#### Board Members:

Ashley Schaber, Pharmacist (Chairperson)

James Henderson, Pharmacist

> Carla Hebert, Pharmacist

> Ramsey Bell, Pharmacist

Sylvain Nouvion, Pharmacist

> C. Saharai Thompson, Pharmacy Technician

Sara Rasmussen, Public Member

#### Staff:

Michael Bowles, Executive Administrator

Briggham Perez, Records and Licensing Supervisor

> Amy Glenn, Licensing Examiner

Sarah Jones, Licensing Examiner

Beth Harp, Licensing Examiner

**Upcoming Meetings:** 

November 14, 2024



## ALASKA BOARD OF PHARMACY MEETING AGENDA

**AUGUST 20, 2024** 

Discussion of the following topics may require executive session. Only authorized members will be permitted to remain in the Board/Zoom room during executive session.

#### **Meeting Details**

Meeting Name: Alaska Board of Pharmacy Quarterly Meeting

Meeting Start Time: 9:00 AM

Meeting Start Date: August 20, 2024

Meeting End Time: 5:00 PM

Meeting End Date: August 20, 2024

Meeting Locations: 1. Board/Staff - Suite 1560, Atwood Building, Anchorage, AK

2. Zoom for Public Attendees (Limited In-Person Space)

Meeting Registration Link:

https://us02web.zoom.us/meeting/register/tZMtcuGvrjovG9aLGkE

PaSglH-p8z2i twbM

Dial ID: 870 5870 1512

Passcode: 194717

#### Links

Board of Pharmacy Homepage: <a href="mailto:pharmacy.alaska.gov">pharmacy.alaska.gov</a>

Prescription Drug Monitoring Program State page: pdmp.alaska.gov

#### **Agenda**

- 1. Roll Call/Call to Order (9:00 9:02)
- 2. Ethics Disclosures (9:02-9:03)
- 3. Consent Agenda Items (9:03 9:05)
  - Review/Approve Meeting Agenda
  - NABP Delegate Resolution
  - Review/Approve Previous Meeting Minutes
    - o April 11, 2024
  - Review Lost or Stolen Controlled Substances/DEA 106s
  - Review Well Being Index
    - o APhA Well-Being Index for Pharmacy Personnel, April 2024 Edition
    - o APhA Well-Being Index for Pharmacy Personnel, May 2024 Edition
    - o APhA Well-Being Index for Pharmacy Personnel, June 2024 Edition
- 4. Investigations Review (9:05 9:45)
  - Introduction of New Investigator, Greg Gober
  - Holly Handley, Investigator
    - o Investigative Report
    - Discuss Potential Investigator Training Opportunities
    - o Case Reviews, Confidential Executive Session
      - **2023-000430**
      - **2**023-001122
      - **2**023-001200
      - **2024-000101**
      - **2**024-000122
      - **2**024-000196
      - **2**024-000197
      - **2**024-000222
      - **2024-000248**
      - **2**024-000339

- 5. Division of Corporations, Business, and Professional Licensing Updates (9:45 11:15)
  - Melissa Dumas, Administrative Operations Manager (9:45 10:00)
    - Budget Report for 3rd Quarter Fiscal Year 2024
    - Fee Change Process
  - Lisa Sherrell, PDMP Manager (10:00 10:15)
    - PDMP Updates
    - o PDMP Work Group Update
    - o PDMP Disciplinary Matrix Update
  - Michael Bowles, Executive Administrator of the Board of Pharmacy (10:15 11:15)
    - Application Review Confidential Executive Session
    - North Star Behavioral Health System Request One Pharmacist in Charge for Multiple Pharmacies
    - Update of Renewal Period
    - Decision Making Framework
    - Regulation Project Opening Questionnaire
- 6. Public Comment Period (11:15 11:30)
- 7. Industry Updates (11:30 12:30)
  - Dr. Sarah Spencer, DO, FASAM Ninilchik Traditional Council (11:30 12:00)
  - Dr. Tom Wadsworth, PharmD, BCPS Dean, UAA/ISU College of Pharmacy (12:00 12:15)
  - Dr. Charles Semling, PharmD Pharmacy & Ancillary Services Manager, Alaska
     Department of Health (12:15 12:30)
- 8. Adjourn for Lunch (12:30 1:00)
- 9. Roll Call/Call to Order (12:30 12:35)
- 10. Public Comment Period (12:35 12:50)
- 11. Board Business (12:50 4:50)
  - NABP Annual Meeting Summary
    - Ashley Schaber and Michael Bowles
      - NABP Verify
  - DEA Supply Chain Conference Summary
    - James Henderson

#### ALASKA DEPARTMENT OF COMMERCE, COMMUNITY, AND ECONOMIC DEVELOPMENT

- Drug Order Logistics
  - o Sara Watson, CPhT, Manager, State Regulatory Outreach, Cardinal Health
  - o Will Dane, Senior Director, State Government Affairs, Healthcare Distribution Alliance
- Review Strategic Plan
- Investigative Committee Discussion
- Emerging Topics
  - Sara Chambers, Boards and Regulations Advisor
  - Pharmacists Administering Injectables
  - o IV Hydration Clinics
  - Compounding Weight Loss Drugs
- Controlled Substance Advisory Committee Discussion
- Way Forward on Just Culture
  - Possible Partnerships within Alaska
  - Expectations of CQI Programs
- Board Letter Commission on Human Rights
- Statutes Discussion
  - o HB 226 Review
- Regulations Discussion
  - Regulation Project 2024200135 Public Comment Review
  - Streamlining Regulations to Incorporate Standard of Care Concept
  - Background Checks
    - Review and Discuss SBAR
  - Emergency Refills
  - Continuing Education
    - Attending Meetings
    - Advanced Cardiac Life Support
    - Other Continuing Medical Education
  - Name Tags to Identify Staff
  - o Remove Excessive Reinstatement Fees for Pharmacists
  - Remove Notarization Requirement for Applications

#### ALASKA DEPARTMENT OF COMMERCE, COMMUNITY, AND ECONOMIC DEVELOPMENT

- 2024 Upcoming Conference Attendee Discussion
  - AKPhA Health System Pharmacy and Leadership Conference, Girdwood, AK –
     September 12-14, 2024
    - Attending Member C. Saharai Thompson
  - Alaska Hospital and Healthcare Association Annual Conference, Girdwood, AK September 24-25, 2024
    - Attending Member James Henderson
  - o NABP Executive Officer Forum, Mount Prospect, Il September 25-26, 2024
    - Executive Administrator Michael Bowles
  - NABP Task Force to Review Institutional Pharmacy and Compounding Model Rules,
     Mount Prospect, II September 31 October 01, 2024
    - Attending Member Ashley Schaber
  - o NABP District Meeting, Albuquerque, NM October 20-24, 2024
    - Executive Administrator Michael Bowles
    - Attending Member Carla Hebert
  - o NABP Member Forum, Mount Prospect, Il December 04-05, 2024
    - Attending Member TBD
  - o AKPhA Annual Meeting, Anchorage, AK February 14-16, 2025
    - Executive Administrator Michael Bowles
    - Attending Member TBD
  - NABP Committee on Law Enforcement/Legislation, Mount Prospect, Il March 03-04,
     2024
    - Executive Administrator Michael Bowles
  - o NABP Annual Meeting, Ft. Lauderdale, FL May 13-16, 2024
    - Executive Administrator Michael Bowles
    - Attending Member TBD
    - Attending Member TBD
- Tentative 2025 Meeting Dates
  - o February TBD, 2025
  - o May 22, 2025
  - o August 21, 2025

#### ALASKA DEPARTMENT OF COMMERCE, COMMUNITY, AND ECONOMIC DEVELOPMENT

- o November 20, 2025
- Tasks List Review and Update
- 12. Chair Final Comments (4:50 5:00)
  - Set Regulation Committee Special Meeting Date
  - Next Quarterly Meeting November 14, 2024
- 13. Adjourn (5:00)

#### Acronym Key:

AKPhA - Alaska Pharmacy Association

APhA - American Pharmacists Association

BCPS - Pharmacotherapy Specialty Certification

CPhT - Certified Pharmacy Technician

CQI - Continuous Quality Improvement

DEA - Drug Enforcement Administration

DO - Doctor of Osteopathic Medicine

PHARMD - Doctor of Pharmacy

FASAM - Fellow, American Society of Addiction Medicine

ISU - Idaho State University

NABP - National Association of Boards of Pharmacy

PDMP - Prescription Drug Monitoring Program

SBAR - Situation, Background, Assessment, and Recommendation

TBD - To Be Determined

UAA - University of Alaska, Anchorage

## Alaska Board of Pharmacy Agenda Item #1



Roll Call/Call to Order

#### **Alaska Board of Pharmacy Roster**

Board Member Name	Initial Appointment	Reappointed	Term End
Ashley Schaber, PharmD	07/01/2021	03/01/2024	03/01/2028
Sylvain Nouvion, PharmD., Ph.D.	05/31/2023		03/01/2027
James Henderson, RPh	03/01/2017	03/01/2021	03/01/2025
Ramsey Bell, RPh	03/01/2022		03/01/2026
Carla Hebert, RPh	01/05/2023	03/01/2024	03/01/2028
C. Saharai Thompson, CPhT	05/24/2024		03/01/2028
Sara Rasmussen, Public Member	03/01/2023		03/01/2027

Name	Position	Committee Membership/Additional Duties
Ashley Schaber	Chair	Statutes and Regulations
James Henderson	Vice Chair	Statutes and Regulations, Compounding
Ramsey Bell	Secretary	Well-Being
Carla Hebert		Compounding, Well-Being
Sara Rasmussen		Statutes and Regulations, Controlled Substances Advisory Committee Chair
Sylvain Nouvion		Statutes and Regulations
C. Saharai Thompson		

## Alaska Board of Pharmacy Agenda Item #2



**Ethics Disclosures** 

## Alaska Board of Pharmacy Agenda Item #3



Consent Agenda Items

## Delegates Approve Four Resolutions at the 120<sup>th</sup> NABP Annual Meeting

MOUNT PROSPECT, IL – Delegates from the member boards of pharmacy adopted four resolutions during the 120<sup>th</sup> National Association of Boards of Pharmacy<sup>®</sup> (NABP<sup>®</sup>) Annual Meeting, held in Fort Worth, TX, on May 14-17, 2024. The resolutions address the following:

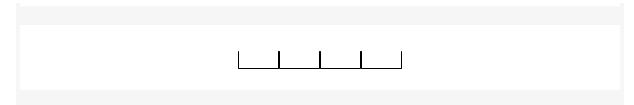
- Drug Shortages. NABP will collaborate with organizations, including industry, federal agencies, pharmacy associations, and pharmacy benefit managers, to develop additional strategies and technological tools to address drug shortages.
- Expanding Access to NABP Competency Assessment Examinations.

  NABP will convene a task force to examine feasible options for NABP and state boards of pharmacy to expand access to NABP competency examination administration processes. Such options may include, but are not limited to, providing more testing center choices, enhancing communication between schools and colleges of pharmacy and NABP to alleviate delays in the posting of graduate transcripts, and allowing candidates to take the North American Pharmacist Licensure Examination<sup>®</sup> and/or Multistate Pharmacy Jurisprudence Examination<sup>®</sup> prior to anticipated graduation.
- Development of National Forum for Pharmacy Professional Recovery Programs. NABP will collaborate with other interested stakeholders to convene a forum of pharmacist recovery programs and/or other state recovery programs to discuss common topics of interest, issues, and concerns.

Additionally, a recognition resolution honoring members of the Association who have passed away was unanimously approved.

The complete text of the resolutions will be available in the <u>News</u> section on the NABP website.

NABP is the independent, international, and impartial Association that assists its member boards in protecting the public health. Visit <a href="https://www.nabp.pharmacy">www.nabp.pharmacy</a> to learn more.



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NABP 1600 Feehanville Dr Mount Prospect, IL 60056



# Well-being Index For Pharmacy Personnel

State Report
For State Boards of Pharmacy
NABP District Seven States

April 2024





pharmacist.com



# DISTRESS PERCENT CHANGES National and District March 2024 versus April 2024





### **Changes in Distress Levels**



As of April 2024

State	Change in Distress % March 2024 vs April 2024	State Rank for Distress Percent April 2024	Distress Percent April 2024		
Largest <i>Increase</i> in Distress Percent					
Vermont	+2.28%	16	36.21%		
Montana	+0.85%	34	30.16%		
District of Columbia	+0.72%	47	26.09%		
Connecticut	+0.65%	5	43.18%		
North Carolina	+0.43%	15	36.57%		
Washington	-1.53%	8	40.37%		
Nevada	-1.22%	1	54.90%		
North Dakota	-0.81%	32	30.77%		
Kansas	-0.76%	11	38.35%		
Massachusetts	-0.68%	14	36.93%		
Change in National Distress Percent					
NATIONAL	<b>+0.02</b> 015		31.02%		



### Changes in Distress Levels – District Seven

As of April 2024



	Change in Distress % Mar 2024 vs Apr 2024		Distress % State Rank Apr 2024	Change in Distress % Feb 2024 vs Mar 2024	State Rank	Distress % State Rank Feb 2024	Distress % State Rank Jan 2024	Distress % State Rank Dec 2023	Distress % State Rank Jul 2023	State Rank	Distress % State Rank May 2022	State Rank	Distress % State Rank Dec 2021	State Rank	Distress % State Rank May 2020	State Rank
Alaska	-0.32%	29.03%	40	-0.32%	25	38	39	36 (T)	39	37	38	33	48	49	49	49
Idaho	-0.54%	26.90%	45	-0.56%	43	44	37	35	35	32	22	27	31	34	40	39
Montana	0.85%	30.16%	34	-3.38%	37	25	14	13	12	10	11	11	10	12	19 (T)	24
Oregon	-0.42%	33.98%	20	-0.29%	18	18	17	17	17	17	31	29	27 (T)	28	36	37
Washington	-1.53%	40.37%	8	-1.31%	8	6	6	6	8	7	8	9	11	11	12	13
Wyoming	No Change	28.13%	41	-0.90%	42	40	41	43	52	51	52	52	52	51	~	~

(T) = Tied rank with another state(s).  $\sim$ =Too Few Assessors Note: Some historic data from 2020/2021/2022/2023 has been removed to allow space for current month. Refer to previous months' reports or contact <u>ashaughnessy@aphanet.org</u> for data.





# DISTRESS PERCENT MONTHLY REPORTS State-Specific March 2024 versus April 2024





#### **APRIL 2024**

As of April 2024, the Alaska distress percent was 29.03% (ranked 40/52) with 56 assessors.



#### **MARCH 2024**

As of March 2024, the Alaska distress percent was 29.35% (ranked 25/52) with 56 assessors.



#### **STATE COMPARISON**

As of April 2024

Nevada is the highest at 54.09% (n=44)

<sup>29.35%</sup> 29.03% AK **WELL-BEING** 

<sup>\*</sup>Distress Percent is the percentage of individuals with a Well-Being Index (WBI) score ≥5. It measures the percent of individuals that are at a high level of distress.



#### **APRIL 2024**

As April 2024, the Idaho distress percent was 26.90% (ranked 45/52) with 109 assessors.



#### **MARCH 2024**

As March 2024, the Idaho distress percent was 27.44% (ranked 43/52) with 103 assessors.



#### **STATE COMPARISON**

As of April 2024

Nevada is the highest at 54.09% (n=44)

<sup>27.44%</sup> 26.90% ID **WELL-BEING** 

<sup>\*</sup>Distress Percent is the percentage of individuals with a Well-Being Index (WBI) score ≥5. It measures the percent of individuals that are at a high level of distress.



#### **APRIL 2024**

As of April 2024, the Montana distress percent was 30.16% (ranked 34/52) with 50 assessors.



#### **MARCH 2024**

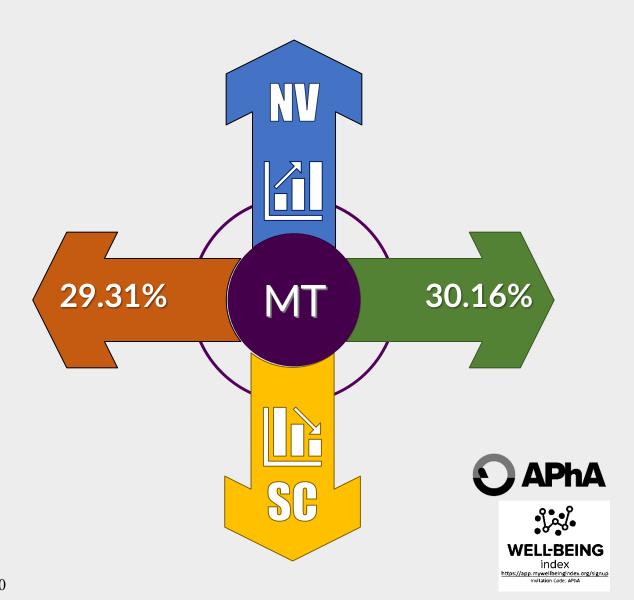
As of March 2024, the Montana distress percent was 29.31% (ranked 37/52) with 48 assessors.



#### **STATE COMPARISON**

As of April 2024

Nevada is the highest at 54.09% (n=44)



<sup>\*</sup>Distress Percent is the percentage of individuals with a Well-Being Index (WBI) score ≥5. It measures the percent of individuals that are at a high level of distress.



#### **APRIL 2024**

As of April 2024, the Oregon distress percent was 33.98% (ranked 20/52) with 140 assessors.



#### **MARCH 2024**

As of March 2024, the Oregon distress percent was 34.40% (ranked 18/52) with 136 assessors.

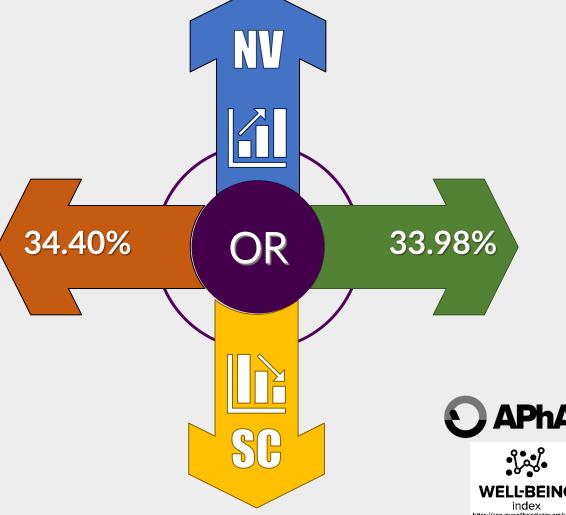


#### STATE COMPARISON

As of April 2024

Nevada is the highest at 54.09% (n=44)

<sup>34.40%</sup> 



<sup>\*</sup>Distress Percent is the percentage of individuals with a Well-Being Index (WBI) score ≥5. It measures the percent of individuals that are at a high level of distress.



#### **APRIL 2024**

As of April 2024, the Washington distress percent was 40.37% (ranked 8/52) with 239 assessors.



#### **MARCH 2024**

As of March 2024, the Washington distress percent was 41.90% (ranked 8/52) with 225 assessors.



#### **STATE COMPARISON**

As of April 2024

Nevada is the highest at 54.09% (n=44)

<sup>41.90%</sup> 40.37% WA **WELL-BEING** 

<sup>\*</sup>Distress Percent is the percentage of individuals with a Well-Being Index (WBI) score ≥5. It measures the percent of individuals that are at a high level of distress.

#### **APRIL 2024**



As of April 2024, the Wyoming distress percent was 29.13% (ranked 41/52) with 20 assessors.



#### **MARCH 2024**

As of March 2024, the Wyoming distress percent was 28.13% (ranked 42/52) with 20 assessors.



#### **STATE COMPARISON**

As of April 2024



Nevada is the highest at 54.09% (n=44)

<sup>28.13%</sup> 29.13% WY **WELL-BEING** 

<sup>\*</sup>Distress Percent is the percentage of individuals with a Well-Being Index (WBI) score ≥5. It measures the percent of individuals that are at a high level of distress.



# Well-being Resources Promo Slides\* For Your Use in State Social Media and Periodicals

<sup>\*</sup>Please do not change the content of these promotional slides



#### **Burnout** is real.

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It's 100% anonymous, free, and you do not need to be an APhA member.

Resources are available once you submit your assessment.

Well-being Index for Pharmacists, Student Pharmacists, & Pharmacy Technicians www.pharmacist.com/wbi

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#### Your experiences - positive and negative - tell a powerful story!

Your experience can be the spark that helps change and enhance the pharmacy workplace, pharmacy personnel well-being, and patient safety.

Submit your experience report to

Pharmacy Workplace and Well-being Reporting.

www.pharmacist.com/pwwr

Your report is confidential, anonymous, and protected by the Alliance for Patient Medication Safety - a recognized national patient safety organization.

Share the PWWR link with your colleagues!



# Well-being Index For Pharmacy Personnel

State Report
For State Boards of Pharmacy
NABP District Seven States

May 2024







# **National and District**April 2024 versus May 2024





### **Changes in Distress Levels**



As of May 2024

State	Change in Distress % April 2024 vs May 2024	State Rank for Distress Percent May 2024	Distress Percent May 2024		
Largest <i>Increase</i> in Distress Percent					
New Mexico	+2.50%	21	34.02%		
Utah	+1.74%	43	28.33%		
Hawaii	+1.60%	15	37.50%		
District of Columbia	+1.31%	45	27.40%		
Wyoming	+1.28%	37 (T)	29.41%		
Nevada	-1.13%	1	53.77%		
Louisiana	-1.00%	4	46.62%		
North Dakota	-0.77%	34	30.00%		
Connecticut	-0.76%	6	42.42%		
Montana	-0.75%	37 (T)	29.41%		
Change in National Distress Percent					
NATIONAL	<b>+0.28</b> 029		31.30%		

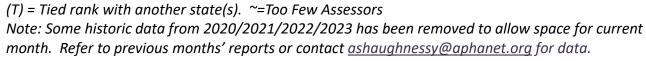


### Changes in Distress Levels – District Seven

As of May 2024



	Change in Distress % Apr 2024 vs May 2024	Distress % May 2024		Change in Distress % Mar 2024 vs Apr 2024		State Rank	State Rank	Distress % State Rank Jan 2024	Distress % State Rank Jul 2023	Distress % State Rank Apr 2023	Distress % State Rank May 2022	State Rank	Distress % State Rank Dec 2021	State Rank	Distress % State Rank May 2020	State Rank
Alaska	-0.03%	29.00%	40	-0.32%	40	25	38	39	39	37	38	33	48	49	49	49
Idaho	-0.50%	26.40%	47	-0.54%	45	43	44	37	35	32	22	27	31	34	40	39
Montana	-0.75%	29.41%	37 (T)	0.85%	34	37	25	14	12	10	11	11	10	12	19 (T)	24
Oregon	1.09%	35.07%	19	-0.42%	20	18	18	17	17	17	31	29	27 (T)	28	36	37
Washington	-0.47%	39.90%	8	-1.53%	8	8	6	6	8	7	8	9	11	11	12	13
Wyoming	1.28%	29.41%	37 (T)	No Change	41	42	40	41	52	51	52	52	52	51	~	~







# DISTRESS PERCENT MONTHLY REPORTS State-Specific May 2024 versus April 2024





#### **MAY 2024**

As of May 2024, the Alaska distress percent was 29.00% (ranked 40/52) with 62 assessors.



#### **APRIL 2024**

As of April 2024, the Alaska distress percent was 29.03% (ranked 40/52) with 56 assessors.



#### **STATE COMPARISON**

As of May 2024

Nevada is the highest at 53.77% (n=47)

<sup>29.03%</sup> 29.00% AK **WELL-BEING** 

<sup>\*</sup>Distress Percent is the percentage of individuals with a Well-Being Index (WBI) score ≥5. It measures the percent of individuals that are at a high level of distress.



#### **MAY 2024**

As May 2024, the Idaho distress percent was 26.40% (ranked 47/52) with 115 assessors.



#### **APRIL 2024**

As April 2024, the Idaho distress percent was 26.90% (ranked 45/52) with 109 assessors.



#### **STATE COMPARISON**

As of May 2024

Nevada is the highest at 53.77% (n=47)

<sup>26.90%</sup> 26.40% ID **WELL-BEING** 

<sup>\*</sup>Distress Percent is the percentage of individuals with a Well-Being Index (WBI) score ≥5. It measures the percent of individuals that are at a high level of distress.



#### **MAY 2024**

As of May 2024, the Montana distress percent was 29.41% (ranked tied at 37/52) with 53 assessors.



#### **APRIL 2024**

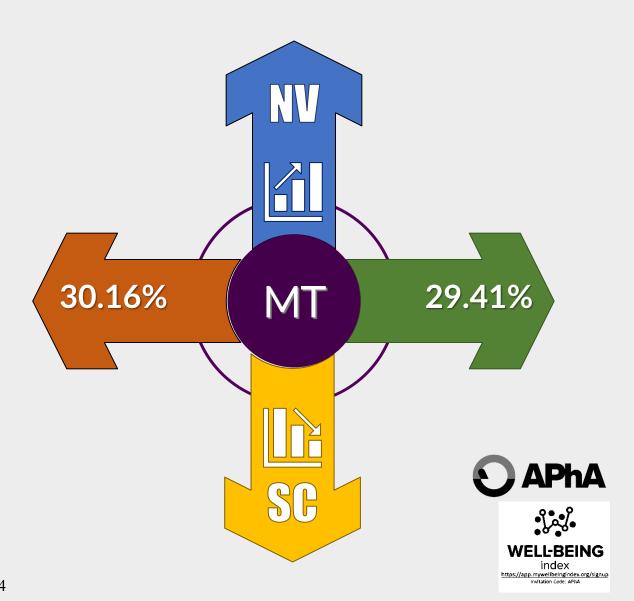
As of April 2024, the Montana distress percent was 30.16% (ranked 34/52) with 50 assessors.



#### **STATE COMPARISON**

As of May 2024

Nevada is the highest at 53.77% (n=47)



<sup>\*</sup>Distress Percent is the percentage of individuals with a Well-Being Index (WBI) score ≥5. It measures the percent of individuals that are at a high level of distress.



