June 16, 2022 - Alaska Board of Pharmacy Meeting

Alaska Division of Corporations, Business and Professional Licensing
https://us02web.zoom.us/meeting/register/tZMlcu2srDkiHNCcFLpSW-mIts1O60v1eTMP
Jun 16, 2022 9:00 AM - Jun 23, 2022 3:00 PM AKDT

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STATE OF ALASKA

Department of Commerce, Community, and Economic Development
Professional Licensing

ALASKA BOARD OF PHARMACY

June 16, 2022 Meeting

Board Packet

Alaska Board of Pharmacy Roster

Board Member Name	Initial Appointment	Reappointed	Term End
Justin Ruffridge, PharmD (Chair)	03/01/2020	03/01/2019	03/01/2024
Ashley Schaber, PharmD (Vice Chair)	07/01/2021		03/01/2024
James Henderson, RPh	03/01/2017	03/01/2017	03/01/2025
Leif Holm, PharmD	03/01/2015		03/01/2023
Ramsey Bell, RPh	03/01/2022		03/01/2026
Vacant (Public Member)			
Vacant (Public Member)			

Position	Name
Chair	Justin Ruffridge
Vice Chair	Ashley Schaber
CSAC Chair/Delegate	Justin Ruffridge
Secretary	James Henderson

Updated 03/24/2022

State of Alaska 2022 HOLIDAY CALENDAR

State Holidays

Date	Holiday
01/01/2022	New Year's Day (observed 12/31/2021)
01/17/2022	MLK Jr.'s Birthday
02/21/2022	Presidents' Day
03/28/2022	Seward's Day
05/30/2022	Memorial Day
07/04/2022	Independence Day
09/05/2022	Labor Day
10/18/2022	Alaska Day
11/11/2022	Veterans' Day
11/24/2022	Thanksgiving Day
12/25/2022	Christmas Day (observed 12/26/2022)

Please refer to appropriate collective bargaining unit agreement for more information regarding holidays.

Holiday

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State calendar maintained by the
Division of Finance, Department of Administration

http://doa.alaska.gov/calendars.html

Revised 01/11/2

ALASKA BOARD OF PHARMACY MEETING

TENTATIVE AGENDA

JUNE 16, 2022 MEETING

Meeting ID: 878 5442 2864
Passcode: 969348

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

Board Members:

Justin Ruffridge, *PharmD (Chair)*

Ashley Schaber, *Pharm D (Vice Chair)*

James Henderson, *RPh (Secretary)*

Leif Holm, *PharmD*

Ramsey Bell, *RPh*

Vacant, *Public Member*

Vacant, *Public Member*

Staff:

Laura Carrillo *Executive Administrator*

Bradley Johnson Occupational Licensing Examiner

Vacant, Occupational Licensing Examiner

Upcoming Meetings:

Sept. 22-23, 2022 (Anchorage)

Nov. 17-18, 2022 Anchorage

Meeting Details

Meeting Name: June 16, 2022 - Alaska Board of Pharmacy Meeting

Meeting Start Time: 9:00 AM AKDT

Meeting Start Date: 06/16/2022 (Thursday)

Meeting End Time: 4:00 PM AKDT

Meeting End Date: 06/16/2022 (Thursday)

Meeting Location: Zoom & Anchorage – Robert Atwood Building, Suite 1550, 550 W. 7th Ave, Anchorage Alaska 99501

Meeting Registration Link:
https://us02web.zoom.us/meeting/register/tZMlcu2srDkiHNCcFLpSW-mIts1O60v1eTMP

Agenda

I. Agenda Item #1 – 9:00 a.m. Roll Call/Call to Order (Chair Ruffridge)
II. Agenda Item #2 – 9:02 a.m. Review/Approve Agenda (Chair Ruffridge)
III. Agenda Item #3 – 9:05 a.m. Ethics Disclosures (Chair Ruffridge)
IV. Agenda Item #4 – 9:06 a.m. Review/Approve Meeting Minutes (Chair Ruffridge)
    a. February 17-18, 2022 draft
    b. March 25, 2022 draft
V. Agenda Item #5 – 9:30 a.m. PDMP Update

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Ashley Schaber, *Pharm D (Vice Chair)*

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VII. Agenda Item #7 – 10:45 a.m. Public Comment #1

VIII. Agenda Item #8 – 11:00 a.m. Pharmacy Locker Demo (Bryan Rigney)

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a. Review/Approve FY22 Annual Report
b. Review/Approve 2023 Strategic plan
c. Application Review
d. Review Lost/Stolen Rx
e. Correspondence
f. Position Statements/Guidance (dual tech/intern licenses, 42 CFR Part 2)
g. Other

X. Agenda Item #10 – 12:15 p.m. Statute Updates

a. HB 306
b. HB 145
c. SB 132
d. Other

XI. Agenda Item #11 – 12:30 p.m. Regulations

a. Update on renewal/military/EA; file #2022200056
b. Review large project/approve for public comment release (rekeyed)
c. New regulations (kiosks, remote pharmacies, lost/stolen notices by wholesalers, PDMP ASAP fields, MPJE, manufacturers, annual report)
d. HB 145 regulations (effective July 2023)
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a. Controlled Substances Advisory Subcommittee (delegate chair)
b. PDMP Board Chairs
c. Healthcare Board Chairs
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e. Compounding (tabled during February 2022 meeting)

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XIV. Agenda Item #14 – 2:00 p.m. Budget Report (Melissa Dumas)

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Sept. 22-23, 2022 (Anchorage)

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XV. Agenda Item #15 – 2:30 p.m. Industry Updates

a. AKPhA (Renee Robinson)

b. DHSS (TBD)

XVI. Agenda Item #16 – 2:45 p.m. Administrative Update (Laura Carrillo)

a. Gov. Dunleavy's Administrative Order

b. Form Updates

c. Renewal Progress

d. Cooperative Practice Agreement

e. Travel/Conference Notes

f. Task List Review

XVII. Agenda Item #17 – 3:45 p.m. Public Comment #2

XVIII. Agenda Item #18 – 4:00 p.m. Adjourn

Links

Board of Pharmacy Homepage: pharmacy.alaska.gov

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

CONFIDENTIAL

ETHICS SUPERVISOR DETERMINATION FORM

(Board or Commission Member)

Board or Commission: _____

Member Disclosing Potential Ethics Violation: _____

I have determined that the situation described on the attached ethics disclosure form

- ☐ does or would violate AS 39.52.110 - .190. Identify applicable statute below.
- ☐ does <u>not</u> or would not violate AS 39.52.110 - .190.

_____
Signature of Designated Ethics Supervisor (Chair)

_____
Printed Name of Designated Ethics Supervisor

Date: _____

COMMENTS (Please attach a separate sheet for additional space):

Note: Disclosure Form must be attached. Under AS 39.52.220, if the chair or a majority of the board or commission, not including the disclosing member, determines that a violation of AS 39.52.110-39.52.190 will exist if the member participates, the member shall refrain from voting, deliberating, or participating in the matter. A member will not be liable under the Ethics Act for action in accordance with such a determination so long as the member has fully disclosed all facts reasonably necessary to the determination and the attorney general has not advised the member, chair, or board or commission that the action is a violation. Forward disclosures with determinations to the State Ethics Attorney as part of your quarterly report. Quarterly reports are submitted to Litigation Assistant, Opinions, Appeals & Ethics, Department of Law, 1031 W. 4th Avenue, Suite 200, Anchorage, AK 99501.

Revised 2012

WHO IS MY DESIGNATED ETHICS SUPERVISOR?

Every state public officer, employee or board or commission member, has a designated ethics supervisor.

Executive Agencies

The ethics supervisor for each agency is the Commissioner or a senior manager to whom the Commissioner has delegated the function. The current ethics supervisor for each agency is listed below. The ethics supervisor for a Commissioner is Shawn Henderson, Director of Administrative Services in the Office of Governor, by delegation from the Governor.

Boards and Commissions

The Chair of each board and commission serves as the ethics supervisor for the other members and any executive director. The ethics supervisor for the Chair is Shawn Henderson, Director of Administrative Services in the Office of Governor, by delegation from the Governor. If a board or commission employs staff, the executive director serves as the ethics supervisor for these employees.

Public Corporations

The Chair of the board serves as the ethics supervisor for the other members of the board and any executive director. The executive director is the ethics supervisor for employees of the corporation.

Office of the Governor

The ethics supervisor for the Governor and Lieutenant Governor is the Attorney General. By delegation from the Governor, the ethics supervisor for the staff of the offices of the Governor and Lieutenant Governor is Shawn Henderson, Director of Administrative Services.

University of Alaska

By delegation of the University President, the ethics supervisor for university employees is Associate General Counsel Andy Harrington.

EXECUTIVE BRANCH AGENCIES

Administration: Dave Donley, Deputy Commissioner

Commerce, Community & Economic Development: Amy Demboski, Assistant Commissioner

Corrections: April Wilkerson, Administrative Services Director

Education & Early Development: Bobi Jo Grimes, HR Consultant III

Environmental Conservation: Theresa Zimmerman, Human Resources Manager

Fish & Game: Samantha Gatton, Acting Admin Services Director

Health & Social Services: Kimberley King, Human Resource Manager

Labor & Workforce Development: Cathy Muñoz, Deputy Commissioner

Law: Maria Bahr, Assistant Attorney General

Military & Veterans Affairs: Stanley A. Wright, Special Assistant to the Commissioner

Natural Resources: Peter Caltagirone, Special Assistant

Public Safety: Kelly Howell, Special Assistant to the Commissioner

Revenue: Brad Ewing, Administrative Services Director

Transportation & Public Facilities:

- Facility Services: John Binder, Deputy Commissioner
- Aviation: John Binder, Deputy Commissioner
- Central Region: Wolfgang Junge, Regional Director
- Northern Region: Rob Carpenter, Regional Director
- Southcoast Region: Lance Mearig, Regional Director
- Alaska Marine Highway System: Rob Carpenter, Deputy Commissioner
- Headquarters: Rob Carpenter, Deputy Commissioner
    - Administrative Services Division
    - Division of Program Development
    - Information Systems and Services Division
    - Statewide Design and Engineering Services Division

Updated June 2020

ETHICS INFORMATION FOR MEMBERS OF BOARDS & COMMISSIONS (AS 39.52)

Introduction

This is an introduction to AS 39.52, the *Alaska Executive Branch Ethics Act*. This guide is not a substitute for reading the law and its regulations. State board and commission members who have further questions should contact their board chair or staff.

The Ethics Act applies to all current and former executive branch public employees and *members of statutorily created boards and commissions*.

Scope of Ethics Act (AS 39.52.110)

Service on a state board or commission is a public trust. The Ethics Act prohibits substantial and material conflicts of interest. Further, board or commission members, and their immediate family, may not improperly benefit, financially or personally, from their actions as board or commission members. The Act does not, however, discourage independent pursuits, and it recognizes that minor and inconsequential conflicts of interest are unavoidable.

Misuse of Official Position (AS 39.52.120)

Members of boards or commissions may not use their positions for personal gain or to give an unwarranted benefit or treatment to any person. For example, board members may not:

- use their official positions to secure employment or contracts;
- accept compensation from anyone other than the State for performing official duties;
- use State time, equipment, property or facilities for their own personal or financial benefit or for partisan political purposes;
- take or withhold official action on a matter in which they have a personal or financial interest; or
- coerce subordinates for their personal or financial benefit.
- attempt to influence outcome of an administrative hearing by privately contacting the hearing officer.

Terry knew that a proposal that was before the board would harm Terry's business competitor. Instead of publicly disclosing the matter and requesting recusal, Terry voted on the proposal.

Board member Mick has board staff employee Bob type an article for him that Mick hopes to sell to an Alaskan magazine. Bob types the article on State time.

Improper Gifts (AS 39.52.130)

A board member may not solicit or accept gifts if a person could reasonably infer from the circumstances that the gift is intended to influence the board member's action or judgment. "Gifts" include money, items of value, services, loans, travel, entertainment, hospitality, and employment. All gifts from registered lobbyists are presumed to be improper, unless the giver is immediate family of the person receiving the gift.

A gift worth more than $150 to a board member or the board member's immediate family must be reported within 30 days if:

- the board member can take official action that can affect the giver, or
- the gift is given to the board member because he or she is on a state board.

