Board Members:

Ashley Schaber, Pharmacist (Chairperson)

James Henderson, Pharmacist

Carla Hebert, Pharmacist

Ramsey Bell, Pharmacist

Sylvain Nouvion, Pharmacist

Vacant, 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

Upcoming Meetings:

August 22, 2024 (Tentative)

November 14, 2024 (Tentative)

ALASKA BOARD OF PHARMACY MEETING

AGENDA

APRIL 11, 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:	April 11, 2024
Meeting End Time:	5:00 PM
Meeting End Date:	April 11, 2024
Meeting Locations:	1. Board/Staff - Suite 1550, Atwood Building, Anchorage, AK
	2. Zoom for Public Attendees (Limited In-Person Space)
	Meeting Registration Link: https://us02web.zoom.us/meeting/register/tZcldOmspj8tGt06OBrYnFKrI6cJIDBLT_9y
	Dial ID: 838 3048 4709 Passcode: 855459

Links

Board of Pharmacy Homepage: pharmacy.alaska.gov

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
    - Review/Approve Previous Meeting Minutes
        - February 15, 2024
    - Review Lost or Stolen Controlled Substances/DEA 106s
    - Review Well Being Index
        - American Pharmacists Association's (APhA) Well-Being Index for Pharmacy Personnel, February 2024 Edition
        - American Pharmacists Association's (APhA) Well-Being Index for Pharmacy Personnel, March 2024 Edition
4. Investigations Review (9:05 – 10:00)
    - Holly Handley, Investigator
        - Investigative Report
        - Board Member Review Training
        - Case Reviews, Confidential - Executive Session
            - 2022-000634
            - 2023-000283
            - 2023-000684
            - 2023-000910
5. Public Comment Period (10:00 – 10:15)
6. Statutes and Regulations (10:15 – 12:00)
    - Review Public Comments for Regulations Project 2023200594
    - Update the Statute and Regulation Committee Members
    - Set a Statute and Regulation Committee Meeting Date
        - Tentatively Early June
    - Select an Alternative Legislative Point Person
    - National Background Checks

- Bills to Review
  - HB 187 / SB 219 Prior Auth Exempt for Health Providers
  - HB 228 / SB 166 Mental Health/Psychedelic Med. Task Force
  - HB 314 / SB 225 Occupational Licensing Fees
    - Glenn Saviers, Deputy Director for the Division of Corporations, Business, and Professional Licensing

7. Industry Updates (12:00 – 12:30)
   - Alaska Pharmacists Association (AKPhA) – Brandy Seignemartin, PharmD
   - Alaska Department of Health – John Boston, DO, CMD
8. Adjourn for Lunch (12:30 – 1:00)
9. Roll Call/Call to Order (1:00 – 1:05)
10. Division Updates (1:05 – 2:00)
    - Michael Bowles, Executive Administrator of the Board of Pharmacy (1:05 – 1:15)
      - Update of Renewal Period
    - Melissa Dumas, Administrative Operations Manager for the Division of Corporations, Business, and Professional Licensing (1:15 – 1:30)
      - Budget Report for 2nd Quarter Fiscal Year 24
    - Lisa Sherrell, Prescription Drug Monitoring Program (PDMP) Manager (1:30 – 1:45)
      - PDMP Updates
11. Public Comment Period (1:45 – 2:00)
12. Board Business (2:00 – 4:50)
    - Rx and Illicit Drug Summit Review
      - Sylvain Nouvion
      - Michael Bowles
      - Lisa Sherrell
    - Review and Update Strategic Plan
    - Annual Report Discussion
    - SBAR Format Discussion
    - Past Disciplinary Action Discussion
    - Review and Approve Updated Disciplinary Matrix
    - Law Questions for Alaska Law Exam

    - Select Board Member to Choose and Update Questions
- Review Inspection Sheets for Needed Updates
- Controlled Substance Advisory Committee Discussion
- Way Forward on Just Culture
- Tasks List Review and Update

13. Chair Final Comments (4:50 – 5:00)
    - Meeting Evaluation
    - August 22, 2024
    - November 14, 2024
14. Adjourn (5:00)

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, Pharm.D	07/01/2021	03/01/2024	03/01/2028
Sylvain Nouvion, Pharm.D., 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
Sara Rasmussen, Public Member	03/01/2023		03/01/2027
Vacant (Pharmacy Technician)			

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

Updated 03/21/2024

Alaska Board of Pharmacy

Agenda Item #2

Ethics Disclosures

Alaska Board of Pharmacy

Agenda Item #3

Consent Agenda Items

APhA

WELL-BEING index

Well-being Index For Pharmacy Personnel

State Report
For State Boards of Pharmacy
NABP District Seven States

February 2024

pharmacist.com

For Every Pharmacist. For All of Pharmacy.

DISTRESS PERCENT CHANGES

National and District

January 2024 versus February 2024

WELL-BEING index
https://app.mywellbeingindex.org/signup
Invitation Code: APhA

Changes in Distress Levels

As of February 2024

State	Change in Distress % January 2024 vs February 2023	State Rank for Distress Percent February 2024	Distress Percent February 2024
Largest *Increase* in Distress Percent			
Puerto Rico	+3.13%	2	53.13%
Maine	+1.38%	50	23.75%
New Hampshire	+1.09%	3	50.00%
Wisconsin	+0.45%	47	25.94%
Nevada	+0.45%	1	58.51%
Montana	-4.45%	25	32.69%
Idaho	-2.22%	44	28.00%
North Dakota	-1.90%	30	31.43%
Washington	-1.81%	6	43.21%
Connecticut	-1.40%	5	44.05%
Change in National Distress Percent			
NATIONAL	-0.03	---	30.96%

Changes in Distress Levels – District Seven

As of February 2024

	Change in Distress % Feb 2024 vs Jan 2024	Distress % Feb 2024	Distress % State Rank Feb 2024	Change in Distress % Jan 2024 vs Dec 2023	Distress % State Rank Jan 2024	Distress % State Rank Dec 2023	Distress % State Rank Nov 2023	Distress % State Rank Oct 2023	Distress % State Rank Jul 2023	Distress % State Rank Apr 2023	Distress % State Rank May 2022	Distress % State Rank Apr 2022	Distress % State Rank Dec 2021	Distress % State Rank Apr 2021	Distress % State Rank May 2020	Distress % State Rank Apr 2020
Alaska	**No Change**	**29.67%**	**38**	-0.33%	39	36 (T)	40	38	39	37	38	33	48	49	49	49
Idaho	**-2.22%**	**28.00%**	**44**	-0.21%	37	35	35	35	35	32	22	27	31	34	40	39
Montana	**-4.45%**	**32.68%**	**25**	No Change	14	13	13	12	12	10	11	11	10	12	19 (T)	24
Oregon	**-0.65%**	**34.69%**	**18**	-0.34%	17	17	17	17	17	17	31	29	27 (T)	28	36	37
Washington	**-1.81%**	**43.21%**	**6**	-0.23%	6	6	6	6	8	7	8	9	11	11	12	13
Wyoming	**No Change**	**29.03%**	**40**	1.44%	41	43	43	50	52	51	52	52	52	51	~	~

(T) = Tied rank with another state(s). ~=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 ashaughnessy@aphanet.org for data.

DISTRESS PERCENT MONTHLY REPORTS
State-Specific
January 2024 versus February 2024

WELL-BEING INDEX FOR PHARMACY PERSONNEL

STATE DISTRESS PERCENT*

FEBRUARY 2024

As of February 2024, the Alaska distress percent was 29.67% (ranked 38/52) with 55 assessors.

JANUARY 2024

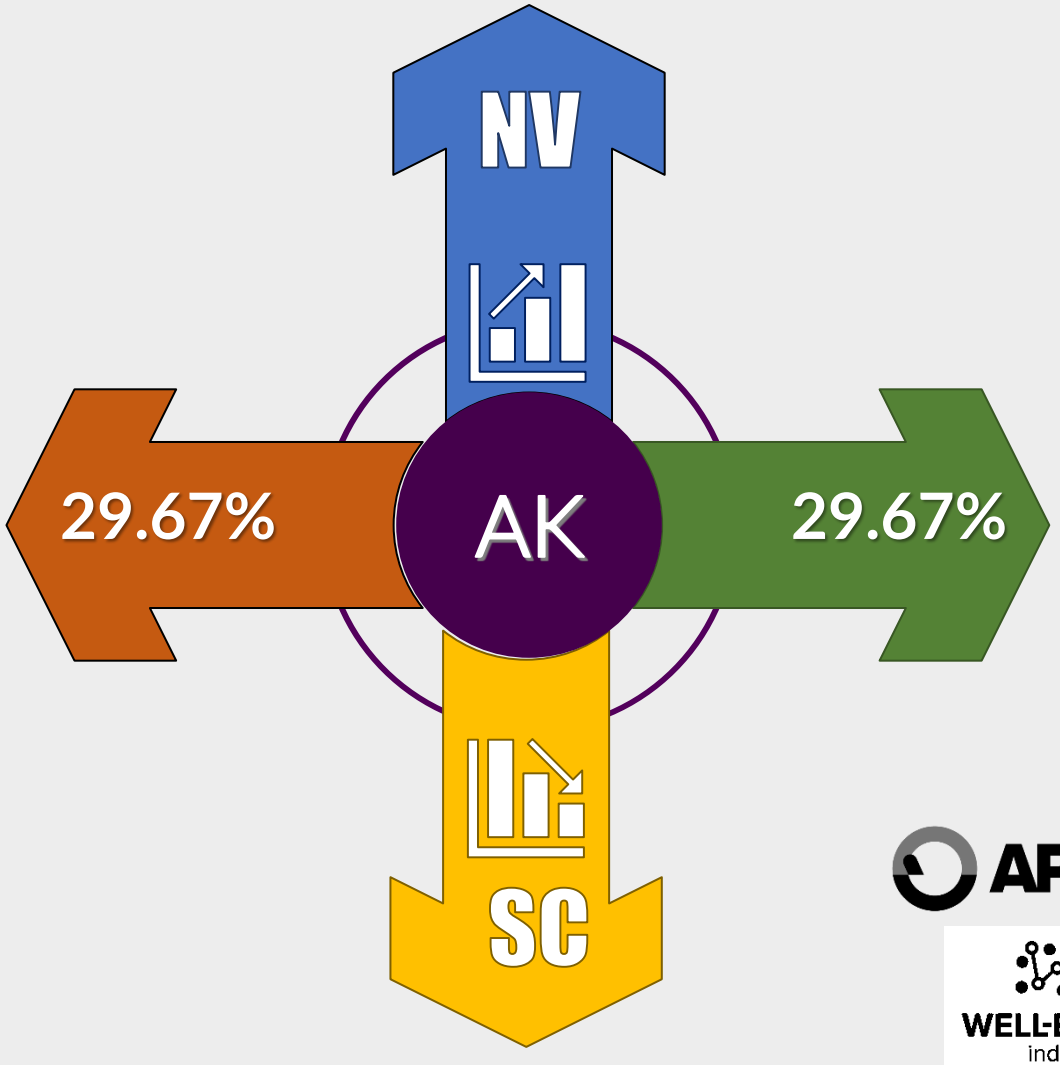
As of January 2024, the Alaska distress percent was 29.67% (ranked 39/52) with 55 assessors.

STATE COMPARISON

As of February 2024

Nevada is the highest at 58.51% (n=40)

South Carolina has the lowest 20.46% (n=595)



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.

APhA

WELL-BEING index
https://app.mywellbeingindex.org/signup
Invitation Code: APhA

WELL-BEING INDEX FOR PHARMACY PERSONNEL

STATE DISTRESS PERCENT*

FEBRUARY 2024

As February 2024, the Idaho distress percent was 28.00% (ranked 44/52) with 93 assessors.

JANUARY 2024

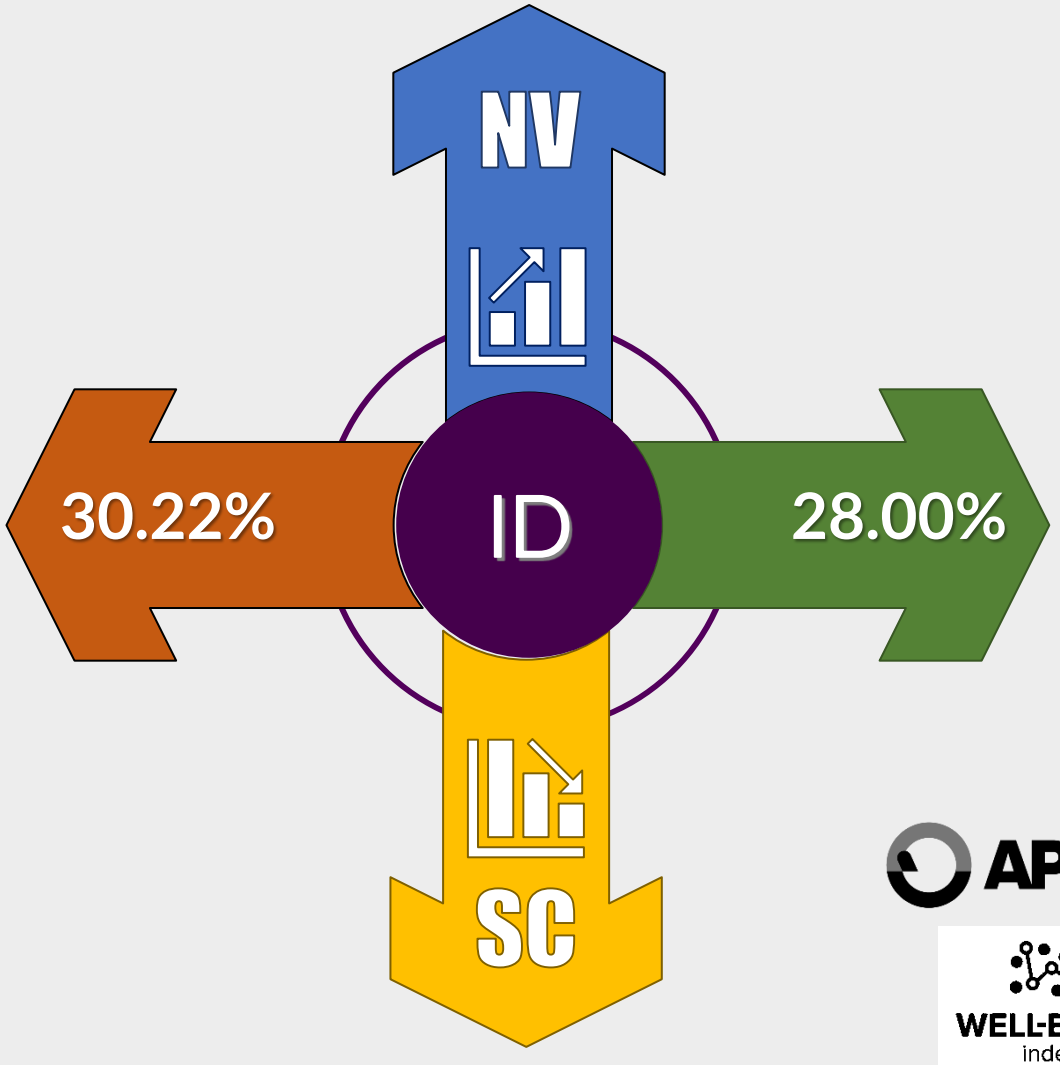
As January 2024, the Idaho distress percent was 30.22% (ranked 37/52) with 82 assessors.

STATE COMPARISON

As of February 2024

Nevada is the highest at 58.51% (n=40)

South Carolina has the lowest 20.46% (n=595)



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WELL-BEING INDEX FOR PHARMACY PERSONNEL

STATE DISTRESS PERCENT*

FEBRUARY 2024

As of February 2024, the Montana distress percent was 32.69% (ranked 25/52) with 45 assessors.

JANUARY 2024

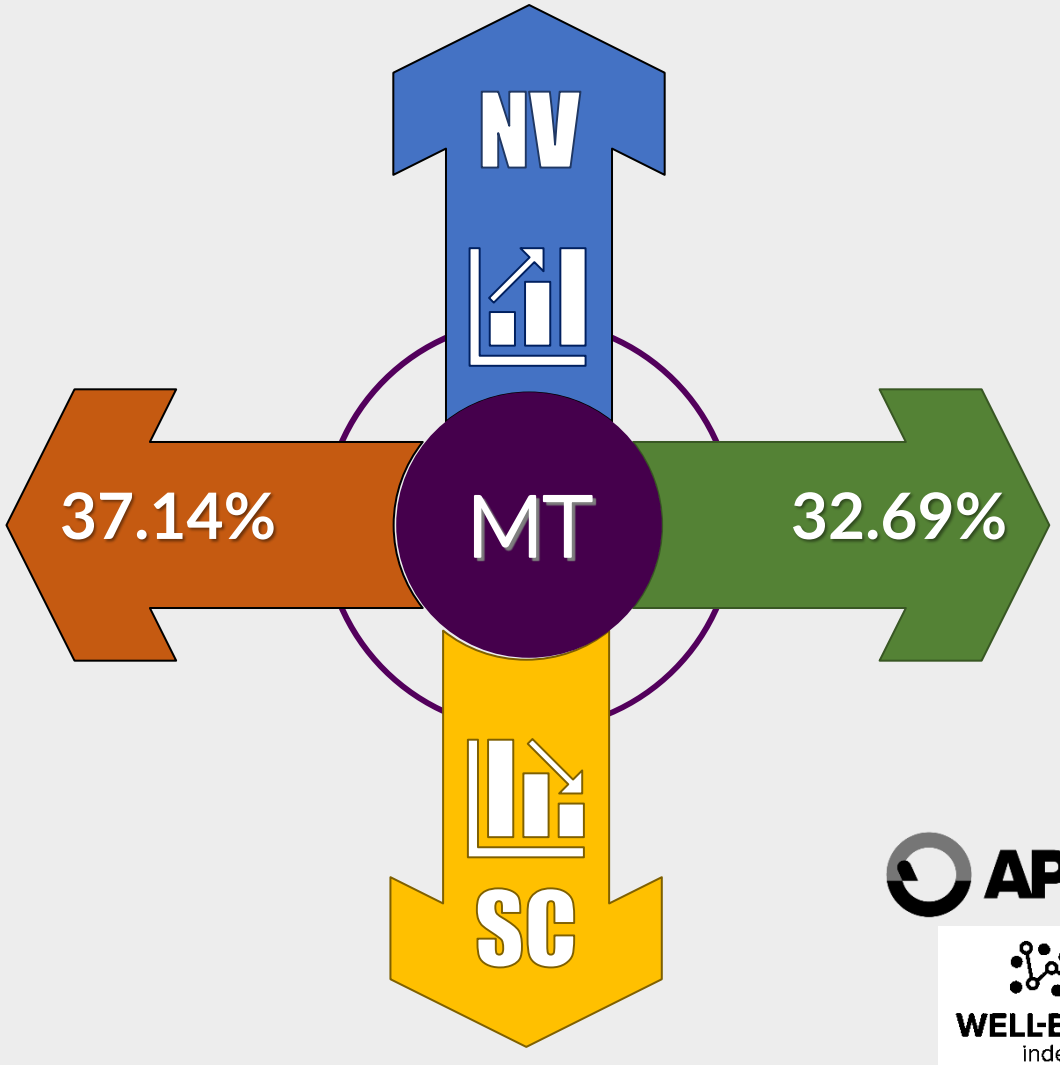
As of January 2024, the Montana distress percent was 37.14% (ranked 14/52) with 28 assessors.

STATE COMPARISON

As of February 2024

Nevada is the highest at 58.51% (n=40)

South Carolina has the lowest 20.46% (n=595)



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WELL-BEING INDEX FOR PHARMACY PERSONNEL

STATE DISTRESS PERCENT*

FEBRUARY 2024

As of February 2024, the Oregon distress percent was 34.69% (ranked 18/52) with 132 assessors.

JANUARY 2024

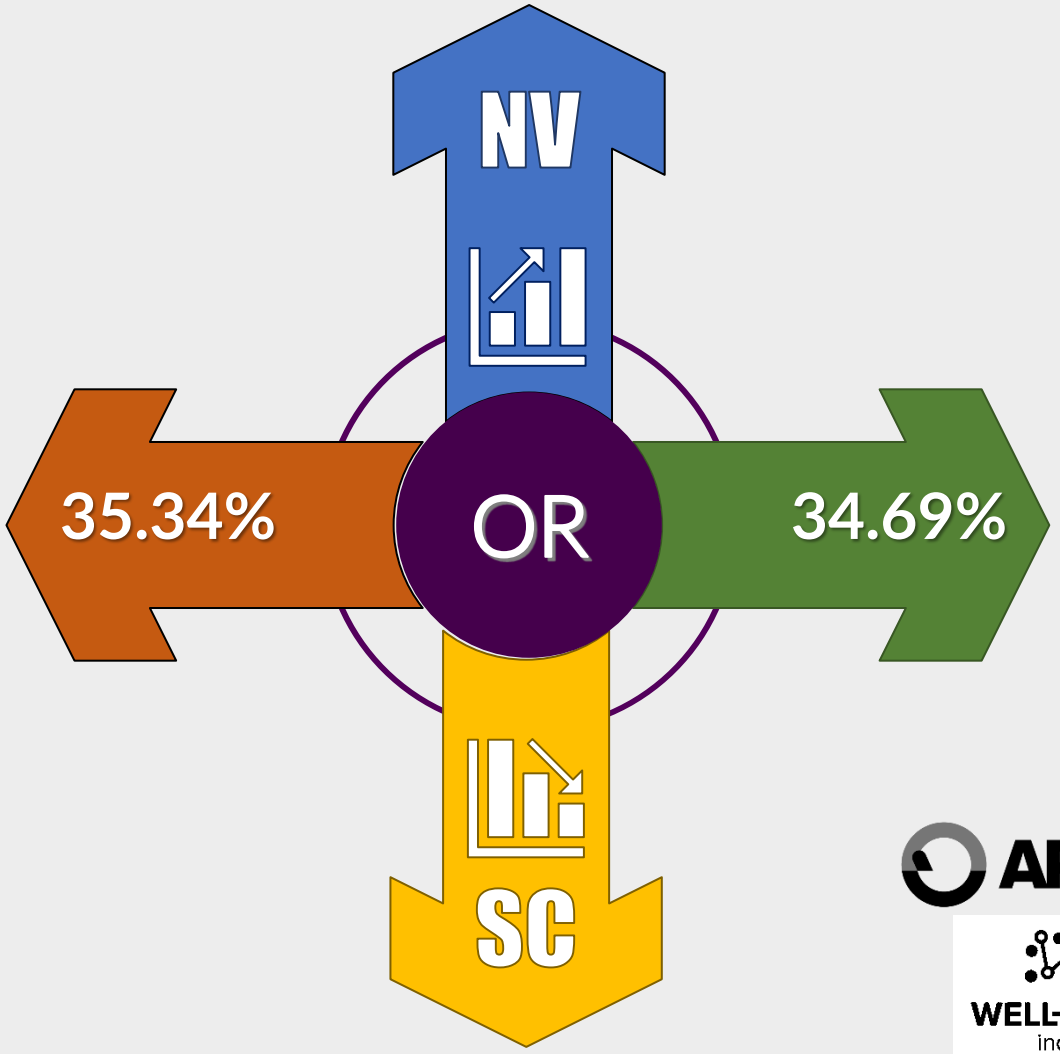
As of January 2024, the Oregon distress percent was 35.34% (ranked 17/52) with 120 assessors.

STATE COMPARISON

As of February 2024

Nevada is the highest at 58.51% (n=40)

South Carolina has the lowest 20.46% (n=595)



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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 INDEX FOR PHARMACY PERSONNEL

STATE DISTRESS PERCENT*

FEBRUARY 2024

As of February 2024, the Washington distress percent was 43.21% (ranked 6/52) with 194 assessors.

JANUARY 2024

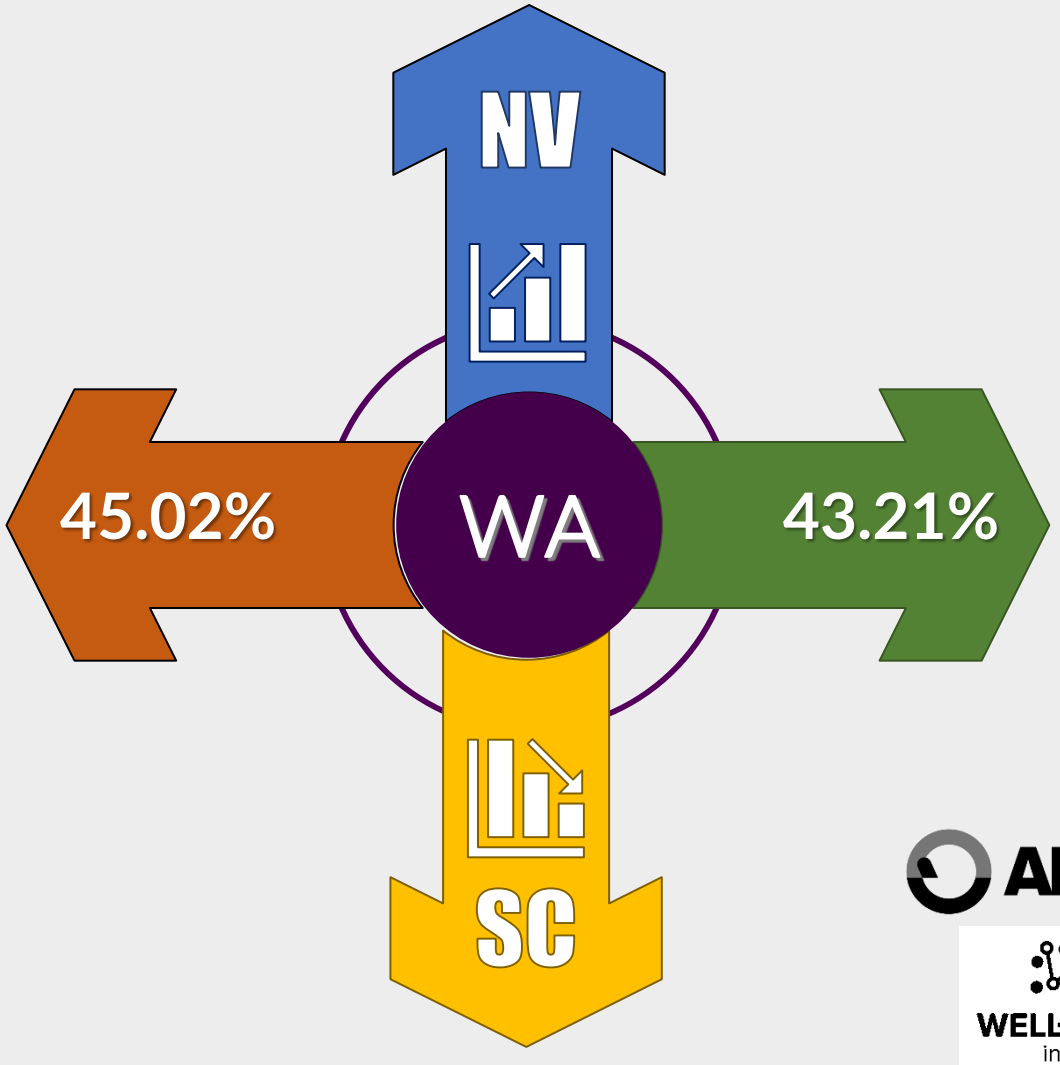
As of January 2024, the Washington distress percent was 45.02% (ranked 6/52) with 187 assessors.

STATE COMPARISON

As of February 2024

Nevada is the highest at 58.51% (n=40)

South Carolina has the lowest 20.46% (n=595)



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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 INDEX FOR PHARMACY PERSONNEL

STATE DISTRESS PERCENT*

FEBRUARY 2024

As of February 2024, the Wyoming distress percent was 29.03% (ranked 40/52) with 19 assessors.