#### **MAY 2024**

As of May 2024, the Oregon distress percent was 35.07% (ranked 19/52) with 147 assessors.



#### **APRIL 2024**

As of April 2024, the Oregon distress percent was 33.98% (ranked 20/52) with 140 assessors.



#### **STATE COMPARISON**

**As of May 2024** 

Nevada is the highest at 53.77% (n=47)

<sup>33.98%</sup> 35.07% OR https://app.mywellbeingindex.org/signup

<sup>\*</sup>Distress Percent is the percentage of individuals with a Well-Being Index (WBI) score ≥5. It measures the percent of individuals that are at a high level of distress.



#### **MAY 2024**

As of May 2024, the Washington distress percent was 39.90% (ranked 8/52) with 265 assessors.



#### **APRIL 2024**

As of April 2024, the Washington distress percent was 40.37% (ranked 8/52) with 239 assessors.



#### **STATE COMPARISON**

As of May 2024

Nevada is the highest at 53.77% (n=47)

<sup>40.37%</sup> 39.90% WA **WELL-BEING** 

<sup>\*</sup>Distress Percent is the percentage of individuals with a Well-Being Index (WBI) score ≥5. It measures the percent of individuals that are at a high level of distress.

# **MAY 2024**



As of May 2024, the Wyoming distress percent was 29.41% (ranked tied at 37/52) with 29.41 assessors.



As of April 2024, the Wyoming distress percent was



<sup>29.13% (</sup>ranked 41/52) with 20 assessors. 29.13% 29.41% WY **STATE COMPARISON** As of May 2024 Nevada is the highest at 53.77% (n=47) South Carolina has the lowest 20.84% (n=610) **WELL-BEING** \*Distress Percent is the percentage of individuals with a Well-Being Index (WBI) 037

score ≥5. It measures the percent of individuals that are at a high level of distress.



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<sup>\*</sup>Please do not change the content of these promotional slides



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It's 100% anonymous, free, and you do not need to be an APhA member.

Resources are available once you submit your assessment.

Well-being Index for Pharmacists, Student Pharmacists, & Pharmacy Technicians www.pharmacist.com/wbi

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www.pharmacist.com/pwwr

Your report is confidential, anonymous, and protected by the Alliance for Patient Medication Safety - a recognized national patient safety organization.

Share the PWWR link with your colleagues!





State Report
For State Boards of Pharmacy
NABP District Seven States

June 2024







# **National and District**May 2024 versus June 2024





# **Changes in Distress Levels**



**As of June 2024** 

State	Change in Distress % May 2024 vs June 2024	State Rank for Distress Percent June 2024	Distress Percent June 2024
Largest Increase in Distress Percent			
Vermont	+1.08%	15	37.29%
Oregon	+0.80%	18	35.87%
lowa	+0.66%	38	29.36%
Arkansas	+0.59%	11 (T)	38.78%
Kentucky	+0.52%	29	32.17%
Montana	-2.38%	44 (T)	27.03%
Nevada	-1.48%	2	52.29%
Idaho	-1.00%	47	25.40%
Illinois	-0.90%	32	31.21%
Connecticut	-0.84%	6	41.58%
Change in National Distress Percent			
NATIONAL	<b>-0.04</b> % <sub>043</sub>		31.26%

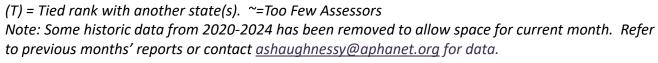


# Changes in Distress Levels – District Seven

As of June 2024



	Change in Distress % May 2024 vs Jun 2024	Distross %	Distress % State Rank Jun 2024	Change in Distress % Apr 2024 vs May 2024		State Rank	Distress % State Rank Mar 2024	Distress % State Rank Jan 2024	Distress % State Rank Jul 2023	State Rank	Distress % State Rank May 2022	State Rank	Distress % State Rank Dec 2021	State Rank	Distress % State Rank May 2020	State Rank
Alaska	0.41%	29.41%	36 (T)	-0.03%	40	40	25	39	39	37	38	33	48	49	49	49
Idaho	-1.00%	25.40%	47	-0.50%	47	45	43	37	35	32	22	27	31	34	40	39
Montana	-2.38%	27.03%	44 (T)	-0.75%	37 (T)	34	37	14	12	10	11	11	10	12	19 (T)	24
Oregon	0.80%	35.87%	18	1.09%	19	20	18	17	17	17	31	29	27 (T)	28	36	37
Washington	-0.71%	39.19%	8	-0.47%	8	8	8	6	8	7	8	9	11	11	12	13
Wyoming	No Change	29.41%	36 (T)	1.28%	37 (T)	41	42	41	52	51	52	52	52	51	~	~







# DISTRESS PERCENT MONTHLY REPORTS State-Specific June 2024 versus May 2024





# **JUNE 2024**

As of June 2024, the Alaska distress percent was 29.41% (ranked tied at 36/52) with 64 assessors.



# **MAY 2024**

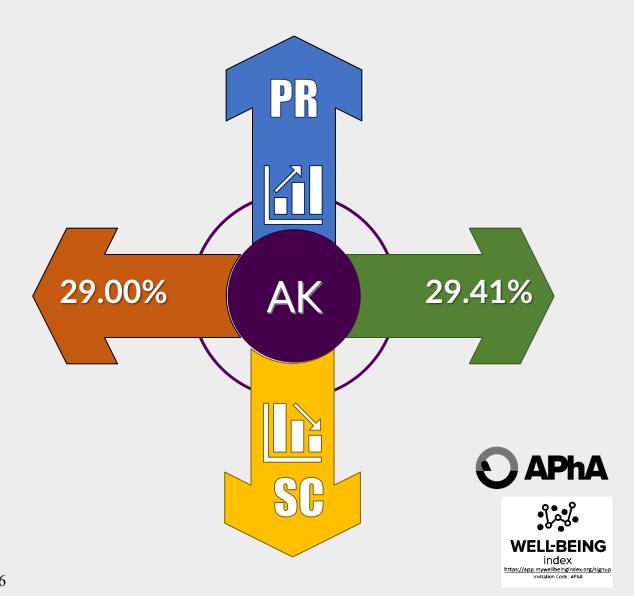
As of May 2024, the Alaska distress percent was 29.00% (ranked 40/52) with 62 assessors.



# **STATE COMPARISON**

As of June 2024

Puerto Rico is the highest at 52.78% (n=30)



<sup>\*</sup>Distress Percent is the percentage of individuals with a Well-Being Index (WBI) score ≥5. It measures the percent of individuals that are at a high level of distress.



# **JUNE 2024**

As June 2024, the Idaho distress percent was 25.40% (ranked 47/52) with 122 assessors.



# **MAY 2024**

As May 2024, the Idaho distress percent was 26.40% (ranked 47/52) with 115 assessors.



# **STATE COMPARISON**

As of June 2024

Puerto Rico is the highest at 52.78% (n=30)

<sup>26.40%</sup> 25.40% ID **WELL-BEING** 

<sup>\*</sup>Distress Percent is the percentage of individuals with a Well-Being Index (WBI) score ≥5. It measures the percent of individuals that are at a high level of distress.



# **JUNE 2024**

As of June 2024, the Montana distress percent was 27.03% (ranked tied at 44/52) with 58 assessors.



# **MAY 2024**

As of May 2024, the Montana distress percent was 29.41% (ranked tied at 37/52) with 53 assessors.



# **STATE COMPARISON**

As of June 2024

Puerto Rico is the highest at 52.78% (n=30)

<sup>29.41%</sup> 27.03% MT **WELL-BEING** 

<sup>\*</sup>Distress Percent is the percentage of individuals with a Well-Being Index (WBI) score ≥5. It measures the percent of individuals that are at a high level of distress.



# **JUNE 2024**

As of June 2024, the Oregon distress percent was 35.87% (ranked 18/52) with 149 assessors.



# **MAY 2024**

As of May 2024, the Oregon distress percent was 35.07% (ranked 19/52) with 147 assessors.



# **STATE COMPARISON**

As of June 2024

Puerto Rico is the highest at 52.78% (n=30)

<sup>35.07%</sup> 35.87% OR https://app.mywellbeingindex.org/signup

<sup>\*</sup>Distress Percent is the percentage of individuals with a Well-Being Index (WBI) score ≥5. It measures the percent of individuals that are at a high level of distress.



# **JUNE 2024**

As of June 2024, the Washington distress percent was 39.19% (ranked 8/52) with 285 assessors.



# **MAY 2024**

As of May 2024, the Washington distress percent was 39.90% (ranked 8/52) with 265 assessors.



# **STATE COMPARISON**

As of June 2024

Puerto Rico is the highest at 52.78% (n=30)

<sup>39.90%</sup> 39.19% WA **WELL-BEING** 

<sup>\*</sup>Distress Percent is the percentage of individuals with a Well-Being Index (WBI) score ≥5. It measures the percent of individuals that are at a high level of distress.

# **JUNE 2024**



As of June 2024, the Wyoming distress percent was 29.41% (ranked tied at 36/52) with 22 assessors.



As of May 2024, the Wyoming distress percent was 29.41% (ranked tied at 37/52) with 22 assessors.



# **STATE COMPARISON**

As of June 2024



Puerto Rico is the highest at 52.78% (n=30)

<sup>29.41%</sup> 29.41% WY **WELL-BEING** 

<sup>\*</sup>Distress Percent is the percentage of individuals with a Well-Being Index (WBI) score ≥5. It measures the percent of individuals that are at a high level of distress.



# Well-being Resources Promo Slides\* For Your Use in State Social Media and Periodicals

<sup>\*</sup>Please do not change the content of these promotional slides



# **Burnout** is real.

Take advantage of APhA's online screening tool, invented by the Mayo Clinic, to evaluate your fatigue, depression, burnout, anxiety, and stress and assess your well-being. It takes less than 5 minutes to answer 9 short questions.

It's 100% anonymous, free, and you do not need to be an APhA member.

Resources are available once you submit your assessment.

Well-being Index for Pharmacists, Student Pharmacists, & Pharmacy Technicians www.pharmacist.com/wbi

**Invitation Code: APhA** 

Or Scan







# Your experiences - positive and negative - tell a powerful story!

Your experience can be the spark that helps change and enhance the pharmacy workplace, pharmacy personnel well-being, and patient safety.

Submit your experience report to

Pharmacy Workplace and Well-being Reporting.

www.pharmacist.com/pwwr

Your report is confidential, anonymous, and protected by the Alliance for Patient Medication Safety - a recognized national patient safety organization.

Share the PWWR link with your colleagues!

# Alaska Board of Pharmacy Agenda Item #4



Investigations Review



# Department of Commerce, Community, and Economic Development

DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING

550 West Seventh Avenue, Suite 1500 Anchorage, AK 99501-3567 Main: 907.269.8160

Fax: 907.269.8156

#### **MEMORANDUM**

DATE:

August 05, 2024

TO:

Board of Pharmacy

THRU:

Erika Prieksat, Chief Investigator  $\mathcal{B}\mathcal{H}$ 

FROM:

Holly Handley, Investigator

RE:

Investigative Report for the August 20, 2024 Meeting

The following information was compiled as an investigative report to the Board for the period of April 09, 2024 thru August 05, 2024; this report includes cases, complaints, and intake matters handled since the last report.

Matters opened by the Paralegals in Anchorage and Juneau, regarding continuing education audits and license action resulting from those matters are covered in this report.

#### **OPEN - 55**

Case Number	Violation Type	<u>Case Status</u>	<b>Status Date</b>
OUT OF STATE PHARM	IACY		
2024-000453	Violation of licensing regulation	Complaint	05/30/2024
2024-000550	Violation of licensing regulation	Complaint	07/02/2024
2022-000746	Violation of licensing regulation	Investigation	06/02/2023
2023-000147	Violation of licensing regulation	Investigation	01/19/2024
2023-000349	Action in another state	Investigation	03/26/2024
2023-000430	Unlicensed practice or activity	Investigation	07/24/2023
2023-000616	Action in another state	Investigation	04/30/2024
2023-000887	Unlicensed practice or activity	Investigation	05/08/2024
2024-000197	Violation of licensing regulation	Investigation	05/06/2024

#### **PHARMACIST**

2024-000623	Violation of licensing regulation	Intake	07/03/2024
2024-000638	Violation of licensing regulation	Intake	07/09/2024
2024-000648	Violation of licensing regulation	Intake	06/27/2024
2024-000660	Violation of licensing regulation	Intake	07/18/2024
2023-000958	PDMP Violation	Complaint	09/14/2023
2024-000307	Violation of licensing regulation	Complaint	06/04/2024
2024-000487	PDMP Violation: Failure to Register	Complaint	06/05/2024
2024-000540	PDMP Violation: Failure to Register	Complaint	07/08/2024
2024-000589	PDMP Violation: Failure to Register	Complaint	06/26/2024
2024-000595	Violation of licensing regulation	Complaint	07/03/2024
2024-000645	Violation of licensing regulation	Complaint	08/01/2024
2024-000693	Violation of licensing regulation	Complaint	08/01/2024
2023-001200	Violation of licensing regulation	Investigation	
2024-000122	Violation of licensing regulation	Investigation	04/08/2024
2024-000196	Violation of licensing regulation	Investigation	04/29/2024
2024-000222	Violation of licensing regulation	Investigation	04/15/2024
2024-000339	Violation of licensing regulation	Investigation	05/23/2024
	~=		
PHARMACIST IN CHAR	GE .		
2024-000485	Violation of licensing regulation	Complaint	07/19/2024
PHARMACY			
2024-000317	Violation of licensing regulation	Intake	04/04/2024
2024-000622	Violation of licensing regulation	Intake	04/09/2024
2024-000435	Violation of Profession Statute or Regulation	Complaint	05/23/2024
2024-000572	Violation of licensing regulation	Complaint	06/25/2024
2024-000621	Violation of licensing regulation	Complaint	07/08/2024
2024-000667	Violation of licensing regulation	Complaint	07/25/2024
PHARMACY TECHNICI	AN		
2024-000401	Violation of licensing regulation	Complaint	06/25/2024

2024-000546	Violation of licensing regulation	Complaint	07/02/2024
2024-000647	Violation of licensing regulation	Complaint	08/01/2024
2023-001122	Violation of licensing regulation	Investigation	05/01/2024
2024-000101	Unprofessional conduct	Investigation	06/03/2024
2024-000248	Violation of licensing regulation	Investigation	04/29/2024
WHOLESALE DRUG DISTRIBUTOR			
2024-000433	Violation of licensing regulation	Complaint	05/14/2024
2024-000547	Violation of licensing regulation	Complaint	06/25/2024
2024-000553	Violation of licensing regulation	Complaint	06/18/2024
2024-000569	Violation of licensing regulation	Complaint	06/25/2024
2024-000570	Violation of licensing regulation	Complaint	07/03/2024
2024-000571	Violation of licensing regulation	Complaint	07/03/2024
2024-000588	Violation of licensing regulation	Complaint	07/03/2024
2024-000593	Violation of licensing regulation	Complaint	07/02/2024
2024-000596	Violation of licensing regulation	Complaint	07/10/2024
2024-000597	Violation of licensing regulation	Complaint	07/10/2024
2024-000598	Violation of licensing regulation	Complaint	06/27/2024
2024-000624	Violation of licensing regulation	Complaint	07/10/2024
2024-000625	Violation of licensing regulation	Complaint	07/10/2024
2024-000630	Violation of licensing regulation	Complaint	07/24/2024
2024-000646	Violation of licensing regulation	Complaint	07/31/2024
2023-001010	Unlicensed practice or activity	Investigation	02/26/2024

Closed	_	<b>70</b>	

Case #	Violation Type	Case Status	<b>Closed</b>	<u>Closure</u>
OUT OF STATE PHARM	<b>МАСУ</b>			
2024-000295	Violation of licensing regulation	Closed-Intake	05/17/2024	Review Complete
2024-000368	Violation of licensing regulation	Closed-Intake	05/16/2024	No Action - Lack of Jurisdiction
2024-000371	Violation of licensing regulation	Closed-Intake	06/17/2024	Incomplete Complaint

2024-000388	Violation of licensing regulation	Closed-Intake	06/11/2024	Incomplete Complaint
2024-000447	Violation of licensing regulation	Closed-Intake	07/25/2024	No Action - No Violation
2024-000060	Violation of licensing regulation	Closed-Complaint	05/24/2024	No Action - No Violation
2024-000282	Violation of licensing regulation	Closed-Complaint	07/25/2024	No Action - No Violation
2024-000418	Violation of licensing regulation	Closed-Complaint	07/25/2024	Other (See Abstract)
2024-000442	Violation of licensing regulation	Closed-Complaint	07/25/2024	License Lapsed - Flagged Do Not Renew
2023-000283	Violation of licensing regulation	Closed-Investigation	04/30/2024	License Action
2023-000684	Violation of licensing regulation	Closed-Investigation	04/30/2024	License Action
2023-001084	Violation of licensing regulation	Closed-Investigation	05/16/2024	Advisement Letter
2023-001124	Violation of licensing regulation	Closed-Investigation	04/17/2024	Advisement Letter
PHARMACIST				
2024-000477	Violation of licensing regulation	Closed-Intake	07/23/2024	Incomplete Complaint
2024-000566	Violation of licensing regulation	Closed-Intake	07/19/2024	Review Complete
2024-000126	Violation of licensing regulation	Closed-Complaint	04/15/2024	No Action - No Violation
2024-000192	Violation of licensing regulation	Closed-Complaint	05/24/2024	No Action - No Violation
2024-000214	Violation of licensing regulation	Closed-Complaint	06/07/2024	No Action - No Violation
2024-000283	Violation of licensing regulation	Closed-Complaint	04/30/2024	Application Withdrawn
2024-000324	Violation of licensing regulation	Closed-Complaint	07/23/2024	No Action - No Violation
2024-000369	Violation of licensing regulation	Closed-Complaint	07/23/2024	No Action - No Violation
2024-000396	Violation of licensing regulation	Closed-Complaint	07/23/2024	No Action - No Violation
2024-000397	Violation of licensing regulation	Closed-Complaint	06/17/2024	No Action - No Violation
2024-000436	Violation of licensing regulation	Closed-Complaint	07/23/2024	No Action - No Violation
2023-000957	PDMP Violation	Closed-Investigation	07/16/2024	Advisement Letter
2024-000090	Violation of licensing regulation	Closed-Investigation	04/29/2024	Advisement Letter

2024-000160	PDMP Violation: Failure to Register	Closed-Investigation	07/25/2024	Advisement Letter
2024-000208	Violation of licensing regulation	Closed-Investigation	04/30/2024	Advisement Letter
2024-000326	Violation of licensing regulation	Closed-Investigation	06/17/2024	Advisement Letter
PHARMACIST INTERN				
2023-001217	Violation of licensing regulation	Closed-Complaint	05/24/2024	Review Complete
PHARMACY				
2024-000242	Violation of licensing regulation	Closed-Intake	04/29/2024	Incomplete Complaint
2024-000267	Violation of licensing regulation	Closed-Intake	04/29/2024	Incomplete Complaint
2024-000348	Violation of licensing regulation	Closed-Intake	06/07/2024	Incomplete Complaint
2024-000402	Violation of licensing regulation	Closed-Intake	05/03/2024	Incomplete Complaint
2024-000582	Violation of licensing regulation	Closed-Intake	07/29/2024	Incomplete Complaint
2024-000594	Violation of licensing regulation	Closed-Intake	07/11/2024	Review Complete
2024-000672	Compliance Inspection	Closed-Intake	07/26/2024	Compliance
2023-001085	Violation of licensing regulation	Closed-Complaint	04/30/2024	No Action - No Violation
2024-000036	Violation of licensing regulation	Closed-Complaint	05/24/2024	No Action - No Violation
2024-000328	Violation of licensing regulation	Closed-Complaint	07/23/2024	No Action - No Violation
2024-000471	Violation of licensing regulation	Closed-Complaint	07/23/2024	No Action - Unfounded
2022-000634	Violation of licensing regulation	Closed-Investigation	04/30/2024	License Action
2023-000910	Violation of licensing regulation	Closed-Investigation	04/30/2024	License Action
2023-001044	Violation of licensing regulation	Closed-Investigation	05/30/2024	No Action - No Violation
2023-001188	Compliance Inspection	Closed-Investigation	04/30/2024	Advisement Letter
2024-000037	Violation of licensing regulation	Closed-Investigation	04/29/2024	Advisement Letter
2024-000062	Violation of licensing regulation	Closed-Investigation	04/29/2024	Advisement Letter
2024-000064	Violation of licensing regulation	Closed-Investigation	04/29/2024	Advisement Letter

2024-000115	Violation of licensing regulation	Closed-Investigation	05/03/2024	Advisement Letter
2024-000300	PDMP Violation: Failure to Register	Closed-Investigation	06/19/2024	Advisement Letter
2024-000327	Violation of licensing regulation	Closed-Investigation	07/23/2024	Advisement Letter
PHARMACY TECHNIC	IAN			
2024-000189	Violation of licensing regulation	Closed-Complaint	07/19/2024	Application Withdrawn
2024-000268	Violation of licensing regulation	Closed-Complaint	04/15/2024	Application Withdrawn
2023-000543	License Application Problem	Closed-Investigation	04/29/2024	Consent Order
2023-000885	Continuing education	Closed-Investigation	04/17/2024	Advisement Letter
2024-000006	Violation of licensing regulation	Closed-Investigation	05/24/2024	Advisement Letter
2024-000346	Violation of licensing regulation	Closed-Investigation	07/09/2024	Advisement Letter
WHOLESALE DRUG DISTRIBUTOR				
2024-000333	Violation of licensing regulation	Closed-Intake	06/17/2024	Review Complete
2024-000334	Violation of licensing regulation	Closed-Intake	06/17/2024	Review Complete
2023-001064	Violation of licensing regulation	Closed-Complaint	04/30/2024	No Action - No Violation
2024-000188	Violation of licensing regulation	Closed-Complaint	04/15/2024	No Action - No Violation
2024-000425	Violation of licensing regulation	Closed-Complaint	06/19/2024	No Action - No Violation
2023-000345	Violation of licensing regulation	Closed-Investigation	05/24/2024	Advisement Letter
2023-000683	Violation of licensing regulation	Closed-Investigation	06/19/2024	Advisement Letter
2023-000733	Violation of licensing regulation	Closed-Investigation	04/18/2024	Advisement Letter
2023-000763	Violation of licensing regulation	Closed-Investigation	04/18/2024	Advisement Letter
2023-000764	Violation of licensing regulation	Closed-Investigation	04/18/2024	Advisement Letter
2023-000765	Violation of licensing regulation	Closed-Investigation	04/18/2024	Advisement Letter
2024-000031	Violation of licensing regulation	Closed-Investigation	07/23/2024	Advisement Letter

END OF REPORT

2024-000137

# Alaska Board of Pharmacy Agenda Item #5



Division Updates

Poard of Pharmany		FV 40	FV 10	Diamaium		FY 20	FY 21	Diameiros		FY 22	FY 23	Diameiron	1	FY 24 st - 3rd QTR
Board of Pharmacy		FY 18	FY 19	Biennium		FT ZU	F1 21	Biennium		FT ZZ	F1 23	Biennium	┝	st - sra QTK
<u>Revenue</u>														
Revenue from License Fees	5	801,317 \$	213,770	\$ 1,015,087	\$	631,105 \$	1,121,447	\$ 1,752,552	\$	444,975 \$	1,169,195	\$ 1,614,170	\$	192,040
General Fund Received		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	,	, -,:,:		\$		-	Ś	29,810 \$	7,668	37,478	Ś	-
Allowable Third Party Reimbursements		210	962	1,172	Ś	- \$	_	_	Ś	1,650 \$	1,500	3,150	Ś	88
TOTAL REVENUE	Ş		214,732	\$ 1,016,259	\$	631,105 \$	1,121,447	\$ 1,752,552	\$	476,435 \$	1,178,363		\$	192,128
<u>Expenditures</u>														
Non Investigation Expenditures														
1000 - Personal Services		204,727	194,745	399,472		199,334	278,612	477,946		284,719	335,119	619,838		267,916
2000 - Travel		13,704	8,299	22,003		2,641	-	2,641		6,363	14,252	20,615		4,590
3000 - Services		21,960	27,781	49,741		45,283	46,180	91,463		29,584	20,174	49,758		22,544
4000 - Commodities		-	26	26		521	-	521		82	90	172		300
5000 - Capital Outlay		-		-		-	-	-		-	-	-		-
Total Non-Investigation Expenditures		240,391	230,851	471,242		247,779	324,792	572,571		320,748	369,635	690,383		295,350
Investigation Expenditures														
1000-Personal Services		68,679	69,997	138,676		57,738	106,494	164,232		94,519	128,331	222,850		128,715
2000 - Travel			-	-		1,260	-	1,260		5,221	3,182	8,403		-
3023 - Expert Witness		-	-	-		-	-	-		-	-	-		-
3088 - Inter-Agency Legal		-	3,062	3,062		2,537	1,269	3,806		12,011	10,018	22,029		1,620
3094 - Inter-Agency Hearing/Mediation		-	-	-		694	152	846		1,758	68	1,826		15,943
3000 - Services other			400	400		269	216	485		338	545	883		458
4000 - Commodities			-	-		-	-	-		-	10	10		-
Total Investigation Expenditures		68,679	73,459	142,138		62,498	108,131	170,629		113,847	142,155	256,001		146,736
Total Direct Expenditures	1 -	309,070	304,310	613,380		310,277	432,923	743,200	$\perp$	434,595	511,790	946,384		442,086
Total Direct Experiatures		303,070	304,310	013,380		310,277	432,323	743,200		434,333	311,730	540,364		442,000
Indirect Expenditures														
Internal Administrative Costs		150,986	155,128	306,114		164,443	191,897	356,340		182,236	190,056	372,292		142,542
Departmental Costs		78,139	81,374	159,513		58,131	75,431	133,562		76,951	76,872	153,823		57,654
Statewide Costs		30,555	27,069	57,624		33,868	52,856	86,724		47,667	50,400	98,067		37,800
Total Indirect Expenditures		259,680	263,571	523,251		256,442	320,184	576,626		306,854	317,328	624,182		237,996
				-			0=0,=0	-			0_1,0_0	32.7,202		=0.7000
TOTAL EXPENDITURES	Ş	568,750 \$	567,881	\$ 1,136,631	\$	566,719 \$	753,107	\$ 1,319,826	\$	741,449 \$	829,118	\$ 1,570,566	\$	680,082
Cumulative Surplus (Deficit)														
Beginning Cumulative Surplus (Deficit)	5	,	507,993		\$	154,844 \$	219,230		\$	587,570 \$	322,556		\$	671,801
Annual Increase/(Decrease)		232,777	(353,149)			64,386	368,340		<u> </u>	(265,014)	349,245	]		(487,954)
Ending Cumulative Surplus (Deficit)		507,993	154,844		\$	219,230 \$	587,570		\$	322,556 \$	671,801		\$	183,847
	$\dashv \vdash$													
Statistical Information														
Number of Licenses for Indirect calculation		5,680	6,203			5,934	6,917			6,542	6,428			

# **Additional information:**

<sup>•</sup> General fund dollars were received in FY21-FY23 to offset increases in personal services and help prevent programs from going into deficit or increase fees.