The receipt of a gift worth less than $150 may be prohibited if a person could reasonably infer from the circumstances that the gift is intended to influence the board member's action or judgment. Receipt of such a gift should be disclosed.

Any gift received from another government, regardless of value, must be reported; the board member will be advised as to the disposition of this gift.

A form for reporting gifts is available at www.law.alaska.gov/doclibrary/ethics or from the board or commission staff.

This restriction on gifts does not apply to lawful campaign contributions.

☹ The commission is reviewing Roy's proposal for an expansion of his business. Roy invites all the board members out to dinner at an expensive restaurant. He says it will be okay, since he isn't excluding any of the members.

☺ Jody receives a holiday gift every year from Sam. Jody was recently appointed to a state board, but Sam has no business that is before the board. Jody may accept the gift.

Improper Use or Disclosure of Information (AS 39.52.140)

No former or current member of a board may use or disclose any information acquired from participation on the board if that use or disclosure could result in a financial or personal benefit to the board member (or immediate family), unless that information has already been disseminated to the public. Board members are also prohibited from disclosing confidential information, unless authorized to do so.

☺ Sheila has been on the board for several years. She feels she has learned a great deal of general information about how to have a successful business venture. So she sets up her own business and does well.

☺ Delores has always advised and assisted the other doctors in her clinic on their continuing education requirements. After Delores is appointed to the medical board, she discloses this role to the board and continues to advise the doctors in her clinic.

☹ Jim reviews a confidential investigation report in a licensing matter. He discusses the practitioner's violation with a colleague who is not a board member.

Improper Influence in State Grants, Contracts, Leases or Loans (AS 39.52.150)

A board member, or immediate family, may not apply for, or have an interest in a State grant, contract, lease, or loan, if the board awards or takes action to administer the State grant, contract, lease, or loan.

A board member (or immediate family) may apply for or be a party to a *competitively solicited* State grant, contract or lease, if the board as a body does not award or administer the grant, contract, or lease and so long as the board member does not take official action regarding the grant, contract, or lease.

A board member (or immediate family) may apply for and receive a State loan that is generally available to the public and has fixed eligibility standards, so long as the board member does not take (or withhold) official action affecting the loan's award or administration.

Board members must report to the board chair any personal or financial interest (or that of immediate family) in a State grant, contract, lease or loan that is awarded or administered by the agency the board member serves. *A form for this purpose is available at www.law.alaska.gov/doclibrary/ethics or from the board or commission staff.*

☹ John sits on a board that awards state grants. John hasn't seen his daughter for nearly ten years so he figures that it doesn't matter when her grant application comes up before the board.

☹ The board wants to contract out for an analysis of the board's decisions over the last ten years. Board member Kim would like the contract since she has been on the board for ten years and feels she could do a good job.

Improper Representation (AS 39.52.160)

A board or commission member may not represent, advise, or assist a person in matters pending before the board or commission for compensation A nonsalaried board or commission member may represent, advise, or assist in matters in which the member has an interest that is regulated by the member's own board or commission, if the member acts in accordance with AS 39.52.220 by disclosing the involvement in writing and on the public record, and refraining from all participation and voting on the matter. This section does not allow a board member to engage in any conduct that would violate a different section of the Ethics Act.

☺ Susan sits on the licensing board for her own profession. She will represent herself and her business partner in a licensing matter. She discloses this situation to the board and refrains from participation in the board's discussions and determinations regarding the matter.

Restriction on Employment After Leaving State Service (AS 39.52.180)

For two years after leaving a board, a former board member may not provide advice or work for compensation on any matter in which the former member personally and substantially participated while serving on the board. This prohibition applies to cases, proceedings, applications, contracts, legislative bills, regulations, and similar matters. This section does not prohibit a State agency from contracting directly with a former board member.

With the approval of the Attorney General, the board chair may waive the above prohibition if a determination is made that the public interest is not jeopardized.

Former members of the governing boards of public corporations and former members of boards and commissions that have regulation-adoption authority, except those covered by the centralized licensing provisions of AS 08.01, may not lobby for pay for one year.

☹ The board has arranged for an extensive study of the effects of the Department's programs. Andy, a board member, did most of the liaison work with the contractor selected by the board, including some negotiations about the scope of the study. Andy quits the board and goes to work for the contractor, working on the study of the effects of the Department's programs.

☺ Andy takes the job, but specifies that he will have to work on another project.

Aiding a Violation Prohibited (AS 39.52.190)

Aiding another public officer to violate the Ethics Act is prohibited.

Agency Policies (AS 39.52.920)

Subject to the Attorney General's review, a board may adopt additional written policies further limiting personal or financial interests of board members.

Disclosure Procedures

DECLARATION OF POTENTIAL VIOLATIONS BY MEMBERS OF BOARDS OR COMMISSIONS (AS 39.52.220)

A board member whose interests or activities could result in a violation of the Ethics Act if the member participates in board action must disclose the matter on the public record and in writing to the board chair who determines whether a violation exists. *A form for this purpose is available at www.law.alaska.gov/doclibrary/ethics or from the board or commission staff*. If another board member objects to the chair's ruling or if the chair discloses a potential conflict, the board members at the meeting (excluding the involved member) vote on the matter. If the chair or the board determines a violation will occur, the member must refrain from deliberating, voting, or participating in the matter. For more information, see *Ethics Act Procedures for Boards and Commissions* available at the above noted web site.

When determining whether a board member's involvement in a matter may violate the Ethics Act, either the chair or the board or commission itself may request guidance from the Attorney General.

ATTORNEY GENERAL'S ADVICE (AS 39.52.240-250)

A board chair or a board itself may request a written advisory opinion from the Attorney General interpreting the Ethics Act. A former board member may also request a written advice from the Attorney General. These opinions are confidential. Versions of opinions without identifying information may be made available to the public.

REPORTS BY THIRD PARTIES (AS 39.52.230)

A third party may report a suspected violation of the Ethics Act by a board member in writing and under oath to the chair of a board or commission. The chair will give a copy to the board member and to the Attorney General and review the report to determine whether a violation may or does exist. If the chair determines a violation exists, the board member will be asked to refrain from deliberating, voting, or participating in the matter.

Complaints, Hearings, and Enforcement

COMPLAINTS (AS 39.52.310-330)

Any person may file a complaint with the Attorney General about the conduct of a current or former board member. Complaints must be written and signed under oath. The Attorney General may also initiate complaints based on information provided by a board. A copy of the complaint will be sent to the board member who is the subject of the complaint and to the Personnel Board.

All complaints are reviewed by the Attorney General. If the Attorney General determines that the complaint does not warrant investigation, the complainant and the board member will be notified of

the dismissal. The Attorney General may refer a complaint to the board member's chair for resolution.

After investigation, the Attorney General may dismiss a complaint for lack of probable cause to believe a violation occurred or recommend corrective action. The complainant and board member will be promptly notified of this decision.

Alternatively, if probable cause exists, the Attorney General may initiate a formal proceeding by serving the board or commission member with an accusation alleging a violation of the Ethics Act. Complaints or accusations may also be resolved by settlement with the subject.

CONFIDENTIALITY (AS 39.52.340)

Complaints and investigations prior to formal proceedings are confidential. If the Attorney General finds evidence of probable criminal activity, the appropriate law enforcement agency shall be notified.

HEARINGS (AS 39.52.350-360)

An accusation by the Attorney General of an alleged violation may result in a hearing. An administrative law judge from the state's Office of Administrative Hearings serves as hearing officer and determines the time, place and other matters. The parties to the proceeding are the Attorney General, acting as prosecutor, and the accused public officer, who may be represented by an attorney. Within 30 days after the hearing, the hearing officer files a report with the Personnel Board and provides a copy to the parties.

PERSONNEL BOARD ACTION (AS 39.52.370)

The Personnel Board reviews the hearing officer's report and is responsible for determining whether a violation occurred and for imposing penalties. An appeal may be filed by the board member in the Superior Court.

PENALTIES (AS 39.52.410-460)

When the Personnel Board determines a board member has violated the Ethics Act, it will order the member to refrain from voting, deliberating, or participating in the matter. The Personnel Board may also order restitution and may recommend that the board member be removed from the board or commission. If a recommendation of removal is made, the appointing authority will immediately remove the member.

If the Personnel Board finds that a former board member violated the Ethics Act, it will issue a public statement about the case and will ask the Attorney General to pursue appropriate additional legal remedies.

State grants, contracts, and leases awarded in violation of the Ethics Act are voidable. Loans given in violation of the Ethics Act may be made immediately payable.

Fees, gifts, or compensation received in violation of the Ethics Act may be recovered by the Attorney General.

The Personnel Board may impose a fine of up to $5,000 for each violation of the Ethics Act. In addition, a board member may be required to pay up to twice the financial benefit received in violation of the Ethics Act.

Criminal penalties are in addition to the civil penalties listed above.

DEFINITIONS (AS 39.52.960)

Please keep the following definitions in mind:

Benefit - anything that is to a person's advantage regardless financial interest or from which a person hopes to gain in any way.

Board or Commission - a board, commission, authority, or board of directors of a public or quasi-public corporation, established by statute in the executive branch, including the Alaska Railroad Corporation.

Designated Ethics Supervisor - the chair or acting chair of the board or commission for all board or commission members and for executive directors; for staff members, the executive director is the designated ethics supervisor.

Financial Interest - any property, ownership, management, professional, or private interest from which a board or commission member or the board or commission member's immediate family receives or expects to receive a financial benefit. Holding a position in a business, such as officer, director, partner, or employee, also creates a financial interest in a business.

Immediate Family - spouse; another person cohabiting with the person in a conjugal relationship that is not a legal marriage; a child, including a stepchild and an adoptive child; a parent, sibling, grandparent, aunt, or uncle of the person; and a parent or sibling of the person's spouse.

Official Action - advice, participation, or assistance, including, for example, a recommendation, decision, approval, disapproval, vote, or other similar action, including inaction, by a public officer.

Personal Interest - the interest or involvement of a board or commission member (or immediate family) in any organization or political party from which a person or organization receives a benefit.

For further information and disclosure forms, visit our Executive Branch Ethics web site or please contact:

State Ethics Attorney
Alaska Department of Law
1031 West 4th Avenue, Suite 200
Anchorage, Alaska 99501-5903
(907) 269-5100
attorney.general@alaska.gov

Revised 9/2013

EXECUTIVE BRANCH ETHICS ACT

Responsibilities of Designated Ethics Supervisors for Boards and Commissions

Boards and commissions subject to the Ethics Act have designated ethics supervisors. The chair serves as the designated ethics supervisor for board or commission members and the executive director. The executive director is the designated ethics supervisor for staff. The designated ethics supervisor for a chair is the governor, who has delegated this responsibility to Guy Bell, Administrative Director of the Office of the Governor.

Designated ethics supervisors should refer to the **2019 Designated Ethics Supervisors Handbook** (503KB PDF), available from the state ethics attorney, regarding their responsibilities under the Ethics Act. Briefly, as designated ethics supervisor, you must --

1. Ensure that members and employees are provided copies of the guides, Ethics Information for Members of Boards and Commissions and Ethics Act Procedures for Boards and Commissions -- and keep a supply of disclosure forms.
    1. These guides, other educational materials, disclosure forms, statutes and regulations are available for review and copying on the Department of Law ethics web site. If access to this page is not available, please contact the Attorney General's office at 269-5275.
2. Review all disclosures, investigate potential ethics violations, make determinations regarding conduct, and take action.
3. Keep member or employee disclosure statements (of potential violations, receipt of gifts, and interests in grants/contracts/leases/loans) on file in your office. Disclosure of a gift received from another government must be forwarded to the Office of the Governor.
4. Submit an ethics report to the Department of Law in April, July, October and January for the preceding quarter. You will receive a reminder. There is a sample report on the ethics web page.
    1. Mail, email or fax to Jennifer L. Williams, Paralegal, Department of Law, Opinions, Appeals & Ethics Section, 1031 W. 4th Avenue, Suite 200, Anchorage, AK, 99501, ethicsreporting@alaska.gov, fax no. 907-258-4978.

You may request ethics advice from your agency's Assistant Attorney General or from the State Ethics Attorney, Maria Bahr, at 269-5285 or maria.bahr@alaska.gov. Please direct questions about reporting procedures to Jennifer L. Williams at 269-5275 or jennifer.williams1@alaska.gov.