JANUARY 2024

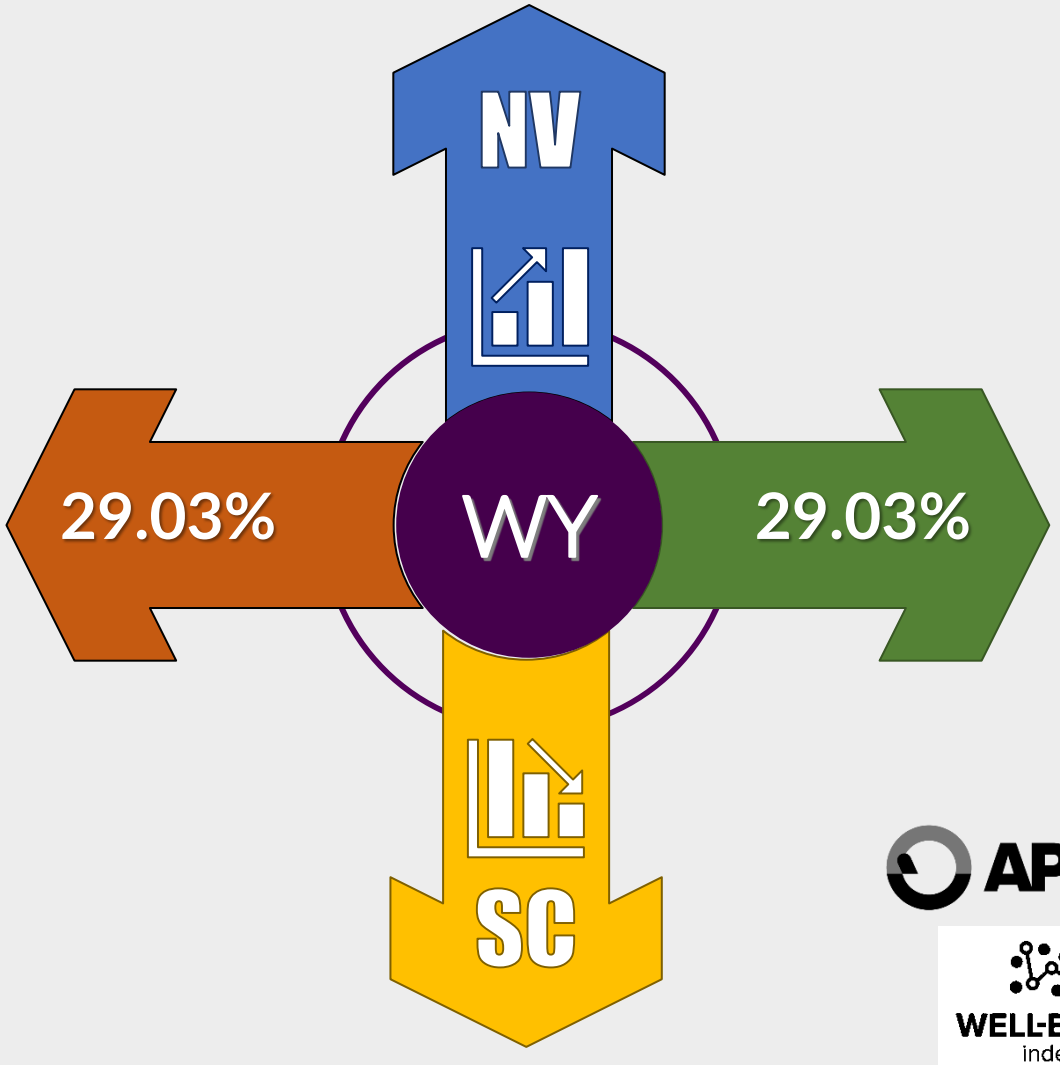
As of January 2024, the Wyoming distress percent was 29.03% (ranked 41/52) with 19 assessors.

STATE COMPARISON

As of February 2024

Nevada is the highest at 58.51% (n=40)

South Carolina has the lowest 20.46% (n=595)



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WELL-BEING index
https://app.mywellbeingindex.org/signup
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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

**Please do not change the content of these promotional slides*

WELL-BEING index

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

APhA

You're committed to pharmacy.
We're committed to your well-being.
www.pharmacist.com/wellbeing

PHARMACY WORKPLACE & WELL-BEING REPORTING

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!

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WELL-BEING index

Well-being Index For Pharmacy Personnel

State Report
For State Boards of Pharmacy
NABP District Seven States

March 2024

pharmacist.com

For Every Pharmacist. For All of Pharmacy.

Zero Tolerance Flyer

Addressing pharmacy personnel harassment and bullying by patients

Zero Tolerance Flyer

A flyer to address patient harassment experienced by pharmacy personnel

Why was the Zero Tolerance flyer developed?

- Identified through reports submitted to Pharmacy Workplace and Well-being Reporting (**PWWR**), pharmacy personnel encountering bullying and harassment from patients/customers is one of the primary contributors to stressful pharmacy working conditions.
- The **Pharmacist's Fundamental Responsibilities and Rights** is focused on pharmacists' responsibilities and workplace expectations needed to fulfil their responsibilities. Pharmacy personnel have a fundamental right to be treated in a considerate, respectful, and professional manner by patients and supported by employers and supervisors. Additionally, workplaces should be free of any form of harassment. This flyer supports these fundamental responsibilities and rights
- The flyer is designed to be posted at pharmacies alert their patients and their caregivers. It is available (at no cost) from the APhA website here.

DISTRESS PERCENT CHANGES

National and District

February 2024 versus March 2024

WELL-BEING index
https://app.mywellbeingindex.org/signup
Invitation Code: APhA

Changes in Distress Levels

WELL-BEING index
https://app.mywellbeingindex.org/signup
Invitation Code: APhA

As of March 2024

State	Change in Distress % February 2024 vs March 2023	State Rank for Distress Percent March 2024	Distress Percent March 2024
Largest *Increase* in Distress Percent			
Vermont	+2.45%	20	33.93%
Arkansas	+1.65%	14	36.76%
Maine	+0.94%	49	24.69%
Alabama	+0.84%	25	33.07%
New Mexico	+0.75%	30	31.52%
Largest *Decrease* in Distress Percent			
Montana	-3.38%	37	29.31%
Nevada	-2.39%	1	56.12%
Puerto Rico	-1.61%	2	51.52%
Connecticut	-1.52%	6	42.53%
Illinois	-1.39%	27	31.73%
Change in National Distress Percent			
NATIONAL	+0.04	---	31.00%

Changes in Distress Levels – District Seven

As of March 2024

	Change in Distress % Mar 2024 vs Feb 2024	Distress % Mar 2024	Distress % State Rank Mar 2024	Change in Distress % Feb 2024 vs Jan 2024	Distress % State Rank Feb 2024	Distress % State Rank Jan 2024	Distress % State Rank Dec 2023	Distress % State Rank Nov 2023	Distress % State Rank Jul 2023	Distress % State Rank Apr 2023	Distress % State Rank May 2022	Distress % State Rank Apr 2022	Distress % State Rank Dec 2021	Distress % State Rank Apr 2021	Distress % State Rank May 2020	Distress % State Rank Apr 2020
Alaska	**-0.32%**	**29.35%**	**25**	No Change	38	39	36 (T)	40	39	37	38	33	48	49	49	49
Idaho	**-0.56%**	**27.44%**	**43**	-2.22%	44	37	35	35	35	32	22	27	31	34	40	39
Montana	**-3.38%**	**29.31%**	**37**	-4.45%	25	14	13	13	12	10	11	11	10	12	19 (T)	24
Oregon	**-0.29%**	**34.40%**	**18**	-0.65%	18	17	17	17	17	17	31	29	27 (T)	28	36	37
Washington	**-1.31%**	**41.90%**	**8**	-1.81%	6	6	6	6	8	7	8	9	11	11	12	13
Wyoming	**-0.90%**	**28.13%**	**42**	No Change	40	41	43	43	52	51	52	52	52	51	~	~

(T) = Tied rank with another state(s). ~=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 ashaughnessy@aphanet.org for data.

DISTRESS PERCENT MONTHLY REPORTS
State-Specific
February 2024 versus March 2024

WELL-BEING index
https://app.mywellbeingindex.org/signup
Invitation Code: APhA

WELL-BEING INDEX FOR PHARMACY PERSONNEL

STATE DISTRESS PERCENT*

MARCH 2024

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

FEBRUARY 2024

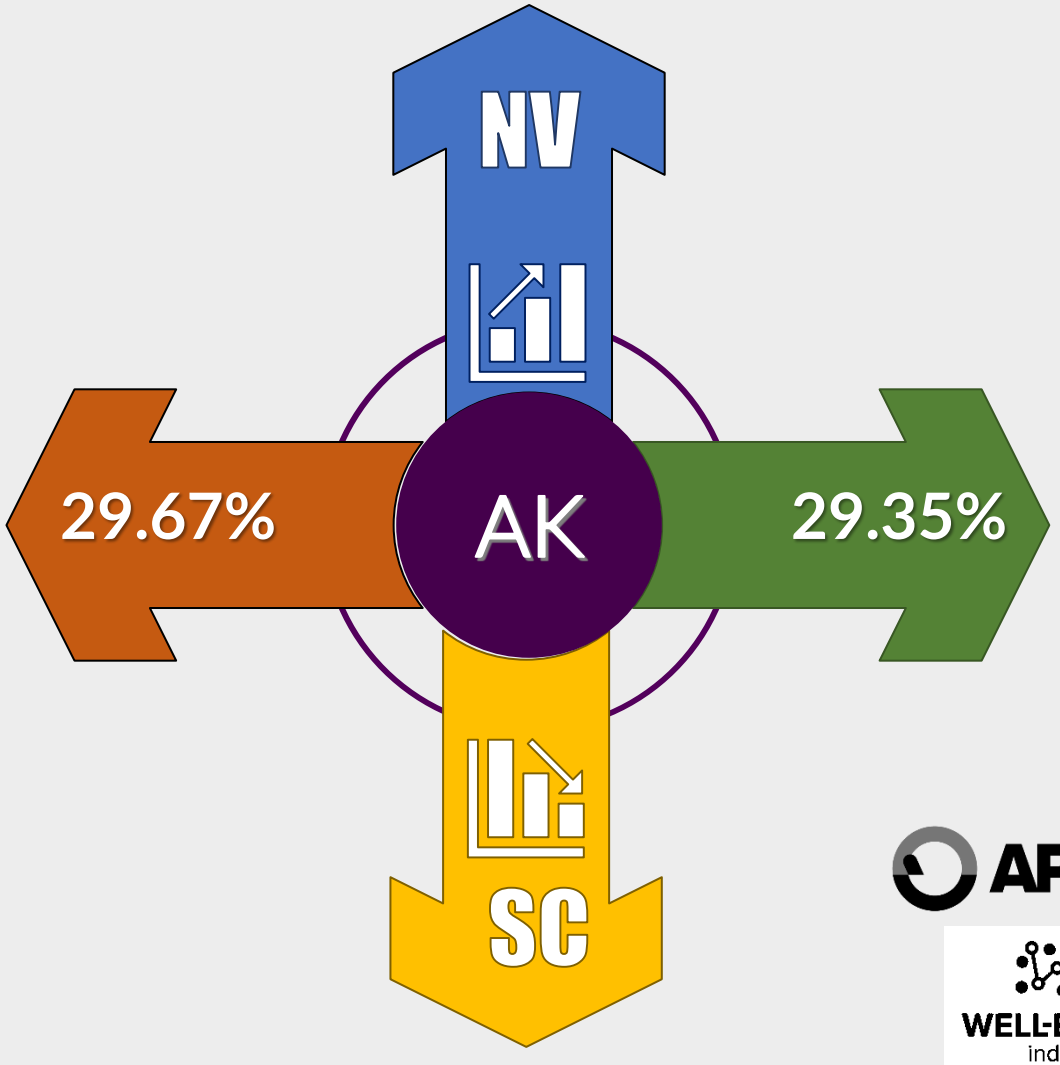
As of February 2024, the Alaska distress percent was 29.67% (ranked 38/52) with 55 assessors.

STATE COMPARISON

As of March 2024

Nevada is the highest at 56.12% (n=43)

South Carolina has the lowest 20.62% (n=600)



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WELL-BEING index
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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 INDEX FOR PHARMACY PERSONNEL

STATE DISTRESS PERCENT*

MARCH 2024

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

FEBRUARY 2024

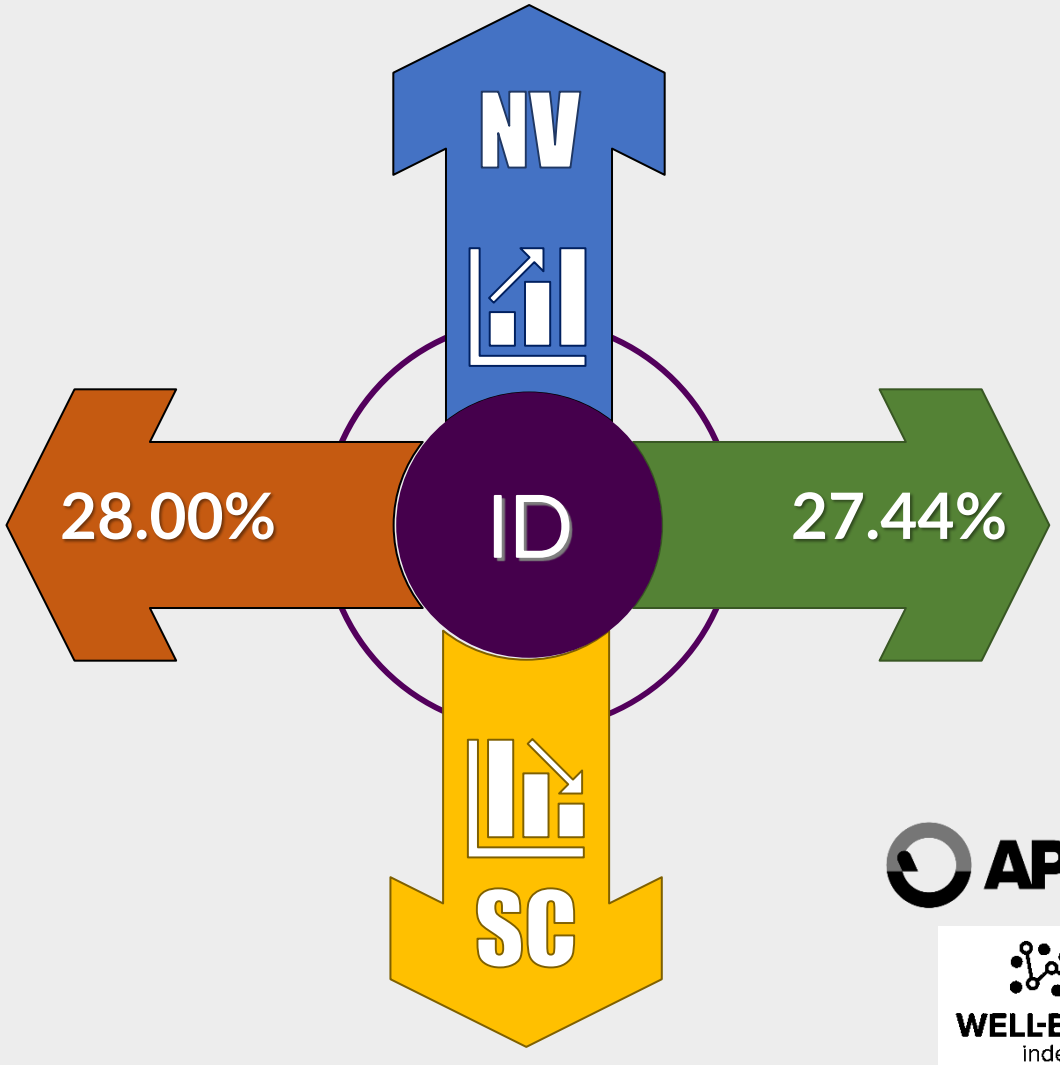
As February 2024, the Idaho distress percent was 28.00% (ranked 44/52) with 93 assessors.

STATE COMPARISON

As of March 2024

Nevada is the highest at 56.12% (n=43)

South Carolina has the lowest 20.62% (n=600)



APhA

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WELL-BEING INDEX FOR PHARMACY PERSONNEL

STATE DISTRESS PERCENT*

MARCH 2024

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

FEBRUARY 2024

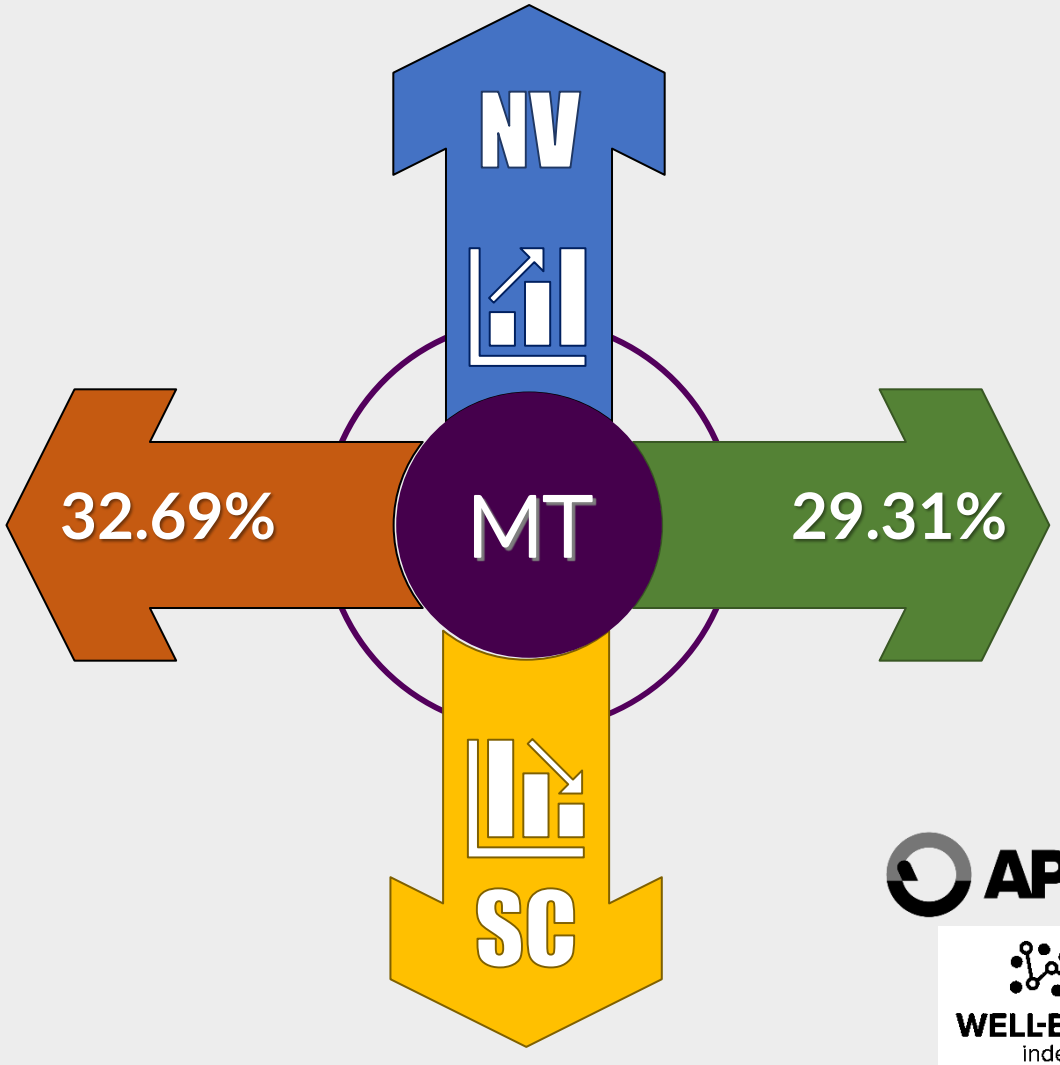
As of February 2024, the Montana distress percent was 32.69% (ranked 25/52) with 45 assessors.

STATE COMPARISON

As of March 2024

Nevada is the highest at 56.12% (n=43)

South Carolina has the lowest 20.62% (n=600)



APhA

WELL-BEING index
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WELL-BEING INDEX FOR PHARMACY PERSONNEL

STATE DISTRESS PERCENT*

MARCH 2024

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

FEBRUARY 2024

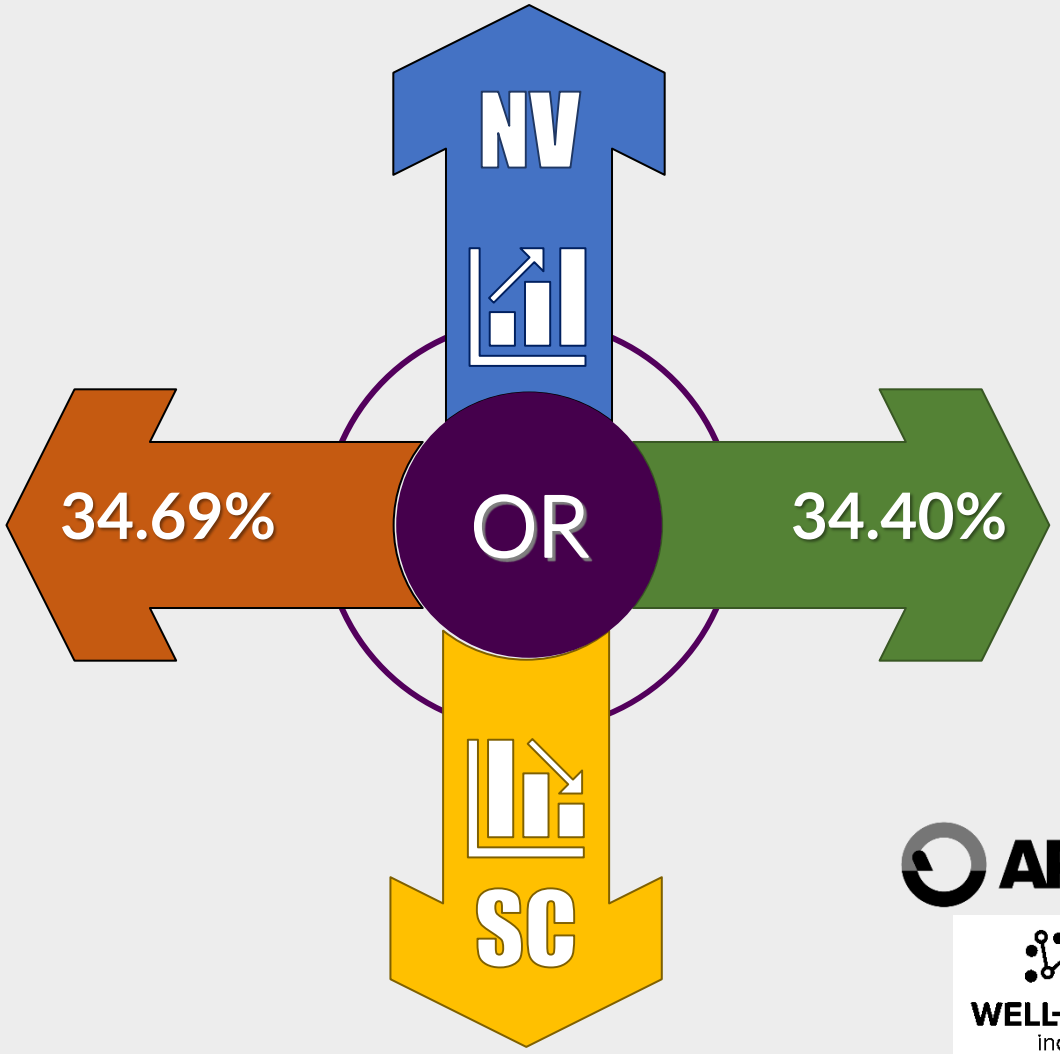
As of February 2024, the Oregon distress percent was 34.69% (ranked 18/52) with 132 assessors.

STATE COMPARISON

As of March 2024

Nevada is the highest at 56.12% (n=43)

South Carolina has the lowest 20.62% (n=600)



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APhA

WELL-BEING index
https://app.mywellbeingindex.org/signup
Invitation Code: APhA

WELL-BEING INDEX FOR PHARMACY PERSONNEL

STATE DISTRESS PERCENT*

MARCH 2024

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

FEBRUARY 2024

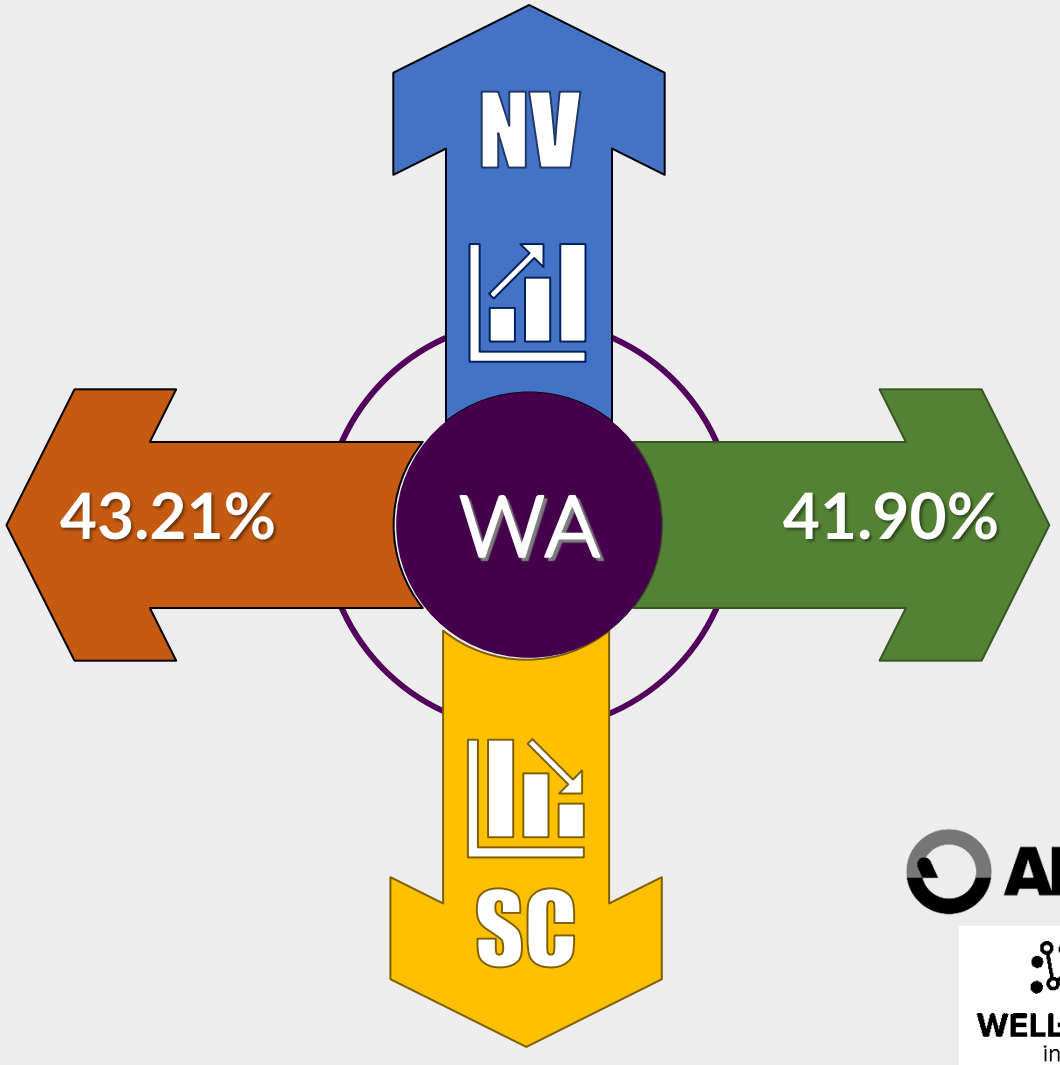
As of February 2024, the Washington distress percent was 43.21% (ranked 6/52) with 194 assessors.

STATE COMPARISON

As of March 2024

Nevada is the highest at 56.12% (n=43)

South Carolina has the lowest 20.62% (n=600)



APhA

WELL-BEING index
https://app.mywellbeingindex.org/signup
Invitation Code: APhA

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 INDEX FOR PHARMACY PERSONNEL

STATE DISTRESS PERCENT*

MARCH 2024

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

FEBRUARY 2024

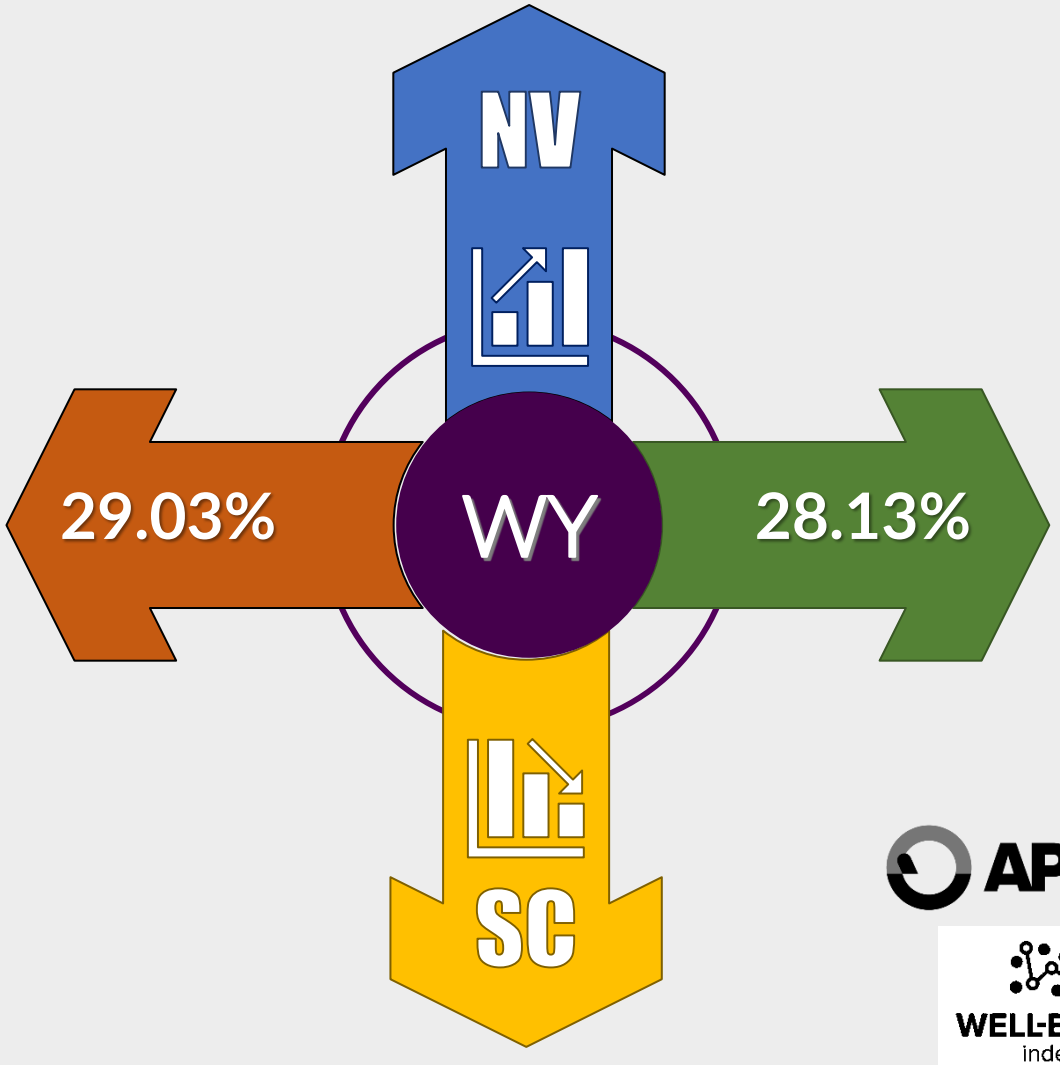
As of February 2024, the Wyoming distress percent was 29.03% (ranked 40/52) with 19 assessors.

