**STATE OF ALASKA**

**Department of Commerce, Community, and Economic Development**
**Professional Licensing**

# ALASKA BOARD OF PHARMACY

August 30 – 31, 2018

Board Meeting

Anchorage

**Board Packet**

PUBLIC COPY
(DAY 2)

# Alaska Board of Pharmacy Roster

| Board Member Name | Initial Appointment | Reappointed | Term End |
|---|---|---|---|
| Leif Holm, PharmD (Chair) | 03/01/2015 | | 03/01/2019 |
| Richard Holt, PharmD, MBA (Vice Chair) | 03/01/2016 | | 03/01/2020 |
| Sharon Long, Public Member | 03/01/2018 | | 03/01/2022 |
| Lana Bell, RPh | 05/31/2016 | 03/01/2018 | 03/01/2018 |
| Phil Sanders, RPh | 03/01/2016 | | 03/01/2020 |
| James Henderson, RPh | 03/01/2017 | | 03/01/2021 |
| Tammy Lindemuth, Public Member | 01/24/2018 | | 03/01/2021 |

# ALASKA BOARD OF PHARMACY MEETING

# TENTATIVE AGENDA

## AUGUST 31, 2018 (DAY 2)

**Teleconference Line: 1-800-315-6338**
**Access Code: 52550**

**Board Members:**

Richard Holt, *PharmD, MBA (Chair)*

Leif Holm, *PharmD (Vice Chair)*

James Henderson, *RPh*

Lana Bell, *RPh*

Phil Sanders, *RPh*

Tammy Lindemuth, *Public Member*

Sharon Long, *Public Member*

**Upcoming Meetings:**

TBD

## Meeting Details

Meeting Name: Alaska Board of Pharmacy Meeting - Day 2

Meeting Start Time: 9:00 AM Alaskan Daylight Time

Meeting Start Date: 8/31/2018

Meeting End Time: 4:30 PM Alaskan Daylight Time

Meeting End Date: 8/31/2018

Meeting Location: Robert Atwood Building, 550 W 7th Ave, ACC 102

## Agenda

I. Agenda Item #16 - 9:00 a.m. Roll Call/Call to Order

II. Agenda Item #17 - 9:05 a.m. Review/Approve Agenda

III. Agenda Item #18 - 9:10 a.m. Review/Approve Minutes

- A. February 28 - March 2, 2018
- B. March 22, 2018
- C. May 10 - 11, 2018

IV. Agenda Item #19 - 9:30 a.m. Board Business (Part II)

- A. Discuss/Draft Regulations (Regulations Workflow)

1. SB 37 Regulations: Executive Administrator, Out-of-State Wholesale Drug Distributors, Third-Party Logistic Providers, an Outsourcing Facilities
    a. SB 37 (Signed on 07/24/18)
    b. NABP Model Act-Rules
2. 12 AAC 52.470 - Prescription Refills (Suggestions to amend)
3. 12 AAC 52.120 - Pharmacist Intern License Application (Suggestions to amend)
4. 12 AAC 52.150 - Indian Health Service Pharmacists (Add new section; revisit)
5. 12 AAC 52.340 – Approved Programs (add approved presenters)
6. Outstanding Regulation Project List (Draft from October 2017)
    a. Draft Regulations with LAW Edits – 08-21-2018
7. SB 32 Regulations Reviewed by LAW - Comments from Megyn W. 08-29-2018

B. Legislative Changes (HB 240)

V. Agenda Item #19 - 4:00 p.m. Adjourn

**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
**February 28 – March 2, 2018**

**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 February 28 – March 2, 2018.**

**These are draft minutes that have not yet been approved by the board.**

**Agenda Item 1** **Call to Order/Roll Call** **Time: 9:43 a.m.**

The **February 28, 2018** meeting day was called to order by Chair, Leif Holm at 9:43 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
Tammy Lindemuth, Public Member
Sharon Long, Public Member (effective 03/01/2018; via phone)

Division staff present:

Donna Bellino, Occupational Licensing Examiner
Laura Carrillo, Records & Licensing Supervisor
Melissa Dumas, Administrative Officer
Marilyn Zimmerman, Paralegal
Brian Howes, Investigator

Public members present:

Greg Estep, #PHAP2259, Walgreens (via phone)

Lis Houchen, NW Regional Director, National Association of Chain Drug Stores
Caren Robinson, Alaska Pharmacists Association

**Agenda Item 2** **Review/Approve Agenda** **Time: 9:44 a.m.**

Chair Holm prompted the board to review the agenda. There were no suggested additions or Amendments for February 28, 2018.

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

**RESOLVED to accept the February 28, 2018 agenda as written.**

**Agenda Item 3** **Review/Approve Minutes** **Time: 9:44 a.m.**

The board addressed the meeting minutes from the November 30 – December 1, 2017 meeting and took time to review the draft minutes.

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

**RESOLVED to approve the November 30 – December 1, 2017 meeting minutes as written.**

**Agenda Item 4** **Ethics Disclosures** **Time: 9:48 a.m.**

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

*Brian Howes joined the room telephonically at 9:44 a.m.*
*Brian Howes left the room telephonically at 9:55 a.m.*

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

Investigator, Brian Howes provided his investigative report for the February 28 – March 2, 2018, which included the period of November 15, 2017 through February 7, 2018. Brian Howes informed the board that the division opened four (4) files and closed seven (7) matters, with eight (8) cases still open as reflected on the investigative memorandum provided to the board.

Rich Holt inquired to Mr. Howes as to whether they would have an update on some of the matters that were opened in 2016, to which Mr. Howes responded that these matters will likely be discussed at the board's next meeting.

Chair Holm commented on the 2016 open cases, inquiring whether there were specific hang-ups delaying resolution of these outstanding matters. Mr. Howes indicated that some of the matters would be resolved and that some may carry additional charges. Chair Holm commented that the drug diversion matter should be having more momentum and Rich Holt added that the unresolved two-year unprofessional conduct case should been resolved. Speaking on this delay, Chair Holm reiterated legislative audit's previous findings that investigative matters were not being resolved in a timely manner. Chair Holm acknowledged the work load Mr. Howes has with investigations relating to pharmacy as well as to the Prescription Drug Monitoring Program (PDMP), but encouraged close follow-up with these cases to be resolved more timely.

**Agenda Item 6 Public Comment Time: 9:53 a.m.**

Hearing nothing further on investigations, Chair Holm entertained review of public comments. As indicated at the board's previous meeting, no oral public comments on the proposed SB 74 regulations, PDMP fees, and various changed to licensure requirements, collaborative practice, refills, wholesale distributor licensing, and disciplinary actions were going to be heard at this time. Before reviewing written public comments submitted to the regulations specialist and in the interest of time, Chair Holm called for Caren Robinson to present on behalf of the Alaska Pharmacist Association.

*(Suspend review and discussion of public comment at 9:55 a.m.)*
*(Resume review and discussion of public comment at 10:16 a.m.)*

**Agenda Item 12 Pharmacy Industry Update Time: 9:55 a.m.**

Alaska Pharmacists Association

Addressing the pharmacy industry update, Caren Robinson with the Alaska Pharmacists Association presented to the board a summary of the bills supported by the association as well as an update on pharmacy school student activities. Ms. Robinson informed the board that ten (10) pharmacy school students will be attending the senior center to do vaccinations and will be here on Friday to shadow the board's meeting on Friday, March 2nd. Ms. Robinson reviewed Senate Bill 32 (the bill addressing biologics), HB 240 (fair audit bill), and Senate Bill 37, which the board will discuss under Agenda Item #17, Legislative Update.

**Agenda Item 6 Public Comment Time: 10:16 a.m.**

The board had three separate regulations projects out for public comment and were ready to review them. Donna Bellino clarified that the regulation project that closed for public comment on February 26, 2018 was not yet ready for review as some of the comments arrived via snail mail and couldn't be included in the board packet in time.

PDMP Fee Regulations (Closed February 21, 2018)

The board first reviewed public comments relating to the proposed PDMP fee under centralized regulation, 12 AAC 02.107, which would establish an initial registration fee of $50.00 as well as a $50.00 renewal fee to be paid every two years. Lana Bell commented that she has received feedback from several licensees opposing this proposal, to which Chair Holm agreed but indicated that when the bill on this was being heard, licensees didn't come forward to testify against it. Chair Holm added that because the authority for establishing fees for the database is now written in statute, the board doesn't have the ability to retract the proposed fee or to not require such. Lana Bell inquired as to whether the fee could be lowered, to which Ms. Carrillo responded that the division would be reviewing all 245 public comments before making any final determination on the proposed fees. Chair Holm prompted Ms. Carrillo for clarification as to whether the board is required to take action on the public comments, to which Ms. Carrillo indicated this was not required as the proposed change is to a centralized regulation rather than to the board's regulations under 12 AAC 52. Tammy Lindemuth inquired as to what the reason is for now charging a fee when the database has been in place since 2008, to which Chair Holm and Rich Holt stated that the database is entirely grant funded and will need to be sustained by fees. Chair Holm added that it's possible the fee could be adjusted to only cover the costs that are necessary regardless of whether there's an available grant to cover some of the costs. The board expressed interest in hearing what other states require a registration fee or renewal fee.

**TASK**

Laura Carrillo will post a notice to the board's website stating that the board has reviewed the public comments relating to the PDMP fees, but that the board cannot take action on the comments due to the fee language being under centralized regulations rather than the board's regulations. The board requests that further language be added to clarify that the division will review all comments before the fee is implemented.

**TASK**

Laura Carrillo will send out a poll asking what states require a registration fee.

Senate Bill 74 Regulations (Pertaining to PDMP access; closed February 15, 2018)

The board then moved on to reviewing written public comments on the SB 74 regulations pertaining to PDMP requirements, including changes to:

- 12 AAC 52. 855 – Registration requirements with the PDMP
- 12 AAC 52. 860 – Access and conditions for use
- 12 AAC 52. 865 – Reporting and reviewing requirements
- 12 AAC 52. 870 – Waiver of electronic submission of data
- 12 AAC 52. 880 – Correct statute citation referencing Medicaid reform
- 12 AAC 52. 885 – Purge of database records
- 12 AAC 52. 890 – Grounds for discipline and reporting of PDMP violations
- 12 AAC 52. 920 – Disciplinary guidelines for PDMP violations

- 12 AAC 52. 995 - Definition of practitioner relating to PDMP

Chair Holm called for break at 10:50 a.m.

*Off record at 10:50 a.m.*
*On record at 11:02 a.m.*

Returning for break, the board honed in on a comment submitted by Health and Social Services, Deputy Commissioner, Jon Sherwood who wanted to bring to the board's attention a recommended citation to use in lieu of the citation in the current proposed language in 12 AAC 52.855(e). Ms. Carrillo commented that the statute in the current proposed change makes reference to AS 47.07.038, which is actually no longer in effect; Jon Sherwood recommended instead to cite AS 47.05.270. Chair Holm requested additional information on the latter statute as it is unclear as to how the statute relates specifically to the PDMP.

The board then addressed confusion of the time computation, however, it was clarified that this is already clearly articulated under 12 AAC 02.920(b).

**TASK**
Ms. Carrillo will ask for further clarification for DHSS on the relevance of AS 47.05.270 to the PDMP.

**Agenda Item 8 Budget Report/Division Update Time: 11:38 a.m.**

*Melissa Dumas joined the room at 11:38 a.m.*
*Melissa Dumas left the room at 11:42 a.m.*

Melissa Dumas, Administrative Officer, joined the room to provide the board's budget report for the FY18 2nd quarter. Ms. Dumas reminded the board that they're currently in a renewal year and are incurring revenue. It was added that the board has incurred $86,000 this year but will likely bring in $800,000 for the total year. Ms. Dumas also informed the board that their total personal services so far is $107,837, that their travel expenses is at $3,664, and that there is no anticipated fee increase for the board at this time.

**Agenda Item 9 Board Business Time: 11:44 a.m.**

*Marilyn Zimmerman joined the room at 11:44 a.m.*
*Marilyn Zimmerman left the room at 12:16 a.m.*

Review Applications
After a concise and informative budget report, the board moved onto board business, beginning with the review of applications. Due to the nature of the discussions relating to tabled applications and default revocations, the board entertained a motion to enter executive session.

**On a motion duly made by Anne Gruening 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, Laura Carrillo, and Marilyn Zimmerman were authorized to remain in the room.**

*Off record for executive session at 11:46 a.m.*
*On record for public discussion at 11:58 a.m.*

Upon return from executive session, Chair Holm clarified for the record that no motions were made during executive session, but indicated that the board was ready to take action on tabled applications and matters involving default revocations and a voluntary surrender

**On a motion duly made by Anne Gruening to approve the pharmacy technician application for Ric Allen in consideration of AS 08.80.261(4), seconded by Phil Sanders, and opposed unanimously, it was:**

**RESOLVED to deny the pharmacy technician application for Ric Allen.**

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

No further discussion.

**On a motion duly made by Anne Gruening to accept the default revocations for Candice Aguilar, Sheila Epling, Jamie Bell, Terry Morris, and Karlee Sturdevant, seconded by Phil Sanders, and approved unanimously, it was:**

**RESOLVED to accept the default revocations for Candice Aguilar, Sheila Epling, Jamie Bell, Terry Morris, and Karlee Sturdevant.**

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

No further discussion.

**On a motion duly made by Rich Holt to accept the voluntary surrender of Tarnisha Bedward-Davis, seconded by Tammy Lindemuth, and approved unanimously, it was:**

**RESOLVED to accept the voluntary surrender of Tarnisha Bedward-Davis.**

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

No discussion.

**TASK**

Ms. Carrillo will be sure to add the applications for Rex Malcom and Jennifer La Tourelle for discussion at the board's next meeting.

<u>Review Reports of Lost or Stolen Rx:</u>

Hearing nothing further on disciplinary actions, default revocations, or voluntary surrenders, the board moved to reviewing reports of lost or stolen prescriptions. Included in the board's packet were reports submitted by the Alaska Managed Care Pharmacy #1829, Carrs Pharmacy #1812 and CVS Pharmacy #1704. Ms. Carrillo inquired to the board what the typical protocol is for reviewing these reports, and whether the board usually takes action based upon what is reported. Chair Holm clarified that these reports are only reviewed, but that action may be taken if there are outstanding concerns that warrant further investigation.

Review and Approval of Outstanding Continuing Education Audits

The board then moved on to discussion of continuing education audits from the June 30, 2016 renewal period. Donna Bellino informed the board that the certificates of completion have already been screened during a preliminary administrative review.

**On a motion duly made by Rich Holt to accept the continuing education certificates for individuals with outstanding audits, seconded by James Henderson, and approved unanimously, it was:**

**RESOLVED to close the 2016 continuing education audits for Melanie Kluck, Heidi Brainerd, Giyae Lee-Thompson, Sean Berkey, Constance Reyes, Vincent Greear, Margaret Saam, Leanne Stephenson, Mary Bowen, David Thompson, Robert Grogan, Eric LeBoeuf, Lisa Gore, Mike Branson, Ronald Simono, John Davis, Sonja Marie Foutty, Katherine Farrington, Lester Kish, Marlene Perschbacher, Elaine Grant, Amy Rowan, Sonia Ceng, Jane Russell, Lorinda Girourard, Cynthia McCoy, Rodney Gordon, Barbara Antal, Brant Herman, David Atahey, Jamie Lynn Malstrom, Justin May, Emily Thomas, Chhayal Dalal Thomas, Wilbur Graves, Randal Brown, Jared Rawlings, Gary Scott, Jeffrey Gaarder, Alexander Kappleman, Ronald Houle, Gale Rae Berkey, Susan Wheeler, Ben Jensen, Sean Berkey, Denise Every, Kali Allen, Deborah Padilla, Elizabeth Leraas, Nancy Schaefer, Carrie Lang, Laura Olienyk, Deon Pretorius, Jeffrey Stevens, Forrest Fentress, Piper Machamer, Emily Phipps, Mark Johnson, Jill Reid, Killsoo Jang, Adam Vorke, Erin Bollinger, Robyn Goff, Ryan Hardcastle, Lisa Babiak, Tolulope Balogun, Donat Doni, Ashley Kobylinski, Donald Schumacher, Jeffrey Unger, Dominique Lauten, Esnaldo Franco-Ferrer, Howard Ganser, Robert May, David Denio, Tracey Hysong, Hsiao-Lan Ng, Kim Boehmer, Julie Mannello, Joyce Schramm, Charles Barnett, Bruce Christensen, Katherine Pratt, Paul Gionet, Lori Devito, Douglas Bartko, Richard Green, Carroll Mortenson, Roger Paul Penrod, and Patrice Bohrer.**

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

Discussion: It was noted that audits for Jessica LaTourelle and Rex Malcom would be addressed at a later date.

**TASK**

Staff will send audit closed letters to all pharmacists whose continuing education audits have closed.

**Agenda Item 10** **Recess** **Time: 12:48 p.m.**

The board recessed the meeting at 12:48 p.m. and would resume on March 1, 2018.

**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**
**February 28 – March 2, 2018**

**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 February 28 – March 2, 2018.**

**These are draft minutes that have not yet been approved by the board.**

**Agenda Item 11** **Call to Order/Roll Call** **Time: 9:05 a.m.**

The **March 1, 2018** meeting day was called to order by Chair, Leif Holm at 9:05 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
Tammy Lindemuth, Public Member
Sharon Long, Public Member (effective 03/01/2018; via phone)

Division staff present:

Donna Bellino, Occupational Licensing Examiner
Laura Carrillo, Records & Licensing Supervisor
Virginia Geary, Occupational Licensing Examiner, Board of Veterinary Examiners
Gail Bernth, Executive Administrator, Board of Nursing (via phone)
Debora Stovern, Executive Administrator, Medical Board (via phone)
Sher Zinn, Records & Licensing Supervisor

Public members present:

Greg Estep, #PHAP2259, Walgreens (via phone)
Jacob Cooper, Client Relations Manager, Appriss Health
Aimee Bushnell, Office of Senator Hughes
Jeremy Brown
Sara Supe, #PHAP2258
Lis Houchen, NW Regional Director, National Association of Chain Drug Stores
Hal Geiger, Board of Veterinary Examiners, Public Member
Lori DeVito, #PHAP837, Accreditation Commission for Health Care
Marny Rivera, NPC Research, PDMP – DDPI Evaluator
Christine Michetti, #VETV483

**Agenda Item 12** **Review/Approve Agenda** **Time: 9:06 a.m.**

Chair Holm addressed the agenda for March 1st and commented that the board should re-address their position on Senate Bill 32 relating to equivalent generic drugs and interchangeable biological products, which the board had previously opposed. Chair Holm entertained a motion to add this topic to Agenda Item #13, Pharmacy Industry Updates.

**On a motion duly made by Leif Holm to add the topic of reassessing the board's position on Senate Bill 32 relating to biologics, seconded by Lana Bell, and approved unanimously, it was:**

**RESOLVED to approve the March 1, 2018 agenda as amended.**

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

No discussion.

**Agenda Item 13** **Pharmacy Industry Updates** **Time: 9:10 a.m.**

*Debora Stovern joined the room telephonically at 9:29 a.m.*
*Gail Bernth joined the room telephonically at 9:34 a.m.*
*Debora Stovern and Gail Bernth left the room at 12:57 p.m.*

Hearing nothing further on reviewing the agenda, Chair Holm prompted discussion on updates to the pharmacy industry.

Discussion of Senate Bill 32

Chair Holm commented to the board that about a year ago, the board had written a letter in opposition to SB32, which would allow substitution of biosimilar products at a pharmacy level. Chair Holm added that one of the main points against the bill was the requirement for pharmacists to report to the physician whenever a substitution was made, which seemed to place an onerous responsibility to pharmacists. After discussing with bill sponsors the implications this bill would have, the process in actually seemed relatively more similar. Chair Holm clarified that this would involve submitting a claim electronically through a pharmacy benefit manager (PBM) where it would be adjudicated. This method of reporting would effectively satisfy the pharmacist's reporting requirement because physicians have access to these adjudicated reports. Chair Holm further commented that if this bill passes, individuals would have access to these interchangeable drugs without putting an undue burden on pharmacists for providing alternative medications and reporting them. Based on this, Chair Holm recommended that the board support this bill.

Phil Sanders inquired what the impact would be on an institutional facility in tracking these substitutions in whether physicians have been informed when an interchangeable product has been provided. Rich Holm commented that as long as the information is submitted through an interoperable electronic medical record system, an electronic prescribing technology, a pharmacy benefits manager, or a pharmacy record, this reporting requirement will suffice. Chair Holm reiterated this, asserting that there would be nothing further that a pharmacist would need to do.

Lana Bell provided a response from a personal perspective, expressing her opposition to having to substitute one prescription before becoming eligible for the other, which seemed to unfairly be done in favor of insurance companies that may have a coverage preference. Ms. Bell emphasized her position as a private person, stating that her opinion isn't to dissuade the board from supporting this bill. Chair Holm stated that the drug does have to be an interchangeable biosimilar in order for a substitution to qualify, alluding to the idea that the specificity and efficacy profiles of the drugs, thereby eliminating concerns of lower quality medications.

Rich Holt reiterated language in the bill stating that the prescription may indicate to dispense as written, so if stated otherwise and if the prescriber has full confidence in allowing a substitution, this could be done, so long as the patient has the opportunity to provide consent. Mr. Holt commented that when you start a biologic there could be a chance of experiencing a different reaction, which is the risk one takes with chemical and physiological interactions. The board continued to discuss this bill and the implications it has on pharmacists.

**On a motion duly made by Leif Holm to write a letter in support of SB 32, seconded by Rich Holt, and approved unanimously, it was:**

**RESOLVED to write a letter in support of SB 32.**

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

No discussion.

Alaska Pharmacist Association Convention (Update from Rich Holt)

Rich Holt provided a summary of his presentation at the Alaska Pharmacist Association Convention that was held on February 10, 2018. Mr. Holt stated that he believed the presentation was well received and that it was overall a positive experience. Chair Holm agreed, adding that it resulted in good feedback from licensees. Ms. Bellino inquired what the feedback was on the technicians, to which Rich stated that he presented this topic last because he knew it was a hot topic; technicians expressed some concerns about liability, and Rich Holt stated to them that this would require a review of regulations to address those concerns. Rich added that he also commented to licensees the importance of participating in opportunities for public comments on regulations. Ms. Carrillo asked for clarification on the background of this issue, to which Rich stated that technicians are concerned that as the board re-evaluates technician regulations and moves to recognizing nationally certified technicians and adds more responsibilities to technicians that pharmacists otherwise may have done, this may inadvertently result in technicians not working due to potential liability issues. Phil Sanders commented that this is the trend in which the pharmacy industry is shifting to, and that Alaska should pursue this to stay on track. Rich Holt again reiterated the importance of engaging in public comment at the time these are solicited rather than providing feedback after the fact.

Controlled Substance Advisory Committee

Lana Bell provided an update from the November 14th CSAC meeting, of which she's a current member along eight other subject-matter experts. Ms. Bell added that the current chair of the committee is the attorney general, and the priority agenda item being addressed at this time is the scheduling of drugs on an emergency basis. Ms. Bell commented that because the dilemma of some drugs not currently controlled or otherwise considered illegal, such as kraytom, efforts to take street drugs off the streets are limited because these are neither state nor federally scheduled. It was added that in order to pursue emergency scheduling for regulating these drugs, it would require a legislative process. Ms. Bell's thought was that the authority for emergency scheduling of drugs might fall under the Board of Pharmacy. Ms. Carrillo commented that the bill doesn't explicitly mention AS 08.80, so resources to schedule these meetings would likely stay under the

Department of Law with the attorney general rather than transferring the duties of such scheduling under the purview of the board. Ms. Bell then stated that the committee is tracking the progress of the Office of Substance Misuse of Addiction Prevention (OSMAP), led by Andy Jones, to oversee strategic plan efforts for the opioid issue in relation to criminal justice-involved populations. Ms. Bell also informed the board that the CSAC is working with the Department of Corrections to develop treatment plans for inmates with a history of drug abuse with the ultimate goal of reducing the likelihood of recidivism and relapse upon release. With all these efforts, Ms. Bell added that OSMAP would be working to develop relevant stakeholders involved in these initiatives.

NABP Annual Meeting

The Board discussed the NABP annual meeting that will be held on from May 5 – 8, 2018 in Colorado. Chair Holm inquired as to whether the NABP would cover this cost, to which Ms. Bellino affirmed. Chair Holm and Phil Sanders indicated their interest in possibly attending. Lana expressed her positive experience in previously attending the meeting, and Donna Bellino indicated that a travel grant is available for an attendee from our state.

**TASK**

Leif Holm and Phil Sanders will provide staff with an update by mid-March as to whether they would be attending the NABP annual meeting.

Poison Prevention Packaging Act (PPPA), Investigations, and Inspections

The board reviewed documents relating to the PPPA provided by David Burns from the U.S. Consumer Protection act and how it relates to inspections. What David Burns is proposing is to reimburse the board for conducting inspections, however, the board may only be compelled to engage in an inspection if the issue relates to a federal law regarding the practice of pharmacy. After further review, Chair Holm noted that the document indicates the reimbursement inspection services would be only for in-state independent pharmacies and would not apply to an out-of-state pharmacy, and that the focus of the inspection would be on child-resistant packaging. Lana Bell commented that focusing only on this aspect of an inspection wouldn't be an efficient investment of the board's time. After the board discussed this opportunity, it was determined that there is no current need for this service. Chair Holm stated that the need is for assistance with in-state inspections, not for out-of-state inspections who are already required to submit inspection reports from their

The board also discussed the differences between investigations and inspections. It was clarified for Ms. Carrillo that the two are separate, but that latter is not regularly done even though the board has the authority to provide inspections under AS 08.80.030(b)(3) with inspectors defined under 12 AAC 52.995. Inspections have been geographically limited to the Anchorage area because of the lack of resources to send inspectors to other parts of the state.

**TASK**

Laura Carrillo will follow-up with David Burns on the board's discussion of the PPPA and reimbursement proposal.

Off record at 10:14 a.m.
On record at 10:25 a.m.

Prescription Drug Monitoring Program

Laura Carrillo provided an update on the PDMP by first providing a summary of new registration, prescription, and dispensation data. Ms. Carrillo then gave the board a summary of her PDMP presentation from the Connecting with Data 2018 Pre-Summit Conference in Anchorage on January 15th. Ms. Carrillo informed the board that the presentation included a summary of PDMP goals, a timeline of database implementation, interaction requirements, database enhancements such as prescriber report cards, and challenges such as identifying individuals who are required to register. Chair Holm inquired as to whether we know if we're at 100% registration, or in other words if we know whether all licensees required to register are in fact registered, to which Ms. Carrillo stated currently, the PDMP doesn't have a license integration feature and that CBPL doesn't track DEA registrations. This makes it difficult to capture all the currently active licensees who also hold an active DEA registration, which is the criteria used to determine whether a practitioner is required to register with the database. Jacob Cooper added that Appriss Health works with 42 other states and tracking who and who isn't required to register or review patient prescription history is a ubiquitous challenge, but this is an aspect that the board can improve on with the assistance of Appriss. Another concern was the issue of purging records, which Chair Holm stated was a finding made during the board's last legislative audit. Jacob Cooper stated the purging of records can be arranged based upon Alaska's needs and obligations. With regards to prescriber reports, Ms. Carrillo stated that secondary specialties are used as a comparison measure on prescriber reports and Jacob Cooper commented that Appriss is currently exploring a way to compare prescribing practices on the tertiary specialty level. Chair Holm then expressed concern about purging of records, which was noted as a deficit on the board's last legislative audit. Jacob affirmed that the board could work with Appriss Health to set up a purging mechanism.