<sup>•</sup> Most recent fee change: New fee FY24 (retired)

<sup>•</sup> Annual license fee analysis will include consideration of other factors such as board and licensee input, potential investigation load, court cases, multiple license and fee types under one program, and program changes per AS 08.01.065.

Appropriation Name (Ex)	(Multiple Items)
Sub Unit	(All)
PL Task Code	PHA1

Sum of Budgetary Expenditures	Object Type Name (Ex)				
Object Name (Ex)	1000 - Personal Services	2000 - Travel	3000 - Services	4000 - Commodities	<b>Grand Total</b>
1011 - Regular Compensation	206,265.71				206,265.71
1014 - Overtime	408.91				408.91
1016 - Other Premium Pay	478.92				478.92
1021 - Allowances to Employees	288.00				288.00
1023 - Leave Taken	34,197.26				34,197.26
1028 - Alaska Supplemental Benefit	14,806.83				14,806.83
1029 - Public Employee's Retirement System Defined Benefits	334.25				334.25
1030 - Public Employee's Retirement System Defined Contribution	12,662.05				12,662.05
1034 - Public Employee's Retirement System Defined Cont Health Reim	8,578.06				8,578.06
1035 - Public Employee's Retiremnt Sys Defined Cont Retiree Medical	2,413.11				2,413.11
1037 - Public Employee's Retiremnt Sys Defined Benefit Unfnd Liab	36,233.10				36,233.10
1040 - Group Health Insurance	70,683.50				70,683.50
1041 - Basic Life and Travel	34.21				34.21
1042 - Worker's Compensation Insurance	1,643.00				1,643.00
1047 - Leave Cash In Employer Charge	5,544.19				5,544.19
1048 - Terminal Leave Employer Charge	3,840.63				3,840.63
1053 - Medicare Tax	3,329.70				3,329.70
1077 - ASEA Legal Trust	246.84				246.84
1079 - ASEA Injury Leave Usage	25.12				25.12
1080 - SU Legal Trst	54.55				54.55
1970 - Personal Services Transfer	(5,437.05	)			(5,437.05)
2007 - In-State Non-Employee Lodging		845	5.73		845.73
2008 - In-State Non-Employee Meals and Incidentals		210	0.00		210.00
2009 - In-State Non-Employee Taxable Per Diem		48	3.00		48.00
2010 - In-State Non-Employee Non-Taxable Reimbursement		198	3.32		198.32
2012 - Out-State Employee Airfare		128	3.34		128.34
2013 - Out-State Employee Surface Transportation		36	5.00		36.00
2014 - Out-State Employee Lodging		2,260	).14		2,260.14
2015 - Out-State Employee Meals and Incidentals		920	).78		920.78
2016 - Out-State Employee Reimbursable Travel Costs		30	0.00		30.00
2970 - Travel Cost Transfer		(87	7.63)		(87.63)
3000 - Training/Conferences			2,5	75.00	2,575.00
3002 - Memberships			2	50.00	250.00
3035 - Long Distance				53.00	53.00
3036 - Local/Equipment Charges				2.02	2.02
3044 - Courier				19.38	19.38
3045 - Postage			4	39.11	439.11
3046 - Advertising			1,3	96.08	1,396.08
3085 - Inter-Agency Mail			4	20.43	420.43
3088 - Inter-Agency Legal			8,8	09.94	8,809.94
3093 - Inter-Agency Education/Training				65.00	65.00
3094 - Inter-Agency Hearing/Mediation			26,5	35.60	26,535.60
4002 - Business Supplies				300.	300.00
Grand Total	396,630.89	4,589	0.68 40,5	65.56 300.	00 442,086.13

#### PROFESSIONAL LICENSING DECISION-MAKING

# **FRAMEWORK**

#### PART ONE: SHOULD WE DELIBERATE ON THIS TOPIC?

### **Authority**

forward.

#### **Public Protection**

# If we don't address this issue, is the public threatened or harmed?

If yes, begin work on the issue. If no, determine whether it meets a different criterion or whether the board should address it at a future date.

## **Public Interest**

mandate and mission?

#### Does our decision make a material difference to stakeholders?

If yes, move to the next criterion. If no, the board should identify a decision-making body better suited to resolve the issue and decline to move

Stakeholders may include lthe general public, licensees, potential patients, related agencies or organizations, etc.

If yes, move to the next criterion.

If no, determine whether to work on it at a future date--or at all.

Is the issue within the board's statutory

# **Ownership**

#### Are we the best group to lead this effort?

Does it make sense for this board to *lead* the effort, or is another group better resourced, more educated, or otherwise better positioned to take the reins? Identify partners next.

#### **Partners**

# Will we need to collaborate with other groups?

Weighing another person or group's availability may impact how the board moves forward. Connect with everyone whose input is needed. If public comment is advisable, identify opportunities and methods to obtain that input.

# **Priority**

# Where does this matter rank among other items we are facing?

Evaluate how the board will work this matter into its busy schedule. Is there a hard deadline to complete the work? Could the board form a committee to focus on this while other members work concurrently on other projects? Are more meetings needed?

#### Resources

# Does our board have access to the resources needed to address this issue?

If yes, move to the next criterion. If no, determine what resources are needed. Invite division managers to collaborate on how to obtain resources. If resources are not available, the board may need to look to a different organization to assist with the issue.

# Perception

# Are there intangible ways we can be impacted by pursuing this issue?

Whether good or bad, perception matters. Enter into the deliberative process anticipating any pitfalls or opportunities. If the board decides not to move forward because of a negative perception, ensure that it is not shirking its statutory responsibility: If #1 is yes, the board may have no choice.



#### **Board or Commission Regulation Project Opening Questionnaire**

#### Part I: Completed by Board

- The purpose of this worksheet is to provide the agency's regulation specialist with a detailed overview of the proposed regulation change(s), including specific information as required by statute or the Department of Law.
- This worksheet must be completed by the board during a meeting or delegated to a board member, then submitted to agency staff.
- Details should be kept brief yet comprehensive. If a section of the form is not relevant to the project, please mark it as "N/A."
   Do not leave any sections blank.
- The regulation specialist may reach out to staff or board members at any stage during the project for additional information needed to compile the FAQ. The FAQ will be posted in the Online Public Notice System and on the board website during the public comment period.
- If the proposed regulation changes comprise more than one subject matter, the board must complete a separate worksheet for each subject. For example, if the intent is to (a) update continuing education requirements for license renewals, (b) repeal redundant provisions, and (c) introduce new regulations following statutory changes, the board would submit a total of three worksheets, one for each the subjects (a), (b), and (c).

Board:		Date of Meeting:				
General Subject Matter/Topic:						
Regulation(s) to be amended:						
Board member submitting worksheet:		Date to Staff:				
TO BE COMPLETED BY THE BOARD OR A DESIGNATED BOARD MEMBER:						
1. Which of the following motions has the board passed on the record:						
Approve draft language to initiate a regulations project.						

# 1. Which of the following motions has the board passed on the record: Approve draft language to initiate a regulations project. Approve for public comment, unless substantive changes are made by regulations specialist or Department of Law. Approve an oral hearing on the proposed regulations (if applicable). 2. What will this regulation do? 3. What is the public need or reason for this regulation?

4. What is the known or estimated annual cost of the new regulation to a private person, a state agency, or a municipality?*
5. How will this have a <u>positive</u> or <u>negative</u> impact on public or private people, businesses, or organizations?
6. If any <u>negative</u> consequences, please address the reasons why the public need for this change outweighs the negative impact.
Not Applicable
<ol> <li>List all questions and concerns you anticipate licensees or the public may raise about the proposal. Include the board's response to these concerns. Anticipate any perceptions and potential unintended consequences. This information will be included on the public FAQ and is required. Attach an additional sheet, if needed.</li> </ol>
8. In addition to interested parties, who should receive public notice?
All licensees
Certain license types (list types):
Other stakeholders:

A private person: \$50-\$200 per applicant/licensee biannually

A state agency: None knownA municipality: None known

<sup>\*</sup> Cost information is described simply as an estimate of annual costs within the board's ability to determine due to its familiarity with the regulated community. Example: A board is proposing to require three CE credits to their continuing competency standards for biennial license renewal. The proposal requires licensees to take additional courses, so it may cost:

# **Board or Commission Regulation Project Opening Questionnaire**

# Part II: Completed by Staff

Board:			Date of Meeting:				
General Su	ubject Matter/Topic:						
Regulation	n(s) to be amended:						
Staff subm	nitting worksheet:		Date to Regulations Specialist:				
Will implementation include changes to official public forms or internal checklists?  If yes, provide a list of form numbers to the publications specialist to initiate the					Yes		No
	forms revision	process.			·		
2. If	<ol> <li>If a public hearing was requested by motion, please include complete teleconference details:</li> <li>Not Applicable</li> </ol>						
<ul> <li>3. Have you attached an excerpt of the meeting minutes that reflects:</li> <li>Board discussion about the proposal.</li> <li>Draft language of the proposal.</li> <li>Motion reflecting intent to propose the draft language, including approval for public notice if no significant changes are made by the regulations specialist or drafting attorney.</li> </ul>					Yes		No
4. Do you anticipate any questions, concerns, or other controversy to arise from the public or licensees regarding this regulation? If yes, explain briefly:		cor	Yes		No		
5. D	o you anticipate this r	egulation will increase the activity or wo	rkload of any staff mem	ber —			
	r require additional co				Yes		No

6.	6. Does this project have any companion regulations (fees, related regulations proposed by other boards, etc. if applicable)?		Yes	No
If yes, describe:				
7.	What is the date of the next meeting when the board plans to address regulations, if known?			
8.	Does the change add a new license type?		Yes	No
	If yes:			
	a. Does it affect current licensees?		Yes	No
	b. Do current licensees/non-licensees already perform the service for which the new license type is required?		Yes	No
	c. Is a date included in the regulation to allow for a transition period?		Yes	No
9.	Does it affect continuing education/competency requirements?		Yes	No
	If yes:			
	a. Does it add additional requirements or hours?		Yes	No
	b. Does it clarify existing regulations?		Yes	No
	c. Is there an effective date in the future to give licensees time to comply?		Yes	No
10. Does it require a fee change or a new fee in centralized regulations?			Yes	No
If yes, please explain:				 
11	1. Does it make changes to the qualifications or requirements of licensees?		Yes	No
	If yes:			
	a. All licensees		Yes	No
	b. Only initial licensees		Yes	No
	c. Certain licensees (List types below)		Yes	No

12. Is the new regulation required by a certain date?			Yes	No
If yes,				
a.	What is the date the regulation should be effective?			
b. Explain the reason (statute change, renewal qualifications, etc.):				
С.	Is a date included in the regulation to allow for a transition period?		Yes	No
	If yes, what date?			

# Alaska Board of Pharmacy Agenda Item #6



**Public Comment Period** 

# Alaska Board of Pharmacy Agenda Item #7



Industry Updates

# Access to Care: Eliminating Barriers to MOUD in Tribal and Rural Communities AK Pharmacy Board, August 2024

Sarah Spencer DO, FASAM Ninilchik Tribal Council Community Clinic

### **Disclosure Information**

I have no financial conflicts of interest to disclose

I am currently employed by the Ninilchik Traditional Council

I work as an addiction treatment consultant for non-profit agencies including the Opioid Response Network and the Alaska Native Tribal Health Consortium

I am the volunteer medical director of Alaska's first rural syringe access program in Homer



Sarah Spencer DO, FASAM

### **Abbreviations**

**OUD: Opioid Use Disorder** 

**OTP: Opioid Treatment Program (methadone clinic)** 

**MOUD: Medication for OUD (vs MAT)** 

**BUP: Buprenorphine** 

**SLBUP: Sublingual Buprenorphine** 

**XRBUP: Long-acting Injectable Buprenorphine** 

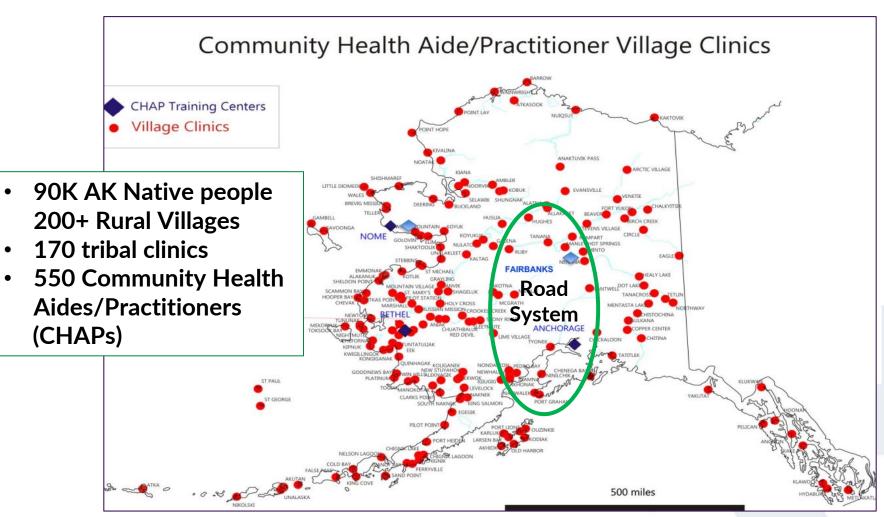
**CHAP: Community Health Aide Practitioner** 

**BHA: Behavioral Health Aid** 

**ANTHC: Alaska Native Tribal Health Consortium** 

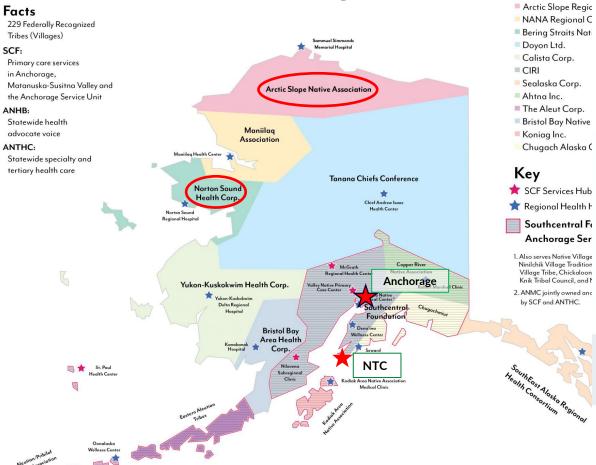
**ANMC: Alaska Native Medical Center** 

076



Currently **MOUD** offered by >80% of regional healthcare hubs but at few village clinics

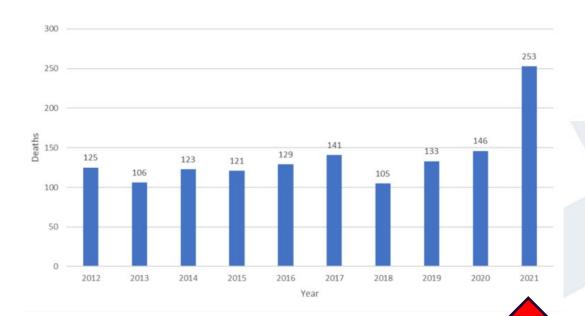
### Alaska Native Health System



Regional N

Corporatio

# Overdose deaths in Alaska rose by 75% in 2021, largest increase nationwide



2023 Largest Nationwide increase 35%

- Alaskan Natives
   OD rate 77/110K
- White OD rate 28/100K
- Meth OD up 150%
- Fentanyl OD up 150%

### Barriers to MOUD Access in Rural AK



Travel costs (over \$1,000 per trip to ANC) and time

No local pharmacies, weather holds/ Rx delayed in the mail

No local licensed medical/BH providers (only CHAPs/BHAs)

No local OTP or inpatient withdrawal management

Lack of anonymity, STIGMA

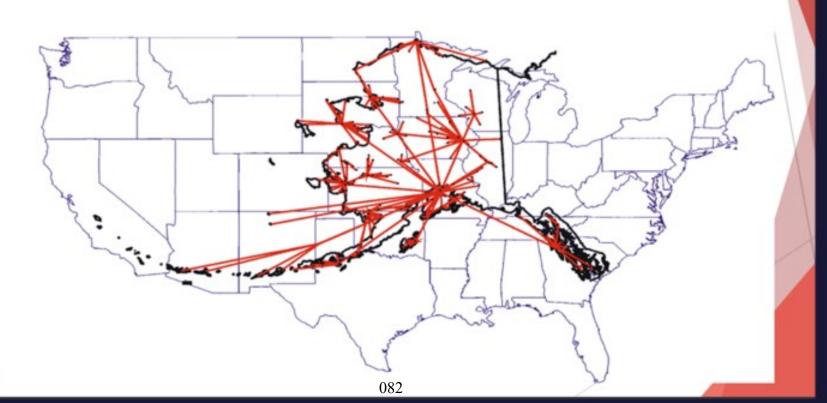


In 2023 completed a 3-year FORE grant project to increase telemedicine access to remote villages

- Identifying barriers to access
- Develop MOUD telehealth provider consultation service
- Develop AK Native MOUD ECHO service
- Develop rural MOUD toolkit
- Develop care management tools for population tracking
- Expand to 15 tribal organizations over 2 years with 10 new prescribing providers

# Alaska Native Health Care System Referral Pattern and Telehealth Network

Same Scale Comparison - Alaska Area to Lower 48 States



# Community Health Aides and Community Health Practitioners (CHA/Ps)

#### Clinical skills include:

- Taking a history
- Performing a physical exam
- Performing lab skills
- Use of the Community Health Aide Manual (CHAM) to make Assessments
- Report
- Following plans per the CHAM
- Giving patient education
- Administering medicines
- Performing certain treatment procedures
- Documenting patient encounters



CHAPs and BHAs can do home visits



#### Internet Eligible Controlled Substance Provider Exception (IECSP)

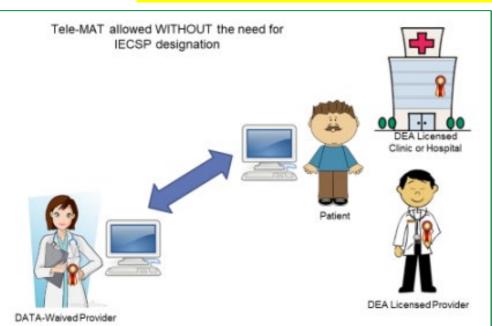
IHS Announces a New Policy to Expand Access to Medication Assisted Treatment in Remote Locations

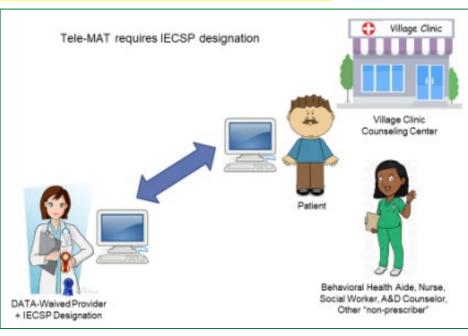
The Internet Eligible Controlled Substance Provider exception to the Ryan Haight Act allows IHS-designated providers to prescribe buprenorphine over telemedicine when the patient is not in the presence of a DEA-registered practitioner and regardless of DEA facility registration status. This exception will expand access to the full spectrum of treatment options for opioid use disorder to individuals in rural and remote areas. Expanding Medication Assisted Treatment locations will reduce the time for patients to start their recovery journey, potentially lower the risk for return to drug use, and may reduce the potential of death from overdose. An example where this policy exception could be used is in a remote Alaska village clinic that is staffed only by a community health aide.

#### Tele-MOUD in IHS

"IHS is committed to improving access to MOUD. Expanding MOUD locations will reduce the time for patients to start their recovery journey, potentially lower the risk of return to drug use and may reduce the potential of death from overdose.

Tele-MOUD can expand access to a highly needed service to address OUD in areas and communities where this service has been difficult to establish or maintain"





### Advantages of XRBUP In Remote Native Alaskan Villages

#### No concern for diversion

Diversion concerns and stigma around SLBUP is a barrier. Avoids challenges in monitor medication compliance in remote locations (no need for medication counts and drug testing)

Reduces risk of withdrawal and relapse related to Rx interruption

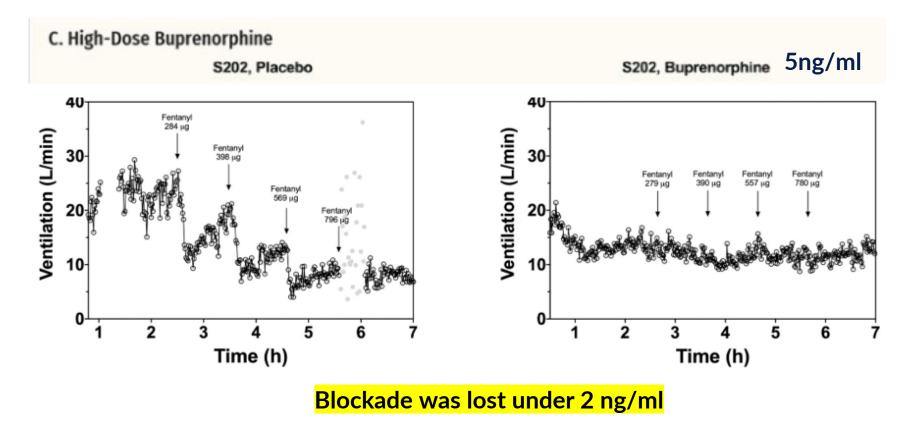
Mail delivery in the bush frequently interrupted due to weather holds and logistics (reduced flights during COVID) that can result in delayed Rx refills → acute withdrawal → relapse → overdose

Flexible dosing q4-6 weeks, slow reduction in levels reduces w/d sxs

#### Long-lasting opioid blockade

Reduces overdose risk for patients with prolonged medication interruption (fishermen, oil field workers, incarcerated)

#### High Dose XRBUP blocks fentanyl induced respiratory depression



https://journals.plos.org/plosone/article/figure?id=10.1371/journal.pone.0256752.g004

Fig. 6 a 300/100 mg BUP-XR Buprenorphine concentration (ng/mL) + 2 months Patients stable on 100 mg may 2 ng/mL 56 72 80 24 32 64 Time (weeks) b 300/300 mg BUP-XR Buprenorphine concentration (ng/mL) + 5 months 2 ng/mL 24 56 80 32 Time (weeks) 088

### **Extended opioid** blockade after XRBUP cessation

have blockade for 2 months (1 missed shot)

Patients stable on 300 mg may have blockade for 5 months (4 missed shots)

https://link.springer.com/article/10.1007/s40262-020-00957-0

Pharmacokinetic parameters	SUBUTEX daily stabilization		SUBLOCADE		
Mean	12 mg (steady-state)	24 mg (steady-state)	300 mg#	100 mg* (steady-state)	300 mg* (steady-state)
C <sub>avg,ss</sub> (ng/mL)	1.71	2.91	2.19	3.21	6.54
C <sub>max,ss</sub> (ng/mL)	5.35	8.27	5.37	4.88	10.12
C <sub>min,ss</sub> (ng/mL)	0.81	1.54	1.25	2.48	5.01

During the first month of XRBUP, the serum drug levels drop to levels that may not be therapeutic for some patients, thus supplemental SLBUP is indicated in patients who experience craving or withdrawal in early treatment



### Low Threshold XR-BUP

- Tele-med intakes (less no-shows)
- Given regardless of active drug/alcohol use
- No required drug testing
- Flexible dosing schedule (4-8 weeks)
- Walk-in appointments for injections
- 1-day medication starts for opioid tolerant
- Flexible dose
- SL supplementation available
- Available in pregnancy (2<sup>nd</sup>/3<sup>rd</sup> trimester)
- Mail to clinic closest to patient

### Mainstreaming Addiction Treatment (MAT) Act Alaska specific changes



 Allows for telemedicine starts of buprenorphine without in person visit if patient is located at a village clinic staffed only by a Community Health Aid Practitioner (CHAP)



Allows CHAPS to administer and dispense buprenorphine per order of remote prescriber



# Mainstreaming Addiction Treatment (MAT) Act Alaska specific changes

cated

Practi



 Allows for telemed person visit if part by a Community



 Allows CHAPS to per order of remote prenorphine without in illage clinic staffed only er (CHAP)

ense buprenorphine

**Not included in Omnibus Bill!!** 



# Mainstreaming Addiction Treatment (MAT) Act Alaska specific changes



 Allows for telemed person visit if part by a Community



 Allows CHAPS to per order of remote



ense buprenorphine

**Not included in Omnibus Bill!!** 



 And, still cannot ship XRUP to the village clinic if there is no DEA licensed prescriber registered there...



# Mainstreaming Addiction Treatment (MAT) Act Alaska specific changes



 Allows for telemed person visit if par by a Community



 Allows CHAPS to per order of remote



ense buprenorphine

**Not included in Omnibus Bill!!** 



 And, still cannot ship XRUP to the village clinic if there is no DEA licensed prescriber registered there... And rural native run clinics cannot bill Medicaid for medication (no buy&bill)!



