information" means the state issued license number of the prescribing practitioner, and the dispensing pharmacist or practitioner.

(d) Within 72 hours of discovering an error in information submitted under AS 17.30.200(b), a pharmacist or practitioner required to submit the information under AS 17.30.200(b) must submit information correcting the error to the PDMP administrator. The time computation under 12 AAC 02.920(b) applies to a submission of information correcting an error in information submitted under AS 17.30.200(b).

(e) Unless excused from reporting under AS 17.30.200(u), or a waiver is granted under 12 AAC 52.870, a pharmacist or practitioner required to submit information under AS 17.30.200(b)must submit the information to the PDMP electronically through the website provided by the board.

(f) Unless excused from reviewing the PDMP under AS 17.30.200(k)(4)(A) – (B), a practitioner, but not a pharmacist, must review the information in the PDMP to check a patient's prescription records before dispensing, prescribing, or administering a schedule II or III controlled substance under federal law.

(Eff. 12/29/2011, Register 200; am ___/___/____, Register ____)

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

12 AAC 52.870 is amended to read:

**12 AAC 52.870. Waiver of electronic submission requirement by pharmacist or practitioner [DISPENSER].** (a) The department shall waive the electronic submission requirements of 12 AAC

52.865**(e)** [(B)] for good cause. The **pharmacist or practitioner** [DISPENSER] requesting the waiver is responsible for establishing the basis for the requested waiver under this section.

(b) To establish good cause for purposes of this section, a **pharmacist or practitioner** [DISPENSER] must submit an application and sworn statement showing that

(1) a natural disaster or other emergency beyond the control of the **pharmacist or practitioner** [DISPENSER] prevents the **pharmacist or practitioner** [DISPENSER] from complying with 12 AAC 52.865**(e)** [(B)];

(2) the **pharmacist or practitioner** [DISPENSER] will only dispense controlled substances as part of a controlled research project approved by an accredited institution of higher education or under the supervision of a government agency;

(3) **repealed / /** [THE DISPENSER WILL DISPENSE NINE OR FEWER PRESCRIPTIONS OF CONTROLLED SUBSTANCES A MONTH];

(4) the **pharmacist's or practitioner's** [DISPENSER] business is located in an area that lacks access to the telecommunication services needed to comply with 12 AAC 52.865(e) [(B)]; or

(5) the **pharmacist or practitioner** [DISPENSER] will suffer financial hardship if required to acquire the technology necessary to comply with 12 AAC 52.865(e) [(B)].

(c) The department may not grant a waiver under this section unless the **pharmacist or practitioner** [DISPENSER] first agrees in writing that, if the waiver is granted, the **pharmacist or practitioner** [DISPENSER] will satisfy the reporting requirements of AS 17.30.200(b) by submitting the required information by United States mail to the board **on at least a daily basis** using a form approved by the board.

(d) A request for a waiver under this section must be in writing using an application form **provided** by the board and sent to the board.

(e) The department's grant or denial of a waiver request constitutes a final agency action unless, no later than 30 days after the department issues notice of the grant or denial, the **pharmacist or practitioner** [DISPENSER] files a written notice of appeal with the board.

(f) A waiver granted under this section expires at the end of the year in which it is granted.

(g) A **pharmacist or practitioner** [DISPENSER] **must** inform the board within 30 days if the basis for the waiver of electronic reporting no longer exists. (Eff. 12/29/2011, Register 200; am ___/___/____, Register ____)

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

Article 9 is amended by adding a new section to read:

**12 AAC 52.885. Purge database records.** The following information will be purged from the PDMP database after two years have elapsed from the date the prescription was dispensed:

(a) the name of the prescribing practitioner and the practitioner's federal Drug Enforcement Administration registration number or other appropriate identifier;

(b) the date of the prescription;

(c) the date the prescription was filled and the method of payment;

(d) the name, address, and date of birth of the person for whom the prescription was written;

(e) the name and national drug code of the controlled substance;

(f) the quantity and strength of the controlled substance dispensed;

(g) the name of the drug outlet dispensing the controlled substance; and

(h) the name of the pharmacist or practitioner dispensing the controlled substance and other appropriate identifying information. (Eff. ___/___/____, Register ____).