Hal Geiger, public member with the Board of Veterinary Examiners commented that veterinarians face unique challenges because of their patient base and identifying them. Mr. Geiger inquired whether it was known how many veterinarians are registered and whether they're complying, to which Ms. Carrillo stated that approximately 80% of licensed veterinarians are registered, but that knowing whether they're compliant would require an audit. Christine Michetti, veterinarian, stated that the specific challenge in identifying patients is the birthdate and name. The board discussed this concern and the unique challenges the veterinarian board faces. Jacob Cooper added that AWARxE has a power algorithm to determine whether one pet is the same pet as another, and providers can also consolidate accounts when aspects of a pet's profile differs slightly, e.g.: misspellings in name or change in birth date. Ultimately, the Board of Veterinarian Examiners can establish regulations for identifying patients. Dr. Michetti expressed concern of veterinarians being disciplined for not catch pet owners who divert drugs. Chair Holm commented that at minimum, practitioners only do their due diligence to review a patient's prescription history, so if a

veterinarian isn't able to catch a pet owner who abuses their animal's prescriptions or diverts them, they are still fulfilling their obligation to review the database. Chair Holm added that as long as the veterinarian is registered and reviews as required, they shouldn't be worried of being noncompliant with the PDMP interaction requirements. The board discussed limitations of supply for veterinarians, which Ms. Carrillo stated is limited to a seven-day supply for an initial opioid prescription for animal patient. Dr. Michette stated that veterinarians sometimes prescribe more than a seven-day supply, which Chair Holm stated that this should be charted in clinic notes when a supply exceeds the initial limitation.

On PDMP data updates, Ms. Carrillo commented that since 2016, registrations have doubled and review of patient prescription history has increased substantially, with the peak coinciding with the date in which mandatory review requirements went into effect in July, 2017. Ms. Carrillo also stated that registrations appear to be going down slightly since the effective date, to which James Henderson inquired as to whether this may be due people leaving the state. Ms. Carrillo acknowledged this, stating that the data isn't population adjusted but is a good aspect to consider. It was further added that some information provided in the PDMP report is also included in and expounded upon within the 2018 legislative report.

Ms. Carrillo then moved on to forms that would be created as a result of the PDMP receiving its own program in the CBP licensing database, which is the current intent moving forward. Forms would include an initial payment form, renewal payment form, and PDMP change in status form. Ms. Carrillo stated that practitioners choose not to renew their professional license or DEA registration, their access to the PDMP should be inactivated, so the status form would prompt this account change. Similarly, delegates who are no longer employed by a certain provide should also not have access to the PDMP.

Ms. Carrillo then addressed the legislative report for the board's review and approval, which includes a summary of the database and information on the PDMP vendor and platform, Appriss Health and AWARxE, respectively. Additionally, the legislative report includes updates on the board's progress with regards to overseeing registration requirements and completing deliverables as a result of receiving federal grants, including creating an awareness survey and feedback questionnaire as a result of a receiving a Data Driven Prevention Initiative (DDPI) grant from the CDC. Marny Rivera, an evaluator contracted by DHSS was on the line to comment on the need for board member interviews in gauging progress with the PDMP and collaboration with DHSS. The board continued to review the legislative report and ultimately decided that a few topics should be added before the board approves it.

Rich turned the board's attention to data access, citing AS 17.30.200(j) indicated that the board is to notify any person whose prescription information is improperly accessed. Ms. Carrillo stated that the board has not yet done this and there is not an established standard for notifying patients. The board discussed inadvertent consequences of contacting a patient to inform them of the information that was inappropriately accessed as this could potentially be a confidentiality breach issue, or nonetheless very sensitive. The board requested a legal opinion on this statute.

**TASK**
Laura Carrillo will request a legal opinion on AS 17.30.200(j), specifically what the board is required to do and how this should be carried out.

**TASK**
Laura Carrillo will add information to the legislative report regarding mass mail-outs to unregistered licensees

**TASK**
Leif Holm will contact Marny Rivera to participate in a board member interview for the DDPI grant.

Accreditation Commission for Health Care

Lori Devito presented to the board information on ACHC's PCAB accreditation, which Ms. Devito clarified is not an inspection—that it actually exceeds qualities of inspections—and that ACHC is not a regulatory agency, but an entity that establishes standards that state regulatory agencies can choose adopt. Ms. Devito added that PCAB accreditation is a program that the commission acquired in 2014, and that results aren't sent to the board but can be if required or recommended by the board. Some states have required PCAB accreditation, such as Michigan, but ACHC ultimately encourages this accreditation as a standard for compounding pharmacies rather than encourages that this standard be put in statute or regulation. Ms. Devito further added that a big focus on ACHC is quality control and that they provide workshops for pharmacists. Ms. Devito summarized the PCABP process and stated the cost is approximately $8,500, which is incurred by individual pharmacies, not by the state. Chair Holm commented that this is a top notch company, and encouraged the board to support ACHC PCAB as a compounding pharmacy standard. Rich Holt commented that inspections from out-of-state pharmacies are only required to submit inspections from their home jurisdiction that was completed within the two years preceding their application, alluding to the need to clarify whether this standard could be implemented even for out-of-state pharmacies.

Chair Holm called for break.

*Off record at 12:05 p.m.*
*On record at 12:13 p.m.*

Appriss Health

Jacob Cooper introduced himself as the client relations manager for Alaska, informing the board that Appriss started in Alaska back in 1999 with a victim notification program partnership with the Alaska Department of Corrections. Chair Holm inquired about this program, and Jacob Cooper stated that this is the first program in which Appriss began working with sensitive data; the victim notification program sends updates to victims when their perpetrator is released from jail, goes on probation, or are otherwise recorded by the criminal justice system as having a new action. Jacob cooper then moved on to the PDMP program in Alaska, including updates on PMP InterConnect,

PDMP milestones, registration growth and interaction statistics—pointing out that activity tends to dip in December during the holidays, relevant statute changes, clinical alerts, EHR integration, and NarxCare. Chair Holm inquired about sharing PDMP data with other states through PMP InterConnect, to which Ms. Carrillo stated that the data sharing is done only after a memorandum of understanding (MOU) is signed. Ms. Carrillo stated that an MOU was signed in 2015, and Tammy Lindemuth inquired as to what states we are currently sharing with. Alaska shares data with seven other states, however, Chair Holm expressed concern about this since Alaska is a private state and that patients may not know that their information can be accessed from other states. Jacob Cooper clarified that Alaska patient information can't be exported from the PDMP into another state's database, but that PMP InterConnect essentially creates a secure channel for other states to simply view the data. Chair Holm emphasized the need to address this at the division level and to explain this access in the legislative report.

The board was also particularly interested in looking further into the NarxCare program. Narxcare is a holistic substance misuse platform that helps practitioners interpret data in a meaningful and fast way by providing a report at the treatment setting (Figure 1). A NarxCare report shows risk scores for narcotics, stimulants, and sedatives, overall improving saliency of red flags. Jacob Cooper commented that what Appriss has observed is that a lot of overdoses don't have prescriptions at the time of overdose; they get the prescription, then get a hold of street drugs, then have an overdose after their prescription is no longer active. An additional function of NarxCare is to prompt practitioners to recommend treatment facilities, so Appriss is currently working with Medicaid assisted treatment centers. Lana Bell inquired as to what the cost of the program is, to which Jacob Cooper clarified that it depends on the number of licensees a state has.

**TASK**

Laura Carrillo will look further into PMP InterConnect and will include a section of this in the legislative report.

**TASK**

Laura Carrillo will look into the cost of NarxCare as an enhancement to the PDMP.

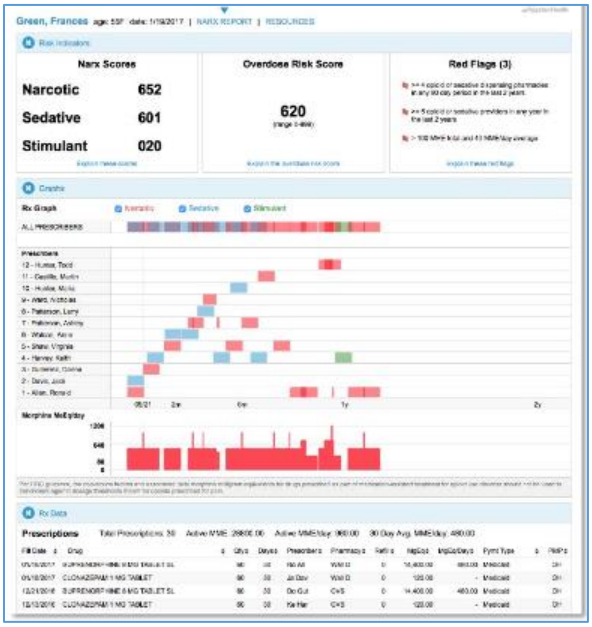



*Figure 1. NarxCare report*

**Agenda Item 14** **Recess** **Time: 12:57 p.m.**

After the PDMP update, Phil Sanders and Chair Holm called for recess at 12:57 p.m.

**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
**February 28 – March 2, 2018**

**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 February 28 – March 2, 2018.**

**These are draft minutes that have not yet been approved by the board.**

**Agenda Item 1** **Call to Order/Roll Call** **Time: 8:58 a.m.**

The **March 2, 2018** meeting day was called to order by Chair, Leif Holm at 8:58 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
Tammy Lindemuth, Public Member
Sharon Long, Public Member (effective 03/01/2018; via phone)

Division staff present:

Donna Bellino, Occupational Licensing Examiner
Laura Carrillo, Records & Licensing Supervisor
Jun Maiquis, Regulations Specialist

Public members present:

Greg Estep, #PHAP2259, Walgreens (via phone)
Dirk White

**Agenda Item 14** **Review/Approve Agenda** **Time: 9:06 a.m.**

Chair Holm addressed the agenda for March 2nd and commented that the board should establish the board's new secretary.

**On a motion duly made by Lana Bell to add voting of a board secretary to the agenda, seconded by Rich Holt, and approved unanimously, it was:**

**RESOLVED to approve the March 2, 2018 agenda as amended.**

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

No discussion.

**Agenda Item 15** **Board Business** **Time: 9:06 a.m.**

*Dirk White joined the room at 9:28 a.m.*
*Dirk White left the room at 10:12 a.m.*

*Anne Gruening joined the room at 10:00 a.m.*
*Anne Gruening left the room at 10:23 a.m.*

Board Positions
The board moved to voting on a board secretary.

**On a motion duly made by Lana Bell to vote Tammy Lindemuth as the board secretary, seconded by Rich Holt, and approved unanimously, it was:**

**RESOLVED to elect Tammy Lindemuth as the board secretary effective 03/02/2018.**

| | APPROVE | DENY | ABSTAIN | ABSENT |
|---|---|---|---|---|
| Leif Holm | x | | | |

| | |
|---|---|
| Richard Holt | x |
| Phil Sanders | x |
| James Henderson | x |
| Anne Gruening | x |
| Lana Bell | x |
| Tammy Lindemuth | x |
| Sharon Long | x |

No discussion.

Legislative Report

Sharon Long inquired as to whether the board would be reviewing and approving the legislative report that was drafted by Ms. Carrillo, to which Chair Holm commented that in the interest of time, the board would be reviewing and approving via an email ballot.

Board Contacts

Leif Holm and Rich Holt will continue to serve as legislative contacts on behalf of the board.

Review Legislation

Chair Holm then prompted the board to discuss the various pieces of legislation that the board is affected by, as well as legislation that the board is tracking as FYI bills.

- HB9/SB37: Pharma BD & Employees; Drug Dist/Manu
  - Licensing of out of state wholesale distributors and providing for an executive administrators
  - Already passed the Senate, needs hearing in House Finance
  - Would require substantial regulations
- HB43: New Drugs for the Terminally Ill
  - Passed House unanimously
  - FYI
- HB90: Occ. Licensing Fees; Investigation Costs
  - Withdrawn effective 02/23/2018
- HB262: Military Spouse Courtesy License
  - DCCED would have to report licenses to join committee each year
  - Submit report to legislature
  - Must provide a temporary license
- SB32: Prescriptions for Biological Products
  - Board changed position in support of bill
  - Would require regulations
- SB79: Opioids; Prescriptions; Database; Licenses
  - Removes, "cannot be shared with federal government"

- Similar to HB 159 language
- SB112: Workers Compensation; Drug Database
  - Intent is to get folks back to work and reduce dependency on opioids
  - Is a priority of the Alaska Chamber of Commerce
  - Reduce unproductive litigation; attempts to shift time and money from workers comp board and onto effective and impartial administrative procedures
- SB146: AG Schedule Controlled Substances
  - Changes chair of CSAC from attorney general to president of Board of Pharmacy or president's delegate
  - Participate in emergency scheduling of drugs
- HB326/SB120: Naturopaths; Licensing; Practice
  - Would give prescriptive authority to naturopaths
  - FYI
- SB209: Prescription Drug Pricing
  - Scheduled for hearing on March 7th, 2018
  - Already in practice that pharmacists disclose and document price for out-of-pocket and retail

*Off record at 10:13 a.m.*
*On record at 10:27 a.m.*

**Agenda Item 6** **Public Comment** **Time: 10:27 a.m.**

*Jun Maiquis entered the room at 10:58 a.m.*
*Jun Maiquis left the room at 11:03 a.m.*

The board returned to reviewing public comments, which was first addressed on day 1 of the meeting. Having already reviewed public comments relating to PDMP use and access. As well as comments relating to the PDMP fees, Chair Holm prompted the board to address the public comments that ended on February 26, 2018, including:

- 12 AAC 52.120 - Review of pharmacist intern license application, is proposed to be changed to amend the checklist requirements for pharmacist intern license application.
- 12 AAC 52.130 - Registration of pharmacies located outside of the state, is proposed to be changed to clarify the provisions related to applications for registration of pharmacies located outside of this state.
- 12 AAC 52.200 - Pharmacist-in-charge, is proposed to be changed to amend the requirements for a pharmacist designated to replace the pharmacist-in-charge of a pharmacy.
- 12 AAC 52.240 - Pharmacist collaborative practice authority, is proposed to be changed to amend the pharmacist collaborative practice authority requirements.
- 12 AAC 52.470 - Refills, is proposed to be changed to amend the provisions related to
- prescription drug order refills.

- 12 AAC 52.510 - Substitution, is proposed to be changed to clarify the provisions related to notes or wording on the prescription drug order.
- 12 AAC 52.610 - Wholesale drug distributor license, is proposed to be changed to amend the provisions related to a change in facility manager.
- 12 AAC 52.991 - Disciplinary decision or conviction reporting requirement, is proposed to be changed to add the requirement that a licensed or registered facility report in writing to the board any disciplinary decision or conviction

James Henderson addressed the proposed changes 12 AAC 52.470 pertaining to refills, inquiring what the rational for the 30 days was, to which Chair Holm stated that the intent was to see whether a patient does well with this day supply before providing for a longer supply. Phil Sanders pointed to a study included along with one of the comments, stating that patients with 90-day refills had greater medication adherence, greater persistency, normal wasteage, and greater savings. Rich indicated that it is a restriction, so it might be reasonable to expand to 90 days. The board deliberated on whether to extend to 90 days or to 100 days.

The board then discussed proposed changes to 12 AAC 52.120, which would require a pharmacy intern to submit a certificate of moral character from two reputable citizens. Some comments on this proposed regulation included concern that this requirement would add to the already delayed processing of inter applications. Ms. Bellino commented that with the addition of the jurisprudence questionnaire, the processing time can now be more efficient as this eliminates waiting time; prior to the board's resolution at the November - December 2017 meeting to include the jurisprudence questionnaire, the questionnaire was to applicants after their documents were received. Lana Bell stated that currently, intern licenses aren't issued until one month before their rotation is supposed to start, to which Ms. Bellino stated this is the timeline that has always been in place. Ms. Carrillo inquired as to whether this requirement is in regulation or an established preference by the board. Rich Holt and Ms. Bellino stated that this has been the typical process, but Ms. Carrillo suggested that the licenses be issued upon completion rather than waiting until a month before a rotation begins. Chair Holm prompted the discussion to focus back on the public comment concern of processing time. Ms. Bellino stated that the certificates of moral character could be included in the application itself, so it wouldn't really add to the processing delay.

**TASK**
Ms. Carrillo will discuss with the other Records & Licensing Supervisor who supervises pharmacist interns and technicians the idea of issuing intern licenses upon application completion rather than one month prior to the intern's rotation.

After reviewing public comments to the proposed regulations, Chair Holm called for motions.

**On a motion duly made by Rich Holt that in light of public comment, to accept regulations 12 AAC 52.120 (pharmacy intern application), 12 AAC 52.130 (review of applications of pharmacies located outside of the state), 12 AAC 52.200 (pharmacists-in-charge), 12 AAC 52.240 (pharmacists collaborative practice authority), 12 AAC 52.510**

**(substitution), 12 AAC 52.610 (wholesale drug distributor), 12 AAC 52.991 (disciplinary decision or conviction reporting); amend 12 AAC 52.470(d) to state: "If an original prescription drug order is prescribed as a 30-day supply, the pharmacist may dispense up to a 100-day supply on refills provided that the"; strike 90-day to 100-day, strike (1) patient has completed and initial 30-day supply of the drug". Seconded by Tammy Lindemuth, and approved unanimously, it was:**

**RESOLVED to accept proposed regulations 12 AAC 52.120, 12 AAC 52.130, 12 AAC 52.200, 12 AAC 52.240, 12 AAC 52.510, 12 AAC 52.610, and 12 AAC 52.991 as written, and to accept 12 AAC 52.470(d) as amended.**

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

No further discussion.

**On a motion duly made by Rich Holt that in light of public comment to accept 12 AAC 52.855 with amending section (e) to read "a pharmacist or practitioner required to register with the PDMP may access information in the PDMP using another registrants credentials only as authorized by a contract executed by the department for the purposes of" and replace existing statute AS 47.07.038 to read AS 47.05.270, and to accept 12 AAC 52.860, 12 AAC 52.865, 12 AAC 52.870, 12 AAC 52.880, 12 AAC 52. 885, 12 AAC 52.890, 12 AAC 52.920, and 12 AAC 52.995 as written, seconded by Tammy Lindemuth, and approved unanimously, it was:**

**RESOLVED to accept the proposed change to 12 AAC 52.855(e) as amended and to accept 12 AAC 52.860, 12 AAC 52.865, 12 AAC 52.870, 12 AAC 52.880, 12 AAC 52.885, 12 AAC 52.890, 12 AAC 52.920, and 12 AAC 52.995 as written.**

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

| | |
|---|---|
| Anne Gruening | x |
| Lana Bell | x |
| Tammy Lindemuth | x |
| Sharon Long | x |

No further discussion.

Jun Maiquis entered the room at 10:58 a.m. Leif inquired whether new public comment is needed if a change is being made based on the comments, to which Jun Maiquis indicated that another round for public comment as long as the intent of the proposed changes don't change. Mr. Maiquis affirmed that this is correct, and that the Department of Law will determine whether the intent changed as a result of amendments made after consideration of public comment.

**TASK**
Ms. Carrillo will forward the board's resolutions to the proposed regulation changes to the regulations specialist for implementation.

**Agenda Item 9** **Board Business** **Time: 11:44 a.m.**

The board resumed board business.

Annual Report
Rich Holt, Laura Carrillo, and Donna Bellino will collaborate to work on the annual report due June 1st.

Wall Certificates
Chair Holm signed wall certificates.

Upcoming Travel
The board addressed travel opportunities, including the NABP Annual Meeting that will be held in May in Colorado. Leif Holm and Phil Sanders reiterated that they would inform the staff whether they could attend in by mid-March. A conference in Atlanta titled, The National Rx Abuse and Heroin Summit was also brought to the board's attention, and Lana Bell expressed her interest in attending on behalf of the board and for her role as a Pharmacy Board designee on the Controlled Substance Advisory Committee. Chair Holm inquired as to how attendance would be of benefit, to which Lana stated that some of the topics discussed during CSACs include complex issues that Ms. Bell would be able to discuss at a more involved level if she had a better understanding of opioid issues. Ms. Bell believes that attendance at this conference would enable more active participation and contribution to the committee.

**TASK**
Ms. Carrillo will submit a travel approval request for Lana Bell to attend the National Rx Drug Abuse and Heroin Summit from April 2 – 5, 2018 in Atlanta, GA

Reschedule May Meeting

Due to time conflicts with board member and Ms. Carrillo's schedules, the board rescheduled their next meeting to be held on May 10th all day and May 11th half day.

Correspondence

The board received a piece of correspondence from a physician who expressed concerns about the DEA registration number being conspicuously displayed on the prescriber report. The board discussed possibilities of altering the format and available information on the prescriber report, however, it was noted that this particular concern on this matter has been the only one brought forward for their attention thus far. In addition, the board acknowledged that DEA numbers are included on prescriptions, and that including this number is not a violation of HIPAA. Since there doesn't appear to be more widespread concern of DEA confidentiality, there didn't appear to be sufficient justification for requesting a change order from Appriss Health. The board still encouraged staff to find out the cost of this, which was alluded to earlier by Jacob Cooper as being a fairly expensive change.

**TASK**

Ms. Carrillo will inquire about the cost of obscuring DEA registration numbers on the prescriber report.

In the interest of time, the board entertained a motion to table outstanding topics that were scheduled for discussion under Old Business.

**On a motion duly made by Leif Holm to table pharmaceutical waste and disposal, compounding regulations, proof of satisfactory documentation form draft, and the IHS pharmacist form draft until the next meeting, seconded by Phil Sanders, and approved unanimously, it was:**

**RESOLVED to table the topics listed under Old Business for discussion at the May 10 – 11, 2018 meeting.**

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

No further discussion.

**Agenda Item 16** **Adjourn** **Time: 11:30 a.m.**

Hearing nothing further, Chair Holm entertained a motion to adjourn.

**On a motion duly made by Tammy Lindemuth to adjourn the meeting, seconded by Lana Bell, and approved unanimously, it was:**

**RESOLVED to adjourn the meeting at 11:30 a.m.**

_____

Laura Carrillo, Records & Licensing Supervisor

_____

Rich Holt, Chair

**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
## March 22, 2018 Teleconference

**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 teleconference at the State Office Building, Conference Room B in Juneau, Alaska on March 22, 2018.**

**These are draft minutes that have not yet been approved by the board.**

**Agenda Item 1** **Call to Order/Roll Call** **Time: 10:31 a.m.**

The **March 22, 2018** meeting day was called to order by Chair, Rich Holt at 10:31 a.m.

Board members present, constituting a quorum:

Richard Holt, PharmD #PHAP2008, MBA – *Chair*
Leif Holm, PharmD #PHAP1606
Phil Sanders, RPh #PHAP776
James Henderson, RPh #PHAP1683
Lana Bell, RPh #PHAP893
Sharon Long, Public Member

Division staff present:

Donna Bellino, Occupational Licensing Examiner
Laura Carrillo, Records & Licensing Supervisor
Marilyn Zimmerman, Paralegal

**Agenda Item 2** **Review/Approve Agenda** **Time: 10:33 a.m.**

The board reviewed the agenda, which reflects three main topics for discussion: a consent agreement, default revocations, and reviewing the letter of support for SB32.

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

**RESOLVED to accept the March 22, 2018 agenda as written.**

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

The motion passed with no further discussion.

**Agenda Item 3** **Board Business** **Time: 10:36 a.m.**

The board then moved on to addressing the consent agreement and default revocations. Ms. Carrillo informed the board that the individual for which the consent agreement pertains to had explicitly requested a private discussion.

**On a motion duly made by Lana Bell and seconded by James Henderson 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, Laura Carrillo, and Marilyn Zimmerman were authorized to remain in the room.

*Off record for executive session at 10:39 a.m.*
*On record for public discussion at 10:51 a.m.*

Upon return from executive session, Chair Holt clarified for the record that no motions were made under executive session and that division staff remained in the room.

**On a motion duly made by Lana Bell to accept the consent agreement for Walter Ibardo as presented during executive session under Case No. 2018-000160, seconded by James Henderson, and approved unanimously, it was:**

**RESOLVED to approve the consent agreement for Walter Ibardo, Case No. 2018 000160.**

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

The motion passed with no further discussion.

Chair Holt then moved to approving the default revocations that the board had previously been reviewed during their February 28 – March 2, 2018 board meeting.

**On a motion duly made by Lana Bell to accept the default revocations for Candice Aguilar, seconded by Rich Holt, and approved unanimously, it was:**

**RESOLVED to accept the default revocations for Candice Aguilar based upon failure to respond to the random continuing education audit for the 2016 renewal cycle as required under 12AAC 02.960(e) and 12 AAC 52.350 (audit of records by the board). In accordance with 12 AAC 02.960(i), failure to comply with continuing education audit requirements authorizes the consideration of grounds for imposition of a disciplinary sanction, and AS 08.80.261(6) further authorizes the board to impose a disciplinary action for failure to comply with any provision in AS 08.80 or 12 AAC 52.**

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

The motion passed with no further discussion.

**On a motion duly made by Lana Bell to accept the default revocations for Sheila Epling, seconded by Rich Holt, and approved unanimously, it was:**

**RESOLVED to accept the default revocations for Sheila Epling based upon failure to respond to the random continuing education audit for the 2016 renewal cycle as required under 12AAC 02.960(e) and 12 AAC 52.350 (audit of records by the board). In**

**accordance with 12 AAC 02.960(i), failure to comply with continuing education audit requirements authorizes the consideration of grounds for imposition of a disciplinary sanction, and AS 08.80.261(6) further authorizes the board to impose a disciplinary action for failure to comply with any provision in AS 08.80 or 12 AAC 52.**

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

The motion passed with no further discussion.

**On a motion duly made by Lana Bell to accept the default revocations for Jamie Bell, seconded by Rich Holt, and approved unanimously, it was:**

**RESOLVED to accept the default revocations for Jamie Bell based upon failure to respond to the random continuing education audit for the 2016 renewal cycle as required under 12AAC 02.960(e) and 12 AAC 52.350 (audit of records by the board). In accordance with 12 AAC 02.960(i), failure to comply with continuing education audit requirements authorizes the consideration of grounds for imposition of a disciplinary sanction, and AS 08.80.261(6) further authorizes the board to impose a disciplinary action for failure to comply with any provision in AS 08.80 or 12 AAC 52.**

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

The motion passed with no further discussion.