### New DEA Rule to Dispense Methadone

# Dispensing of Narcotic Drugs To Relieve Acute Withdrawal Symptoms of Opioid Use Disorder

A Rule by the Drug Enforcement Administration on 08/08/2023

(b) Nothing in this section shall prohibit a practitioner, who is not specifically registered to conduct a narcotic treatment program, from dispensing (but not prescribing) narcotic drugs, in accordance with applicable Federal, State, and local laws relating to controlled substances, to one person or for one person's use at one time for the purpose of initiating maintenance treatment or detoxification treatment (or both). Not more than a three-day supply of such medication may be dispensed to the person or for the person's use at one time while arrangements are being made for referral for treatment. Such  $\square$  emergency treatment may not be renewed or extended.

ED/Hospital can dispense (not prescribe) up to 3 days of methadone to bridge to treatment

https://www.federalregister.gov/documents/2023/08/08/2023-16892/dispensing-of-narcotic-drugs-to-relieve-acute-withdrawal-symptoms-of-opioid-use-disorder

### **XRBUP Storage and Shipping**

- Must store in lock box (single) in locked refrigerator in a locked room
- Must keep log of all receipts, administrations and disposals
- ▶ Patients own medication cannot be transferred to another clinic or given to another patient
- Patients own med with is unused at 45 days must be disposed (increased from 2 weeks)
- Buy and bill medication can be used for any patient and kept until expiration date

#### Sublocade (buprenorphine extended-release)

https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm? NDA #209819 event=IndvRemsDetails.page&REMS=376

REMS last update: 07/03/2023

- View the Sublocade Prescribing Information and Medication Guide at DailyMed.
- View Sublocade's Regulatory Information at Drugs@FDA

**REMS Materials** Update history Goals Summary Assessment Plan

What updates have been made to the REMS?

09/22/2021 Modified to make changes in response to recent updates with the Drug Enforcement Administration (DEA) interim final rule (IFR) published on November 2, 2020, that amended regulations for consistency with the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018 (the SUPPORT Act). REMS materials were updated to clarify that the pharmacy can deliver SUBLOCADE to either the prescribing practitioner or the practitioner administering the controlled **substance**, as applicable. Materials affected include the REMS Fact Sheet and the REMS Website.

https://www.accessdata.fda.gov/drugsatfda docs/rems/Sublocade 2023 07 03 REMS Document.pdf https://www.sublocaderems.com/ResourceDownloadRaw/HCPLetter/inline

### Black Bag Exemption

Question: Can a physician transport controlled substances and administer at the patient's home residence (the so-called "black bag exception")? Answer: Yes, with a limit. DEA will permit a physician who is registered with DEA to dispense controlled substances at a particular location in a state to travel to other unregistered locations in the same state to dispense controlled substances on an "as-needed and random basis," so long as the physician does not maintain a principal place of professional practice at any of those unregistered locations. If a physician intends to dispense controlled substances from a particular location several times a week or month, he must first file a separate registration for the location.

### AK Medicaid Coverage of Buprenorphine

AK Medicaid covers all forms of buprenorphine for OUD

- ▶ No PA needed for 24 mg or less of SL BUP/NL
  - ▶ May authorize more than 24mg on a case-by-case basis. The call center has been coached to send all Rx exceeding 24mg to the state for review, which can include consultation with the specialists at University of Washington telepain
- Mono BUP limited to pregnant individuals
- https://health.alaska.gov/dhcs/Documents/pharmacy/forms/AK\_MAT\_Provider\_Standards\_of\_Care\_Attestation\_Form-20220401.pdf

### 2024 Consolidated Appropriations Act

- Permanently requiring states' Medicaid plans to cover all medications for opioid use disorders.
- Making permanent the state Medicaid option to cover treatment at a residential or inpatient substance use disorder program with over 16 beds.
- Prohibiting states from terminating Medicaid enrollment for incarcerated individuals.
- Mandating guidance from the Department of Health and Human Services on improving the behavioral health workforce.

"Through expanding coverage for evidence-based SUD medication, eliminating barriers to care based on treatment facility size, and improving access to care for incarcerated people — for whom continuity of care is critical in lowering the risk of overdose — this law will better enable people

#### National Policy Changes Could Increase Access to MOUD via Telehealth

- Change DEA regs to allow XRBUP to ship to remote village clinics (staffed only by CHAP/Iterant licensed providers)
- Allow XRBUP to be keep until expired to reduce waste (Must throw away \$1,700 med after 45 days)
- TREATS act: Eliminates in-person visit requirement for buprenorphine prescribing for MOUD <a href="https://www.congress.gov/bill/117th-congress/house-bill/1647/text?r=3&s=1">https://www.congress.gov/bill/117th-congress/house-bill/1647/text?r=3&s=1</a>

# ASAM and AAAP Announce New Clinical Practice Guideline to Address Rising Stimulant Use Disorders

Nov 7, 2023

Download



https://downloads.asam.org/sitefinity-production-blobs/docs/default-source/quality-science/stud\_guideline\_document\_final.pdf?sfvrsn=71094b38\_162

# Contingency Management is #1

Board certified providers may consider Rx stimulants in select patients with close monitoring

Review > J Addict Med. 2023 Sep-Oct;17(5):509-516. doi: 10.1097/ADM.00000000001189. Epub 2023 Jun 16.

#### Evidence on Buprenorphine Dose Limits: A Review

Lucinda A Grande 1, Dave Cundiff, Mark K Greenwald, MaryAnne Murray, Tricia E Wright,

Conclusions: In light of established research and profound harms from fentanyl, the Food and Drug Administration's current recommendations on target dose and dose limit are outdated and causing harm. An update to the buprenorphine package label with recommended dosing up to 32 mg/d and elimination of the 16 mg/d target dose would improve treatment effectiveness and save lives.

#### REVIEW

### ASAM Clinical Considerations: Buprenorphine Treatment of Opioid Use Disorder for Individuals Using High-potency Synthetic Opioids

Weimer, Melissa B. DO, MCR, DFASAM; Herring, Andrew A. MD; Kawasaki, Sarah S. MD, FASAM; Meyer, Marjorie MD; Kleykamp, Bethea A. PhD; Ramsey, Kelly S. MD, MPH, MA, FACP, DFASAM

Author Information ⊗

Journal of Addiction Medicine 17(6):p 632-639, 11/12 2023. | DOI: 10.1097/ADM.000000000001202 @

## Reps. Norcross, Bacon Lead Introduction of the Modernizing Opioid Treatment Access Act

March 6, 2023

WASHINGTON, DC – Today, U.S. Congressmen Donald Norcross (D-NJ-01) and Don Bacon (R-NE-02) unveiled the Modernizing Opioid Treatment Access (MOTA) Act (H.R. 1359). This evidence-based legislation would increase access to care for people experiencing opioid use disorder (OUD) by reforming the outdated regulations governing the prescription and dispensing of methadone. Methadone is one of the most effective medicines used for the treatment of OUD and is considered an "essential medicine" by the World Health Organization. U.S. Representatives Annie Kuster (D-NH-02), David Trone (D-MD-06), Brain Fitzpatrick (R-PA-01), Paul Tonko (D-NY-20), Brittany Pettersen (D-CO-07), and Andy Kim (D-NJ-03) are original cosponsors of the bill.

"Improving access to treatment saves lives, period," **said Congressman Norcross**. "This legislation lowers barriers to care at a time when we are still suffering staggering losses due to the ongoing opioid epidemic. We must end the monopoly on this life-saving medicine that only serves to enrich a cartel of for-profit clinics and stigmatize patients."

"There are only six certified methadone clinics in Nebraska, making it a significant obstacle for those seeking treatment to overcome their opioid addiction," **said Congressman Bacon**. "The current law requires patients to visit a clinic daily, which is not physically possible outside of the Omaha/Lincoln metro areas. It's time make the treatment for opioid addiction more accessible than opioids themselves."

The legislation makes two crucial changes to FDA regulations that have governed methadone since the 1970s and are not supported by modern medical science:

- Allowing board-certified addiction physicians and addiction psychiatrists to prescribe methadone.
- Allowing pharmacies to dispense methadone.

### Sarah Spencer DO, FASAM Addiction Medicine Specialist & Consultant

Ninilchik Traditional Council Community Clinic Ninilchik, Alaska Cell 907-299-7460 sarahspencerak@gmail.com



## Q&A

# Alaska Board of Pharmacy Agenda Item #8



Adjourn for Lunch

# Alaska Board of Pharmacy Agenda Item #9



Roll Call/Call to Order

## **Alaska Board of Pharmacy Roster**

Board Member Name	Initial Appointment	Reappointed	Term End
Ashley Schaber, PharmD	07/01/2021	03/01/2024	03/01/2028
Sylvain Nouvion, PharmD., Ph.D.	05/31/2023		03/01/2027
James Henderson, RPh	03/01/2017	03/01/2021	03/01/2025
Ramsey Bell, RPh	03/01/2022		03/01/2026
Carla Hebert, RPh	01/05/2023	03/01/2024	03/01/2028
C. Saharai Thompson, CPhT	05/24/2024		03/01/2028
Sara Rasmussen, Public Member	03/01/2023		03/01/2027

Name	Position	Committee Membership/Additional Duties
Ashley Schaber	Chair	Statutes and Regulations
James Henderson	Vice Chair	Statutes and Regulations, Compounding
Ramsey Bell	Secretary	Well-Being
Carla Hebert		Compounding, Well-Being
Sara Rasmussen		Statutes and Regulations, Controlled Substances Advisory Committee Chair
Sylvain Nouvion		Statutes and Regulations
C. Saharai Thompson		

# Alaska Board of Pharmacy Agenda Item #10



**Public Comment Period** 

# Alaska Board of Pharmacy Agenda Item #11



**Board Business** 

### **NABP Verify**

NABP Verify is a license monitoring service created to help member boards as they seek new ways to regulate pharmacies and pharmacists, who are playing an ever-increasingly important role in the health care system. For example, the NABP Verify program can provide additional insight and oversight of out-of-state pharmacists practicing via an interstate practice model. Participating boards can reduce administrative burden on board staff by taking advantage of the service's ongoing verification that Verified Pharmacists maintain active licenses in good standing, pursuant to program requirements.

NABP Verify is not an authorization to practice pharmacy; it is evidence of licensure in good standing. The authorization to practice is defined by state statutes or regulations that can reference this credential as a requirement to practice in the manner described by that state. While NABP Verify can serve as a new tool to provide appropriate board oversight to enable nonresident practice models, it does not serve as an alternative to state licensure, either by examination or via endorsement, for in-person practice within a state. As always, licensure and practice decisions will remain at the sole discretion of the boards of pharmacy.

#### NABP Verify enables boards of pharmacy to:

- Allow for the issuance of state credentials based upon continued evidence of ongoing licensure in good standing, with little impact on their staff resources.
- Develop state-specific credentials and define the practice authority via statutory, regulatory, or
  policy reference. Practice outside of these references would exceed the credential authority and
  require full licensure in that state.
- Enable or expand board oversight of existing and/or innovative new nonresident practice models. NABP Verify does not serve as an alternative to state licensure, either by examination or via endorsement, for in-person practice within a state.

#### Benefits of NABP Verify for the Boards

- Reduces administrative burden on board staff to verify license status
- Provides a system for continuous monitoring of license status across all states
- Provides member boards insight and oversight on interstate practitioners
- State-specific credential issued which has authority defined within statutes, regulations, or policies

#### **NABP Verify Program Requirements**

The NABP Verify program verifies that an applicant's license(s) are maintained in good standing. Once initially verified, the applicant's license(s) are subject to ongoing monitoring by National Association of Boards of Pharmacy (NABP) to confirm they remain in good standing. Program participants pay an annual fee for the verification and ongoing monitoring services.

NABP issues credentials to applicants who meet the NABP Verify program requirements. NABP Verify does not convey authorization to practice pharmacy. State and jurisdictional boards of pharmacy must accept the credential in order for credential holders to provide pharmacy-related services in the applicable state or jurisdiction.

Credentials that NABP issues through its NABP Verify program can be maintained by credential holders based upon ongoing licensure in good standing, as determined via the NABP Verify monitoring service, and maintaining an active NABP Verify monitoring subscription.

The practice authority will be defined by individual state or jurisdictional statutes, regulations, or policies. These laws, rules, or policies may reference the NABP Verify credential as a requirement to practice in the manner authorized by that state or jurisdictional licensing agency. There are three NABP Verify credential statuses:

**Active**: Credential holders that continue to subscribe and meet program requirements are accorded active status for all state or jurisdictional-specific credentials.

**Inactive**: Credential holders that do not meet program requirements addressing licensure or discipline are accorded inactive status for all state or jurisdictional-specificcredentials. At the request of a state or jurisdiction, NABP will place the corresponding credential on inactive status. If the credential holder holds one or more additional tate or jurisdictional specific credentials, those statuses remain active so long as the holder continues to subscribe and meet program requirements.

**Closed:** Credential holders who do not renew or who terminate their subscription are accorded closed status for all state or jurisdictional-specific credentials. NABP staffcan close a state or jurisdictional-specific credential based upon the credential holder's explicit direction.

A credential holder can view the status of their NABP Verify subscription as well as all state-specific credentials within their NABP e-Profile.

Be aware that by applying to the NABP Verify program or continuing to hold a credential issued through the Program, you agree to the NABP Verify Terms and Conditions.

All individuals who wish to hold a credential must meet the following NABP Verify program requirements for participation.

#### **Program Requirements:**

- A state-specific NABP Verify credential will be issued to an applicant who:
  - 1. Holds at least one license or registration that is:
    - issued by a state or jurisdictional board of pharmacy in the United States; and
    - active, unconditional, and in good standing; and
  - 2. May hold one or more additional licenses or registrations, in which case:
    - the status may be expired, inactive, non-renewed, or meet the requirements in Section 1; and
    - none have a current and/or unresolved disciplinary sanction; and
    - Has a valid, passing score or result on a pharmacist licensure examination administered in the United States.

- For the purposes of the NABP Verify Program, "Good standing" means that a license or registration is not suspended, revoked, surrendered, conditioned under terms of probation, or otherwise in a status that in any manner restricts the activity of the licensee or registrant.
- Any individual holding a license or registration with an active disciplinary sanction of probation, suspension, revocation, or surrendered, will not be issued an NABP Verify credential and will not be able to hold an NABP Verify credential.
- An individual that applies for and holds an NABP Verify credential must continuously subscribe to NABP Verify for ongoing monitoring of license status. NABP utilizes state and jurisdictional board of pharmacy databases and disciplinary actions reported to the NABP Disciplinary Clearinghouse to confirm active unconditional licensure in good standing.
- The NABP Verify credential holder must renew their monitoring subscription at the annual renewal date, and meet program requirements addressing licensure and discipline, to continue participating in the program and holding one or more state-specific NABP Verify credentials. In the event that a credential holder does not renew their monitoring subscription, the subscription terminates, and the holder's credential(s) and program participation status changes to closed.
- A state or jurisdictional board of pharmacy may direct NABP to remove the corresponding credential from an NABP Verify credential holder if the credential holder failed to comply with state or federal laws or rules applicable to the practice of pharmacy in that state. NABP will change the status of that state-specific credential to inactive. This state-specific action will not impact the status of other holder credentials if the holder continues to meet all NABP Verify program requirements.
- Any NABP Verify credential holder who subsequently is found to have a newly reported license sanction that renders the individual to no longer meet the program requirements, will have their program participation displayed as "expired" and any issued state-specific credentials will change to a status of "inactive."
- If NABP does not issue the applicant a Program credential or the Program credential is inactivated and the applicant has documentation, or a board of pharmacy contact, that can confirm licensure information demonstrating the applicant's adherence to the Program Requirements, the applicant must contact NABP's licensure team at <a href="MABPVerify@nabp.pharmacy">NABPVerify@nabp.pharmacy</a> within 30 days of the non-issuance or inactivation of the Program credential. If an error occurred, NABP will issue a coupon code that will enable the applicant to re-apply to the Program at no additional cost subject to compliance with the <a href="Subscription Plan Policy">Subscription Plan Policy</a>.



# ALASKA BOARD OF PHARMACY

2024 STRATEGIC PLAN

The Alaska Board of Pharmacy endeavors to promote, preserve, and protect the public health, safety, and welfare by and through the effective control and regulation of the practice of pharmacy.

GOALS	STRATEGIES
1. Engage in effective communication and promote transparency of public information.	<ul> <li>1.1 Improve customer service by providing timely and informative updates to applicants and licensees.</li> <li>1.2 Maximize communication channels through the Board of Pharmacy website and List Service.</li> <li>1.3 Maintain accuracy of website content and ensure accessibility of upto-date resources</li> </ul>
2. Adhere to and strive for improved organizational efficiencies without compromising quality of record keeping.	<ul> <li>2.1 Avoid delays in application processing by maintaining adequate staffing and exploring flexible retention strategies.</li> <li>2.2 Maintain a proactive approach to licensing by consulting historical knowledge, researching national trends, and encouraging innovation in the planning process.</li> <li>2.3 Automate initial licensure through online applications.</li> <li>2.4 Exercise fiscal discipline through effective budget management.</li> <li>2.5 Embrace innovation by exploring integration and/or delegation opportunities to support core administration functions.</li> </ul>
<b>3.</b> Ensure competency and qualifications prior to licensure and renewal.	<ul> <li>3.1 Adhere to established licensing standards by reviewing education, experience, and examination requirements.</li> <li>3.2 Take a proactive approach to application and form revision subsequent to regulation changes.</li> </ul>
<b>4.</b> Grow the economy while promoting community health and safety.	<ul> <li>Develop a license application for manufacturers.</li> <li>Ensure a 30 day or less processing time for licensee applications, and a 60 day or less licensing time for facility applications.</li> </ul>
	<ul><li>4.1 Routinely review effectiveness of regulations that reduce barriers to licensure without compromising patient health and safety.</li><li>4.2 Combat the opioid crisis by effective administration of the state's</li></ul>
the following resources:  pharmacy.alaska.gov gram (PDMP): pdmp.alaska.gov a.gov	Prescription Drug Monitoring Program (PDMP), including collaboration with providers and key stakeholders.  4.3 Advocate for legislation as the pharmacy profession evolves and new opportunities for improved patient safety arise.  4.4 Anticipate changes to the Drug Supply Chain Security Act and respond proactively. Address changes to compounding.
	1. Engage in effective communication and promote transparency of public information.  2. Adhere to and strive for improved organizational efficiencies without compromising quality of record keeping.  3. Ensure competency and qualifications prior to licensure and renewal.  4. Grow the economy while promoting community health and safety.  the following resources:  pharmacy.alaska.gov  pram (PDMP): pdmp.alaska.gov



Hangover cure. Immune system boost. Long COVID-19 relief. Jet lag treatment. General wellness. Informed by entertainment and social media influencers, streaming shows, websites, word of mouth, and more, consumers seeking these, and many more health benefits, have turned intravenous (IV) hydration therapy into big business. According to one market research company, IV hydration therapy (often called IV vitamin therapy) was estimated to be a \$2.57 billion global industry in 2023 and expected to grow to \$3.92 billion by 2028. It takes place at designated clinics, within medical practices, at so-called drip bars, in medical spas, through mobile sites, at patients' homes, and many other locations. But even as businesses offering IV hydration therapy services have proliferated, regulatory oversight remains spotty, to the increasing concern of the regulatory community and others concerned with patient safety.

In general, IV hydration clinics provide patients with a basic IV saline solution to which other substances have been added, such as vitamins, minerals, amino acids, antioxidants, and anti-nausea medications. While Food and Drug Administration (FDA) views the preparation of these solutions as sterile compounding, and more than one state has made it clear that providing such treatments constitutes the practice of medicine, consumers often seem to view the treatments as self-care on par with a luxury spa treatment but with a medical slant. A bachelorette party weekend can feature anti-hangover IV infusions as part of the group activities; a famous model or actress might post rapturously about the IV vitamin boost she is undergoing in the comfort of her home; a patron at a luxury Las Vegas casino hotel may schedule IV treatments in-room or at the hotel drip lounge. Treatments are rarely covered by insurance and can cost hundreds of dollars per IV bag, lending status to the promise of "wellness."

And yet any IV treatment entails some risk (such as infection, blood clots, fluid overload, and air embolisms) and IV hydration or vitamin therapy without strict medical need carries more (including organ stress and heart attack). Human error, inadequately trained personnel, and failure to uphold cleanliness or sterility standards further raise the odds of serious adverse events. FDA, for example,

found unsanitary conditions in a facility that supplied the IV vitamin treatment for a woman who was hospitalized for suspected septic shock with multi-organ failure. Recently, the Texas Medical Board cited the public safety hazards of IV vitamin treatments administered by unlicensed personnel operating with inadequate supervision and protocols when it ordered the temporary suspension of a physician's license after a woman died while undergoing a vitamin IV treatment at the medical spa for which he was medical director.

Despite these known facility and process-associated risks, most states do not license IV hydration therapy clinics, nor do they regularly inspect them. To the extent that most states oversee the clinics at all, jurisdiction may be divided between regulatory boards, and current laws may not address the gaps. Nurses and physicians often play a central role in the ownership and operation of clinics, and most regulatory activity has focused on them rather than on the facilities themselves. Oversight therefore tends to be reactive in nature, ie, responding to complaints. State boards of pharmacy, which have sterile compounding expertise and perform facility inspections as part of their regular duties, usually do not have the jurisdiction to inspect IV hydration clinics and in some states may be left out of the equation entirely.

As one legal blogger for the American Med Spa Association noted, "Historically, IV therapy has been like the wild west from a compliance perspective."

On the federal level, Federal Trade Commission responds to false advertising claims, such as an IV clinic stating that its treatments are "clinically proven" to cure cancer or COVID-19, or a variety of other health problems. FDA, meanwhile, issued a compounding risk alert in October 2021 advising health care providers about drugs being compounded in unsanitary conditions at IV hydration clinics and has worked with state regulators to investigate reports of IV clinics compounding under unsanitary conditions. The agency has also encouraged the reporting of adverse events or quality problems but does not directly regulate IV clinics.

Some states have taken steps to address regulatory gray areas. The Alabama Board of Medical Examiners, for example, issued a declaratory ruling on the topic in late 2022, following an investigation that found many IV therapy businesses operating out of compliance with state law. Among other things, the ruling clarified that IV therapy is the practice of medicine, emphasized the need for a good faith exam prior to diagnosis and treatment, and specified which health care providers may prescribe and administer IV therapy. The Mississippi State Board of Medical Licensure issued similar guidance the following year, noting that "many clinics"

## "Historically, IV therapy has been like the wild west from a compliance perspective."

or spas engaging in this therapy are adopting business and/or practice models without realizing IV hydration therapy constitutes the practice of medicine." In South Carolina, meanwhile, the state's pharmacy, nursing, and medical boards issued a 10-page joint advisory opinion giving guidance on retail IV clinics. Other states, including Massachusetts, North Carolina, and Oklahoma, have clarified such aspects as nurses' scope of practice and roles in providing IV therapy.

While regulation has made some progress catching up to this rapidly growing and evolving industry, IV hydration clinics remain a source of concern for those tasked with protecting public safety. Collaboration and communication between pharmacy, medical, and nursing boards will be crucial as regulators work to navigate this complicated intersection of social media-driven wellness fad and medical care. lacktriangle

#### **NABP Survey Indicates Many IV Hydration Clinics Are Not Regulated**

In early 2024, NABP sent a survey to the state boards of pharmacy asking about intravenous (IV) hydration clinic regulation in each state. Of the 18 responding boards, 12 indicated that their state did not currently have a licensing or permitting requirement for these facilities and there were no current known plans for doing so. An additional two states (Alaska and North Dakota) reported no existing licensing requirement but noted that preliminary conversations about how to deal with the IV clinic issue were ongoing.

Four states – North Carolina, Ohio, Rhode Island, and South Carolina – reported that state licensing requirements did affect retail IV therapy businesses. The following are some of their insights:



North Carolina: North Carolina law defines a pharmacy as "any place where prescription drugs are dispensed or compounded."

Since "the vast majority" of hydration clinics do not hold a pharmacy permit, they are technically operating illegally.



**Ohio:** The Ohio Board of Pharmacy issues licenses to IV hydration clinics and does periodic inspections as part of that process. The Board

reported that inspections commonly reveal insufficient oversight, training, and cleanliness, and that clinic personnel often do not realize

that they may be engaging in compounding. A recent investigation discovered numerous sites operating without a license. Mobile clinics are increasingly common, sometimes with the businesses headquartered in a residence. The Board noted the need to work with other regulatory boards, particularly on scope-of-practice issues.



Rhode Island: IV hydration clinics are considered part of a medical practice; the Board of Pharmacy does not license or inspect them. Oversight is

retrospective to complaints and is handled by the relevant professional licensing board.

Compounding may only take place with

physician supervision and must be in accordance with pharmacy regulations for compounding.



**South Carolina:** The South Carolina Board of Pharmacy issues non-dispensing drug outlet permits to retail IV clinics, with the exception of

clinics that are entirely practitioner owned, and does periodic inspections. The Board noted the need to educate licensees and the importance of close collaboration with other licensing boards.

Source: NABP internal survey of boards of pharmacy, with 18 states responding. Results are not conclusive.



### Alaska State Commission For Human Rights

1901 Bragaw Street, Suite 301 Anchorage, Alaska 99508 Main: 907.274.4692 / 907.276.7474 TTY/TDD: 711 for Alaska Relay

April 8, 2024

RECEIVED

APR 1 0 2024

Ashley Schaber, PharmD, MBA, BCPS Alaska Board of Pharmacy PO Box 110806 Juneau, AK 99811-0806

RE: ASCHR Resolution 2024-01

Dear Chairperson Schaber,

The Alaska State Commission for Human Rights ("ASCHR" or the "Commission") adopted one resolution during its meeting on March 18, 2024, that is enclosed for the Board of Pharmacy's consideration.

Resolution 2024-01 calls on the Alaska Board of Pharmacy to adopt regulations encouraging pharmacies to adopt the National Council of Disability's best practices on pharmaceutical labeling and calls upon individual pharmacies to voluntarily abide by these best practices to better serve their visually impaired clientele.