6/19

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

Alaska Board of Pharmacy

DRAFT MINUTES OF THE MEETING

February 17, 2022 Videoconference

By authority of AS 08.01.070(2), and in compliance with the provisions of AS 44.62, Article 6, a scheduled meeting of the Board of Pharmacy via videoconference on February 17, 2022. Due to the COVID-19 pandemic, in-person attendance was not available.

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

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

The **February 17, 2022** videoconference was called to order by Chair, Dr. Ruffridge at 9:02 a.m.

Board members present, constituting a quorum:

Justin Ruffridge, PharmD #PHAP1787
Ashley Schaber, PharmD, #PHAP1697
Lana Bell, RPh #PHAP893
James Henderson, RPh #PHAP1683
Tammy Lindemuth

Division staff present:

Laura Carrillo, Executive Administrator
Lisa Sherrell, PDMP Manager
Heather Noe, Occupational Licensing Examiner
Bradley Johnson, Occupational Licensing Examiner
Charley Larson, Occupational Licensing Examiner
Melissa Dumas, Administrative Officer
Michael Bowles, Investigator
Marilyn Zimmerman, Paralegal

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Members from the public present/registered:

Keith Koscielski, PharMerica
Gail Elliott, Kaiser Permanente
Lorri Walmsley, Walgreens
Samantha Chessie, Animal Policy Group
David Besh, Self
Coral Seaman, Public
Benny Ndahiriwe, none - member of the public
Sheila Sinclair, Trilogy MedWaste
Maimuna Bruce Uzzell, CAH
Daniel Nelson, TCC
Jennifer Adams, ISU
Olga Brophy, Carrs/Safeway
Mary Ann Hollick, self
Jessie Leyva , NABP
Sarah Coburn, AK Veterinary Medical Association
Caren Robinson, AkPhA
Renee Robinson, AKPhA
Rachel Berngartt, Board of Veterinary Examiners
Jessica Adams, TelePharm
Mark Johnston, CVS Health
Callista Carlton, Southcentral Foundation
Ursula Chizhik, FLAVORx
Neal Watson, NABP
Rebecca Carrillo, Public
Lauren Paul, CVS Health
Pat Anderson, Self

Agenda Item 2 **Review/Approve Agenda** **Time: 9:03 a.m.**

The board reviewed the meeting agenda. Ms. Lindemuth move that we switch item #8 with agenda item #9.

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

RESOLVED to approve the February 17, 2022 meeting agenda as written.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell				x
Tammy Lindemuth	x			

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James Henderson	x		
Ashley Schaber	x		
Leif Holm			x
Sharon Long			x

The motion passed with no further discussion.

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

RESOLVED to accept the February 17, 2022 meeting agenda as amended.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell				x
Tammy Lindemuth	x			
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Sharon Long				x

The motion passed with no further discussion.

Agenda Item 3 **<u>Ethics Disclosures</u>** **Time: 9:05 a.m.**

Dr. Schaber disclosed that she is a member of AKPhA, Member; By-Laws & Nominations Committee Chair), Co-treasurer, and a member of the Legislative & Convention Committees.

Dr. Ruffridge is currently a candidate for state house, district 7. Dr. Ruffridge stated activity to official run began in the beginning in 2022 and in no way affects his position on the board.
.

Agenda Item 4 **<u>Review/Approve Minutes</u>** **Time: 9:06 a.m.**

The board reviewed the draft November 18, 2021 meeting minutes. Dr. Schaber pointed out the inconsistencies in the motion and approvals for denials made during the previous meeting. Since the vote was not in the affirmative but were voted on negatively, some responses needed to properly reflect the denials. Ms. Carrillo added there was a typo on line 13 and that it would be changed from August 12 to the correct date.

On a motion duly made by Tammy Lindemuth to amend the agenda by switching the times for the Subcommittee Update, Agenda Item #8, with the Division/Budget Report, Agenda Item #9, seconded by Ashley Schaber, and approved unanimously, it was:

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RESOLVED to switch agenda items #8 and #9.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell				x
Tammy Lindemuth	x			
James Henderson	x			
Ashley Schaber				x
Leif Holm				x
Sharon Long				x

The motion passed with no further discussion.

TASK 1
Ms. Carrillo will correct the meeting minutes as discussed during the meeting and will send to Dr. Ruffridge for his signature.

Agenda Item 5 **<u>Industry Updates</u>** **Time: 9:15 a.m.**

AKPhA (Renee Robinson)
Brandy Seignemartin is the new Executive Director with a joint appointment with the UAA Doctor of Pharmacy program. The AKPhA recently held an election; Renee Robinson is now president. On committee updates and accomplishments, the association offered a hybrid virtual convention which offered live-stream access to presentations for 16 hours of continuing education. The association also held a Pharmacy Leadership Development program.

The association expanded academic and student outreach by holding immunization clinics at UAA, Carrs Safeway, Three bears, as well as with the Alaska Black Caucus. They recently established a partnership with DHSS and will be holding a joint virtual health fair. On legislative updates, the association supports HB145 and HB306 and opposes HB237.

NABP Interactive Forum (Ashley Schaber)
Dr. Schaber summarized highlights from her participation in the NABP Interactive Form. She stated that states discussed emergency rules, the federal PREP Act, vaccinators, and waivers. There were discussions from other states about adding the ability for technicians to administer flu vaccines and efforts to change the definition of when emergency supplies of medications can be dispensed. States also looked to increase a 30-day supply to 90-day supply without a new prescription. Some state boards of pharmacies worked with hospitals for labeling inhalers and other bulk items to ensure patients could take them home. Some states extended trainee licensees. Dr. Schaber added there were discussions on how states don't always look at pharmacists as practitioners. Some states focused on man-power barriers and removing barriers to get technicians into the workforce, including looking at using the national guard without requiring a technician license.

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Dr. Schaber stated other topics discussed included workplace conditions and well-being. North Dakota lead this topic and requires national certification of their technicians; what they're seeing is that they're being retained longer and have less of a technician shortage like is being seen in other states. Dr. Schaber stated this is timely because it is currently being discussed in Alaska. Another discussion was mandatory breaks; the inspector would ask team members about whether they are given regular breaks. Some states are required to provide for breaks, but there is also a responsibility for pharmacists to schedule breaks where staff must take a break. Several states have partnerships in place with schools of pharmacies, board members, associations, chain drug stores, etc. to improve workplace wellness. Dr. Schaber also shared other states were also looking at prescriptive authority and the issues of white and brown bagging. White bagging requires medications to be filled at a specialty pharmacy whereas brown bagging involves insurance companies requiring medications to be shipped directly to the patient and then brought to the hospital or clinic for administration.

On the PDMP, Dr. Schaber stated North Dakota received a grant and implemented a screening tool for risk of OD at the point of dispensing to then dispense naloxone. The program is called OneRx. Another state passed opioid registration fee for distributors based on the number of pills they dispense in the state, but what they received was substantially lower than what had been projected.

Dr. Schaber informed the board that the NABP has taken significant steps to address NAPLEX issues as many states received score reports that were blank. Dr. Schaber also discussed the Drug Supply Chain and Security Act (DSCSA) and diversion schemes occurring where drugs are purchased under a pharmacy license but sold by a wholesaler and transferred within the company.

Dr. Schaber stated the NABP's 118th Annual Meeting would be held between May 19-21. Ms. Bell stated that as first year board member, she could not stress enough how much it benefited her in so many ways. Ms. Bell encouraged board members to participate in NABP-sponsored training whenever possible.

Well-Being Index Report (Laura Carrillo)

Ms. Carrillo stated the pharmacy workplace and well-being report is an anonymous questionnaire developed by the Mayo clinic and is analyzed by the Alliance for Patient Medication Safety. The goal was to collect experience on work-place conditions and how it affects personnel satisfaction as well as patient safety. There were 431 negative experiences and only 9 positive experiences among all district 7 states.

Some highlights as a result of experiencing high distress in the workplace include:

- 3-fold higher risk of low quality of life
- 8-fold higher risk of burnout
- 2.5 risk of high fatigue and intent to leave their employer
- a 2-fold higher risk of medication error.

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Dr. Ruffridge stated this presentation is reflective of a trend experienced by Alaska pharmacists for some time now. Dr. Ruffridge highlighted the data on distress percent by practice setting; showing that pharmacists working in community-chain pharmacy settings demonstrate the highlights stress response nationally, compared to the academic setting, which is lowest (46.61% in January 2022 versus 21.38%.). Dr. Ruffridge stated a lot of the stress also falls to technicians, so looks forward to further discussion on how we can improve conditions for them. There were some measures where Alaska data couldn't be reported due to a small sample size. Dr. Schaber stated there needed be at least 100 participants to see aggregate data.

Dr. Ruffridge suggested the survey be sent out through the ListServ.

TASK 2
Ms. Carrillo will send the well-being index survey on pharmacy workplace conditions out through the ListServ.

Dr. Ruffridge called for break at 9:56 a.m.

Off record at 9:56 a.m.
Back on record at 10:02 a.m.

Agenda Item 6 **<u>Investigative Report</u>** **Time: 10:02 a.m.**

Investigator Bowles joined the board to present its investigative report, which included matters from November 17, 2021 through February 7, 2022. The division opened 34 cases and closed 9. Inv. Bowles advised there were sensitive matters to be discussed confidentially.

On a motion duly made by Justin Ruffridge in accordance with AS 44.62.310(c)(2), the board unanimously moved to enter executive session for the purpose of discussing subjects that tend to prejudice the reputation and character of any person, provided the person may request a public discussion.

RESOLVED to enter into executive session in accordance with AS 44.62.310(c)(2). Staff, Michael Bowles and Laura Carrillo were authorized to remain in the room.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth	x			
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x

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Sharon Long			x

The motion passed with no further discussion.

Off record at 10:08 a.m.
On record at 10:23 a.m.

On a motion duly made by Ashley Schaber to approve the application for case #2021-000944, seconded by James Henderson, and denied unanimously, it was:

RESOLVED to deny the application for case #2021-000944.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge		x		
Lana Bell			x	
Tammy Lindemuth		x		
James Henderson		x		
Ashley Schaber		x		
Leif Holm				x
Sharon Long				x

The motion did not pass.

On a motion duly made by Tammy Lindemuth to approve the imposition of civil fine for case #2021-000938 in the amount of $500 without censure or reprimand, seconded by James Henderson, and approved unanimously, it was:

RESOLVED to approve the imposition of civil fine for case #2021-000938 in the amount of $500 without censure or reprimand.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth	x			
James Henderson	x			
Ashley Schaber			x	
Leif Holm				x
Sharon Long				x

The motioned passed with no further discussion.

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On a motion duly made by Tammy Lindemuth to approve the imposition of civil fine for case #2021-000763 in the amount of $250 without censure or reprimand, seconded by Ashley Schaber, and approved unanimously, it was:

> **RESOLVED to approve the imposition of civil fine for case #2021-000763 in the amount of $250 without censure or reprimand.**

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth	x			
James Henderson			x	
Ashley Schaber	x			
Leif Holm				x
Sharon Long				x

The motion passed with no further discussion.

On a motion duly made by Tammy Lindemuth to approve the imposition of civil fine for case #2021-000054 in the amount of $500 without censure or reprimand, seconded by Ashley Schaber, and approved unanimously, it was:

> **RESOLVED to approve the imposition of civil fine for case #2021-000054 in the amount of $500 without censure or reprimand.**

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge			x	
Lana Bell	x			
Tammy Lindemuth	x			
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Sharon Long				x

The motion passed with no further discussion.

TASK 3

Dr. Ruffridge will return the signed agreements to Inv. Bowles.

Agenda Item 7 **<u>Public Comment #1</u>** **Time: 10:32 a.m.**

Daniel Nelson

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Mr. Nelson thanked the board and expressed appreciation for their timely work. Mr. Nelson expressed his concern that there is a lot of work put on the executive administrator, and in relation to the fee decrease proposal, he prefers to pay the current fee and have more timely responses to applicants. Mr. Nelson supports the boards' proposed regulation change allowing approval of applications by the EA. He also expressed his support for HB145 and also encouraged the board to support it.

Agenda Item 9 **Subcommittee Updates** **Time: 10:38 a.m.**

Healthcare Board Chairs (Dr. Ruffridge)
Dr. Ruffridge provided the update that legislation continued to be the main topic of discussion. Dr. Ruffridge reminded the board that when members speak individually to legislators, that those conversations must reflect full discussion of the board. He stated the group continues to discuss COVID-19 and military licensing priorities. With the board's sunset bill up, he then explained that in the past, legislators were able to choose which sunset bills to support, but that this year, boards were to find a sponsor; Dr. Ruffridge and AKPhA's Caren Robinson were able to seek Representative Andi Story's support for HB306.