**On a motion duly made by Lana Bell to accept the default revocations for Terry Morris, seconded by Rich Holt, and approved unanimously, it was:**

**RESOLVED to accept the default revocations for Terry Morris based upon**

**failure to respond to the random continuing education audit for the 2016 renewal cycle as required under 12AAC 02.960(e) and 12 AAC 52.350 (audit of records by the board). In accordance with 12 AAC 02.960(i), failure to comply with continuing education audit requirements authorizes the consideration of grounds for imposition of a disciplinary sanction, and AS 08.80.261(6) further authorizes the board to impose a disciplinary action for failure to comply with any provision in AS 08.80 or 12 AAC 52.**

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

The motion passed with no further discussion.

**On a motion duly made by Lana Bell to accept the default revocations for Karlee Sturdevant, seconded by Rich Holt, and approved unanimously, it was:**

**RESOLVED to accept the default revocations for Karlee Sturdevant based upon failure to respond to the random continuing education audit for the 2016 renewal cycle as required under 12AAC 02.960(e) and 12 AAC 52.350 (audit of records by the board). In accordance with 12 AAC 02.960(i), failure to comply with continuing education audit requirements authorizes the consideration of grounds for imposition of a disciplinary sanction, and AS 08.80.261(6) further authorizes the board to impose a disciplinary action for failure to comply with any provision in AS 08.80 or 12 AAC 52.**

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

The motion passed with no further discussion.

**Agenda Item 4** **Review/Approve SB32 Support Letter** **Time: 11:02 a.m.**

Hearing nothing further on consent agreements or default revocations, Chair Holt moved to review and approval of Senate Bill 32 relating to biologics. The board had previously discussed this bill and their position to support the bill at their February 28 – March 2, 2018 meeting. The board voted via the online board meeting platform, OnBoard. For the record, a roll call vote was conducted to capture responses (Figure 1).

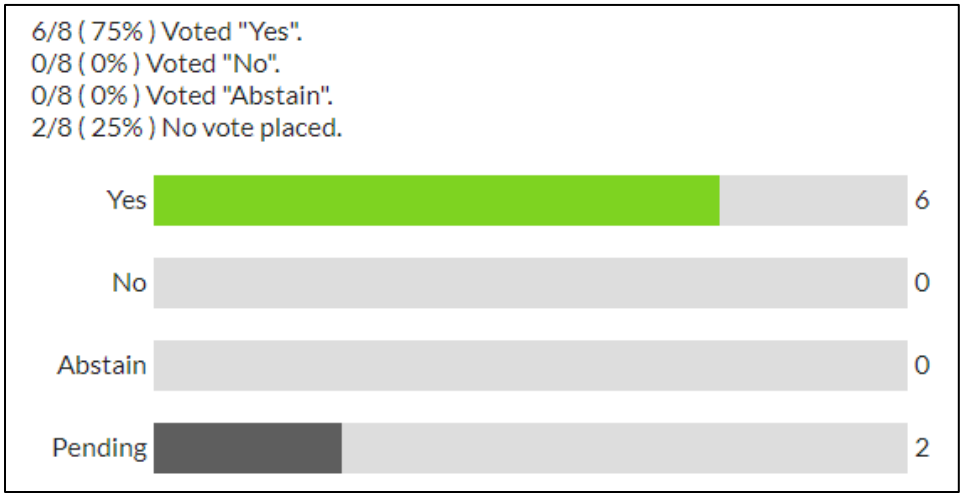



*Figure 1. 100% of board members present voted in support of SB32. The two (2) pending votes were for admins, Laura Carrillo and Donna Bellino.*

*Lana Bell left the room via teleconference at 11:06 a.m.*
*Lana Bell returned to the room via teleconference at 11:06 a.m.*

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

**TASK:**
Laura Carrillo will forward the letter of support to the division's legislative liaison for distribution to the office of Senator Hughes.

**Agenda Item 5** **Adjourn** **Time: 11:21 a.m.**

On a motion duly made by Phil Sanders, seconded by Lana Bell the board adjourned at 11:21 a.m.

**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
## May 10, 2018 Teleconference via OnBoard

**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 teleconference at the State Office Building, Conference Room A in Juneau, Alaska on May 10th, 2018.**

**These are draft minutes that have not yet been approved by the board.**

**Agenda Item 1** **Call to Order/Roll Call** **Time: 9:26 a.m.**

The **May 10, 2018** meeting day was called to order by Chair, Rich Holt at 9:26 a.m.

Board members present, constituting a quorum:

Richard Holt, PharmD #PHAP2008, MBA – *Chair*
Leif Holm, PharmD #PHAP1606
Phil Sanders, RPh #PHAP776
James Henderson, RPh #PHAP1683
Lana Bell, RPh #PHAP893 (Absent)
Tammy Lindemuth, Public Member
Sharon Long, Public Member (Absent)

Division staff present:

Donna Bellino, Occupational Licensing Examiner
Deborah Roesch, Occupational Licensing Examiner
Laura Carrillo, Records & Licensing Supervisor
Brian Howes, Investigator
Marilyn Zimmerman, Paralegal
Melissa Dumas, Administrative Officer
Marylene Wales, Accountant

**Agenda Item 2** **Review/Approve Agenda** **Time: 9:27 a.m.**

The board reviewed the agenda.

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

**RESOLVED to accept the May 10, 2018 agenda as written.**

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

The motion passed with no further discussion.

**Agenda Item 3** **Ethics** **Time: 9:29 a.m.**

The board then moved on to addressing ethics, however, there were no ethics disclosures to report.

**Agenda Item 4** **PDMP Update** **Time: 9:29 a.m.**

PDMP Reports

Hearing nothing further on ethics disclosures, Laura Carrillo addressed the Board of Pharmacy report for the PDMP update. Ms. Carrillo informed the board that new board quarterly reports for all PDMP affected boards would be created on a quarterly basis. For the Board of Pharmacy, there were 1,053 currently registered pharmacists and 42 pharmacy technician delegates, with registration compliance at 93%; the highest compliance rate among all PDMP boards. Ms. Carrillo then pointed to another figure on the report, which showed the opioid volume by pharmacies. To note was that Veteran Affairs pharmacies dispensed the most days-supply of opioids relative to the top two other pharmacies at 2,812,597 days-supply. Next, Ms. Carrillo pointed to a figure showing the number of opioid dispensations relative to the number of patient history requests, which seemed to show an inverse relationship. The last figure on the report represented the number of PDMP users, which peaked at 1,539 newly registered users in July 2017, the month that mandatory registration went into effect. Ms. Carrillo then briefly reviewed the Board of Veterinary Examiners PDMP report, informing the board she would be presenting this at the VET board meeting the next day.

Ms. Carrillo then informed the board that a press release was issued earlier in the month detailing that opioid prescriptions decreased by nearly 13% from 2016 to 2017.

Enhancement Features

Ms. Carrillo then addressed enhancement features, including Clinical Alerts and NarxCare. Both enhancement features were previously reviewed by the board during their February – March 2018 meeting. Clinical Alerts is an automated alert feature that sends direct messages to prescribers when a patient has met or exceeded the threshold of five (5) prescribers and five (5) pharmacies over a three (3) month period. NarxCare is a feature that provides visual snap shots of risk-scores related to opioid addiction, abuse, and overdose. Chair Holt commented that some pharmacies are already integrating this feature into their business practices. Ultimately, the consensus was not to move forward with providing NarxCare as an enhancement feature. Chair Holt then inquired as to where the 5, 5, 3 threshold came from, to which Donna Bellino indicated was recommended to the board in 2014 and discussed at one of their regularly scheduled board meetings. Ms. Carrillo added that it may have been a recommended threshold based on other states with a similar population size of prescribers and patients.

**TASK:**

Donna Bellino will look for the minutes pertaining to the 5, 5, 3 threshold for the board to assess the context of how this threshold level was determined.

Chair Holt further inquired about whether practitioners and pharmacists would receive the alerts or if the direct alert would just be pushed to the practitioner. Also of interest was whether the alert would be sent to all practitioners who have a treating relationship with the patient or only the practitioner who prescribed a medication that made the patient meet or exceed the threshold.

**TASK:**

Ms. Carrillo will inquire with Appriss Health as to who would receive the clinical alerts.

Ms. Carrillo stated that the Clinical Alerts feature would be covered by grant funds obtained by the Alaska Department of Health and Social Services, to which Tammy Lindemuth inquired as to where subsequent funds would come from. Ms. Carrillo speculated that funds would continue to come from grant funding, however, PDMP fees may help to pay for the feature as well. Leif Holm expressed concern about alert fatigue, stating that it can be overwhelming to receive numerous notices on a daily basis, and that practitioners should already be aware of whether a patient might be exceeding threshold levels since mandatory reviewing is already in effect. Ms. Carrillo agreed, stating that PDMP administrators in other states expressed similar concerns with regards to alert fatigue, however, Ms. Carrillo encouraged the board to continue looking into obtaining this feature.

Awareness and Feedback Questionnaire

Ms. Carrillo then addressed the PDMP Awareness and Feedback Questionnaire, which is a CDC-DDPI grant deliverable activity required as a condition of receiving federal funding. The board was informed that the questionnaire would be posted on May 15th and would be open for two weeks. Tammy Lindemuth inquired as to who would evaluate the results and also expressed concern that two weeks wasn't long enough to thoroughly collect responses. Ms. Carrillo

responded that external evaluators hired by DHSS could analyze the results. Ultimately, it was decided that the questionnaire would remain open for 4 weeks.

PDMP Education and Outreach

An education and outreach survey was sent out to 188 practitioners and pharmacists in Juneau at the end of March 27, 2018 soliciting participation in PDMP-related training. Ms. Carrillo let the board know that she has since participated in about half a dozen sessions, which include topics such as mandatory reporting and reviewing requirements, PDMP state website resources, PDMP legislative reports, and profession-specific high-level data.

PDMP Renewal and Forms

The board was then informed of the upcoming PDMP renewal, which will coincide with each licensing program's renewal date. Since the Board of Pharmacy is renewing at the end of June, its licensees will be the first to undergo the PDMP renewal process, for which there is a $25.00 fee and separate renewal form. Ms. Carrillo presented to the board the other forms that were developed for the PDMP, including a DEA registration status and an initial registration form. Chair Holt noticed a typo on the DEA registration status form, 08-4763.

**TASK:**

MS. Carrillo will correct the typo on the DEA Registration Status form #08-4763.

**Agenda Item 5** **Pharmacy Industry Updates** **Time: 10:32 a.m.**

FDA Continuing Education – Drug Supply Chair Security Act (DSCSA)

Chair Holt indicated to the board that he attended this CE opportunity and directed the board to the DSCSA presentation slides that were included in the board packet. The slides covered an overview of the DSCSA, DSCSA goals, trading partners, products, transactions, reporting, packaging, and product tracing documentation. Chair Holt commented that overall, the presentation was insightful, but that he wished they had expounded more upon wholesale drug distributors and 503(b)s.

PDMP Conference/Meeting Updates – Nation Rx Drug Abuse and Heroin Summit

After attending the summit in Atlanta, Lana Bell and Ms. Carrillo prepared summaries of their experience there. Though Ms. Lana Bell was not able to attend this board meeting, included in the board packet was her overview of the conference reflecting a number of tracks she participated in, including pharmacy, treatment, and law enforcement sessions. To note was that Ms. Bell was impressed at federal, state, and local coordination efforts to respond to the opioid problem. Ms. Bell reiterated the importance of shifting away from the negative stigma surrounding drug addiction, reported on the focus of treatment resources for pregnant women, and shared the need for increased accessibility to medication assisted therapy (MAT) and naloxone resources. Ms. Carrillo also shared her summary on her experience attending the conference, which mainly included participation in PDMP-specific sessions. Topics included Washington's opioid response plan, prescriber report format, public dashboard, and provisions allowing the issuance of facility or

group prescriber reports. The latter allows the chief medical officer of a facility to view prescribing metrics of employees, which is mainly used for quality improvement and to drive adoption of prescribing guidelines. In comparison, Alaska does not allow direct issuance of prescriber reports to practitioners other than to those for whom the prescriber report is concerning. Ms. Carrillo also discussed Wisconsin and Rhode Island's PDMP programs as well as states implementing e-prescribing laws to reduce fraudulent prescriptions.

PDMP Conference/Meeting Updates – BJA West Regional Meeting

Ms. Carrillo attended the BJA grantee meeting in Albuquerque, where other state PDMP administrators convened to discuss a number of topics, including prescriber report cards, e-prescribing to reduce prescription errors, challenges for veterinarians, gateway integration, pre-criminal intervention programs for doctor shoppers, interstate data-sharing, prescriptive guidelines, and PDMP fees.

**Agenda Item 6 Investigative Report Time: 10:50 a.m.**

*Brian Howes joined the room telephonically at 10:49 a.m.*

Investigator, Brian Howes joined the room to present to the board the investigative report, which included activity from February 7th to May 7th, 2018. Mr. Howes informed the board that eight (8) matters had opened, eleven (11) had closed, and that three (3) matters were ongoing.

Case #2017-000557 (license surrender)

Mr. Howes also informed the board of a fraud case that led to the licensee's voluntary surrender of his license, which prompted the board to make a motion.

**On a motion duly made by Rich Holt and with unanimous approval to accept the voluntary surrender of Alaska Pharmacist License #PHAP2124, case #2017-000557 pursuant to AS 08.01.075, AS 08.80.261(a)(2), (a)(9), (a)(11), (a)(14), and 12 AAC 52.920(a)(4)(10), it was:**

**RESOLVED to accept the voluntary license surrender of license # PHAP2124 by Joshua Fillible.**

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

The motion passed.

*Brian Howes left the room telephonically at 11:00 a.m.*

**TASK:**
Chair Holt will sign the voluntary surrender document and return it to the department.

**Agenda Item 7** **Board Business** **Time: 11:00 a.m.**

Before addressing board business, Ms. Carrillo introduced licensing examiner, Deborah Roesch, who recently transitioned to assisting with administrative duties for the Board of Pharmacy. Ms. Roesch is specifically handling pharmacy technician and intern initial and renewal applications.

Annual Report
Chair Holt moved to discussing the annual report, which he reminded the board is due on an annual basis by June 1st. Chair Holt presented his draft to the board for review. Tammy Lindemuth commented on two typos, which Ms. Carrillo noted to be corrected. Leif also commented that his duty station needed to be corrected to North Pole.

**TASK:**
Ms. Carrillo will correct the last name typo, will capitalize the 'a' in Anchorage before forwarding the annual report to the publications specialist, and will update Leif Holm's duty station from Fairbanks to North Pole.

**On a motion duly made by Tammy Lindemuth and seconded by Phil Sanders, it was:**

**RESOLVED to accept the 2018 Annual Report as amended.**

Review Applications
Hearing nothing further on the annual report, Chair Holt addressed the continuing education audit of Rex Malcom, who requested the board to consider accepting college credit to meet CE requirements. Ms. Carrillo commented that 12 AAC 52.340(a) would allow licensees to apply college credit to CE requirements in lieu of other approved programs under 12 AAC 52.340, and Phil Sanders added that this would potentially be the case if the program was specifically accredited by the ACPE and is assigned an ACPE course number. The board discussed this college credit and found no indication that the courses have been accredited by the ACPE.

*Leif Holm left the room telephonically at 11:30 a.m.*

**On a motion duly made by Rich Holt and seconded by James Henderson to accept the college education classes by Rex Malcom, PHAP1523 as evidence of satisfactory completion of required continuing education under AS 08.80.165, 12 AAC 52.320, 12 AAC 52.340, and 12 AAC 52.350, it was:**

**RESOLVED to reject the request by Rex Malcom to apply college education courses to the credit hours required for the 2016 – 2018 renewal cycle.**

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

The motion did not pass.

The board then moved on to discussing the continuing education audit of Jessica LaTourelle, who requested that the board consider accepting 15 hours of participation in an ACLS/PALS course to satisfy the required 30 hours for license renewal. Pointing to 12 AAC 52.340(1), Rich reiterated that any program accredited by the ACPE should be considered acceptable but that the course should also indicate an ACPE-assigned course number. Phil Sanders stated that there needs to be clarification as to what specifically is being accredited; the American Heart Association (AHA) or the courses themselves. The board continued to discuss this and requested the presence of paralegal, Marilyn Zimmerman, as the board didn't immediate have access to the certificates of completion indicating how many hours were included and whether they were accredited by the ACPE or AHA.

*Marilyn Zimmerman joined the room at 12:06 p.m.*

Ms. Zimmerman joined the room and provided board staff with the certificates of completion submitted by Ms. LaTourelle, which specified that the ACLS/PALS course was approved under the AHA but was provided by the Alaska Learning Institute and presented by LifeTek, neither of which are currently ACPE accredited. Ms. Zimmerman pointed out that LifeTek is listed as an approved presenter by the AHA, meaning the AHA has authorized them to present courses on their behalf. Ms. Zimmerman added that if the board were to deny this request, the Office of Administrative Hearings (OAH) may find that AHA's authorization of LifeTek to present the course is a valid basis for accepting the credit under current board regulations. Chair Holt stated that the regulations should be amended to accommodate situations in which the AHA authorizes providers to present courses on their behalf.

**TASK:**
Ms. Carrillo will add to the board's agenda for the next meeting the regulation topic of adding language to accommodate authorized presenters of approved providers.

Phil Sanders prompted the board for clarification on whether the 1 credit hour required for CPR will be accepted and if the 15 hours will be accepted as an AHA presented course. Ms. Carrillo

clarified that the 15 will cover the 1 hour for CPR and the remaining 14 hours would satisfy the remaining credits.

**On a motion duly made by Rich Holt and seconded by James Henderson to accept the ACLS/PALS course totaling 15 hours towards Jessica LaTourelle's continuing education requirements under AS 08.80.165, 12 AAC 52.320, 12 AAC 52.340, and 12 AAC 52.350, it was:**

**RESOLVED to accept the request by Jessica LaTourelle, PHAP1912, to apply the 15 hours inclusive in the ACLS/PALS course to the 30 credit hours required for the 2016 – 2018 renewal cycle.**

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

The motion passed.

**Agenda Item 8 <u>Lunch</u> Time: 12:41 p.m.**

Chair Holt called for a lunch at 12:41 p.m.

*Off record for lunch at 12:41 p.m.*
*Back on record at 1:23 p.m.*

*Melissa Dumas, Administrative Officer, joined the room at 12:41 p.m.*

**Agenda Item 9 <u>Budget Report</u> Time: 1:23 p.m.**

Returning from lunch, the board was joined by Melissa Dumas, who presented the board's FY18 3rd quarter budget report. Ms. Dumas reminded the board that as they're in a renewal year, their revenue as reported is dramatically understated; that the board can anticipate collecting $700,000 – $80,000 from this renewal cycle. Ms. Dumas also reviewed the board's direct and indirect expenditures, and RSAs.

*Melissa Dumas, Administrative Officer, left the room at 1:32 p.m.*

**Agenda Item 7 <u>Board Business</u> Time: 1:35 p.m.**

The board then moved to discussing initial applications for out-of-state pharmacies: Avita Drugs,

Entirely Pets, OMRO Pharmacy, and Sterling Specialty Pharmacy, as well as a pharmacy technician application submitted by Elita Cleveland. Due to the new Division-wide policies governing email voting processes using OnBoard, board members had limited voting options and lack of opportunity to explain their vote. As such, the applications were brought to the meeting for board discussion. With more time needed to review these applications, it was ultimately decided to re-open the online voting ballots and to return for discussion on these applications on May 11th.

**TASK:**
Ms. Bellino will re-open the online voting ballots for Avita Drugs, Entirely Pets, OMRO Pharmacy, Sterling Pharmacy, and Elita Cleveland.

**Agenda Item 10** **New Business** **Time: 2:08 p.m.**

Change of Pharmacy Manager Form

Hearing nothing further on the budget report, Donna Bellino addressed the need to revise the change of pharmacy manager form. Currently, the change of pharmacy manager or pharmacist-in-charge (PIC) status change form is to be filled out by a new or incoming pharmacist in charge. Ms. Bellino stated, however, that many states require notifications from both the outgoing and incoming PIC, suggesting that there can be a more robust way to accurately capture when a change has taken place. Ms. Bellino added that often times, PIC changes are submitted to the department in a delayed manner that is outside of the required 10-day timeframe. Ms. Carrillo commented that since timely notifications of PIC changes are required in regulation, this is something that needs to be reinforced, to which Chair Holt agreed. Chair Holt expounded on this issue, saying that if a PIC fails to notify the department, the previous PIC will be listed on file as the current PIC indefinitely. Ms. Bellino stated that one PIC was listed as the current PIC even though she had left two years before. Ms. Carrillo stated that moving forward, an investigative memo consistent with our division policies and procedures will be drafted when a PIC fails to notify the department of the change within the required 10 days.

**TASK:**
Staff will route delayed PIC notifications to the Investigations section according to P&P28.

Inspection Report Forms

The board acknowledged a need to update the formatting and context of the in-state and out-of-state inspection reports.

**TASK:**
Staff will work towards updating in-state and out-of-state inspection reports in coordination with Chair Holt. Ms. Carrillo will have fillable versions updated by the August 2018 meeting for the board to review.

Pharmacy Closure Form

Included in the board packet was an example form from Kansas that is used by pharmacies to notify the KS Board of Pharmacy when a pharmacy closure has occurred. The board discussed adding language to regulations indicating that pharmacies will need to fill out a pharmacy closure form provided by the department.

**TASK:**
Rich Holt will work on draft language to be added to regulation regarding pharmacy closures.

Addiction Resources for Pharmacists

The board then addressed a letter that was submitted by a former pharmacist who was pursuing licensure in Alaska; however, because of a past history of substance abuse, is unable to resume practice in Alaska for a certain amount of time. Ms. Carrillo cited AS 08.01.050, which allows the department to contract with professional organizations to provide licensed practitioners with treatment resources for substance abuse. The Board of Pharmacy is specifically included in this statute, however, the way it is currently written, the resources only applies to actively licensed pharmacists. Chair Holt agreed with the need to provide such resources, and suggested perusing programs offered by the NABP.

**TASK:**
The board will continue looking at addiction resources offered by the NABP.

*Leif Holm joined the room at 2:10 p.m.*

Photo Identification Laws

Ms. Bellino commented that she sometimes receives calls from folks concerned that an unauthorized person has picked up a prescription not intended for them, suggesting that this could be an opportunity to add photo identification regulations. Leif Holm commented that the Drug Enforcement Administration has already established guidelines to address these concerns; if a pharmacist is in doubt, s/he has the authority to request a photo ID, so adding language may be redundant to what is federally recommended. Chair Holt agreed, reiterating that it's the pharmacist's prerogative to ask for an ID in questionable circumstances.

Military PDMP Reporting Agreement

The board briefly discussed AS 17.30.200(f), which provides the board with the authority to enter into agreements with dispensers in the state that aren't regulated, e.g.: pharmacists working in VA or IHS pharmacies. Ms. Carrillo informed the board that the VA and IHS facilities have issued directives for all its practitioner and pharmacist employees to register with state PDMPs, so a form based on this agreement may not be necessary.

Interstate Data-sharing

Since the board will be repealing a section of their regulations in 12 AAC 52.855 effective June 7 regarding sharing data, new language will need to be added to engage in interstate data sharing.

This could be accomplished by adding language to 12 AAC 52.860 regarding access under a memorandum of agreement.

**TASK:**
Ms. Carrillo will add interstate datasharing as a regulation project for discussion at the board's August meeting.

**Agenda Item 11** **Legislative Update** **Time: 3:06 p.m.**

The board then moved to discussing legislative updates. Chair Holt informed the board that Senate Bill 32 relating to biosimilars passed, as did Senate Bill 37, which relates to wholesale drug distributors, third-party logistics providers, out-sourcing facilities, and a new executive administrator position. Chair Holt encouraged the board to become familiar with these bills as they will begin delving into the development of corresponding regulations, adding that he had already started a draft project. Senate Bill 119 relating to drug pricing did not pass.

**Agenda Item 12** **Correspondence** **Time: 3:10 p.m.**

The board briefly reviewed correspondence from the FDA – APA meeting update in Nashville, the CE monitoring via mobile app, and NABP update to the VIPPS program. The board also reviewed correspondence from pharmacist, Gerald Brown, concerning questions relating to the PDMP. Ms. Carrillo informed the board that responses had already been sent to him by the Board of Nursing, who he also addressed the letter to. Ms. Carrillo and Rich Holt had both drafted responses to Mr. Brown, which will be forwarded to him shortly after the meeting. One of the questions asked relates to whether pharmacists are required to submit to the PDMP, which depends on whether such clinics are considered healthcare facilities. Ms. Bellino commented on her recollection from investigator, Al Kennedy, that methadone clinics are considered healthcare facilities and thus required to register with the board as a drug room.

**TASK:**
Ms. Bellino will locate minutes pertaining to methadone clinics being considered a healthcare facility. A legal opinion may be necessary to clarify.

**TASK:**
Ms. Carrillo will follow-up with Gerald Brown to respond to the PDMP-specific questions he submitted to the board**.**

**Agenda Item 13** **Review of Lost/Stolen Rx** **Time: 3:22 p.m.**

Ms. Carrillo informed the board that these documents weren't saved to OnBoard properly, so the board will address this topic on May 11th.

**Agenda Item 13** **Administrative Business** **Time: 3:24 p.m.**

The board then briefly addressed the continuing education audit renewal letter templates and audit complete letters prepared by Ms. Carrillo. Phil Sanders noticed a typo, which will be corrected by Ms. Carrillo before the letters are sent. There were no wall certificates to sign.

**TASK:**
Ms. Carrillo will fix the typo on the continuing education audit letter.

**Agenda Item** **Recess** **Time: 3:33 p.m.**

On a motion duly made by Phil Sanders, seconded by Rich Holt, the board recessed at 3:33 p.m.

**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
## May 11, 2018 Teleconference via OnBoard

**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 teleconference at the State Office Building, Conference Room A in Juneau, Alaska on May 11th, 2018.**

**These are draft minutes that have not yet been approved by the board.**

**Agenda Item 15** **Call to Order/Roll Call** **Time: 9:07 a.m.**

The **May 11, 2018** meeting day was called to order by Chair, Rich Holt at 9:07 a.m.

Board members present, constituting a quorum:

Richard Holt, PharmD #PHAP2008, MBA – *Chair*
Leif Holm, PharmD #PHAP1606 (Absent)
Phil Sanders, RPh #PHAP776
James Henderson, RPh #PHAP1683
Lana Bell, RPh #PHAP893 (Absent)
Tammy Lindemuth, Public Member
Sharon Long, Public Member (Absent)

Division staff present:

Donna Bellino, Occupational Licensing Examiner
Deborah Roesch, Occupational Licensing Examiner
Laura Carrillo, Records & Licensing Supervisor

**Agenda Item 16** **Review/Approve Agenda** **Time: 9:08 a.m.**

Upon opening the meeting, Chair Holt inquired to the board whether there were any suggestions to amend the written agenda. Phil Sanders expressed a desire to discuss drug disposal regulations, to which Chair Holt responded that he had previously prepared a regulations draft and that this

topic could be discussed at the regulations portion of the meeting. Hearing nothing further on amending the agenda, the board motioned to approve the agenda.