Thank you for your time and review of this resolution.

Sincerely,

Robert W. Corbisier Executive Director

V. lestine

Enclosure: Resolution 2024-01.



# Alaska State Commission for Human Rights

800 A Street, Suite 204 Anchorage, Alaska 99501-3669 Main: 907.274.4692 / 907.276.7474 TTY/TDD: 711 for Alaska Relay Fax: 907.278-8588

#### **RESOLUTION 2024-01**

#### Encouraging Best Practices in Prescription Labeling for the Visually Impaired

WHEREAS, the Alaska State Commission for Human Rights is the State of Alaska's civil rights enforcement agency; and,

WHEREAS, the Alaska State Commission for Human Rights enforces the Alaska Human Rights Act, AS 18.80 et seq.; and,

WHEREAS, 28 CFR § 36.303 requires that places of public accommodation take reasonable steps to provide auxiliary aids and services to ensure that people with disabilities are not discriminated against, and 28 CFR § 36.104(1)(ii)(B)(6) explicitly includes pharmacies as places of public accommodation; and,

WHEREAS, Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, § 904, 126 Stat. 993 (2012) convened a working group to establish best practices concerning prescription drug labeling for the visually impaired, the work product of which can be found in the National Council on Disability's Best Practices for Accessible Prescription Drug Labeling; and,

WHEREAS, the National Council on Disability determined best practices in the field to include affixing large print or braille labels to prescription bottles, providing text-to-speech functionality for warning labels, or similar incorporations of smart technologies; and,

WHEREAS, AS 18.80.230 makes it unlawful for places of public accommodation to discriminate on the basis of disability; and,

WHEREAS, visually impaired individuals may take multiple prescription medications and taking the wrong dosage of these medications due to inaccessible labeling could have a deadly impact; and,

WHEREAS, national pharmacy chains such as Walmart and CVS are implementing programs such as ScripTalk and SpokenRX that allow visually impaired customers to have their prescription labels read aloud via RFID tags or QR codes.

NOW, THEREFORE, BE IT RESOLVED that the Alaska State Commission for Human Rights

calls on the Alaska Board of Pharmacy to adopt regulations encouraging Alaskan pharmacies to adopt the National Council of Disability's best practices on pharmaceutical labeling and calls upon pharmacies across the state of Alaska to voluntarily abide by these best practices to better serve their visually impaired clientele.

Copies of this resolution shall be forwarded to the Alaska Board of Pharmacy and individual pharmacies in Alaska.

ADOPTED in Anchorage, Alaska, this 18th day of March, 2024.

Zookany Gottshall

DocuSigned by:

Zackary Gottshall

Chairperson

Alaska State Commission for Human Rights

I hereby certify that the foregoing Resolution 2024-01 is a true and accurate copy of the language adopted by the Commission on

April 8th, 2024.

Gina Aumuvae

Secretary

Alaska State Commission for Human Rights



# LAWS OF ALASKA 2024

Source SCS CSHB 226(L&C)

Chapter	No.
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#### **AN ACT**

Relating to insurance; relating to pharmacy benefits managers; relating to dispensing fees; 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

1	Relating to insurance; relating to pharmacy benefits managers; relating to dispensing fees; and
2	providing for an effective date.
3	
4	* Section 1. AS 08.80.297(d)(2) is amended to read:
5	(2) "pharmacy benefits manager" has the meaning given in
6	<u>AS 21.27.975</u> [AS 21.27.955].
7	* Sec. 2. AS 21.27.901 is amended to read:
8	Sec. 21.27.901. Registration of pharmacy benefits managers; scope of
9	business practice. (a) A person may not conduct business in the state as a pharmacy
10	benefits manager unless the person is registered with the director [AS A THIRD-
11	PARTY ADMINISTRATOR UNDER AS 21.27.630].
12	(b) A pharmacy benefits manager registered under this section
13	[AS 21.27.630] may
14	(1) contract with an insurer to administer or manage pharmacy benefits

I	provided by an insurer for a covered person, including claims processing services for
2	and audits of payments for prescription drugs and medical devices and supplies; and
3	(2) contract with network pharmacies [;
4	(3) SET THE COST OF MULTI-SOURCE GENERIC DRUGS
5	UNDER AS 21.27.945; AND
6	(4) ADJUDICATE APPEALS RELATED TO MULTI-SOURCE
7	GENERIC DRUG REIMBURSEMENT].
8	* Sec. 3. AS 21.27.901 is amended by adding new subsections to read:
9	(c) A pharmacy benefits manager
10	(1) shall apply for registration following the same procedures for
11	licensure set out in AS 21.27.040;
12	(2) is subject to hearings and orders on violations; denial, nonrenewal,
13	suspension, or revocation of registration; penalties; and surrender of registration under
14	the procedures set out in AS 21.27.405 - 21.27.460.
15	(d) Each day that a pharmacy benefits manager conducts business in the state
16	as a pharmacy benefits manager without being registered is a separate violation of this
17	section, and each separate violation is subject to the maximum civil penalty under
18	AS 21.97.020.
19	* Sec. 4. AS 21.27.905(a) is amended to read:
20	(a) A pharmacy benefits manager shall biennially renew a registration with the
21	director following the procedures for license renewal in AS 21.27.380.
22	* Sec. 5. AS 21.27 is amended by adding a new section to read:
23	Sec. 21.27.907. Duty of care. (a) A pharmacy benefits manager owes a duty of
24	care to a plan sponsor, benefits administrator, and covered person. A pharmacy
25	benefits manager shall adhere to the practices set out in this section.
26	(b) A pharmacy benefits manager shall
27	(1) perform the manager's duties with care, skill, prudence, diligence,
28	fairness, transparency, and professionalism and in the best interest of the plan sponsor,
29	benefits administrator, and covered person as required by this section; and
30	(2) notify the plan sponsor in writing of any activity, policy, or practice
31	of the pharmacy benefits manager that directly or indirectly presents any conflict of

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\* **Sec. 6.** AS 21.27.940 is amended to read:

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Sec. 21.27.940. Pharmacy audits; restrictions. The requirements of

interest with the duties imposed by this chapter.

- (c) The duty of care owed to a covered person under this section takes precedence over the duty of care owed to any other person.
- (d) A pharmacy benefits manager that receives from a drug manufacturer or labeler a payment or benefit of any kind in connection with the use of a prescription drug by a covered person, including a payment or benefit based on volume of sales or market share, shall pass that payment or benefit on in full to the plan sponsor.
  - (e) Upon request by a plan sponsor, a pharmacy benefits manager shall
- (1) provide information showing the quantity of drugs purchased by the covered person and the net cost to the covered person for the drugs; the information must include all rebates, discounts, and other similar payments; if requested by the plan sponsor, the pharmacy benefits manager shall provide the quantity and net cost information on a drug-by-drug basis by national drug code registration number rather than on an aggregated basis; and
- (2) disclose to the plan sponsor all financial terms and arrangements for remuneration of any kind that apply between the pharmacy benefits manager and a prescription drug manufacturer or labeler, including formulary management and drugsubstitution programs, educational support, claims processing, and data sales fees.
- (f) A pharmacy benefits manager providing information to a plan sponsor under (e) of this section may designate that information as confidential. Information designated as confidential may not be disclosed by the plan sponsor to another person without the consent of the pharmacy benefits manager, unless ordered by a court.
- (g) If a pharmacy dispenses a substitute prescription drug for a prescribed drug to a covered person and the substitute prescription drug costs more than the prescribed drug, the pharmacy benefits manager shall disclose to the plan sponsor the cost of both drugs and any benefit or payment directly or indirectly accruing to the pharmacy benefits manager as a result of the substitution. The pharmacy benefits manager shall transfer in full to the plan sponsor a benefit or payment received in any form by the pharmacy benefits manager as a result of a prescription drug substitution.

1	AS 21.27.901 - <b>21.27.975</b> [21.27.955] do not apply to an audit
2	(1) in which suspected fraudulent activity or other intentional or wilful
3	misrepresentation is evidenced by a physical review, a review of claims data, a
4	statement, or another investigative method; or
5	(2) of claims paid for under the medical assistance program under
6	AS 47.07.
7	* <b>Sec. 7.</b> AS 21.27.945(a) is amended to read:
8	(a) A pharmacy benefits manager shall
9	(1) <b>provide</b> [MAKE AVAILABLE] to each network pharmacy at the
10	beginning of the term of the network pharmacy's contract, and upon renewal of the
11	contract, the methodology and sources used to determine the [DRUG PRICING] list;
12	(2) provide the list to a network pharmacy without charge;
13	(3) [(2)] provide and keep current a telephone number at which a
14	network pharmacy may contact an employee of a pharmacy benefits manager [TO
15	DISCUSS THE PHARMACY'S APPEAL];
16	(4) [(3)] provide a process for a network pharmacy to have ready
17	access to the list specific to that pharmacy;
18	(5) [(4)] review and update applicable list information at least once
19	every seven business days to reflect modification of list pricing;
20	(6) [(5)] update list prices within one business day after a significant
21	price update or modification provided by the pharmacy benefits manager's national
22	drug database provider; and
23	(7) [(6)] ensure that dispensing fees are not included in the calculation
24	of the list pricing.
25	* Sec. 8. AS 21.27.945(b) is repealed and reenacted to read:
26	(b) Before placing or maintaining a specific drug on the list, a pharmacy
27	benefits manager shall ensure that
28	(1) if the drug is therapeutically equivalent and pharmaceutically
29	equivalent to a prescribed drug, the drug is listed as therapeutically equivalent and
30	pharmaceutically equivalent "A" or "B" rated in the most recent edition or supplement
31	of the United States Food and Drug Administration's Approved Drug Products with

1	I nerapeutic Equivalence Evaluations, also known as the Orange Book;
2	(2) if the drug is a different biological product than a prescribed drug,
3	the drug is an interchangeable biological product;
4	(3) the drug is readily available for purchase from national or regional
5	wholesalers operating in the state; and
6	(4) the drug is not obsolete or temporarily unavailable.
7	* Sec. 9. AS 21.27.945 is amended by adding new subsections to read:
8	(c) The list a pharmacy benefits manager provides to a network pharmacy
9	under (a) of this section must
10	(1) be maintained in a searchable electronic format that is accessible
11	with a computer;
12	(2) identify each drug for which a reimbursement amount is
13	established;
14	(3) specify for each drug
15	(A) the national drug code;
16	(B) the national average drug acquisition cost, if available;
17	(C) the wholesale acquisition cost, if available; and
18	(D) the reimbursement amount; and
19	(4) specify the date on which a drug is added to or removed from the
20	list.
21	(d) In this section,
22	(1) "interchangeable biological product" has the meaning given in
23	AS 08.80.480;
24	(2) "pharmaceutically equivalent" means a drug has identical amounts
25	of the same active chemical ingredients in the same dosage form and meets the
26	standards of strength, quality, and purity according to the United States Pharmacopeia
27	published by the United States Pharmacopeial Convention or another similar
28	nationally recognized publication;
29	(3) "significant price update or modification" means
30	(A) an increase or decrease of 10 percent or more in the
31	pharmacy acquisition cost;

1	(B) a change in the methodology in which the maximum
2	allowable cost for a drug is determined; or
3	(C) a change in the value of a variable involved in the
4	methodology used to determine the maximum allowable cost for a drug;
5	(4) "therapeutically equivalent" means a drug is from the same
6	therapeutic class as another drug and, when administered in an appropriate amount,
7	provides the same therapeutic effect as, and is identical in duration and intensity to,
8	the other drug;
9	(5) "therapeutic class" means a group of similar drug products that
10	have the same or similar mechanisms of action and are used to treat a specific
11	condition.
12	* Sec. 10. AS 21.27 is amended by adding new sections to read:
13	Sec. 21.27.951. Patient access to clinician-administered drugs. (a) An
14	insurer or its pharmacy benefits manager may not
15	(1) refuse to authorize, approve, or pay a provider for providing
16	covered clinician-administered drugs and related services to a covered person if the
17	provider has agreed to participate in the insurer's health care insurance policy
18	according to the terms offered by the insurer or its pharmacy benefits manager;
19	(2) if the criteria for medical necessity are met, condition, deny,
20	restrict, or refuse to authorize or approve a provider for a clinician-administered drug
21	because the provider obtained the clinician-administered drug from a pharmacy that is
22	not a network pharmacy in the insurer's or its pharmacy benefits manager's network;
23	(3) require a pharmacy to dispense a clinician-administered drug
24	directly to a covered person or agent of the insured with the intention that the covered
25	person or the agent of the insured will transport the medication to a provider for
26	administration;
27	(4) require or encourage the dispensing of a clinician-administered
28	drug to a covered person in a manner that is inconsistent with the supply chain security
29	controls and chain of distribution set by 21 U.S.C. 360eee - 360eee-4 (Drug Supply
30	Chain Security Act);
31	(5) require that a clinician-administered drug be dispensed or

l	administered to a covered person in the residence of the covered person or require use
2	of an infusion site external to the office, department, or clinic of the provider of the
3	covered person; nothing in this paragraph prohibits the insurer or its pharmacy
4	benefits manager, or an agent of the insurer or its pharmacy benefits manager, from
5	offering the use of a home infusion pharmacy or external infusion site.
6	(b) If a health insurance policy provides in-network and out-of-network
7	benefits and there is not an in-network health care provider or health care facility
8	within a 50-mile radius of the primary residence of a covered person, the health
9	insurance policy must provide coverage to the covered person for clinician-
10	administered drugs at the minimum in-network benefit level.
11	(c) In this section, "clinician-administered drug" means a drug, other than a
12	vaccine, that requires administration by a provider and that the United States Food and
13	Drug Administration or the drug's manufacturer has not approved for self-
14	administration.
15	Sec. 21.27.952. Penalties. In addition to any other penalty provided by law, if
16	a person violates AS 21.27.945 - 21.27.975, the director may, after notice and hearing,
17	impose a penalty in accordance with AS 21.27.440.
18	Sec. 21.27.953. Regulations relating to pharmacy benefits manager claims,
19	grievances, activities, and appeals. The director shall adopt regulations that provide
20	standards and criteria for
21	(1) the structure and operation of pharmacy benefits manager
22	reimbursement of pharmacy claims under this chapter;
23	(2) procedures maintained by a pharmacy benefits manager to ensure
24	that a pharmacy has the opportunity for appropriate resolution of grievances;
25	(3) an independent review of pharmacy benefits manager activities
26	under this title; and
27	(4) requiring a pharmacy benefits manager to hear pricing appeals.
28	* Sec. 11. AS 21.27 is amended by adding a new section to article 9 to read:
29	<b>Sec. 21.27.975. Definitions.</b> In AS 21.27.901 - 21.27.975,
30	(1) "affiliate" means a business, pharmacy, pharmacist, or provider
31	who, directly or indirectly through one or more intermediaries, controls, is controlled

1	by, or is under common control with a pharmacy benefits manager;
2	(2) "audit" means an official examination and verification of accounts
3	and records;
4	(3) "claim" means a request from a pharmacy or pharmacist to be
5	reimbursed for the cost of filling or refilling a prescription for a drug or for providing
6	a medical supply or device;
7	(4) "covered person" means an individual receiving medication
8	coverage or reimbursement provided by an insurer or its pharmacy benefits manager
9	under a health care insurance policy;
10	(5) "drug" means a prescription drug;
11	(6) "extrapolation" means the practice of inferring a frequency or
12	dollar amount of overpayments, underpayments, invalid claims, or other errors on any
13	portion of claims submitted, based on the frequency or dollar amount of
14	overpayments, underpayments, invalid claims, or other errors actually measured in a
15	sample of claims;
16	(7) "insurer" has the meaning given to "health care insurer" in
17	AS 21.54.500;
18	(8) "list" means a list of drugs for which a pharmacy benefits manager
19	has established predetermined reimbursement amounts, or methods for determining
20	reimbursement amounts, to be paid to a network pharmacy or pharmacist for
21	pharmacy services, such as a maximum allowable cost or maximum allowable cost list
22	or any other list of prices used by a pharmacy benefits manager;
23	(9) "maximum allowable cost" means the maximum amount that a
24	pharmacy benefits manager will reimburse a pharmacy for the cost of a drug;
25	(10) "national average drug acquisition cost" means the average
26	acquisition cost for outpatient drugs covered by Medicaid, as determined by a monthly
27	survey of retail pharmacies conducted by the federal Centers for Medicare and
28	Medicaid Services;

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with providers, provides or arranges for access by groups of covered persons to health

care services by providers who are not otherwise or individually contracted directly

(11) "network" means an entity that, through contracts or agreements

l	with an insurer or its pharmacy benefits manager;
2	(12) "network pharmacy" means a pharmacy that provides covered
3	health care services or supplies to an insured or a member under a contract with a
4	network plan to act as a participating provider;
5	(13) "pharmacy" has the meaning given in AS 08.80.480;
6	(14) "pharmacy acquisition cost" means the amount that a
7	pharmaceutical wholesaler or distributor charges for a pharmaceutical product as listed
8	on the pharmacy's invoice;
9	(15) "pharmacy benefits manager" means a person that contracts with a
10	pharmacy on behalf of an insurer to process claims or pay pharmacies for prescription
11	drugs or medical devices and supplies or provide network management for
12	pharmacies;
13	(16) "plan sponsor" has the meaning given in AS 21.54.500;
14	(17) "provider" means a physician, pharmacist, hospital, clinic
15	hospital outpatient department, pharmacy, or other person licensed or otherwise
16	authorized in this state to furnish health care services;
17	(18) "recoupment" means the amount that a pharmacy must remit to a
18	pharmacy benefits manager when the pharmacy benefits manager has determined that
19	an overpayment to the pharmacy has occurred;
20	(19) "wholesale acquisition cost" has the meaning given in 42 U.S.C.
21	1395w-3a(c)(6)(B).
22	* Sec. 12. AS 21.36 is amended by adding a new section to article 5 to read:
23	Sec. 21.36.520. Unfair trade practices. (a) An insurer providing a health care
24	insurance policy or its pharmacy benefits manager may not
25	(1) interfere with a covered person's right to choose a pharmacy or
26	provider;
27	(2) interfere with a covered person's right of access to a clinician-
28	administered drug;
29	(3) interfere with the right of a pharmacy or pharmacist to participate
30	as a network pharmacy;
31	(4) reimburse a pharmacy or pharmacist an amount less than the

1	amount the pharmacy benefits manager reimburses an affiliate for providing the same
2	pharmacy services, calculated on a per-unit basis using the same generic product
3	identifier or generic code number;
4	(5) impose a reduction in reimbursement for pharmacy services
5	because of the person's choice among pharmacies that have agreed to participate in the
6	plan according to the terms offered by the insurer or its pharmacy benefits manager;
7	(6) use a covered person's pharmacy services data collected under the
8	provision of claims processing services for the purpose of soliciting, marketing, or
9	referring the person to an affiliate of the pharmacy benefits manager;
10	(7) prohibit or limit a pharmacy from mailing, shipping, or delivering
11	drugs to a patient as an ancillary service; however, the insurer or its pharmacy benefits
12	manager
13	(A) is not required to reimburse a delivery fee charged by a
14	pharmacy unless the fee is specified in the contract between the pharmacy
15	benefits manager and the pharmacy;
16	(B) may not require a patient signature as proof of delivery of a
17	mailed or shipped drug if the pharmacy
18	(i) maintains a mailing or shipping log signed by a
19	representative of the pharmacy or keeps a record of each notification of
20	delivery provided by the United States mail or a package delivery
21	service; and
22	(ii) is responsible for the cost of mailing, shipping, or
23	delivering a replacement for a drug that was mailed or shipped but not
24	received by the covered person;
25	(8) prohibit or limit a network pharmacy from informing an insured
26	person of the difference between the out-of-pocket cost to the covered person to
27	purchase a drug, medical device, or supply using the covered person's pharmacy
28	benefits and the pharmacy's usual and customary charge for the drug, medical device,
29	or supply;
30	(9) conduct or participate in spread pricing in the state;
31	(10) assess, charge, or collect a form of remuneration that passes from

1	a pharmacy or a pharmacist in a pharmacy network to the pharmacy benefits manager,						
2	including claim processing fees, performance-based fees, network participation fees,						
3	or accreditation fees;						
4	(11) reverse and resubmit the claim of a pharmacy more than 90 days						
5	after the date the claim was first adjudicated, and may not reverse and resubmit the						
6	claim of a pharmacy unless the insurer or pharmacy benefits manager						
7	(A) provides prior written notification to the pharmacy;						
8	(B) has just cause;						
9	(C) first attempts to reconcile the claim with the pharmacy; and						
10	(D) provides to the pharmacy, at the time of the reversal and						
11	resubmittal, a written description that includes details of and justification for						
12	the reversal and resubmittal.						
13	(b) A provision of a contract between a pharmacy benefits manager and a						
14	pharmacy or pharmacist that is contrary to a requirement of this section is null, void,						
15	and unenforceable in this state.						
16	(c) A violation of this section or a regulation adopted under this section is an						
17	unfair trade practice and subject to penalty under this chapter.						
18	(d) For purposes of this section, a violation has occurred each time a						
19	prohibited act is committed.						
20	(e) Nothing in this section may interfere with or violate a patient's right under						
21	AS 08.80.297 to know where the patient may have access to the lowest-cost drugs or						
22	the requirement that a patient must receive notice of a change to a pharmacy network,						
23	including the addition of a new pharmacy or removal of an existing pharmacy from a						
24	pharmacy network.						
25	(f) The director may adopt regulations to provide an appeals process for						
26	claims adjudicated under this section.						
27	(g) In this section,						
28	(1) "affiliate" has the meaning given in AS 21.27.975;						
29	(2) "clinician-administered drug" has the meaning given in						
30	AS 21.27.951(c);						
31	(3) "covered person" has the meaning given in AS 21 27 975:						

1	(4)	"drug"	has the	meaning	given	in AS	21.2	27.97	5;
	\ /				0				- 7

- 2 (5) "insurer" has the meaning given to "health care insurer" in AS 21.54.500;
  - (6) "network pharmacy" has the meaning given in AS 21.27.975;
- 5 (7) "out-of-pocket cost" means a deductible, coinsurance, copayment, 6 or similar expense owed by a covered person under the terms of the covered person's 7 health care insurance policy;
  - (8) "provider" has the meaning given in AS 21.27.975;
  - (9) "spread pricing" means the method of pricing a drug in which the contracted price for a drug that a pharmacy benefits manager charges a health care insurance policy differs from the amount the pharmacy benefits manager directly or indirectly pays the pharmacist or pharmacy for pharmacist services.
  - \* **Sec. 13.** AS 21.27.950 and 21.27.955 are repealed.

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- \* **Sec. 14.** The uncodified law of the State of Alaska is amended by adding a new section to read:
- APPLICABILITY. This Act applies to an insurance policy or contract, including a contract between a pharmacy benefits manager and a pharmacy or pharmacist, issued, delivered, entered into, renewed, or amended on or after the effective date of secs. 1 13 of this Act.
- \* Sec. 15. The uncodified law of the State of Alaska is amended by adding a new section to read:
- TRANSITION: REGULATIONS. The director of the division of insurance may adopt regulations necessary to implement the changes made by this Act under AS 21.06.090. 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. 16. Section 15 of this Act takes effect immediately under AS 01.10.070(c).
- \* Sec. 17. Except as provided in sec. 16 of this Act, this Act takes effect January 1, 2025.

#### 2024 Statute Change Projects and Concepts

#### Concepts

- AS 08.80.030(b) is amended to read: (19) prohibit, limit, or provide conditions relating to the dispensing of a prescription drug that the United States Food and Drug Administration or the prescription drug's manufacturer has not approved for self-administration to ensure the effectiveness and security of a prescription drug to be administered by infusion or in a clinical setting.
- Statute changes to AS 08.80.337 to allow pharmacists to practice at the top of their clinical ability.
- Remove sections (4) and (6) from AS 08.80.145
- Background checks through regulation?

#### **2024 Regulation Change Projects and Concepts**

In Process

#### PHA-0324

- 1. **12 AAC 52.235. Pharmacy technician with national certification,** is proposed to be updated to allow Pharmacy Technicians with a national certification to practice at the top of their scope of practice.
- 2. **12 AAC 52.240. Pharmacist collaborative practice authority**, is proposed to be amended to remove the requirement for Board approval of collaborative practice agreements, and clarifies that the written protocol only be submitted for board awareness.
- 3. **12 AAC 52.430. Guidelines relating to sterile pharmaceuticals,** is proposed to remove the "Sterile Pharmaceuticals" pamphlet that is currently adopted by reference, and replace this with the current standard of care.
- 4. **12 AAC 52.698. Manufacturer license,** is proposed to add the requirement of the most recent Good Manufacturing Practice inspection by the FDA. This will bring the regulations into alignment with outsourcing facilities regulations.
- 5. 12 AAC 52.855. Registration with the prescription drug monitoring program, is proposed to be updated to clarify the language outlining who is required to register with the Prescription Drug Monitoring Program.
- 6. **12 AAC 52.940.** Use of alcohol or controlled substances, is proposed to allow the board to grant non-punitive alternatives to probation for licensees that self-refer for addiction treatment.
- 7. **12 AAC 52.995. Definitions,** is proposed to add definitions for the terms "owner" and "change of ownership", and clarify that written protocols are proposed to no longer be approved by the board.