PDMP Board Chairs (Dr. Ruffridge)
Dr. Ruffridge informed the board that the group continues to discuss a uniform agreement to establish consistency amongst boards with regards to what the PDMP is to be used for, how they would like data to be presented, the type of data to provide, and what matters needed to be prioritized with the investigative unit. Dr. Ruffridge stated it was very helpful to have data stewards from other departments to provide from their expertise as the group welcomed a presentation on overdose data from DHSS in a recent meeting.

Controlled Substances Advisory Subcommittee (Tammy Lindemuth)
Ms. Lindemuth shared that veterinarians attended a recent CSAC meeting to seek support for exemption from the PDMP. The committee was working on finalizing a letter to the Governor regarding scheduling of gabapentin and kratom. Ms. Lindemuth shared the committee is now in the process of addressing a designer drug, N -Pyrrolidino Etonitazene, a derivative of fentanyl, and exploring the possibility of it being emergency scheduled. The issue was brought to the CSAC's attention by the crime lab in Fairbanks. The CSAC's next meeting will be April 20th at 12:00 p.m.

Compounding Subcommittee (Dr. Ruffridge)
Ms. Carrillo noted there has not been an update from this subcommittee in a long time and inquired whether the board wished to table the committee. Dr. Ruffridge stated it is an important subcommittee, but it has been difficult to convene to discuss current issues due to competing priorities.

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On a motion duly made by Justin Ruffridge to table the compounding subcommittee until a later date when new members are formed, seconded by Tammy Lindemuth, and approved unanimously, it was:

RESOLVED to table the compounding subcommittee.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth	x			
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Sharon Long				x

The motion passed with no further discussion.

Lana Bell left the room at 10:57 a.m.

Agenda Item 11 **PDMP Update** **Time: 10:58 a.m.**

Ms. Sherrell updated the board that Charley Larson was recently hired as the PDMP occupational licensing examiner. Ms. Sherrell also informed the board that interactive prescriber report cards were launched in November and now allows prescribers to dial into their treatment details. The interactive report also allows admin to view how many prescribers have viewed their report. Ms. Sherrell also provided an update on form revisions and clean-up to capture which providers are directly dispensing. The PDMP team continues to explore ways to make the database easier to use.

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

Melissa Dumas joined the board provided its budget update. The board's total revenue for Q1 and Q2 of FY22 is $233,365. The total non-investigative expenditures is $120,156, personal services is $46,158, which includes investigative time, and division direct, which includes the admin officer, director, deputy director, and about 25 other staff who contribute time to the entire division, is at $95,000. The board's total indirect expenditures is $160,093 and has a surplus of $493,037. Ms. Dumas pointed to the statistical information near the bottom of the page; Dr. Ruffridge inquired where to find comprehensive licensing statistics and Ms. Dumas demonstrated how to navigate to the division reports page.

Ms. Dumas then reviewed the PDMP budget report, sharing that 99% of expenditures are funded through grants with DHSS. Revenue from the $25.00 registration and renewal fee, which has since been reduced to zero, brought in $26,000 in revenue.

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Agenda Item 10 **Lunch** **Time: 11:50 a.m.**

Dr. Ruffridge called for a lunch break at 11:50 a.m.

Off record for lunch at 11:50 a.m.
Back on record at 12:50 p.m.

Agenda Item 12 **Board Business** **Time: 12:50 a.m.**

Upon return from lunch, Justin Ruffridge, Tammy Lindemuth, James Henderson, and Ashley Schaber were present, constituting a quorum.

Application Review

The board reviewed applications for licensure as well as for shared pharmacy services.

On a motion duly made by Justin Ruffridge to table the shared pharmacy services application for Pipeline Rx, seconded by Tammy Lindemuth, and approved unanimously, it was:

RESOLVED to table the shared pharmacy application for Pipeline Rx.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell				x
Tammy Lindemuth	x			
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Sharon Long				x

The motion passed with no further discussion.

TASK 4

Ms. Carrillo will update Pipeline Rx on their tabled application.

On a motion duly made by Justin Ruffridge in accordance with AS 44.62.310(c)(2), and seconded by James Henderson, the board unanimously moved to enter executive session for the purpose of discussing subjects that tend to prejudice the reputation and character of any person, provided the person may request a public discussion.

RESOLVED to enter into executive session in accordance with AS 44.62.310(c)(2). Staff, Laura Carrillo, was authorized to remain in the room.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			

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Lana Bell			x
Tammy Lindemuth	x		
James Henderson	x		
Ashley Schaber	x		
Leif Holm			x
Sharon Long			x

The motion passed with no further discussion.

Off record at 12:56 a.m.
On record at 1:33 p.m.

Upon return from executive session, Chair Ruffridge indicated there were no motions made in executive session. Ms. Bell also returned to the meeting.

On a motion duly made by Tammy Lindemuth to approve the pharmacy technician application for Kathleen Ramp (in-process #181933) in consideration of a felony conviction and moral turpitude per AS 08.80.261(a)(4) and AS 08.80.261(a)(8), seconded by James Henderson, and denied by the majority with one abstention, it was:

> **RESOLVED to deny the pharmacy technician application for Kathleen Ramp per AS 08.80.261(a)(4) and AS 08.80.261(a)(8).**

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge		x		
Lana Bell			x	
Tammy Lindemuth		x		
James Henderson		x		
Ashley Schaber		x		
Leif Holm				x
Sharon Long				x

The motion did not pass and there was no further discussion.

On a motion duly made by Tammy Lindemuth to approve the pharmacist intern application for David Besh (in-process #180952), seconded by James Henderson and approved unanimously, it was:

> **RESOLVED to approve the pharmacy intern license application for David Besh.**

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell			x	

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Tammy Lindemuth	x	
James Henderson	x	
Ashley Schaber	x	
Leif Holm		x
Sharon Long		x

The motion passed with no further discussion.

TASK 5

Ms. Carrillo will send a notice to Ms. Ramp regarding the board's decision and will forward a copy of the denial documents to Investigator Bowles.

TASK 6

Ms. Carrillo will process the pharmacist intern license application for David Besh.

Lost/Stolen records

The board reviewed four DEA 106 forms of lost/stolen prescriptions: one each for CVS Pharmacy #113861, CVS Pharmacy 113890, PMOA, Inc. #131158, and Costco Pharmacy #PHAR465. Dr. Ruffridge noted that the notification for #113890 was only an initial notification of a loss from October 15, 2021 and that the notice indicated an update would be provided every 45 days. Dr. Ruffridge inquired whether we received the DEA 106, to which Ms. Carrillo stated she would follow-up.

TASK 7

Ms. Carrillo will follow-up with CVS pharmacy #113890 on the status of the initial loss of prescriptions from October 15, 2021 and will update the board at its next meeting.

Correspondence

Anonymous: An Alaska licensee wrote to the NABP about concerns with staffing and public safety in chain retail pharmacies. The letter is a call to action to the board of pharmacy to address medication dispensing errors and job satisfaction. Dr. Schaber suggests setting up a work group or subcommittee to work through these solutions; partnership with AKPhA, and employers with the state.

TASK 8

Ms. Carrillo will reach out to Department of Labor, the AKPhA, and UAA, and will continue to keep this on the agenda as a potential for a new work group.

Keith Koscielski – Mr. Koscielski wrote to the board requesting authorization to place a CubexRxNow machine—which functions as an electronic eKit and first-dose kit—into skilled nursing facility (a long-term care facility "LTCF"), Prestige Care & Rehabilitation Center, which holds an out-of-state registration by the board. Dr. Ruffridge inquired why the authorization request is being made since the board doesn't regulate kiosks. Ms. Bell suggested the issue may be around stocking the machine. Mr. Koscielski clarified the regulations, 12 AAC 52.830 and 12 AAC

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52.840, do speak to emergency drug kits but don't speak to whether it can be electronic. To Ms. Bell's comment, Mr. Koscielski stated it is only dispensed when there's a valid prescription by a prescriber, that controlled drugs are restricted by access code. Mr. Koscielski further stated the request is whether the machine can be restocked with cubies instead of pharmacists physically restocking it as required by regulation. The process is that the pharmacist only prepares for restock but it is ultimately stocked by nursing staff. Ms. Bell inquired whether the facility is a DEA registrant, to which Mr. Koscielski stated it is not, but that the machine is registered under the prescriber's DEA. Ms. Bell expressed her understanding that a LTCF cannot stock controlled substances unless the facility is a DEA registrant and employs a medical director.

Ms. Bell suggested the board request a legal opinion from the Department of Law, to which Ms. Lindemuth agreed. Dr. Ruffridge also supported a legal opinion but indicated he would like to solidify his understanding with applicable laws. Mr. Koscielski referenced DEA regulations related to emergency kits in LTCFs. Dr. Ruffridge read aloud the pertinent section of the manual:

> A pharmacy may place an emergency kit with controlled substances in a non-DEA registered LTCF if the appropriate state agency or regulatory authority specifically approves the placement and promulgates procedures that delineate:
>
> 1. The source from which the LTCF may obtain controlled substances for emergency kits and that the source of supply is a DEA registered hospital/clinic, pharmacy, or practitioner.
> 2. The security safeguards for each emergency kit stored at the LTCF, including who may have access to the emergency kit, and specific limitation of the type and quantity of controlled substances permitted in the kit.
> 3. The responsibility for proper control and accountability of the emergency kit within the LTCF, including the requirement that the LTCF and the supplying registrant maintain complete and accurate records of the controlled substances placed in the emergency kit, the disposition of the controlled substances, and the requirement to take and maintain periodic physical inventories.

Dr. Ruffridge noted the DEA does allow emergency kits *if* the state agency has the specific regulatory authority, but that the board doesn't currently have regulations codifying standards for placement of kits containing controlled substances. Mr. Koscielski recommended looking at other state regulations, such as Washington.

TASK 9

Ms. Bell and Ms. Carrillo will work on draft regulations for emergency drug kits, both electronic and physical for potential amendments to 12 AAC 52.830 and 12 AAC 52.840.

Rich Holt – Dr. Holt shared that some states, including Colorado, Kentucky, Maine, Michigan, and others, delegate the determination of eligibility to the NABP. Ms. Carrillo shared that the NABP confirms eligibility by reviewing their qualifications, like transcripts, and ultimately grants eligibility to the applicant. Neal Watson with the NABP was on the line to provide details on this process, adding it does provide efficiency for states. Dr. Schaber inquired how often the Alaska specific

questions get updated, to which Mr. Watson stated is done annually with the MPJE item development and testing workshops for state administrators and board members to participate in.

Dr. Ruffridge inquired whether the NABP does background checks. Mr. Watson stated the NABP does not currently but that they do receive actions via ClearingHouse and allows state agencies to access this.

The board continued discussing the option of delegating MPJE-eligibility to the NABP instead of it being done by licensing staff. Dr. Ruffridge requested adding 12 AAC 52.092 (Approval to Sit for Examination) to the day 2 agenda during the regulations discussion.

TASK 10
Ms. Carrillo will add 12 AAC 52.092 as a new regulation project for the board to further discuss during day 2 of the February meeting.

Telepharm – the board reviewed correspondence from TelePharm, which proposed revising 12 AAC 52.423 to remove the 10 road mile restriction. Dr. Ruffridge stated that he owns the only remote pharmacy in Alaska and is a customer of TelePharm so would recuse himself from the discussion. Mr. Henderson recalled that Dr. Holm's previous concern was that if there was already a remote pharmacy present and a new pharmacy came in, it would force the remote pharmacy out of business. Jessica Adams from TelePharm was on the line for discussion and historical context. Ms. Adams stated that COVID-19 highlighted the disparities in marginal populations where access to pharmacy services is a challenge, adding that telepharmacy services would alleviate this issue and help balance the workload of full pharmacies. Ms. Adams stated the 10-mile limitation prevents pharmacies from pursuing telepharmacy services as an option, adding that 10 miles may not seem very long, but with rurality of Alaska and limited transportation, and harsh road conditions, mobility limitations, it can become a difficult trek. Ms. Carrillo inquired how the 10-mile was determined, to which Mr. Henderson stated it seemed reasonable but that it may have been established arbitrarily.