STATE COMPARISON

As of March 2024

Nevada is the highest at 56.12% (n=43)

South Carolina has the lowest 20.62% (n=600)



APhA

WELL-BEING index
https://app.mywellbeingindex.org/signup
Invitation Code: APhA

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

**Please do not change the content of these promotional slides*

WELL-BEING index

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

APhA

000037

You're committed to pharmacy.
We're committed to your well-being.
www.pharmacist.com/wellbeing

PHARMACY WORKPLACE & WELL-BEING REPORTING

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

THE STATE of ALASKA

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: April 08, 2024

TO: Board of Pharmacy

THRU: Erika Prieksat, Chief Investigator BH

FROM: Holly Handley, Investigator

RE: Investigative Report for the April 11, 2024 Meeting

The following information was compiled as an investigative report to the Board for the period of February 07, 2024 thru April 08, 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 - 51

Case Number	Violation Type	Case Status	Status Date
OUT OF STATE PHARMACY			
2024-000282	Violation of licensing regulation	Intake	03/26/2024
2024-000295	Violation of licensing regulation	Intake	04/01/2024
2023-000616	Action in another state	Complaint	07/24/2023
2023-000887	Unlicensed practice or activity	Complaint	10/02/2023
2024-000197	Violation of licensing regulation	Complaint	03/15/2024
2022-000746	Violation of licensing regulation	Investigation	06/02/2023
2023-000147	Violation of licensing regulation	Investigation	01/19/2024
2023-000283	Violation of licensing regulation	Investigation	08/07/2023
2023-000349	Action in another state	Investigation	03/26/2024
2023-000430	Unlicensed practice or activity	Investigation	07/24/2023

2023-000684	Violation of licensing regulation	Investigation	02/05/2024
2023-001084	Violation of licensing regulation	Investigation	02/05/2024
2023-001124	Violation of licensing regulation	Investigation	01/25/2024

PHARMACIST

2024-000283	Violation of licensing regulation	Intake	03/27/2024
2024-000307	Violation of licensing regulation	Intake	04/03/2024
2024-000324	Violation of licensing regulation	Intake	04/08/2024
2023-000957	PDMP Violation	Complaint	09/14/2023
2023-000958	PDMP Violation	Complaint	09/14/2023
2024-000090	Violation of licensing regulation	Complaint	03/06/2024
2024-000122	Violation of licensing regulation	Complaint	02/01/2024
2024-000160	PDMP Violation: Failure to Register	Complaint	02/23/2024
2024-000196	Violation of licensing regulation	Complaint	03/19/2024
2024-000208	Violation of licensing regulation	Complaint	03/13/2024
2024-000214	Violation of licensing regulation	Complaint	03/13/2024
2024-000222	Violation of licensing regulation	Complaint	03/19/2024

PHARMACY

2024-000242	Violation of licensing regulation	Intake	03/18/2024
2023-001044	Violation of licensing regulation	Complaint	10/11/2023
2023-001085	Violation of licensing regulation	Complaint	11/06/2023
2024-000037	Violation of licensing regulation	Complaint	02/05/2024
2024-000062	Violation of licensing regulation	Complaint	02/05/2024
2024-000064	Violation of licensing regulation	Complaint	02/05/2024
2024-000115	Violation of licensing regulation	Complaint	03/12/2024
2024-000300	PDMP Violation: Failure to Register	Complaint	04/03/2024
2022-000634	Violation of licensing regulation	Investigation	10/20/2022
2023-000910	Violation of licensing regulation	Investigation	10/25/2023

PHARMACY TECHNICIAN

2023-001122	Violation of licensing regulation	Complaint	11/16/2023

2024-000006	Violation of licensing regulation	Complaint	01/05/2024
2024-000101	Unprofessional conduct	Complaint	01/29/2024
2024-000189	Violation of licensing regulation	Complaint	03/11/2024
2024-000268	Violation of licensing regulation	Complaint	03/27/2024
2023-000543	License Application Problem	Investigation	12/08/2023
2023-000885	Continuing education	Investigation	10/19/2023

WHOLESALE DRUG DISTRIBUTOR

2023-000763	Violation of licensing regulation	Complaint	08/15/2023
2023-001064	Violation of licensing regulation	Complaint	11/01/2023
2024-000031	Violation of licensing regulation	Complaint	01/10/2024
2023-000345	Violation of licensing regulation	Investigation	07/25/2023
2023-000683	Violation of licensing regulation	Investigation	12/28/2023
2023-000733	Violation of licensing regulation	Investigation	12/21/2023
2023-000764	Violation of licensing regulation	Investigation	01/17/2024
2023-000765	Violation of licensing regulation	Investigation	01/17/2024
2023-001010	Unlicensed practice or activity	Investigation	02/26/2024

Closed - 33

Case #	Violation Type	Case Status	Closed	Closure
OUT OF STATE PHARMACY				
2023-000289	Contested license denial	Closed-Intake	03/21/2024	Other (See Abstract)
2022-000434	Violation of licensing regulation	Closed-Investigation	03/04/2024	License Action
2023-000365	Violation of licensing regulation	Closed-Investigation	03/04/2024	License Action
2023-000680	Violation of licensing regulation	Closed-Investigation	02/20/2024	No Action - No Violation
2023-000824	Violation of licensing regulation	Closed-Investigation	03/04/2024	License Action
2023-000919	Violation of licensing regulation	Closed-Investigation	02/14/2024	Advisement Letter
2023-000972	Violation of licensing regulation	Closed-Investigation	03/04/2024	License Action

PHARMACIST

2023-001176	Violation of licensing regulation	Closed-Intake	02/14/2024	Incomplete Complaint
2023-000766	Criminal action - conviction	Closed-Investigation	04/01/2024	Advisement Letter
2023-001157	Violation of licensing regulation	Closed-Investigation	03/01/2024	Advisement Letter
2023-001177	Violation of licensing regulation	Closed-Investigation	02/23/2024	Advisement Letter

PHARMACY

2024-000136	Violation of licensing regulation	Closed-Intake	03/01/2024	No Action - Unfounded
2024-000206	Violation of licensing regulation	Closed-Intake	04/04/2024	Incomplete Complaint
2024-000210	Compliance Inspection	Closed-Intake	03/06/2024	Compliance
2024-000211	Compliance Inspection	Closed-Intake	03/22/2024	Compliance
2024-000258	Compliance Inspection	Closed-Intake	03/22/2024	Compliance
2024-000259	Compliance Inspection	Closed-Intake	03/22/2024	Compliance
2024-000261	Compliance Inspection	Closed-Intake	03/22/2024	Compliance
2023-001116	Probation violation	Closed-Complaint	02/23/2024	No Action - No Violation
2022-001188	License Application Problem	Closed-Investigation	02/23/2024	No Action - No Violation
2023-000746	Compliance Inspection	Closed-Investigation	03/04/2024	License Action
2023-000942	Violation of licensing regulation	Closed-Investigation	03/04/2024	License Action

PHARMACY TECHNICIAN

2024-000009	Violation of licensing regulation	Closed-Intake	02/20/2024	Incomplete Complaint
2023-001178	Violation of licensing regulation	Closed-Investigation	03/04/2024	Review Complete

WHOLESALE DRUG DISTRIBUTOR

2024-000035	Violation of licensing regulation	Closed-Complaint	04/01/2024	No Action - No Violation
2023-000194	Violation of licensing regulation	Closed-Investigation	03/04/2024	License Action
2023-000753	Violation of licensing regulation	Closed-Investigation	03/04/2024	License Action
2023-000823	Violation of licensing regulation	Closed-Investigation	04/03/2024	Advisement Letter

2023-000911	Violation of licensing regulation	Closed-Investigation	03/04/2024	License Action
2023-001009	Violation of licensing regulation	Closed-Investigation	03/04/2024	License Action
2023-001011	Violation of licensing regulation	Closed-Investigation	03/04/2024	License Action
2023-001012	Violation of licensing regulation	Closed-Investigation	03/04/2024	License Action
2023-001165	Violation of licensing regulation	Closed-Investigation	02/14/2024	Advisement Letter

END OF REPORT

Investigative Process Overview

PRESENTED BY THE INVESTIGATIONS SECTION

DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING

Who Are We?

State of Alaska

↓

Department of Commerce, Community, and Economic Development

↓

Division of Corporations, Business and Professional Licensing

↓

Investigations

What Do We Do?

The mission of the Division of Corporations, Business and Professional Licensing is to ensure that **competent**, **professional** and **regulated** commercial services are available to Alaska consumers.

Three License Types

01

Professional License: Individual specialty such as a Nurse, Doctor, Dentist, Massage Therapist, etc…

02

Business License: (AS 43.70.020) If providing any service for the exchange of money, a business license is required in the state of Alaska.

03

Corporate Entity (Corporation): A group of persons who are deemed in law to be a single legal ***entity.*** The ***corporate entity*** is legally distinct from its members; it has legal personality and can hold property, sue and be sued in its own name as if it were a natural person.

Who Needs a Professional License Through the State of Alaska?

- Acupuncturists
- Architects, Engineers, and Land Surveyors
- Athletic Trainers
- Audiologists & Speech-Language Pathologists
- Barbers & Hairdressers
- Behavior Analysts
- Big Game Commercial Services Board
- Chiropractic Examiners
- Collection Agencies
- Concert Promoters
- Construction Contractors
- Dental Examiners
- Dietitians & Nutritionists
- Dispensing Opticians
- Electrical Administrators
- Euthanize Domestic Animals
- Geologists
- Guardians & Conservators
- Hearing Aid Dealers
- Home Inspectors
- Marine Pilots
- Marital & Family Therapy
- Massage Therapists
- Mechanical Administrators
- Medical Board
- Midwives
- Morticians
- Naturopathy
- Nursing
- Nurse Aide Registry
- Nursing Home Administrators
- Optometry
- Pawnbrokers
- Pharmacy
- Physical Therapy & Occupational Therapy
- Prescription Drug Monitoring Program
- Professional Counselors
- Psychologist and Psychological Associate
- Public Accountancy
- Real Estate Appraisers
- Real Estate Commission
- Social Work Examiners
- Telemedicine Business Registry
- Underground Storage Tank Worker
- Veterinary Examiners

What Do We Investigate?

Statutes & Regulations

- **AS = Alaska Statutes:** Are passed by either the US Congress or State Legislatures: The legislatures create bills that, when passed by a vote, become statutory law.
- **AAC = Alaska Administrative Code // Regulation**: Regulations, on the other hand, are standards and rules adopted by administrative agencies (Boards) that govern how laws will be enforced.

Difference between Statutes and Regulations:

Although many people use the terms "statute" and "regulation" interchangeably, they aren't the same. Governing bodies, such as the United States Congress or a state legislature, enact statutes. On a local level, the statutes enacted by municipalities are known as ordinances. Regulations put those statutes to work, fleshing out the details.

Different Roles

EXAMPLE:

- AK Legislature creates Statutes.
- Boards create Regulations.
- Investigations investigate ***alleged violations*** of Statutes and/or Regulations.
- Board Members **verify whether or not a violation occurred** when reviewing a case from investigations.

Investigators gather information. Licensed board members determine if a violation of statute or regulation has occurred.

How Does Someone File a Complaint?

Public Website

https://www.commerce.alaska.gov/web/cbpl/Investigations.aspx

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

ADM
FOR DIVISION USE ONLY

Investigations Section
550 West 7th Avenue, Suite 1500, Anchorage, AK 99501
Phone: (907) 269-8174 · Fax: (907) 269-8195
Website: *CBPLinvestigations.Alaska.Gov*
Email: *Investigations@Alaska.Gov*

Investigations — Request for Contact

The division investigates matters pertaining to business licenses, the sale of tobacco products, and licensed professionals. Not all issues will fall within our jurisdiction. You may have to contact other agencies for assistance. We encourage you to call to ensure that we are able to assist you.

This is only a request for contact. You may submit this form via US Mail, fax, or email, to the contact information listed above. Once the division has reviewed this information you will be contacted and may be asked to fill out a complaint package.

PART I Your Contact Information

Complete Name:	First Name:	Middle Name:	Last Name:		
Mailing Address:	Address:	City:	State:	Zip Code:	
Contact Phone:	(☐☐☐) ☐☐☐ – ☐☐☐☐				
Email Address:					

PART II Description of Incident

Type of Business or Profession Involved:	
Name(s) of Person or Business Involved:	
Date(s) Which Incident Occurred:	
Brief Description of Incident:	

08-4604 Rev 05/24/18 Investigations — Request for Contact

Contact Us Directly

Contact Us

State of Alaska/DCCED
Division of Corporations, Business and Professional Licensing
Investigations Section
550 West 7th Avenue, Suite 1500
Anchorage, AK 99501-3567
Phone: (907) 269-8124
Fax: (907) 269-8195

Email: Investigations@Alaska.gov

Next Step: Is the Complaint Jurisdictional?

- Review informal guidelines established by the Board or Commission, and the statutes and regulations of that specific practice area.
- If the complaint does not appear to allege a violation that is within the Board's jurisdiction, the Division may close the complaint.

Next Step: Is the Complaint Jurisdictional?

Complaints that are typically not jurisdictional are:

- Criminal complaints (Law Enforcement)
- Money or civil matters (Alaska Court System)
- "Bedside Manner"
- Quality of work complaints (Contractors)
- Unfair or deceptive business practices (Alaska Consumer Protection)
- Landlord Tenant Laws

The Complaint is Jurisdictional. What Happens Next?

The complainant is asked to complete a complaint packet.

The packet provides the complainant to:

- Provide a summary of the incident
- Include supporting documentation
- Sign a release of information
- Sign an Affidavit

The Division does not generally accept anonymous complaints, except in unusual instances.

We require consumers to be accountable for their allegations; thereby avoiding manipulation of our process by unscrupulous parties seeking to eliminate competition or pursue personal or professional vendettas.

Complaint Packet

STATE OF ALASKA
DEPARTMENT OF
COMMERCE
COMMUNITY AND
ECONOMIC DEVELOPMENT

Division of Corporations, Business and Professional Licensing – Investigations
550 West 7th Avenue, Suite 1500, Anchorage, AK 99501-3567
Telephone: (907) 269-8437 Fax: (907) 269-8195 Website: www.commerce.state.ak.us/oce

COMPLAINT FILED BY:

NAME (Last, First Middle Initial)

ADDRESS

CITY STATE ZIP

WORK PHONE HOME PHONE

COMPLAINT FILED AGAINST:

NAME and TITLE

ADDRESS

CITY STATE ZIP

WORK PHONE HOME PHONE

SUMMARY OF COMPLAINT

Please describe your complaint in detail. If necessary, please use an additional sheet of paper. Please provide any additional supporting documents.

AFFIDAVIT

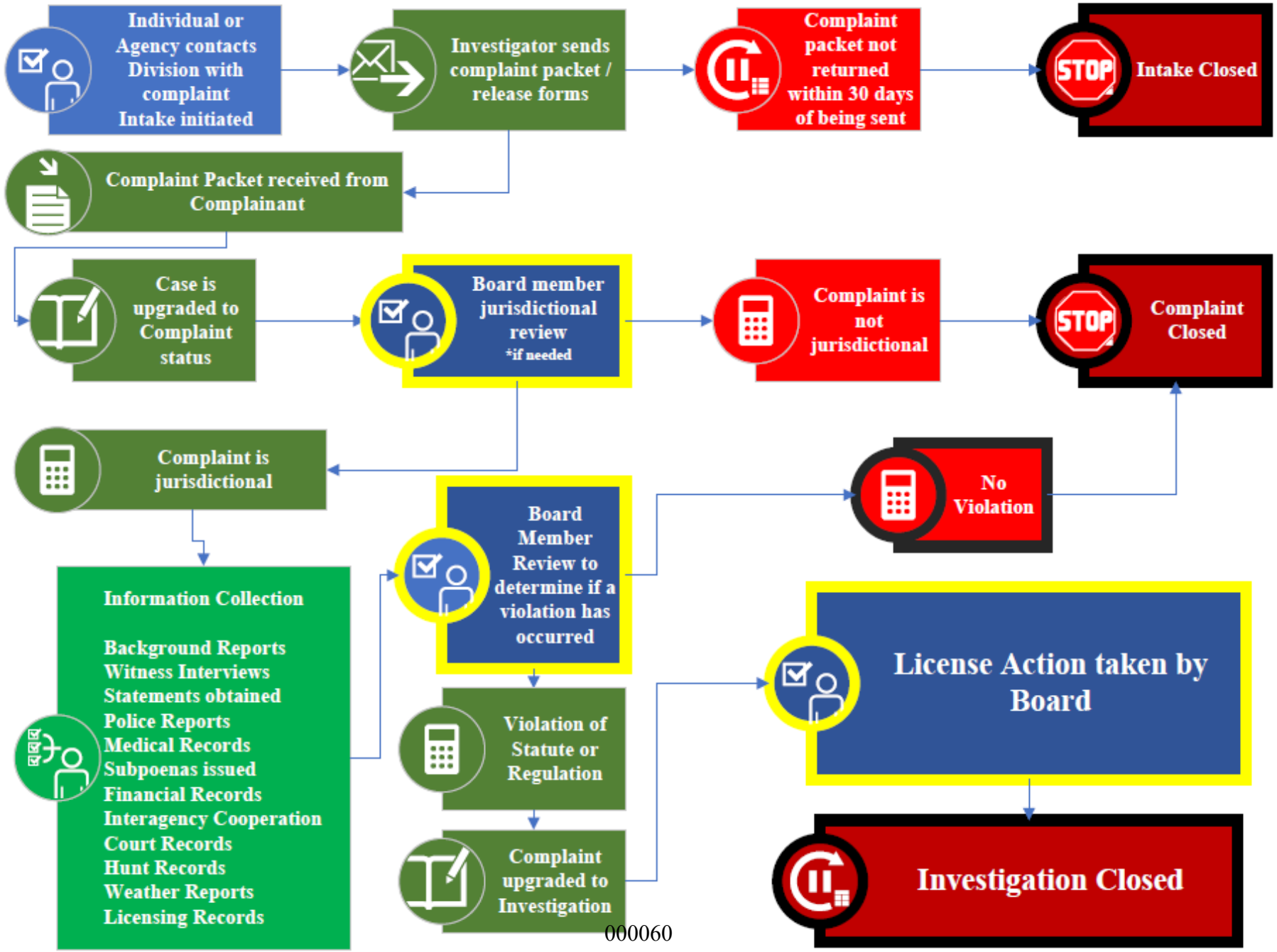
State of _____ City/Borough of _____

I, _____ hereby state under penalty of unsworn falsification: That I am the complainant in the named above and to the best of my knowledge and belief, this statement is true and correct.

Signature of Complainant: _____ Date: _____

AS 11.56.210(a)(2) of the Alaska Statutes makes it a class A misdemeanor of offense for a person to intentionally issue a false written or recorded statement, which is punishable by imprisonment for not more than one (1) year, a $5,000 fine, or both.

INVESTIGATIVE PROCESS



Three Stages of "Investigation"

INTAKE:
Preliminary information stage

- Typically generated upon receipt of a Request for Contact form or a Referral Email.

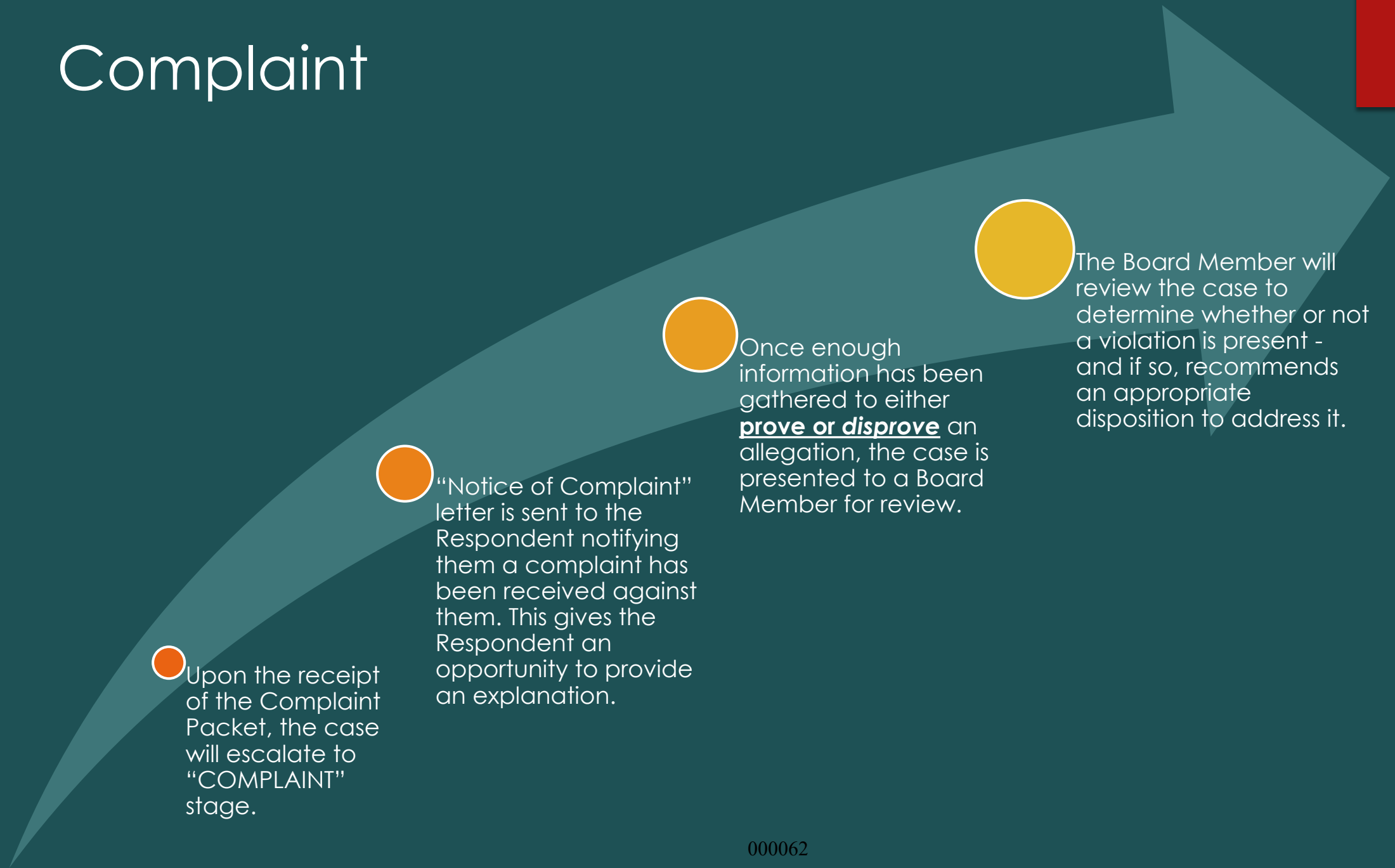
COMPLAINT:
Fact-gathering stage

- Escalates when a Complaint Packet is received.

INVESTIGATION:
Violation verified stage

- Following a Board Member review, case escalates when a Board Member confirms a violation is present.

Complaint



Upon the receipt of the Complaint Packet, the case will escalate to "COMPLAINT" stage.

"Notice of Complaint" letter is sent to the Respondent notifying them a complaint has been received against them. This gives the Respondent an opportunity to provide an explanation.

Once enough information has been gathered to either **prove or *disprove*** an allegation, the case is presented to a Board Member for review.

The Board Member will review the case to determine whether or not a violation is present - and if so, recommends an appropriate disposition to address it.

Investigation

Violation is verified, case escalates to "INVESTIGATION"

"Notice of Investigation" letter is sent to the Respondent explaining WHY his/her actions were violation(s).

Board Member's Recommendation:

1. Non-disciplinary Letter of Advisement

(Closes Case)

2. License Action

(Consent Agreement, Fine, Suspension, etc..)

License Action:

Offered to Respondent

1. If agrees, License Action is presented to Board for adoption: If adopted, closes case.

2. If disagrees & refuses, Division moves forward with the LITIGATION PROCESS & files an Accusation.

Administrative Hearing:

Division prepares the case for Administrative Hearing and the case is presented to an Administrative Law Judge (ALJ).

ALJ Decision is presented to the Board for final consideration.

Investigation

After a licensed Board Member Reviewer determines a violation of statute or regulation is present:

- Case escalates to "INVESTIGATION"
- A Notice of Investigation (NOI) is sent to the Respondent, notifying them a violation was verified.
- RBM recommends the appropriate action (Disciplinary or Non-Disciplinary) to address the violation:

Disciplinary Action:

- Consent Agreement
  - Probation
  - Civil Fine
  - Continuing Education
- Imposition of Civil Fine
- Suspension
- Revocation
- Etc..

Non-Disciplinary Action:

Non-Disciplinary Letter of Advisement

Three Investigation Case Types

- **Application Matters:** Inquires initiated by Licensing to review applications for truthfulness & accuracy.
- **Consumer Complaints**: Inquiries initiated upon the receipt of a Complaint Packet (or written complaint).
- **Inspections:** Onsite inspections to ensure operations are in accordance to AS 43.70 & 12 AAC 12

Confidentiality

- Investigations are required by statute to be kept confidential.
- This often prevents the complainant, licensee, and the Board from obtaining progress reports or information that may disclose the current status of an open investigation.
- This also protects the reputation of licensees who may be accused of wrongdoing but the allegations against them are unproven.
- Cases often involve other agencies, businesses, and practices; disclosing information during an on-going case can compromise the investigation, create conflicts for reviewing Board members, or result in unnecessary hardship to the licensee.

Questions / Discussion

INVESTIGATIVE OVERVIEW

Reviewing Board Member Process Updates
March 2024

The Division of Corporations, Business and Professional Licensing is updating certain forms and processes used to assist reviewing board members (RBMs) in understanding and navigating their important case review responsibilities. This memo provides a rationale for and overview of these changes, as well as the outcomes desired from these updates.

RATIONALE

Reviewing board members play a crucial role in ensuring best outcomes of matters under investigation. RBMs provide expertise and insight that only a similarly licensed provider could offer. Although division investigators are professionally trained and certified, they are not licensees and do not have the understanding and context to evaluate complex or sophisticated practice situations that comes with licensed practice.

RBMs also serve as proxies for full board review. It would be impossible for the entire board to perform a full review of every case—no board has the amount of time or resources to fully examine every case file. So, the RBM steps into deeply analyze the details and offer a thoughtful recommendation for the board to consider.

The Department of Law has recently offered guidance on multiple situations relating to RBM review and participation in deliberation. A few takeaways regarding RBM responsibilities have urged the department to assist the division in developing additional resources:

RBMs have the responsibility to:

1. Ensure they do not have conflicts of interest with any elements of the case.
2. Ensure they do not share case information with other persons without express authorization by the investigator, including other board members.
3. Review precedent for similar cases and consider any mitigating or aggravating circumstances.
4. Provide a full written review to assist the board in their deliberation, including explanation of any noteworthy relevant facts, especially if the reviewer recommends a departure from precedent in similar matters.
5. Ensure their written review and recommendation are free of bias and are based on the relevant facts, statutes, and regulations.
6. Request recusal from deliberation and voting on any case they reviewed.

Following these guidelines will help achieve best outcomes for the case:

1. They help preserve due process of the respondent. This is an important provision of state law and is a fundamental value of American society.
2. They help assure appropriate decisionmaking standards are being followed.
3. They help ensure the correct administrative processes have been followed: Failure to follow the Administrative Procedure Act can open opportunities to overturn the board's decision upon appeal.
4. They help support the Department of Law's ability to defend the board's decision.
5. They help defend public safety: Delaying or overturning a board's disciplinary decision can place an unsafe or unfit licensee back into public practice.
6. They protect board members from individual legal or financial liability.

OVERVIEW

The changes being made to the board member review process are not dramatic; however, they will provide additional education and understanding to members, help boards more fully understand the basis for the reviewing

board member's recommendation, and assist the investigator in assessing any risk associated with board member review of the matter.

1. The new *RBM Case Review Agreement* spells out the mutually agreed-upon standards for board member evaluation of a matter. It will help set expectations up front and prompt any questions an RBM may have prior to investing time and energy into case review.
2. The *Board Member Review Form* is being updated to clarify certain terms and offer a space for the RBM to thoroughly explain their recommendation and rationale. The goal of this update is to provide boards more information to aid in their decisionmaking without placing the process or final outcome at risk.
3. A new *RBM Risk Assessment Worksheet* has been created to assist investigators in identifying the level of legal or process risk associated with a particular board case. This internal tool is for informational and educational use so investigators can best identify next steps in obtaining guidance for a board when preparing to enter the deliberative process.

DESIRED OUTCOMES

- Reviewing board members will feel more empowered in understanding the expectations and parameters of case review.
- RBMs will provide a written analysis of their recommendations and the reasons why they support that pathway.
- Board members will receive the RBM's written analysis within the investigative memo.
- Board members will feel confident in the additional information provided by the RBM, aiding in decisionmaking and resulting in consistent adherence to the decisionmaking processes advised by department staff and board attorneys.

Board members are urged to provide feedback on these improvements so they can continually be refined and remain useful and relevant tools to support members in fulfilling their boards' missions.