#### Concepts

- Align statutes and regulations with Pharmacist Intern vs Pharmacy Intern language. "Pharmacy Intern" is used 5 times in statute and 11 times in regulation. "Pharmacist Intern" is used 0 times in statute and 47 times in regulation.
- Accreditation for attending meetings NUR language
- Emergency refills
  - o This was a topic I've heard come up a few times at NABP online and in person meetings, and reading Alabama's recent regulation updates re-enforced this (Ashley).
- Background checks
- Reinstatement fees for pharmacists
- Pharmacy Techs that late renew are not allowed to have a PIC sign off on CEs for first renewal
- Remove Notarization requirement for applications
- Remove affidavit of experience, it's in the eLTP

### NOTICE OF PROPOSED CHANGES IN THE REGULATIONS OF THE ALASKA BOARD OF PHARMACY

BRIEF DESCRIPTION: The Board of Pharmacy (Board) proposes to adopt regulation changes in Title 12, Chapter 52 of the Alaska Administrative Code, dealing with pharmacy technicians, collaborative practice authorities, sterile pharmaceutical guidelines, manufacturer license requirements, PDMP registration, alternative to probation program, and definitions, including the following:

- 1. 12 AAC 52.235. Pharmacy technician with national certification, is proposed to be updated to allow pharmacy technicians with a national certification to perform a final check of and distribute a non-controlled substance prescription if the pharmacy uses software that displays the image or graphical description of the correct drug being verified or the institutional facility uses software that performs and verifies a barcode scan before administration. Language that required a pharmacist to review and dispense an order due to deviation between the image or graphical depiction and the actual product being distributed is proposed for repeal.
- 2. 12 AAC 52.240. Pharmacist collaborative practice authority, is proposed to be amended to remove the requirement for Board approval of collaborative practice agreements, proposes repeal of the authorization for the board to require additional training if the board is not satisfied that the pharmacist has been adequately trained in the subject of a written protocol, and clarifies that the written protocol only be submitted for board awareness.
- 3. **12 AAC 52.430.** Guidelines relating to sterile pharmaceuticals, is proposed to remove the *Sterile Pharmaceuticals* pamphlet that is currently adopted by reference and replace this with the acceptable standard of care defined in 12 AAC 52.995(a).
- 4. **12 AAC 52.698. Manufacturer license,** is proposed to add the requirement of the most recent Good Manufacturing Practice inspection by the United States Food and Drug Administration (FDA). This will bring the regulations into alignment with outsourcing facilities regulations.
- 5. 12 AAC 52.855. Registration with the prescription drug monitoring program, is proposed to be updated to clarify the language outlining when registration with the Prescription Drug Monitoring Program (PDMP) controlled substance database is required.
- 6. 12 AAC 52.930. Terms of probation, proposes a technical change to an obsolete expression.
- 7. 12 AAC 52.940. Use of alcohol or controlled substances, proposes technical changes and is proposed to allow the board to grant non-punitive alternatives to probation for licensees that self-refer for addiction treatment.
- 8. **12 AAC 52.995. Definitions,** is proposed to add definitions for the terms "owner" and "change of ownership", and clarify that written protocols no longer to be approved by the board.

You may comment on the proposed regulation changes, including the potential costs to private persons of complying with the proposed changes, by submitting written comments to Stefanie Davis, Regulations Specialist, Division of Corporations, Business and Professional Licensing, P.O. Box 110806, Juneau, AK 99811-0806. Additionally, the Board will accept comments by facsimile at (907) 465-2974 and by electronic mail at <a href="RegulationsAndPublicComment@alaska.gov">RegulationsAndPublicComment@alaska.gov</a>. Comments may also be submitted through the Alaska Online Public Notice System by accessing this notice on the system at <a href="http://notice.alaska.gov/215641">http://notice.alaska.gov/215641</a>, and using the comment link. The comments must be received not later than 4:30 p.m. on July 8, 2024.

You may submit written questions relevant to the proposed action to Stefanie Davis, Regulations Specialist, Division of Corporations, Business and Professional Licensing, P.O. Box 110806, Juneau, AK 99811-0806 or by e-mail at RegulationsAndPublicComment@alaska.gov. The questions must be received at least 10 days before the end of the public comment period. The Board will aggregate its response to substantially similar questions and make the questions and responses available on the Alaska Online Public Notice System and on the Board's website at <a href="https://www.commerce.alaska.gov/web/cbpl/ProfessionalLicensing/BoardofPharmacy.aspx">https://www.commerce.alaska.gov/web/cbpl/ProfessionalLicensing/BoardofPharmacy.aspx</a>.

If you are a person with a disability who needs a special accommodation in order to participate in this process, please contact Stefanie Davis at (907) 465-2537 or <a href="RegulationsAndPublicComment@alaska.gov">RegulationsAndPublicComment@alaska.gov</a> not later than July 1, 2024 to ensure that any necessary accommodation can be provided.

A copy of the proposed regulation changes is available on the Alaska Online Public Notice System and by contacting Stefanie Davis at (907) 465-2537, <u>RegulationsAndPublicComment@alaska.gov</u>, or at <a href="https://www.commerce.alaska.gov/web/portals/5/pub/PHA-0324.pdf">https://www.commerce.alaska.gov/web/portals/5/pub/PHA-0324.pdf</a>.

After the public comment period ends, the Board will either adopt the proposed regulation changes or other provisions dealing with the same subject, without further notice, or decide to take no action. The language of the final regulation may be different from that of the proposed regulation. You should comment during the time allowed if your interests could be affected.

**Statutory Authority:** AS 08.01.075; AS 08.80.005; AS 08.80.030; AS 08.80.157; AS 08.80.159; AS 08.80.168; AS 08.80.261; AS 08.80.480; AS 11.71.900; AS 17.30.200; AS 17.30.900

**Statutes Being Implemented, Interpreted, or Made Specific:** AS 08.01.075; AS 08.80.005; AS 08.80.030; AS 08.80.157; AS 08.80.159; AS 08.80.261; AS 08.80.480; AS 17.30.200

**Fiscal Information:** The proposed regulation changes are not expected to require an increased appropriation.

For each occupation regulated under the Division of Corporations, Business and Professional Licensing, the Division keeps a list of individuals or organizations who are interested in the regulations of that occupation. The Division automatically sends a Notice of Proposed Regulations to the parties on the appropriate list each time there is a proposed change in an occupation's regulations in Title 12 of the Alaska Administrative Code. If you would like your address added to or removed from such a list, send your request to the Division at the address above, giving your name, either your e-mail address or mailing address (as you prefer for receiving notices), and the occupational area in which you are interested.

DATE:	6/6/2024	/s/	
		Stefanie Davis, Regulations Specialist	
		Division of Corporations, Business and	
		Professional Licensing	

## ADDITIONAL REGULATION NOTICE INFORMATION (AS 44.62.190(d))

- **1. Adopting agency:** Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing Board of Pharmacy.
- 2. General subject of regulation: Pharmacy technicians, collaborative practice authorities, sterile pharmaceutical guidelines, manufacturer license requirements, PDMP registration, alternative to probation program, and definitions.
- 3. Citation of regulation: 12 AAC 52.235 through 12 AAC 52.995
- 4. Department of Law file number: 2024200135.
- 5. Reason for the proposed action: Update and clarification of current regulations; compliance with state statute.
- **6. Appropriation/Allocation:** Corporations, Business and Professional Licensing #2360.
- 7. Estimated annual cost to comply with the proposed action to:

A private person: None known. Another state agency: None known. A municipality: None known.

- 8. Cost of implementation to the state agency and available funding (in thousands of dollars): No costs are expected in FY 2024 or in subsequent years.
- 9. The name of the contact person for the regulation:

Michael Bowles, Executive Administrator

Alaska Board of Pharmacy

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

Telephone: (907) 465-1073

E-mail: Michael.Bowles@Alaska.Gov

10.	The origi	The origin of the proposed action: Staff of state agency.						
11.	Date:	6/6/2024	Prepared by:	/s/				
		_		Stefanie Davis				
				Regulations Specialist				

Register,2024 PROFESSIONAL REGULATIONS					
Chapter 52. Board of Pharmacy.					
(Words in <b>boldface and underlined</b> indicate language being added; words [CAPITALIZED AND BRACKETED] indicate language being deleted. Complete new sections are not in boldface or underlined.)					
12 AAC 52.235(a)(1)(C) is amended to read:					
(C) the pharmacy uses software that displays the image or graphical					
description of the correct drug being verified, or the institutional facility uses software					
that performs and verifies a barcode scan before administration [; HOWEVER, IF					
THERE IS ANY DEVIATION BETWEEN THE IMAGE OR GRAPHICAL					
DESCRIPTION AND THE ACTUAL PRODUCT BEING DISTRIBUTED, A					
PHARMACIST MUST REVIEW AND DISPENSE THE ORDER]; and					
(Eff. 4/3/2020, Register 234; am 8/30/2020, Register 235; am 5/19/2023, Register 246; am					
/, Register)					
<b>Authority:</b> AS 08.80.005 AS 08.80.030 AS 08.80.168					
12 AAC 52.240(a) is amended to read:					
(a) A pharmacist planning to exercise collaborative practice authority in the pharmacist's					
practice by initiating or modifying drug therapy, in accordance with a written protocol					
established and approved for the pharmacist's practice by a practitioner authorized to prescribe					
drugs under AS 082 must submit the completed written protocol to the board [AND BE					
APPROVED BY THE BOARD BEFORE IMPLEMENTATION].					
12 AAC 52.240(d) is repealed:					
(d) Repealed/ [UNLESS THE BOARD IS SATISFIED THAT THE					
PHARMACIST HAS BEEN ADEQUATELY TRAINED IN THE PROCEDURES OUTLINED					

Register	_, 2024	4 PROFESSIONAL REGULATIONS
IN THE WRIT	TTEN PROTOCOL, T	ΓHE BOARD WILL SPECIFY AND REQUIRE
COMPLETIO	N OF ADDITIONAL	TRAINING THAT COVERS THOSE PROCEDURES
BEFORE ISSU	JING APPROVAL O	OF THE PROTOCOL].
12 AAC 52.24	0(f) is amended to rea	ad:
(f) <u>An</u>	authorizing practitio	oner or a pharmacist may terminate the [THE] written
protocol [MAY	Y BE TERMINATED	D] upon written notice [BY THE AUTHORIZING
PRACTITION	ERS OR PHARMAC	CISTS]. The <b>pharmacist</b> [PHARMACISTS] shall notify the
board in writing	ng <u>not more than</u> [WI	ITHIN] 30 days after a written protocol is terminated.
12 AAC 52.24	0(g) is amended to rea	ead:
(g) Any	y modification to the v	written protocol must be <b>submitted to</b> [APPROVED BY] the
board as requir	red by this section for	a new written protocol.
12 AAC 52.24	0(i) is amended to rea	ad:
(i) A si	gned copy of the [API	PROVED COLLABORATIVE PRACTICE APPLICATION
AND] protoco	ls must remain at the p	pharmacy location at all times. (Eff. 11/10/2001, Register
160; am 2/11/2	2004, Register 169; an	m 11/16/2012, Register 204; am 10/13/2019, Register 232;
am 1/19/2024,	Register 249; am	_/, Register)
Authority:	AS 08.80.030	AS 08.80.480
12 AAC 52.43	0 is amended to read:	:
12 AA	C 52.430. <u>Standard o</u>	of care [GUIDELINES] relating to preparation or
dispensing of	sterile pharmaceutic	cals. A pharmacy or pharmacist that prepares or dispenses

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sterile pharmace	euticals shall adhere to	o the <u>accepted standard of care</u> [GUIDELINES
ESTABLISHEI	BY THE BOARD I	N THE PAMPHLET TITLED "STERILE
PHARMACEUT	TCALS, " DATED FE	BRUARY 2008, AND INCORPORATED BY
REFERENCE I	N THIS SECTION].	(Eff. 1/16/98, Register 145; am 10/9/2008, Register 188;
am/	, Register	
Authority: A	AS 08.80.030	AS 08.80.157

[EDITOR'S NOTE: THE PAMPHLET INCORPORATED BY REFERENCE IN 12

AAC 52.430, "STERILE PHARMACEUTICALS" MAY BE OBTAINED FROM THE

DEPARTMENT OF COMMERCE, COMMUNITY, AND ECONOMIC DEVELOPMENT,

DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING, BOARD

OF PHARMACY, STATE OFFICE BUILDING, 9TH FLOOR, 333 WILLOUGHBY

AVENUE, JUNEAU, ALASKA, 99801; PHONE (907) 465-2589.]

12 AAC 52.698(b) is amended to read:

- (b) A manufacturer license will be issued to an applicant who
  - (1) submits a complete application on a form provided by the department;
  - (2) pays the applicable fees **set out under** [REQUIRED IN] 12 AAC 02.310;
- (3) provides the name of the designated representative who will manage the manufacture of drugs or devices for the wholesale drug facility;
  - (4) submits an attestation that
  - (A) a self-inspection of the premises using the form provided by the department was completed within the last two years; or
  - (B) an inspection of the premises by a third party was completed within the last two years; [AND]

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	(5) submits an attestation that the applicant holds a license as a manufacturer in
another jurisdi	ction and that the license is in good standing, if applicable; and
	(6) submits the results of the applicant's most recent Good Manufacturing
Practice (GM	P) inspection by the United States Food and Drug Administration.
(Eff. 7/15/202	3, Register 247; am/, Register)

AS 08.80.157

AS 08.80.480

AS 08.80.030

AS 08.80.005

**Authority:** 

12 AAC 52.855(b) is amended to read:

(b) A licensed pharmacist who dispenses [PRACTICING IN THIS STATE SHALL REGISTER WITH THE PDMP. REGISTRATION MUST BE COMPLETED NOT LATER THAN 30 DAYS AFTER INITIAL LICENSURE IF THE PHARMACIST'S PRACTICE IS EXPECTED TO INVOLVE DISPENSING] a schedule II, III, or IV controlled substance [UNDER FEDERAL LAW. A PHARMACIST WHO WAS NOT DISPENSING A SCHEDULE II, III, OR IV CONTROLLED SUBSTANCE UNDER FEDERAL LAW AT THE TIME OF INITIAL LICENSURE BUT PLANS TO BEGIN DISPENSING A SCHEDULE II, III, OR IV CONTROLLED SUBSTANCE UNDER FEDERAL LAW SHALL REGISTER WITH THE PDMP BEFORE DISPENSING A SCHEDULE II, III, OR IV CONTROLLED SUBSTANCE UNDER FEDERAL LAW] in this state shall register with the PDMP not more than 30 days after the pharmacist dispenses that substance for the first time.

The introductory language of 12 AAC 52.855(c) is amended to read:

(c) Except as provided in (a) of this section, before dispensing, prescribing, or administering a schedule II, III, or IV controlled substance under federal law, a pharmacist or

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practitioner re	equired to register	with th	ne PDMP <u><b>shall</b></u> [M	fUST]	
•••					
12 AAC 52.8	355(e) is amended	to read	:		
(e) A	pharmacist or prac	ctitione	er required to regis	ter with the PDMP sha	II [MUST] access
information i	n the PDMP datab	ase usi	ng the credentials	identified in (c)(1)(A)	and (B) of this
section.					
(Eff. 12/29/20	011, Register 200;	am 6/7	7/2018, Register 22	26; am 5/6/2021, Regis	ster 238; am
3/17/2022; R	egister 241; am 7/	15/202	3, Register 247; aı	m/, 1	Register)
Authority:	AS 08.80.005	A	AS 08.80.030	AS 17.30.200	
The introduct	tory language of 12	2 AAC	52.930 is amende	ed to read:	
12 A	AC 52.930. Terms	of pro	obation. The board	d <u>may</u> [WILL, IN ITS	DISCRETION,]
subject a lice	nsee who is placed	l on pro	obation to one or n	more of the following to	erms of probation,
and to other r	relevant terms of p	robatio	on, including those	e in 12 AAC 52.940 - 1	2 AAC 52.960:
•••					
(Eff 1/16/98	Register 145: am		/ /	, Register	
(EII. 1/10/50)	, register 115, um				,
The introduct	tory language of 12	2 AAC	52.940(a) is amer	nded to read:	
				obation set out in 12 AA	AC 52 930 the
. ,			•	he habitual use of alcoh	· <del></del>
			-	o one or more of the fo	_
or controlled	substances [WA I	ALSO	, DE SODJECT] ((	o one of more of the fo	nowing.
•••					

Register	_,2024 PROFESSIONAL REGULATIONS
12 AAC 52.94	40(a)(3) is amended to read:
	(3) <u>abstention</u> [ABSTAINING] from the personal use of alcohol or controlled
substances in	any form, except when lawfully prescribed by a practitioner licensed to practice in
the state [AL	ASKA];
12 AAC 52.94	40(b) is amended to read:
(b) <u><b>Th</b></u>	e board may restrict a licensee's access [ACCESS] to a controlled substance in
the work setti	ng [WILL, IN THE BOARD'S DISCRETION, BE RESTRICTED].
12 AAC 52.94	40 is amended by adding a new subsection to read:
(c) The	e board may offer a licensee subject to this section an opportunity to participate in
an alternative	to probation program. A licensee that participates in an alternative to probation
program shall	meet the probation terms required by the board under the alternative to probation
program. The	board will keep a licensee's participation in an alternative to probation program
confidential, e	except as required by law. (Eff. 1/16/98, Register 145; am/,
Register	
Authority:	AS 08.01.075 AS 08.80.030 AS 08.80.261
	AS 08.80.005
12 AAC 52.99	95(a) is amended by adding new paragraphs to read:
	(46) "owner", within the meaning given in AS 08.80.480, includes a person or
entity who is	the legal operator of a licensed pharmacy or facility and is assigned a unique
federal emplo	yer identification number (EIN) for the transaction of business;
	(47) "change of ownership"

(A) means a change in the federal employer identification number (EIN) at the parent level, or any transfer of a beneficial interest in a business entity licensed or registered by the board to any person or entity in which the transfer results in the transferee's holding 50 percent or more of the beneficial interest in that license or registration; a person or entity that engages in a change of ownership includes

- (i) an individual who sells a pharmacy or facility;
- (ii) an individual who enters into a partnership with others;
- (iii) an individual who becomes incorporated;
- (iv) a partnership who sells a pharmacy or facility;
- (v) a partnership whose membership changes and dissolves;
- (vi) a partnership who becomes incorporated;
- (vii) a corporation that sells or disposes all assets;
- (viii) a corporation that changes from a limited liability corporation to a corporation; or
- (ix) a corporation that merges into or consolidates with another corporation;

#### (B) does not include

- (i) an individual incorporating only the individual incorporates only the individual, without other shareholders;
- (ii) an individual or entity that engages in a stock change of 20 percent or less; or
- (iii) a managing officer who transfers from or leaves the job position, and the change in managing officers does not result in a change described in (A) of this paragraph.

Register,	_2024	PROFESSIONAL REGULATIONS
12 AAC 52 995(c)(3) is amend	led to re	ead.

(3) ordering and evaluating the results of laboratory tests relating to drug therapy, including blood chemistries and cell counts, drug levels in blood, urine, tissue, or other body fluids, and culture and sensitivity tests that are performed in accordance with a written protocol [APPROVED] under 12 AAC 52.240.

(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 10/31/2019, Register 232; am 4/3/2020, Register 234; am 8/30/2020, Register 235; am 7/15/2023, Register 247; am 1/19/2024, Register 249; am 5/19/2024, Register 250; am

\_\_\_\_/\_\_\_, Register \_\_\_\_)

 Authority:
 AS 08.80.005
 AS 08.80.159
 AS 17.30.200

 AS 08.80.030
 AS 11.71.900
 AS 17.30.900

AS 08.80.157

(((Publisher: please replace the period that follows 12 AAC 52.995(a)(45) with a semicolon.)))

From: <u>Joy Shaw</u>

**To:** Regulations and Public Comment (CED sponsored)

Subject: Public comment on proposed regulation

Date: Thursday, June 6, 2024 4:29:32 PM

Attachments: Outlook-n1jmr5uv.png

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**CAUTION:** This email originated from outside the State of Alaska mail system. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hello,

I would like to submit a comment regarding the proposed change for **12 AAC 52.235**. **Pharmacy technician with national certification**.

I am opposed to this change for the following reasons:

- 1. A pharmacy technician, whether or not they hold a national certification, by-in-large does not feel the same level of commitment, accountability, or potential for repercussions (ex. possible loss of professional license and livelihood) as a pharmacist to ensure that a prescription is filled accurately before being dispensed to a patient. Our pharmacy will soon require all techs to obtain their national certification within a year of hire; holding the national certification does not mean every one of them has the capacity to operate under this proposed regulation, it just shows they have jumped through the HR hoops to keep their job;
- 2. First Databank often times does not have images or descriptions for legend drugs that come from repackagers (ex. duloxetine 20mg DR caps from Golden State Medical Supply), so this is not an infallible safety check;
- 3. This proposal makes it likely that the lines of communication between pharmacists and techs will break down during day-to-day operations resulting in supervising pharmacist(s) no longer having a good idea of what is happening within their pharmacy;
- 4. This opens the door for patients requiring counseling, based on a pharmacist's professional judgement, to not receive said counseling because of a breakdown in communication (noted in #3 above) occurring when a pharmacist is not involved in the prescription verification step;
- 5. If I read the proposal correctly, it sounds as though this also applies to hospital-admitted patients (". . . or the institutional facility uses software that performs and verifies a barcode scan before administration"). This opens the door for more frequent nearmisses and/or sentinel-events to occur when a technician is entrusted with verifying the medication dispensed to the inpatient unit. When a nurse fails to barcode scan the patient and/or drug before administration and gives them the incorrect drug and/or

dose, etc., we have circumvented not only one safety check (the pharmacist), we've circumvented two (pharmacist and barcode scanning).

Please do not pass this proposed regulation as it is ripe for error.

Thank you for your time and consideration,

Joy Shaw, Pharm.D.
Clinical and Infusion Pharmacist
Southeast Alaska Regional Health Consortium
222 Tongass Drive, Sitka, AK 99835
email: joys@searhc.org
Office Ph: (907) 966-8436



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From: Rep. Jamie Allard
To: Davis, Stefanie L (CED)

**Subject:** Re: Notice of Proposed Regulations (Alaska Board of Pharmacy 12 AAC 52.235 - 52.995)

**Date:** Tuesday, June 11, 2024 1:02:20 PM

Attachments: image003.png

image004.png image005.png

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Interesting.

#### Representative Jamie Allard

House District 23 Eagle River Valley

State Capitol Office Room 415 Juneau, Alaska 99801 907-465-6858

image001.png		
	?	

From: Davis, Stefanie L (CED) <stefanie.davis@alaska.gov>

**Sent:** Thursday, June 6, 2024 2:19:44 PM

**To:** GOV All Legislators <GOV.AllLegislators@alaska.gov>; Lieutenant Governor Nancy Dahlstrom (GOV sponsored) <lt.governor@alaska.gov>

**Cc:** Robb, Sylvan S (CED) <sylvan.robb@alaska.gov>; Saviers, Glenn A (CED)

<glenn.saviers@alaska.gov>; Chambers, Sara C (CED) <sara.chambers@alaska.gov>; Childress,
Chelsea S (CED) <chelsea.childress@alaska.gov>; Fowler, Micaela R (CED)

<micaela.fowler@alaska.gov>; Bowles, Michael P (CED) <michael.bowles@alaska.gov>

Subject: Notice of Proposed Regulations (Alaska Board of Pharmacy 12 AAC 52.235 - 52.995)

Good afternoon,

The Alaska Board of Pharmacy proposes to update various regulations regarding pharmacy technicians, collaborative practice authorities, sterile pharmaceutical guidelines, manufacturer license requirements, PDMP registration, alternative to probation program, and definitions.

For more information, please open the attached copy of the public notice and draft of the proposed regulation changes. Please click the following link to view the <u>Frequently Asked Questions</u> for this

project. This link is also provided on the Board of Pharmacy webpage, and as an attachment on the Online Public Notice system.

#### Thank you,



Stefanie L. Davis (she/her)
Regulations Specialist
Division of Corporations, Business and Professional Licensing
regulationsandpubliccomment@alaska.gov
Office: 907-465-2537

Office: 907-465-2537 www.commerce.alaska.gov



From: <u>Kristine Burrows</u>

To: Regulations and Public Comment (CED sponsored)

Subject: Public Comment - 12AAC 52.698 Manufacturer License

**Date:** Wednesday, June 12, 2024 11:55:12 AM

Attachments: Outlook-kjxaslmo.png

SLS Alaska Public Comment.pdf

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Hello,

I would like to submit the attached as public comment to the proposed changes to 12AAC 52.698 Manufacturer License.

Thank you.

Best regards,

Kristine Burrows Chief Operating Officer State License Servicing, Inc.

845-544-2482 x203 kburrows@slsny.com



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June 12, 2024

Stefanie Davis
Regulations Specialist
Division of Corporations, Business and Professional Licensing
PO Box 110806
Juneau, Alaska 99811-0806

Dear Ms. Davis,

I am writing to submit public comment on the proposed change to **12AAC 52.698 Manufacturer license**, which would require applicants to submit their most recent FDA inspection.

It is my understanding that the Alaska Board of Pharmacy currently grants a Manufacturer license to both physical manufacturers and virtual manufacturers. It is also my understanding that the FDA does not typically inspect virtual manufacturers as they do not physically manufacturer product. Virtual manufacturers do not have drugs or medical devices on site. Rather, they partner with an FDA-registered contract manufacturer (often based outside the United States) to make product listed with the virtual manufacturer's FDA-issued labeler code. The product is then delivered to, or picked up by, a licensed Third-Party Logistics Provider for warehousing and distribution.

I would like to request that the Division consider this business model in this regulation change and allow alternative options for virtual manufacturers. Rather than an FDA inspection, perhaps consider an inspection from the virtual manufacturer's home state, a self-inspection, or proof of their contract manufacturer's FDA registration.

Thank you for your time and consideration.

Sincerely,

Kristine Burrows

Kristine Burrows Chief Operating Officer State License Servicing, Inc. From: Bowles, Michael P (CED)

To: Lam, Maggie P.

**Cc:** Regulations and Public Comment (CED sponsored)

**Subject:** RE: Notice of Proposed Regulations (Alaska Board of Pharmacy 12 AAC 52.235 - 52.995)

**Date:** Wednesday, June 12, 2024 3:36:28 PM

Attachments: <u>image002.png</u>

image003.pnq image004.pnq image005.pnq image006.pnq

#### Good afternoon,

There is not a differentiation between virtual and non-virtual in this proposed regulation change.