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

**RESOLVED to accept the May 11, 2018 agenda as amended.**

| | APPROVE | DENY | ABSTAIN | ABSENT |
|---|---|---|---|---|
| Richard Holt | x | | | |
| Phil Sanders | x | | | |
| James Henderson | x | | | |
| Tammy Lindemuth | x | | | |

The motion passed with no further discussion.

**Agenda Item 17** **Public Comment** **Time: 9:10 a.m.**

There were members from the public available for public comment.

**Agenda Item 13** **Review of Lost/Stolen Rx** **Time: 9:12 a.m.**

The board reviewed one report from Alaska CVS Pharmacy, LLC, in which the pharmacy reported a loss of $3,199. Ms. Lindemuth inquired about how the pharmacy recoups this loss, to which Chair Holt stated it may be covered by insurance or may be a cost that they'll have to shoulder. Chair Holt then informed the board that another pertinent part of the form to hone in on is whether the pharmacy has reported numerous losses or thefts, stating that there were no losses previously reported.

**Agenda Item 7** **Board Business** **Time: 9:18 a.m.**

The board then resumed their discussion on review of applications from the previous day.

Avita Drugs

This application had one 'abstain', one 'yes', and one 'no' which was being opened up for discussion and re-voting because the reasons for voting 'no' and 'abstain' were unclear. Mr. Sanders commented that he indicated an 'abstain' vote due to the applicant's employer having previously been convicted of a felony charge. Of particular concern to Mr. Sanders was that the employee who had been convicted of a felony was allowed to work with the pharmacy. Chair Holt also commented that in reviewing the application, he noticed that the owners of the pharmacy were not licensed pharmacists. It was also added that one of the owners was put on probation, but that eventually was no longer working as an officer with the pharmacy.

**On a motion duly made by Rich Holt and seconded by Tammy Lindemuth to approve the registration application for out-of-state pharmacy, Avita Drugs in accordance with AS 08.80.158 and 12 AAC 52.130, it was:**

**RESOLVED to approve the out-of-state pharmacy registration application for Avita Drugs.**

| | APPROVE | DENY | ABSTAIN | ABSENT |
|---|---|---|---|---|
| Richard Holt | x | | | |
| Phil Sanders | x | | | |
| James Henderson | x | | | |
| Tammy Lindemuth | x | | | |

The motion passed with no further discussion.

Entirely Pets

This application had one 'abstain', two 'yes' votes, and was reopened for board discussion to more clearly understand the reason for the abstain vote. The board reviewed the four major citations against the pharmacy to determine a timeline of events. It was noted that the home state license was suspended, but had since been reinstated. Seeing that the pharmacy was currently in good standing in its home state, the board prepared a motion.

**On a motion duly made by Tammy Lindemuth and seconded by James Henderson to approve the registration application for out-of-state pharmacy, Entirely Pets in accordance with AS 08.80.158 and 12 AAC 52.130, it was:**

**RESOLVED to approve the out-of-state pharmacy registration application for Entirely Pets.**

| | APPROVE | DENY | ABSTAIN | ABSENT |
|---|---|---|---|---|
| Richard Holt | x | | | |
| Phil Sanders | x | | | |
| James Henderson | x | | | |
| Tammy Lindemuth | x | | | |

The motion passed with no further discussion.

OMRO Pharmacy

The board then reviewed the out-of-state pharmacy registration application of OMRO Pharmacy, with which the board had concerns regarding the criminal history of the owner who is also the pharmacist-in-charge. In his review, Chair Holt came across a previous case of a pharmacy the

board had denied and provided a brief synopsis of this case and why the board had denied this application.

**On a motion duly made by Rich Holt, and upon review of the out-of-state pharmacy registration application from OMRO Pharmacy applying under the authority of AS 08.80.158 and 12 AAC 52.130, it was moved to accept the application in consideration of case number 2659-01-001 OAH #08-0344-PHA, AS 08.80.261(a), and AS 08.80.157(d)((h)(2), which grants the board the authority to evaluate out-of-state pharmacies applications based on convicted felonies of owners and officers of the company, and demonstrated proof of providing specific needs to patients in Alaska. It was with unanimous consent:**

**RESOLVED to deny the out-of-state pharmacy registration application for OMRO Pharmacy per AS 08.80.261(a) and AS 08.80.157(d) which authorizes the board to deny a registration if approving the registration would not be in the public interest, and per AS 08.80.157(h)(2), which authorizes the board to deny a registration if an owner of the pharmacy has been convicted of a felony.**

| | APPROVE | DENY | ABSTAIN | ABSENT |
|---|---|---|---|---|
| Richard Holt | | x | | |
| Phil Sanders | | x | | |
| James Henderson | | x | | |
| Tammy Lindemuth | | x | | |

The motion did not pass.

Sterling Pharmacy

This application previously resulted in one 'yes' and two 'no' responses, for which the reasons for the latter were unclear. Mr. Sanders commented on his concerns regarding one of the pharmacy owners being cited for diverting controlled substances, in which the owner was making available a controlled substance to himself without a valid prescription. Ms. Lindemuth commented that the owner had surrendered the license and entered an agreement to address the issue. Mr. Sanders added that after meeting the conditions of probation, the license was subsequently reinstated in 2009; however, Chair Holt commented that having the license reinstated, the individual was then convicted of a DUI.

**On a motion duly made by Tammy Lindemuth and seconded by Rich Holt to approve the registration application for out-of-state pharmacy, Sterling Pharmacy in accordance with AS 08.80.158 and 12 AAC 52.130, it was:**

**RESOLVED to approve the out-of-state pharmacy registration application for Sterling Pharmacy.**

| | APPROVE | DENY | ABSTAIN | ABSENT |
|---|---|---|---|---|
| Richard Holt | x | | | |
| Phil Sanders | x | | | |
| James Henderson | x | | | |
| Tammy Lindemuth | x | | | |

The motion passed with no further discussion.

After completing discussion and voting for the out-of-state pharmacy registrations, the board then moved to discussing the pharmacy technician application for Elita Cleveland.

**On a motion duly made by Rich Holt 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, Laura Carrillo, and Deborah Roesch were authorized to remain in the room.

*Off record for executive session at 10:35 a.m.*
*On record for public discussion at 10:51 a.m.*

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

**On a motion duly made by Rich Holt to accept the pharmacy technician application of Elita Cleveland pursuant to 12 AAC 52.140 and AS 08.80.030(b)(9), and in consideration of AS 08.80.261(a)(1) that the non-disclosure of criminal information was unintentional, it was with unanimous consent:**

**RESOLVED to deny the pharmacy technician license application of Elita Cleveland pursuant to 12 AAC 52.140, AS 08.80.030(b)(9), and AS 08.80.261(a)(1) which authorizes the board to evaluate competency and qualifications, and to deny a license based on intentional misrepresentation.**

| | APPROVE | DENY | ABSTAIN | ABSENT |
|---|---|---|---|---|
| Richard Holt | | x | | |
| Phil Sanders | | x | | |
| James Henderson | | x | | |
| Tammy Lindemuth | | x | | |

The motion did not pass.

Chair Holt called for a short break.

*Off record at 11:01 a.m.*
*On record at 11:17 a.m.*

**Agenda Item 18** **Regulation Projects** **Time: 11:17 a.m.**

Chair Holt informed the board that the regulation workflow was included in the board packet for the review and reference. To note was that the PDMP regulations had been signed by the Lt. Governor on May 8th and are to take effect on June 7th, 2018.

Chair Holt added that the provisions enacted under SB 37 will go into effect on January 1, 2017, and indicated to the board that he started the draft of wholesale drug distributors, third-party logistics providers, outsourcing facilities, and the executive administrator position on this day. The draft was sent to Ms. Bellino for distribution to the board.

Discussion: Gross Immorality and Moral Turpitude (12 AAC 52.995)
Chair Holt stated that new regulations relating to these topics are being introduced because the board's investigator had previously brought a matter to his attention which involved immorality and moral turpitude, but that the board ultimately couldn't take a disciplinary action against a license based on this because it had not been incorporated into regulation. Ms. Bellino prompted the board to clarify if their intent is to create a new section relating to these topics so as to provide a basis for the board to deny or discipline a license. Mr. Henderson inquired as to whether there was current authority to discipline a license based in AS 08.80.261(8); however, these terms are not defined, which would be provided in regulation. Mr. Sanders expressed his concerns about the wording of the proposed language to be amended from "moral turpitude means" to "moral turpitude may mean", so that the language isn't so absolute. Ms. Carrillo suggested that the board incorporate timelines to consider whether an aged crime is significant enough to be considered in weighing the individual's application. Tammy Lindemuth also suggested that the board consider adding language to specify that the crime is a conviction rather than a charge.

The board discussing establishing a matrix to guide the board in making determinations on applications based on immorality. Ms. Lindemuth inquired whether the matrix would have to be sent to the board, to which Ms. Carrillo stated it could be sent to LAW at the time the regulations draft is reviewed. Chair Holt reiterated that the board historically has sent drafts to law for precursory review; although not required, the board prefers this so they have immediate feedback as to whether they have the statutory authority to implement desired regulations.

Discussion: Prescription Thresholds
Chair Holt indicated that they'll hold off until the board receives clarification on where the 5, 5, 3 threshold came from.

Discussion: Pharmacist-in-Charge (12 AAC 52.200)

Chair Holt then moved to the proposed language for 12 AAC 52.200 (pharmacist-in-charge) and inquired why a pharmacist-in-charge would have to practice at a specific location if they've allowed one particular PIC to be in charge at several different pharmacy locations. Mr. Henderson suggested striking the phrase, "must designate a pharmacist who practices in that pharmacy location". Mr. Sanders commented that it doesn't make sense to him to allow one particular PIC over several pharmacies, but is still unsure on how to change the wording. Chair Holt stated that in New York, you have to work a certain number of hours per week to be considered a PIC at a pharmacy. Mr. Sanders agreed that the number of hours or percentage of time could be defined in regulation. Ms. Carrillo inquired as to whether the board was aware of other states allowing for an alternative PIC, to which Ms. Bellino affirmed, stating that some states do allow for an interim PIC. Chair Holt suggested adding language regarding limitations of pharmacies in which a PIC can be in charge over; e.g.: not be a PIC in more than two locations.

Discussion: Prescription Thresholds

Returning back to the discussion on the 5,5,3 threshold, Ms. Bellino informed the board that this was determined during their January 29 - 31, 2014 board meeting. Thresholds are used as a ballpark for a basis of issuing unsolicited reports, and most states use 5>5>3 as a guideline.

Discussion: Pharmacist-in-Charge (12 AAC 52.200)

The board then continued their discussion on change of PIC notifications. Ms. Bellino reiterated the need to improve the formality of the process, and Ms. Carrillo added that these changes need to be closely followed and reinforced. Mr. Henderson stated that there needs to be protection for the out-going PIC if the incoming PIC fails to submit the required form. Ms. Carrillo reiterated the significant responsibilities that pharmacists in charge shoulder. Ms. Carrillo stated for example that in HB 159, all pharmacists are required to report, however, in the board of pharmacy's statutes, the pharmacist-in-charge is specifically responsible for all data reporting. Mr. Henderson suggested having the in-coming and out-going PIC status be on one form. The board continued to discuss whether we should have separate forms for ingoing and ongoing, or if they should be consolidated onto one form. The board also discussed appropriate disciplinary actions for failing to report PIC changes.

**TASK**

Ms. Carrillo will consult with Investigations as to whether boards have fines for similar situations involving failure to notify the department of a required change.

Mr. Henderson commented on the language in 12 AAC 52.200(a), which states that a pharmacy must have a PIC before the license is issued, but was wondering what would be the case if one was not assigned after the license was issued. Chair Holt stated that a new section could be added stating that the pharmacy could not remain open if there was no active PIC. Ms. Carrillo inquired to the board whether it would be more appropriate to add the language to the section pertaining to the pharmacy, to which Mr. Henderson agreed it could be added to both the 12 AAC 52.200 and the section on facilities. Chair Holt added that the language could be added 12 AAC 52.020 in the section relating to facility licenses.

Discussion: Transfer of a Prescription Drug Order (12 AAC 52.500)

The board discussed removing the wording 'refill', and Chair Holt stated that at present, patients can take their refill bottle to any pharmacy as long as the pharmacy that is refilling the prescription calls the originating pharmacy to verify the refill prescription. Ms. Lindemuth inquired to the whether this would allow for a transfer of an initial prescription, to which Chair Holt stated that this could be fulfilled if the language relating to "refills" is removed. Ms. Bellino stated that in this case, a pharmacy that does not have the prescription in stock could refers the patient to another pharmacy to have the prescription filled based on that one prescription drug order. James stated this would allow for transfer of orders to different pharmacies for both the initial fill and for refills.

Discussion: Generic Drugs and Biolsimilar Substitutions (Senate Bill 32; 12 AAC 52.210)

This bill effectively changed the statutory definition of equivalents and included biosimilar interchangeable; it created a definition that contained language relating to generic drugs and biosimilars. The new changes were as follows:

** Sec. 6. AS 08.80.480(34) is amended to read: (34) "substitute" ["SUBSTITUTION"] means to dispense, without the prescriber's expressed authorization,*
*(A) an equivalent drug product in place of the prescribed drug; or*
*(B) an interchangeable biological product in place of the prescribed biological product;*

Looking at the draft regulations in 12 AAC 52.210, Mr. Henderson commented that mentioning the cost doesn't seem to fit well in regulation and was concerned that this would be stipulating what can and cannot be dispensed based on the cost of the drug. Mr. Henderson suggested that the intention may have been to protect consumers from unscrupulous prescribers from prescribing high drug prices. Chair Holt stated he reviewed the statutes and regulations to see if there is mention of drug prices, to which there was not. Mr. Henderson suggested striking (a)(3) of 12 AAC 52.510.

Chair Holt called for lunch.

*Off record for lunch at 1:23 p.m.*
*Back on record at 1:49 p.m.*

Break for a short lunch at 1:23 a.m.
Back on record from 1:49 p.m.

The board resumed discussion on regulations, returning to 12 AAC 52.510(a)(3), which states "the substitute drug product costs the patient less than the prescribed drug product; and"; the board is leaning towards removing this line.

Discussion: Senate Bill 37 Regulations
The board discussed what qualifications the executive administrator (EA) and what duties they would perform. Not having a clear guidance on how to proceed the board will review other EA position descriptions for direction on the best way to proceed.

Discussion: Drug Disposal Regulations
Chair Holt advised that Alaska is one of the few states that does not have regulations regarding this. The board was in consensus this is an important issue and Mr. Sanders was happy to take this project on and will create draft regulations regarding drug disposal.

**TASK**
Mr. Sanders will begin draft regulations on drug disposals.

The board moved to making a motion on approving the regulations draft:

**12 AAC 52.995 DEFINITIONS**

**(36) In AS 08.80.261(8),**

**"gross immorality" means conduct that goes flagrantly beyond accepted standards of what is right or just in behavior or is unmitigated in any way.**

**"moral turpitude" means**

**(a) conduct that is considered contrary to community standards of justice, honesty, or good morals,**

**(b) conduct that is wrong in itself even if no statute were to prohibit the conduct, or**

**(c) a crime that includes a conviction or indictment of**

**(1) homicide;**

**(2) manslaughter;**

**(3) assault;**

**(4) stalking;**

**(5) kidnapping;**

**(6) sexual assault;**

**(7) sexual abuse of a minor;**

**(8) unlawful exploitation of a minor, including possession or distribution of child pornography;**

**(9) indecent exposure;**

**(10) unlawful distribution or possession for distribution of a controlled substance;**

**(11) prostitution;**

**(12) sex trafficking.**

**(13) murder;**

**(14) human trafficking;**

**(15) criminal sexual conduct;**

**(16) incest;**

**(17) robbery;**

**(18) extortion;**

**(19) forgery;**

**(20) theft;**

**(21) endangering the welfare of a child;**

**(22) endangering the welfare of a vulnerable adult; or**

**(23) reckless endangerment.**

**12 AAC 52.200. PHARMACIST-IN-CHARGE.**

(a) Before the board will issue a license to a pharmacy, the owner of the pharmacy must designate a pharmacist who practices in that pharmacy location as the pharmacist-in-charge of the pharmacy in accordance with AS 08.80.330. For a remote pharmacy, the owner of the central pharmacy must designate a pharmacist in the central pharmacy as the pharmacist-in-charge of the remote pharmacy. The board will indicate the name of the pharmacist-in-charge on the face of the pharmacy license.

(b) The responsibilities of the pharmacist-in-charge include

(1) compliance with all laws and regulations governing the activities of the pharmacy;

(2) training of all pharmacy personnel;

(3) establishing policies and procedures for pharmacy operations;

(4) maintaining required records;

(5) storage of all materials, including drugs and chemicals;

(6) establishing and maintaining effective controls against theft or diversion of prescription drugs; and

(7) on request, reporting to the board the names of all pharmacists employed by the pharmacy.

(c) A pharmacist designated to replace the pharmacist-in-charge of a pharmacy shall notify the board within 10 days of that designation **on a form provided by the department**.

**(d) An out-going pharmacist-in-charge shall notify the board within 10 days when they are no longer the current pharmacist-in-charge of the licensed facility on a form provided by the department.**

**(e) In accordance with AS 08.80.330, a pharmacy cannot be open for business without a pharmacist-in-charge on the license.**

**12 AAC 52.020. FACILITY LICENSE.** (a) An applicant for a facility license shall submit

(1) the fees required in 12 AAC 02.310;

(2) a completed application on a form provided by the department;

(3) within 14 days after commencement of business, a completed self-inspection of the premises questionnaire on a form provided by the department; and

(4) the name of the pharmacy or pharmacist that will provide consultant pharmacist services as required in AS 08.80.390, if applicable.

(b) *Repealed 1/17/2007.*

(c) An application for a remote or other pharmacy license must include the name of the pharmacist designated to be the pharmacist-in-charge as required in AS 08.80.330 and 12 AAC 52.200.

(d) An application for a pharmacy license must include the name and specific location of each remote pharmacy that will be under that pharmacy's control.

(e) An application for a remote pharmacy license must include the name and, if it has been issued, the license number of the pharmacy that is the central pharmacy.

**(f) In accordance with AS 08.80.330, a pharmacy cannot be open for business without a pharmacist-in-charge on the license.**

**12 AAC 52.050. CLOSED PHARMACIES.**

(a) When a pharmacy ceases operations, the pharmacist-in-charge of that pharmacy shall

(1) ~~**submit to**~~ **notify** the board **on a form provided by the department** ~~**a written notice**~~ of the cessation of pharmacy operations; the ~~**written notice**~~ **form** must be submitted within 10 days after the cessation of operations and include

**12 AAC 52.500. TRANSFER OF A PRESCRIPTION DRUG ORDER.**

(a) For the purpose of dispensing ~~**a refill of**~~ a prescription drug order, original prescription drug order information may be transferred between pharmacies if the requirements of 12 AAC 52.460 and this section are met.

**12 AAC 52.510. SUBSTITUTION.**

(a) A pharmacist may dispense ~~**an equivalent drug**~~ **a substitute drug** product instead of the prescribed drug if

(1) the prescribing practitioner does not hand write or electronically note on the prescription drug order that a specific brand must be dispensed, using language such as "brand medically necessary" or similar wording;

(2) the patient is notified and consents to the substitution;

(3) **repeal.** the equivalent drug product costs the patient less than the prescribed drug product; and

(4) for the **substitute** drug product actually dispensed, the pharmacist notes on the prescription drug order one of the following:

(A) the drug product's manufacturer or distributor;

(B) national drug code number;

(C) short name code; or

(D) trade name.

(b) The determination of the **substitute** drug product to be dispensed for a prescription drug order is a professional responsibility of the pharmacist. A pharmacist may not dispense any product that in the pharmacist's professional opinion is not ~~**an equivalent drug product**~~ **a substitute** as the term "~~**equivalent drug product**~~ **substitute**" is defined in AS 08.80.480.

**(c) In AS 08.80.295(e), "Entry into an electronic records system" means creating an electronic dispensing record in the patient profile of the pharmacy computer system regardless if the practitioner has direct electronic access to the pharmacy computer system.**

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

**12 AAC 52.340 APPROVED PROGRAMS.**

(a) The following programs will be accepted by the board as continuing education for pharmacists and pharmacy technicians under 12 AAC 52.320 and 12 AAC 52.325:

(1) any program presented by a provider accredited by the ACPE **and results in a continuing education certificate showing the date of the course and the ACPE Universal Activity Number associated with the program**;

(2) cardiopulmonary resuscitation (CPR) courses presented by the American Red Cross or the American Heart Association that lead to CPR certification; the board will accept no more than one contact hour of continuing education credit in a 24 month period for completion of a CPR course.

(b) The following programs will be accepted by the board as continuing education under 12 AAC 52.325, when the subject contributes directly to the professional competency of a pharmacy technician and is directly related to pharmacy principles and practice:

(1) any program presented or approved by the Alaska Pharmacists Association;

(2) any program presented or approved by the Pharmacy Technician Certification Board (PTCB) or the National Pharmacy Technician Association (NPTA).

(c) An individual who presents an approved continuing education program may receive credit for the time spent during the actual presentation of the program. An individual may not receive credit for the same presentation more than once during a licensing period.

**On a motion duly made by Rich Holt to accept the amended changes and additions to the drafted regulations, and seconded by Tammy Lindemuth with unanimous consent, it was:**

**RESOLVED to approve the draft regulations and to send the draft to the regulations specialist for cursory review by the department of law.**

| | APPROVE | DENY | ABSTAIN | ABSENT |
|---|---|---|---|---|
| Richard Holt | x | | | |
| Phil Sanders | x | | | |
| James Henderson | x | | | |
| Tammy Lindemuth | | x | | |

The motion passed.

Agenda item #s 19 and 20 related to regulation projects; however, the board did briefly return to discussing PDMP fees. It was clarified for that only pharmacists who are dispensing federally scheduled II – IV controlled substances in Alaska are required to register and pay the fee.

**TASK**
Ms. Carrillo will create a PDMP pharmacist dispensing status form for Chair Holt to review.

**Agenda Item 21** **Set Meeting Dates** **Time: 2:45 p.m.**

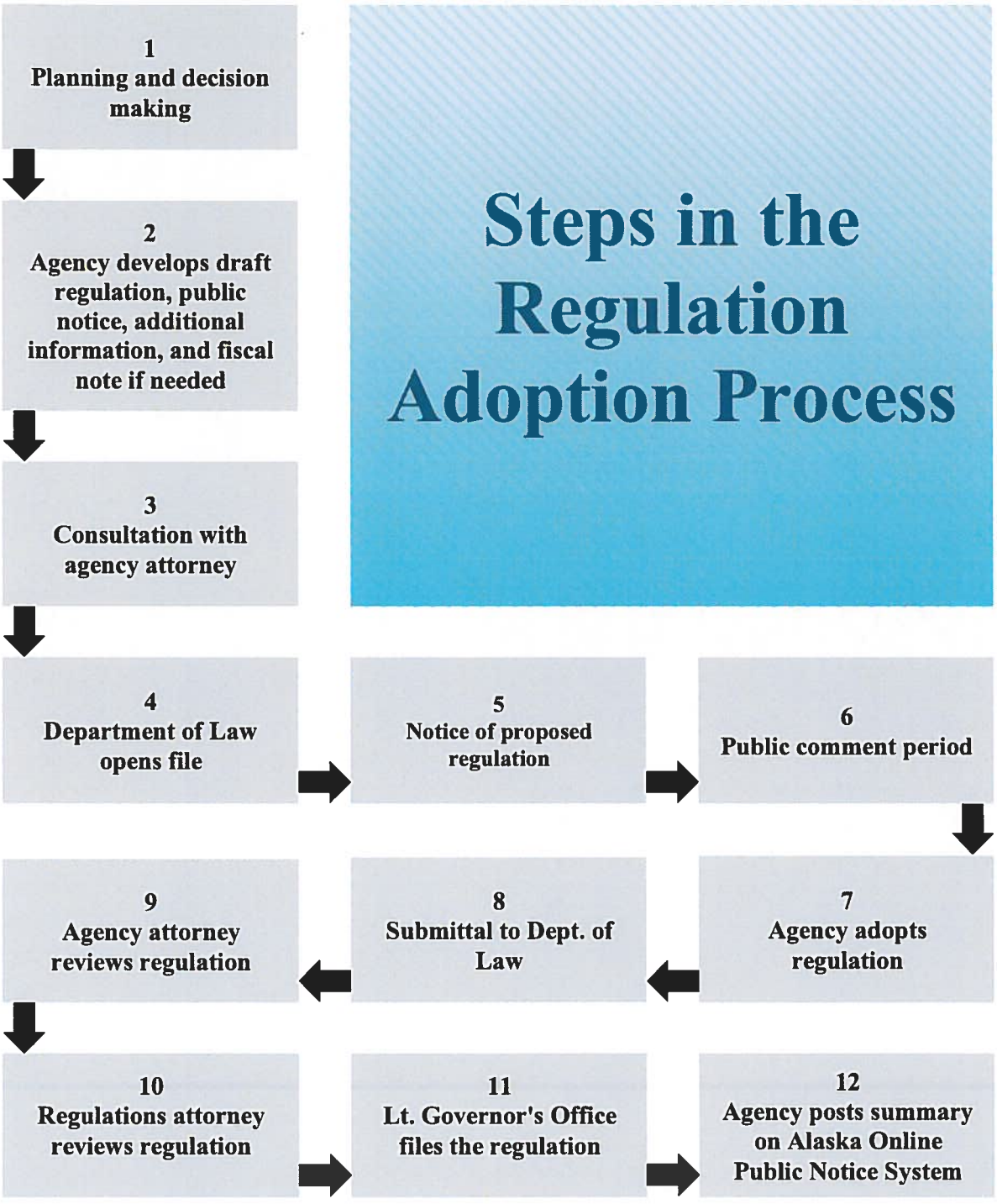
Ms. Bellino reminded the board that the August 16 – 17, 2018 meeting date was already set and that it would be held in Anchorage. Ms. Bellino stated she would send an email survey to the board to establish a date for the November 2018 meeting.

**TASK**
Ms. Bellino will send out a survey to gauge board member availability for the November 2018 meeting.

**Agenda Item** **Adjourn** **Time: 3:08 p.m.**

On a motion duly made by Phil Sanders and seconded by James Henderson, the board decided to adjourn at 3:08 p.m.

# Steps in the Regulation Adoption Process



STATE OF ALASKA
DEPARTMENT OF COMMERCE AND ECONOMIC DEVELOPMENT
**POLICY AND PROCEDURES**

| P & P No. | Page |
|---|---|
| DOL-19 | 1 OF 3 |
| Effective Date: December 1995 | |
| Supersedes P & P No. | Dated |
| DOL-19 | 10/95 |
| APPROVED BY | |

SUBJECT
BOARD/COMMISSION ACTION ON REGULATIONS

DIVISION
OCCUPATIONAL LICENSING

SECTION

REQUEST FOR REGULATIONS: When a board/commission requests a change in its regulations, the board/commission should explain, on the record during a properly noticed public meeting, the reason for the change and give detailed information on the change requested. The staff person responsible for the meeting minutes is also responsible for relaying the board/commission's request to the regulations specialist through a draft copy of the minutes, plus any other information that explains the board/commission's request.