Alaska Board of Pharmacy

Agenda Item #5

Public Comment Period

Alaska Board of Pharmacy

Agenda Item #6

Statutes and Regulations

From: Bruce Marden Jr
To: Regulations and Public Comment (CED sponsored)
Subject: Re: [CBPLRegulations2] Notice of Proposed Regulations (Alaska Board of Pharmacy 12 AAC 52.050 - 52.995)
Date: Monday, March 11, 2024 1:13:02 PM

Shut down the board save money and you won't have any change to the opioid epidemic. It will still be there you are not changing anything the only thing your changing is the fact that people can't buy pills but can still manufacture the same opioid...

Yahoo Mail: Search, Organize, Conquer

On Mon, Mar 11, 2024 at 8:08 AM, Regulations and Public Comment (CED sponsored) <regulationsandpubliccomment@alaska.gov> wrote:

> Dear Licensee,
>
> The Alaska Board of Pharmacy proposes to update various regulations relating to pharmacy closures and examination requirements.
>
> 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 Frequently Asked Questions for this project. This link is also provided on the Board Pharmacy webpage, and as an attachment on the Online Public Notice system.
>
> Thank you,
>
> Board of Pharmacy
>
> _____
> List Name: CBPLRegulations2@list.state.ak.us
> You subscribed as: brucemardenjr@yahoo.com
> Unsubscribe at:
> https://list.state.ak.us/mailman/options/cbplregulations2/brucemardenjr%40yahoo.com

From:	Tasha Waters
To:	Regulations and Public Comment (CED sponsored)
Subject:	Re: [CBPLRegulations2] Notice of Proposed Regulations (Alaska Board of Pharmacy 12 AAC 52.050 - 52.995)
Date:	Wednesday, March 13, 2024 1:50:31 PM

Thank you.

On Monday, March 11, 2024 at 08:07:57 AM AKDT, Regulations and Public Comment (CED sponsored) <regulationsandpubliccomment@alaska.gov> wrote:

Dear Licensee,

The Alaska Board of Pharmacy proposes to update various regulations relating to pharmacy closures and examination requirements.

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 Frequently Asked Questions for this project. This link is also provided on the Board Pharmacy webpage, and as an attachment on the Online Public Notice system.

Thank you,

Board of Pharmacy

From:	Walmsley, Lorri
To:	Regulations and Public Comment (CED sponsored)
Cc:	Bowles, Michael P (CED); Kroeger, Victoria
Subject:	Walgreens Comments
Date:	Friday, March 29, 2024 9:39:49 AM
Attachments:	image001.png AK Comments March 2024.pdf

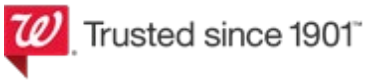
Hi Michael,

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



Lorri Walmsley, RPh., FAzPA
Director, Pharmacy Affairs
Walgreen Co.
5330 E. Washington St, Ste. 105
Phoenix, AZ 85034
p: 602-214-6618
lorri.walmsley@walgreens.com

March 13th, 2024

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

Via Email:

RE: Notice of Proposed Regulations 12 AAC 52.050 and 12 AAC 52.060

Dear Director Bowles and Board Members,

On behalf of all pharmacies owned and operated by Walgreen Co., licensed in the state of Alaska, I thank the Board for the opportunity to comment on the proposed rules regarding the transfer of prescriptions.

Walgreens is supportive of the board's intent to ensure continuous care for patients in Alaska in the event of a pharmacy closure. Walgreens requests the board to consider clarifying the language in 12 AAC 52.050 and 060. Does the board intend to require a pharmacy to notify the board when a closure occurs because of a staffing issue that lasted only a few hours? When a pharmacy closes due to an extreme but self-limiting weather event, such as a snowstorm? Walgreens asks the board to clearly define what temporary closures this rule is intended for to avoid unnecessary notifications to the board and clarity for the pharmacists in charge and suggest the potential amendment below to 12 AAC 52.060.

Additionally, Walgreens would like to ensure the board is aware of the current limitations of providing electronic transfers for electronic prescriptions for controlled substances (EPSCs). While the recently published final rules from the Drug Enforcement Agency (DEA) technically do allow these transfers, the technology needed to support these transfers and ensure that the prescription remains in an unaltered electronic form is not available until further action is taken by the Centers for Medicare and Medicaid Services (CMS). Action by CMS is needed to allow the corresponding updates to be made to the National Council for Prescription Drug Programs (NCPDP) standards which allows for the transfer transaction to include the digital signature between pharmacies. Until the new version of the NCPDP SCRIPT Standards is named by CMS, it is not possible for pharmacies to comply with this requirement for CII transfers and other unfilled controlled substance prescription in accordance with federal law. It is imperative that the board delays enforcement action of these proposed rules until the National Council of Prescription Drug Programs (NCPDP) and CMS act and complete the update of their standards allowing the technology industry to make this type of electronic prescription transfer a reality.

12 AAC 52.050(a)(2)

(2) arrange for [THE TRANSFER OF PRESCRIPTION DRUG ORDERS OR COMPUTER PRESCRIPTION RECORDS TO ANOTHER PHARMACY TO FACILITATE] continuous patient care, including the transfer of prescription drug orders or computer prescription records to another pharmacy; and

12 AAC 52.060(d)
In this section, "other disaster" includes a [ANY] disaster situation that causes a pharmacy to [THE] need to move to a temporary location, temporarily close for greater than 1 business day excluding holidays and weekends, or results in damage to the pharmacy's drug or device inventory

Walgreens thanks the Board for the opportunity to comment on these proposed regulations. If the Board would like additional information, please feel free to contact me.

Sincerely,

Lorri Walmsley

Lorri Walmsley, RPh, FAzPA

From: Bohrer, Mark
To: Regulations and Public Comment (CED sponsored)
Subject: Support of Proposed Changes
Date: Sunday, April 7, 2024 5:42:07 PM
Attachments: image001.png

Hello,

I am in support of all changes in the current regulations package as snipped below:

1. **12 AAC 52.050. Closed pharmacies,** is proposed to be amended to clarify that a closed pharmacy must arrange for continuous patient care.
2. **12 AAC 52.060. Fire or other disaster,** is proposed to be amended to clarify that an applicable disaster includes one that causes pharmacy to need to temporarily close.
3. **12 AAC 52.070. Application for pharmacist license by examination; 12 AAC 52.310. Reinstatement of an expired pharmacist or pharmacy technician license; 12 AAC 52.985. Emergency preparedness,** are proposed to be updated to correct regulation references and language based on the proposed removal of the multistate pharmacy jurisprudence examination requirement.
4. **12 AAC 52.090. Examination requirements and registration; 12 AAC 52.092. Eligibility to sit for examination; 12 AAC 52.095. Application for pharmacist license by reciprocity,** is proposed to be amended to remove and replace the multistate pharmacy jurisprudence examination requirement implemented as the Alaska Pharmacy Jurisprudence Examination as referenced.
5. **12 AAC 52.098. Alaska pharmacy jurisprudence examination,** is proposed to be added as a new section, setting out the prerequisites for being provided the Alaska pharmacy jurisprudence examination.
6. **12 AAC 52.150. Proof of licensure for individual pharmacists working for tribal health programs,** is proposed to be repealed to remove the requirement for a pharmacist practicing in the federal Indian Health Services system to submit an exemption for Alaska licensure.

Under #4 and #5- I would concur with the FAQ document that shared by the BOP. From a work perspective, I have had candidates that would fail this exam.
I do believe the BOP is correct in their assessment as to the why. I do strongly support these changes to the removal of the MPJE and replacing with the Alaska pharmacy Jurisprudence examination

Mark Bohrer
District 9 Pharmacy Practice Coordinator
(907)267-6786
mark.bohrer@fredmeyer.com

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 closure of a pharmacy and examination requirements for licensure was passed by the Board of Pharmacy during its April 11, 2024 meeting.

I certify under penalty of perjury that the foregoing is true.

Date: _____

_____
Michael Bowles, Executive Administrator

State of Alaska
Anchorage, Municipality of Anchorage

ORDER CERTIFYING THE CHANGES TO
REGULATIONS OF THE BOARD OF PHARMACY

The attached eight pages of regulations, dealing with closure of a pharmacy and examination requirements for licensure, are certified to be a correct copy of the regulation changes that the Board of Pharmacy adopted at its April 11, 2024 meeting, under the authority of AS 08.01.065, AS 08.01.100, AS 08.80.005, AS 08.80.030, AS 08.80.110, AS 08.80.116, AS 08.80.120, AS 08.80.145, AS 08.80.147, AS 08.80.150, AS 08.80.157, AS 08.80.160, AS 08.80.165, AS 08.80.270, and AS 08.80.330, 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: _____

_____
Michael Bowles, Executive Administrator
Alaska Board of Pharmacy

FILING CERTIFICATION

I, Nancy Dahlstrom, Lieutenant Governor for the State of Alaska, certify that on _____, 2024 at _____.m., I filed the attached regulations according to the provisions of AS 44.62.040 - 44.62.120.

_____
Nancy Dahlstrom, Lieutenant Governor

Effective: _____.

Register: _____.

NOTICE OF PROPOSED CHANGES ON TEMPORARY CLOSURES AND EXAMINATIONS IN THE REGULATIONS OF THE ALASKA BOARD OF PHARMACY

BRIEF DESCRIPTION: The Board of Pharmacy (Board) proposes to adopt regulation changes relating to pharmacy closures and examination requirements.

The Board of Pharmacy proposes to adopt regulation changes in Title 12, Chapter 52 of the Alaska Administrative Code, dealing with closure of a pharmacy and examination requirements for licensure, including the following:

1. **12 AAC 52.050. Closed pharmacies,** is proposed to be amended to clarify that a closed pharmacy must arrange for continuous patient care.

2. **12 AAC 52.060. Fire or other disaster,** is proposed to be amended to clarify that an applicable disaster includes one that causes pharmacy to need to temporarily close.

3. **12 AAC 52.070. Application for pharmacist license by examination; 12 AAC 52.310. Reinstatement of an expired pharmacist or pharmacy technician license; 12 AAC 52.985. Emergency preparedness,** are proposed to be updated to correct regulation references and language based on the proposed removal of the multistate pharmacy jurisprudence examination requirement.

4. **12 AAC 52.090. Examination requirements and registration; 12 AAC 52.092. Eligibility to sit for examination; 12 AAC 52.095. Application for pharmacist license by reciprocity,** is proposed to be amended to remove and replace the multistate pharmacy jurisprudence examination requirement implemented as the Alaska Pharmacy Jurisprudence Examination as referenced.

5. **12 AAC 52.098. Alaska pharmacy jurisprudence examination,** is proposed to be added as a new section, setting out the prerequisites for being provided the Alaska pharmacy jurisprudence examination.

6. **12 AAC 52.150. Proof of licensure for individual pharmacists working for tribal health programs,** is proposed to be repealed to remove the requirement for a pharmacist practicing in the federal Indian Health Services system to submit an exemption for Alaska licensure.

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 RegulationsAndPublicComment@alaska.gov. Comments may also be submitted through the Alaska Online Public Notice System by accessing this notice on the system at http://notice.alaska.gov/214524, and using the comment link. **The comments must be received not later than 4:30 p.m. on April 10, 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 https://www.commerce.alaska.gov/web/cbpl/ProfessionalLicensing/BoardofPharmacy.aspx.

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 RegulationsAndPublicComment@alaska.gov not later than April 3, 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, RegulationsAndPublicComment@alaska.gov, or at https://www.commerce.alaska.gov/web/portals/5/pub/PHA-1223.pdf.

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 08.01.065; AS 08.01.100; AS 08.80.005; AS 08.80.030; AS 08.80.110; AS 08.80.116; AS 08.80.120; AS 08.80.145; AS 08.80.147; AS 08.80.150; AS 08.80.157; AS 08.80.160; AS 08.80.165; AS 08.80.270; AS 08.80.330

Statutes Being Implemented, Interpreted, or Made Specific: AS 08.80.005; AS 08.80.030; AS 08.80.120; AS 08.80.145

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: 3/11/2024

/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:** Add regulations relating to pharmacy closures; update the jurisprudence examination requirements, remove requirement for pharmacist practicing in the federal IHS system to submit an exemption for Alaska licensure.

3. **Citation of regulation:** 12 AAC 52.050 through 12 AAC 52.995

4. **Department of Law file number:** 2023200594

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 origin of the proposed action:** Staff of state agency.

11. **Date:** 3/11/2024 **Prepared by:** /s/
    Stefanie Davis
    Regulations Specialist

Chapter 52. Board of Pharmacy.

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

12 AAC 52.050(a)(2) is amended to read:

(2) arrange for [THE TRANSFER OF PRESCRIPTION DRUG ORDERS OR COMPUTER PRESCRIPTION RECORDS TO ANOTHER PHARMACY TO FACILITATE] continuous patient care**, including the transfer of prescription drug orders or computer prescription records to another pharmacy**; and

12 AAC 52.060(d) is amended to read:

(d) In this section, "other disaster" includes **a** [ANY] disaster situation that causes a pharmacy **to** [THE] need to move to a temporary location**, temporarily close,** or results in damage to the **pharmacy's** drug or device inventory.

(Eff. 1/16/98, Register 145; am 4/3/2020, Register 234; am 8/30/2020, Register 235; am 12/28/2022, Register 244; am ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.330
AS 08.80.030

The introductory language of 12 AAC 52.070(b) is amended to read:

(b) An applicant for licensure under this section **shall** [MUST] submit to the department

. . .

12 AAC 52.070(b)(5) is amended to read:

(5) verification **that the applicant has passed the examination required under**

12 AAC 52.090, sent directly to the department by the National Association of Boards of Pharmacy [, THAT THE APPLICANT HAS PASSED THE EXAMINATIONS REQUIRED IN 12 AAC 52.090];

(Eff. 1/16/98, Register 145; am 2/15/2006, Register 177; am 7/1/2007, Register 182; am 10/31/2019, Register 232; am 12/28/2022, Register 244; am 1/19/2024, Register 249; am ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.110 AS 08.80.270
AS 08.80.030 AS 08.80.116

12 AAC 52.090 is amended to read:

12 AAC 52.090. Examination requirements and registration. (a) **An** [IN ADDITION TO THE REQUIREMENTS IN AS 08.80.110, AN] applicant for a pharmacist license shall pass the

[(1)] North American Pharmacy licensing examination (NAPLEX)**,** administered by the National Association of Boards of Pharmacy**,** with a NAPLEX scaled score of 75 or **higher** [ABOVE; AND

(2) ALASKA PHARMACY JURISPRUDENCE EXAMINATION WITH A SCALED SCORE OF 75 OR ABOVE].

(b) Repealed ____/____/_____ [AN APPLICANT FOR A TEMPORARY PHARMACIST LICENSE SHALL PASS THE ALASKA PHARMACY JURISPRUDENCE EXAMINATION WITH A SCALED SCORE OF 75 OR ABOVE].

(c) An applicant for a pharmacist license **who** [THAT] has passed the NAPLEX examination in another licensing jurisdiction shall make arrangements for the National Association of Boards of Pharmacy to send verification of **the applicant's** examination **score**

[SCORES] directly to the department.

(d) An applicant for licensure by examination **shall** [MUST] submit an application under 12 AAC 52.070 and be **determined to be eligible** [APPROVED] under 12 AAC 52.092 before **the applicant may sit** [SITTING] for examination under this section.

(e) Repealed ____/____/_____ [AN APPLICANT WHO HAS FAILED THE ALASKA PHARMACY JURISPRUDENCE EXAMINATION SPECIFIED IN (f) OF THIS SECTION MAY NOT RETAKE THE EXAMINATION FOR AT LEAST 30 DAYS].

(f) Repealed ____/____/_____ [THE MULTISTATE PHARMACY JURISPRUDENCE EXAMINATION ADMINISTERED BY THE NATIONAL ASSOCIATION OF BOARDS OF PHARMACY (NABP) IS THE EXAMINATION ADOPTED BY THE BOARD AS THE ALASKA PHARMACY JURISPRUDENCE EXAMINATION. AN APPLICANT SHALL SATISFY ALL OTHER LICENSE REQUIREMENTS WITHIN ONE YEAR AFTER PASSING THE ALASKA PHARMACY JURISPRUDENCE EXAMINATION OR RETAKE THE EXAMINATION].

(g) An applicant applying for a **pharmacist** [PHARMACY] license by examination shall **submit an** [MAKE] application within one year of successfully passing the NAPLEX. **If it has been** [AN APPLICANT APPLYING] more than one year **since the applicant passed** [AFTER PASSING] the NAPLEX**, the applicant** shall

(1) retake the NAPLEX **in accordance with this section;** or

(2) apply for a **pharmacist** [PHARMACY] license under AS 08.80.145. (Eff. 1/16/98, Register 145; am 2/26/2000, Register 153; am 5/5/2000, Register 154; am 8/21/2002, Register 163; am 5/15/2004, Register 170; am 7/1/2007, Register 182; am 8/12/2007, Register 183; am ____/____/_____, Register _____)

Authority: AS 08.01.065 AS 08.80.110 AS 08.80.150

AS 08.80.005 AS 08.80.120 AS 08.80.160

AS 08.80.030

12 AAC 52.092 is amended to read:

12 AAC 52.092. Eligibility to sit for examination. An applicant for licensure by examination who has submitted documents that meet the requirements set out **under** [IN] 12 AAC 52.070 will be referred **by the board** to the National Association of Boards of Pharmacy [BY THE BOARD] to determine eligibility to sit for the North American Pharmacy Licensing Examination (NAPLEX) [AND THE MULTISTATE PHARMACY JURISPRUDENCE EXAMINATION (MPJE)] required under 12 AAC 52.090. (Eff. 7/1/2007, Register 182; am 12/28/2022, Register 244; am ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.110

12 AAC 52.095(b) is amended to read:

(b) An applicant for licensure under this section who has not taken the **Alaska pharmacy jurisprudence examination set out under 12 AAC 52.098 will receive the examination from the department once** [MULTISTATE PHARMACY JURISPRUDENCE EXAMINATION (MPJE) REQUIRED UNDER 12 AAC 52.090 IS APPROVED TO SIT FOR THAT EXAMINATION IF] the applicant has submitted the documents required under (a)(1) – (4) of this section. **The applicant is required to pass the examination to be eligible for licensure by reciprocity under this section.**

(Eff. 7/1/2007, Register 182; am 10/31/2019, Register 232; am 12/28/2022, Register 244; am 1/19/2024, Register 249; am ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.145

12 AAC 52 is amended by adding a new section to read:

12 AAC 52.098. Alaska pharmacy jurisprudence examination. The department will submit the Alaska pharmacy jurisprudence examination to an applicant for licensure by reciprocity who has submitted documents that meet the requirements set out under 12 AAC 52.095. The Alaska pharmacy jurisprudence examination is prepared by the board and covers the provisions of AS 08.80, AS 17.30.200, and 12 AAC 52, relating to the practice of pharmacy. (Eff. ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.110 AS 08.80.145
AS 08.80.030 AS 08.80.120

12 AAC 52.150 is repealed:

12 AAC 52.150. Proof of licensure for individual pharmacists working for tribal health programs. Repealed ____/____/_____ [(a) A PHARMACIST WHO ENGAGES IN THE PRACTICE OF PHARMACY IN A TRIBAL HEALTH PROGRAM IN THIS STATE AND WHO IS NOT LICENSED BY THE BOARD MUST PROVIDE THE BOARD NOTICE THAT THEY ARE PRACTICING UNDER ANOTHER LICENSE IN ACCORDANCE WITH 25 U.S.C. 1621t (SEC. 221, INDIAN HEALTH CARE IMPROVEMENT ACT). NOTICE REQUIRED UNDER THIS SECTION MUST BE RECEIVED NO LATER THAN 30 DAYS AFTER AN INDIVIDUAL BEGINS WORKING AT A TRIBAL HEALTH PROGRAM IN THIS STATE, AND MUST INCLUDE

(1) A COMPLETED ALASKA STATE PHARMACIST LICENSE EXEMPTION FORM PROVIDED BY THE DEPARTMENT;

(2) A CERTIFIED TRUE COPY OF A CURRENT, VALID PHARMACIST LICENSE IN GOOD STANDING FROM ANOTHER JURISDICTION; AND

(A) PROOF OF EMPLOYMENT BY A TRIBAL HEALTH PROGRAM THAT IS OPERATING UNDER AN AGREEMENT WITH THE FEDERAL INDIAN HEALTH SERVICE UNDER 25 U.S.C. 450 – 458ddd-2 (INDIAN SELF-DETERMINATION AND EDUCATION ASSISTANCE ACT); OR

(B) PROOF OF STATUS AS AN INDEPENDENT CONTRACTOR, INCLUDING A COPY OF THE CONTRACT, IF THE OUT-OF-STATE PHARMACIST IS WORKING FOR THE TRIBAL HEALTH PROGRAM AS AN INDEPENDENT CONTRACTOR.

(b) A PHARMACIST PRACTICING UNDER THE EXEMPTION MAY NOT PRACTICE BEYOND THE SCOPE OF THE OTHER STATE LICENSE.

(c) THE LICENSING EXEMPTION DOES NOT EXTEND TO SERVICES PROVIDED TO NON-TRIBAL HEALTH PROGRAMS. IN ADDITION, AN OUT-OF-STATE LICENSED PHARMACIST WORKING OUTSIDE THE SCOPE OF THE INDIVIDUAL'S CONTRACTED EMPLOYMENT WITH A TRIBAL HEALTH PROGRAM MUST APPLY FOR LICENSURE AS A PHARMACIST IN ACCORDANCE WITH AS 08.80]. (Eff. 10/31/2019, Register 232; repealed ____/____/_____, Register _____)

12 AAC 52.310(c)(5) is amended to read:

(5) qualifies by

(A) retaking and passing the **examination** [EXAMINATIONS] required under 12 AAC 52.090(a); or

(B) providing verification that the applicant has continually practiced

pharmacy in another state under a license issued by the authority of that state for the period that the license has been lapsed [, AND BY MEETING THE REQUIREMENTS OF 12 AAC 52.090(a)(2)]; for purposes of AS 08.80.147 and this subparagraph, an applicant has continually practiced pharmacy if the pharmacist has actively practiced pharmacy in the other state for at least six months during each year that the license in **the** [THIS] state was lapsed; and

(Eff. 1/16/98, Register 145; am 5/5/2000, Register 154; am 8/21/2002, Register 163; am 2/11/2004, Register 169; am 5/26/2006, Register 178; am 9/17/2011, Register 199; am 8/1/2014, Register 211; am 1/19/2024, Register 249; am ____/____/_____, Register _____)

Authority: AS 08.01.100 AS 08.80.030 AS 08.80.165
AS 08.80.005 AS 08.80.147

12 AAC 52.985(f)(2) is repealed:

(2) repealed ___/___/_____ [THE NOTICE REQUIRED UNDER 12 AAC 52.150(a) NEED NOT BE PROVIDED UNTIL 30 DAYS AFTER THE DATE THAT THE DISASTER EMERGENCY ENDS];

(Eff. 10/31/2019, Register 232; am 4/3/2020, Register 234; am 8/30/2020, Register 235; am ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.995(a) is amended by adding a new paragraph to read:

(42) "NAPLEX" means the North American Pharmacy Licensing Examination, administered by the National Association of Boards of Pharmacy.

(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 ____/____/_____, 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)(41) with a semicolon.)))

HOUSE BILL NO. 187

IN THE LEGISLATURE OF THE STATE OF ALASKA

THIRTY-THIRD LEGISLATURE - FIRST SESSION

BY REPRESENTATIVE SUMNER

Introduced: 5/3/23
Referred: Health and Social Services, Labor and Commerce

A BILL

FOR AN ACT ENTITLED

"An Act relating to utilization review entities; exempting certain health care providers from making preauthorization requests for certain services; and providing for an effective date."

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

*** Section 1.** AS 21.07.005(a) is amended to read:

(a) The director shall adopt regulations to provide standards and criteria for

(1) the structure and operation of utilization review and benefit determination processes**, including processes for utilization review entities under AS 21.07.100**;

(2) the establishment and maintenance of procedures by health care insurers to ensure that a covered individual has the opportunity for appropriate resolution of grievances; and

(3) an independent review of an adverse determination or final adverse determination.

*** Sec. 2.** AS 21.07 is amended by adding a new section to read:

Sec. 21.07.100. Utilization review entities. (a) A utilization review entity may not require a health care provider to complete a prior authorization for a health care service for a covered person to receive coverage for the health care service if, during the most recent 12-month period, the utilization review entity has approved or would have approved at least 80 percent of the prior authorization requests submitted by the health care provider for that health care service.

(b) A utilization review entity may evaluate whether a health care provider continues to qualify for an exemption under (a) of this section not more than once every 12 months. A utilization review entity is not required to evaluate an existing exemption, and nothing prevents a utilization review entity from establishing a longer exemption period.

(c) A health care provider is not required to request an exemption to qualify for an exemption.

(d) If a health care provider does not receive an exemption under (a) of this section, the health care provider may, once every 12 months of providing health care services, request the utilization review entity to provide evidence to support its determination. A health care provider may appeal a determination to deny a prior authorization exemption under (a) of this section. The utilization review entity shall provide to the health care provider an explanation of how to appeal the determination.

(e) A utilization review entity may revoke an exemption under (a) of this section after 12 months if the utilization review entity

(1) makes a determination that the health care provider would not have met the 80 percent approval criteria based on a retrospective review of the claims for the health care service for which the exemption applies for the previous three months or the period needed to reach a minimum of 10 claims for review;

(2) provides the health care provider with the information used by the utilization review entity to make the determination to revoke the exemption; and

(3) provides an explanation to the health care provider on how to appeal the determination.

(f) An exemption under (a) of this section remains in effect until the 30th day

after the date the utilization review entity notifies the health care provider of its determination to revoke the exemption or, if the health care provider appeals the determination, the fifth day after the revocation is upheld on appeal.

(g) A determination to revoke or deny an exemption by a utilization review entity must be made by a health care provider licensed in the state with the same or a similar specialty as the health care provider being considered for an exemption and must have experience in providing the health care service for which the requested exemption applies.

(h) A utilization review entity must provide a health care provider who receives an exemption under (a) of this section with a notice that includes a

(1) statement that the health care provider qualifies for an exemption from a prior authorization requirement and the duration of the exemption; and

(2) list of health care services for which the exemption applies.

(i) A utilization review entity may not deny or reduce payment for a health care service exempted from a prior authorization requirement under (a) of this section, including a health care service performed or supervised by another health care provider when the health care provider who ordered the service received a prior authorization exemption, unless the health care provider providing the health care service

(1) knowingly and materially misrepresented the health care service in a request for payment submitted to the utilization review entity with the specific intent to deceive and obtain an unlawful payment from a utilization review entity; or

(2) failed to substantially perform the health care service.

(j) In this section,

(1) "health care service" means

(A) the provision of pharmaceutical products, services, or durable medical equipment; or

(B) a health care procedure, treatment, or service provided

(i) in a health care facility licensed in this state; or

(ii) by a doctor of medicine, by a doctor of osteopathy, or within the scope of practice of a health care professional who is

licensed in this state;

(2) "health maintenance organization" has the meaning given in AS 21.86.900;

(3) "prior authorization" means the process used by a utilization review entity to determine the medical necessity or medical appropriateness of a covered health care service before the health care service is provided or a requirement that a covered person or health care provider notify a health care insurer or utilization review entity before providing a health care service;

(4) "utilization review entity" means an individual or entity that performs prior authorization for

(A) an employer in this state with employees covered under a health benefit plan or health insurance policy;

(B) a health care insurer;

(C) a preferred provider organization;

(D) a health maintenance organization; or

(E) an individual or entity that provides, offers to provide, or administers hospital, outpatient, medical, prescription drug, or other health care benefits to a person treated by a health care provider licensed in this state under a health care policy, plan, or contract.

*** Sec. 3.** This Act takes effect immediately under AS 01.10.070(c).

SENATE BILL NO. 219

IN THE LEGISLATURE OF THE STATE OF ALASKA

THIRTY-THIRD LEGISLATURE - SECOND SESSION

BY SENATOR WILSON

Introduced: 2/7/24
Referred: Labor and Commerce, Health and Social Services

A BILL

FOR AN ACT ENTITLED

"An Act relating to utilization review entities; exempting certain health care providers from making preauthorization requests for certain services; and providing for an effective date."

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

*** Section 1.** AS 21.07.005(a) is amended to read:

(a) The director shall adopt regulations to provide standards and criteria for

(1) the structure and operation of utilization review and benefit determination processes**, including processes for utilization review entities under AS 21.07.100**;

(2) the establishment and maintenance of procedures by health care insurers to ensure that a covered individual has the opportunity for appropriate resolution of grievances; and

(3) an independent review of an adverse determination or final adverse determination.

*** Sec. 2.** AS 21.07 is amended by adding a new section to read:

Sec. 21.07.100. Utilization review entities. (a) A utilization review entity may not require a health care provider to complete a prior authorization for a health care service for a covered person to receive coverage for the health care service if, during the most recent 12-month period, the utilization review entity has approved or would have approved at least 80 percent of the prior authorization requests submitted by the health care provider for that health care service.

(b) A utilization review entity may evaluate whether a health care provider continues to qualify for an exemption under (a) of this section not more than once every 12 months. A utilization review entity is not required to evaluate an existing exemption, and nothing prevents a utilization review entity from establishing a longer exemption period.

(c) A health care provider is not required to request an exemption to qualify for an exemption.

(d) If a health care provider does not receive an exemption under (a) of this section, the health care provider may, once every 12 months of providing health care services, request the utilization review entity to provide evidence to support its determination. A health care provider may appeal a determination to deny a prior authorization exemption under (a) of this section. The utilization review entity shall provide to the health care provider an explanation of how to appeal the determination.