Michael Bowles Executive Administrator, Board of Pharmacy Corporations, Business and Professional Licensing

michael.bowles@alaska.gov Office: 907-465-1073 www.commerce.alaska.gov



From: Lam, Maggie P. < MPLam@porziolicensing.com>

Sent: Tuesday, June 11, 2024 12:51 PM

To: Regulations and Public Comment (CED sponsored) < regulations and public comment @alaska.gov >

**Subject:** Notice of Proposed Regulations (Alaska Board of Pharmacy 12 AAC 52.235 - 52.995)

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Dear Sir or Madam,

Per the attached notice, it is my understanding that virtual manufacturers (companies that use 3<sup>rd</sup> parties to manufacture and ship their product) would not be impacted by this proposed change to provide a FDA inspection report.

<b>Vind</b>	111	confirm.
K III II I	I V	COLLINIA

Regards,

Maggie

**4. 12 AAC 52.698. Manufacturer license,** is proposed to add the requirement of the most recent Good Manufacturing Practice inspection by the United States Food and Drug Administration (FDA). This will bring the regulations into alignment with outsourcing facilities regulations.

#### Maggie P. Lam

V.P., Distribution and Licensing Services MPLam@porziolicensing.com

Phone: (973) 889-5193

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From: <u>GMB-StateLicensing</u>

To: Regulations and Public Comment (CED sponsored)

Cc: <u>Dixon, Terry</u>

Subject: Comment on Proposed Change to Title 12, Chapter 52 of the Alaska Administrative Code

**Date:** Monday, June 17, 2024 9:53:04 AM

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To: Stefanie Davis, Regulations Specialist, Division of Corporations, Business and Professional Licensing, P.O. Box 110806, Juneau, AK 99811-0806

RegulationsAndPublicComment@alaska.gov

Comment on Proposed Change to Title 12, Chapter 52 of the Alaska Administrative Code

Catalent Pharma Solutions respectfully submits a comment to the Proposed Regulation change at 12 AAC 52.698(b). We propose that the Board clarifies that the requirement for an FDA inspection report is only required for a facility/establishment required to register with the FDA under 21 C.F.R. § 207.

The definition of *Commercial Distribution* at 21 C.F.R. § 207.1 excludes drugs "for investigational use under part 312 of this chapter", < <a href="https://www.ecfr.gov/current/title-21/chapter-l/subchapter-C/part-207">https://www.ecfr.gov/current/title-21/chapter-l/subchapter-C/part-207</a>>

This change is necessary since a site/establishment that only manufacture investigational drugs is not required to register with the FDA and will not be routinely inspected by the FDA, and therefore cannot fulfil the requirement as currently proposed.

Catalent suggests the change as follows:

- 12 AAC 52.698(b) is amended to read:
- (b) A manufacturer license will be issued to an applicant who
- (1) submits a complete application on a form provided by the department;
- (2) pays the applicable fees set out under [REQUIRED IN] 12 AAC 02.310;
- (3) provides the name of the designated representative who will manage the manufacture of drugs or devices for the wholesale drug facility;
- (4) submits an attestation that (A) a self-inspection of the premises using the form provided by the department was completed within the last two years; or (B) an inspection of the premises by a third party was completed within the last two years; [AND]
- (5) submits an attestation that the applicant holds a license as a manufacturer in another jurisdiction and that the license is in good standing, if applicable; and
- (6) for a facility/establishment required to be registered with the United States Food and Drug Administration under 21 C.F.R. § 207, submits the results of the applicant's most recent Good Manufacturing Practice (GMP) inspection by the United States Food and Drug Administration. (Eff. 7/15/2023, Register 247; am \_\_\_\_/\_\_\_\_\_, Register \_\_\_\_\_)
  Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480 AS 08.80.030

Kind Regards, Terry Dixon

Terese Dixon Director, Regulatory Affairs Catalent Pharma Solutions St. Petersburg, FL 33716 M (727) 698-3536

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From: Walmsley, Lorri

To: Bowles, Michael P (CED); Regulations and Public Comment (CED sponsored)

**Subject:** Walgreens Comments

**Date:** Wednesday, July 3, 2024 2:35:38 PM

Attachments: Outlook-om0izant.png

Alaska Comments Tech Check Tech CPA June 2024 (1).pdf

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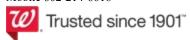
Hello,

Please accept the attached comments for the record on behalf of Walgreens.

Warm Regards,

Lorri

Lorri Walmsley, RPh, FAzPA Director, Pharmacy Affairs Walgreen Co. She/Her why this matters Mobile 602-214-6618



Member of Walgreens Boots Alliance

#### Book time with Walmsley, Lorri: Meeting with Lorri Walmsley

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July 3<sup>rd</sup>, 2024

Lorri Walmsley, R.Ph.
Director, Pharmacy Affairs
Walgreen Co.
5330 E. Washington D-105
Phoenix, AZ 85034
p: 602-214-6618
Lorri.Walmsley@walgreens.com

#### Via Email

Alaska State Board of Pharmacy Attention: Michael Bowles, Executive Director P.O. Box 110806 Juneau, AK 99811

Via Email: michael.bowles@alaska.gov

Re: Notice of Proposed Changes in the Regulations of the Alaska Board of Pharmacy

Dear Director Bowles and Members of the Alaska Board of Pharmacy,

On behalf of all pharmacies owned and operated by Walgreens Co., licensed in the state of Alaska, I thank the Board for the opportunity to comment on the proposed rules regarding pharmacy technicians and collaborative practice authorities as noticed.

Walgreens applauds the board's continued support of novel and innovative practice models to improve patient access to pharmaceutical care. With the suggested edits to 12 AAC 52.235(a)(1)(C), the board recognizes the various practice models and technologies that support a certified technician's ability to perform the final check and distribute a non-controlled medication. Walgreens thanks the board for removing overly prescriptive language and transitioning from a prescriptive rule-based regulation to a model that defines regulation through a standard of care. This transition is also evident in the proposed changes in 12 AAC 52.240(a) for collaborative practice authorities. We are in full support of the removal of the requirement for Board approval before the implementation of a Collaborative Practice Agreement. We appreciate the Board's approach to moving to a standard-of-care model of regulation and the reduction of administrative burdens for permit holders. We believe these changes continue to protect patient safety while supporting novel and innovative practice models that will improve access to care.

Sincerely,

Lorri Walmsley, RPh, FAzPA

Loui Walmsley

From: Sarah Koger

To: Regulations and Public Comment (CED sponsored)

Subject: Board of Pharmacy concern for proposal 12 AAC 52.235.

**Date:** Sunday, July 7, 2024 8:17:09 PM

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July 2, 2024

Sarah Schock 5335 S Old Glenn Hwy Palmer AK 99645

(907) 745-7443

sockeyesarah@yahoo.com

Alaska Board of Pharmacy,

I am writing regarding the proposal 12 AAC 52.235. concerning a pharmacy technician with national certification performing a final check on non-controlled substance prescriptions. I am very concerned about patient safety. I have been a pharmacist in the state of Alaska for 21 years and have experienced a lot of change during that time. I have never written to the Alaska board of pharmacy before about any proposed changes. However out of concern for safety I decided to write regarding this proposal. The final verification stage at a retail pharmacy allows for one last chance for the pharmacist to check that the prescription is correct and to complete a final review. During every shift I stop at least one error that a technician would not have the knowledge to notice. The final verification check is important because it allows pharmacists to also look at other medications the patient is taking, review for interactions, duplications, and changes in treatment. A technician would not have the education or experience to complete this review.

I am also concerned about the liability I would have for mistakes the technicians could make on a prescription before it goes out the door. Since I am the one responsible for each prescription we fill, I feel it's important for me to have the final verification check on all work done on the prescription before it is complete. I am worried about patient safety, this proposal will cause more errors causing a hazard to patients.

Thank you for listening to my concerns,

Sarah Schock (PHAP1477)

### ORDER CERTIFYING THE CHANGES TO REGULATIONS OF THE BOARD OF PHARMACY

The attached eight pages of regulations, dealing with pharmacy technicians, collaborative practice authorities, sterile pharmaceutical guidelines, manufacturer license requirements, PDMP registration, alternative to probation program, and definitions, are certified to be a correct copy of the regulation changes that the Board of Pharmacy adopted at its August 20, 2024 meeting, under the authority of AS 08.01.075, AS 08.80.005, AS 08.80.030, AS 08.80.157, AS 08.80.159, AS 08.80.168, AS 08.80.261, AS 08.80.480, AS 11.71.900, AS 17.30.200, and AS 17.30.900, and after compliance with the Administrative Procedure Act (AS 44.62), specifically including notice under AS 44.62.190 and 44.62.200 and opportunity for public comment under AS 44.62.210.

This action is not expected to require an increased appropriation.

On the record, in considering public comments, the Board of Pharmacy paid special attention to the cost to private persons of the regulatory action being taken.

The regulation changes described in this order take effect on the 30th day after they have been filed by the lieutenant governor, as provided in AS 44.62.180.

DATE: _										
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		1	Nancy Da	ahlstr	om, Lie	euten	ant Gov	ernor		
Effective:		_·								
Register:		_•								

#### **CERTIFICATION OF BOARD ACTION**

I, Michael Bowles, Executive Administrator for the Board of Pharmacy, under penalty of perjury, state the following:

The attached motion dealing with pharmacy technicians, collaborative practice authorities, sterile pharmaceutical guidelines, manufacturer license requirements, PDMP registration, alternative to probation program, and definitions was passed by the Board of Pharmacy during its August 20, 2024 meeting.

I certify under penalty of perjury that the fo	oregoing is true.
Date:	
	Michael Bowles, Executive Administrator
State of Alaska Anchorage, Municipality of Anchorage	

#### **Regulations Projects SBAR**

#### > Situation

HB 112 allows the board to require federal background checks for Pharmacist and Pharmacy Technician initial applicants. The board likely has the authority in statute to create regulations that require fingerprint cards/background checks under:

- AS 08.80.030(b)(2): License by examination or by license transfer the applicants who are qualified to engage in the practice of pharmacy.
- AS 08.80.030(b)(4): Adopt regulations to carry out the purposes of this chapter.
- AS 08.80.030(b)(6): Establish and enforce compliance with professional standards and rules of conduct for pharmacists engaged in the practice of pharmacy.
- AS 08.80.030(b)(9): License and regulate the training, qualifications, and employment of pharmacy interns and pharmacy technicians.
- AS 08.80.261(a)(4), (10), and (11): The board may deny a license to an applicant or, after a hearing, impose a disciplinary sanction authorized under AS 08.01.075 on a person licensed under this chapter when the board finds that the applicant or licensee, as applicable, has been convicted of a felony or has been convicted of another crime that affects the applicant's or licensee's ability to practice competently and safely or was convicted of selling federal legend drugs without the prescription of a person licensed to prescribe federal legend drugs or violated state or federal laws or regulations pertaining to drugs or pharmacies.

Executive Administrator recommends Pharmacy Intern initial applicants also be required to submit federal background checks.

#### > Background

Historically, the time it took for the division to internally receive a fingerprint card then send it off to Department of Public Safety (DPS) varied on the number of cards coming in and how often the division would send them to DPS. It took about 5-7 minutes to check the card, enter info into CBP Portal, update the checklist, create the letter to DPS (using a template), and drop off the envelope in the outgoing mail. It took anywhere from 2-6 weeks from the time the division submits a fingerprint card to DPS to the time the division gets the background check in our system for processing (longer, if the FP cards are rejected by DPS).

Applicants cannot give their fingerprint cards directly to DPS or an equivalent organization themselves. Regardless of where the applicant is, they have to mail the fingerprint cards to the division and the division will have to submit them to DPS. That's the only way DPS can return the background check directly to the division. DPS doesn't allow for them to have the reports sent to someone other than the submitter. This is something the division is working with DPS to hopefully change, but it sounds like the earliest that will change is 2026 when DPS has a new database/system.

DPS cannot accept electronic fingerprints at this time, so it will always have to be hardcopy FBI Standard FD-258 fingerprint cards. Current fingerprint information is available here: <a href="https://www.commerce.alaska.gov/web/cbpl/ProfessionalLicensing/FingerprintInformation.aspx">https://www.commerce.alaska.gov/web/cbpl/ProfessionalLicensing/FingerprintInformation.aspx</a>

#### > Assessment

NABP Model Act has language recommending federal fingerprint based criminal background checks for Pharmacist and Pharmacy Technician applicants as well as Facility and Pharmacy owners.

There have been instances where applicants did not fully disclose past criminal history which was either caught by the investigations team during application reviews or went through without the division finding out. Background checks would catch all previous criminal history of applicants.

Creating a statute and/or regulation requiring the division to collect fingerprint cards to obtain background checks will increase application processing times. The responsibility of collecting and processing fingerprint cards will fall on an Administrative Assistant 1 position. This position has been unable to be kept filled and remains vacant at this time.

The Division will charge each applicant submitting a fingerprint card \$75 for the fingerprint processing so there will be a fee increase associated with this requirement.

#### > Recommendation

Federal background checks will increase public safety and assist staff in identifying applicants that fail to disclose serious criminal history. The board should discuss this regulation concept alongside historical information, current division staffing shortage information, application timeframes, and the effects it will have on division staff vs. what the background checks will accomplish.



## **ALABAMA STATE** BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

#### Alabama Rule Changes Effective January 14, 2024

#### Collaborative Practice

The Alabama State Board of Pharmacy and the Alabama Board of Medical Examiners amended Rule 680-X-2-.44 Collaborative Practice to empower pharmacists to test and treat patients with an "acute, uncomplicated illness or injury," including influenza and streptococcus. The protocol for test to treat influenza and streptococcus was approved by the Board of Pharmacy and the Board of Medical Examiners at their respective December board meetings.

A copy of the updated rule and protocol is available on the Board website at <u>www.albop.com</u>. Application information is also available on the Board website.

#### **Emergency Prescription Refills**

The Board of Pharmacy and the Board of Medical Examiners amended Rule 680-X-2-.26 to expand authorization of pharmacist dispensing of emergency refills.

(1) If a pharmacist receives a request for a prescription refill, and the pharmacist is unable to readily obtain refill authorization from the prescriber, the pharmacist may dispense a **one-time** emergency refill of up to a 72-hour supply of the prescribed

medication or the smallest dispensable package size if a 72 hour supply is not readily available, under the following conditions:

> (a) The prescription is not a medicinal agent listed in Schedule I or II pursuant to Title 20,

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Chapter 2, or the controlled substance list for Schedule I or II maintained by the State Board of Health.

- (b) The medication is essential to the maintenance of life or the continuation of therapy and in the pharmacist's professional judgement, the interruption of therapy might reasonably produce undesirable health consequences or may cause physical or mental discomfort.
- (c) The pharmacist has a record of a prescription at the pharmacy or has been presented proof of a prescription filled within the last 90 days in the name of the patient for whom the request of the emergency supply is being made.
- (d) A pharmacist or pharmacy shall not dispense or sell the same drug to the same patient, as provided in this section, more than one time in any 12-month period.
- (e) The pharmacist must inform the patient or the patient's representative at the time of dispensing that the refill is being provided without the practitioner's authorization, and that practitioner authorization is required for any future refill.
- (f) The dispensing pharmacist shall create a written prescription order containing all of the prescription information required by federal and state statutes, rules and regulations and shall also include the statement "Emergency Fill."
- (g) The dispensing pharmacist shall notify the prescriber orally or in writing of the emergency dispensing within twenty-four (24) hours after such dispensing.

# Drug Manufacturers; Wholesale Distributors; Private Label Distributors, Repackagers, Third-Party Logistics Providers, Outsourcing Facilities; Reverse Distributors; Retail Medical Oxygen Suppliers

The Board amended 680-X-2-.23 to address the additional requirement for registering designated representatives and added application and renewal requirements, which allowed for the repeal of 680-X-2-.25.

- (a) The Alabama State Board of Pharmacy shall require that manufacturers, wholesale drug distributors, private label distributors, repackagers, and third-party logistics providers have a designated representative who has appropriate education and/or experience to assume responsibility for positions related to compliance with state licensing requirements.
  - 1. All designated representatives shall register with the Alabama State Board of Pharmacy. The initial registration fee and renewal fee shall be one

hundred dollars (\$100). All designated representatives shall pay the renewal fee annually with this fee being due on October 31 and delinquent after December 31 annually. All designated representative registrations shall expire on December 31 annually. If the renewal is not timely received by the board, the applicant shall pay a penalty of fifty dollars (\$50) for each month the renewal is late.

- 2. The designated representative shall:
  - i. Be at least 21 years of age.
  - ii. Be a citizen of the United States or, if not a citizen of the United States, a person who is legally present in the United States with appropriate documentation for the federal government.
  - iii. Be employed by the facility full-time in a position of authority and be physically present at the facility for a minimum of 50% of the hours the facility is in operation or at least thirty (30) hours per week, whichever is less.
  - iv. Be actively involved in and aware of the actual daily operation of the facility.
  - v. Serve as a designated representative for only one physical location for a permitted facility at any one time.
  - vi. Not have been convicted of a violation of any federal, state, or local law relating to any drug offense.
  - vii. Not have been convicted, received adjudication, community supervision, or deferred prosecution of any felony offense or any crime related to fraud, violence, sexual violations or related to the practice of pharmacy.
- 3. If the permit holder's designated representative will be or is no longer employed or no longer desires to act as a designated representative, the permit holder shall notify the Board within ten (10) days of the change in designated representative by completing the "Notice of Change of Designated Representative" form provided by the Board.
- 4. If the permit holder is unable to maintain a designated representative, the permit holder shall notify the Board within ten (10) days with an action plan to designate another designated representative. This plan shall not exceed ninety (90) days before the permit holder is in violation of operating a facility without a designated representative, at which time the Board may require closure of the facility until a designated representative assumes his/her duties.

5. In addition to all other applicable requirements for registration as a designated representative and a prerequisite for consideration of registration as a designated representative, each individual seeking registration shall consent and be subject to a Board approved criminal background check, the cost of which to be paid by the applicant. The information received as a result of the background check shall be relied upon in determining whether the applicant meets the applicable qualifications to obtain the referenced registration.

(b) The Alabama State Board of Pharmacy shall require that outsourcing facilities have an Alabama licensed supervising pharmacist for the individual location and comply with 680-X-2-.12.

#### A Special Thank You to Our Volunteers

Thank you to all the pharmacists who have attended work group and focus group meetings over the past several months. These meetings have been valuable in obtaining feedback from practitioners related to many areas of regulatory compliance. The Board will continue to coordinate these meetings, and licensees should know that the continued communication will aid Board members as they review and address rules and regulations going forward.

#### 2023 Milestones

#### Celebrating 50 Years of Pharmacy Licensure

- Vance Alexander
- · Ricky Bearden
- Jerry Bonner
- Richard Bowie
- Roger Burnett
- Virginia Chambers
- Ralph Christopher
- William Crew
- Danny Guest
- Thomas Henderson
- Kerry Kelley

- Donald Kyle
- James Marbut
- William McGuffey
- Anita Pritchett
- · Wendell Qualls
- Raymond Robertson
- · Richard Ryan
- Linda Sellers
- Clifton Shaw
- · Gary Sheffield
- Robert Slay

- Audrey Spangler
- Charles Synco
- George Thompson
- Joseph Vacca

- George Wheeler
- · Daniel Williamson
- Grover Young

#### Celebrating 60 Years of Pharmacy Licensure

- William Beasley
- James Jackson
- · Bobby Maise

- George Payne
- Roy Sanderson
- Mark Shelley

#### Celebrating 65 Years of Pharmacy Licensure

- Clinton Hardy
- · John Cleveland
- Anthony Brooklere



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Donna Yeatman, RPh, Executive Secretary - State News Editor

Lemrey "Al" Carter, PharmD, MS, RPh - National News Editor & Executive Editor

Megan Pellegrini - Publications and Editorial Manager

111 Village St | Birmingham, AL 35242 | Tel: 205/981-2280 | Fax: 205/981-2330

## Alaska Board of Pharmacy Agenda Item #12



**Chair Final Comments** 

## Alaska Board of Pharmacy Agenda Item #13



Adjourn

## Alaska Board of Pharmacy



Meeting Resources



#### **Boards and Commissions**

Office of the Governor

550 W 7<sup>th</sup> Ave. Suite 1700 Anchorage, Alaska 99501 907-269-0006

#### **Introduction to Robert's Rules of Order**

#### What is parliamentary procedure?

It is a set of rules for conduct at meetings, which allows everyone to be heard and to make decisions without confusion.

#### Why is parliamentary procedure important?

Because it is a time-tested method of conducting business at meetings and public gatherings. It can be adapted to fit the needs of any organization. Today, Robert's Rules of Order Newly Revised is the basic handbook of operation for most clubs, organizations, and other groups. It is important that everyone is familiar with these basic rules!

#### **Order of Business:**

Organizations using parliamentary procedure usually follows a fixed order of business. A typical example:

- 1. Call to order.
- 2. Roll call of members present.
- 3. Reading of minutes of last meeting.
- 4. Officer's reports.
- 5. Committee reports.
- 6. Special orders --- Important business previously designated for consideration at this meeting.
- 7. Unfinished business.
- 8. New business.
- 9. Announcements.
- 10. Adjournment.

#### **Motions:**

The method used by members to express themselves is in the form of moving motions. A motion is a proposal that the entire membership take action or a stand on an issue. Individual members can:

- 1. Call to order.
- 2. Second motions.
- 3. Debate motions.
- 4. Vote on motions.

#### **Types of Motions:**

- 1. Main Motions: The purpose of a main motion is to introduce items to the membership for their consideration. They cannot be made when any other motion is on the floor, and yield to privileged, subsidiary, and incidental motions.
- 2. Subsidiary Motions: Their purpose is to change or affect how a main motion is handled, and is voted on before a main motion.
- 3. Privileged Motions: Their purpose is to bring up items that are urgent about special or important matters unrelated to pending business.
- 4. Incidental Motions: Their purpose is to provide a means of questioning procedure concerning other motions and must be considered before the other motion.

www.boards.alaska.gov/resources

boards@alaska.gov

Robert's Rules 11th ed. Page 1 of 6

#### How is a Motion Presented?

- 1. Obtaining the floor:
  - a. Wait until the last speaker has finished.
  - b. Rise and address the Chairman by saying, "Mr. Chairman, or Mr. President."
  - c. Wait until the Chairman recognizes you.
- 2. Make Your Motion:
  - a. Speak in a clear and concise manner.
  - b. Always state a motion affirmatively. Say, "I move that we ..." rather than, "I move that we do not ...".
  - c. Avoid personalities and stay on your subject.
- 3. Wait for Someone to Second Your Motion.
- 4. Another member will second your motion or the Chairman will call for a second.
- 5. If there is no second to your motion, it is lost.
- 6. The Chairman States Your Motion:
  - a. The Chairman will say, "it has been moved and seconded that we ..." Thus, placing your motion before the membership for consideration and action.
  - b. The membership then either debates your motion or may move directly to a vote.
  - c. Once your motion is presented to the membership by the Chairman it becomes "assembly property" and cannot be changed by you without the consent of the members.
- 7. Expanding on Your Motion:
  - a. The time for you to speak in favor of your motion is at this point, rather than at the time you present it.
  - b. The mover is always allowed to speak first.
  - c. All comments and debate must be directed to the Chairman.
  - d. Keep to the time limit for speaking that has been established.

The mover may speak again only after other speakers are finished, unless called upon by the Chairman.

- 1. Putting the Question to the Membership:
  - a. The Chairman asks, "Are you ready to vote on the question?"
  - b. If there is no more discussion, a vote is taken.
  - c. On a motion to move, the previous question may be adapted.

#### **Voting on a Motion:**

The method of vote on any motion depends on the situation and the by-laws of policy of your organization. There are five methods used to vote by most organizations, they are:

- 1. By Voice -- The Chairman asks those in favor to say, "aye", those opposed to say "no". Any member may move for an exact count.
- 2. By Roll Call -- Each member answers "yes" or "no" as his name is called. This method is used when a record of each person's vote is required.
- 3. By General Consent -- When a motion is not likely to be opposed, the Chairman says, "if there is no objection ..." The membership shows agreement by their silence, however if one member says, "I object," the item must be put to a vote.
- 4. By Division -- This is a slight verification of a voice vote. It does not require a count unless the chairman so desires. Members raise their hands or stand.
- 5. By Ballot -- Members write their vote on a slip of paper, this method is used when secrecy is desired.

There are two other motions that are commonly used that relate to voting.

- 1. Motion to Table -- This motion is often used in the attempt to "kill" a motion. The option is always present, however, to "take from the table", for reconsideration by the membership.
- 2. Motion to Postpone Indefinitely -- This is often used as a means of parliamentary strategy and allows opponents of motion to test their strength without an actual vote being taken. Also, debate is once again open on the main motion.

Parliamentary Procedure is the best way to get things done at your meetings. It will only work if you use it properly. Most importantly, *BE COURTEOUS*.

- 1. Allow motions that are in order.
- 2. Have members obtain the floor properly.
- 3. Speak clearly and concisely.
- 4. Obey the rules of debate.

#### Additional Resources:

Simplified Handbook of Parliamentary Procedure
Robert's Rules of Order Archive
FAQs
Motions

#### **Parliamentary Words and Terms**

**Abstain** – not voting one way or the other

**Adjourn** – ending the meeting

Adopt – to okay or accept

Agenda – an outline of items to address at a meeting

**Amendment** – adding on to a motion, usually to improve it, enlarge its intent, or to make it more understandable

**Appeal the decision of the Chair** – to question the Chairperson's decision and ask the group to change it

**Appoint** – to place someone in a job or position

By-laws – the rules a group has agreed to follow and the goals of the organization

**Caucus** – getting together outside the regular meeting to decide on plans, position, policy and/or people to nominate

Chair – the position held by the meeting's leader

**Committee** – a group that reviews and reports on a special task given to them by the larger membership. A committee may recommend actions to be taken based upon its findings.

General Consent – approval by the group. If even one member objects, a vote must be taken.