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

12 AAC 52.880(a) is amended to read:

12 AAC 52.880. Reports (a) The board will maintain a register for patient profile requests solicited under [12 AAC 52.855(b) or] 12 AAC 52.875. The register includes the following information:

…

12 AAC 52.880(a)(3) is amended to read:

(3) the name, title, [BUSINESS,] and address of the individual requesting the profile. [AND, IF THE INDIVIDUAL IS A PRACTITIONER, THE PRACTITIONER'S CURRENT FEDERAL DRUG ENFORCEMENT ADMINISTRATION REGISTRATION NUMBER];

…

(Eff. 12/29/2011, Register 200; am ___/___/____, Register ____)

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

12 AAC 52.890 is amended to read:

**12 AAC 52.890. Grounds for discipline.** A violation of 12 AAC 52.855—12 AAC 52.890 by a pharmacist is grounds for the imposition of disciplinary sanctions under AS 08.01.075 and AS 08.80.261. A violation of 12 AAC 52.855—12 AAC 52.890 by a practitioner not licensed by this board shall be reported to the practitioner's licensing board. (Eff. 12/29/2011, Register 200; am ___/___/____, Register ____)

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

12 AAC 52.920 is amended by adding a new section to read:

(22) violating AS 17.30.200 or a regulation adopted thereunder dealing with the PDMP;

(Eff. 1/16/98, Register 145; am ___/___/____, Register ____)

**Authority:** AS 08.01.075 AS 08.80.005 AS 08.80.030

AS 08.80.261 AS 08.80.315 AS 08.80.460

AS 17.30.200

12 AAC 52.995 is amended by adding a new subsection to read:

(d) In AS 17.30.200, and 12 AAC 52.855—12 AAC 52.895, "practitioner" has the meaning given in AS 11.71.900.

(Eff. 1/16/98, Register 145; am 5/5/2000, Register 154; am 11/10/2001, Register 160; am 8/21/2002, Register 163; am 2/15/2006, Register 177; am 8/12/2007, Register 183; am 9/11/2010, Register 195; am 12/29/2011, Register 200; am 8/1/2014, Register 211; am ___/___/____, Register ____)

**Authority:** AS 08.80.005 AS 08.80.030 AS 08.80.157

AS 11.71.900 **AS 17.30.200**

**Chapter 52. Board of Pharmacy.**

(Words in **boldface and underlined** indicate language being added; words [CAPITALIZED AND BRACKETED] indicate language being deleted. Complete new sections are not in boldface or underlined.)

12 AAC 52.120(b) is amended by adding a new paragraph to read:

(8) submits two affidavits from reputable citizens that the applicant has known for at least one year attesting to the applicant's good moral character.

(Eff. 1/16/98, Register 145; am 2/11/2004, Register 169; am 2/15/2006, Register 177; am 1/17/2007, Register 181; am 11/16/2012, Register 204; am ___/___/____, Register ____)

**Authority:** AS 08.80.005 AS 08.80.110 AS 08.80.116

AS 08.80.030

The section heading for 12 AAC 52.130 is amended to read:

**12 AAC 52.130. <u>Registration</u> [REVIEW OF APPLICATIONS FOR REGISTRATION] of pharmacies located outside of the state.**

…

12 AAC 52.130(c) is amended to read:

(c) A pharmacy located outside of the state that ships, mail, or delivers prescription drugs **<u>into the state</u>** more than twice during a 12-month period [TO INDIVIDUAL PATIENTS IN THE STATE] shall register with the board.

…

12 AAC 52.130 is amended by adding a new section to read:

(d) In AS 08.80.158(b)(4) "proof satisfactory" means a sworn statement that the pharmacy maintains its records of prescription drugs dispensed to persons in the state so that the records are readily retrievable from the records of other prescription drugs dispensed by the pharmacy, with either a written description or a copy of the pharmacy's Policies and Procedures. (Eff. 1/16/98, Register 145; am 6/2/2004, Register 170; am 2/15/2006, Register 177; am ___/___/____, Register ____)

**Authority:** AS 08.80.005 AS 08.80.030 AS 08.80.158

12 AAC 52.200(c) is amended to read:

(c) A pharmacist designated to replace the pharmacist-in-charge of a pharmacy shall notify the board **<u>by submitting a completed change of pharmacist-in-charge form provided by the department and paying the applicable fees established in 12 AAC 02.105</u>** within 10 days of that

designation. (Eff. 1/16/98, Register 145; am 2/26/2000, Register 153; am 2/15/2006, Register 177; am ___/___/____, Register ____)

**Authority:** AS 08.80.005 AS 08.80.157 AS 08.80.330
AS 08.80.030 **AS 08.80.160**

12 AAC 52.240(a) is amended to read:

(a) A pharmacist planning to exercise collaborative practice authority in the pharmacist's practice by initiating or modifying drug therapy in accordance with a written protocol established and approved for the pharmacist's practice by a practitioner authorized to prescribe drugs under AS 08 must submit the completed written protocol to the board [AND BE APPROVED BY THE BOARD BEFORE IMPLEMENTATION.].

…

12 AAC 52.240(d) is repealed:

(d) repealed.

…

12 AAC 52.240(g) is amended to read:

(g) Any modification to the written protocol must be approved [BY THE BOARD] as required by this section for a new written protocol.