(e) A utilization review entity may revoke an exemption under (a) of this section after 12 months if the utilization review entity

(1) makes a determination that the health care provider would not have met the 80 percent approval criteria based on a retrospective review of the claims for the health care service for which the exemption applies for the previous three months or the period needed to reach a minimum of 10 claims for review;

(2) provides the health care provider with the information used by the utilization review entity to make the determination to revoke the exemption; and

(3) provides an explanation to the health care provider on how to appeal the determination.

(f) An exemption under (a) of this section remains in effect until the 30th day

after the date the utilization review entity notifies the health care provider of its determination to revoke the exemption or, if the health care provider appeals the determination, the fifth day after the revocation is upheld on appeal.

(g) A determination to revoke or deny an exemption by a utilization review entity must be made by a health care provider licensed in the state with the same or a similar specialty as the health care provider being considered for an exemption and must have experience in providing the health care service for which the requested exemption applies.

(h) A utilization review entity must provide a health care provider who receives an exemption under (a) of this section with a notice that includes a

(1) statement that the health care provider qualifies for an exemption from a prior authorization requirement and the duration of the exemption; and

(2) list of health care services for which the exemption applies.

(i) A utilization review entity may not deny or reduce payment for a health care service exempted from a prior authorization requirement under (a) of this section, including a health care service performed or supervised by another health care provider when the health care provider who ordered the service received a prior authorization exemption, unless the health care provider providing the health care service

(1) knowingly and materially misrepresented the health care service in a request for payment submitted to the utilization review entity with the specific intent to deceive and obtain an unlawful payment from a utilization review entity; or

(2) failed to substantially perform the health care service.

(j) In this section,

(1) "health care service" means

(A) the provision of pharmaceutical products, services, or durable medical equipment; or

(B) a health care procedure, treatment, or service provided

(i) in a health care facility licensed in this state; or

(ii) by a doctor of medicine, by a doctor of osteopathy, or within the scope of practice of a health care professional who is

licensed in this state;

(2) "health maintenance organization" has the meaning given in AS 21.86.900;

(3) "prior authorization" means the process used by a utilization review entity to determine the medical necessity or medical appropriateness of a covered health care service before the health care service is provided or a requirement that a covered person or health care provider notify a health care insurer or utilization review entity before providing a health care service;

(4) "utilization review entity" means an individual or entity that performs prior authorization for

(A) an employer in this state with employees covered under a health benefit plan or health insurance policy;

(B) a health care insurer;

(C) a preferred provider organization;

(D) a health maintenance organization; or

(E) an individual or entity that provides, offers to provide, or administers hospital, outpatient, medical, prescription drug, or other health care benefits to a person treated by a health care provider licensed in this state under a health care policy, plan, or contract.

*** Sec. 3.** This Act takes effect immediately under AS 01.10.070(c).

CS FOR HOUSE BILL NO. 228(STA)

IN THE LEGISLATURE OF THE STATE OF ALASKA

THIRTY-THIRD LEGISLATURE - SECOND SESSION

BY THE HOUSE STATE AFFAIRS COMMITTEE

Offered: 4/3/24
Referred: Rules

Sponsor(s): REPRESENTATIVE ARMSTRONG

A BILL

FOR AN ACT ENTITLED

"An Act establishing the Alaska task force for the regulation of psychedelic medicines approved by the United States Food and Drug Administration; and providing for an effective date."

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

*** Section 1.** The uncodified law of the State of Alaska is amended by adding a new section to read:

ALASKA TASK FORCE FOR THE REGULATION OF PSYCHEDELIC MEDICINES APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION. (a) The Alaska task force for the regulation of psychedelic medicines approved by the United States Food and Drug Administration is established in the legislature. The purpose of the task force is to prepare for the potential medicalization of psychedelic medicines by the United States Food and Drug Administration; to make policy recommendations to the Alaska State Legislature concerning insurance and licensure, given the unique nature of the administration of psychedelic medicines; and to ensure the state is

prepared if psychedelic medicines become available for prescription. The task force shall

(1) assess the potential use of psychedelic medicine in addressing the state's ongoing mental health crisis;

(2) consider barriers to implementation and equitable access;

(3) consider and recommend licensing and insurance requirements for practitioners in the state in the event that psychedelic medicines are federally reclassified and approved by the United States Food and Drug Administration; and

(4) consider legal and regulatory changes that could be necessary in the state after federal medical approval of psychedelic medicines.

(b) The task force consists of the following members:

(1) the commissioner of health, or the commissioner's designee;

(2) the commissioner of military and veterans' affairs, or the commissioner's designee;

(3) the commissioner of commerce, community, and economic development, or the commissioner's designee;

(4) one member representing mental health issues in the state, selected by the state chapter of a national alliance focused on mental health and mental illness;

(5) two members representing the health care needs of Alaska Native communities, selected by the board of directors of the Alaska Native Health Board;

(6) one member representing the health care needs of survivors of domestic violence and sexual assault, selected by the Alaska Network on Domestic Violence and Sexual Assault;

(7) one member representing the psychiatric profession, selected by the governing body of the Alaska Psychiatric Association;

(8) one member representing licensed therapists or counselors, selected by the board of directors of the Alaska Addiction Professionals Association;

(9) one member representing psychiatric nurse practitioners, selected by the board of directors of the Alaska Advanced Practice Registered Nurse Alliance;

(10) one member of the faculty of the division of population health sciences at the University of Alaska, selected by the president of the University of Alaska;

(11) one member of the senate appointed by the president of the senate;

(12) one member of the house of representatives appointed by the speaker of the house of representatives;

(13) up to three members selected by the task force, once assembled, that the task force determines would serve the purpose of the task force; the task force is not required to make an appointment under this paragraph.

(c) The members appointed by the president of the senate and the speaker of the house of representatives under (b)(11) and (12) of this section shall serve as co-chairs of the task force.

(d) A vacancy on the task force shall be filled in the same manner as the original selection or appointment.

(e) Members of the task force serve without compensation.

(f) The task force shall

(1) meet at least four times to fulfill the purpose of the task force; and

(2) on or before December 31, 2024, submit to the senate secretary, the chief clerk of the house of representatives, and the governor a report consisting of its recommendations, and notify the legislature that the report is available.

(g) The task force terminates when the First Regular Session of the Thirty-Fourth Alaska State Legislature convenes.

(h) In this section, "task force" means the Alaska task force for the regulation of psychedelic medicines approved by the United States Food and Drug Administration.

*** Sec. 2.** This Act takes effect immediately under AS 01.10.070(c).

CS FOR SENATE BILL NO. 166(JUD)

IN THE LEGISLATURE OF THE STATE OF ALASKA

THIRTY-THIRD LEGISLATURE - SECOND SESSION

BY THE SENATE JUDICIARY COMMITTEE

Offered: 3/7/24
Referred: Rules

Sponsor(s): SENATORS DUNBAR, Gray-Jackson, Tobin

A BILL

FOR AN ACT ENTITLED

"An Act establishing a legislative task force on mental health and psychedelic medicine; and providing for an effective date."

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

*** Section 1.** The uncodified law of the State of Alaska is amended by adding a new section to read:

ALASKA MENTAL HEALTH AND PSYCHEDELIC MEDICINE TASK FORCE. (a) The Alaska mental health and psychedelic medicine task force is established as a task force of the Alaska State Legislature. The purpose of the task force is to prepare for the potential medicalization of psychedelic medicines by the United States Food and Drug Administration; to make policy recommendations to the Alaska State Legislature concerning insurance and licensure, given the unique nature of the administration of psychedelic medicines; and to ensure the state is prepared if psychedelic medicines become available for prescription. The task force shall

(1) assess the potential use of psychedelic medicine in addressing the state's

ongoing mental health crisis, as well as in treating chronic and terminal illnesses and in end-of-life care;

(2) consider barriers to implementation and equitable access;

(3) consider and recommend licensing and insurance requirements for practitioners in the state in the event that psychedelic medicines are federally reclassified and approved by the United States Food and Drug Administration; and

(4) consider legal and regulatory changes that could be necessary in the state after federal medical approval of psychedelic medicines.

(b) The task force consists of the following members:

(1) the commissioner of health, or the commissioner's designee;

(2) the commissioner of military and veterans' affairs, or the commissioner's designee;

(3) the commissioner of commerce, community, and economic development, or the commissioner's designee;

(4) one member representing mental health issues in the state, selected by the state chapter of a national alliance focused on mental health and mental illness;

(5) two members representing the health care needs of Alaska Native communities, selected by the board of directors of the Alaska Native Health Board;

(6) one member representing the health care needs of survivors of domestic violence and sexual assault, selected by the Alaska Network on Domestic Violence and Sexual Assault;

(7) one member representing the psychiatric profession, selected by the governing body of the Alaska Psychiatric Association;

(8) one member representing psychiatric nurse practitioners, selected by the board of directors of the Alaska Advanced Practice Registered Nurse Alliance;

(9) one member representing licensed therapists or counselors, selected by the board of directors of the Alaska Addiction Professionals Association;

(10) one member of the faculty of the division of population health sciences at the University of Alaska, selected by the president of the University of Alaska;

(11) one member of the senate appointed by the president of the senate;

(12) one member of the house of representatives appointed by the speaker of

the house of representatives;

(13) up to three members selected by the task force, once assembled, that the task force determines would serve the purpose of the task force; the task force is not required to make an appointment under this paragraph.

(c) The task force shall elect a chair from among its members.

(d) A vacancy on the task force shall be filled in the same manner as the original selection or appointment.

(e) Members of the task force serve without compensation.

(f) The task force shall

(1) meet at least four times to fulfill the purpose of the task force; and

(2) on or before December 31, 2024, submit to the senate secretary, the chief clerk of the house of representatives, and the governor a report consisting of its recommendations, and notify the legislature that the report is available.

(g) The task force terminates when the First Regular Session of the Thirty-Fourth Alaska State Legislature convenes.

(h) In this section, "task force" means the Alaska mental health and psychedelic medicine task force.

*** Sec. 2.** This Act takes effect immediately under AS 01.10.070(c).

SENATE BILL NO. 225

IN THE LEGISLATURE OF THE STATE OF ALASKA

THIRTY-THIRD LEGISLATURE - SECOND SESSION

BY THE SENATE RULES COMMITTEE BY REQUEST OF THE GOVERNOR

Introduced: 2/12/24
Referred: Labor and Commerce, Finance

A BILL

FOR AN ACT ENTITLED

"An Act relating to occupational licensing fees; and providing for an effective date."

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

*** Section 1.** AS 08.01.065(a) is amended to read:

(a) Except for business licenses, the department shall adopt regulations that establish the amount and manner of payment of application fees, examination fees, license fees, registration fees, permit fees, [INVESTIGATION FEES,] and all other fees as appropriate for the occupations covered by this chapter.

*** Sec. 2.** AS 08.01.065(c) is amended to read:

(c) Except as provided in (f) - (k) of this section, the department shall establish fee levels under (a) of this section so that the total amount of fees collected for an occupation approximately equals the actual regulatory costs for the occupation. The department shall annually review each fee level to determine whether the regulatory costs of each occupation are approximately equal to fee collections related to that occupation. If the review indicates that an occupation's fee collections and regulatory costs are not approximately equal, the department shall calculate fee adjustments and

adopt regulations under (a) of this section to implement the adjustments. In January of each year, the department shall report on all fee levels and revisions for the previous year under this subsection to the office of management and budget. If a board regulates an occupation covered by this chapter, the department shall consider the board's recommendations concerning the occupation's fee levels and regulatory costs before revising fee schedules to comply with this subsection. [IN THIS SUBSECTION, "REGULATORY COSTS" MEANS COSTS OF THE DEPARTMENT THAT ARE ATTRIBUTABLE TO REGULATION OF AN OCCUPATION PLUS

(1) ALL EXPENSES OF THE BOARD THAT REGULATES THE OCCUPATION IF THE BOARD REGULATES ONLY ONE OCCUPATION;

(2) THE EXPENSES OF A BOARD THAT ARE ATTRIBUTABLE TO THE OCCUPATION IF THE BOARD REGULATES MORE THAN ONE OCCUPATION.]

*** Sec. 3.** AS 08.01.065 is amended by adding a new subsection to read:

(*l*) In this section, "regulatory costs" means costs of the department that are attributable to regulation of an occupation, including all expenses of a board that regulates the occupation if the board regulates only one occupation or the expenses of a board that are attributable to the occupation if the board regulates more than one occupation. In this section, "regulatory costs" does not include costs attributable to disciplinary investigations and actions involving a person engaged in an unlicensed practice or legal and actual costs associated with complaints, hearings, mediation, and settlement.

*** Sec. 4.** AS 08.13.185(b) is amended to read:

(b) The department shall set fees under AS 08.01.065 for examination [AND INVESTIGATION].

*** Sec. 5.** AS 08.61.090 is amended to read:

Sec. 08.61.090. Fees. The department shall set fees under AS 08.01.065 for application, license issuance, **and** license renewal [, AND INVESTIGATION] under this chapter.

*** Sec. 6.** AS 08.62.040(a) is amended to read:

(a) The board shall

(1) provide for the maintenance of efficient and competent pilotage service on the inland and coastal water of and adjacent to the state to assure the protection of shipping, the safety of human life and property, and the protection of the marine environment;

(2) consistent with the law, adopt regulations, subject to AS 44.62 (Administrative Procedure Act), establishing the qualifications of and required training for pilots and providing for the examination of pilots and the issuance of original or renewal pilot licenses to qualified persons;

(3) keep a register of licensed pilots, licensed deputy pilots, and agents;

(4) adopt regulations establishing

(A) pilotage regions in the state;

(B) the criteria for concurring in the amount of license, application, training, [INVESTIGATION,] and audit fees proposed by the department under AS 08.01.065;

(C) the criteria for recognizing pilot organizations under AS 08.62.175;

(5) make available, upon request, copies of this chapter and the regulations adopted under this chapter;

(6) review and approve the articles, bylaws, and rules of pilot organizations;

(7) audit a pilot organization or an individual pilot as necessary to implement and enforce this chapter;

(8) review and approve training programs conducted by pilot organizations; the board shall cooperate with the Department of Environmental Conservation in the review and approval of training programs for pilots of tank vessels;

(9) establish and publish the dates of future license examinations; and

(10) approve or disapprove rates for pilotage services as provided under AS 08.62.046.

*** Sec. 7.** AS 08.62.140(a) is amended to read:

(a) The department shall set fees under AS 08.01.065 for applications, licenses, agent registrations, [INVESTIGATIONS,] audits, and training.

*** Sec. 8.** AS 08.70.150 is amended to read:

Sec. 08.70.150. Fees. The department shall set fees under AS 08.01.065 for examination and **evaluation** [INVESTIGATION] of persons applying for a license, initial license, and license renewal.

*** Sec. 9.** AS 08.80.160 is amended to read:

Sec. 08.80.160. Fees. The Department of Commerce, Community, and Economic Development shall set fees under AS 08.01.065 for the following:

(1) examination;

(2) reexamination;

(3) **evaluation** [INVESTIGATION] for licensing by license transfer;

(4) pharmacist license;

(5) temporary license;

(6) pharmacy technician license;

(7) pharmacy intern license;

(8) emergency permit;

(9) license amendment or replacement;

(10) licensure of a facility classified under AS 08.80.157(b).

*** Sec. 10.** AS 08.98.190 is amended to read:

Sec. 08.98.190. Fees. The department shall set fees under AS 08.01.065 for the following:

(1) application;

(2) examination;

(3) **evaluation** [INVESTIGATION] of credentials;

(4) license;

(5) license renewal;

(6) temporary license;

(7) temporary permit.

*** Sec. 11.** This Act takes effect July 1, 2024.

HOUSE BILL NO. 314

IN THE LEGISLATURE OF THE STATE OF ALASKA

THIRTY-THIRD LEGISLATURE - SECOND SESSION

BY THE HOUSE RULES COMMITTEE BY REQUEST OF THE GOVERNOR

Introduced: 2/9/24
Referred: Labor and Commerce

A BILL

FOR AN ACT ENTITLED

"An Act relating to occupational licensing fees; and providing for an effective date."

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

*** Section 1.** AS 08.01.065(a) is amended to read:

(a) Except for business licenses, the department shall adopt regulations that establish the amount and manner of payment of application fees, examination fees, license fees, registration fees, permit fees, [INVESTIGATION FEES,] and all other fees as appropriate for the occupations covered by this chapter.

*** Sec. 2.** AS 08.01.065(c) is amended to read:

(c) Except as provided in (f) - (k) of this section, the department shall establish fee levels under (a) of this section so that the total amount of fees collected for an occupation approximately equals the actual regulatory costs for the occupation. The department shall annually review each fee level to determine whether the regulatory costs of each occupation are approximately equal to fee collections related to that occupation. If the review indicates that an occupation's fee collections and regulatory costs are not approximately equal, the department shall calculate fee adjustments and

adopt regulations under (a) of this section to implement the adjustments. In January of each year, the department shall report on all fee levels and revisions for the previous year under this subsection to the office of management and budget. If a board regulates an occupation covered by this chapter, the department shall consider the board's recommendations concerning the occupation's fee levels and regulatory costs before revising fee schedules to comply with this subsection. [IN THIS SUBSECTION, "REGULATORY COSTS" MEANS COSTS OF THE DEPARTMENT THAT ARE ATTRIBUTABLE TO REGULATION OF AN OCCUPATION PLUS

(1) ALL EXPENSES OF THE BOARD THAT REGULATES THE OCCUPATION IF THE BOARD REGULATES ONLY ONE OCCUPATION;

(2) THE EXPENSES OF A BOARD THAT ARE ATTRIBUTABLE TO THE OCCUPATION IF THE BOARD REGULATES MORE THAN ONE OCCUPATION.]

*** Sec. 3.** AS 08.01.065 is amended by adding a new subsection to read:

(*l*) In this section, "regulatory costs" means costs of the department that are attributable to regulation of an occupation, including all expenses of a board that regulates the occupation if the board regulates only one occupation or the expenses of a board that are attributable to the occupation if the board regulates more than one occupation. In this section, "regulatory costs" does not include costs attributable to disciplinary investigations and actions involving a person engaged in an unlicensed practice or legal and actual costs associated with complaints, hearings, mediation, and settlement.

*** Sec. 4.** AS 08.13.185(b) is amended to read:

(b) The department shall set fees under AS 08.01.065 for examination [AND INVESTIGATION].

*** Sec. 5.** AS 08.61.090 is amended to read:

Sec. 08.61.090. Fees. The department shall set fees under AS 08.01.065 for application, license issuance, **and** license renewal [, AND INVESTIGATION] under this chapter.

*** Sec. 6.** AS 08.62.040(a) is amended to read:

(a) The board shall

(1) provide for the maintenance of efficient and competent pilotage service on the inland and coastal water of and adjacent to the state to assure the protection of shipping, the safety of human life and property, and the protection of the marine environment;

(2) consistent with the law, adopt regulations, subject to AS 44.62 (Administrative Procedure Act), establishing the qualifications of and required training for pilots and providing for the examination of pilots and the issuance of original or renewal pilot licenses to qualified persons;

(3) keep a register of licensed pilots, licensed deputy pilots, and agents;

(4) adopt regulations establishing

(A) pilotage regions in the state;

(B) the criteria for concurring in the amount of license, application, training, [INVESTIGATION,] and audit fees proposed by the department under AS 08.01.065;

(C) the criteria for recognizing pilot organizations under AS 08.62.175;

(5) make available, upon request, copies of this chapter and the regulations adopted under this chapter;

(6) review and approve the articles, bylaws, and rules of pilot organizations;

(7) audit a pilot organization or an individual pilot as necessary to implement and enforce this chapter;

(8) review and approve training programs conducted by pilot organizations; the board shall cooperate with the Department of Environmental Conservation in the review and approval of training programs for pilots of tank vessels;

(9) establish and publish the dates of future license examinations; and

(10) approve or disapprove rates for pilotage services as provided under AS 08.62.046.

*** Sec. 7.** AS 08.62.140(a) is amended to read:

(a) The department shall set fees under AS 08.01.065 for applications, licenses, agent registrations, [INVESTIGATIONS,] audits, and training.

*** Sec. 8.** AS 08.70.150 is amended to read:

Sec. 08.70.150. Fees. The department shall set fees under AS 08.01.065 for examination and **evaluation** [INVESTIGATION] of persons applying for a license, initial license, and license renewal.

*** Sec. 9.** AS 08.80.160 is amended to read:

Sec. 08.80.160. Fees. The Department of Commerce, Community, and Economic Development shall set fees under AS 08.01.065 for the following:

(1) examination;

(2) reexamination;

(3) **evaluation** [INVESTIGATION] for licensing by license transfer;

(4) pharmacist license;

(5) temporary license;

(6) pharmacy technician license;

(7) pharmacy intern license;

(8) emergency permit;

(9) license amendment or replacement;

(10) licensure of a facility classified under AS 08.80.157(b).

*** Sec. 10.** AS 08.98.190 is amended to read:

Sec. 08.98.190. Fees. The department shall set fees under AS 08.01.065 for the following:

(1) application;

(2) examination;

(3) **evaluation** [INVESTIGATION] of credentials;

(4) license;

(5) license renewal;

(6) temporary license;

(7) temporary permit.

*** Sec. 11.** This Act takes effect July 1, 2024.

Alaska Board of Pharmacy

Agenda Item #7

Industry Updates

AKPhA
ALASKA PHARMACY ASSOCIATION

Industry Update

Brandy Seignemartin, PharmD

Current Issue Update

- Access issues for buprenorphine containing products to treat Opioid Use Disorder (OUD)
- Heightened scrutiny from wholesalers and DEA is hindering patient care
- No transparency in ratios or limitations on a pharmacy's ability to order buprenorphine containing products
- Pharmacies around Alaska unable to take on new OUD patients - compounded access issue due to PBMs
- DEA Letter to wholesalers, Guidance Document

- There may be limitations set forth in state level opioid settlement to look into

AKPhA
ALASKA PHARMACY ASSOCIATION

Dear DEA Registrant,

In 2022, 6.1 million people in the United States had an opioid use disorder (OUD). Among them, only 18.3% received medication-assisted treatment. The removal of the Drug Addiction Treatment Act of 2000 "x-waiver" in December 2022 eliminated a significant barrier to treatment for OUD, dramatically increasing the number of medical professionals who can prescribe buprenorphine from the previously eligible 130,000 prescribers.

The Drug Enforcement Administration (DEA) and the Department of Health and Human Services (HHS) are committed to ensuring safe and ready access to medications for opioid use disorder (MOUD), especially in rural or underserved areas where treatment options have been limited. With the passage of the Consolidated Appropriations Act, 2023,[1] there was an immediate and significant increase in the number of practitioners who can prescribe schedule III MOUD products (e.g., buprenorphine combination products containing buprenorphine and naloxone) for patients with OUD.

As access to treatment increases, it is understood that the use of MOUD products will likely increase at the same time. DEA recognizes that there have been recent increases in demand for certain schedule III MOUD controlled substances as compared to years prior to the Opioid Public Health Emergency, and that there may be a corresponding increase in prescriptions for these medications from medical providers. DEA supports collaboration amongst all DEA registrants to ensure there is an adequate and uninterrupted supply of MOUD products when these products are appropriately prescribed. Distributors should carefully examine quantitative thresholds they have established to ensure that individuals with OUD who need buprenorphine are able to access it without undue delay. DEA has posted a guidance document on its portal related to this issue: https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-065)(EO-DEA258)_Q_A_SOR_and_Thresholds_(Final).pdf.

For more information, please visit www.samhsa.gov and/or www.DEAdiversion.usdoj.gov. It is our sincere hope that the remarkable increase in the number of medical professionals who can prescribe this life-saving medication will not only change the lives of individuals with OUD, but will also stem the escalating rate of opioid-related deaths at a population level.

Please join us in this fight to save lives.

Sincerely,

Anne M. Milgram
Administrator,
Drug Enforcement Administration
Department of Justice

Rachel L. Levine, M.D.
ADM, USPHS
Assistant Secretary for Health
Department of Health and Human

Miriam E. Delphin-Rittmon, Ph.D.
Assistant Secretary for Mental
Health and Substance Use
Department of Health and Human
Services

[1] Pub. L. No. 117-328, 136 Stat. 4459 (2022).

Drug Enforcement Administration
Diversion Control Division
Guidance Document

Title: DEA-Registered Manufacturer and Distributor Established Controlled Substance Quantitative Thresholds and the Requirement to Report Suspicious Orders

Summary: This guidance document clarifies that neither the Controlled Substance Act (CSA) nor the Drug Enforcement Administration (DEA) regulations establish quantitative thresholds or place limits on the volume of controlled substances DEA registrants can order and dispense. This document also reminds all DEA registrants of the requirement to establish systems to identify and report suspicious orders of controlled substances to include Medication for Opioid Use Disorder (MOUD).

Activity: Reporting Suspicious Orders of Controlled Substances Including MOUD

To Whom it Applies: DEA Registrants

Question: Are DEA-registered manufacturers or distributors required by the CSA or DEA regulations to establish limits (quantitative thresholds) on the amounts of controlled substances, including MOUD, that another DEA registrant can order or dispense?

Answer: No. Neither the CSA nor DEA regulations establish quantitative thresholds or limits on the amounts of controlled substances, including MOUD, that DEA registrants may order or dispense, nor do they require registrants to set such thresholds or limits.

The CSA, as amended by the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment Act (SUPPORT Act) requires each DEA registrant to: 1) design and operate a system to identify suspicious orders for the registrant; 2) ensure that the system complies with applicable Federal and State privacy laws; and 3) upon discovering a suspicious order or series of orders, notify the Administrator of the DEA and the Special Agent in Charge of the Division Office of the DEA for the area in which the registrant is located or conducts business. 21 U.S.C. 832(a). Suspicious orders may include, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. 21 U.S.C. 802(57). Furthermore, all applicants and registrants must maintain effective controls and procedures to guard against theft and diversion. 21 CFR 1301.71(a).

To comply with these statutory and regulatory requirements, many DEA-registered manufacturers and distributors establish controlled substance monitoring systems that set thresholds that may limit the amount of a customer's controlled substance purchases and may prompt a report of a suspicious order to DEA. However, whether to set such thresholds (if any) and at what levels are decisions that each manufacturer or distributer may make in the design and implementation of its controlled substance monitoring system. DEA does not have a role in establishing or revising thresholds for controlled substances that manufacturers or distributors may set for their customers as part of the required monitoring systems.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or Department of Justice policies.

EO-DEA258, DEA-DC-065, January 20, 2023.

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

Agenda Item #10

Division Updates

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

Summary of All Professional Licensing
Schedule of Revenues and Expenditures

Board of Pharmacy	FY 18	FY 19	Biennium	FY 20	FY 21	Biennium	FY 22	FY 23	Biennium	FY 24 1st & 2nd QTR
Revenue										
Revenue from License Fees	$ 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					$ -	-	$ 29,810	$ 7,668	37,478	$ -
Allowable Third Party Reimbursements	210	962	1,172	$ -	$ -	-	$ 1,650	$ 1,500	3,150	$ 88
TOTAL REVENUE	$ 801,527	$ 214,732	$ 1,016,259	$ 631,105	$ 1,121,447	$ 1,752,552	$ 476,435	$ 1,178,363	$ 1,654,798	$ 192,128
Expenditures										
Non Investigation Expenditures										
1000 - Personal Services	204,727	194,745	399,472	199,334	278,612	477,946	284,719	335,119	619,838	152,228
2000 - Travel	13,704	8,299	22,003	2,641	-	2,641	6,363	14,252	20,615	3,866
3000 - Services	21,960	27,781	49,741	45,283	46,180	91,463	29,584	20,174	49,758	13,916
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	170,310
Investigation Expenditures										
1000-Personal Services	68,679	69,997	138,676	57,738	106,494	164,232	94,519	128,331	222,850	72,505
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	1,603
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	19
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	90,070
Total Direct Expenditures	309,070	304,310	613,380	310,277	432,923	743,200	434,595	511,790	946,384	260,380
Indirect Expenditures										
Internal Administrative Costs	150,986	155,128	306,114	164,443	191,897	356,340	182,236	190,056	372,292	95,028
Departmental Costs	78,139	81,374	159,513	58,131	75,431	133,562	76,951	76,872	153,823	38,436
Statewide Costs	30,555	27,069	57,624	33,868	52,856	86,724	47,667	50,400	98,067	25,200
Total Indirect Expenditures	259,680	263,571	523,251	256,442	320,184	576,626	306,854	317,328	624,182	158,664
			-			-				
TOTAL EXPENDITURES	**$ 568,750**	**$ 567,881**	**$ 1,136,631**	**$ 566,719**	**$ 753,107**	**$ 1,319,826**	**$ 741,449**	**$ 829,118**	**$ 1,570,566**	**$ 419,044**
Cumulative Surplus (Deficit)										
Beginning Cumulative Surplus (Deficit)	$ 275,216	$ 507,993		$ 154,844	$ 219,230		$ 587,570	$ 322,556		$ 671,801
Annual Increase/(Decrease)	232,777	(353,149)		64,386	368,340		(265,014)	349,245		(226,916)
Ending Cumulative Surplus (Deficit)	$ 507,993	154,844		$ 219,230	$ 587,570		$ 322,556	$ 671,801		$ 444,885
Statistical Information										
Number of Licenses for Indirect calculation	5,680	6,203		5,934	6,917		6,542	6,428		

Additional information:

- *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.*
- *Most recent fee change: New fee FY24 (retired)*
- *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	Grand Total
1011 - Regular Compensation	119,663.46				119,663.46
1014 - Overtime	319.98				319.98
1016 - Other Premium Pay	478.92				478.92
1021 - Allowances to Employees	180.00				180.00
1023 - Leave Taken	17,950.62				17,950.62
1028 - Alaska Supplemental Benefit	8,505.51				8,505.51
1029 - Public Employee's Retirement System Defined Benefits	220.93				220.93
1030 - Public Employee's Retirement System Defined Contribution	7,252.57				7,252.57
1034 - Public Employee's Retirement System Defined Cont Health Reim	4,904.93				4,904.93
1035 - Public Employee's Retiremnt Sys Defined Cont Retiree Medical	1,382.42				1,382.42
1037 - Public Employee's Retiremnt Sys Defined Benefit Unfnd Liab	20,729.49				20,729.49
1040 - Group Health Insurance	40,111.16				40,111.16
1041 - Basic Life and Travel	34.21				34.21
1042 - Worker's Compensation Insurance	943.92				943.92
1047 - Leave Cash In Employer Charge	3,178.57				3,178.57
1048 - Terminal Leave Employer Charge	2,201.77				2,201.77
1053 - Medicare Tax	1,916.53				1,916.53
1077 - ASEA Legal Trust	149.94				149.94
1079 - ASEA Injury Leave Usage	25.12				25.12
1080 - SU Legal Trst	20.17				20.17
1970 - Personal Services Transfer	(5,437.05)				(5,437.05)
2012 - Out-State Employee Airfare		706.44			706.44
2013 - Out-State Employee Surface Transportation		36.00			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		30.00			30.00
2970 - Travel Cost Transfer		(87.63)			(87.63)
3000 - Training/Conferences			900.00		900.00
3035 - Long Distance			23.59		23.59
3044 - Courier			19.38		19.38
3046 - Advertising			1,396.08		1,396.08
3088 - Inter-Agency Legal			6,991.61		6,991.61
3093 - Inter-Agency Education/Training			65.00		65.00
3094 - Inter-Agency Hearing/Mediation			22,085.70		22,085.70
4002 - Business Supplies				300.00	300.00
Grand Total	**224,733.17**	**3,865.73**	**31,481.36**	**300.00**	**260,380.26**

Alaska Board of Pharmacy

Agenda Item #11

Public Comment Period

Alaska Board of Pharmacy

Agenda Item #12

Board Business

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.