**Majority** opinion – the decision of more than half the voting members

**Minority** opinion – the position held by less than half of the voting members

Minutes – official record of a meeting

**Motion** – a member's proposal for action

Nominate – to recommend a person for election to office

Pending – still up in the air and undecided

**Personal privilege** – calling attention to something having to do with the well being of the people at the meeting, such as asking to have a window opened

Point of Information – asking for more information before making a decision

Point of Order – correcting a mistake that is against the rules of the organization

**Pro Tem** – temporary

**Proxy** – permission given, usually in writing, by one member for another member to vote in his or her name

Orders of the Day – calling for the group to get back to the agenda or the main business of the meeting Question – a motion that is under discussion with a vote to be taken on it

**Recess** – taking a short break

**Rescind** – to take back or withdraw

**Resolution** – usually a policy statement being suggested to the group for approval

**Second** – support for a motion. Before a group can handle a proposal, it must know that two people want to have it discussed

**Standing Committee** – a committee that goes year round such as a program planning committee Suspending of the

**Rules** – discussing something without sticking to the rules of the meeting Veto – to turn "thumbs down" on a motion or idea

#### **Robert's Rules of Order Motions Chart**

Based on Robert's Rule of Order Newly Revised (11<sup>th</sup> Edition) <a href="https://robertsrules.org/motionsprint.html">https://robertsrules.org/motionsprint.html</a>

Part 1, Main Motions. These motions are listed in order of precedence. A motion can be introduced if it is higher on the chart than the pending motion.

§ indicates the section from Robert's Rules.

§	<b>PURPOSE:</b>	YOU SAY:	INTERRUPT?	<b>2ND?</b>	<b>DEBATE?</b>	AMEND?	VOTE?
§21	Close meeting	I move to adjourn	No	Yes	No	No	Majority
§20	Take break	I move to recess for	No	Yes	No	Yes	Majority
§19	Register complaint	I rise to a question of privilege	Yes	No	No	No	None
§18	Make follow agenda	I call for the orders of the day	Yes	No	No	No	None
§17	Lay aside temporarily	I move to lay the question on the table	No	Yes	No	No	Majority
§16	Close debate	I move the previous question	No	Yes	No	No	2/3
§15	Limit or extend debate	I move that debate be limited to	No	Yes	No	Yes	2/3
§14	Postpone to a certain time	I move to postpone the motion to	No	Yes	Yes	Yes	Majority
§13	Refer to committee	I move to refer the motion to	No	Yes	Yes	Yes	Majority
§12	Modify wording of motion	I move to amend the motion by	No	Yes	Yes	Yes	Majority
§11	Kill main motion	I move that the motion be postponed indefinitely	No	Yes	Yes	No	Majority
§10	Bring business before assembly (a main motion)	I move that [or "to"]	No	Yes	Yes	Yes	Majority

Part 2, Incidental Motions. No order of precedence. These motions arise incidentally and are decided immediately.

§	<b>PURPOSE:</b>	YOU SAY:	INTERRUPT?	<b>2ND?</b>	<b>DEBATE?</b>	AMEND?	VOTE?
§23	Enforce rules	Point of Order	Yes	No	No	No	None
§24	Submit matter to assembly	I appeal from the decision of the chair	Yes	Yes	Varies	No	Majority
§25	Suspend rules	I move to suspend the rules	No	Yes	No	No	2/3
§26	Avoid main motion altogether	I object to the consideration of the question	Yes	No	No	No	2/3
§27	Divide motion	I move to divide the question	No	Yes	No	Yes	Majority
§29	Demand a rising vote	I move for a rising vote	Yes	No	No	No	None
§33	Parliamentary law question	Parliamentary inquiry	Yes, if urgent	No	No	No	None
§33	Request for information	Point of information	Yes, if urgent	No	No	No	None

Part 3, Motions That Bring a Question Again Before the Assembly.
No order of precedence. Introduce only when nothing else is pending.

	No order of precedence. Introduce only when nothing else is pending.								
§	<b>PURPOSE:</b>	YOU SAY:	INTERRUPT?	<b>2ND?</b>	<b>DEBATE?</b>	AMEND?	VOTE?		
§34	Take matter from table	I move to take from the table	No	Yes	No	No	Majority		
§35	Cancel previous action	I move to rescind	No	Yes	Yes	Yes	2/3 or Majority with notice		
§37	Reconsider motion	I move to reconsider	No	Yes	Varies	No	Majority		

# THE STATE OF ALASKA MIKE DUNLEAVY GOVERNOR

#### **Boards and Commissions**

Office of the Governor

550 W 7<sup>th</sup> Ave. Suite 1700 Anchorage, Alaska 99501 907-269-0006

#### **Ground Rules for Successful Meetings**

Thank you for volunteering to serve Alaska, as a designee of the State, on behalf of the Office of the Governor. The simple, yet effective, rules below serve as a set of expectations to keep board and commission meetings productive and respectful. Most important, the consistent use of the cornerstones of Robert's Rules builds the public's trust and reflects positively on all involved.

- 1. **Everyone participates.** As the Chair, encouraging the full participation of team members allows your support staff and the public to have a clear understanding of everyone's view of the issue at hand. Call on quiet team members, as they may only need a clarification or an explanation.
- 2. **Different opinions are welcome, but the board must stay on track.** The Chair helps guide the team to places of agreement, so the discussion should focus on areas that need clarification, legal advice, or further vetting. Keep the discussion on track or you may find yourself in the middle of a disagreement in which there are no winners and no productive actions.
- 3. **Limit side conversations.** A quick question or clarification is one thing, but it can be disconcerting when whispered conversations are held between members of the board during an open meeting. It does nothing to encourage trust between the board and the public, and the Chair should not allow it.
- 4. **Re-state the motion and clarify amendments.** This is a simple way for the Chair to be sure that everyone on the team is on the same page as you move through the process. It also gives support staff the opportunity to clarify the language or intent if needed. It can be surprising how often people are halfway through an argument before they realize they didn't have a clear understanding of the motion or amendment before them. As a member of the board or commission, don't hesitate to ask for clarification if you are unsure.
- 5. **Hold team members accountable.** If a board member is interrupting others, rude to staff, or refusing to keep their comments on track, the Chair should call for a brief at ease and address it with them directly. Honest mistakes or over-eagerness can be quietly corrected at a break, but deliberate bad behavior by anyone should never be tolerated by the Chair.
- 6. **Listen respectfully and thoughtfully to public testimony.** Remember that the public has an important role in the process. They have given their time and effort to be heard, and the issue at hand is probably very important to them personally. If testimony gets heated, the Chair can always call for an at ease so that tempers can cool.
- 7. **Cell phones off.** Ringing phones are annoying, but texting someone in the audience or another board member during the meeting is disconcerting and secretive. This does not encourage trust between the team members themselves or the public.
- 8. **Speak clearly.** When before the public, always speak so that they can hear you. You may not have a good sound system to amplify your voice, so speak loudly and clearly.

# THE STATE OF ALASKA MIKE DUNLEAVY GOVERNOR

#### **Boards and Commissions**

Office of the Governor

550 W 7<sup>th</sup> Ave. Suite 1700 Anchorage, Alaska 99501 907-269-0006

#### **Open Meetings Act**

The State of Alaska's Open Meetings Act (AS 44.62.310-.312) requires that all meetings of a public entity's governing body be open to the public and that the body provide reasonable notice of its meetings. The Open Meetings Act (OMA) is intended to ensure that decisions made and actions taken are public knowledge and represent the will of the public that the governing body serves. In essence, the OMA protects the public's right to know.

To be able to protect the public's right to know, the OMA requires that:

- all deliberations and action taken by a public entity must be done in public view, with limited exceptions;
- the public must be provided prior knowledge of all steps occurring in the decision-making process, with limited exceptions; and that
- individual actions of an official are made known.

In order for these requirements to have full effect, meetings must occur as provided in the notice; and, with few exceptions, the public must be allowed to involve itself in the meeting. The public must also have access to materials being considered during the meeting.

In addition to laying out specific steps required for meetings and allowable exceptions, the statutes addressing open meetings speak about the state's policy regarding what authority the public has delegated to governing bodies. Following is a synopsis.

According to the 'State Policy Regarding Meetings' (AS 44.62.312):

- The government exists to aid in conducting the people's business.
- Government units should act and deliberate openly.
- The people do not yield sovereignty to government agencies that serve them.
- Public servants have not been given the right to decide what is good or not good for the people to know.
- People should remain informed so they may retain control over the government they created.
- The use of teleconferences is for the convenience of the parties, public, and government.
- The Open Meetings Act should be narrowly construed to effectuate these policies and avoid unnecessary exemptions.

#### What is the Open Meetings Act?

The State of Alaska's Open Meetings Act (AS 44.62.310-.312), is a law that addresses the meetings of public entities; it protects the public's right to know and their opportunity to be heard. Among other things, the Act:

- defines public meetings and public entities;
- lays out specific requirements for public notice;
- requires that all meetings of a governmental body of a public entity are open to the public;
- lays out provisions for attendance at meetings and voting methods;
- lays out provisions for distribution of meeting materials; and
- lists the few exceptions to the Act, as well as matters that may be discussed in executive session.

In order to assure that the public information/participation provisions of the Act are met, the Act requires that the public entity must provide "reasonable" notice that meets the requirements of the Act. To meet these notice requirements, the notice must:

- be provided within a reasonable amount of time prior to the meeting;
- include the date, time, and place of the meeting;
- be posted at the principal office of the public entity, in addition to any other methods and locations stated in local ordinance; and
- be done in the same way each time (consistent).

#### What is the definition of a meeting that would fall under the provisions of the Open Meetings Act?

AS 44.62.310(h) provides detailed definitions of "governmental body," "meeting," and "public entity" that, when combined, define what constitutes a public meeting. The Act makes a distinction between what constitutes a meeting of a policy/decision-making body and what constitutes a meeting of an advisory-only body.

A meeting of a <u>decision- or policy-making</u> body occurs when more than three members, or a majority of the members, whichever is less, engage collectively in discussion of a *subject that the body is authorized to act and set policy on* and is therefore subject to the Open Meetings Act. Under this definition, it doesn't matter where the meeting occurs, if it was prearranged, or who arranged it and could include unplanned casual or social contact.

A meeting of an <u>advisory-only</u> body is a prearranged gathering to consider a matter on which the entity is *authorized to advise and assist the decision-making body* and is subject to the provisions of the Act. The Act doesn't specify a number, so two or more members, if the gathering is prearranged for the purpose of conducting any business of the entity, could constitute a meeting.

#### What types of meetings might be conducted that would require notice under the Open Meetings Act?

Following are the most common types of meetings that would be subject to the Open Meetings Act:

Regular Meetings: State law requires that the governing body conduct its business at regularly scheduled meetings that are open to the public. Regular meetings must be held at least once a month and may be held more often, as required or established in local ordinance. The local code of ordinances should provide the date, time, and place of regular meetings so that everyone knows when regular meetings will take place. The public shouldn't have to wonder about the meeting time, date, and place always changing. If at times it is necessary to reschedule the regular meeting, notice must be posted informing the public that the regular meeting has been rescheduled and when it will be held.

Special Meetings: Special meetings have the same requirements as regular meetings, except that they are called for a different time than that fixed for regular meetings. For example, local ordinance may require that the governing body hold its regular meeting on the third Tuesday of each month at 7:00 PM at the municipal offices. If the governing body must meet earlier, it can call a special meeting for a different date. The special meeting does not take place instead of the regular meeting, it is in addition to the regular meeting. Special meetings should be held rarely and only to address time sensitive issues. A special meeting may be held with less than 24-hour's notice if all members are present or if absent members have waived in writing the required notice. Waiver of notice can be made before or after the special meeting is held.

<u>Emergency Meetings</u>: Emergency meetings are held to address situations that are so urgent that the governing body must meet right away. An emergency meeting may be held if a majority of the members are given at least 24 hours oral or written notice and reasonable efforts are made to notify all members.

Committee Meetings: Permanent ("standing") committees and temporary ("ad hoc") committees of the governing body may be formed to study particular issues in more detail. Standing committees may include the finance committee, public works committee, and/or a facilities committee. Ad hoc committees are formed to address a specific situation and are disbanded once the situation has been dealt with. Committees may be composed of all members of the governing body (referred to as a committee of the whole), or of fewer members, usually three. A committee cannot take action on behalf of the full governing body but instead makes a recommendation to the governing body for the governing body's action. Usually the committee of the whole meets to discuss items that are not ready for action but need further discussion in an informal setting. For example, the annual budget usually requires a work session before it is formally adopted.

**Board of Equalization:** The governing body, or its appointees, sits as the Board of Equalization in municipalities that levy a property tax. AS 29.45.200(a) states, "the governing body sits as a board of equalization for the purpose of hearing an appeal from a determination of the assessor." A property owner who believes the assessor has made a mistake in the yearly valuation of their property may appeal the assessor's decision to the board of adjustment, which meets once a year.

#### How much notice is required to meet the "reasonable" public notice provision of the Open Meetings Act?

How much notice is required depends on the complexity of the issue and the potential effect it will have. Proper public notice must be provided in advance of the proposed action and local ordinances should state the minimum number of days that notice is required. This number should be adjusted up if the situation warrants additional notice. Special and emergency meetings require only 24-hour notice or less. If less notice is given, absent members must waive the notice requirement. Notice requirements for work sessions and committee meetings should follow the same guidelines as those established in local ordinance for regular meetings.

There are minimum mandatory notice requirements for certain actions, such as notice of a public hearing on a proposed ordinance, or election notice. There is, however, no specific number of days spelled out in statute that defines "reasonable." The general tone of case law on the subject has essentially found that reasonable notice provides enough notice that a concerned party will have notice of a proposed action within enough time to be involved in the deliberations. This could vary anywhere from three months to three days. The notice also has to provide enough information to let the public know what subjects will be covered in the meeting. If a complete agenda isn't available at the time of posting, a summary will work until the complete agenda is available.

Local ordinances should contain all of the requirements for public notice of meetings including what to include in the notice, where the notices are posted, and how soon before the meeting the notices are posted.

#### Where and how does notice have to occur?

State law, AS 44.62.310(e), requires that reasonable notice include the date, time, and place of the meeting; and, if by teleconference, the location of any teleconferencing facilities. It also provides that notice may be given in print or broadcast media; that it be posted at the principal office of the public entity or, if no principle office, at a location designated by the governing body; and that it be done in the same way each time "consistent."

In addition to the locations required in statute, notice should be posted at well-used locations in the community like the post office, the store, government offices, and the community bulletin board. It may also be published in a newspaper of general circulation in the community or broadcast over a local radio station in addition to any other means and locations stated in local ordinance.

Are there exceptions to the Open Meetings Act and what subjects may be discussed in executive session? Exceptions to the OMA are discussed in the <u>Executive Session</u> section of LOGON.

#### Is secret ballot voting allowed under the act?

Almost always, no. In addition to requiring that deliberations of a governing body be open to the public, the act also requires that the vote shall be conducted in such a manner that the public may know the vote of each person entitled to vote, including meetings conducted by teleconference. The one exception is organizational meetings of a governing body to elect members to various offices, which are exempted from the requirement that the vote of each member be made public (AS 44.62. 310(a)).

#### Is telephone polling considered a violation of the Open Meetings Act?

Whether a phone poll by a member or agent of the governing body would be considered a violation of the act, depends on the subject matter. If the matter involves an administrative or procedural issue that would not warrant public discussion, a phone poll may be conducted. If, however, the phone poll touches on an issue that should be discussed in an open meeting or can have the effect of swaying opinion on a public issue, it could be considered a violation of the act.

#### Who enforces the Open Meetings Act?

It is the responsibility of the administration and governing body to assure that the provisions of the Open Meetings Act are enforced. Any individual may contest an action administratively through local channels that they think was done in violation of the Open Meetings Act and ultimately may, within 180 days, file a court action if the issue isn't remedied locally AS 44.62.310(f).

There are several court cases that have ruled in favor of the Open Meetings Act. When deciding these cases, the court doesn't just consider whether a violation has occurred, but also considers whether the action has interfered with the public process that the act was intended to protect.

#### What is the cure for a violation of the Open Meetings Act?

Actions taken at meetings that are found to be in violation of the Open Meetings Act may be voided. Failing to provide proper notice can cost a great deal of money to defend in addition to the wasted time and effort involved. The governing body can attempt an informal cure by holding another meeting in compliance with the Open Meetings Act and conducting a substantial and public reconsideration of the matters.

If a lawsuit is filed, the court may void any action taken by the governing body if the court finds that, considering all of the circumstances, the public interest in compliance with the law outweighs the harm that would be caused by voiding the action AS 44.62.310(f)).

In deciding whether to void an action, the court must consider:

- (1) the expense that may be incurred if the action is voided;
- (2) the disruption that may be caused if the action is voided;
- (3) the possibility of additional litigation if the action is voided:
- (4) the extent to which the subject has previously been considered in compliance with the act;
- (5) the amount of time that has passed since the action was taken;
- (6) the degree to which the action has come to be relied on;
- (7) whether and to what extent the governmental body has, before or after the lawsuit was filed, engaged in or attempted to engage in public reconsideration of the matter;
- (8) the degree to which the violations were willful, flagrant, or obvious;
- (9) the degree to which the governing body failed to adhere to the policy under AS 44.62.312 (a).

This does not apply to an advisory only body that that has no authority to establish policies and make decisions for the public entity (AS 44.62.310(g)).

#### What effect does attorney client privilege have in dealings between a public entity and its attorney?

Executive session procedure requires that the reason for calling the executive session is clearly stated. The attorney-client privilege exemption to the Open Meetings Act is limited to matters where public interest may be injured. This might include how to avoid legal liability, litigation strategies and candid discussion of facts, a proposed settlement conference, and a conference on a decision to appeal.

### In addition to the rights protected under the Open Meetings Act, what rights can the public expect under state law?

In addition to the rights protected under the Open Meetings Act, Title 29 reiterates the requirement that all meetings be open to the public and provides that the public will have the right to be heard at regular and special meetings AS 29.20.020.

AS 29.20.160 lays out the procedures that a governing body must follow in conducting its meetings. These procedures include:

- Provision for identification of the presiding and deputy-presiding officers;
- The requirement that the governing body hold at least one regular monthly meeting, unless otherwise provided by ordinance;
- The requirement that the governing body shall provide at least 24-hour notice for special meetings or absent members must waive the notice requirement;
- Clarification on how actions of the governing body are adopted and what constitutes a quorum;
- The requirement that all members present shall vote on every question, unless required to abstain; and

The requirement that a governing body maintain a journal of its proceedings that is available to the public.

- AS 29.20.380 assigns certain meeting duties and responsibilities to the municipal clerk. These include:
- Attendance at public meetings;
- Keeping the journal;
- Assuring that notice and other requirements for public meetings are complied with;
- Assuring that public records are available for public inspection;
- Managing and maintaining public records; and

Preparing agendas and agenda packets.

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#### Who enforces the local rules under which a municipality conducts its meetings?

Governing bodies must have procedures in place and follow them for their meetings. Some of these procedures are in Title 29 and other statutes. Others are in the local ordinances, which are usually more specific and detailed than Title 29, or in rules of procedure adopted by the governing body.

Essentially, the presiding officer enforces the rules by following them when conducting a meeting and, when there is a question of procedure, the clerk, acting as parliamentary advisor, researches the question and proposes an answer, which the presiding officer then rules on. Members of the public also enforce the rules by questioning whenever something occurs that doesn't seem to follow the rules. The last resort for enforcement is a lawsuit.

#### **Additional Resources**

Alaska's Open Meetings Law by Gordon J Tans Open Meetings Act AS 44.62.310-.312

#### Sec. 44.62.310. Government meetings public.

- (a) All meetings of a governmental body of a public entity of the state are open to the public except as otherwise provided by this section or another provision of law. Attendance and participation at meetings by members of the public or by members of a governmental body may be by teleconferencing. Agency materials that are to be considered at the meeting shall be made available at teleconference locations if practicable. Except when voice votes are authorized, the vote shall be conducted in such a manner that the public may know the vote of each person entitled to vote. The vote at a meeting held by teleconference shall be taken by roll call. This section does not apply to any votes required to be taken to organize a governmental body described in this subsection.
- (b) If permitted subjects are to be discussed at a meeting in executive session, the meeting must first be convened as a public meeting and the question of holding an executive session to discuss matters that are listed in (c) of this section shall be determined by a majority vote of the governmental body. The motion to convene in executive session must clearly and with specificity describe the subject of the proposed executive session without defeating the purpose of addressing the subject in private. Subjects may not be considered at the executive session except those mentioned in the motion calling for the executive session unless auxiliary to the main question. Action may not be taken at an executive session, except to give direction to an attorney or labor negotiator regarding the handling of a specific legal matter or pending labor negotiations.
- (c) The following subjects may be considered in an executive session:
- (1) matters, the immediate knowledge of which would clearly have an adverse effect upon the finances of the public entity;
- (2) subjects that tend to prejudice the reputation and character of any person, provided the person may request a public discussion;
  - (3) matters which by law, municipal charter, or ordinance are required to be confidential;
  - (4) matters involving consideration of government records that by law are not subject to public disclosure.
- (d) This section does not apply to
- (1) a governmental body performing a judicial or quasi-judicial function when holding a meeting solely to make a decision in an adjudicatory proceeding;
  - (2) juries;
  - (3) parole or pardon boards;
  - (4) meetings of a hospital medical staff;
- (5) meetings of the governmental body or any committee of a hospital when holding a meeting solely to act upon matters of professional qualifications, privileges, or discipline;
- (6) staff meetings or other gatherings of the employees of a public entity, including meetings of an employee group established by policy of the Board of Regents of the University of Alaska or held while acting in an advisory capacity to the Board of Regents;
- (7) meetings held for the purpose of participating in or attending a gathering of a national, state, or regional organization of which the public entity, governmental body, or member of the governmental body is a member, but only if no action is taken and no business of the governmental body is conducted at the meetings; or
- (8) meetings of municipal service area boards established under <u>AS 29.35.450</u> 29.35.490 when meeting solely to act on matters that are administrative or managerial in nature.
- (e) Reasonable public notice shall be given for all meetings required to be open under this section. The notice must include the date, time, and place of the meeting and if, the meeting is by teleconference, the location of any teleconferencing facilities that will be used. Subject to posting notice of a meeting on the Alaska Online Public Notice

System as required by <u>AS 44.62.175(a)</u>, the notice may be given using print or broadcast media. The notice shall be posted at the principal office of the public entity or, if the public entity has no principal office, at a place designated by the governmental body. The governmental body shall provide notice in a consistent fashion for all its meetings.

- (f) Action taken contrary to this section is voidable. A lawsuit to void an action taken in violation of this section must be filed in superior court within 180 days after the date of the action. A member of a governmental body may not be named in an action to enforce this section in the member's personal capacity. A governmental body that violates or is alleged to have violated this section may cure the violation or alleged violation by holding another meeting in compliance with notice and other requirements of this section and conducting a substantial and public reconsideration of the matters considered at the original meeting. If the court finds that an action is void, the governmental body may discuss and act on the matter at another meeting held in compliance with this section. A court may hold that an action taken at a meeting held in violation of this section is void only if the court finds that, considering all of the circumstances, the public interest in compliance with this section outweighs the harm that would be caused to the public interest and to the public entity by voiding the action. In making this determination, the court shall consider at least the following:
- (1) the expense that may be incurred by the public entity, other governmental bodies, and individuals if the action is voided;
- (2) the disruption that may be caused to the affairs of the public entity, other governmental bodies, and individuals if the action is voided;
- (3) the degree to which the public entity, other governmental bodies, and individuals may be exposed to additional litigation if the action is voided;
- (4) the extent to which the governing body, in meetings held in compliance with this section, has previously considered the subject;
  - (5) the amount of time that has passed since the action was taken;
  - (6) the degree to which the public entity, other governmental bodies, or individuals have come to rely on the action;
- (7) whether and to what extent the governmental body has, before or after the lawsuit was filed to void the action, engaged in or attempted to engage in the public reconsideration of matters originally considered in violation of this section;
  - (8) the degree to which violations of this section were wilful, flagrant, or obvious;
  - (9) the degree to which the governing body failed to adhere to the policy under AS 44.62.312(a).
- (g) Subsection (f) of this section does not apply to a governmental body that has only authority to advise or make recommendations to a public entity and has no authority to establish policies or make decisions for the public entity.
- (h) In this section.
- (1) "governmental body" means an assembly, council, board, commission, committee, or other similar body of a public entity with the authority to establish policies or make decisions for the public entity or with the authority to advise or make recommendations to the public entity; "governmental body" includes the members of a subcommittee or other subordinate unit of a governmental body if the subordinate unit consists of two or more members;
  - (2) "meeting" means a gathering of members of a governmental body when
- (A) more than three members or a majority of the members, whichever is less, are present, a matter upon which the governmental body is empowered to act is considered by the members collectively, and the governmental body has the authority to establish policies or make decisions for a public entity; or
- (B) more than three members or a majority of the members, whichever is less, are present, the gathering is prearranged for the purpose of considering a matter upon which the governmental body is empowered to act, and the governmental body has only authority to advise or make recommendations for a public entity but has no authority to

establish policies or make decisions for the public entity;

(3) "public entity" means an entity of the state or of a political subdivision of the state including an agency, a board or commission, the University of Alaska, a public authority or corporation, a municipality, a school district, and other governmental units of the state or a political subdivision of the state; it does not include the court system or the legislative branch of state government.

#### Sec. 44.62.312. State policy regarding meetings.

- (a) It is the policy of the state that
  - (1) the governmental units mentioned in AS 44.62.310(a) exist to aid in the conduct of the people's business;
- (2) it is the intent of the law that actions of those units be taken openly and that their deliberations be conducted openly;
  - (3) the people of this state do not yield their sovereignty to the agencies that serve them;
- (4) the people, in delegating authority, do not give their public servants the right to decide what is good for the people to know and what is not good for them to know;
- (5) the people's right to remain informed shall be protected so that they may retain control over the instruments they have created;
- (6) the use of teleconferencing under this chapter is for the convenience of the parties, the public, and the governmental units conducting the meetings.
- (b) AS 44.62.310(c) and (d) shall be construed narrowly in order to effectuate the policy stated in (a) of this section and to avoid exemptions from open meeting requirements and unnecessary executive sessions.