Lorri Walmsley, Arizona board member and Walgreens pharmacist, shared the state does have remote pharmacy regulations but does not impose a mileage restriction, adding there hasn't been many issues. Jennifer Adams from Idaho State University shared that historically, Idaho had a 50-mile limit, which similarly was arbitrarily determined by the board. It was later reviewed by the board who ultimately removed the limit. Dr. Adams stated hasn't been a huge increase in the number of telepharmacies since. Jessica Adams shared other states without mileage limitations, such as Oregon, Washington, and Illinois.

On a motion duly made by Ashley Schaber to add 12 AAC 52.423 regarding remote pharmacy licensure to the February 18, day 2 agenda, seconded by Tammy Lindemuth and approved by the majority with one abstention, it was:

RESOLVED to add 12 AAC 52.423 to the day 2 agenda.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell			x	
Tammy Lindemuth	x			
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Sharon Long				x

The motion passed without further discussion.

TASK 11
Ms. Carrillo will add 12 AAC 52.423 to the day 2 agenda under regulations.

FDA – The board reviewed correspondence from the FDA addressing the modified Risk Evaluation and Mitigation (REMS) program for clozapine, which has created barriers in patient access to the drug. The FDA's letter states it does not intend to enforce certain REMS requirements, including on pharmacies if they dispense clozapine without applying to REMS for a Request to Dispense Authorization (RDA). Dr. Ruffridge stated that access to clozapine is a major issue and requested this correspondence be distributed through the ListServ. asks that we post this through the ListServ.

TASK 12
Laura will send the FDA's Clozapine correspondence out via ListServ.

NABP – The board discussed the MPJE exam writing workshop from March 9-11, 2022. Ms. Carrillo and Dr. Schaber volunteered to participate.

TASK 13
Laura Carrillo and Ashley Schaber will participate in the MPJE writing workshop on March 9-11th virtually.

The board reviewed additional correspondence, include age-related COVID-19 vaccine mix-ups and reporting to the Vaccine Adverse Event Reporting System (VAERS), as well as compounding for the FDA's 2022 compounding quality center for excellence training opportunity.

Dr. Ruffridge called for break at 3:10 p.m.

Off record at 3:10 p.m.
On record at 3:19 p.m.

Agenda Item 12 **<u>Board Business</u>** **Time: 3:20 a.m.**

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PHA Disciplinary Matrix

Ms. Carrillo and Dr. Schaber presented the draft comprehensive disciplinary matrix for the board's review and approval. Mr. Henderson noted a possible typo with a fine amount for unlicensed practice; Ms. Carrillo clarified it should be $25,000, not $2,500. Dr. Schaber commented on formatting edits and suggested the PDMP violations be moved to the PDMP-specific matrix. Dr. Ruffridge requested sending the matrix out via the ListServ.

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

RESOLVED to approve the disciplinary matrix as amended.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth	x			
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Sharon Long				x

The motion passed with further discussion. Mr. Henderson inquired whether advertising for services is as egregious as shipping without a license. Dr. Ruffridge stated that advertising is costly and is done with the intent to obtain and procure business, so should be treated similarly. Dr. Ruffridge added that if after an investigative review, the facility only advertised but did not ship any products, the discipline could ultimately be determined by the reviewing board member.

TASK 14

Ms. Carrillo will make corrections to the matrix and will send it out through the ListServ.

PDMP Disciplinary Matrix

Dr. Ruffridge stated this is a work in progress. Ms. Carrillo suggested establishing clear guidance, e.g.: whether or not they missed a day of reporting and disciplining accordingly. Mr. Henderson expressed interest in being more lenient especially for providers who miss 1 or reports occasionally.

Media concerns

The board addressed an Alaska Watchman article where there was conflation between the board's CE notice and its position on dispensing ivermectin. Dr. Ruffridge reiterated the that the board has never taken a position against dispensing ivermectin; that its only position has been in collaboration with the Nursing and Dental boards in addressing safe dispensing of it.

Agenda Item 13 **Public Comment #2** **Time: 4:21 a.m.**

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Jennifer Adams: Dr. Adams thanked Dr. Ruffridge and Dr. Schaber for volunteering as evaluators for the UAA/ISU pharmacy law evaluation class.

Agenda Item 14 **Recess** **Time: 4:30 p.m.**

Dr. Ruffridge recessed the meeting until February 18, 2022.

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

Alaska Board of Pharmacy

DRAFT MINUTES OF THE MEETING

February 18, 2022 Videoconference

By authority of AS 08.01.070(2), and in compliance with the provisions of AS 44.62, Article 6, a scheduled meeting of the Board of Pharmacy via videoconference on February 18, 2022. Due to the COVID-19 pandemic, in-person attendance was not available.

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

Agenda Item 1 **Call to Order/Roll Call** **Time: 9:03 a.m.**

The **February 18, 2022** videoconference was called to order by Chair, Dr. Ruffridge at 9:02 a.m.

Board members present, constituting a quorum:

Justin Ruffridge, PharmD #PHAP1787
Ashley Schaber, PharmD, #PHAP1697
Lana Bell, RPh #PHAP893
James Henderson, RPh #PHAP1683
Tammy Lindemuth,

Division staff present:

Laura Carrillo, Executive Administrator
Lisa Sherrell, PDMP Manager
Heather Noe, Occupational Licensing Examiner
Bradley Johnson, Occupational Licensing Examiner

Members from the public present/registered:

Gail Elliott, Kaiser Permanente
Lorri Walmsley, Walgreens
Samantha Chessie, Animal Policy Group
Coral Seaman, Public
Benny Ndahiriwe, member of the general public
Maimuna Bruce, CAH
Jennifer Adams, ISU
Sarah Coburn, AK Veterinary Medical Association
James Delker DVM, Alaska Veterinary Medical Association
Lauren Paul, CVS Health
Callista Carlton, Southcentral Foundation
Jessica Adams, Cardinal health
Margaret Soden, self
Patricia Anderson, none
Rachel Berngartt, Board of Veterinary Examiners
Caren Robinson, AkPhA
Justin Macy, NABP
William Cover, NABP

Agenda Item 2 **Review/Approve Agenda** **Time: 9:05 a.m.**

The board reviewed the meeting agenda. Ms. Lindemuth move that we switch item #8 with agenda item #9.

On a motion duly made by Ashley Schaber to add 12 AAC 52.423, remote pharmacy, to the meeting agenda for discussion, seconded by Lana Bell, and approved by the majority with one abstention, it was:

RESOLVED to add the discussion of remote pharmacies to the agenda.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge			x	
Lana Bell	x			
Tammy Lindemuth				x
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Sharon Long				x

The motion passed with no further discussion.

On a motion duly made by Ashley Schaber to approve the amended agenda, seconded by Lana Bell, and approved unanimously, it was:

RESOLVED to approve the February 18, 2022 meeting agenda as amended.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge			x	
Lana Bell	x			
Tammy Lindemuth				x
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Sharon Long				x

The motion passed with no further discussion.

Agenda Item 3 **Ethics Disclosures** **Time: 9:08 a.m.**

Dr. Schaber disclosed that she is a member of AKPhA, Member; By-Laws & Nominations Committee Chair), Co-treasurer, and a member of the Legislative & Convention Committees.

Dr. Ruffridge is currently a candidate for state house, district 7. Dr. Ruffridge stated activity to official run began in the beginning in 2022 and in no way affects his position on the board.

Agenda Item 4 **Public Comment #3** **Time: 9:09 a.m.**

James Delker, DVM – Dr. Delker prefaced his comment with the statement that most of his frustration is directed at issues that occurred prior to the current board makeup. Introducing himself, Dr. Delker stated he has been a practicing veterinarian for 19 years and that he has been involved with the PDMP since 2013. He stated he identified numerous problems with the PDMP, and at the time, he presented at the Board of Pharmacy's November 21st, 2013 meeting about how veterinarians can comply with the system. Dr. Delker stated he was told the board would table the topic until the next meeting, but never received a response. Dr. Delker stated veterinarians have been expressed as whiners who don't want to do their job, but that they have not been invited to participate in discussions around the system. He further expressed concern around why data disappears when it is being entered and added that veterinarian data shows miniscule risk of diversion. Dr. Delker reiterated that the veterinarian's licensing fees are among the highest in the country and spoke to Director Chamber's comments during the SB132 hearing about investigative costs being paid for by grants, stating it is not the whole story. Concerns about why veterinarians were not included on the Joint Committee on Prescriptive Guidelines establishing MME standards were also expressed. Dr. Delker requested that the board consider removing the onus of veterinarians to comply with the requirements, adding veterinarians are happy to continue helping

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combat the opioid pandemic, but that they must have measurable data to show how they can make a difference.

Dr. Ruffridge inquired whether his testimony was written and if Dr. Delker could forward it to Ms. Carrillo for distribution to the board.

TASK 15
Ms. Carrillo will forward Dr. Delker's testimony on veterinary exemption from the PDMP to the board.

Callista Carlton – Dr. Carlton introduced herself as the pharmacy clinical director with South Central Foundation, stating that curbside dispensing module arose as a solution during the pandemic, adding it allows for medication-pick-up without having to come into the lobby. Dr. Carlton stated they have since realized it's not sustainable, but that a pharmacy locker would be a more sensible and permanent solution. Dr. Carlton inquired whether a presentation to the board would be helpful, to which the board agreed. Dr. Carlton stated she would be prepared to also share regulations from other states.

TASK 16
Laura Carrillo will place Callista Carlton on the board's next meeting agenda for a presentation on pharmacy lockers.

Margaret Soden – Ms. Soden stated she has been a pharmacist in Alaska for 52 years and recently retired from practice. Ms. Soden was on the board twice; first from 1983 to 1989 and then again from 1998 to 2006 where she served as president from 2000-2004. Speaking to Dr. Delker's comment, Ms. Soden stated she was not on the board when it discussed veterinary participation in the PDMP but agreed with him. Ms. Soden stated she was on the call for historical reference per Dr. Schaber's request to discuss remote pharmacy licensure.

Dr. Schaber asked where the 10-mile restriction came from come. Ms. Soden stated it was an emerging topic in early 2000 and there was little knowledge about where remote pharmacies could be placed. The context at the time was a pharmacy out of Fairbanks wanted to put in a remote location in Healy or Delta Junction, but that a concern was that a remote pharmacy could end up hiring full staff to where it is no longer providing remote services. Ms. Soden further recalled the board discussing a 3-mile restriction as well as the 10-mile restriction, suggesting the latter may have been a compromise. Ms. Lindemuth expressed thanks to Ms. Soden for her time, her years of work on the board, and for the foundational insight she provided.

Mr. Henderson inquired whether it would be appropriate for Ms. Soden to speak to Dr. Delker's comments. Ms. Soden stated when that when she was on the board in 2004, she and Bill Altland met with a representative from a pharmaceutical company and they were presenting sample regulations on the PDMP. Ms. Soden recalled the goal was to control the amount of controlled

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substances that were being inappropriately prescribed by physicians, nurse practitioners, and dentists, but that at the time there wasn't a consideration to include optometrists and veterinarians. Ms. Soden added she didn't think of these professions as being a source of inappropriate prescribing and that including veterinarians in the PDMP only by virtue they prescribe is a stretch. Ms. Soden agreed it must be difficult to access information and report daily.

Agenda Item 5 **Legal Opinion Updates** **Time: 9:34 a.m.**

White/brown bagging

Dr. Ruffridge stated there seems to be certain aspects the board can regulate with regards to white and brown bagging but doesn't match up fully to what the boards want to have oversight on. Dr. Schaber commented it seems to fall more under the purview of the Division of Insurance.

Pharmacy technicians with national certification

Dr. Ruffridge stated this will be discussed further under statutes under Agenda Item #9.

Medication therapy management

LAW provided input on whether pharmacies registered outside of the state could engage in providing medication therapy management without being registered by the board. Dr. Ruffridge stated pharmacists employed in out-of-state pharmacies would be providing this service. Mr. Henderson stated there is no statute that allows the board to regulate out-of-state personnel, which in part is due to the statute for regulating these pharmacies being weak; they are registered rather than licensed by the board. Ms. Bell stated this is why she is worried about controlled substances and out-of-state pharmacies installing machines.

Dr. Ruffridge pointed to AS 08.80.030(b) regarding licensure required for practicing in the state, suggesting a need for a legal opinion on what "in" the state means.