GUIDING PRINCIPLES	GOALS	STRATEGIES	
COMMUNICATION	**1.** Engage in effective communication and promote transparency of public information.	**1.1**	Improve customer service by providing timely and informative updates to applicants and licensees.
		1.2	Maximize communication channels through the Board of Pharmacy website and List Service.
		1.3	Maintain accuracy of website content and ensure accessibility of up-to-date resources
ADMINISTRATION	**2.** Adhere to and strive for improved organizational efficiencies without compromising quality of record keeping.	**2.1**	Avoid delays in application processing by maintaining adequate staffing and exploring flexible retention strategies.
		2.2	Maintain a proactive approach to licensing by consulting historical knowledge, researching national trends, and encouraging innovation in the planning process.
		2.3	Automate initial licensure through online applications.
		2.4	Exercise fiscal discipline through effective budget management.
		2.5	Embrace innovation by exploring integration and/or delegation opportunities to support core administration functions.
LICENSURE	**3.** Ensure competency and qualifications prior to licensure and renewal.	**3.1**	Adhere to established licensing standards by reviewing education, experience, and examination requirements.
		3.2	Take a proactive approach to application and form revision subsequent to regulation changes.
		3.3	Develop a license application for manufacturers.
		3.4	Ensure a 30 day or less processing time for licensee applications, and a 60 day or less licensing time for facility applications.
REGULATION & ENFORCEMENT	**4.** Grow the economy while promoting community health and safety.	**4.1**	Routinely review effectiveness of regulations that reduce barriers to licensure without compromising patient health and safety.
		4.2	Combat the opioid crisis by effective administration of the state's 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.

For more information, please visit the following resources:

Board of Pharmacy Homepage: pharmacy.alaska.gov
Prescription Drug Monitoring Program (PDMP): pdmp.alaska.gov

Email: boardofpharmacy@alaska.gov
Phone: 907-465-1073

SBAR (SITUATION, BACKGROUND, ASSESSMENT, RECOMMENDATION)

Quality Glossary Definition: SBAR (/quality-resources/quality-glossary/s)

SBAR (Situation, Background, Assessment, Recommendation) is a verbal or written communication tool that helps provide essential, concise information, usually during crucial situations. In some cases, SBAR can even replace an executive summary in a formal report because it provides focused and concise information.

SBAR was introduced by the United States military in the 1940s and later targeted specifically for nuclear submarines where concise and relevant information was essential for safety. Since then, the SBAR communication tool has been used in a variety of industries, and its ability to improve safety is well documented.

SBAR PROCEDURE

SBAR can be written or provided verbally, but the purpose is to provide essential, concise information, usually during crucial situations.

Situation

In this initial section, the exact circumstances of the situation get explained. Non-essential information is excluded. The focus should be on the seriousness of the situation.

Background

The background section presents essential information related to the situation. This information should pertain only to the current situation.

Assessment

The assessment is a precise statement based on the situation and background information. The assessment must be made by a qualified staff person.

Recommendation

The qualified staff person makes a recommendation for resolving the issue based on the situation, background, and assessment.

SBAR EXAMPLE

Example 1

Because of its simplicity and usefulness in crucial situations, SBAR has many implementations in healthcare. It can be used between professional staff such as nurses and physicians, and it also has value for hand-offs by nurses between change of shifts or patient transfers. Below is a basic example of how SBAR communication can be used in a healthcare setting, but SBAR can be used as a leadership communication tool in any industry.

Situation: The patient has been hospitalized with an upper respiratory infection. Respiration are labored and have increased to 28 breaths per minute within the past 30 minutes. Usual interventions are ineffective.

Background: The patient is a 72-year-old female with a history of congestive heart failure and chronic obstructive pulmonary disease. Her husband has requested to be notified if the patient's condition changes.

Note: The patient's past illnesses are highly relevant to the current situation, but the patient's home address is not.

Assessment: Patient's breathing has deteriorated in the last 30 minutes. Usual interventions (i.e., inhaler, oxygen, breathing treatments) have been ineffective and are not relieving symptoms.

Note: The assessment must be made by a qualified staff person, such as a registered nurse, but it is not a diagnosis unless it is made by a provider such as a medical doctor or physician assistant.

Recommendation: Consider intubation immediately. Call physician STAT or initiate Rapid Response Team.

Example 2

Table 1 below is an example of an SBAR communication to hospital leadership written by a primary care physician.

Table 1: SBAR Communication for Community Services

1. Situation	Community X has a population that includes many residents with mental health needs. However, mental health care is fragmented and not tied to primary care or to the community hospital.
2. Background	Community X is a rural community with one critical access hospital (CAH) that does not provide mental health services. Patients with mental health issues are seen in the emergency department, which is ineffective and costly. There are no systematic referral systems among the hospital, primary care physicians, and mental health practitioners.
3. Assessment	A collaborative care model among the hospital, primary care, and mental health practitioners needs to be developed to provide patients with better mental health care.
4. Recommendation	Hospital leadership needs to seek out mental health practitioners in the community for discussion. Additionally, leadership should consult with the American Psychiatric Association to review the applicability of their collaborative care model to Community X.

Developed by Kelly Podgorny and the ASQ Quality Management Division. To connect with members of the Quality Management Division, join our community (https://my.asq.org/communities/home/28) for discussions and events.

ALASKA BOARD OF PHARMACY - DISCIPLINARY MATRIX

Violation Type	Statute/Regulation	Precedence List	Recommended Action
Continuing Education			

• Failure to meet continuing education requirements
• Failure to comply with mandatory continuing education audit
	AS 08.80.165, 12 AAC 02.950(2)~~60(e)~~, 12 AAC 52.300, 12 AAC 52.325, 12 AAC 52.350.	• Civil fine of $250 only
		• Consent agreement with $200 fine, reprimand, 2 mandatory audits
		• Consent agreement with $250 fine, reprimand, 2 mandatory audits
		• Consent agreement with $300 fine, reprimand, 2 mandatory audits
		• Consent agreement with $1,000 fine, reprimand, 2 mandatory audits
		• License revocation
		• License surrender
			• Pharmacists
			  ○ Base fine = $1000~~500~~
			  ○ Fine/credit hour missed = $200~~100~~
			  ○ Mandatory audits = 2
			  ○ Reprimand = yes
			  ○ Consent Agreement = yes
			• Pharmacy technician
			  ○ Base fine = $250~~125~~
			  ○ Fine/credit hour missed = $50~~25~~
			  ○ Mandatory audits = 2
			  ○ Reprimand = yes
			  ○ Consent Agreement = yes

Falsified Application/failure to disclose – technical			
• *Examples: wrong SSN, forgot to report criminal history of any felony or misdemeanor less than 7 year ~~an aged minor criminal history~~ (e.g.: shoplifting from3 ~~20~~ years ago)*	AS 08.80.261(a)(1), AS08.80.261(a)(14), 12 AAC 52.920(a)(13)	• Non-disciplinary letter of advisement • Civil fine of $500 only • Civil fine of $1,000 only • Civil fine of $2,000 only • Consent agreement with $1,000 fine and reprimand • Consent agreement with $3,000 fine and reprimand	• Non-disciplinary letter of advisement • C~~or c~~ivil fine of up to $3000~~500~~ • Imposition of civil fine without censure or reprimand (technical violation not related to the delivery of health care); Civil Fine of $1,000 for each violation. Discipline to be commensurate with the severity of the violation.

Current ~~PHA – disciplinary matrix –~~ as of

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ALASKA BOARD OF PHARMACY - DISCIPLINARY MATRIX

Falsified Application/failure to disclose – scope of practice			
• *Examples: not qualified for licensure (e.g.: did not really hold a license in another jurisdiction when applied via reciprocity; had license revoked in another jurisdiction and didn't report)* • Ffailing to provide information or providing false or fraudulent information on an application, notification, or other document required in AS 08.80 or this chapter; (12 AAC 52.920(a)(13))	AS 08.80.261(a)(1), AS08.80.261(a)(14), 12 AAC 52.920(a)(13)	• Non-disciplinary letter of advisement • Civil fine of $500 only • Civil fine of $1,000 only • Civil fine of $2,000 only • Consent agreement with $1,000 fine and reprimand • Consent agreement with $3,000 fine and reprimand	• Civil fine beginning at $1000500 and up to $5,0003,000 • Imposition of civil fine without censure or reprimand (technical violation not related to the delivery of health care); Civil Fine of $1,000 for each violation. Discipline to be commensurate with the severity of the violation. • License Suspension • License revocation • License denial
Negligence			
• Iintentionally or negligently engaged in or permitted the performance of patient care by persons under the applicant's or licensee's supervision (AS 08.80.261)(a)(5).	12 AAC 52.230 (a)(2), AS 08.80.330(a), AS 08.80.261(a)(5)(6), 12 AAC 52.920(a)(16)and (b)(4)	• Non-disciplinary letter of advisement • Consent agreement with $2,750 civil fine	• Civil fine beginning at $1000500 and up to $5,000 if patient injury involved 3,000 • License Suspension • License revocation • License denial
• Iintentionally or negligently engages in conduct that results in a significant risk to the health or safety of a patient or injury to a patient; (revocation; 12 AAC 52.920(b)(4))	12 AAC 52.230 (a)(2), AS 08.80.330(a), AS 08.80.261(a)(5)(6), 12 AAC 52.920(a)(16) and (b)(4)	• Non-disciplinary letter of advisement • Consent agreement with $2,750 civil fine	• Civil fine beginning at $1000500 and up to $5,0003,000 • License Suspension • License revocation • License denial
Unlicensed Practice			
• Kknowingly delegating any aspect of practice of pharmacy to unlicensed person inconsistent with delegation allowed in AS 08 (12 AAC 52.920(a)(16)	AS 08.80.261(a)(14), 12 AAC 52.920(a)(3), AS 08.80.261(a)(1), 12 AAC 52.920(a)(13)	• Consent agreement with fine excused/letter of advisement • Consent agreement with $5,000 fine	Refer to unprofessional conduct.

Current ~~PHA – disciplinary matrix –~~ as of

ALASKA BOARD OF PHARMACY - DISCIPLINARY MATRIX

• Engaging in unlicensed activities defined in "practice of Pharmacy in AS 08.80.480(30), except for tribal pharmacists exempt from licensure in 12 AAC 52.150, provided they submit the required form.		• Consent agreement with fine excused/letter of advisement • Consent agreement with $5,000 fine	~~• Non-disciplinary letter of advisement if submitted between 31 days and 90 days~~ • Consent agreement ~~Civil fine with~~of $1,000~~250~~ if 3~~9~~1 – 90~~120~~ days • Consent agreement ~~Civil fine with~~of $3,000~~500~~ if 121 – 180~~360~~ days • Civil fine of $5,000 if 181 – 360 days or more • Cease and Desist Order
• Practicing as an intern before obtaining licensure in the state	12 AAC 52.120	• Consent agreement with fine excused/letter of advisement • Consent agreement with $5,000 fine	Relates to delegation of duties on the part of the pharmacist; refer to unprofessional conduct. Consider whether it was inadvertent, a misunderstanding, unknowing misrepresentation vs. intentionally providing fraudulent information. Range of actions may be appropriate.
• Practicing as an intern without personal pharmacist supervision	AS 08.80.480(a)(14)(A), 12 AAC 52.220(b)	• Consent agreement with fine excused/letter of advisement • Consent agreement with $5,000 fine	Consider length of time without personal supervision (e.g.: 1 hour vs. 1 month) • Fine for both (intern = $200~~250~~, pharmacist on duty = $1000~~500~~)
• Performing manipulative, non-discretionary functions and working in the dispensing area without holding a pharmacy technician license	12 AAC 50.230	• Consent agreement with fine excused/letter of advisement • Consent agreement with $5,000 fine	Consider length of time without personal supervision (e.g.: 1 hour vs. 1 month) • Fine for both (tech = $100~~150~~, pharmacist on duty = $1000~~500~~

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ALASKA BOARD OF PHARMACY - DISCIPLINARY MATRIX

• Shipping, mailing, delivering, or advertising pharmacy services without holding ~~an out-of-state~~ a pharmacy ~~registration~~ license or without holding a wholesale drug distributor, third-party logistics provider, manufacturer, or outsourcing facility license	AS 08.80.157(a), AS 08.80.159(a)	• Consent agreement with fine excused/letter of advisement • Consent agreement with $5,000 fine	• Imposition of civil fine of $5,000 fine for each shipment~~$25,000~~
• Distributing prescription drugs or devices directly to patients by a wholesaler, except for dialysates ~~without holding a wholesaler or pharmacy license~~	AS 08.80.157(h)(7)	• Consent agreement with fine excused/letter of advisement • Consent agreement with $5,000 fine	• Imposition of civil fine of $5,000 fine for each shipment~~$25,000~~
Unprofessional Conduct			
• ~~Knowingly~~ D~~d~~ispensinges~~~~ invalid prescription	12 AAC 52.920	• Non-disciplinary letter of advisement • Civil fine of $250 • Civil fine of $500	• ~~Non-disciplinary letter of advisement (1)~~ • Civil fine of $500~~250~~ (1) • Civil fine of $1000~~500~~ (2) • Civil fine of $5~~1~~,000 (1) if patient injury involved • Probation, if repeated
• Dispenses unsafe quantities/dosages/supply-days	12 AAC 52.920	• Non-disciplinary letter of advisement • Civil fine of $250 • Civil fine of $500	• ~~Non-disciplinary letter of advisement (1)~~ • Consent agreement with • $1,000 fine ~~Civil fine of $250~~ (1) • Consent agreement with • $3,000 fine ~~Civil fine of $500~~ (2) • Consent agreement with • $5,000 fine~~Civil fine of $1,000~~ (1) if patient injury involved • Probation, if repeated
• Acquiring, possessing, or attempting to possess Rx in criminal manner	12 AAC 52.920	• Non-disciplinary letter of advisement • Civil fine of $250 • Civil fine of $500	• License revocation • License suspension for up to two years AND probation for at least two years for: willfully/repeatedly violating AS 08 or 12 AAC 52 OR for professional incompetence

Current ~~PHA – disciplinary matrix –~~ as of

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ALASKA BOARD OF PHARMACY - DISCIPLINARY MATRIX

• Distributing Rx to practitioner/pharmacy outside of professional practice	12 AAC 52.920	• Non-disciplinary letter of advisement • Civil fine of $250 • Civil fine of $500	~~• Non-disciplinary letter of advisement~~ • Civil fine of $500~~250~~ • Civil fine of $1,000~~500~~ • Civil fine of $5,000~~1,000~~ if patient injury involved
• Refusing to keep, maintain, or furnish records	12 AAC 52.920	• Non-disciplinary letter of advisement • Civil fine of $250 Civil fine of $500	~~• Non-disciplinary letter of advisement~~ • Civil fine of $500~~250~~ • Civil fine of $1,000~~500~~ • Civil fine of $2,000~~1,000~~
• Refusing Inspection	12 AAC 52.920	• Non-disciplinary letter of advisement • Civil fine of $250 • Civil fine of $500	~~• Non-disciplinary letter of advisement~~ • Civil fine of $500~~250~~ • Civil fine of $1,000~~500~~ • Civil fine of $2,000~~1,000~~
• Making false claims for reimbursements	12 AAC 52.920	• Non-disciplinary letter of advisement • Civil fine of $250 • Civil fine of $500	~~• Reprimand, if minimal/infrequent~~ • License suspension • License Probation with Reprimand, if minimal/infrequent • License Revocation
• Operating an unsafe pharmacy	12 AAC 52.920	• Non-disciplinary letter of advisement • Civil fine of $250 • Civil fine of $500	• Consider USP 797/795 • Non-disciplinary letter of advisement • Civil fine of $500~~250~~ • Civil fine of $1,000~~500~~ • Civil fine of $5,000~~1,000~~ if patient injury involved • License Suspension • License Probation • License Revocation
• Refilling Rx > 1 year than date of issue	12 AAC 52.920	• Non-disciplinary letter of advisement • Civil fine of $250 • Civil fine of $500	~~• Non-disciplinary letter of advisement~~ • Civil fine of $1,000~~250~~ • Probation, if repeated

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Current ~~PHA – disciplinary matrix –~~ as of

ALASKA BOARD OF PHARMACY - DISCIPLINARY MATRIX

• Violating a board order or agreement	12 AAC 52.920	• Non-disciplinary letter of advisement • Civil fine of $250 • Civil fine of $500	~~• Non-disciplinary letter of advisement~~ • Civil fine of $1,000~~250~~ • Civil fine of $3,000~~500~~ • Civil fine of $5,000~~1,000~~ if patient injury involved • License Suspension • License Probation • License Revocation

• Failing to provide information or providing false information on a form/application	12 AAC 52.920	• Non-disciplinary letter of advisement • Civil fine of $250 • Civil fine of $500	Refer to fraud/misrepresentation or failure to report/submit.
• Failing to establish/maintain effective controls against diversion/loss	12 AAC 52.920	• Non-disciplinary letter of advisement • Civil fine of $250 • Civil fine of $500	• Non-disciplinary letter of advisement ~~• Civil fine of $250 (non-CS)~~ • Civil fine of $1,000~~500~~total (non-CS) • Civil fine of $2,000 per each drug involved~~1,000~~ (CS)
• Failing to use reasonable knowledge, skills, judgment	12 AAC 52.920	• Non-disciplinary letter of advisement • Civil fine of $250 • Civil fine of $500	• Non-disciplinary letter of advisement • Civil fine of $500~~250~~ • Civil fine of $1,000~~500~~ • Civil fine of $5,000~~1,000~~ if patient injury involved • License Suspension • License Probation • License Revocation
• Knowingly delegating any aspect of practice of pharmacy to unlicensed person inconsistent with delegation allowed in AS 08	12 AAC 52.920	• Non-disciplinary letter of advisement • Civil fine of $250 • Civil fine of $500	• Non-disciplinary letter of advisement • Civil fine of $1,000~~250~~ no drug interaction ~~• Civil fine of $500~~ • Civil fine of $5,000~~1,000~~with drug interaction • License Suspension • License Probation • License Revocation

Current ~~PHA – disciplinary matrix –~~ as of

ALASKA BOARD OF PHARMACY - DISCIPLINARY MATRIX

• Failing to exercise adequate supervision	12 AAC 52.920	• Non-disciplinary letter of advisement • Civil fine of $250 • Civil fine of $500	• Non-disciplinary letter of advisement • Civil fine of $500~~250~~ • Civil fine of $1,000~~500~~ • Civil fine of $5,000 if patient injury involved ~~1,000~~ • License Suspension • License Probation • License Revocation
• Violating confidentiality of records	12 AAC 52.920	• Non-disciplinary letter of advisement • Civil fine of $250 • Civil fine of $500	• Non-disciplinary letter of advisement • Civil fine of $1,000~~250~~ • ~~Civil fine of $500~~ • ~~Civil fine of $1,000~~ • License Suspension • License Probation • License Revocation
• Discrimination	12 AAC 52.920	• Non-disciplinary letter of advisement • Civil fine of $250 • Civil fine of $500	• License Suspension • License Probation • License Revocation
• Offering, giving, soliciting, receiving compensation for patient referrals	12 AAC 52.920	• Non-disciplinary letter of advisement • Civil fine of $250 • Civil fine of $500	• Non-disciplinary letter of advisement • Civil fine of $250 • Civil fine of $500 • Civil fine of $1,000 • License Suspension • License Probation • License Revocation
Fraud or Misrepresentation			
• Secured or attempted to secure a license through deceit, fraud, or intentional misrepresentation	AS 08.80.261, 12 AAC 52.920	• Non-disciplinary letter of advisement • License surrender • Civil fine of $3,000	• Reprimand; Civil Fine of ~~at least~~ $5,000~~10,000~~; License suspension for a minimum of 30 days. Discipline to be commensurate with the severity of the violation. • License revocation • License suspension for up to two years AND probation for at least two years for willfully/repeatedly violating

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Current ~~PHA – disciplinary matrix –~~ as of

ALASKA BOARD OF PHARMACY - DISCIPLINARY MATRIX

			AS 08 or 12 AAC 52 OR for professional incompetence
• Engaged in deceit, fraud, or intentional misrepresentation in the course of providing professional services or engaging in professional activities;	AS 08.80.261, 12 AAC 52.920	• Non-disciplinary letter of advisement • License surrender • Civil fine of $3,000	• Reprimand; Civil Fine of $5,000~~at least $10,000~~; License suspension for a minimum of 30 days. Discipline to be commensurate with the severity of the violation. • License revocation • License suspension for up to two years AND probation for at least two years for willfully/repeatedly violating AS 08 or 12 AAC 52 OR for professional incompetence
Prohibited Advertising/Use of Symbols			
• Using the following terms without the business having a regular/continuously employing a licensed pharmacist: ○ Pharmacist ○ Assistant pharmacist ○ Druggist ○ Pharmacy ○ Drug store ○ Drug sundries ○ Drug ○ Using the symbol, "Rx".	AS 08.80.430		~~• Non-disciplinary letter of advisement~~ ~~• Civil fine of $250~~ ~~• Civil fine of $500~~ ~~• Civil fine of $1,000~~ ~~• License Suspension~~ ~~• License Probation~~ ~~• License Revocation~~Cease and Desist Order • Refer to appropriate state entity
Violation of Change Requirements			
• Pharmacist-in-charge (PIC) change notification not submitted within 30 days	AS 08.80.330(a), 12 AAC 52.200		• If 1 – 3 days = grace period • 4 – 7 days = letter of advisement • 8 – 14 days = $100 fine • 15 – 30 days = $200 fine • 30 days ≤ than a year = $300 fine • ≥ 1 year = $500 fine
• PIC failing to submit a change notification following a change in ownership, physical location, or name.	AS 08.80.330(a), 12 AAC 52.020, 12 AAC 52.200(2)		• If 1 – 3 days = grace period • 4 – 7 days = letter of advisement • 8 – 14 days = $100 fine • 15 – 30 days = $200 fine • 30 days ≤ than a year = $300 fine • ≥ 1 year = $500 fine

Current ~~PHA – disciplinary matrix –~~ as of

ALASKA BOARD OF PHARMACY - DISCIPLINARY MATRIX

• Designated representative of a facility failing to submit a change notification following a change in ownership, physical location, or name.	12 AAC 52.635		• If 1 – 3 days = grace period • 4 – 7 days = letter of advisement • 8 – 14 days = $100 fine • 15 – 30 days = $200 fine • 30 days ≤ than a year = $300 fine ≥ 1 year = $500 fine
Failure to Report/Submit			
• Failure to report information to the board relating to an applicant or licensee who was incapable of engaging in the practice of pharmacy	AS 08.80.261(a)(12)		• Non-disciplinary letter of advisement • Civil fine of $500~~250~~ • Civil fine of $1000~~500~~ • Civil fine of $5,000 if patient injury involved~~1,000~~ • Suspension • Revocation
• ~~Failure of an intern to file a report of experience within 30 days following completion or termination of an internship~~	~~12 AAC 52.220~~	NO LONGER REQUIRED	• ~~Non-disciplinary letter of advisement~~
• Failure to submit a copy of DEA form 106 following a theft or loss of a controlled substances	12 AAC 52.540		• There is no timeframe currently required in 12 AAC 52; consider requiring the form to be submitted within 1 day consistent with DEA requirements
• Failure of a licensee to report a disciplinary decision, felony charge, or criminal conviction within 30 days after the date of the disciplinary decision, felony charge, or criminal conviction.	12 AAC 52.991(a)		• 1 – 5 days late = letter of advisement • 6 days – 1 month late = $500~~250~~ fine • > 1 month – 6 months late = $1,000~~500~~ fine • > 6 months – 1 year = $2,000~~1,000~~ fine • ≥ 1 year = $3,000 with an additional $1,000 for each additional year~~1,250~~ fine • Consider severity
• Failure of a licensed facility to report any disciplinary action or any felony charge or criminal conviction under federal, state, or local law of an owner, designated representative, pharmacist-in-charge, or officer of the licensed	12 AAC 52.991(b)		• 1 – 5 days late = letter of advisement • 6 days – 1 month late = $500 fine • > 1 month – 6 months late = $1,000 fine • > 6 months – 1 year = $2,000 fine • ≥ 1 year = $3,000 with an additional $1,000 for each additional year fine

Current ~~PHA – disciplinary matrix –~~ as of

facility not later than 30 days after the date of the disciplinary decision, felony charge, or criminal conviction.			• Consider severity~~1 – 5 days late = letter of advisement~~ • ~~6 days – 1 month late = $250 fine~~ • ~~> 1 month – 6 months late = $500 fine~~ • ~~> 6 months – 1 year = $1,000 fine~~ • ~~≥ 1 year = $1,250 fine~~ • ~~Consider severity~~

Action/Authority	Criteria
Limitation 12 AAC 52.920	• Licensees who practice or attempts to practice while afflicted with a physical or mental illness, deterioration, or disability that interferes with the individual's practice of pharmacy (12 AAC 52.920(d))
Probation 12 AAC 52.930, 12 AAC 52.940, 12 AAC 52.950, 12 AAC 52.960	• Licensees completing a two-year suspension as a result of willfully/repeatedly violating statutes and/or regulations or for practicing incompetently and placing the public at risk (12 AAC 52.920(c) • Terms of probation include requirements for licensees to (12 AAC 52.930): ○ Obey all laws relating to practice of pharmacy ○ Fully comply with probation program established by board ○ Notify board in writing of dates of departure/return if the licensee leaves state ○ Report into the board during meetings ○ Submit written reports and verifications to the board ○ Submit documentation from employer acknowledging employee's probation ○ Be employed as a pharmacist only under supervision and does not act as a supervisor • Terms of probation involving alcohol or controlled substances (12 AAC 52.940): ○ Physical and mental health exams ○ Participation in rehabilitative program ○ Abstain from personal use of substance ○ Submit to testing and sampling

	○ Restricted access to controlled substances while employed • Terms of probation for professional incompetence (12 AAC 52.950): ○ Successful completion of course as determined by the board before the end of probationary period or ○ 15 additional hours of appropriate continuing education • Terms of probation for mental or physical disabilities (12 AAC 52.960; review similarities in 12 AAC 52.930): ○ Physical and mental health examinations ○ Completion of treatment program that includes progress reports from care provider

Current ~~PHA – disciplinary matrix –~~ as of

ALASKA BOARD OF PHARMACY - DISCIPLINARY MATRIX

Suspension AS 08.80.157(h)	• Pharmacies and facilities: ○ Violating state or federal law ○ Felony conviction of owner of facility ○ Providing false or fraudulent information on an application related to drug/device manufacturing or distribution ○ Suspension or revocation of federal, state, or local jurisdiction ○ Obtaining renumeration by fraud or deceit ○ Dealing with drugs or devices known to have been stolen ○ Distributing drugs or devices directly to patients without holding a wholesaler or pharmacy license ○ A pharmacy failing to comply with applicable laws (AS 08.80.158(d)) ○ • Individuals: ○ Felony conviction of pharmacy employee ○ Applicants/licensees for emergency permits/courtesy license
Revocation 12 AAC 52.920, AS 08.80.157(h)	• Licensees who practice or attempts to practice while afflicted with a physical or mental illness, deterioration, or disability that interferes with the individual's practice of pharmacy (12 AAC 52.920(d)) • Pharmacies and facilities: ○ Violating state or federal law ○ Felony conviction of owner of facility ○ Providing false or fraudulent information on an application related to drug/device manufacturing or distribution ○ Suspension or revocation of federal, state, or local jurisdiction ○ Obtaining renumeration by fraud or deceit ○ Dealing with drugs or devices known to have been stolen ○ Distributing drugs or devices directly to patients without holding a wholesaler or pharmacy license ○ A pharmacy failing to comply with applicable laws (AS 08.80.158(d)) • Individuals: ○ Felony conviction of pharmacy employee ○ Applicants/licensees for emergency permits/courtesy license

Current ~~PHA – disciplinary matrix –~~ as of

ALASKA BOARD OF PHARMACY - DISCIPLINARY MATRIX

Deny
AS 08.80.157(h), AS 08.80.261
	• Anything listed in AS 08.80.261
	• Pharmacies and facilities:
	  ○ Violating state or federal law
	  ○ Felony conviction of owner of facility
	  ○ Providing false or fraudulent information on an application related to drug/device manufacturing or distribution
	  ○ Suspension or revocation of federal, state, or local jurisdiction
	  ○ Obtaining renumeration by fraud or deceit
	  ○ Dealing with drugs or devices known to have been stolen
	  ○ Distributing drugs or devices directly to patients without holding a wholesaler or pharmacy license
	  ○ A pharmacy failing to comply with applicable laws (AS 08.80.158(d))
	• Individuals:
	  ○ Felony conviction of pharmacy employee
	  ○ Applicants/licensees for emergency permits/courtesy license

Refuse to renew
AS 08.80.157(h)
	• Pharmacies and facilities:
	  ○ Violating state or federal law
	  ○ Felony conviction of owner of facility
	  ○ Providing false or fraudulent information on an application related to drug/device manufacturing or distribution
	  ○ Suspension or revocation of federal, state, or local jurisdiction
	  ○ Obtaining renumeration by fraud or deceit
	  ○ Dealing with drugs or devices known to have been stolen
	  ○ Distributing drugs or devices directly to patients without holding a wholesaler or pharmacy license
	• Individuals:
	  ○ Felony conviction of pharmacy employee
	  ○ Applicants/licensees for emergency permits/courtesy license

*Please note - these are suggested guidelines based on case precedent for the board to consider, and the board has the ultimate and final decision.