The regulations specialist will provide a draft copy of the requested changes in the regulations. It may be necessary to consult with the Department of Law on the board/commission's authority to make the changes requested. It may also be necessary for the board/commission to provide additional information on its intent before the regulations changes are drafted.

PUBLIC NOTICE OF REGULATIONS CHANGES: Once a board/commission has reviewed the draft of proposed regulations and agreed on the wording of the proposed changes, the board/commission must pass a motion approving the regulations for public notice. The board/commission should state on the record whether it intends to hold a public hearing on the regulations. The responsible staff should give a draft copy of the minutes to the regulations specialist and provide the date, location, and time of the public hearing, if applicable.

The regulations specialist will prepare and distribute the public notice, including providing a copy of the notice and regulations to all board/commission members and the affected staff.

PUBLIC COMMENTS ON REGULATIONS: All notices of proposed regulations include an opportunity for the public to give written comments on the regulations and a specific invitation for comments on the cost of the proposed regulatory action. The board/commission is obligated to seriously consider all written comments, and oral comments if a hearing is held, before taking final action on the regulations. To be considered, written or oral comments must be submitted as instructed in the public notice.

The public notice also includes a deadline for submitting written comments. This deadline is strictly enforced, and letters received after the deadline will not be forwarded to a board/commission for its consideration. Written comments must be received at the address given in the public notice by the deadline date; the postmark date is not considered.

Comments received by phone will not be considered as written comments. The division will accept faxed comments. Staff should inform anyone submitting oral comments outside of the public hearing that the comments will not become a part of the record of the regulations project.

Comment letters should be addressed to the regulations specialist. **If a staff member other than the regulations specialist receives a letter commenting on proposed regulations, the letter should be given to the regulations specialist immediately.**

| STATE OF ALASKA<br>DEPARTMENT OF COMMERCE AND ECONOMIC DEVELOPMENT<br>**POLICY AND PROCEDURES** | P & P No. DOL-19 | Page 2 OF 3 |
|---|---|---|
| | Effective Date<br>December 1995 | |
| SUBJECT<br>BOARD/COMMISSION ACTION ON REGULATIONS | Supersedes P & P No.<br>DOL-19 | Dated<br>10/95 |
| | APPROVED BY | |
| DIVISION<br>OCCUPATIONAL LICENSING | SECTION | |

At the close of the public comment period, the regulations specialist will compile the written comments and provide them to staff for distribution to board/commission members. The board/commission chair should ensure that all members have carefully considered the public comment letters before the board/commission takes action on the regulations.

REGULATION HEARINGS: If a board/commission chooses to hold a hearing on proposed regulations, the information about the public hearing must be included in the original or a supplemental notice of the proposed regulations. Hearings are usually held in conjunction with a regularly-scheduled meeting of the board/commission, and are always recorded. A board/commission may choose to use teleconferencing sites for the regulations hearing.

If a board/commission has not given notice of a public hearing, the board/commission may not accept any oral comments on the regulations. If the board/commission accepts oral comments without having given notice of a public hearing, the board/commission is required to give supplemental notice and hold a hearing at a later date to allow other interested parties to give oral comments.

The board/commission chair often presides over the hearing. The general principle for conducting a regulations hearing is fairness. The board/commission may impose a time limit on commenters, but each commenter must be treated equally.

Staff should provide a sign-up sheet at the beginning of the hearing for those who plan to give oral comments.

FINAL ACTION BY THE BOARD/COMMISSION ON PROPOSED REGULATIONS: After carefully considering the written comments, any oral comments if a hearing was held, and discussing the costs of the proposal, the board/commission may take final action on proposed regulations. The board/commission's final action must be taken during a properly-noticed public meeting.

The board/commission may adopt the regulations as proposed, amend and adopt the regulations, or take no action on the regulations. If the board/commission amends the regulations beyond the summary of proposed changes it has given during the public notice process, the board/commission must give additional notice before adopting the regulations. It is important for the board/commission to explain the reason for its actions on the record. This is not only helpful in the preparation of the final draft of the regulations, but it is also important during the review of the regulations by the Department of Law and in case of a legal challenge to the regulations.

The record of the meeting should include how the board/commission considered the public comment in its deliberations. Also, the board/commission chair or other board/commission member must make a statement on the record indicating how the board/commission gave special consideration to the cost to private persons. The board/commission must discuss the costs to private persons on the record, even if no comments on costs were submitted or if there are no apparent costs.

The board/commission's final action must be in the form of a motion that is passed.

| STATE OF ALASKA<br>DEPARTMENT OF COMMERCE AND ECONOMIC DEVELOPMENT<br>**POLICY AND PROCEDURES** | P & P No. DOL-19 | Page 3 OF 3 |
|---|---|---|
| | Effective Date<br>December 1995 | |
| SUBJECT<br>BOARD/COMMISSION ACTION ON REGULATIONS | Supersedes P & P No.<br>DOL-19 | Dated<br>10/95 |
| | APPROVED BY | |
| DIVISION<br>OCCUPATIONAL LICENSING | SECTION | |

The staff person responsible for the minutes of the meeting is also responsible for giving a draft copy of the minutes to the regulations specialist as soon as possible after the meeting.

FINAL REVIEW OF ADOPTED REGULATIONS: After a board/commission has adopted regulations, the regulations specialist will prepare the proper paperwork and submit the project to the Department of Law for final review. If approved by the Department of Law, t the project is sent to the Lieutenant Governor's office for filing.

The regulations specialist will notify board/commission members and affected staff of the effective date of approved regulations.

# LAWS OF ALASKA

# 2018

**Source**
HCS CSSB 37(RLS) am H

**Chapter No.**
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## AN ACT

Relating to the Board of Pharmacy; relating to the licensing of certain entities and inspection of certain facilities located outside the state; relating to drug supply chain security; creating a position of executive administrator for the Board of Pharmacy; reducing the membership of the Alaska Commercial Fisheries Entry Commission to two individuals; relating to the duties of the commissioner serving as chair of the commission; providing that a single commissioner may exercise all powers and duties of the commission if there is a vacancy on the commission; providing for commissioner compensation; relating to tie votes of the commission; and providing for an effective date.

_____

**BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF ALASKA:**

THE ACT FOLLOWS ON PAGE 1

**AN ACT**

Relating to the Board of Pharmacy; relating to the licensing of certain entities and inspection of certain facilities located outside the state; relating to drug supply chain security; creating a position of executive administrator for the Board of Pharmacy; reducing the membership of the Alaska Commercial Fisheries Entry Commission to two individuals; relating to the duties of the commissioner serving as chair of the commission; providing that a single commissioner may exercise all powers and duties of the commission if there is a vacancy on the commission; providing for commissioner compensation; relating to tie votes of the commission; and providing for an effective date.

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*** Section 1.** AS 08.80.030(b) is amended to read:

(b) In order to fulfill its responsibilities, the board has the powers necessary

for implementation and enforcement of this chapter, including the power to

(1) elect a president and secretary from its membership and adopt rules for the conduct of its business;

(2) license by examination or by license transfer the applicants who are qualified to engage in the practice of pharmacy;

(3) assist the department in inspections and investigations for violations of this chapter, or of any other state or federal statute relating to the practice of pharmacy;

(4) adopt regulations to carry out the purposes of this chapter;

(5) establish and enforce compliance with professional standards and rules of conduct for pharmacists engaged in the practice of pharmacy;

(6) determine standards for recognition and approval of degree programs of schools and colleges of pharmacy whose graduates shall be eligible for licensure in this state, including the specification and enforcement of requirements for practical training, including internships;

(7) establish for pharmacists and pharmacies minimum specifications for the physical facilities, technical equipment, personnel, and procedures for the storage, compounding, and dispensing of drugs or related devices, and for the monitoring of drug therapy;

(8) enforce the provisions of this chapter relating to the conduct or competence of pharmacists practicing in the state, and the suspension, revocation, or restriction of licenses to engage in the practice of pharmacy;

(9) license and regulate the training, qualifications, and employment of pharmacy interns and pharmacy technicians;

(10) issue licenses to persons engaged in the manufacture and distribution of drugs and related devices;

(11) establish and maintain a controlled substance prescription database as provided in AS 17.30.200;

(12) establish standards for the independent administration by a pharmacist of vaccines and related emergency medications under AS 08.80.168, including the completion of an immunization training program approved by the board;

(13) establish standards for the independent dispensing by a pharmacist of an opioid overdose drug under AS 17.20.085, including the completion of an opioid overdose training program approved by the board;

(14) require that a licensed pharmacist register with the controlled substance prescription database under AS 17.30.200(o)**;**

**(15) establish the qualifications and duties of the executive administrator and delegate authority to the executive administrator that is necessary to conduct board business**.

*** Sec. 2.** AS 08.80.030(b), as amended by sec. 1 of this Act, is amended to read:

(b) In order to fulfill its responsibilities, the board has the powers necessary for implementation and enforcement of this chapter, including the power to

(1) elect a president and secretary from its membership and adopt rules for the conduct of its business;

(2) license by examination or by license transfer the applicants who are qualified to engage in the practice of pharmacy;

(3) assist the department in inspections and investigations for violations of this chapter, or of any other state or federal statute relating to the practice of pharmacy;

(4) adopt regulations to carry out the purposes of this chapter;

(5) establish and enforce compliance with professional standards and rules of conduct for pharmacists engaged in the practice of pharmacy;

(6) determine standards for recognition and approval of degree programs of schools and colleges of pharmacy whose graduates shall be eligible for licensure in this state, including the specification and enforcement of requirements for practical training, including internships;

(7) establish for pharmacists and pharmacies minimum specifications for the physical facilities, technical equipment, personnel, and procedures for the storage, compounding, and dispensing of drugs or related devices, and for the monitoring of drug therapy;

(8) enforce the provisions of this chapter relating to the conduct or competence of pharmacists practicing in the state, and the suspension, revocation, or

restriction of licenses to engage in the practice of pharmacy;

(9) license and regulate the training, qualifications, and employment of pharmacy interns and pharmacy technicians;

(10) issue licenses to persons engaged in the manufacture and distribution of drugs and related devices;

(11) establish and maintain a controlled substance prescription database as provided in AS 17.30.200;

(12) establish standards for the independent administration by a pharmacist of vaccines and related emergency medications under AS 08.80.168, including the completion of an immunization training program approved by the board;

(13) establish standards for the independent dispensing by a pharmacist of an opioid overdose drug under AS 17.20.085, including the completion of an opioid overdose training program approved by the board;

(14) require that a licensed pharmacist register with the controlled substance prescription database under AS 17.30.200(o);

(15) establish the qualifications and duties of the executive administrator and delegate authority to the executive administrator that is necessary to conduct board business**;**

**(16) license and inspect the facilities of wholesale drug distributors, third-party logistics providers, and outsourcing facilities located outside the state under AS 08.80.159**.

*** Sec. 3.** AS 08.80.030 is amended by adding a new subsection to read:

(c) The minimum specifications for facilities, equipment, personnel, and procedures for the compounding, storage, and dispensing of drugs established under (b)(7) of this section must be consistent with the requirements of secs. 201 - 208, P.L. 113-54 (Drug Supply Chain Security Act).

*** Sec. 4.** AS 08.80.157 is amended by adding a new subsection to read:

(k) This section applies to wholesale drug distributors, third-party logistics providers, and outsourcing facilities located outside the state under AS 08.80.159.

*** Sec. 5.** AS 08.80 is amended by adding a new section to read:

**Sec. 08.80.159. Licensing and inspection of facilities outside of state.** (a)

Before shipping, mailing, or delivering prescription drugs to a licensee in the state or advertising in the state, a wholesale drug distributor, third-party logistics provider, or an outsourcing facility that is located outside the state shall

(1) obtain a license under AS 08.80.157;

(2) appoint an agent on whom process can be served in the state; and

(3) authorize inspection of the facility by a designee of the board under (c) of this section.

(b) In addition to the requirements of (a) of this section, an outsourcing facility shall

(1) register as an outsourcing facility with the United States Food and Drug Administration; and

(2) comply with the requirements of 21 U.S.C. 353b (Drug Quality and Security Act).

(c) Upon application by a wholesale drug distributor, third-party logistics provider, or an outsourcing facility for a license under this section, the board may

(1) require an inspection of the applicant's facility located outside the state; and

(2) approve a designee to conduct the inspection.

(d) The board shall adopt regulations necessary to implement this section.

*** Sec. 6.** AS 08.80 is amended by adding a new section to article 2 to read:

**Sec. 08.80.270. Executive administrator of the board.** (a) The board shall employ an executive administrator to carry out the duties established under (b) of this section. The executive administrator is the principal executive officer of the board. The executive administrator is in the partially exempt service under AS 39.25.120 and is entitled to receive a monthly salary equal to a step in Range 23 on the salary schedule set out in AS 39.27.011(a).

(b) The executive administrator shall

(1) perform duties associated with the licensing and regulation of licensees under this chapter as prescribed by the board; and

(2) serve as a liaison to the legislative and executive branches of state government, the media, and other state pharmacy boards.

*** Sec. 7.** AS 08.80.480 is amended by adding new paragraphs to read:

(37) "outsourcing facility" means a facility at one geographic location or address that is engaged in the compounding of sterile drugs for a facility at another geographic location;

(38) "third-party logistics provider" means an entity that provides or coordinates warehousing or other logistics services for a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of the product, and that does not take ownership of the product or have responsibility to direct the sale or disposition of the product.

*** Sec. 8.** AS 16.43.020 is amended to read:

**Sec. 16.43.020. Alaska Commercial Fisheries Entry Commission.** (a) There is established the Alaska Commercial Fisheries Entry Commission as a regulatory and quasi-judicial agency of the state. The commission consists of **two** [THREE] members appointed by the governor and confirmed by the legislature in joint session.

(b) The governor shall designate one member of the commission as **chair** [CHAIRMAN] of the commission. The **designated** member **serves** [DESIGNATED SHALL SERVE] as **chair** [CHAIRMAN] for a term of two years [,] and may be designated **chair** [CHAIRMAN] for successive two-year terms. **When there is a vacancy in the executive director position, the member serving as chair is responsible for and has authority over the internal administrative and personnel practices and procedures of the commission.**

*** Sec. 9.** AS 16.43.030(c) is amended to read:

(c) **If there is a** [A] vacancy on the commission**,** [DOES NOT IMPAIR THE AUTHORITY OF] a **single commissioner may** [QUORUM OF COMMISSIONERS TO] exercise all the powers and perform all the duties of the commission.

*** Sec. 10.** AS 16.43.040 is amended to read:

**Sec. 16.43.040. Quorum. Unless there is a vacancy on the commission, two** [TWO] members of the commission constitute a quorum for the transaction of business, for the performance of a duty, or for the exercise of a power of the commission.

*** Sec. 11.** AS 16.43.050 is amended to read:

**Sec. 16.43.050. Qualifications.** The commission shall consist of **two** [THREE] members with a broad range of professional experience, **neither** [NONE] of whom has a vested economic interest in an interim-use permit, entry permit, commercial fishing vessel or gear, or in any fishery resource processing or marketing business.

*** Sec. 12.** AS 16.43.060 is amended to read:

**Sec. 16.43.060. Compensation.** Members of the commission are in the exempt service and are entitled to a monthly salary equal to a step in Range **25** [27] of the salary schedule in AS 39.27.011.

*** Sec. 13.** AS 16.43.110 is amended by adding a new subsection to read:

(f) In case of a tie vote between commissioners in an adjudicatory proceeding, the decision of the hearing officer is the final administrative decision of the commission subject to review by a superior court under AS 44.62 (Administrative Procedure Act).

*** Sec. 14.** AS 16.43.960(d) is amended to read:

(d) **Except when there is a vacancy as provided in AS 16.43.030(c), the** [THE] show cause hearing shall be conducted before a quorum of commissioners and shall be presided over by a hearing officer appointed by the commission who shall rule on the presentation of evidence and other procedural matters. Hearings shall be conducted in accordance with regulations adopted under AS 16.43.110(b).

*** Sec. 15.** AS 39.25.120(c)(7) is amended to read:

(7) the principal executive officer of the following boards, councils, or commissions:

(A) Alaska Public Broadcasting Commission;

(B) Professional Teaching Practices Commission;

(C) Parole Board;

(D) Board of Nursing;

(E) Real Estate Commission;

(F) Alaska Royalty Oil and Gas Development Advisory Board;

(G) Alaska State Council on the Arts;

(H) Alaska Police Standards Council;

(I) Alaska Commission on Aging;

(J) Alaska Mental Health Board;

(K) State Medical Board;

(L) Governor's Council on Disabilities and Special Education;

(M) Advisory Board on Alcoholism and Drug Abuse;

(N) Statewide Suicide Prevention Council;

(O) State Board of Registration for Architects, Engineers, and Land Surveyors;

(P) Alaska Health Care Commission;

**(Q) Board of Pharmacy;**

*** Sec. 16.** The uncodified law of the State of Alaska is amended by adding a new section to read:

APPLICABILITY. AS 16.43.060, as amended by sec. 12 of this Act, applies to the compensation of commissioners of the Alaska Commercial Fisheries Entry Commission appointed after the effective date of sec. 12 of this Act.

*** Sec. 17.** The uncodified law of the State of Alaska is amended by adding a new section to read:

TRANSITION: REGULATIONS. The Department of Commerce, Community, and Economic Development and the Board of Pharmacy may adopt regulations necessary to implement the changes made by secs. 1 - 7 of this Act. The regulations take effect under AS 44.62 (Administrative Procedure Act), but not before the effective date of the relevant provision of this Act implemented by the regulation.

*** Sec. 18.** Sections 1, 6, and 8 - 17 of this Act take effect immediately under AS 01.10.070(c).

*** Sec. 19.** Except as provided in sec. 18 of this Act, this Act takes effect July 1, 2019.

# NABP Model Rules for the Licensure of Manufacturers, Repackagers, Third-Party Logistics Providers, and Wholesale Distributors

## Section 1. Requirements for Licensure.

Manufacturers, Repackagers, Third-Party Logistics Providers, and Wholesale Distributors that provide services within this State, whether located within this State or outside this State, shall be licensed by the Board and shall annually renew their license with the Board using an application provided by the Board. Third-Party Logistics Providers and Wholesale Drug Distributors must report license status to FDA as outlined in Federal law. Manufacturers, Repackagers, Third-Party Logistics Providers, and Wholesale Distributors cannot operate from a place of residence. Where operations are conducted at more than one location, each such location shall be licensed by the Board of Pharmacy.[1]

(a) Every Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor who engages in the Manufacturing, Repackaging, or Distribution of Prescription Drugs or Devices shall license annually with the Board by application and provide information required by the Board on an application approved by the Board, including but not limited to:

(1) all trade or business names used by the licensee (includes "is doing business as" and "formerly known as"), which cannot be identical to the name used by another unrelated entity licensed to purchase Prescription Drugs or Devices in the State;

(2) name(s) of the owner and operator of the licensee (if not the same person), including:

(i) if a Person: the name, business address, Social Security number, and date of birth;

(ii) if a partnership: the name, business address, and Social Security number and date of birth of each partner, and the name of the partnership and federal employer identification number;

(iii) if a corporation: the name, business address, Social Security number and date of birth, and title of each corporate officer and director, the corporate names, the state of incorporation, federal employer identification number, and the name of the parent company, if any; the name, business address, and Social Security number of each shareholder owning ten percent (10%) or more of the voting stock of the corporation, including over-the-counter (OTC) stock, unless the stock is traded on a major stock exchange and not OTC;

(iv) if a sole proprietorship: the full name, business address, Social Security number, and date of birth of the sole proprietor and the name and federal employer identification number of the business entity;

(v) if a limited liability company: the name of each member, the name of each manager, the name of the limited liability company and federal employer identification number, and the name of the state in which the limited liability company was organized; and

(vi) any other relevant information that the Board requires.

(3) name(s), business address(es), and telephone number(s) of a person(s) to serve as the Designated Representative(s) for each facility of a Wholesale Distributor that engages in the Wholesale Distribution of Prescription Drugs or Devices and additional information as required in Section 10 (Record Keeping);

[1] The application and screening process for licensing entities engaging in the Distribution of Product represents a critical point in efforts to prevent the introduction of Counterfeit and Contraband Products into the medication distribution system. An application that requires detailed information about the applicant and key individuals involved in the operations of the entity is critical.

(4) a list of all State and Federal licenses, registrations, or permits, including the license, registration, or permit numbers issued to the Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor by any other State and Federal authority that authorizes the Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor to Manufacture, purchase, possess, Repackage, or Distribute Prescription Drugs;

(5) a list of all disciplinary actions by State and Federal agencies against the Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor as well as any such actions against principals, owners, directors, or officers;

(6) a full description of each facility and warehouse, including all locations utilized for Prescription Drug storage and/or Wholesale Distribution. The description should include the following:
   (i) square footage;
   (ii) security and alarm system descriptions;
   (iii) terms of lease or ownership;
   (iv) address; and
   (v) temperature and humidity controls.

(7) a copy of the deed for the property on which the Manufacturer's, Repackager's, Third-Party Logistics Provider's, or Wholesale Distributor's establishment is located, if the property is owned by the Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor; or a copy of the Manufacturer's, Repackager's, Third-Party Logistics Provider's, or Wholesale Distributor's lease for the property on which the establishment is located that has an original term of not less than one (1) calendar year, if the establishment is not owned by the Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor;

(8) information regarding general and Product liability insurance, including copies of relevant policies;

(9) a description of the Manufacturer's, Repackager's, Third-Party Logistics Provider's, or Wholesale Distributor's Drug import and export activities; and

(10) a copy of the Manufacturer's, Repackager's, Third-Party Logistics Provider's, or Wholesale Distributor's written policies and procedures as required in Section 11 (Policies and Procedures).

(11) The information collected pursuant to Section 1(a)(6) and (a)(10) shall be made available only to the Board, a third party recognized by the Board, and to State and Federal law enforcement officials. The Board shall make provisions for protecting the confidentiality of the information collected under this section.

(b) A "surety" bond of not less than $100,000, or other equivalent means of security acceptable to the Board or a third party recognized by the Board such as insurance, an irrevocable letter of credit, or funds deposited in a trust account or financial institution, to secure payment of any administrative penalties imposed by the Board and any fees or costs incurred by the Board regarding that licensee when those penalties, fees, or costs are authorized under state law and the licensee fails to pay thirty (30) days after the penalty, fee, or costs becomes final. A separate "surety" bond or other equivalent means of security is not required for each company's separate locations or for affiliated companies/groups when such separate locations or affiliated companies/groups are required to apply for or renew their Third-Party Logistics Provider's or Wholesale Distributor's license with the Board. The Board may make a claim against such bond or other equivalent means of security until one year after the Third-Party Logistics Provider's or Wholesale Distributor's license ceases to be valid or until sixty (60) days after any administrative or legal proceeding before or on behalf of the Board that involves the Third-Party Logistics Provider or Wholesale Distributor is concluded, including any appeal, whichever occurs later. Manufacturers and Repackagers shall be exempt from

securing a "surety" bond or other equivalent means of security acceptable to the Board or a third party recognized by the Board. The Board may waive the bond requirement, if the Third-Party Logistics Provider or Wholesale Distributor:[2]

(1) has previously obtained a comparable surety bond or other equivalent means of security for the purpose of licensure in another state, where the Third-Party Logistics Provider or Wholesale Distributor possesses a valid license in good standing; or

(2) is a publicly held company.

(c) Every Manufacturer, Repackager, Third Party Logistics Provider, or Wholesale Distributor who engages in Manufacturing, Repackaging, or Wholesale Distribution shall submit a reasonable fee to be determined by the Board.

(d) Each facility that engages in Distribution must undergo an inspection by the Board or a third party recognized by the Board for the purpose of inspecting the Distribution operations prior to initial licensure and periodically thereafter in accordance with a schedule to be determined by the Board .

(e) All Manufacturers, Repackagers, Third-Party Logistics Providers, and Wholesale Distributors must publicly display or have readily available all licenses and the most recent inspection report administered by the Board if applicable.

(f) Changes in any information in this Section shall be submitted to the Board, or to a third party recognized by the Board, within 30 days of such change (unless otherwise noted).

(g) Information submitted by the Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor to the Board or a third party recognized by the Board that is considered trade secret or proprietary information, as defined under this State's privacy and trade secret/proprietary statutes, shall be maintained by the Board or a third party recognized by the Board as private or trade secret/proprietary information and be exempt from public disclosure.[3]

(h) Per Federal requirements, States shall license Third-Party Logistics Providers (those that provide storage and logistical operations related to Drug Distribution) separately from Wholesale Drug Distributors. Minimum requirements for Wholesale Drug Distributor licensure may also apply to Third-Party Logistics Providers if applicable.[4]

(i) Per Federal requirements, States shall license Repackagers and Manufacturers separately from Wholesale Drug Distributors. Minimum requirements for Wholesale Drug Distributor licensure may also apply to Repackagers and Manufacturers if applicable.

(j) Supply chain Trading Partners (Wholesale Drug Distributors and Third-Party Logistics Providers) should report State licensure status and other required information to FDA.

## Section 2. Minimum Qualifications.

(a) The Board will consider the following factors in determining the eligibility for, and renewal of, licensure of Persons who engage in the Wholesale Distribution of Drugs or Devices:

(1) any findings by the Board that the applicant has violated or been disciplined by a regulatory agency in any state for violating any Federal, State, or local laws relating to Drug or Device Wholesale Distribution;

(2) any criminal convictions of the applicant under Federal, State, or local laws;

[2] Although Wholesale Distributors may be licensed in multiple states, it is not intended for Wholesale Distributors to procure a separate "surety" bond (or other equivalent means) for each state of licensure. States should consider waiving this requirement if the Wholesale Distributor has procured a "surety" bond (or other equivalent means) for the purposes of licensure in another state, or if the wholesaler is a publicly traded company.

[3] The Board may designate a third party to conduct inspections and ensure that all requirements for licensure established by the legislature and Board are fulfilled. The NABP Verified-Accredited Wholesale Distributors® (VAWD®) program is available to the states.

[4] If a State does not have a licensure category for Third-Party Logistics Providers, facilities that engage in interstate transport of Prescription Mrugs must obtain Federal registration.

(3) the applicant's past experience in the Manufacture or Wholesale Distribution of Drugs or Devices;
(4) the furnishing by the applicant of false or fraudulent material in any application made in connection with Drug or Device Manufacturing or Wholesale Distribution;
(5) Suspension, sanction, or Revocation by federal, State, or local government against any license currently or previously held by the applicant or any of its owners for violations of State or Federal laws regarding Drugs or Devices;
(6) compliance with previously granted licenses of any kind;
(7) compliance with the requirements to maintain and/or make available to the Board licensing authority or to Federal, State, or local law enforcement officials those records required to be maintained by Wholesale Distributors; and
(8) any other factors or qualifications the Board considers relevant to and consistent with the public health and safety.