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

The board ultimately agreed the following question should be posed to LAW:

Can the board through regulations define what it means to practice in the state as referenced in AS 08.80.030(b)(8), to include being physically located in the state as well as providing services to the state? And if yes, can the board require pharmacists located outside of the state who are providing services for a registered out-of-state pharmacy to be licensed in Alaska without a statute change?

On a motion duly made by Justin Ruffridge to direct Ms. Carrillo to request a legal opinion from the Department of Law on whether the board has authority to regulate pharmacists providing services in the state but located outside of the state, seconded by Tammy Lindemuth, and approved unanimously, it was:

RESOLVED to request a legal opinion on regulation of out-of-state pharmacy personnel.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth	x			
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Sharon Long				x

The motion passed with no further discussion.

TASK 17
Laura Carrillo will submit a Department of Law legal opinion request through Deputy Director Hoskinson on whether the board can require licensure for out-of-state pharmacy personnel given AS 08.80.030(b)(8).

Purchaser of wholesale drugs
Dr. Ruffridge suggests adding to 12 AAC 52.620(d) that professions listed in AS 08.80.400 are excluded.

Monoclonal antibodies
Dr. Ruffridge stated the opinion excludes oral antivirals because the FDA prohibits that.

Dr. Ruffridge called for break at 10:10 a.m.

Off record at 10:10 a.m.
On record at 10:16 a.m.

Agenda Item 6 **Regulations** **Time: 10:17 a.m.**

Regulations out for public comment

Fee reductions
Dr. Ruffridge provided an overview of the fee reduction proposals. Ms. Carrillo clarified that this is a division regulation so public comments need to be submitted in writing. Public comments are accepted through March 4th.

Military, emergency permit, courtesy license, renewal, and executive administrator
Ms. Carrillo stated this is out for public comment until March 8th.

963 Remaining regulations project from 2021 (reviewed by LAW)
964
965 • *12 AAC 52.020 – pharmacy license*. Ms. Carrillo explained that LAW is striking "checklist"
966 because the way it is currently worded already describes items required for licensure.
967 • *12 AAC 52.030 – change of pharmacy location or name*. Ms. Carrillo stated this section is being
968 struck because it's proposed to be incorporated into a larger section addressing changes.
969 • *12 AAC 52.040 – Change of pharmacy ownership*. This is also being repealed because it is being
970 incorporated into a new section.
971 • *12 AAC 52.070 – application for pharmacist license by exam*. The proposed changes include
972 review and approval of applications to be completed by the board's executive administrator
973 instead of by the board and for the transcript be replaced with a copy of the original
974 diploma. Dr. Ruffridge expressed concern around it being more difficult to require a
975 certified diploma. Dr. Adams commented that it is significantly easier to get a transcript
976 sent than a certified copy of a diploma. Ms. Carrillo stated the reason why the transcript
977 requirement was being repealed initially was because the NABP requires a transcript to
978 schedule exams. Dr. Schaber, Ms. Lindemuth, and Mr. Henderson agreed to striking both
979 the diploma and transcript requirement since the NABP already requires the latter. Dr.
980 Ruffridge called for a motion to repeal 12 AAC 52.070(b)(4).
981
982 **On a motion duly made by Justin Ruffridge to repeal 12 AAC 52.070(b)(4) pertaining to**
983 **transcript and diploma requirements, seconded by Tammy Lindemuth, and approved**
984 **unanimously, it was:**
985
986 **RESOLVED to repeal 12 AAC 52.070(b)(4).**
987

988

	APPROVE	DENY	ABSTAIN	ABSENT
989 Justin Ruffridge	x			
990 Lana Bell	x			
991 Tammy Lindemuth	x			
992 James Henderson	x			
993 Ashley Schaber	x			
994 Leif Holm				x
995 Sharon Long				x

996 The motion passed with further discussion. Mr. Henderson inquired about the process for
997 granting eligibility to take the NABP exams and how an applicant would receive an authorization
998 to test (ATT). Dr. Ruffridge clarified that the eligibility section is a separate regulation in 12 AAC
999 52.092. Ms. Carrillo stated the regulations section exam eligibility is "approval to sit for
1000 examination" whereas ATT is what is issued by the NABP to the applicant after the state
1001 regulatory board has administratively granted the applicant eligibility for the exam. Per the board's
1002 earlier discussion on delegating eligibility approval to the NABP, Ms. Carrillo added that the board
1003 could amend this section and 12 AAC 52.092 so they're put in place at the same time, as well as

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take into consideration the time it might take to finalize a delegation agreement with the NABP so changes occur seamlessly.

Ms. Carrillo stated not all of 12 AAC 52.070(b)(4) can be repealed because the board still needs to address foreign graduates.

On a motion duly made by Justin Ruffridge to create a subsection 8 pertaining to foreign pharmacy graduates and the FPGEC, seconded by Ashley Schaber, and approved unanimously, it was:

> **RESOLVED to create a subsection 8 addressing pharmacy graduates and the FPGEC.**

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth	x			
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Sharon Long				x

The motion passed with further discussion.

The board then discussed affidavits of moral character. Dr. Ruffridge inquired whether this should still be a requirement since anyone could write a letter of recommendation for an applicant. Ms. Carrillo stated it is in statute, AS 08.80.110. Dr. Ruffridge suggested repealing this but requiring a background check. Ms. Carrillo inquired if most employers require background checks, to which Dr. Schaber stated most but not all do. Ms. Carrillo then inquired whether the board would want to require state-level background checks or national background checks; the former could be done via a regulation change but the latter would require a statute change to add the Board of Pharmacy to AS 12.62.400. Dr. Schaber expressed interest in continuing to discuss this.

TASK 18
Ms. Carrillo will add national background checks, AS 12.62.400, to the board's next meeting as a potential statute change.

Mr. Henderson inquired about 12 AAC 52.070(b)(6), the requirement to verify 1,500 hours of experience and whether it is sent to the NABP. Ms. Carrillo stated it is just reviewed by board staff then asked whether this is standard. Dr. Adams stated that 1,700 hours is required in Idaho but that all states require at least 1,500 hours. Mr. Henderson suggested striking this subsection altogether because every pharmacy school requires that graduates complete a minimum of 1,500 hours.

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On a motion duly made by James Henderson to repeal 12 AAC 52.070(b)(6) and replace this requirement with an attestation and signature, seconded by Justin Ruffridge, and approved unanimously, it was:

RESOLVED to amend 12 AAC 52.070(b)(6).

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth	x			
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Sharon Long				x

The motion passed with further discussion.

The board then reviewed 12 AAC 52.070(c) regarding eligibility to take the MPJE. Mr. Henderson suggested striking this because it is redundant to 12 AAC 52.092, approval to sit for examination. On a motion duly made by James Henderson to repeal 12 AAC 52.070(c), seconded by Justin Ruffridge, and approved unanimously, it was:

RESOLVED to repeal 12 AAC 52.070(c).

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth	x			
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Sharon Long				x

The motion passed with further discussion.

The board then discussed potential language for the aforementioned changes to 12 AAC 52.070(b)(8) and 12 AAC 52.070(b)(6).

On a motion duly made by Tammy Lindemuth to create subsection, 12 AAC 52.070(b)(8), to read "…verification that a foreign pharmacy graduate received the Foreign Pharmacy Graduate Examination Committee certificate, sent directly to the department by the National Association of Boards of Pharmacy, if applicable.", seconded by Ashley Schaber, and approved unanimously, it was:

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RESOLVED to create 12 AAC 52.070(b)(8).

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth	x			
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Sharon Long				x

The motion passed with no further discussion.

On a motion duly made by Tammy Lindemuth to amend subsection, 12 AAC 52.070(b)(6) to read, "…a signed attestation that the applicant has completed the internship hours required to graduate from an accredited pharmacy curriculum.", seconded by Ashley Schaber, and approved unanimously, it was:

RESOLVED to amend 12 AAC 52.070(b)(6).

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth	x			
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Sharon Long				x

The motion passed with no further discussion.

- *12 AAC 52.080 – Internship requirements for a pharmacist license.* Dr. Ruffridge stated the board is repealing and replacing 12 AAC 52.070(b)(6) regarding the 1,500 hours, which effectively makes 12 AAC 52.080(a) moot.

On a motion duly made by James Henderson to repeal 12 AAC 52.080, seconded by Tammy Lindemuth, and approved unanimously, it was:

RESOLVED to repeal 12 AAC 52.080.

	APPROVE	DENY	ABSTAIN	ABSENT

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Justin Ruffridge	x		
Lana Bell	x		
Tammy Lindemuth	x		
James Henderson	x		
Ashley Schaber	x		
Leif Holm			x
Sharon Long			x

The motion passed with discussion from Dr. Ruffridge that the editor's note covers accreditation.

- 12 AAC 52.092 – Approval to sit for examination. The board discussed repealing this section and re-adopting it to reflect delegation of NAPLEX and MPJE approval to the NABP instead of it being done by board of pharmacy staff.

On a motion duly made by Tammy Lindemuth to repeal and readopt 12 AAC 52.092 to read, "An applicant for licensure by examination who has submitted documents that meet the requirements set out in 12 AAC 52.070 will be referred to the National Association of Boards of Pharmacy by the board pursuant to a written delegation agreement 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, seconded by Ashley Schaber, and approved unanimously, it was:

RESOLVED to repeal and readopt 12 AAC 52.092.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth	x			
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Sharon Long				x

The motion passed with no further discussion.

- *12 AAC 52.095 – Application for Pharmacist License by Reciprocity*. The board first addressed making amendments to subsection (c)(4) like changes made for transcript/diploma requirements in 12 AAC 52.070(b)(4). Mr. Henderson inquired whether this whole section should be repealed. Dr. Schaber agreed, stating that the graduation and license requirements are already included in (c)(6)(7). The board discussed other requirements to repeal. The board discussed the reciprocity language. Dr. Ruffridge noted the language seems to have been copied and pasted from the examination regulations and that some requirements seem odd, such as the language about states participating in the NABP. Dr.

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Ruffridge stated every state has a board of pharmacy and Dr. Adams stated all state board boards are a member of the NABP. Mr. Henderson stated the license verification requirement makes existing 7 redundant. Dr. Ruffridge suggested to strike proposed (e) on license transfer applications.

On a motion duly made by Tammy Lindemuth to amend 12 AAC 52.095(c) to strike (c)(4), keep (c)(5), repeal (c)(6)-(8), and amend (c)(9) to become (c)(4) to read, "shall submit an application for license transfer through the National Association of Boards of Pharmacy. The license by which the applicant is seeking reciprocity from must be current, unencumbered, and in good standing." seconded by Ashley Schaber, and approved unanimously, it was

RESOLVED to amend 12 AAC 52.095(c).

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth	x			
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Sharon Long				x

The motion passed with no further discussion.

On a motion duly made by Justin Ruffridge to add a new subsection to 12 AAC 52.095 to state, "experience gained during rotation requirements at an accredited institution will be accepted by the board to satisfy AS 08.80.145(5)." seconded by James Henderson, and approved unanimously, it was:

RESOLVED to add a new subsection to 12 AAC 52.095.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth	x			
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Sharon Long				x

The motion passed with no further discussion.

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- 12 AAC 52.120 - Review of pharmacy intern license application. The board reviewed this section. Ms. Carrillo commented the authorization for release of records requirement isn't standard for all boards. The board discussed repealing this section as well as the authorization for release of records requirements for pharmacists. Chair Ruffridge then addressed the proposal to make the intern license valid for 5 years instead of 2, stating it may be too long.

On a motion duly made by Justin Ruffridge to strike the release of records requirement in 12 AAC 52.070(b)(3), 12 AAC 52.092(b)(3), 12 AAC 52.095(b)(3), and 12 AAC 52.120(b)(6), seconded by James Henderson, and approved unanimously, it was:

RESOLVED to strike the release of records requirement for pharmacists and interns.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth	x			
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Sharon Long				x

The motion passed with no further discussion.

- 12 AAC 52.130 – Registration of pharmacies located outside of the state. The board discussed changes to the inspection requirements subsection, (b)(4).

On a motion duly made by Justin Ruffridge to amend 12 AAC 52.130(b)(4) to read, "submits an attestation that a self-inspection report was completed within the last two years. A self-inspection report shall be made available upon request for the duration of the licensing period in which it was completed." seconded by Tammy Lindemuth, and approved unanimously, it was:

RESOLVED to amend 12 AAC 52.130(b)(4).