Current ~~PHA – disciplinary matrix –~~ as of

ALASKA BOARD OF PHARMACY
Division of Corporations, Business and Professional Licensing
Department of Commerce, Community, and Economic Development
550 West 7th Avenue, Suite 1500, Anchorage, AK 99501-3567
Telephone: (907) 269-8160 Fax: (907) 269-8195

Pharmacy Inspection Report

Authority: AS 08.80.030(a)(3) and 12 AAC 52.920(7)

Pharmacy or Facility Name:	Representative during Inspection:	File #:
Address:	Position:	Date/Time:
Phone:	Business Card? Yes ◯ No ◯	Day of Week:

Pharmacist-in-Charge:

License No:

License issue date:

Pharmacist-in-Charge since:

Yes ◯ No ◯ Pharmacist-in-Charge name on the Pharmacy License? (AS08.80.330 and 08.80.157(g))

Yes ◯ No ◯ Was the Board notified of Pharmacist in Charge appointment? (12 AAC 52.200)

Is the Pharmacist-in-Charge responsible for (12 AAC 52.200) :

Yes ◯ No ◯ Training of pharmacy personnel? (Describe)

Yes ◯ No ◯ Establishing policies and procedures? (Locate and review)

Yes ◯ No ◯ Maintaining required records? (Describe)

Yes ◯ No ◯ Reporting theft or Loss? (Describe procedure)

Yes ◯ No ◯ Does the Pharmacist provide patient counseling? (12 AAC 52.505) Other:

Yes ◯ No ● Does the facility have Policies and Procedures for Pharmacy Operations? (12 AAC 52.200)

Is a Pharmacy Technician performing any of the following duties? (12 AAC 52.210)

Yes ◯ No ◯ Receiving an oral prescription drug order, including refill approval or denial that includes any change to the original prescription drug order?

Yes ◯ No ◯ Consulting with a prescriber regarding a patient or prescription?

Yes ◯ No ◯ Interpreting a prescription drug order?

Yes ◯ No ◯ Interpreting data in a patient medication record system?

Yes ◯ No ◯ Consulting with a patient or a patient's agent regarding a prescription of information contained in the patient medication record system?

DEA

Yes ◯ No ◯ Is the Pharmacy locked?

Yes ◯ No ◯ Does the Pharmacy have an alarm system?

Yes ◯ No ◯ Does the Pharmacy have all Schedule II, III, and IV drugs in a locked cabinet or dispersed throughout the secured pharmacy?

Yes ◯ No ◯ Does the Pharmacy maintain paper records for all prescriptions for two years?[i]

Yes ◯ No ◯ Does the Pharmacy store expired drugs? (12 AAC 52.410) (Describe procedure)

Facility Standards (12 AAC 52.400)

Yes ◯ No ◯ Does the Pharmacy have a sink with running Hot and Cold water?

Yes ◯ No ◯ Does the Pharmacy have a copy of the Alaska Pharmacy Statutes and Regs?

Yes ◯ No ◯ Does the Pharmacy have the phone number of the Poison Control Center?

Yes ◯ No ◯ Display of Licensure required (12 AAC 52.990)

Licensee	License Type/No.	Expiration	Other

Questions or additional information:

Confirm, sending a follow-up report to what name and address:

Investigator

(See DEA – 2 options for maintaining paper records)

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

Board of Pharmacy
PO Box 110806, Juneau, AK 99811-0806
(907) 465-2550
Email: *BoardofPharmacy@Alaska.Gov*
Website: *Pharmacy.Alaska.Gov*

Pharmacy Self-Inspection Report

Pharmacy Name:		**Date:**	
Owner Name:			
Mailing Address:			
Pharmacy License *or* Registration:		**Expiration:**	
Date of Inspection:		**Hours of Operation:**	
Telephone #:		**Fax #:**	
DEA Registration #:		**DEA Expiration:**	

Please Check:
☐ Initial Application
☐ Renewal
☐ Change in Ownership
☐ Change in Location
☐ Re-Inspection

Please Check:
☐ Retail
☐ Institutional
☐ Sterile Compounding
☐ Non-Sterile Compounding

The responsibility of the pharmacist-in-charge include compliance with all laws and regulations governing the operation of the pharmacy (12 AAC 52.200(b)(1)). Please identify the pharmacist-in-charge of the above-named pharmacy as well as other pharmacists working in the pharmacy.

Pharmacist-in-Charge:		**License #:**	

List additional Pharmacists: *Attach a separate page if necessary*

Name:		**License #:**	
Name:		**License #:**	
Name:		**License #:**	

Authority	Item	Yes	No	Comments
PHARMACY PERSONNEL (GENERAL)				
AS 08.80.330, 12 AAC 52.200	1) The pharmacy has designated a licensed pharmacist who practices in this location as the pharmacist-in-charge.	☐	☐	
AS 08.80.030, 12 AAC 52.210, 12 AAC 52.220	2) Only the pharmacist or intern, under direct supervision of the pharmacist receives oral prescription drug orders.	☐	☐	
	3) Only the pharmacist or intern, under direct supervision of the pharmacist interprets the prescription drug order and determines the product required.	☐	☐	
	4) Only the pharmacist does the final check on all aspects of the completed prescription.	☐	☐	
AS 08.80.030, AS 08.80.480, 12 AAC 52.220	5) ALL interns, graduate or undergraduate, paid or unpaid, are currently licensed by the Alaska Board of Pharmacy.	☐	☐	
	6) Interns do not represent themselves to be pharmacists.	☐	☐	
	7) Interns perform the duties of a pharmacist only under the direct supervision of a licensed pharmacist.	☐	☐	
	8) Interns do not solely sign or initial any document required to be done by the pharmacist.	☐	☐	
AS 08.80.030, 12 AAC 52.230	9) Interns do not dispense prescriptions before a final check is made by the supervising pharmacist.	☐	☐	
AS 08.80.030, AS 08.80.480, 12 AAC 52.140	10) ALL pharmacy technicians are currently licensed by the Alaska Board of Pharmacy.	☐	☐	
	11) All pharmacy technicians are under direct supervision of the pharmacist.	☐	☐	

FACILITY STANDARDS (GENERAL)				
AS 08.80.157, 12 AAC 52.400	1) The pharmacy department has a sink with hot and cold running water and is maintained in a sanitary condition.	☐	☐	
	2) The temperature of the pharmacy is maintained within a range compatible with the proper storage of drugs.	☐	☐	
	3) The pharmacy has refrigeration facilities with a thermometer and the temperature is maintained within 36 to 46 degrees Fahrenheit.	☐	☐	
AS 08.80.157, 12 AAC 52.410	4) The pharmacy has the equipment, supplies, and reference materials necessary to compound, dispense, label, administer, and distribute drugs and devices.	☐	☐	
AS 08.80.157, 12 AAC 52.420	5) All drugs and devices that have exceeded their expiration date are removed from stock, and quarantined until properly disposed of.	☐	☐	
	6) All drug, devices, and poisons restricted to sale by a pharmacist are kept in the prescription department.	☐	☐	
	7) The pharmacy department is always locked when the pharmacist is not on site.	☐	☐	
	8) The pharmacy has a separate telephone number if its hours differ from the remainder of the store.	☐	☐	
	9) Filled prescriptions are stored in the prescription department only and are not removed unless a pharmacist is present.	☐	☐	

PRACTICE STANDARDS				
AS 08.80.030, 12 AAC 52.470	1) The pharmacy maintains its prescriptions in legible form for the required two year period. 2) No prescriptions are refilled after one year from the date of issue.	☐ ☐	☐ ☐	
AS 08.80.030, 12 AAC 52.480	3) All refills are recorded electronically or on the back of the prescription drug order. 4) All schedule II - V controlled substances dispensed have the label "Caution: Federal Law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."	☐	☐	
AS 08.80.030, 12 AAC 52.490	5) All Prescriptions are labeled with the name, address, and telephone number of pharmacy, Rx number, date and pharmacist's initials. 6) All Prescriptions are labeled with patient name, prescribing practitioner, patient instructions, appropriate cautions, name, strength, and quantity of drug.	☐	☐	
AS 08.80.030, 12 AAC 52.490	7) Electronically transmitted prescriptions are only being received directly from the prescribing practitioner or the prescribing practitioner's agent. 8) All transferred prescriptions for controlled substances in Schedule III, IV, and V are transferred only once from the pharmacy which has the original prescription drug order. 9) Unless the two pharmacies share a common database, transfers of non-control prescriptions may be transferred verbally, electronically or by facsimile. 10) All transfer information is recorded can keep prescriptions, unless an automated data processing system is able to do so.	☐	☐	
AS 08.80.030, 12 AAC 52.510	11) Prescription orders transferred to another pharmacy are no longer refilled by the original pharmacy.	☐	☐	
AS 08.80.030, 12 AAC 52.520	12) When dispensing an equivalent drug product instead of the prescribed drug, the pharmacist notes on the prescription drug order either the manufacturer, distributor, NDC #, short name code, or trade name.	☐	☐	
AS 08.80.030, 12 AAC 52.530	13) If customized patient medication packages (med-paks) are prepared by the pharmacy, records are made and filed for each med-pak.	☐	☐	

AS 08.80.030, 12 AAC 52.52	14) Except in the case of a pharmacy serving an institutional facility, drugs are not accepted for return or exchange after the drugs have been taken from the premises.	☐	☐	
AS 08.80.030, 12 AAC 52.580	15) Patient records are reviewed for over or under utilization, therapeutic duplication, drug-disease, drug-food, and drug-drug interactions, reasonable dose, known allergies, and adverse drug reactions. 16) When a data processing system is used it is capable of producing an audit trail printout for all dispensing.	☐	☐	
AS 08.80.030, 12 AAC 52.585	17) When a data processing system is used it has adequate safeguards to prevent loss of data and reasonable security.	☐	☐	
	18) The pharmacist verbally provides counseling to the patient or the patient's agent with each new patient of the pharmacy, new medication for an existing patient, or a change in dose, strength, route of administration, or directions for use of an existing prescription previously dispensed.	☐	☐	

INSTITUTIONAL PHARMACY STANDARDS *(IF APPLICABLE)*				
AS 08.80.390, 12 AAC 52.700, 12 AAC 52.710	1) The institutional pharmacy is managed by a licensed pharmacist, designated to be the pharmacist-in-charge.	☐	☐	
	2) When the institutional pharmacy is closed, no access is permitted unless a person licensed to handle drugs is designated by the pharmacist-in-charge to enter the institutional pharmacy.	☐	☐	
AS 08.80.030, 12 AAC 52.720	3) When the institutional pharmacy is closed, the designated person licensed to handle drugs records the removal of any drug.	☐	☐	
	4) All E.R. outpatient prepackaged medications bear a label with the name, address, and telephone number of hospital; name, strength, quantity, lot number, and expiration of drug; appropriate cautions; and initials of pharmacist	☐	☐	
	5) Only one prepackaged container of a drug is delivered to emergency room patients unless more than one is required to sustain the patient until a retail pharmacy is open in the community.	☐	☐	

STERILE PHARMACEUTICALS *(IF APPLICABLE)*				
AS 08.80.030, 12 AAC 52.430	1) A policy and procedure manual is present for the compounding, dispensing, and delivery of sterile pharmaceuticals.	☐	☐	
	2) The pharmacy has a functionally separate area used only for the preparation of sterile pharmaceuticals.	☐	☐	
	3) The pharmacy has appropriate environmental control devices capable of maintaining at least a Class 100 environment condition for preparing sterile pharmaceuticals.	☐	☐	
	4) Cytotoxic sterile pharmaceuticals are prepared in appropriate biological safety cabinets.	☐	☐	
	5) The pharmacy uses temperature controlled delivery containers, if appropriate, for delivery of sterile pharmaceuticals to the patient.	☐	☐	
	6) The pharmacy has its laminar airflow hoods or clean rooms re-certified at least every six months.	☐	☐	
	7) The pharmacy has its laminar flow hood or clean room pre-filters replaced and documented on a regular basis.	☐	☐	
	8) The pharmacy has current copy of reference material related to sterile pharmaceutical preparation in the pharmacy.	☐	☐	
	9) All personnel participating in the preparation of sterile pharmaceuticals are trained in this specialized function.	☐	☐	
	10) The pharmacy has a licensed pharmacist accessible 24 hours a day if providing parenteral pharmaceuticals to non-hospitalized patients.	☐	☐	
	4) Cytotoxic sterile pharmaceuticals are prepared in appropriate biological safety cabinets.	☐	☐	
	5) The pharmacy uses temperature controlled delivery containers, if appropriate, for delivery of sterile pharmaceuticals to the patient.	☐	☐	
	6) The pharmacy has its laminar airflow hoods or clean rooms re-certified at least every six months.	☐	☐	
	7) The pharmacy has its laminar flow hood or clean room pre-filters replaced and documented on a regular basis.	☐	☐	

	8) The pharmacy has current copy of reference material related to sterile pharmaceutical preparation in the pharmacy.	☐	☐	
	9) All personnel participating in the preparation of sterile pharmaceuticals are trained in this specialized function.	☐	☐	
	10) The pharmacy has a licensed pharmacist accessible 24 hours a day if providing parenteral pharmaceuticals to nonhospitalized patients.	☐	☐	
	11) All sterile pharmaceuticals dispensed bear the expiration date of the preparation.	☐	☐	
	12) All cytotoxic waste is disposed of in compliance with all applicable local, state, and federal requirements.	☐	☐	
	13) A licensed pharmacist is involved in patient training that relates to sterile pharmaceuticals.	☐	☐	
	14) The pharmacy has a quality control and quality assurance program that is utilized for sterile pharmaceutical preparation and dispensing.	☐	☐	

CONTROLLED SUBSTANCES				
Controlled Substances Act of 1970	1) A Schedule V record bound book is maintained which contains name and address of purchaser, name and quantity of drug, date, and initials of pharmacist. Record book is maintained two years from date of last transaction.	☐	☐	
	2) Prescriptions are not used to supply office stock or "medical bag" for physicians.	☐	☐	
	3) All prescriptions for controlled substances are dated, contain the full name and address of the patient, and the name, address, and DEA number of the physician.	☐	☐	
	4) Schedule II prescriptions are manually signed by the physician, and Schedule II prescriptions are not refilled.	☐	☐	
	5) Schedule III, IV and V prescriptions are refilled only if authorized. Refills are not dispensed more than six months after the issue date or refilled more than five times after the issue date.	☐	☐	
	6) Controlled substances are securely locked or dispersed throughout the non-controlled inventory.	☐	☐	

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

Board of Pharmacy
PO Box 110806, Juneau, AK 99811-0806
(907) 465-2550
Email: *BoardofPharmacy@Alaska.Gov*
Website: *Pharmacy.Alaska.Gov*

Pharmacy Self-Inspection Report Signature Page

Attestation

I, the pharmacist-in-charge, state that all the statements herein contained are each and all strictly true in every respect. I understand that false or forged statements made in connection with this self-inspection report may be grounds for denial or revocation of the drug room license.

Notary Stamp				
	Pharmacist-In-Charge Printed Name:			
	Pharmacist-In-Charge Signature:			
	Notary Public for State of:		**Subscribed and Sworn to Before me on this Day:**	
	Notary's Signature:		**My Commission Expires:**	

NOTE: If any areas on the self-inspection report were checked off as not being in compliance, you must still send in the report. You then have 90 days to bring those areas into compliance. A new report will be sent to you to fill out.

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

Board of Pharmacy
PO Box 110806, Juneau, AK 99811-0806
(907) 465-2550
Email: *BoardofPharmacy@Alaska.Gov*
Website: *Pharmacy.Alaska.Gov*

Drug Room Self-Inspection Report

Official Name:			
DBA Name:			
Address:			
Telephone Number:			
Fax Number:			
Hours of Operation:			
Drug Room License Number:		**Expiration Date:**	
Consultant Pharmacist or pharmacy Name:		**License Number:**	

Check Where Applicable
☐ Initial Application
☐ Renewal
☐ Change in Ownership
☐ Change in Location
☐ Re-Inspection

In accordance with 12 AAC 52.810, a licensed drug room must continuously employ a pharmacist or have a written agreement with a pharmacy or pharmacist for consultant pharmacist services. A copy of the written agreement for consulting services must be attached.

Keep a copy of this report on file.

AUTHORITY	ITEM	YES	NO	COMMENTS
	DRUG ROOM STANDARDS			
AS 08.80.030 12 AAC 52.800	1) The drug room prepares and administers prescription drugs from bulk supplies for patients receiving treatment within the institutional facility.	☐	☐	
AS 08.80.030 12 AAC 52.800	2) The drug room stores and administers prescription drugs that are labeled and dispensed for specific patients by a pharmacy.	☐	☐	
AS 08.80.030 12 AAC 52.810	3) The drug room continuously employs a pharmacist or has a written agreement with a pharmacist for consultant pharmacist services.	☐	☐	
AS 08.80.030 12 AAC 52.820	4) The consultant pharmacist provides evaluations and recommendations concerning drug distribution, control, and use.	☐	☐	
AS 08.80.030 12 AAC 52.820	4) The consultant pharmacist completes on-site reviews to ensure that drug handling and use procedures conform to all statutes, regulations, and recognized standards of practice.	☐	☐	
AS 08.80.030 12 AAC 52.820	5) The consultant pharmacist provides drug information to facility staff and physicians, participates in the facility's staff development program, and assists in establishing policies and procedures to control the distribution and administration of drugs.	☐	☐	
AS 08.80.030 12 AAC 52.820	6) The consultant pharmacist documents pharmacy services that are provided and maintains the documentation for a period of at least two years.	☐	☐	
AS 08.80.030 12 AAC 52.830	7) Emergency drug kits are used only by personnel authorized to administer the drugs to patients receiving treatment within the institutional facility.	☐	☐	
AS 08.80.030 12 AAC 52.830	8) Emergency drug kits are provided, supplied, and maintained in accordance all statutes, regulations, and recognized standards of practice.	☐	☐	
AS 08.80.030 12 AAC 52.840	9) First dose kits are maintained only for the initiation of nonemergency drug therapy to a patient receiving treatment within the institutional facility when the necessary drug is not available from a pharmacy in time to prevent risk of harm to a patient.	☐	☐	
AS 08.80.030 12 AAC 52.840	10) First dose kits are provided, supplied, and maintained in accordance all statutes, regulations, and recognized standards of practice.	☐	☐	

FACILITY STANDARDS (GENERAL)				
AS 08.80.157 12 AAC 52.400	1) The drug room has a sink with hot and cold running water and is maintained in a sanitary condition.	☐	☐	
AS 08.80.157 12 AAC 52.400	2) The temperature of the drug room is maintained within a range compatible with the proper storage of drugs.	☐	☐	
AS 08.80.157 12 AAC 52.400	3) The drug room has refrigeration facilities with a thermometer and the temperature is maintained within 36 to 46 degrees Fahrenheit.	☐	☐	
AS 08.80.157 12 AAC 52.400	4) The drug room has the equipment, supplies, and reference materials necessary to compound, dispense, label, administer, and distribute drugs and devices.	☐	☐	
AS 08.80.157 12 AAC 52.410	5) All drugs and devices that have exceeded their expiration date are removed from stock, and quarantined until properly disposed of.	☐	☐	
AS 08.80.157 12 AAC 52.420	6) The drug room is always locked when the pharmacist is not on site.	☐	☐	
AS 08.80.157 12 AAC 52.990	7) The current drug room license and license of the consultant pharmacist are displayed.	☐	☐	
CONTROLLED SUBSTANCES				
Controlled Substances Act of 1970	1) Drug room supplies are not used to supply office stock or "medical bag" for physicians.	☐	☐	
Controlled Substances Act of 1970	2) All prescriptions for controlled substances are dated, contain the full name and address of the patient, and the name, address, and DEA number of the physician.	☐	☐	
Controlled Substances Act of 1970	3) Schedule II prescriptions are manually signed by the physician, and Schedule II prescriptions are not refilled.	☐	☐	
Controlled Substances Act of 1970	4) Controlled substances are securely locked or dispersed throughout the noncontrolled inventory.	☐	☐	

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

Board of Pharmacy
PO Box 110806, Juneau, AK 99811-0806
(907) 465-2550
Email: *BoardofPharmacy@Alaska.Gov*
Website: *Pharmacy.Alaska.Gov*

Drug Room Self-Inspection Report Signature Page

Attestation

I, the consulting pharmacist, state that all the statements herein contained are each and all strictly true in every respect.

I understand that false or forged statements made in connection with this self-inspection report may be grounds for denial or revocation of the drug room license.

Notary Stamp	**Consulting Pharmacist Printed Name:**			
	Consulting Pharmacist Signature:			
	Notary Public for State of:		**Subscribed and Sworn to Before me on this Day:**	
	Notary's Signature:		**My Commission Expires:**	

NOTE: If any areas on the self-inspection report were checked off as not non-compliant, you must still send in the report. You then have 90 days to bring those areas into compliance. A new report will be sent to you to fill out.

THE STATE of ALASKA
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Website: *Pharmacy.Alaska.Gov*

Remote Pharmacy Self-Inspection Report

Remote Pharmacy Owner Name:	
DBA Name:	
Address:	
Telephone Number:	
Fax Number:	
Hours of Operation:	
Remote Pharmacy License Number:	
DEA Number and Expiration:	
Central Pharmacy Owner Name:	
DBA Name:	
Address:	
Telephone Number:	
Fax Number:	
Hours:	
Central Pharmacy License Number:	
DEA Number and Expiration:	
Pharmacist-in-Charge and License Number:	

Remote Pharmacy Staff: *Must be staffed by pharmacist, pharmacy technician, or pharmacy intern*

☐ Pharmacist	☐ Technician	☐ Intern
☐ Pharmacist	☐ Technician	☐ Intern
☐ Pharmacist	☐ Technician	☐ Intern
☐ Pharmacist	☐ Technician	☐ Intern

Check Where Applicable

- ☐ Initial Application
- ☐ Renewal
- ☐ Change in Ownership
- ☐ Change in Location
- ☐ Re-Inspection

Check Where Applicable

- ☐ Retail
- ☐ Institutional

12 AAC 52.200(b)(1)
Pharmacist-in-Charge
The responsibility of the pharmacist-in-charge include compliance with all laws and regulations governing the operation of the pharmacy.

AUTHORITY	ITEM	YES	NO	COMMENTS
	PHARMACY PERSONNEL (GENERAL)			
AS 08.80.330 12 AAC 52.200	1) The central pharmacy has designated a licensed pharmacist as the pharmacist-in-charge.	☐	☐	
AS 08.80.030 12 AAC 52.210 12 AAC 52.220	2) Only the pharmacist or intern, under direct supervision of the pharmacist receives oral prescription drug orders or refill approvals that include any change to the original Rx or drug order.	☐	☐	
	3) Only the pharmacist or intern, under direct supervision of the pharmacist interprets the prescription drug order and determines the product required.	☐	☐	
	4) Only the pharmacist does the final check on all aspects of the completed prescription.	☐	☐	
AS 08.80.030 AS 08.80.480 12 AAC 52.220	5) ALL interns, graduate or undergraduate, paid or unpaid, are currently licensed by the Alaska Board of Pharmacy.	☐	☐	
	6) Interns do not represent themselves to be pharmacists.	☐	☐	
	7) Interns perform the duties of pharmacist only under the direct supervision of a license pharmacist.	☐	☐	
	8) Interns do not solely sign or initial any document required to be done by the pharmacist.	☐	☐	
AS 08.80.030 12 AAC 52.230	9) Interns do not dispense prescriptions before a final check is made by the supervising pharmacist.			
AS 08.80.030 AS 08.80.480 12 AAC 52.140	10) ALL pharmacy techinians are currently licensed by the Alaska Board of Pharmacy.	☐	☐	
AS 08.80.030 12 AAC 52.230	11) All pharmacy technicians are under direct supervision of the pharmacist.	☐	☐	
AS 08.80.157 12 AAC 52.400	**FACILITY STANDARDS (GENERAL)**			
AS 08.80.157 12 AAC 52.400	1) The pharmacy department has a sink with hot and cold running water and is maintained in a sanitary condition.	☐	☐	

AUTHORITY	ITEM	YES	NO	COMMENTS
AS 08.80.157 12 AAC 52.400	2) The temperature of the pharmacy is maintained with a range compatible with the proper storage of drugs.	☐	☐	
AS 08.80.157 12 AAC 52.400	3) The pharmacy has refrigeration facilities with a thermometer and the temperature is maintained within 36 to 46 degrees Fahrenheit.	☐	☐	
AS 08.80.157 12 AAC 52.420	4) All drugs and devices that have exceeded their expiration date are removed from stock, and quarantined until properly disposed of.	☐	☐	
AS 08.80.157 12 AAC 52.425	5) The remote pharmacy department is always locked when the pharmacist is not available for direct supervision.	☐	☐	
AS 08.80.157 12 AAC 52.425	6) Filled prescriptions are stored in the prescription department only and are not removed unless a pharmacist at the central pharmacy has verified the finished prescription product through the telepharmacy system.	☐	☐	
AS 08.80.030 12 AAC 52.450	**PRACTICE STANDARDS**			
AS 08.80.030 12 AAC 52.425	1) The remote pharmacy maintains a record of all prescriptions filled at that location in numerical order.	☐	☐	
AS 08.80.030 12 AAC 52.470	2) The pharmacy maintains its prescriptions in legible form for the required two year period.	☐	☐	
AS 08.80.030 12 AAC 52.470	3) No prescriptions are refilled after one year from the date of issue.	☐	☐	
AS 08.80.030 12 AAC 52.480	4) All refills are recorded electronically or on the back of the prescription drug order at the central pharmacy.	☐	☐	
AS 08.80.030 12 AAC 52.480	5) All schedule II – V controlled substances dispensed have the label "Caution: Federal Law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."	☐	☐	
AS 08.80.030 12 AAC 52.480	6) All prescriptions are labeled with the name, address, and telephone number of the dispensing pharmacy, Rx number, date and initials of the dispensing pharmacist.	☐	☐	
AS 08.80.030 12 AAC 52.480	7) All prescriptions are labeled with patient name, prescribing practitioner, patient instructions, appropriate cautions, name, strength, and quantity of drug.	☐	☐	

AUTHORITY	ITEM	YES	NO	COMMENTS
AS 08.80.030 12 AAC 52.425	8) Drugs are shipped to remote pharmacy only from its central pharmacy.	☐	☐	
AS 08.80.030 12 AAC 52.425	9) Itemized lists of drugs sent are kept at remote site and central pharmacy for at least 2 years from the date the drugs are shipped.	☐	☐	
AS 08.80.030 12 AAC 52.425	10) Itemized records of drugs shipped or received are verified by supervising pharmacist.	☐	☐	
AS 08.80.030 12 AAC 52.425	11) A pharmacist conducts a physical inventory at the remote site at least annually.	☐	☐	
AS 08.80.030 12 AAC 52.425	12) The telepharmacy system has been tested by the supervising pharmacist of the central pharmacy and found to operate properly.	☐	☐	
AS 08.80.030 12 AAC 52.425	13) The telepharmacy system includes one of the following: (1) still image capture, (2) realtime link, (3) store and forward.	☐	☐	
AS 08.80.030 12 AAC 52.520	14) Except in the case of a pharmacy serving an institutional facility, drugs are not accepted for return or exchange after the drugs have been taken from the premises.	☐	☐	
AS 08.80.030 12 AAC 52.580	15) Patient records are reviewed for over or under utilization, therapeutic duplication, drug-disease, drug-food, and drug-drug interactions, reasonable dose, known allergies, and adverse drug reactions.	☐	☐	
AS 08.80.030 12 AAC 52.580	16) When a data processing system is used it is capable of producing an audit trail printout for all dispensing.	☐	☐	
AS 08.80.030 12 AAC 52.585	17) When a data processing system is used it has adequate safeguards to prevent loss of data and reasonable security.	☐	☐	
AS 08.80.030 12 AAC 52.585	18) The pharmacist verbally provides counseling to the patient or the patient's agent with each new prescription.	☐	☐	
AS 08.80.390 12 AAC 52.700	**REMOTE INSTITUTIONAL PHARMACY STANDARDS *(IF APPLICABLE)***	☐	☐	
AS 08.80.030 12 AAC 52.530	1) If customized patient medication packages (med-paks) are prepared by the pharmacy, records are made and filed for each med-pak.	☐	☐	

AUTHORITY	ITEM	YES	NO	COMMENTS
AS 08.80.030 12 AAC 52.710	2) The institutional pharmacy is managed by a licensed pharmacist, designated to be the pharmacist-in-charge.	☐	☐	
AS 08.80.030 12 AAC 52.720	3) When the institutional pharmacy is closed, the designated person licensed to handle drugs records the removal of any drug.	☐	☐	
AS 08.80.030 12 AAC 52.720	4) All E.R. outpatient prepackaged medications bear a label with the name, address, and telephone number of hospital; name, strength, quantity, lot number, and expiration of drug; appropriate cautions; and initials of pharmacist.	☐	☐	
	5) Only one prepackaged container of drug is delivered to emergency room patients unless more than one is required to sustain the patient until a retail pharmacy is open in the community.	☐	☐	
Controlled Substances Act of 1970	**CONTROLLED SUBSTANCES**			
Controlled Substances Act of 1970	1) Prescriptions are not used to supply office stock or "medical bag" for physicians.	☐	☐	
	2) Controlled substances are securely locked or dispersed throughout the non-controlled inventory.	☐	☐	

THE STATE of ALASKA
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Remote Pharmacy Self-Inspection Report Signature Page

Attestation

I, the pharmacist-in-charge, state that all the statements herein contained are each and all strictly true in every respect.