(b) The Board shall consider the results of a criminal and financial background check of the applicant, including but not limited to, all key personnel involved in the operations of the Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor, including the most senior Person responsible for facility operations, purchasing, and inventory control and the Person or Persons they report to; and all company officers, key management, principals, and owners with ten percent (10%) or greater ownership interest in the company (applying to non-publicly held companies only) to determine if an applicant or others associated with the ownership, management, or operations of the Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor have committed criminal acts that would constitute grounds for denial of licensure. The background check will be conducted in compliance with any applicable State and Federal laws, at the applicant's expense, and will be sufficient to include all States of residence since the Person has been an adult. Manufacturers shall be exempt from criminal and financial background checks.

(c) The applicant shall provide, and attest to, a statement providing a complete disclosure of any past criminal convictions and violations of the State and Federal laws regarding Drugs or Devices or an affirmation and attestation that the applicant has not been involved in, or convicted of, any criminal or prohibited acts.

## Section 3. Personnel.

Each Person that is issued an initial or renewal license as a Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor, whether in State or out of State, must designate in writing on a form required by the Board, a Person for each facility to serve as the Designated Representative.

(a) To be certified as a Designated Representative, a Person must:
(1) submit an application on a form furnished by the Board and provide information that includes, but is not limited to:
(i) information required to complete the criminal and financial background checks required under Section 2(b); [5]
(ii) date and place of birth;
(iii) occupations, positions of employment, and offices held during the past seven (7) years;

[5] Fingerprints represent one of the current means of verifying the identity of the person as well as providing a reliable means to conduct criminal background checks. As technology changes and other means become available to the Board such as retinal scanning or DNA sampling, the Board must stay current with such tec**h**nologies and amend rules as necessary and appropriate.

(iv) principal business and address of any business corporation, or other organization in which each such office of the Person was held or in which each such occupation or position of employment was carried on;

(v) whether the Person, during the past seven (7) years, has been enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating any Federal or State law regulating the possession, control, or Wholesale Distribution of Prescription Drugs or Devices, together with details of such events;

(vi) description of any involvement by the Person with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund, during the past seven (7) years, which Manufactured, Administered, Prescribed, Repackaged, Wholesale Distributed, or stored Prescription Drugs and Devices in which such businesses were named as a party in a lawsuit;

(vii) description of any criminal offense (not including minor traffic violations) of which the Person, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the Person pled guilty or nolo contendere. If the Person indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal of the criminal offense, the applicant must, within 15 days after the disposition of the appeal, submit to the Board a copy of the final written order of disposition;

(viii) photograph of the Person taken within the previous 30 days under procedures as specified by the Board;

(ix) name, address, occupation, and date and place of birth for each member of the Person's immediate family, unless the Person is employed by a Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor that is a publicly held company. As used in this subparagraph, the term "member of the immediate family" includes the Person's spouse(s), children, parents, siblings, the spouses of the Person's children, and the spouses of the Person's siblings; and

(x) any other information the Board deems relevant.

(2) have a minimum of two years of verifiable full-time managerial or supervisory experience in a Pharmacy or Wholesale Distribution facility licensed in this State or another state, where the Person's responsibilities included but were not limited to record keeping, storage, and shipment of Prescription Drugs or Devices;

(3) may serve as the Designated Representative for only one Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor at any one time, except where more than one licensed Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor is co-located in the same facility and such entities are members of an affiliated group, as defined in Section 1504 of the Internal Revenue Code;

(4) be actively involved in and aware of the actual daily operations of the Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor:

(i) employed full-time in a managerial position by the Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor;

(ii) physically present at the Manufacturer, Repackager, Third-Party Logistics Provider, or
Wholesale Distributor during normal business hours, except for time periods when absent due to illness, family illness or death, scheduled vacation, or other authorized absence; and

(iii) aware of, and knowledgeable about, all policies and procedures pertaining to the operations of the Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor.

(b) The information collected pursuant to Section 3(a) shall be made available only to the Board, a third party recognized by the Board, and to State and Federal law enforcement officials. The

Board and a third party recognized by the Board shall make provisions for protecting the confidentiality of the information collected under this section.

(c) Each licensed Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor located outside of this State that Distributes Prescription Drugs or Devices in this State shall designate a registered agent in this State for service of process. Any licensed Distributor that does not so designate a registered agent shall be deemed to have designated the Secretary of State of this State to be its true and lawful attorney, upon who may be served all legal processes in any action or proceeding against such licensed Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor growing out of or arising from such Manufacturing, Repackaging, or Distribution. A copy of any such service of process shall be mailed to such Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor by the Board by certified mail, return receipt requested, postage prepaid, at the address such licensed entity has designated on its application for licensure in this State. If any such Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor is not licensed in this State, service on the Secretary of State only shall be sufficient service.

(d) A Designated Representative must complete:[6]

(1) continuing education programs specified by the Board regarding Federal and State laws in regard to the Wholesale Distribution, handling, and storage of Prescription Drugs or Devices; or

(2) if no formal continuing education is specified by the Board, training programs that address applicable Federal and State laws and are provided by qualified in-house specialists, outside counsel, or consulting specialists with capabilities to help ensure compliance.

## Section 4. Minimum Requirements for the Storage and Handling of Prescription Drugs and for Establishment and Maintenance of Prescription Drug Records.

The following are required for the storage, handling, transport, and shipment of Prescription Drugs or Devices, and for the establishment and maintenance of Wholesale Distribution records by Wholesale Distributors, authorized Trading Partners, and their officers, agents, representatives, and employees.

(a) All facilities at which Prescription Drugs and Devices are received, stored, warehoused, handled, held, offered, marketed, displayed, or transported from shall:

(1) be of suitable construction to ensure that all Prescription Drugs and Devices in the facilities are maintained in accordance with the Product Labeling of such Prescription Drugs and Devices, or in compliance with official compendium standards such as the United State Pharmacopeia–USP-NF;

(2) be of suitable size and construction to facilitate cleaning, maintenance, and proper Wholesale Distribution operations;

(3) have adequate storage areas to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(4) have a quarantine area for storage of Prescription Drugs and Devices that are outdated, damaged, deteriorated, Misbranded, or Adulterated, Counterfeit, or suspected of being Counterfeit, otherwise unfit for Distribution, or that are in immediate or sealed secondary containers that have been opened;

(5) be maintained in a clean and orderly condition;

(6) be free from infestation of any kind;

(7) be a commercial location and not a personal dwelling or residence;

[6] The Board will need to ensure that continuing education programs for the desired content areas are available when considering the implementation of this requirement.

(8) provide for the secure and confidential storage of information with restricted access and policies and procedures to protect the integrity and confidentiality of the information;
(9) provide and maintain appropriate inventory controls in order to detect and document any theft, Counterfeiting, or diversion of Prescription Drugs or Devices.

(b) Wholesale Distributors, Third-Party Logistics Providers, or other Trading Partners involved in the Wholesale Distribution of controlled substances shall be duly registered with Drug Enforcement Administration (DEA) and appropriate state controlled substance agency and in compliance with all applicable laws and rules for the storage, handling, transport, shipment, and Wholesale Distribution of controlled substances.

## Section 5. Security.

(a) All facilities used for Wholesale Distribution shall be secure from unauthorized entry:
(1) access from outside the premises shall be kept to a minimum and be well-controlled;
(2) the outside perimeter of the premises shall be well-lighted; and
(3) entry into areas where Prescription Drugs or Devices are held shall be limited to authorized personnel; all facilities shall be equipped with an alarm system to detect entry after hours.

(b) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(c) All facilities shall be equipped with inventory management and control systems that protect against, detect, and document any instances of theft, diversion, or Counterfeiting.

(d) All common carriers used by a Wholesale Distributor or Third-Party Logistics Provider shall ensure security via one of the following:
(1) a verifiable security system; or
(2) a Board-approved accreditation or certification program.

(e) All facilities shall be equipped with security systems to protect the integrity and confidentiality of data and documents and make such data and documents readily available to the Board and other state and federal law enforcement officials.

## Section 6. Storage.

All Prescription Drugs and Devices shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the Product Labeling of such Prescription Drugs and Devices, or with requirements in the current edition of an official compendium such as the USP-NF.

(a) If no storage requirements are established for a Prescription Drug, the Prescription Drug may be held at "controlled" room temperature, as defined in an official compendium such as USP-NF, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(b) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment and/or logs shall be utilized to document proper storage of Prescription Drugs and Devices.

(c) Packaging of the Prescription Drugs and Devices should be in accordance with an official compendium such as USP-NF and identify any compromise in the integrity of the Prescription Drugs or Devices due to tampering or adverse storage conditions.

(d) Controlled substance Drugs should be isolated from non-controlled substance Drugs and stored in a secure area in accordance with Drug Enforcement Administration security requirements and standards.

(e) The record keeping requirements in Section 10 (Record Keeping) shall be followed for the Wholesale Distribution of all Prescription Drugs and Devices.

## Section 7. Operations.

Manufacturers, Repackagers, Third-Party Logistics Providers, and Wholesale Drug Distributors must comply with all reporting requirements and exchange Transaction History, Transaction Information, and Transaction Statements with authorized Trading Partners as outlined in Federal law.

## Section 8. Due Diligence.

(a) Supply chain Trading Partners (Manufacturers, Repackagers, Wholesale Distributors, and Dispensers) shall receive and transfer Product Transaction data history to subsequent purchasers per federal guidelines.

(b) Supply chain Trading Partners (Manufacturers, Repackagers, Wholesale Distributors, and Dispensers) shall establish a system to:

(1) Quarantine and investigate Suspect Product to determine if it is illegitimate.

(2) Notify FDA, the Board, and immediate Trading Partners if Illegitimate Product is found.

## Section 9. Record Keeping.

(a) Manufacturers, Repackagers, Third-Party Logistics Providers, and Wholesale Distributors shall establish and maintain inventories and records of all Transactions regarding the receipt and Distribution or other disposition of Prescription Drugs and Devices as outlined in Federal law. These records shall include:

(1) dates of receipt and Wholesale Distribution; or

(2) other disposition of the Prescription Drugs and Devices.

(b) Such records shall include the Inventories and records and shall be made available for inspection and photocopying by any authorized official of any State, Federal, or local governmental agency for a period of six (6) years following their creation date.

(c) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by an authorized official of any State or Federal governmental agency charged with enforcement of these rules.

(d) Wholesale Distributors, Third-Party Logistics Providers, Repackagers, and Manufacturers should maintain an ongoing list of Persons with whom they do business.

(e) All facilities shall establish and maintain procedures for reporting Counterfeit and Contraband or suspected Counterfeit and Contraband Drugs or Devices or Counterfeiting and Contraband or suspected Counterfeiting and Contraband activities to the Board and FDA.

(f) Wholesale Distributors shall maintain a system for the mandatory reporting of any theft, suspected theft, diversion, or other significant loss of any Prescription Drug or Device to the Board and FDA, and, where applicable, to DEA.[7]

## Section 10. Policies and Procedures.

[7] This information should be reported to NABP, if serving as a data collection repository, in addition to the other relevant authorities.

Manufacturers, Repackagers, Third-Party Logistics Providers, and Wholesale Distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, transport, and shipping and Wholesale Distribution of Prescription Drugs, including policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. Manufacturers, Repackagers, Third-Party Logistics Providers, and Wholesale Distributors shall include in their written policies and procedures the following:[8]

(a) A procedure to be followed for handling recalls and withdrawals of Prescription Drugs and Devices. Such procedure shall be adequate to deal with recalls and withdrawals due to:
  (1) Any action initiated at the request of FDA or any other federal, state, or local law enforcement or other government agency, including the Board of Pharmacy; or
  (2) Any volunteer action by the Manufacturer to remove defective or potentially defective Prescription Drugs or Devices from the market.

(b) A procedure to ensure that Manufacturers, Repackagers, Third-Party Logistics Providers, and Wholesale Distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of a strike, fire, flood, or other natural disaster, or other situations of local, State, or national emergency.

(c) A procedure to ensure that any outdated Prescription Drugs shall be segregated from other Prescription Drugs and either returned to the Manufacturer or destroyed in accordance with Federal and State laws, including all necessary documentation and the appropriate witnessing. This procedure shall provide for written documentation of the disposition of outdated Prescription Drugs.

(d) A procedure for the destruction of outdated Prescription Drugs in accordance with federal and state laws.

(e) A procedure for the disposing and destruction of containers, Labels, and packaging to ensure that the containers, Labels, and packaging cannot be used in Counterfeiting activities, including all necessary documentation, maintained for a minimum of three (3) years, and the appropriate witnessing of the destruction of any Labels, packaging, Immediate Containers, or containers in accordance with all applicable Federal and State requirements.

(f) A procedure for identifying, investigating and reporting significant Prescription Drug inventory discrepancies involving Counterfeit, suspect of being Counterfeit, Contraband, or suspect of being Contraband, in the inventory and reporting of such discrepancies as required to FDA, Board and/or appropriate Federal or State agency upon discovery of such discrepancies.

(g) A procedure for reporting criminal or suspected criminal activities involving the inventory of Prescription Drug(s) and Device(s) as required to the Board, FDA, and, if applicable, DEA.

(h) A procedure for verifying security provisions of Common Carriers.

## Section 11. Prohibited Acts.[9]

It is unlawful for a Person to knowingly and willfully perform or cause the performance of or aid and abet any of the following acts in this State:

[8] In developing policies and procedures for the management and quality improvement of the Wholesale Distribution activities of a Wholesale Distributor, the Board may want to refer to the Healthcare Distribution Management Association and the National Association of Chain Drug Stores.

[9] Boards should be advised that statutory amendments may be necessary in the State practice acts in order to properly integrate the prohibited and criminal acts. It is highly recommended that boards confer with Board Counsel before adopting the Model Rules to make certain that the appropriate statutory language exists in the state pharmacy practice act to support the Model Rules.

(a) the Manufacture, Repackaging, sale, delivery, or holding or offering for sale any Prescription Drug or Device that is Adulterated, Misbranded, Counterfeit, suspected of being Counterfeit, or has otherwise been rendered unfit for Distribution or Wholesale Distribution;

(b) the Adulteration, Misbranding, or Counterfeiting of any Prescription Drug or Device;

(c) the receipt of any Prescription Drug or Device that is Adulterated, Misbranded, stolen, obtained by fraud or deceit, Counterfeit, or suspected of being Counterfeit, or the delivery or proffered delivery of such Prescription Drug or Device for pay or otherwise;

(d) the Alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the Product Labeling of a Prescription Drug or Device or the commission of any other act with respect to a Prescription Drug or Device that results in the Prescription Drug or Device being Misbranded;

(e) the forging, Counterfeiting, simulating, or falsely representing of any Prescription Drug or Device without the authority of the Manufacturer, or using any mark, stamp, tag, label, or other identification device without the authorization of the Manufacturer;

(f) the purchase or receipt of a Prescription Drug or Device from a Person that is not licensed to Distribute Prescription Drugs or Devices to that purchaser or recipient;

(g) the sale or transfer of a Prescription Drug or Device to a Person who is not legally authorized to receive a Prescription Drug or Device;

(h) the sale or transfer of a Prescription Drug or Device from Pharmacies to Distributors for resale;[10]

(i) the failure to maintain or provide records as required by this Act and Rules;

(j) providing the Board or any of its representatives or any state or federal official with false or fraudulent records or making false or fraudulent statements regarding any matter within the provisions of this Act and Rules;

(k) the Wholesale Distribution of any Prescription Drug or Device that was:
  (1) purchased by a public or private hospital or other health care entity;
  (2) donated or supplied at a reduced price to a charitable organization; or
  (3) stolen or obtained by fraud or deceit.

(l) the failure to obtain a license or operating without a valid license when a license is required;

(m) the Obtaining of or attempting to obtain a Prescription Drug or Device by fraud, deceit, misrepresentation or engaging in misrepresentation or fraud in the Distribution or Wholesale Distribution of a Prescription Drug or Device;

(n) the Distributing of a Prescription Drug or Device to the patient without a Prescription or Prescription Order from a Practitioner licensed by law to use or prescribe the Prescription Drug or Device;

(o) the Distributing or Wholesale Distributing of a Prescription Drug or Device that was previously dispensed by a Pharmacy or distributed by a Practitioner; or

(p) the failure to report any Prohibited Act as listed in these Rules.

## Section 12. Criminal Acts.[11]

(a) A Person who, with intent to defraud or deceive, performs the act of Adulteration, Misbranding, or Counterfeiting of any Prescription Drug or Device commits a felony of the third degree.

[10] Returned purchases from Pharmacies to Wholesale Distributors are not considered to be "transfers, Distributions, or sales," and are not affected by this language.

[11] Boards should be advised that statutory amendments may be necessary in the State practice acts in order to properly integrate the prohibited and criminal acts. It is highly recommended that boards confer with Board Counsel before adopting the Model Rules to make certain that the appropriate statutory language exists in the state pharmacy practice act to support the Model Rules.

(b) A Person who engages in the Wholesale Distribution of Prescription Drug(s) who, with intent to defraud or deceive, falsely swears or certifies that he or she has authenticated any documents related to the Wholesale Distribution of Prescription Drugs, commits a felony of the third degree.

(c) A Person who engages in the Wholesale Distribution of Prescription Drug(s) or Device(s) and knowingly purchases or receives Prescription Drug(s) or Device(s) from a Person, not legally authorized to Wholesale Distribute Prescription Drug(s) or Device(s), in Wholesale Distribution commits a felony of the third degree.

(d) A Person who engages in the Wholesale Distribution of Prescription Drug(s) or Device(s) and knowingly sells, barters, ***brokers***, or transfers Prescription Drug(s) or Device(s) to a Person not legally authorized to purchase Prescription Drug(s) or Device(s), under the jurisdiction in which the Person receives the Prescription Drug(s) or Device(s) in a Wholesale Distribution, commits a felony of the third degree.

(e) A Person who knowingly possesses, actually or constructively, any amount of a Contraband Drug(s) or Device(s), who knowingly sells or delivers, or who possesses with intent to sell or deliver any amount of a Contraband Drug(s) or Device(s) commits a felony of the third degree.

(f) A Person who knowingly forges, Counterfeits, or falsely creates any Label for a Prescription Drug(s) or Device(s) or who falsely represents any factual matter contained in any Label of a Prescription Drug(s) or Device(s) commits a felony of the third degree.

(g) A Person who knowingly Manufactures, purchases, sells, delivers, or brings into the State, or who is knowingly in actual or constructive possession of any amount of Contraband Drug(s) or Device(s), commits a felony of the third degree.

(h) A Person who knowingly Manufactures, purchases, sells, delivers, or brings into the State, or who is knowingly in actual or constructive possession of any amount of Contraband Drug(s) or Device(s), and whose acts result in the death of a Person, commits a felony in the first degree.

(i) A Person found guilty of any offense under this section, under the authority of the Court convicting and sentencing the Person, shall be ordered to forfeit to the State any real or Personal property:

(1) used or intended to be used to commit, to facilitate, or to promote the commission of such offense; and

(2) constituting, derived from, or traceable to the gross proceeds that the defendant obtained directly or indirectly as a result of the offense. Any property or assets subject to forfeiture under this section may be seized pursuant to a warrant obtained in the same manner as a search warrant or as otherwise permitted by law, and held until the case against a defendant is adjudicated. Monies ordered forfeited, or proceeds from the sale of other assets ordered forfeited, shall be equitably divided between the Board and other agencies involved in the investigation and prosecution that led to the conviction. Other property ordered forfeited after conviction of a defendant may, at the discretion of the investigating agencies, be placed into official use by the Board or the agencies involved in the investigation and prosecution that led to the conviction.

## Section 13. Salvaging and Reprocessing.

Wholesale Distributors, Third-Party Logistics Providers, and Trading Partners shall be subject to the provisions of any applicable Federal, State, or local laws or rules that relate to Prescription Drug Product salvaging or reprocessing, including Chapter 21, parts 207, 210, and 211k of the Code of Federal Regulations.

## Section 14. Inspection and Accreditation by a Third Party.

(a) The Board shall have the authority to recognize a third party to inspect and accredit Wholesale Distributors.

(b) The Board may license by reciprocity a Wholesale Distributor and Third-Party Logistics Provider that is licensed under the laws of another state, if:
- (1) the requirements of that State are deemed by the Board to be substantially equivalent; or
- (2) the applicant is accredited by a third party recognized by the Board. An applicant that is accredited by a third party recognized and approved by the Board, shall not be subject to duplicative requirements set by the Board. If an applicant is inspected, but not accredited by a third party, that applicant must comply with the requirements set by the Board through regulation.

(c) Any applicant that is denied accreditation described under paragraph (a), shall have the right of review of the accreditation body's decision, by:
- (1) the accreditation body; and
- (2) the Board.

(d) The Board recognized accreditation body shall ensure that the proprietary information obtained during the accreditation process remains confidential and privileged.

(e) The Board may waive requirements of this Chapter, by regulation, for Wholesale Distributors that have obtained and maintain a Board-approved accreditation.

**Definitions:**

(a2) "Distribute" or "Distribution" means to sell, offer to sell, deliver, offer to deliver, ***broker***, give away, or transfer a Drug, whether by passage of title, physical movement, or both. The term does not include:
- (1) To Dispense or Administer;
- (2) Delivering or offering to deliver a Drug by a common carrier in the usual course of business as a common carrier; or
- (3) Providing a Drug sample to a patient by a Practitioner licensed to prescribe such Drug; a health care professional acting at the direction and under the supervision of a Practitioner; or the Pharmacy of a hospital or of another health care entity that is acting at the direction of such a Practitioner and that received such sample in accordance with the Act and regulations to administer or dispense.

(a7) "Third-Party Logistics Provider" means an entity that:
- (1) Provides or coordinates warehousing, Distribution, or other services on behalf of a Manufacturer, but does not take title to the Prescription Drug or have general responsibility to direct the Prescription Drug's sale or disposition; and
- (2) Is licensed as a Third-Party Logistics Provider.

(b7) "Trading Partner" means:
- (1) a Manufacturer, Repackager, Wholesale Distributor, or Dispenser from whom a Manufacturer, Repackager, Wholesale Distributor, or Dispenser accepts direct ownership of a Product or to whom a Manufacturer, Repackager, Wholesale Distributor, or Dispenser transfers direct ownership of a Product; or
- (2) a Third-Party Logistics Provider from whom a Manufacturer, Repackager, Wholesale Distributor, or Dispenser accepts direct possession of a Product or to whom a Manufacturer, Repackager, Wholesale Distributor, or Dispenser transfers direct possession of a Product.

(c7) "Wholesale Distribution" means the Distribution of a Drug or Device to a Person other than a consumer or patient, or receipt of a Drug or Device by a Person other than the consumer or patient, but does not include[12]:

(1) intracompany Distribution of any Drug between members of an affiliate or within a Manufacturer;
(2) the Distribution of a Drug or an offer to Distribute a Drug among hospitals or other Health Care Entities that are under common control;
(3) the Distribution of a Drug or an offer to Distribute a Drug for Emergency Medical Reasons, including a Public Health Emergency declaration made by the Secretary of the United States Department of Health and Human Services, except that, for purposes of this paragraph, a Drug shortage not caused by a Public Health Emergency shall not constitute an Emergency Medical Reason;
(4) the Dispensing of a Drug pursuant to a Prescription Drug Order;
(5) the Distribution of minimal quantities of a Drug by a licensed retail Pharmacy to a licensed Practitioner for office use;[13]
(6) the Distribution of a Drug or an offer to Distribute a Drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law;
(7) the purchase or other acquisition by a Dispenser, hospital, or other Health Care Entity of a Drug for use by such Dispenser, hospital, or other Health Care Entity;
(8) the Distribution of a Drug by the Manufacturer of such Drug;
(9) the receipt or transfer of a Drug by an authorized Third-Party Logistics Provider, provided that such Third-Party Logistics Provider does not take ownership of the Drug;
(10) a Common Carrier that transports a Drug, provided that the Common Carrier does not take ownership of the Drug;
(11) the Distribution of a Drug or an offer to Distribute a Drug by an authorized Repackager that has taken ownership or possession of the Drug and Repackages it in accordance with Federal law;
(12) salable Drug Returns when conducted by a Dispenser;
(13) the Distribution of a collection of finished medical Devices, which may include a Drug Product or biological Product, assembled in kit form strictly for the convenience of the purchaser or user (referred to in this subparagraph as a "medical convenience kit") if:

(l4) "Normal Distribution Channel" means a chain of custody for a Prescription Drug that goes from a Manufacturer of the Prescription Drug, the Manufacturer's Co-Licensee, the Manufacturer's Third-Party Logistics Provider, or the Manufacturer's Exclusive Distributor to:

(1) a Wholesale Distributor to a Pharmacy to a patient or other designated persons authorized by law to dispense or administer such Prescription Drug to a patient; or
(2) a Wholesale Distributor to a Chain Pharmacy Warehouse to that Chain Pharmacy Warehouse's intracompany Pharmacy to a patient or other designated persons authorized by law to dispense or administer such Prescription Drug to a patient; or
(3) a Chain Pharmacy Warehouse to that Chain Pharmacy Warehouse's intracompany Pharmacy to a patient or other designated persons authorized by law to dispense or administer such Prescription Drug to a patient; or
(4) as prescribed by the Board's regulations.

(b4) "Wholesale Distributor" means any Person (other than a Manufacturer, a Manufacturer's co-licensed partner, a Third-Party Logistics Provider, or Repackager) engaged in Wholesale Distribution of Prescription Drugs or Devices in or into the State.

## Section 501. Licensing.

(a) The following Persons located within this State, and the following Persons located outside this State that provide services to patients within this State, shall be licensed by the Board of Pharmacy and shall annually renew their license with the Board[14]:

(1) persons engaged in the Practice of Pharmacy (including Telepharmacy);
(2) dispensing Practitioners and Practitioner's facilities including those engaged in nonsterile Compounding;[15]
(3) persons engaged in the Manufacture or Repackaging of Drugs or Devices;
(4) persons engaged in the Wholesale Distribution of Drugs or Devices;
(5) persons engaged in Third-Party Logistics Provider activities of Drugs or Devices;
(6) pharmacies where Drugs or Devices are Dispensed, or Compounded, or Pharmacist Care Services are provided;
(7) Outsourcing Facilities;
(8) Pharmacy Benefits Managers; and
(9) Repository Programs

Where operations are conducted at more than one location, each such location shall be licensed by the Board of Pharmacy.

[14] State may require additional licensing/registration requirements.

[15] Licensed Practitioners authorized under the laws of this State to Compound Drugs and to Dispense Drugs to their patients in the practice of their respective professions shall meet the same standards, record keeping requirements, counseling, and all other requirements for the Dispensing of Drugs applicable to Pharmacists.

**From:** Carrillo, Laura N (CED)
**To:** "Richard Holt"
**Subject:** RE: Alaska
**Date:** Monday, August 06, 2018 1:43:00 PM
**Attachments:** image001.png

Added.