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth	x			
James Henderson	x			
Ashley Schaber	x			

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Leif Holm		x
Sharon Long		x

The motion passed with no further discussion

New Regulations

- 12 AAC 52.120 – Review of pharmacist intern license application. The board returned to discussing intern regulations. Ms. Carrillo explained the document before the board was written when she and Dr. Schaber were working on the disciplinary matrix; Dr. Schaber had pulled up NABP model laws pertaining to intern licensure. Ms. Carrillo noted the board's current regulations addresses graduates of foreign pharmacy programs but doesn't have the same language for non-foreign graduates, stating it is unclear whether the existing language allows recent graduates to apply for an intern license or only those who are presently enrolled. The language only states the applicant must be enrolled, but it could be interpreted as being in past and present tense. The board reviewed the suggested language.

On a motion duly made by Tammy Lindemuth to amend 12 AAC 52.120(b)(3)(A) to read, "presently enrolled in a college of pharmacy accredited by the ACPE and is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist; or" seconded by Ashley Schaber, and approved unanimously, it was:

RESOLVED to amend 12 AAC 52.120(b)(3)(A).

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth	x			
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Sharon Long				x

The motion passed with no further discussion.

On a motion duly made by Tammy Lindemuth to amend 12 AAC 52.120(b)(3)(B) to read, "a graduate of an accredited professional degree program from a school or college of pharmacy within one year preceding the date of this application." seconded by Ashley Schaber, and approved unanimously, it was:

RESOLVED to amend 12 AAC 52.120(b)(3)(B).

	APPROVE	DENY	ABSTAIN	ABSENT

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Justin Ruffridge	x	
Lana Bell	x	
Tammy Lindemuth	x	
James Henderson	x	
Ashley Schaber	x	
Leif Holm		x
Sharon Long		x

The motion passed with no further discussion; however, Ms. Carrillo clarified existing subsection (b)(3)(B) would become (b)(3)(C).

- *12 AAC 52.540 – Notification of theft or significant loss.* Dr. Schaber stated there's a requirement to send the form to the DEA within 1 day, but that there isn't a current timeframe requirement for when to send this to the board. Dr. Schaber shared that states have different requirements, like Arizona, which requires the form to be submitted within 10 days. Mr. Henderson inquired whether there is a corresponding statute obligation for pharmacies to submit this. Dr. Schaber stated AS 08.80.157 requires pharmacies to report this. Lorri Walmsley from the Arizona Board of Pharmacy shared they are considering extending the 10-day requirement because it often does take longer to complete the investigation. Dr. Ruffridge believes there should not be a time limit since they are already required to submit it to the DEA. Dr. Ruffridge stated it has not been an issue for the board, so a time limit shouldn't be impoesd now. Ms. Walmsley added that the DEA is considering also extending their 1-day timeframe to 30 days. Ms. Carrillo inquired about loss/theft notifications for wholesalers as many are inquiring whether this is a requirement in Alaska. Dr. Ruffridge suggested adding this as a new regulation item.

TASK 19
Laura Carrillo will add wholesalers to the board's next meeting agenda for a potential change to 12 AAC 52.540 regarding notification of theft or significant loss.

- 12 AAC 52.900 – Display of license certificate. Ms. Carrillo shared that the division plans to no longer print license certificates on license paper, but that it can still be printed on regular paper either by the division or by the licensee via MYLICENSE. Ms. Lindemuth stated that as a member of the public, she appreciates being able to see these displayed at pharmacies because it ensures the licensee has gone through the proper process, and that it adds a level of trust in the provider. Dr. Schaber stated there may also be a requirement by CMS and/or Joint Commission to have it displayed.

On a motion duly made by Tammy Lindemuth to repeal and readopt 12 AAC 52.990 to state, "A licensee shall conspicuously display, in the practice site, the licensee's current license certificate." seconded by Justin Ruffridge, and approved unanimously, it was:

RESOLVED to repeal and readopt 12 AAC 52.990.

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	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth	x			
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Sharon Long				x

The motion passed with no further discussion; however, Chair Ruffridge requested Ms. Carrillo send a notice out via the ListServ that certificates will no longer be printed on special paper.

TASK 20
Laura Carrillo will send a notice via the ListServ informing subscribers that license certificates will not be printed on special paper, but that it may still be printed on regular paper either by the division or by the licensee via MYLICENSE.

TASK 21
Laura Carrillo will notify the NABP of the board's intent to delegate exam eligibility to their organization.

TASK 22
Laura Carrillo will update the board's regulation project document with the changes discussed at this meeting for the board to review/approve at a special teleconference in March.

Chair Ruffridge called for lunch at 1:15 p.m.

Off record for lunch at 1:15 p.m.
On record at 1:43 p.m.

Agenda Item 8 **.Pharmacy Program Presentation** **Time: 1:44 p.m.**

Bill Cover and Justin Macy from the NABP joined the board to present on its .Pharmacy Internet program. Mr. Cover stated that the vast majority of online pharmacies are operating outside of pharmacy laws. Mr. Macey stated the .Pharmacy program used to validate sites and provide digital seals, but in today's technology world, seals are easily becoming counterfeited or used inappropriately. Mr. Macey stated what this program is doing now is look how we can provide reliable information to patients seeking prescriptions from verified sites.

Mr. Macy added that 42% of Americans used an online pharmacy in 2021, up 7% since 2020. Of these patients who used online pharmacies, 59% of the patients believed the pharmacy was either approved by the FDA or a board of pharmacy, but in reality, most were not. Mr. Macy stated there

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are 30,000 – 35,000 illegal online pharmacies operating at any one time and 20 new illegal online pharmacies launching every day. The NABP has identified over 33,000 website that sell in conflict with state and federal laws or pharmacy practice standards. Drugs sold by illegal online pharmacies often contain too much, too little, or no active ingredient, are manufactured in unsafe conditions, and/or contain unsafe materials. It was found that 95% of websites reviewed don't require a valid prescriptions and 83% of websites offer drugs not authorized by the FDA.

Mr. Macy then demonstrated to the board a fake online pharmacy site which uses a counterfeit FDA approval logo and with drugs being sold in dosages never seen in retail pharmacies. Mr. Macy also showed the board how criminals were able to hack into a medical detox program website, getting into their URL and adding new pages to sell drugs illegally. If one were ever to search for this detox program, they would never find the illegal page; however, if someone searched "Xanax online", they would be able find it.

Mr. Macy stated the .Pharmacy program is recognized by Google, Visa, Twitter, and other domains. The. NABP owns .Pharmacy, meaning nobody can have a .pharmacy TLD without going through approval and accreditation process. Before the board were examples of state regulations and legislation around Internet pharmacies. Dr. Ruffridge stated that Alaskans have lot of remote communities shifting customers to look online, especially during COVID-19, then asked Mr. Macy which state may have the best model laws. Mr. Macy stated the perfect model doesn't exist. States have to think about what works for their patients and demographics, for example, DC pharmacies must be a recognized VIPPS Program, which is a pre-requisite to the .Pharmacy program, but only if they are solely an Internet pharmacy. Mr. Macy added that this then begs the question about whether pharmacies that aren't solely based online have to comply.

Since regulation of out-of-state pharmacies has been an ongoing topic of discussion for the last several years, Dr. Ruffridge expressed continuing discussion on this, particularly as a statute change.

TASK 23
Laura Carrillo will add Internet pharmacies and licensing of out-of-state pharmacies to the agenda at the board's next meeting.

Agenda Item 9 **<u>Statutes</u>** **Time: 2:18 p.m.**

<u>White bagging/Brown bagging (Caren Robinson)</u>
Ms. Robinson shared that she had been working with Senator Olson on draft legislation related to patient choice and white bagging/brown bagging but was regretful in having to inform the board it may not be introduced this year.

<u>Board statute interests</u>
Ms. Carrillo stated there was some momentum a few years ago to get a statute project going, but at present there isn't a comprehensive and updated draft. Dr. Ruffridge recommended the board

start working towards a statute draft to be ready by this summer to potentially ask for Governor Dunleavy's support, or alternatively, to have a project ready by the fall to seek legislative sponsors.

The board discussed the following topics but decided not to pursue further efforts at this time:

- ⊗ National certification (New; board can require nationally certification of existing licensed technicians per LAW opinion)
- ⊗ Equivalent drug products (AS 08.80.400; already in HB 145)
- ⊗ Pharmacist reimbursement and recognition as providers (already in HB 145)
- ⊗ The board identified the following areas to potentially build a statute project:

The board ultimately decided to pursue further efforts for the following:

- ✓ Requiring licensure for out-of-state pharmacists (AS 08.80.030)
- ✓ Regulating .Pharmacy/VIPPS Internet Programs (AS 08.80.158)
- ✓ Regulating automated dispensing machines (AS 08.80.400)
- ✓ Adding "apothecary" to prohibited terms (AS 08.80.420)
- ✓ Add technician seat to board membership; possibly remove 1 public seat (AS 08.80.010)

TASK 24
Laura Carrillo will add statute interests to the board's annual report as well as to subsequent meeting agendas for further discussion.

Legislation
HB 237 – pharmacists; dispensing of medication for treatment of COVID-19 and related diseases.
Mr. Henderson stated that the language compelling pharmacists to not evaluate the medication for patient safety is in direct contradiction to what pharmacists do and Dr. Schaber added it is in the listed in the practice of pharmacy definition in AS 08.80.400(30). Dr. Ruffridge was puzzled on how this made its way through legislative drafting. Mr. Henderson stated that this bill is unnecessary because our board has never denied a license or imposed a disciplinary section for dispensing a medication as prescribed by a physician, nor have threatened to discipline. Dr. Ruffridge expressed that a mandate to dispense any medication sets a dangerous precedence.

On a motion duly made by Justin Ruffridge to oppose HB237, an act relating to pharmacists dispensing medication for treatment of COVID-19 and related diseases for reasons stated on the record, seconded by Lana Bell, and approved unanimously, it was:

RESOLVED to oppose HB237.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell	x			

Tammy Lindemuth			x
James Henderson	x		
Ashley Schaber	x		
Leif Holm			x
Sharon Long			x

The motion passed with no further discussion.

HB 145 – Expand pharmacist authority.

Dr. Schaber reiterated previous statements that this was a collaboration with the AKPhA and the board of pharmacy and should be supported. Dr. Ruffridge agrees it should be supported, highlighting it includes non-discrimination language on pharmacists with regards to insurance reimbursement. Dr. Ruffridge further stated the bill should be supported for the following reasons:

- Clarifies language to more closely align with what pharmacists can legally do within their existing scope of practice;
- Adds non-discrimination language for pharmacists with regards to reimbursement;
- Was a collaboration between the AKPhA and the board to elevate pharmacy practice; and
- Expands workforce capacity by allowing a pharmacy technician working under the direction of a pharmacist to administer vaccines or related emergency medication.

On a motion duly made by Justin Ruffridge to support HB145, an act to expand pharmacist authority, seconded by Lana Bell, and approved unanimously, it was:

RESOLVED to support HB145.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth				x
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Sharon Long				x

The motion passed with no further discussion.

HB91/SB132 – Exempt veterinarians from PDMP.

Mr. Henderson stated it Dr. Delker's concerns made sense, for example with birthdays and names of pets not matching up. Dr. Schaber also appreciated hearing the perspective of Dr. Delker but suggested the board should continue to stay neutral as per the letter submitted last year. Mr. Henderson expressed interest in freeing up time for veterinarians otherwise spent on the PDMP.

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Dr. Ruffridge stated that in the past, the board has addressed ways to improve matters but that solutions have not worked. Dr. Ruffridge's opinion is that the veterinarians should be exempt.

Ms. Bell inquired whether intentionally hurting animals is actually occurring. Ms. Carrillo stated she's received calls from veterinarians who believed clients were intentionally hurting their pets. Ms. Carrillo added she referred the veterinarians to file a complaint with the investigative unit so does not know the outcome of those concerns. Dr. Ruffridge shared that the DEA has also heard of veterinarians reporting that clients hurt their animals. Ms. Carrillo added there are concerns across many professions with time constraints but recommended delegating reviewing and reporting duties to delegates, since only 18% of authorized veterinarian delegates are registered. Dr. Ruffridge further expressed support for this bill for the following reasons:

- Drug diversion from pets has not been an issue in Alaska;
- Requirements are burdensome in an already understaffed field; and
- Excusing veterinarians aligns better with the intent for the PDMP to function properly.