I understand that false or forged statements made in connection with this self-inspection report may be grounds for denial or revocation of the Remote Pharmacy license.

Notary Stamp	**Pharmacist-in-Charge Printed Name:**			
	Pharmacist-in-Charge Signature:			
	Notary Public for State of:		**Subscribed and Sworn to Before me on this Day:**	
	Notary's Signature:		**My Commission Expires:**	

NOTE: If any areas on the self-inspection report were checked off as not non-compliant, you must still send in the report. You then have 90 days to bring those areas into compliance. A new report will be sent to you to fill out.

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Self-Inspection Report

PART I Application Type

Application Type:	☐ Initial Application ☐ Renewal ☐ Re-Inspection ☐ Change in Ownership ☐ Change in Location ☐ Change in Name

PART II Facility Information

Facility Type:	☐ Wholesale Drug Distributor ☐ Outsourcing Facility ☐ Third Part Logistics Provider		
Owner Name:			
DBA Name:		**Hours of Operation:**	
Address:	Street City State Zip		
Email:		**Contact Phone:**	
License Number:		**Expiration Date:**	
Facility Manager:			

Keep a copy of this report on file.

PART III Report Information

Authority	Item	Yes	No	Comments
AS 08.80.030, 12 AAC 52.620	The facility has storage areas that ensure proper lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions.	☐	☐	
AS 08.80.030, 12 AAC 52.620	The facility is equipped with an alarm system to detect entry after hours.	☐	☐	
AS 08.80.030, 12 AAC 52.620	The facility has external lighting along the outside perimeter of the facility.	☐	☐	
AS 08.80.030, 12 AAC 52.620	The facility has restricted entry into drug storage areas and is open to authorized personnel only.	☐	☐	
AS 08.80.030, 12 AAC 52.620	The facility has a quarantine area for storage of drugs that are outdated, damaged, or deteriorated.	☐	☐	
AS 08.80.030, 12 AAC 52.620	The facility has storage areas that are free from infestation by insects, rodents, birds, or vermin of any kind.	☐	☐	
AS 08.80.030, 12 AAC 52.620	The facility has internal security policies to provide reasonable protection from theft or diversion of drugs by personnel.	☐	☐	
AS 08.80.030, 12 AAC 52.625	The facility maintains a roster of all officers, directors, and managers responsible for wholesale drug distribution.	☐	☐	
AS 08.80.030, 12 AAC 52.630	The facility has appropriate records kept for ensuring proper temperature and humidity of drug storage.	☐	☐	
AS 08.80.030, 12 AAC 52.640	The facility has written policies and procedures for drug handling and storage.	☐	☐	
AS 08.80.030, 12 AAC 52.650	The facility maintains records and inventories of all transactions or drug products for the last two years.	☐	☐	
AS 08.80.030, 12 AAC 52.670	The facility has a written policy for the handling of a recall of a drug product.	☐	☐	
AS 08.80.030, 12 AAC 52.685	The facility does not distribute drugs directly to a consumer or patient.	☐	☐	

THE STATE of ALASKA

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PHA

FOR DIVISION USE ONLY

Board of Pharmacy
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Email: *BoardOfPharmacy@Alaska.Gov*
Website: *ProfessionalLicense.Alaska.Gov/BoardOfPharmacy*

Notary Signature Page

PART IV Notarized Signature

I hereby certify that I am the person herein named and subscribing to this application and that I have read the complete application, and I know the full content thereof. I declare that all of the information contained herein, and evidence or other documents submitted herewith are true and correct.

I understand that any falsification or misrepresentation of any item or response in this application, or any attachment hereto, or falsification or misrepresentation of documents to support this application, is sufficient grounds for denying, revoking, or otherwise disciplining a license or permit to practice in the state of Alaska.

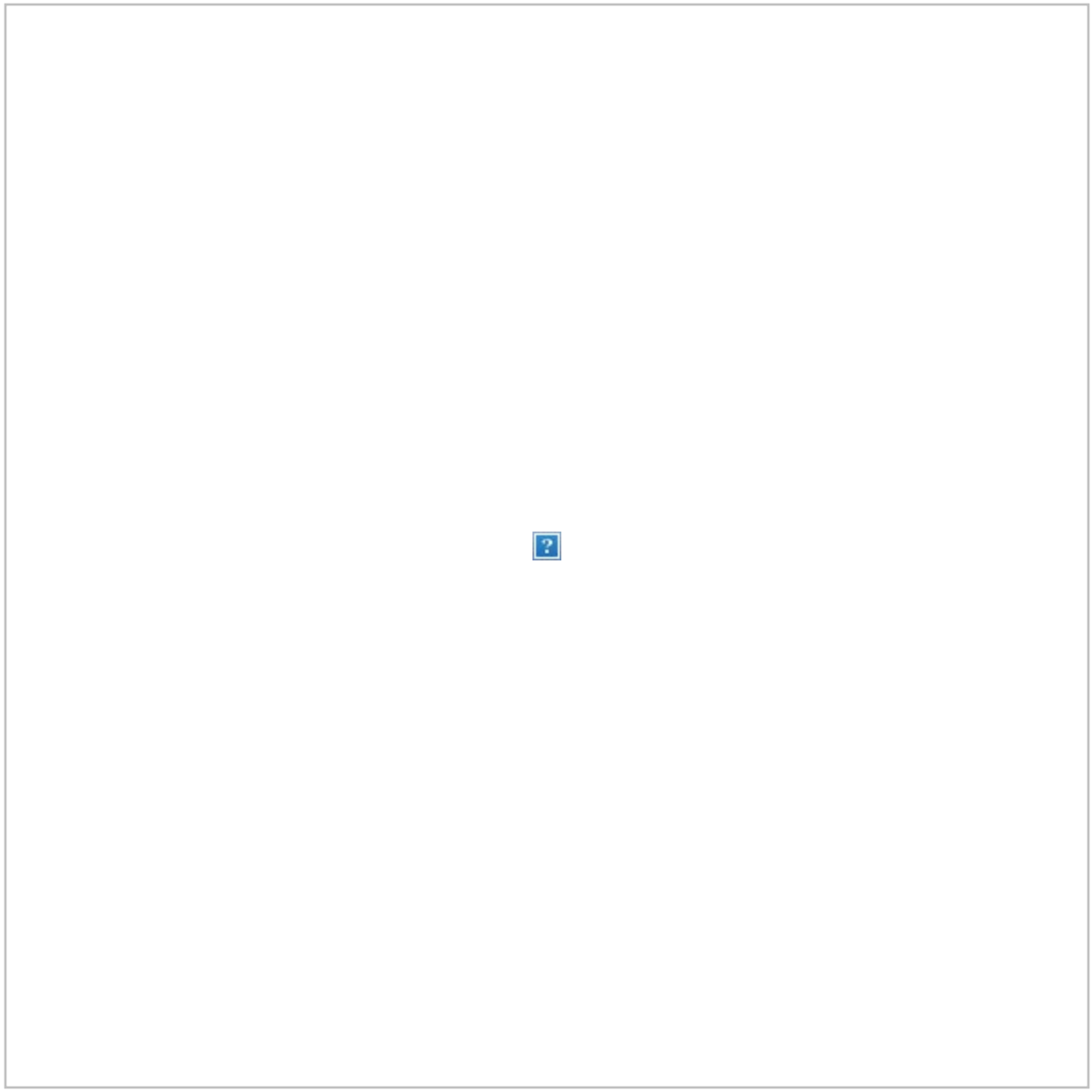
I further understand that it is a Class A misdemeanor under Alaska Statute 11.56.210 to falsify an application and commit the crime of unsworn falsification.

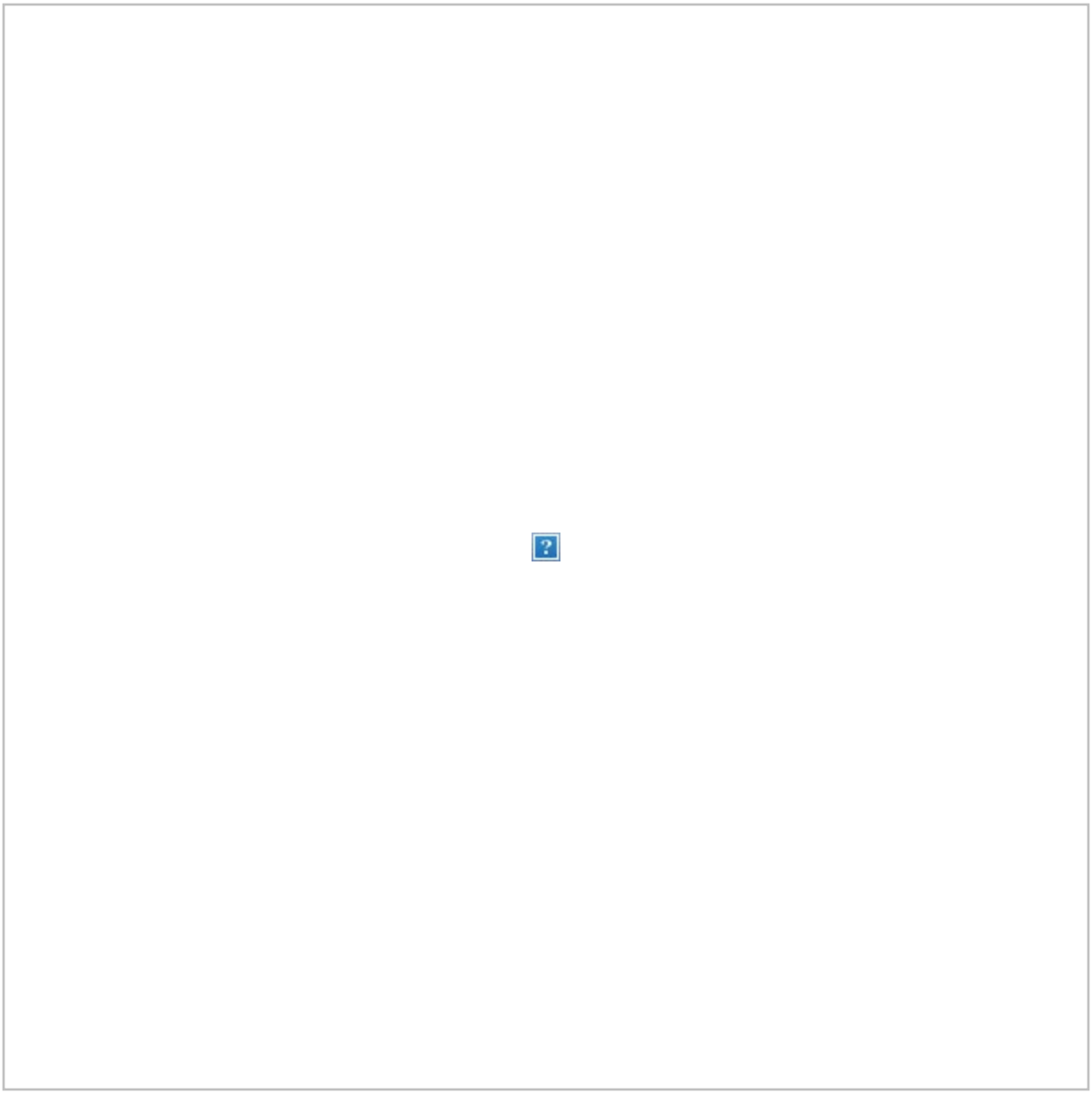
A person who makes a false statement on this application may be subject to civil and criminal penalties, including prosecution for perjury (AS 11.56.200 & AS 11.56.230).

Notary Stamp				
	Facility Manager Printed Name:			
	Facility Manager Signature:			
	Notary Public for State of:		**Subscribed and Sworn to Before me on this Day:**	
	Notary Signature:		**My Commission Expires:**	

From: Schaber, Ashley R
To: Schaber, Ashley R
Subject: FW: APhA meets with DEA officials
Date: Sunday, March 3, 2024 7:55:57 PM

Subject: APhA meets with DEA officials





Dear member,

Pharmacies and pharmacists are on pins and needles with anything related to controlled substances. APhA, along with the National Community Pharmacists Association (NCPA) and the National Association of Chain Drug Stores (NACDS), met with high-level DEA officials on Wednesday, January 31, 2024, to discuss concerns related to heightened scrutiny, audits, dispensing ratios, buprenorphine, and more.

We explained that heightened scrutiny by wholesalers and DEA is hindering patient care, and that more transparency is needed from wholesalers and DEA regarding expectations, ratios, and red flags. We noted the changes in several states regarding the pharmacist's role in dispensing medications for opioid use disorder (MOUD) and that repressive scrutiny and other barriers remain. DEA acknowledged their understanding of the current situation within pharmacies and maintained that they recognize the importance of access to MOUD. DEA further outlined that they do not require, nor set, ratios for wholesalers; rather, ratios are guided by agreements resulting from the multidistrict opioid litigation (MDL). APhA will

continue to work closely on this issue with all relevant parties.

During our conversation where we sought clarification and solutions, DEA asked us to share with you safety measures for pharmacies related to burglaries. DEA asks the pharmacy community, particularly independent pharmacies, to examine their security inside and outside their pharmacies because of a rash of burglaries across the country. They touched on a few security best practices, including placement of cameras, motion sensors, reinforcements, and other multilayer approaches, which we will share with you in the near future. In the meantime, explore where you can strengthen your pharmacy's security and monitoring.

We had an open exchange of ideas, and DEA plans to hold a public discussion on this topic later in the year. There's more work to be done to ease the burdens pharmacists and pharmacies face, but the lines of communication are open and APhA will continue to advocate for change on your behalf.

Please continue to share your experiences to further inform our dialogue and outreach.

Thank you,

Ilisa Bernstein, PharmD, JD, FAPhA
Senior Vice President, Pharmacy Practice & Government Affairs

Congressional Research Service
Informing the legislative debate since 1914

Legal Sidebar

Overview of the Opioid Litigation and Related Settlements and Settlement Proposals

November 25, 2019

According to the latest available data from the Centers for Disease Control and Prevention, the opioid epidemic has claimed the lives of nearly 400,000 people in the United States between 1999 and 2017. As described in an earlier Sidebar, the severity of the epidemic has prompted state and local governments to address the issue not only through legislation and executive actions, but also through court challenges filed around the country that seek to hold certain opioid manufacturers, distributors, or other supply chain entities legally liable for the epidemic. These challenges—which generally seek to recover the costs incurred or will be incurred by the state and local governments to address the epidemic—have generally proceeded in two settings:

- In the opioid multidistrict litigation (MDL) formed in a federal district court, where more than 2,400 cases filed by local governments (and other non-governmental plaintiffs) have been coordinated;
- In various state courts, where state governments have filed their cases.

In recent months, several case settlements or settlement proposals related to these cases have been announced. Some of the settlements are more typical litigation settlements that would settle claims against a defendant in a specific case. Other settlement proposals would more broadly settle cases across both the MDL and state courts. One global settlement proposal, for instance, would globally settle claims against Purdue Pharma, the maker of OxyContin. Under another proposal, four state attorneys general (from North Carolina, Pennsylvania, Tennessee, and Texas) reached a $48 billion global settlement framework with three major drug distributors and two drug manufacturers. This proposal would resolve all state and local government opioid claims against those companies in all 50 states and the District of Columbia. Representatives of certain local governments—particularly those that have cases pending in the MDL—have, however, already voiced their public rejection of this settlement framework.

As Congress continues to analyze the opioid litigation and consider ways to address the opioid epidemic, this Sidebar provides an overview of the pending state and local government opioid litigation and the related settlements or settlement proposals.

Congressional Research Service
https://crsreports.congress.gov
LSB10365

Overview of the State and Local Government Opioid Litigation

The state and local government opioid cases, generally filed against various entities along the opioid prescription supply chain, seek damages resulting from the opioid epidemic. Specifically, as to the opioid manufacturers, the suits have typically alleged that these companies initiated false and misleading marketing campaigns in the 1990s to increase opioid prescriptions. These campaigns allegedly promoted certain improper pain management practices, understated the opioids' risk of addition, and overstated their efficacy. The campaigns' success in altering prescription practices allegedly led to a significant increase in opioid prescription and usage that generated and fueled the opioid epidemic in the affected communities. Among other claims, the complaints typically allege that these marketing practices constitute a civil violation of the Racketeer Influenced and Corrupt Organizations (RICO) Act, created a public nuisance under relevant state law, and violate state consumer protection law. Suits that have been brought against drug distributors, which supply opioids to pharmacies and health care providers, have typically alleged that these companies failed to comply with relevant federal and/or state law that required these entities to monitor for suspicious orders of opioid products to prevent their diversion to illicit markets. By allegedly failing to comply with these requirements, the complaints maintain that distributors fueled the opioid epidemic by allowing disproportionately large orders of prescription opioids to flood into comparatively small communities.

Like the cases that states filed more than two decades ago seeking to recover from tobacco manufacturers the costs incurred for treating smoking-related diseases, the opioid suits generally seek to recover from the defendants the costs the government plaintiffs allegedly expended and expect to be expended to abate the resulting public health crisis. These damages include costs for medical care (including through Medicaid spending), drug treatment, law enforcement, and other social and emergency response services. Unlike the tobacco cases, which states brought and involved relatively few local government plaintiffs, many local governments have initiated their own actions in the opioid context. In general, the state attorneys generals have filed the state government cases in the relevant state courts while the local government opioid cases have been coordinated (along with cases filed by other non-governmental plaintiffs) in the federal MDL.

Recent Notable Developments in the Federal MDL

Pursuant to a special federal procedure designed to streamline the handling of certain complex civil litigation, the federal opioid MDL was formed in the Northern District of Ohio before Judge Dan Polster. The MDL procedures generally permit the Judicial Panel on Multidistrict Litigation (JPML) to transfer civil actions separately filed in different federal districts to a single federal district court for coordinated pretrial proceedings, if the JPML determines that the actions involve one or more common questions of fact. The rules generally require the cases to be remanded back to the transferor court for trial at the conclusion of the pretrial proceedings. In practice, however, most MDL cases are resolved through aggregate settlements in the transferee courts or are finally resolved in other ways there without ever returning to the transferor court.

The JPML formed the opioid MDL in December 2017 after over 60 cities and counties around the country filed, based on the legal theories described above, opioid suits in (or had their suits removed to) various federal district courts. As noted above, the MDL now includes over 2,400 cases that are coordinated before Judge Polster for pretrial proceedings. The MDL proceedings have so far focused on the local government cases because Judge Polster designated two sets of such actions as the first bellwether cases to go to trial. Bellwether cases in an MDL are typically selected because they address legal and/or factual

issues that are shared among the rest of the MDL cases, and, as such, the process of litigating these cases can help litigants understand the strengths and weaknesses of their case and help encourage settlement. In the opioid MDL, the claims of Summit and Cuyahoga counties in Ohio against certain opioid manufacturers and distributors are the first set of bellwether cases and thus have been the focus of the MDL litigation and settlement discussions to date. A second set of bellwether cases involve the claims made against various drug distributors by Cabell County, West Virginia and the City of Huntington in that county.

Even though the MDL court has jurisdiction over only the MDL cases, Judge Polster acknowledged that he has been "very active" in encouraging all sides to consider a broader, global settlement as a means of resolving the opioid cases filed in both the MDL and state courts. He has publicly stated his general view that, given the extent of the opioid crisis, multiple parties, including the MDL defendants, plaintiffs, the federal government, the medical professions, and individual opioid users bear responsibility for the crisis. Thus, in his view, a global settlement that would provide funds to address the epidemic while also implementing additional controls on the flow and proper use of prescription opioids would be the most desirable outcome. In furtherance of this stated goal (which drew objections from certain MDL defendants in the form of a recusal motion that was ultimately rejected by the Sixth Circuit), Judge Polster has sought to coordinate settlement-related discussions not only among the MDL litigants, but also with the state attorneys generals and the Drug Enforcement Administration (DEA). In September 2019, he also certified a novel "negotiation class" comprised of "all cities and counties in the United States" (which would encompass over 33,000 local governments) for the purpose of "creating a unified body to enter into further negotiations" with the MDL defendants. The certification order—novel in part because the local governments generally did not file their cases as class actions—is currently subject to two separate appeals, one by certain distributor defendants in the MDL, and another by certain city plaintiffs in the MDL.

Judge Polster's settlement efforts to date have resulted in settlements with most defendants in the Ohio bellwether cases, including all manufacturer defendants as well as the three major drug distributor defendants. These settlements leave only a number of pharmacy chains that have been sued in their capacity as drug distributors (including Walgreens, Rite Aid, CVS, and Walmart) as the remaining defendants in the Ohio bellwether cases. In addition, Judge Polster stated that the discussions have also helped to precipitate a tentative, broader agreement to settle the claims against Purdue Pharma brought by the local government MDL plaintiffs as well as roughly half of the state attorneys general. Because Purdue Pharma filed for bankruptcy as part of that agreement, the settlement proposal is now subject to approval through the bankruptcy proceedings; as part of the proceedings, the bankruptcy judge has temporarily stayed the roughly 2,600 opioid suits against Purdue. As to the remaining MDL proceedings, Judge Polster has set an October 2020 trial date for the remaining defendants in the Ohio bellwether cases. He has also recommended, given the scope of the opioid MDL, that the JPML strategically remand three cases back to their transferor courts for trial while he continues to preside over the remaining cases and also pursue global settlement discussions.

Recent Notable Developments in the State Litigation

In addition to the federal MDL cases, many state attorneys general have also filed suits in state courts against similar defendants based on comparable claims and allegations as in the MDL cases. By one available tally, 48 states (plus Puerto Rico and the District of Columbia) have filed 89 opioid suits in various state courts as of November 2019. To date, the state attorney general actions have resulted in two key, very different outcomes. First, in an action the North Dakota Attorney General filed against Purdue Pharma that asserted various state law claims based on Purdue's alleged fraudulent and deceptive marketing campaigns to increase the sales of its opioid products, the court dismissed the state's claims on a motion to dismiss. In particular, the court concluded that the federal Food, Drug, and Cosmetic Act

preempted the state's claims because the marketing campaigns were consistent with FDA-approved indication and labeling for the drugs. The North Dakota Attorney General has appealed the lower court's decision to the state supreme court.

Second, the Oklahoma Attorney General initiated a similar action against a number of opioid manufacturers, including Purdue, Teva Pharmaceuticals, and Johnson & Johnson. While Purdue and Teva Pharmaceuticals each settled the claims against them in May 2019, the claims against Johnson & Johnson proceeded to a bench trial—the first trial in any state or federal opioid litigation—on a claim of public nuisance. Following a 33-day bench trial, the court concluded that Johnson & Johnson had "engaged in false and misleading marketing of both their drugs and opioids generally" that "caused exponentially increasing rates of addiction, overdose deaths, and Neonatal Abstinence Syndrome," amounting to a public nuisance under Oklahoma law. The court further concluded that the underlying nuisance could be abated under the state's abatement plan, which includes:

- providing a number of opioid treatment programs;
- incorporating universal screening programs at all primary care practices and emergency departments;
- providing a pain management benefit program;
- expanding naloxone distribution and overdose prevention education, providing medical treatment for infants with Neonatal Abstinence Syndrome; and
- providing funding for certain state law enforcement and regulatory agencies.

While the court noted that the state had offered witnesses who testified that the plan "will take at least 20 years" to work, the court concluded that the state did not present "sufficient evidence of the amount of time and costs necessary, beyond year one, to abate the Opioid Crisis." Accordingly, the court awarded the state abatement proceeds in the sum of approximately $465 million, the estimated amount to carry out the abatement plan in the first year. Johnson & Johnson has appealed the court's judgment to the Oklahoma Supreme Court.

As the state attorneys general litigate the states' opioid cases in state courts, they have taken different stances on the federal MDL cases brought by local governments. Available reports show that many have participated, in varying degrees, in settlement discussions in the federal MDL. Some, however, have expressed the view that the local government suits should be dismissed because they infringe upon the states' authority to assert claims for harms to their citizens' health and welfare. In the weeks leading up to the first bellwether trial in the federal MDL, the Ohio Attorney General, supported by thirteen other state attorneys general, petitioned the Sixth Circuit to block or delay the trial on that basis. The Sixth Circuit denied the petition.

As an additional indication of the tension between state and local governments, four state attorneys general, announced a global settlement framework to which certain local government representatives have already voiced public objections. The proposal would require the settling companies (including drug manufacturers Johnson & Johnson and Teva Pharmaceuticals, and drug distributors AmerisourceBergen, Cardinal Health, and McKesson) to pay $22 billion in cash and an additional $26 billion in (1) medication to treat opiate addiction, (2) product distribution costs for those treatment products, and (3) data-tracking measures. The $22 billion cash settlement would be divided among the states and the local governments based on a formula to be determined and would be used to abate the opioid crisis. Additionally, Johnson & Johnson and Teva would also agree not to market any opioid products while the distributors would agree to implement additional internal processes to monitor and flag suspicious orders of opioids. It remains to be seen whether, and to what extent, other states and local governments would join this global settlement framework.

The sprawling nature of the state and local government opioid litigation suggests that any global settlements across the two litigation tracks may be of significant magnitude, and the terms of the settlements may affect how the opioid epidemic is addressed nationally. Thus, as Congress continues to consider ways to address the epidemic, including ways to coordinate its efforts with state and local governments, the ongoing settlement discussions in the opioid litigation may be something for Congress to watch.

Author Information

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Disclaimer

ALASKA BOARD OF PHARMACY
TASK LIST - ACTION ITEMS
(as of 03/20/2024)

Outstanding Action Items from Previous Meetings	
	Review and update the disciplinary matrix
	Send Martinez application back to Investigations for consent agreement – Mike – OnBoard Vote when signed by applicant
	Task created for the board to pursue additional training on just culture. Add to August Agenda

Action Items from February 15, 2024 Meeting	
	Task created for all board members to review and provide input on the professional fitness questions to address at the next meeting.
	Task created for the board to review the inspection sheet to incorporate continuous quality improvement.
	Task created for the board to put Just Culture on the April agenda and continue the conversation with other boards. Add to August Agenda
	Task created for Michael Bowles to bring the Executive Administrators for the medical board and board of nursing into the conversation with Linda Smith and Ursula McVeigh
	Task created for the board to request the nursing and medical board chairs to collaborate on a letter of resolution to the DEA.
	Task for a member of the board to write a FAQ addressing palliative care and opioid shortages.
	Task created for Michael Bowles to find how many Pharmacy Technicians are in state vs out of state.
	Task created to have Michael schedule the board with the statute and regulations meeting and a meeting with investigations staff concerning recusal during investigative matters.
	Task created to have Michael Bowles follow up with Idaho and Senior Investigator Homestead on DEA 106s.
	Task created to have Michael Bowles see if a regulation cleanup can happen for pharmacy technician language throughout regulations. Started 03/30/2024 – Needs Reg Project, after June
	Task for Ashley to get letter in for national legislation.

Alaska Board of Pharmacy

Agenda Item #13

Chair Final Comments

MEETING EVALUATION

Board/Commission: _____ **Date:** _____ **Member Name** _____

Goal	Agree	Needs Improvement	Suggestions for Improvement
1. The agenda was clear, supported by the necessary documents, and circulated prior to the meeting.			
2. All board members were prepared to discuss materials sent in advance.			
3. Documents were clear and contained needed information.			
4. A variety of opinions was expressed and issues were managed in a respectful manner.			
5. The chair guided the meeting effectively and members participated respectfully and responsibly.			
6. Next steps were identified and responsibility assigned.			
7. All board members were present.			
8. The meeting began and ended on time.			
9. Meeting accommodations were satisfactory.			
10. Presentations/interaction with public and guests was appropriate, productive, and efficient.			
11. The board had enough information to make good decisions on issues.			
12. The objectives of the meeting were met or appropriately tabled until a subsequent scheduled meeting.			

Other Comments (What went well, what needs to be done better next time):

Alaska Board of Pharmacy

Agenda Item #14

Adjourn