Thank you,

**Laura Carrillo**
Pharmacy Board Records & Licensing Supervisor
Prescription Drug Monitoring Program Manager
Telemedicine Business Registry Manager
CBPL - Professional Licensing
State of Alaska – DCCED
Board of Pharmacy/Telemedicine Phone: 907-465-1039
PDMP Phone: 907-269-8404
E-mail: laura.carrillo@alaska.gov
Fax: 907-465-2974

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**From:** Richard Holt <dokholt@mac.com>
**Sent:** Monday, August 06, 2018 12:32 PM
**To:** Carrillo, Laura N (CED) <laura.carrillo@alaska.gov>
**Subject:** Fwd: Alaska

Sent from my iPhone

Begin forwarded message:

> **From:** Leif Holm <lholm36@gmail.com>
> **Date:** August 6, 2018 at 12:28:41 PM AKDT
> **To:** Richard Holt <dokholt@mac.com>
> **Subject: Fwd: FW: Alaska**
>
> can you have this added to agenda if there is time, lis just emailed it to me for discussion. thx
>
> Leif
>
> ---------- Forwarded message ----------
> From: **Lis Houchen** <LHouchen@nacds.org>
> Date: Mon, Aug 6, 2018 at 12:16 PM
> Subject: FW: Alaska
> To: Leif Holm <lholm36@gmail.com>
>
> Leif, I'm sorry to bug you, but what are the chances we could get the 90/100 day rule changed to not apply to refills? In other words to apply to initial fills? I would appreciate your thoughts.

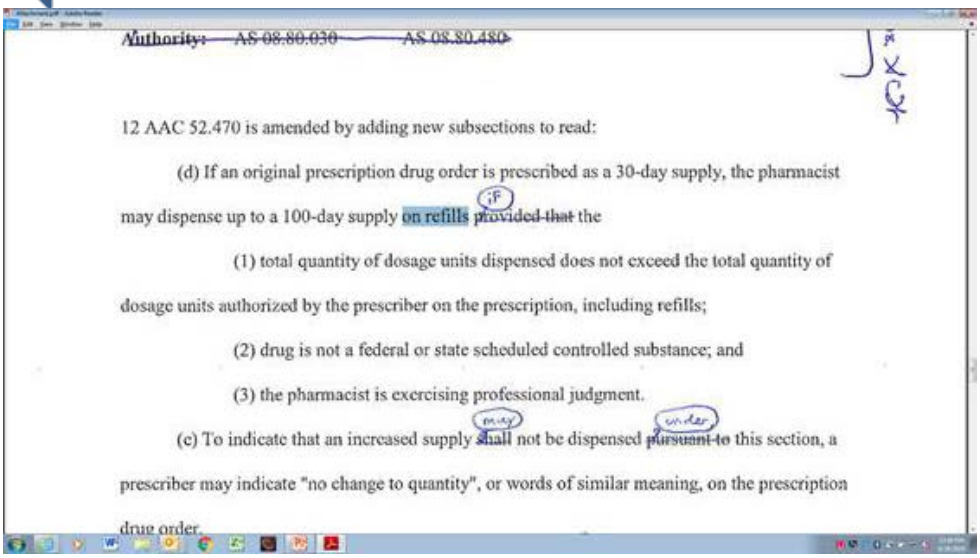
---

**From:** Walmsley, Lorri <lorri.walmsley@walgreens.com>
**Sent:** Thursday, July 5, 2018 12:41 PM
**To:** Lis Houchen <LHouchen@nacds.org>
**Subject:** Alaska

Lis,

Can we ask them to remove the word refills here? Attached is a CMS paper that talks about the benefits of adherence with 90 vs the cost of medication waste. The cost savings due to adherence is greater than that of potential waste so I believe we do have an argument to ask for the change.

Thanks for your help!!



~~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 100-day supply on refills ~~provided that~~ the

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

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

(3) the pharmacist is exercising professional judgment.

(c) 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.

Warm Regards,

*Lorri*

**Lorri Walmsley, RPh**

**Senior Manager, Pharmacy Affairs**

**Walgreen Co.** ¦ 5330 E. Washington D-105, Phoenix, AZ 85034
Mobile 602 214 6618


**Member of Walgreens Boots Alliance**



--
Leif J. Holm Pharm.D., President
Alaska Family Pharmacy
907-488-8101
907-347-6296 (cell)

**From:** Richard Holt
**To:** Carrillo, Laura N (CED)
**Subject:** Fwd: AKPhA on BOP August Agenda?
**Date:** Wednesday, August 01, 2018 12:39:59 PM

---

Please add to August meeting communications.

Thanks,

Sent from my iPhone

Begin forwarded message:

> **From:** Coleman Cutchins <coleman.cutchins@gmail.com>
> **Date:** July 23, 2018 at 5:45:36 PM AKDT
> **To:** AKPhA <akphrmcy@alaska.net>, 'Richard Holt' <dokholt@mac.com>
> **Cc:** "donna.bellino@alaska.gov" <donna.bellino@alaska.gov>, "island.pharm@juno.com" <island.pharm@juno.com>, "dirk@whitesalaska.com" <dirk@whitesalaska.com>, "Carenr@gci.net" <Carenr@gci.net>
> **Subject: RE: AKPhA on BOP August Agenda?**
>
> Just looking to clean some regulations (not necessarily statutes) up for more contemporary terminology. To match payers terms/expectations for cognitive service reimbursement.
>
> -Mainly in 08.80.480 section 21 we would like things more clearly spelled out, such as to change “Pharmaceutical care services” to “pharmaceutical care services including – Medication therapy management and post diagnostic disease management”
>
> -Also if time would allow regarding interns I would like to propose changing 12AAC52.120 to delete the sponsorship declaration requirement (Delete (5) and (12d)). And better define the intern license to include educational experience and employment.
>
> Thank you very much,
> Coleman
>
> ---
>
> **From:** AKPhA
> **Sent:** Friday, July 13, 2018 2:49 PM
> **To:** 'Richard Holt'
> **Cc:** donna.bellino@alaska.gov; Coleman.cutchins@gmail.com; island.pharm@juno.com; dirk@whitesalaska.com; Carenr@gci.net
> **Subject:** RE: AKPhA on BOP August Agenda?

Hi Rich!

Honestly, I'm not sure exactly what needs to happen as we go forward, but I thought the sooner we all get together to discuss the better!

Thanks!

Molly

Molly Gray
Executive Director
Alaska Pharmacists Association
203 W 15th Ave #100
Anchorage, AK 99501
Phone (907) 563-8880, FAX (907) 563-7880
Summer Office Hours: Monday, Wednesday, Friday, 1:00 - 3:30 pm
www.alaskapharmacy.org

*Dedicated to Preserving, Promoting &*
*Leading the Profession of Pharmacy in Alaska*

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**From:** Richard Holt [mailto:dokholt@mac.com]
**Sent:** Wednesday, July 11, 2018 5:54 PM
**To:** AKPhA
**Cc:** donna.bellino@alaska.gov; Coleman.cutchins@gmail.com; island.pharm@juno.com; dirk@whitesalaska.com; Carenr@gci.net
**Subject:** Re: AKPhA on BOP August Agenda?

Hi Molly.

Are the regulatory changes that you are addressing / recommending at this time to the board based on current authority under statute or would statutes have to be changed first?

If the statutes have to be changed then the best route would be to continue and make notes until the statute changes giving the needed authorities to address the regulations.

Thanks,
Rich

Sent from my iPhone

On Jul 9, 2018, at 2:50 PM, AKPhA <akphrmcy@alaska.net> wrote:

Hi Donna and Rich!

During our Board Planning Retreat end of May, we discussed ideas to help advance Provider Status efforts here in Alaska. We also have a Provider Status Workgroup now, (a subgroup of our Legislative Committee), which is chaired by Coleman Cutchins. It sounds like there might be some regulations that may need to be addressed/tweaked as we go forward. In an effort to keep everyone in the loop/brainstorm together as best we can, I was hoping perhaps Coleman and I could be added onto the Board of Pharmacy August meeting agenda? I see on the website the meeting is scheduled to be in Anchorage August 30-31st. I know you all have a ton of items to go through during those few in-person meetings, but do you think we could be added?

Let us know—thank you!

Molly

Molly Gray
Executive Director
Alaska Pharmacists Association
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Anchorage, AK 99501
Phone (907) 563-8880, FAX (907) 563-7880
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www.alaskapharmacy.org

*Dedicated to Preserving, Promoting &*
*Leading the Profession of Pharmacy in Alaska*

**Board of Pharmacy**
**State Pharmacist Licensure Exemption**

A pharmacist employed by a tribal health program in Alaska holding a license in another state in accordance with 25 U.S.C. 1621t are not required to become licensed by the Alaska Board of Pharmacy, however, a notification of employment must be submitted to the board. The notification must be submitted no later than 30 days after the pharmacist begins working at a tribal health program in this state as indicated in 12 AAC 52.150. Please use this form to notify the board of your employment and attach the documents as required below.

Name of Pharmacist: _____

State of licensure: _____ License Number: _____

Address: _____

Phone: _____ Email: _____

Name of Tribal Health Program: _____

Start date of employment: _____

Please attach the following to this notification:

□ Certified true copy of the current, valid pharmacist license from another jurisdiction:

**NOTE:** To obtain a "certified true copy," you must present the notary with the original document along with the photocopy. You must write, "I certify this is a true copy of the original document" and sign your name. The notary will compare the original document with the copy and then notarize your signature.

- AND EITHER -

□ proof of employment by a tribal health program that is operating under an agreement with the federal Indian Health Service under 25 U.S.C. 450-458ddd-2 (Indian Self-Determination and Education Assistance Act)

- OR –

□ proof of status as an independent contractor, including a copy of the contract, if the out-of-state pharmacist is working for the tribal health program as an independent contractor

I HEREBY CERTIFY that the information contained in this form is true and correct to the best of my knowledge. I further certify that all credentials supplied by me are true and correct and acknowledge that I must apply for licensure as a pharmacist in accordance with AS 08.80 before practicing beyond the scope my contract with a tribal health organization.

SIGN HERE ➡ _____
Signature of Applicant

SUBSCRIBED AND SWORN to before me, a notary public, in and for the State of _____ this ____ day of _____, 20____

_____
Notary Public

My Commission Expires: _____

**12 AAC 52.150. Proof of licensure for individual pharmacists working for tribal health programs.** (a) A pharmacist who engages in the practice of pharmacy in a tribal health program in this state and who is not already licensed by the board must provide the board notice that they are practicing under another license in accordance with 25 U.S.C. 1621t (sec. 221, Indian Health Care Improvement Act). Notice required under this section must be received no later than 30 days after an individual begins working at a tribal health program in this state, and must include

(1) a completed Alaska state pharmacist license exemption form provided by the department;

(2) a certified true copy of a current, valid pharmacist license in good standing from another jurisdiction; and

(3) a proof of employment by a tribal health program that is operating under an agreement with the federal Indian Health Service under 25 U.S.C. 450-458ddd-2 (Indian Self-Determination and Education Assistance Act); or

(b) proof of status as an independent contractor, including a copy of the contract, if the out-of-state pharmacist is working for the tribal health program as an independent contractor

(b) A pharmacist practicing under the exemption may not practice beyond the scope of the other state license.

(c) The licensing exemption does not extend to services provided to a non-tribal health program. In addition, an out-of-state licensed pharmacist working outside the scope of their contracted employment with a tribal health program must apply for licensure as a pharmacist in accordance with AS 08.80. (Eff. ____/____/_____, Register _____)

**Authority:** AS 08.80.003 AS 08.80.005 AS 08.80.030

**Commented [JMW1]:** Is there any intent to include other pharamacists not licensed in AK who work for the VA or US Military.

Pharmacists Association, 203 West 15th Avenue, #100, Anchorage, AK 99501, phone: (907) 563-8880, email: akphrmcy@alaska.net also provides certification information.

**12 AAC 52.330. ALTERNATIVE CONTINUING EDUCATION SCHEDULE.** An individual licensed under AS 08.80 may apply to the board for an alternative schedule of continuing education if the individual's failure to meet the continuing education requirements in 12 AAC 52.320 is due to illness or other extenuating circumstances.

**Authority:** AS 08.80.005 AS 08.80.030 AS 08.80.165

**12 AAC 52.340 APPROVED PROGRAMS.** (a) The following programs will be accepted by the board as continuing education for pharmacists and pharmacy technicians under 12 AAC 52.320 and 12 AAC 52.325:

(1) any program presented by a provider accredited by the ACPE;

(2) cardiopulmonary resuscitation(CPR) courses presented by the American Red Cross or the American Heart Association that lead to CPR certification; the board will accept no more than one contact hour of continuing education credit in a 24 month period for completion of a CPR course.

(b) The following programs will be accepted by the board as continuing education under 12 AAC 52.325, when the subject contributes directly to the professional competency of a pharmacy technician and is directly related to pharmacy principles and practice:

(1) any program presented or approved by the Alaska Pharmacists Association;

(2) any program presented or approved by the Pharmacy Technician Certification Board (PTCB) or the National Pharmacy Technician Association (NPTA).

(c) An individual who presents an approved continuing education program may receive credit for the time spent during the actual presentation of the program. An individual may not receive credit for the same presentation more than once during a licensing period.

**Authority:** AS 08.80.005 AS 08.80.147 AS 08.80.165
AS 08.80.030

**12 AAC 52.350. AUDIT OF RECORDS BY THE BOARD.** (a) The board will randomly audit renewal applications for verification of reported continuing education contact hours. To conduct an audit under this section, the board will access and evaluate continuing pharmacy education data reported to the ACPE-NABP CPE Monitor Service during the time period audited.

(b) Upon written request, a pharmacist or pharmacy technician shall provide the board with a copy of each certificate of completion for the continuing education units not reported to the ACPE-NABP CPE Monitor Service during the time period audited by the board.

(c) If the board disallows any continuing education contact units reported on behalf of or by a pharmacist or pharmacy technician, the pharmacist or pharmacy technician shall

(1) complete the number of disallowed contact hours in an approved program and report the completion to the board no later than 90 days after the date the board sends notification of the disallowed contact hours; and

(2) provide the board with copies of certificates of completion for all continuing education units

(A) not reported to the ACPE-NABP CPE Monitor Service; and

(B) completed for the next two licensing periods.

(d) A pharmacist or pharmacy technician who submits to the board a false or fraudulent record relating to the pharmacist's or pharmacy technician's satisfaction of a continuing education requirement under 12 AAC 52.320 or 12 AAC 52.325 is subject to disciplinary action by the board.

(e) In this section,

(1) "ACPE-NABP CPE Monitor Service" means the electronic tracking service of the ACPE and the National Association of Boards of Pharmacy for monitoring continuing pharmacy education that pharmacists and pharmacy technicians receive from participating providers;

(2) "certificate of completion" means a certificate or other document that

(A) is presented to a participant upon successful completion of a continuing education program that is not reported to the ACPE-NABP CPE Monitor Service; and

(B) contains the following information:

(i) the name of the participant;

(ii) the title and date of the program;

(iii) the name of the accredited provider;

(iv) the number of contact hours or continuing education units awarded;

(v) a dated, certifying signature of the accredited provider;

(vi) for a pharmacist renewal, the assigned ACPE universal program number.

**Authority:** AS 08.80.005 AS 08.80.165 AS 08.80.261
AS 08.80.030

## Outstanding Regulations (initially drafted in October 2017)

- 12 AAC 52.150 – Proof of Licensure Requirements for Individual Pharmacists Working for Tribal Health Programs (new section)
- 12 AAC 52.423(c) – Remote Pharmacy License (amendments)
- 12 AAC 52.425(a)(b)(e)(f)(g)(h)(j) – Telepharmacy System for a Remote Pharmacy (amendments)
- 12 AAC 52.465 – Controlled Substance Prescription Drug Orders (new section)
- 12 AAC 52.530 – Guidelines Relating to Sterile Pharmaceuticals
- 12 AAC 52.920 – Disciplinary Guidelines

**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 is amended by adding a new section to read:

**12 AAC 52.150. Proof of Licensure ~~License requirements~~ for individual pharmacists working for tribal health programs.** (a) A pharmacist who engages in the practice of pharmacy in a tribal health program in this state and who is not already licensed by the board must provide ~~be licensed by~~ the board notice ~~unless they notify the board~~ that they are practicing under another license in accordance with 25 U.S.C. 1621t (sec. 221, Indian Health Care Improvement Act). Notice required under this section must be received no later than 30~~14~~ days after an individual begins working ~~employment~~ at a tribal health program in this state, and must include

(1) a completed Alaska state pharmacist license exemption form provided by the department;

(2) a certified true copy of a current, valid pharmacist license in good standing from another jurisdiction; and

(3) (a) proof of employment by a tribal health program that is operating under an agreement with the federal Indian Health Service under 25 U.S.C. 450-458ddd-2 (Indian Self-Determination and Education Assistance Act); or

~~(4)~~ (b) proof of status as an independent contractor, including a copy of the contract, if the out-of-state pharmacist is working for ~~employed with~~ the tribal health program as an independent contractor ~~then the pharmacist must also provide a copy of the contract~~.

(b) A pharmacist practicing under the exemption may not practice beyond the scope of the other state license.

(c) The licensing exemption ~~only applies during time spent working for the tribal health~~

**Commented [JMW1]:** Is there any intent to include other pharamacists not licensed in AK who work for the VA or US Military.

~~program and~~ does not extend to services provided to a non-tribal health program. ~~"moonlighting".~~ In addition, an out-of-state licensed pharmacist working outside the scope of their contracted employment with a tribal health program must apply for licensure as a pharmacist in accordance with AS 08.80. (Eff. ____/____/_____, Register _____)

**Authority:** AS 08.80.003 AS 08.80.005 AS 08.80.030

12 AAC 52.240(b) is amended by adding new paragraphs to read:

(9) a prohibition on the administration or dispensing of any schedule I, II, III, or IV controlled substances; and

(10) an acknowledgement that the authorizing practitioner will not receive any compensation from a pharmacist or pharmacy as a result of the care or treatment of any patient under the agreement.

(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 52.423(c) is amended to read:

(c) An applicant for renewal of a remote pharmacy license must comply with the requirements of 12 AAC 52.300. [A REMOTE PHARMACY LICENSE MAY NOT BE RENEWED IF A NON-REMOTE PHARMACY OPENS FOR BUSINESS WITHIN TEN ROAD MILES OF THE REMOTE PHARMACY SITE UNLESS THE NON-REMOTE PHARMACY IS PREVENTED BY FEDERAL LAW FROM PROVIDING PHARMACY SERVICES TO ALL THE INDIVIDUALS WITHIN THE TEN ROAD MILES.] (Eff. 9/17/2011, Register 199; am ____/____/_____, Register _____)

**Commented [JMW2]:** Is this intended to reach remore pharmacy licenses at tribal health organizations?

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

12 AAC 52.425(a) is amended to read:

(a) Only a **pharmacist employed by a** central pharmacy located in this state may provide pharmacy services to a remote pharmacy through a telepharmacy system. A telepharmacy system must be conducted under the direct supervision of a pharmacist **located in this state**. The pharmacist-in-charge of a **remote** [CENTRAL] pharmacy may supervise one or more remote pharmacies.

The introductory language of 12 AAC 52.425(b) is amended to read:

(b) Before a **pharmacist employed by a** central pharmacy may provide pharmacy services to a remote pharmacy, the telepharmacy system between the central pharmacy and remote pharmacy must be tested by the supervising pharmacist of the central pharmacy and found to operate properly. The supervising pharmacist of the central pharmacy shall make the results of the test available to the board upon request. The computer link and video link with sound of the telepharmacy system must include at least one of the following:

• • •

12 AAC 52.425(e) is amended to read:

(e) Drugs may be shipped to a remote pharmacy [ONLY] from the central pharmacy **or a wholesale distributor**. Drugs must be shipped in a sealed container with an itemized list of the product contained. The itemized list of drugs shipped must be kept on file at both the central pharmacy and the remote pharmacy for at least two years from the date that the drugs are

shipped. [ITEMIZED RECORDS OF DRUGS SHIPPED OR RECEIVED MUST BE VERIFIED BY THE SUPERVISING PHARMACIST AT BOTH THE CENTRAL PHARMACY AND THE REMOTE PHARMACY.]

12 AAC 52.425(f) is amended to read:

(f) A remote pharmacy must keep a record of all prescriptions filled at that location. The central pharmacy must **have access to the records** [ALSO MAINTAIN A RECORD] of the prescriptions **dispensed by** [FILLED AT] the remote pharmacy. [THE RECORD MUST DISTINGUISH PRESCRIPTIONS FILLED AT THE REMOTE PHARMACY FROM THOSE FILLED AT THE CENTRAL PHARMACY AND AT OTHER REMOTE PHARMACY LOCATIONS.]

12 AAC 52.425(g) is amended to read:

(g) The prescription label of a prescription drug **dispensed** [DISTRIBUTED] by a remote pharmacy must meet the requirements of 12 AAC 52.480.

12 AAC 52.425(h) is amended to read:

(h) Under a telepharmacy system a prescription drug is considered as being dispensed by the [CENTRAL PHARMACY AND DISTRIBUTED BY THE] remote pharmacy. A prescription drug may not be **dispensed** [DISTRIBUTED] by a remote pharmacy until a pharmacist **employed by** [AT] the central pharmacy has verified the finished prescription product through the telepharmacy system.

12 AAC 52.425(j) is repealed:

(j) Repealed ____/____/_____ [THE PHARMACIST-IN-CHARGE OF THE

CENTRAL PHARMACY MUST ENSURE THAT THE REMOTE PHARMACY IS IN COMPLIANCE WITH ALL LAWS, INCLUDING REGULATIONS, GOVERNING THE ACTIVITIES OF THE PHARMACY]. (Eff. 2/15/2006, Register 177; am ____/____/_____, Register _____)

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

12 AAC 52 is amended by adding a new section to read:

**12 AAC 52.465. Controlled substance prescription drug orders.** (a) A prescription drug order for a schedule II controlled substance may be partially filled if prescribed for

(1) a terminally ill patient or a patient residing in a long term care facility, in accordance with 21 CFR §1306.13; or

(2) a patient who is not terminally ill or residing in a long term care facility if

(A) the partial fill is requested by the patient or the practitioner that wrote the prescription;

(B) the total quantity dispensed in all partial filling does not exceed the total quantity prescribed;

(C) each partial fill is electronically documented in the patient record;

(D) the remaining portions are filled not later than 30 days after the date on which the prescription is written; and

(E) it only occurs at the pharmacy where the original prescription order is on file. (Eff. ____/____/_____, Register _____)

**Authority:** AS 08.80.005 AS 08.80.030 AS 08.80.345

12 AAC 52.530(a) is amended to read:

(a) **A** [EXCEPT AS PROVIDED IN (b) OF THIS SECTION, A] pharmacy or pharmacist may [NOT] accept a drug for return or exchange after the drug has been taken from the premises where the drug was sold, distributed, or dispensed **if**

**(1) the prescription was dispensed in a manner inconsistent with the original prescription drug order; or**

**(2) the medication was recalled by the manufacturer or FDA; and**

**(3) it is segregated from the normal pharmacy inventory and may not be dispensed**.

Commented [JMW3]: How does this apply if the durg may not be accepted for return?

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

**Authority:** AS 08.80.005 AS 08.80.030

12 AAC 52.920(a)(19) is amended to read:

(19) discriminating on the basis of race, religious creed, color, national origin, ancestry, **sexual orientation, gender identity,** or sex in the provision of a service that is part of the practice of pharmacy;

12 AAC 52.920(a) is amended by adding a new paragraph to read:

(22) failing to meet continuing education requirements will result in a $100 civil fine per missing continuing education credit hour for pharmacists and a $25 civil fine per missing continuing education credit hour for technicians.

Commented [JMW4]: This is the only subparagph of paragraph (a) that sets a particular penalty. If the desire is to set a fine, it should be a separate subparagraph in the nature of (b) or (c)

(Eff. 1/16/98, Register 145; 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

## 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 is amended by adding a new section to read:

**12 AAC 52.150. Proof of licensure for individual pharmacists working for tribal health programs.** (a) A pharmacist who engages in the practice of pharmacy in a tribal health program in this state and who is not already licensed by the board must provide the board notice that they are practicing under another license in accordance with 25 U.S.C. 1621t (sec. 221, Indian Health Care Improvement Act). Notice required under this section must be received no later than 30 days after an individual begins working at a tribal health program in this state, and must include

(1) a completed Alaska state pharmacist license exemption form provided by the department;

(2) a certified true copy of a current, valid pharmacist license in good standing from another jurisdiction; and

(A) proof of employment by a tribal health program that is operating under an agreement with the federal Indian Health Service under 25 U.S.C. 450-458ddd-2 (Indian Self-Determination and Education Assistance Act); or

(B) proof of status as an independent contractor, including a copy of the contract, if the out-of-state pharmacist is working for the tribal health program as an independent contractor.

(b) A pharmacist practicing under the exemption may not practice beyond the scope of the other state license.

(c) The licensing exemption does not extend to services provided to non-tribal health program. In addition, an out-of-state licensed pharmacist working outside the scope of their

contracted employment with a tribal health program must apply for licensure as a pharmacist in accordance with AS 08.80. (Eff. ____/____/_____, Register _____)

**Authority:** AS 08.80.003 AS 08.80.005 AS 08.80.030

12 AAC 52.240(b) is amended by adding new paragraphs to read:

(9) a prohibition on the administration or dispensing of any schedule I, II, III, or IV controlled substances; and

(10) an acknowledgement that the authorizing practitioner will not receive any compensation from a pharmacist or pharmacy as a result of the care or treatment of any patient under the agreement.

(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 52.423(c) is amended to read:

(c) An applicant for renewal of a remote pharmacy license must comply with the requirements of 12 AAC 52.300. [A REMOTE PHARMACY LICENSE MAY NOT BE RENEWED IF A NON-REMOTE PHARMACY OPENS FOR BUSINESS WITHIN TEN ROAD MILES OF THE REMOTE PHARMACY SITE UNLESS THE NON-REMOTE PHARMACY IS PREVENTED BY FEDERAL LAW FROM PROVIDING PHARMACY SERVICES TO ALL THE INDIVIDUALS WITHIN THE TEN ROAD MILES.] (Eff. 9/17/2011, Register 199; am ____/____/_____, Register _____)

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

12 AAC 52.425(a) is amended to read:

(a) Only a **pharmacist employed by a** central pharmacy located in this state may provide

pharmacy services to a remote pharmacy through a telepharmacy system. A telepharmacy system must be conducted under the direct supervision of a pharmacist **located in this state**. The pharmacist-in-charge of a **remote** [CENTRAL] pharmacy may supervise one or more remote pharmacies.

The introductory language of 12 AAC 52.425(b) is amended to read:

(b) Before a **pharmacist employed by a** central pharmacy may provide pharmacy services to a remote pharmacy, the telepharmacy system between the central pharmacy and remote pharmacy must be tested by the supervising pharmacist of the central pharmacy and found to operate properly. The supervising pharmacist of the central pharmacy shall make the results of the test available to the board upon request. The computer link and video link with sound of the telepharmacy system must include at least one of the following:

• • •

12 AAC 52.425(e) is amended to read:

(e) Drugs may be shipped to a remote pharmacy [ONLY] from the central pharmacy **or a wholesale distributor**. Drugs must be shipped in a sealed container with an itemized list of the product contained. The itemized list of drugs shipped must be kept on file at both the central pharmacy and the remote pharmacy for at least two years from the date that the drugs are shipped. [ITEMIZED RECORDS OF DRUGS SHIPPED OR RECEIVED MUST BE VERIFIED BY THE SUPERVISING PHARMACIST AT BOTH THE CENTRAL PHARMACY AND THE REMOTE PHARMACY.]