(Eff. 11/10/2001, Register 160; am 2/11/2004, Register 169; am 11/16/2012, Register 204; am ___/___/____, Register ____)

**Authority:** AS 08.80.030 AS 08.80.480

12 AAC 52.470 is amended by adding new subsections to read:

(d) If an original prescription drug order is prescribed as a 30-day supply, the pharmacist may dispense up to a 90-day supply on refills provided that the

(1) patient has completed an initial 30-day supply of the drug;

(2) total quantity of dosage units dispensed does not exceed the total quantity of dosage units authorized by the prescriber on the prescription, including refills;

(3) drug is not a federal or state scheduled controlled substance; and

(4) the pharmacist is exercising professional judgment.

(e) To indicate that an increased supply shall not be dispensed pursuant to this section, a prescriber may indicate "no change to quantity", or words of similar meaning, on the prescription drug order.

(f) Nothing in this section shall be construed to require a health care service plan, health insurer, workers' compensation insurance plan, pharmacy benefits manager, or any other person or entity, including, but not limited to, a state program or state employer, to provide coverage for a drug in a manner inconsistent with a beneficiary's plan benefit. (Eff. 1/16/98, Register 145; am ___/___/____, Register ____)

**Authority:** AS 08.80.005 AS 08.80.030

12 AAC 52.510(a)(1) is amended to read:

(1) the prescribing practitioner does not **indicate** [HAND WRITE OR ELECTRONICALLY NOTE] on the prescription drug order that a specific brand must be dispensed, using language such as "brand medically necessary"**, "dispense as written", "do not substitute",** or **other** similar wording;

…

12 AAC 52.510(a)(4) is amended to read:

(4) for the drug product actually dispensed, the **pharmacy record shall contain** [PHARMACIST NOTES ON THE PRESCRIPTION DRUG ORDER] one of the following:

. . .

(Eff. 1/16/98, Register 145; am 10/9/2008, Register 188; am ___/___/____, Register ____)

**Authority:** AS 08.80.005 AS 08.80.030 AS 08.80.295

12 AAC 52.610(c) is amended to read:

(c) Within 30 days of a change in facility manager, the new facility manager must **submit**

**(1) the completed change of pharmacy manager form provided by the department;**

**(2) the applicable fees established in 12 AAC 02.310; and**

**(3)** meet the requirements of (a)(4) and (6) of this section. (Eff. 1/16/98, Register 145; am 8/21/2002, Register 163; am 1/17/2007, Register 181; am ___/___/____, Register ____)

**Authority:** AS 08.80.005 AS 08.80.157 AS 08.80.480

AS 08.80.030

12 AAC 52.991 is amended by adding a new section to read:

(b) A licensed or registered facility shall report in writing to the board any disciplinary decision, including suspension or revocation by federal, state, or local government of a license currently or previously held by the applicant or facility for the manufacture or distribution of drugs or devices, including controlled substances, or any felony conviction under federal, state, or local law of an owner of the facility or of an employee of the facility. (Eff. 9/17/2011, Register 199; am 4/16/2016, Register 218; am ___/___/____, Register ____)

**Authority:** AS 08.01.075 AS 08.80.030 AS 08.80.315

AS 08.80.005 AS 08.80.261 AS 08.80.460

AS 08.80.157

**Agenda Item 16** **Correspondence/Report of Theft or Loss** **Time: 1:35 p.m.**

Hearing nothing further on regulation projects, the board discussed correspondence and reports of theft or loss. Donna Bellino clarified that the legislative pre-review is usually done before the meeting, and that HB 9 and SB 37 do not need to be filed again since they go through a two-year cycle. Ms. Carrillo inquired about the difference between these bills, to which Chair Holm and Anne Gruening responded that HB 9 was more thorough and had better language.

The board also reviewed the correspondence from the Harborview Clinic, which is asking the board to support pharmacist-prescriber relationships. The board ultimately decided that this should be referred to the Department of Law.

Reports of theft/loss were reviewed for Safeway Pharmacy #PHAR357, #120121, #110057, Walgreens Pharmacy #PHAR494, Fredmeyer Pharmacy #PHAR387 and #PHAR388, and Alaska Managed Care Pharmacy #120110.

**TASK**
Laura will post the updated VET FAQs provided by AAG, Megyn Greider to the Board of Pharmacy Website.

**TASK**
Ms. Carrillo will forward the correspondence from the Harborview Medical Center's Orthopedic Clinic to the Department of Law for further review.

**On a motion duly made by Anne Gruening, seconded by Phil Sanders, and approved unanimously, it was**

**RESOLVED to adjourn the meeting at 2:01 p.m.**

Laura Carrillo Digitally signed by Laura Carrillo Date: 2018.03.15 13:11:50 -08'00'

Laura Carrillo, Records & Licensing Supervisor

Rich Holt for Leif Holm, PharmD, Chair