12 AAC 52.425(f) is amended to read:

(f) A remote pharmacy must keep a record of all prescriptions filled at that location. The

central pharmacy must **have access to the records** [ALSO MAINTAIN A RECORD] of the prescriptions **dispensed by** [FILLED AT] the remote pharmacy. [THE RECORD MUST DISTINGUISH PRESCRIPTIONS FILLED AT THE REMOTE PHARMACY FROM THOSE FILLED AT THE CENTRAL PHARMACY AND AT OTHER REMOTE PHARMACY LOCATIONS.]

12 AAC 52.425(g) is amended to read:

(g) The prescription label of a prescription drug **dispensed** [DISTRIBUTED] by a remote pharmacy must meet the requirements of 12 AAC 52.480.

12 AAC 52.425(h) is amended to read:

(h) Under a telepharmacy system a prescription drug is considered as being dispensed by the [CENTRAL PHARMACY AND DISTRIBUTED BY THE] remote pharmacy. A prescription drug may not be **dispensed** [DISTRIBUTED] by a remote pharmacy until a pharmacist **employed by** [AT] the central pharmacy has verified the finished prescription product through the telepharmacy system.

12 AAC 52.425(j) is repealed:

(j) Repealed ____/____/_____ [THE PHARMACIST-IN-CHARGE OF THE CENTRAL PHARMACY MUST ENSURE THAT THE REMOTE PHARMACY IS IN COMPLIANCE WITH ALL LAWS, INCLUDING REGULATIONS, GOVERNING THE ACTIVITIES OF THE PHARMACY]. (Eff. 2/15/2006, Register 177; am ____/____/_____, Register _____)

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

12 AAC 52 is amended by adding a new section to read:

**12 AAC 52.465. Controlled substance prescription drug orders.** (a) A prescription drug order for a schedule II controlled substance may be partially filled if prescribed for

(1) a terminally ill patient or a patient residing in a long term care facility, in accordance with 21 CFR §1306.13; or

(2) a patient who is not terminally ill or residing in a long term care facility if

(A) the partial fill is requested by the patient or the practitioner that wrote the prescription;

(B) the total quantity dispensed in all partial filling does not exceed the total quantity prescribed;

(C) each partial fill is electronically documented in the patient record;

(D) the remaining portions are filled not later than 30 days after the date on which the prescription is written; and

(E) it only occurs at the pharmacy where the original prescription order is on file. (Eff. ____/____/_____, Register _____)

**Authority:** AS 08.80.005 AS 08.80.030 AS 08.80.345

12 AAC 52.530(a) is amended to read:

(a) **A** [EXCEPT AS PROVIDED IN (b) OF THIS SECTION, A] pharmacy or pharmacist may [NOT] accept a drug for return or exchange after the drug has been taken from the premises where the drug was sold, distributed, or dispensed **if**

**(1) the prescription was dispensed in a manner inconsistent with the original prescription drug order; or**

**(2) the medication was recalled by the manufacturer or FDA; and**

**(3) it is segregated from the normal pharmacy inventory and may not be**

**dispensed**.

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

**Authority:** AS 08.80.005 AS 08.80.030

12 AAC 52.920(a)(19) is amended to read:

(19) discriminating on the basis of race, religious creed, color, national origin, ancestry, **sexual orientation, gender identity,** or sex in the provision of a service that is part of the practice of pharmacy;

12 AAC 52.920(a) is amended by adding a new paragraph to read:

(23) failing to meet continuing education requirements will result in a $100 civil fine per missing continuing education credit hour for pharmacists and a $25 civil fine per missing continuing education credit hour for technicians.

(Eff. 1/16/98, Register 145; am 6/7/2018, Register 226; 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

## 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 52.020 is amended to read:

**12 AAC 52.020. Facility license.** (a) An applicant for a facility license shall submit

(1) the fees required in 12 AAC 02.310;

(2) a completed application on a form provided by the department;

(3) within 14 days after commencement of business, a completed self-inspection of the premises questionnaire on a form provided by the department; and

(4) the name of the pharmacy or pharmacist that will provide consultant pharmacist services as required in AS 08.80.390, if applicable.

(b) Repealed 1/17/2007.

(c) An application for a remote or other pharmacy license must include the name of the pharmacist designated to be the pharmacist-in-charge as required in AS 08.80.330 and 12 AAC 52.200.

(d) An application for a pharmacy license must include the name and specific location of each remote pharmacy that will be under that pharmacy's control.

(e) An application for a remote pharmacy license must include the name and, if it has been issued, the license number of the pharmacy that is the central pharmacy.

**(f) In accordance with AS 08.80.330, a pharmacy cannot be open for business without a pharmacist-in-charge on the license.** (Eff. 1/16/98, Register 145; am 2/26/2000, Register 153; am 2/11/2004, Register 169; am 2/15/2006, Register 177; am 1/17/2007, Register 181; am ____/____/_____, Register _____)

**Authority:** AS 08.80.005 AS 08.80.157 AS 08.80.330

AS 08.80.030

The introductory language of 12 AAC 52.050(a)(1) is amended to read:

(a) When a pharmacy ceases operations, the pharmacist-in-charge of that pharmacy shall

(1) **notify** [SUBMIT TO] the board **on a form provided by the department** [A WRITTEN NOTICE] of the cessation of pharmacy operations; the **form** [WRITTEN NOTICE] must be submitted within 10 days after the cessation of operations and include

**• • •**

(Eff. 1/16/98, Register 145; am 1/17/2007, Register 181; am ____/____/_____, Register _____)

**Authority:** AS 08.80.005 AS 08.80.157 AS 08.80.330

AS 08.80.030

12 AAC 52.200 is amended to read:

**12 AAC 52.200. Pharmacist-in-charge.** (a) Before the board will issue a license to a pharmacy, the owner of the pharmacy must designate a pharmacist who practices in that pharmacy location as the pharmacist-in-charge of the pharmacy in accordance with AS 08.80.330. For a remote pharmacy, the owner of the central pharmacy must designate a pharmacist in the central pharmacy as the pharmacist-in-charge of the remote pharmacy. The board will indicate the name of the pharmacist-in-charge on the face of the pharmacy license.

(b) The responsibilities of the pharmacist-in-charge include

(1) compliance with all laws and regulations governing the activities of the pharmacy;

(2) training of all pharmacy personnel;

(3) establishing policies and procedures for pharmacy operations;

(4) maintaining required records;

(5) storage of all materials, including drugs and chemicals;

(6) establishing and maintaining effective controls against theft or diversion of prescription drugs; and

(7) on request, reporting to the board the names of all pharmacists employed by the pharmacy.

(c) A pharmacist designated to replace the pharmacist-in-charge of a pharmacy shall notify the board within 10 days of that designation, 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(3).

**(d) An out-going pharmacist-in-charge shall notify the board within 10 days when they are no longer the current pharmacist-in-charge of the licensed facility on a form provided by the department.**

**(e) In accordance with AS 08.80.330, a pharmacy cannot be open for business without a pharmacist-in-charge on the license.** (Eff. 1/16/98, Register 145; am 2/26/2000, Register 153; am 2/15/2006, Register 177; am 6/29/2018, Register 226; 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 53.340(a)(1) is amended to read:

(1) any program presented by a provider accredited by the ACPE **and results in a continuing education certificate showing the date of the course and the ACPE Universal Activity Number associated with the program**;

(Eff. 1/16/98, Register 145; am 5/5/2000, Register 154; am 5/15/2004, Register 170; am 2/15/2006, Register 177; am 8/12/2007, Register 183; am ____/____/_____, Register _____)

**Authority:** AS 08.80.005 AS 08.80.147 AS 08.80.165

AS 08.80.030

12 AAC 52.500(a) is amended to read:

(a) For the purpose of dispensing [A REFILL OF] a prescription drug order, original prescription drug order information may be transferred between pharmacies if the requirements of 12 AAC 52.460 and this section are met.

(Eff. 1/16/98, Register 145; am 7/9/2017, Register 223; am ____/____/_____, Register _____)

**Authority:** AS 08.80.005 AS 08.80.030

12 AAC 52.510 is amended to read:

**12 AAC 52.510. Substitution.** (a) A pharmacist may dispense **a substitute drug** [AN EQUIVALENT DRUG] product instead of the prescribed drug if

(1) the prescribing practitioner does not indicate 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;

(2) the patient is notified and consents to the substitution;

(3) **repealed ____/____/_____** [THE EQUIVALENT DRUG PRODUCT COSTS THE PATIENT LESS THAN THE PRESCRIBED DRUG PRODUCT]; and

(4) for the **substitute** drug product actually dispensed, the pharmacy record contains one of the following:

(A) the drug product's manufacturer or distributor;

(B) national drug code number;

(C) short name code; or

(D) trade name.

(b) The determination of the **substitute** drug product to be dispensed for a prescription drug order is a professional responsibility of the pharmacist. A pharmacist may not dispense any product that in the pharmacist's professional opinion is not **a substitute** [AN EQUIVALENT DRUG PRODUCT] as the term **"substitute"** ["EQUIVALENT DRUG PRODUCT"] is defined in AS 08.80.480.

**(c) In AS 08.80.295(e), "entry into an electronic records system" means creating an electronic dispensing record in the patient profile of the pharmacy computer system regardless if the practitioner has direct electronic access to the pharmacy computer system.**

(Eff. 1/16/98, Register 145; am 10/9/2008, Register 188; am 6/29/2018, Register 226; am ____/____/_____, Register _____)

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

12 AAC 52.995(a) is amended by adding new paragraphs to read:

(37) in AS 08.80.261(8), "gross immorality" means conduct that goes flagrantly beyond accepted standards of what is right or just in behavior or is unmitigated in any way;

(38) "moral turpitude" means

(A) conduct that is considered contrary to community standards of justice, honesty, or good morals;

(B) conduct that is wrong in itself even if no statute were to prohibit the conduct; or

(C) a crime that includes a conviction or indictment of

(i) homicide;

(ii) manslaughter;

(iii) assault;

(iv) stalking;

(v) kidnapping;

(vi) sexual assault;

(vii) sexual abuse of a minor;

(viii) unlawful exploitation of a minor, including possession or distribution of child pornography;

(ix) indecent exposure;

(x) unlawful distribution or possession for distribution of a controlled substance;

(xi) prostitution;

(xii) sex trafficking;

(xiii) murder;

(xiv human trafficking;

(xv) criminal sexual conduct;

(xvi) incest;

(xvii) robbery;

(xviii) extortion;

(xix) forgery;

(xx) theft;

(xxi) endangering the welfare of a child;

(xxii) endangering the welfare of a vulnerable adult; or

(xxiii) reckless endangerment.

(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 6/7/2018, Register 226; am ____/____/_____, Register _____)

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|---|---|---|---|
| **Authority:** | AS 08.80.005 | AS 08.80.157 | AS 17.30.200 |
| | AS 08.80.030 | AS 11.71.900 | AS 17.30.900 |

# LAWS OF ALASKA

# 2018

**Source**
CSHB 240(FIN)

**Chapter No.**
_____

## AN ACT

Relating to prescription prices available to consumers; relating to penalties for certain pharmacy or pharmacist violations; relating to the registration and duties of pharmacy benefits managers; relating to procedures, guidelines, and enforcement mechanisms for pharmacy audits; relating to the cost of multi-source generic drugs and insurance reimbursement procedures; relating to the duties of the director of the division of insurance; and providing for an effective date.

_____

**BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF ALASKA:**

THE ACT FOLLOWS ON PAGE 1

**AN ACT**

Relating to prescription prices available to consumers; relating to penalties for certain pharmacy or pharmacist violations; relating to the registration and duties of pharmacy benefits managers; relating to procedures, guidelines, and enforcement mechanisms for pharmacy audits; relating to the cost of multi-source generic drugs and insurance reimbursement procedures; relating to the duties of the director of the division of insurance; and providing for an effective date.

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*** Section 1.** AS 08.80.297 is amended by adding a new subsection to read:

(b) No contract or agreement may prohibit a pharmacy, pharmacist, or pharmacy benefits manager from informing a patient of a less costly alternative for a prescription drug or medical device or supply, which may include the amount the patient would pay without the use of a health care plan.

*** Sec. 2.** AS 08.80.297 is amended by adding new subsections to read:

(c) A pharmacist or person acting at the direction of a pharmacist shall notify the patient if a known less costly alternative for a prescription drug or medical device or supply is available, which may include the amount the patient would pay without the use of a health care plan.

(d) In this section,

(1) "health care plan" means a policy, contract, benefit, or agreement that provides, delivers, arranges for, pays for, or reimburses any of the costs of health care services under

(A) a health care insurance plan as defined under AS 21.54.500;

(B) a governmental or employee welfare benefit plan under 29 U.S.C. 1001 - 1191 (Employee Retirement Income Security Act of 1974);

(C) a plan offered under AS 39.30.090 or 39.30.091;

(D) a federal governmental plan as defined under AS 21.54.500;

(E) the Medicaid or Medicare program; or

(F) a self-insured employer benefit plan;

(2) "pharmacy benefits manager" has the meaning given in AS 21.27.955.

*** Sec. 3.** AS 08.80.460(a) is amended to read:

(a) **Except for a violation of AS 08.80.297, a** [A] person who violates a provision of this chapter is guilty of a class B misdemeanor.

*** Sec. 4.** AS 08.80.460(b) is amended to read:

(b) A person who violates the provisions of AS 08.80.295 **or 08.80.297 may be punished** [IS PUNISHABLE] by a civil fine in an amount established by the board in a schedule or schedules establishing the amount of civil fine for a particular violation. The schedule or schedules shall be adopted by the board by regulation. Any civil fine imposed under this section may be appealed in the manner provided for appeals in AS 44.62 (Administrative Procedure Act).

*** Sec. 5.** AS 21.27 is amended by adding new sections to read:

**Article 10. Pharmacy Benefits Managers.**

**Sec. 21.27.901. Registration of pharmacy benefits managers; scope of business practice.** (a) A person may not conduct business in the state as a pharmacy benefits manager unless the person is registered with the director as a third-party administrator under AS 21.27.630.

(b) A pharmacy benefits manager registered under AS 21.27.630 may

(1) contract with an insurer to administer or manage pharmacy benefits provided by an insurer for a covered person, including claims processing services for and audits of payments for prescription drugs and medical devices and supplies;

(2) contract with network pharmacies;

(3) set the cost of multi-source generic drugs under AS 21.27.945; and

(4) adjudicate appeals related to multi-source generic drug reimbursement.

**Sec. 21.27.905. Renewal of registration.** (a) A pharmacy benefits manager shall biennially renew a registration with the director.

(b) To renew a registration under this section, a pharmacy benefits manager shall pay a renewal fee established by the director. The director shall set the amount of the renewal fee to allow the renewal and oversight activities of the division to be self-supporting.

**Sec. 21.27.910. Pharmacy audit procedural requirements.** (a) When a pharmacy benefits manager conducts an audit of the records of a pharmacy, the period covered by the audit of a claim may not exceed two years from the date that the claim was submitted to or adjudicated by the pharmacy benefits manager, whichever is earlier. Except as required under AS 21.36.495, a claim submitted to or adjudicated by a pharmacy benefits manager does not accrue interest during the audit period.

(b) A pharmacy benefits manager conducting an on-site audit shall give the pharmacy written notice of at least 10 business days before conducting an initial audit.

(c) A pharmacy benefits manager may not conduct

(1) an audit during the first seven calendar days of any month unless agreed to by the pharmacy;

(2) more than one on-site audit of a pharmacy within a 12-month period; or

(3) on-site audits of more than 250 separate prescriptions at one pharmacy within a 12-month period unless fraud by the pharmacy or an employee of the pharmacy is alleged.

(d) If an audit involves clinical or professional judgment, the individual conducting the audit must

(1) be a pharmacist who is licensed and in good standing under AS 08.80; or

(2) conduct the audit in consultation with a pharmacist who is licensed and in good standing under AS 08.80.

(e) A pharmacy, in responding to an audit, may use

(1) verifiable statements or records, including medication administration records of a nursing home, assisted living facility, hospital, physician, or other authorized practitioner, to validate the pharmacy record;

(2) a legal prescription to validate claims in connection with prescriptions, refills, or changes in prescriptions, including medication administration records, prescriptions transmitted by facsimile, electronic prescriptions, or documented telephone calls from the prescriber or the prescriber's agent.

(f) A pharmacy benefits manager shall audit each pharmacy under the same standards and parameters as other similarly situated pharmacies in a network pharmacy contract in this state.

**Sec. 21.27.915. Overpayment or underpayment.** (a) When a pharmacy benefits manager conducts an audit of a pharmacy, the pharmacy benefits manager shall base a finding of overpayment or underpayment by the pharmacy on the actual overpayment or underpayment and not on a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs, except as provided in (b) of this section.

(b) A pharmacy benefits manager may resolve a finding of overpayment or underpayment by entering into a settlement agreement with the pharmacy. The settlement agreement

(1) must comply with the requirements of AS 21.36.125; and

(2) may be based on a statistically justifiable projection method.

(c) A pharmacy benefits manager may not include the dispensing fee amount in a finding of an overpayment unless

(1) a prescription was not actually dispensed;

(2) the prescriber denied authorization;

(3) the prescription dispensed was a medication error by the pharmacy; or

(4) the identified overpayment is solely based on an extra dispensing fee.

**Sec. 21.27.920. Recoupment.** (a) When a pharmacy benefits manager conducts an audit of a pharmacy, the pharmacy benefits manager shall base the recoupment of overpayments on the actual overpayment of the claim, except as provided in AS 21.27.915(b).

(b) A pharmacy benefits manager conducting an audit of a pharmacy may not

(1) use extrapolation in calculating recoupments or penalties for audits, unless required by state or federal contracts;

(2) assess a charge-back, recoupment, or other penalty against a pharmacy solely because a prescription is mailed or delivered at the request of a patient; or

(3) receive payment

(A) based on a percentage of the amount recovered; or

(B) for errors that have no actual financial harm to the patient or medical plan.

**Sec. 21.27.925. Pharmacy audit reports.** (a) A pharmacy benefits manager shall deliver a preliminary audit report to the pharmacy audited within 60 days after the conclusion of the audit.

(b) A pharmacy benefits manager shall allow the pharmacy at least 30 days following receipt of the preliminary audit report to provide documentation to the pharmacy benefits manager to address a discrepancy found in the audit. A pharmacy benefits manager may grant a reasonable extension upon request by the pharmacy.

(c) A pharmacy benefits manager shall deliver a final audit report to the pharmacy within 120 days after receipt of the preliminary audit report, settlement

agreement, or final appeal, whichever is latest.

**Sec. 21.27.930. Pharmacy audit appeal; future repayment.** (a) A pharmacy benefits manager conducting an audit shall establish a written appeals process.

(b) Recoupment of disputed funds or repayment of funds to the pharmacy benefits manager by the pharmacy, if permitted by contract, shall occur, to the extent demonstrated or documented in the pharmacy audit findings, after final internal disposition of the audit, including the appeals process. If the identified discrepancy for an individual audit exceeds $15,000, future payments to the pharmacy may be withheld pending finalization of the audit.

(c) A pharmacy benefits manager may not assess against a pharmacy a charge-back, recoupment, or other penalty until the pharmacy benefits manager's appeals process has been exhausted and the final report or settlement agreement issued.

**Sec. 21.27.935. Fraudulent activity.** When a pharmacy benefits manager conducts an audit of a pharmacy, the pharmacy benefits manager may not consider unintentional clerical or record-keeping errors, including typographical errors, writer's errors, or computer errors regarding a required document or record, to be fraudulent activity. In this section, "fraudulent activity" means an intentional act of theft, deception, misrepresentation, or concealment committed by the pharmacy.

**Sec. 21.27.940. Pharmacy audits; restrictions.** The requirements of AS 21.27.901 - 21.27.955 do not apply to an audit

(1) in which suspected fraudulent activity or other intentional or wilful misrepresentation is evidenced by a physical review, a review of claims data, a statement, or another investigative method; or

(2) of claims paid for under the medical assistance program under AS 47.07.

**Sec. 21.27.945. Drug pricing list; procedural requirements.** (a) A pharmacy benefits manager shall

(1) make available to each network pharmacy at the beginning of the term of the network pharmacy's contract, and upon renewal of the contract, the methodology and sources used to determine the drug pricing list;

(2) provide a telephone number at which a network pharmacy may

contact an employee of a pharmacy benefits manager to discuss the pharmacy's appeal;

(3) provide a process for a network pharmacy to have ready access to the list specific to that pharmacy;

(4) review and update applicable list information at least once every seven business days to reflect modification of list pricing;

(5) update list prices within one business day after a significant price update or modification provided by the pharmacy benefits manager's national drug database provider; and

(6) ensure that dispensing fees are not included in the calculation of the list pricing.

(b) When establishing a list, the pharmacy benefits manager shall use

(1) the most up-to-date pricing data to calculate reimbursement to a network pharmacy for drugs subject to list prices;

(2) multi-source generic drugs that are sold or marketed in the state during the list period.

**Sec. 21.27.950. Multi-source generic drug appeal.** (a) A pharmacy benefits manager shall establish a process by which a network pharmacy, or a network pharmacy's contracting agent, may appeal the reimbursement for a multi-source generic drug. A pharmacy benefits manager shall resolve an appeal from a network pharmacy within 10 calendar days after the network pharmacy or the contracting agent submits the appeal.

(b) A network pharmacy, or a network pharmacy's contracting agent, may appeal a reimbursement from a pharmacy benefits manager for a multi-source generic drug if the reimbursement for the drug is less than the amount that the network pharmacy can purchase from two or more of its contracted suppliers.

(c) A pharmacy benefits manager may grant a network pharmacy's appeal if an equivalent multi-source generic drug is not available at a price at or below the pharmacy benefits manager's list price for purchase from national or regional wholesalers who operate in the state. If an appeal is granted, the pharmacy benefits manager shall adjust the reimbursement of the network pharmacy to equal the network

pharmacy acquisition cost for each paid claim included in the appeal.

(d) If the pharmacy benefits manager denies a network pharmacy's appeal, the pharmacy benefits manager shall provide the network pharmacy with the

(1) reason for the denial;

(2) national drug code of an equivalent multi-source generic drug that has been purchased by another network pharmacy located in the state at a price that is equal to or less than the pharmacy benefits manager's list price within seven days after the network pharmacy appeals the claim; and

(3) name of a pharmaceutical wholesaler who operates in the state in which the drug may be acquired by the challenging network pharmacy.

(e) A network pharmacy may request a hearing under AS 21.06.170 - 21.06.240 for an adverse decision from a pharmacy benefits manager within 30 calendar days after receiving the decision. The parties may present all relevant information to the director for the director's review.

(f) The director shall enter an order that

(1) grants the network pharmacy's appeal and directs the pharmacy benefits manager to make an adjustment to the disputed claim;

(2) denies the network pharmacy's appeal; or

(3) directs other actions considered fair and equitable.

**Sec. 21.27.955. Definitions.** In AS 21.27.901 - 21.27.955,

(1) "audit" means an official examination and verification of accounts and records;

(2) "claim" means a request from a pharmacy or pharmacist to be reimbursed for the cost of filling or refilling a prescription for a drug or for providing a medical supply or device;

(3) "extrapolation" means the practice of inferring a frequency or dollar amount of overpayments, underpayments, invalid claims, or other errors on any portion of claims submitted, based on the frequency or dollar amount of overpayments, underpayments, invalid claims, or other errors actually measured in a sample of claims;

(4) "list" means the list of multi-source generic drugs for which a

predetermined reimbursement amount has been established such as a maximum allowable cost or maximum allowable cost list or any other list of prices used by a pharmacy benefits manager;

(5) "multi-source generic drug" means any covered outpatient prescription drug that the United States Food and Drug Administration has determined is pharmaceutically equivalent or bioequivalent to the originator or name brand drug and for which there are at least two drug products that are rated as therapeutically equivalent under the United States Food and Drug Administration's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations";

(6) "network pharmacy" means a pharmacy that provides covered health care services or supplies to an insured or a member under a contract with a network plan to act as a participating provider;

(7) "pharmacy" has the meaning given in AS 08.80.480;

(8) "pharmacy acquisition cost" means the amount that a pharmaceutical wholesaler or distributor charges for a pharmaceutical product as listed on the pharmacy's invoice;

(9) "pharmacy benefits manager" means a person that contracts with a pharmacy on behalf of an insurer to process claims or pay pharmacies for prescription drugs or medical devices and supplies or provide network management for pharmacies;

(10) "recoupment" means the amount that a pharmacy must remit to a pharmacy benefits manager when the pharmacy benefits manager has determined that an overpayment to the pharmacy has occurred.

*** Sec. 6.** The uncodified law of the State of Alaska is amended by adding a new section to read:

APPLICABILITY. (a) AS 21.27.901 - 21.27.955, enacted by sec. 5 of this Act, apply to audits of pharmacies conducted by pharmacy benefits managers and contracts entered into or renewed on or after the effective date of sec. 5 of this Act.

(b) AS 08.80.297(b), enacted by sec. 1 of this Act, applies to contracts entered into or renewed on or after the effective date of sec. 1 of this Act.

(c) In this section, "pharmacy" and "pharmacy benefits manager" have the meanings

given in AS 21.27.955, enacted by sec. 5 of this Act.

*** Sec. 7.** The uncodified law of the State of Alaska is amended by adding a new section to read:

TRANSITIONAL PROVISIONS: REGULATIONS. The division of insurance may adopt regulations necessary to implement the changes made by this Act. The regulations take effect under AS 44.62 (Administrative Procedure Act), but not before the effective date of the law implemented by the regulation.

*** Sec. 8.** The uncodified law of the State of Alaska is amended by adding a new section to read:

REVISOR'S INSTRUCTIONS. The revisor of statutes is requested to renumber AS 21.27.900 as AS 21.27.990. The revisor of statutes is requested to change "AS 21.27.900" to "AS 21.27.990" in AS 21.36.475(c)(2) and (4) and AS 21.97.900(27).

*** Sec. 9.** Sections 1, 3, 6(b), and 7 of this Act take effect immediately under AS 01.10.070(c).

*** Sec. 10.** Except as provided in sec. 9 of this Act, this Act takes effect July 1, 2019.

*State of Alaska*

*Office of the Governor*

**Governor Bill Walker**
**requests the pleasure of your company at the**
**bill signing for HB 240**

***Drug Pricing; Pharmacy Benefits Managers***

September 4, 2018
Ron's Apothecary Shoppe
9101 Mendenhall Mall Road
Juneau, Alaska 99801

*Governor's remarks and bill signing*
*8:00am - 8:30am*

RSVP
victoria.schoenheit@alaska.gov