On a motion duly made by Justin Ruffridge to support HB91/SB132, an act to exempt veterinarians from the PDMP**,seconded by Lana Bell, and approved by the majority with one nay, it was:**

RESOLVED to support SB132.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth				x
James Henderson	x			
Ashley Schaber		x		
Leif Holm				x
Sharon Long				x

The motion passed with no further discussion.

HB 266 – information regarding vaccines.

Dr. Ruffridge reviewed this legislation and commented that adding a definition to "vaccine" is unnecessary and expressed opposition that vaccines are designed to be administered only after the patient gives voluntary consent, when this is not what it is designed for. Dr. Schaber expressed an interest in staying neutral. Mr. Henderson also expressed opposition. Dr. Ruffridge further expressed opposition for this bill for the following reasons:

- the definition of vaccine is already implied in the definition of "biological product" in AS 08.80.480; and

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- there is redundancy with regulations in regard to the independent administration of vaccines, including consent, reporting to VAERS, requiring emergency protocols, requiring training prior to giving a vaccine, requiring a display of certificate of training, requiring CPR/AED, and vaccine storage handling and maintenance.

On a motion duly made by James Henderson to oppose HB266, an act related to vaccine information, seconded by Justin Ruffridge, and approved unanimously, it was:

RESOLVED to oppose HB266.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth				x
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Sharon Long				x

The motion passed with no further discussion.

HB306 – Board of Pharmacy sunset.

Dr. Ruffridge stated HB306 should be supported so the board can:

- Benefit Alaskans by promulgating regulations and enforcing regulations for operating pharmacies.
- Administer the PDMP regarding access to dispensing of controlled substances.
- Ensure the practice of pharmacy complies within state law.
- Participate in investigative matters to protect the profession and public.
- Participate in national association activities and collaborate with other state boards.
- Review state exam items regularly and ensure competent applicants can pass them to qualify for licensure.
- Ensure patients have safe and efficient access to medications.
- Ensure the practice of pharmacy is collaborative and cohesive.

Ms. Carrillo also inquired whether she could add the following highlights of board activity:

- Implementing regulations for third-party logistics providers, outsourcing facilities, and third-party logistics providers to improve the safety of the drug supply chain.
- Expanding workforce capacity by creating new regulations and duties for pharmacy technicians who hold a national certification.

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- Expanding the limitation on prescription supply days to ensure patients have an adequate supply of medication.
- Emergency regulations filed in response to the COVID-19 pandemic, allowing expanded shared pharmacy services functions and temporary pharmacy relocations without requiring a separate license, promoting continuation of medication therapy, and providing support to licensees on PREP Act inquiries.

On a motion duly made by Justin Ruffridge to support HB306, an act to expand pharmacist authority, seconded by James Henderson, and approved unanimously, it was:

RESOLVED to support HB306.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth				x
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Sharon Long				x

The motion passed with no further discussion.

TASK 25
Ms. Carrillo will send the letters of opposition and support for introduced legislation for them to be submitted to the bill sponsors.

Agenda Item 10 **<u>Public Comment #4</u>** **Time: 4:02 p.m.**

Sara Coburn
Ms. Coburn stated she is on the board for Alaska veterinary association and expressed thanks to the board for their consideration of SB132. Ms. Coburn spoke to the comments of animal abuse, reiterating it is a crime, separate from the PDMP, and is reported accordingly. She added there are very few cases of animal abuse found through drug diversion and the PDMP.

James Delker
Dr. Delker expressed his appreciation for the board's consideration. Dr. Delker emphasized that fines that will continue and it will to veterinarians to cover increased investigative costs. Dr. Delker stated veterinarians can continue to support the ongoing opioid crisis by requiring continuing education and finding other ways to report.

Rachel Berngartt

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Dr. Berngartt also spoke to opioid-specific continuing education in the fight to continue engaging as part of the solution. Dr. Berngartt emphasized that the veterinarian community is struggling but wanted to offer assurances to the pharmacy board that it would continue efforts to address the opioid crisis, such as requiring opioid-specific continuing education. She then spoke to comments about delegates, stating there simply aren't enough delegates for each veterinarian.

Agenda Item 11 **Administrative Update** **Time: 4:02 p.m.**

Annual reports

Ms. Carrillo stated that 40% of out-of-state pharmacies have not yet submitted their annual reports as of 02/09/2022 and stated another notice will be sent out reminding these pharmacies they are past due. Dr. Ruffridge requested an update on annual reports

Cooperative practice agreements

Ms. Carrillo shared the update that she and the State Medical Board's executive administrator, Natalie Norberg, have continued to meet to develop a joint application and process for cooperative practice agreements to be reviewed/approved. The efforts are ongoing.

Renewal roll-out

Renewal applications will be available on/around April 1st.

ListServ notices

The board reviewed notices sent through the ListServ since its last meeting, including PDMP regulation updates, the board's continuing education matrix, and information related to COVID-19 therapeutics.

MPJE pass rates

The average Alaska MPJE pass rate is around the mid 70% range.

Upcoming travel/conferences/training

The NABP's 118th Annual Meeting will be held from May 19-21, 2022 in Phoenix, AZ. Dr. Schaber or Dr. Ruffridge plan to attend. Ms. Carrillo and Dr. Schaber will also volunteer for the MPJE writing workshop remotely in mid-March.

Set next meeting dates

The board set the next 2022 meeting dates as follows:

- Friday, March 25 – special meeting to adopt regulations 9:00 – 1:00 via Zoom
- June 2 and 3 – in Anchorage
- September 22 and 23 – Anchorage
- November 17, 18 – Anchorage

TASK 26

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Laura Carrillo will provide an update on out-of-state pharmacies who have since submitted their annual report at the board's next meeting.

TASK 27

Laura Carrillo will submit an out-of-state travel approval request for Dr. Schaber or Dr. Ruffridge to attend the NABP's 118th Annual Meeting in Phoenix, AZ.

TASK 28

Laura Carrillo will submit in-state travel approval requests for meetings to be held in Anchorage on June 2-3, September 22-23, and November 17-18.

_____

Laura Carrillo, Executive Administrator Date

_____

Justin Ruffridge, Chair Date

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

Alaska Board of Pharmacy

MOTION LIST

March 25, 2022 Special Teleconference

By authority of AS 08.01.070(2), and in compliance with the provisions of AS 44.62, Article 6, a scheduled meeting of the Board of Pharmacy was held via videoconference on March 25, 2022. Included in this document are a list of motions made during this special teleconference only; these are not meeting minutes. You may request a copy of the recording by emailing boardofpharmacy@alaska.gov.

Agenda Item 1 **Call to Order/Roll Call** **Time: 9:04 a.m.**

No motions.

Agenda Item 2 **Review/Approve Agenda** **Time: 9:05 a.m.**

On a motion duly made by Ashley Schaber to add public comment as Agenda Item #7 and to shift other items downward, seconded by James Henderson, and approved unanimously, it was:

RESOLVED to approve the March 25, 2022 agenda as amended.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Tammy Lindemuth				x
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Ramsey Bell	x			

The motion passed with no further discussion.

Agenda Item 3 **Ethics Disclosures** **Time: 9:05 a.m.**

No motions.

Agenda Item 4 **Regulations** **Time: 9:10 a.m.**

On a motion duly made by Ashley Schaber to amend 12 AAC 52.300(a) regarding renewal to include, "remote pharmacy", "pharmacist" and "pharmacy technician" and to add "unless extended due to an emergency or extenuating circumstance as determined by the board, seconded by James Henderson and approved unanimously, it was:

RESOLVED to amend 12 AAC 52.300(a) as proposed.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Tammy Lindemuth				x
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Ramsey Bell	x			

The motion passed with further discussion. Ms. Carrillo stated the changes are not substantive per Department of Law and do not need to be re-released for public comment.

On a motion duly made by Justin Ruffridge to amend 12 AAC 52.110(a)(3) to read, "submits primary source verification that the applicant is currently licensing in another licensing jurisdiction and the applicant's license in the other jurisdiction is not suspended, revoked, or otherwise restricted except for failure to apply for renewal or failure to obtain the required continuing education requirement;" seconded by James Henderson and approved unanimously, it was:

RESOLVED to amend 12 AAC 52.110(a)(3) as proposed.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Tammy Lindemuth				x
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Ramsey Bell	x			

The motion passed with no further discussion.

On a motion duly made by Ashley Schaber to approve 12 AAC 52.105 related to military licensing as proposed, 12 AAC 52.110 related to emergency permits as amended, 12 AAC 52.300 related to renewal as amended, and 12 AAC 52.993 related to executive

administrator duties as proposed, seconded by James Henderson and approved unanimously, it was:

RESOLVED to amend 12 AAC 52.105, 12 AAC 52.110, 12 AAC 52.300, and 12 AAC 52.993 as proposed.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Tammy Lindemuth				x
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Ramsey Bell	x			

The motion passed with no further discussion.

Agenda Item 5 **<u>Review/Approve Pending Regulations</u>** **Time: 9:51 a.m.**

On a motion duly made by James Henderson to repeal 12 AAC 52.200(b)(7), seconded by Ramsey Bell and approved unanimously, it was:

RESOLVED to repeal 12 AAC 52.200(b)(7).

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Tammy Lindemuth				x
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Ramsey Bell	x			

The motion passed with no further discussion.

On a motion duly made by Ashley Schaber to approve 12 AAC 52.140 related to pharmacy technician licensure as proposed, seconded by James Henderson and approved unanimously, it was:

RESOLVED to amend 12 AAC 52.140 as proposed.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			

Tammy Lindemuth				x
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Ramsey Bell	x			

The motion passed with no further discussion.

On a motion duly made by Justin Ruffridge to amend 12 AAC 52.200(c) to read, "A pharmacist designated to replace the pharmacist-in-charge of a license or registered pharmacy shall notify the board within 10 days of that designation, but submitting a completed change of pharmacist-in-charge form provided by the department and paying the applicable fees established in 12 AAC 52.02.105(3).", seconded by James Henderson and approved unanimously, it was:

RESOLVED to amend 12 AAC 52.200(c) as proposed.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Tammy Lindemuth				x
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Ramsey Bell	x			

The motion passed with no further discussion.

On a motion duly made by James Henderson to add 12 AAC 52.200(d) to read, "Notwithstanding 12 AAC 52.425(a), a pharmacist may not serve as pharmacist in-charge unless he or she is physically present in the pharmacy for a sufficient amount of time to provide supervision and control. A pharmacist may not serve as pharmacist-in-charge for more than one pharmacy at any one time except upon obtaining written permission from the board.", seconded by Ramsey Bell and approved unanimously, it was:

RESOLVED to amend 12 AAC 52.200(d) as proposed.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Tammy Lindemuth				x
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x

Ramsey Bell	x			

The motion passed with no further discussion.

On a motion duly made by Ashley Schaber to approve 12 AAC 52.200 related to pharmacist-in-charge requirements as proposed, seconded by Ramsey Bell and approved unanimously, it was:

RESOLVED to approve 12 AAC 52.200 as proposed.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Tammy Lindemuth				x
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Ramsey Bell	x			

The motion passed with no further discussion.

On a motion duly made by James Henderson to add 12 AAC 52.200(d) to read, "Notwithstanding 12 AAC 52.425(a), a pharmacist may not serve as pharmacist in-charge unless he or she is physically present in the pharmacy for a sufficient amount of time to provide supervision and control. A pharmacist may not serve as pharmacist-in-charge for more than one pharmacy at any one time except upon obtaining written permission from the board.", seconded by Ramsey Bell and approved unanimously, it was:

RESOLVED to amend 12 AAC 52.200(d) as proposed.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Tammy Lindemuth				x
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Ramsey Bell	x			

The motion passed with no further discussion.

On a motion duly made by Ashley Schaber to amend 12 AAC 52.230 related to pharmacy technician duties, seconded by James Henderson and approved unanimously, it was:

RESOLVED to amend 12 AAC 52.230 as proposed.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Tammy Lindemuth				x
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Ramsey Bell	x			

The motion passed with no further discussion.

On a motion duly made by Ashley Schaber to amend 12 AAC 52.430 related to pharmacy technician duties, seconded by James Henderson and approved unanimously, it was:

RESOLVED to amend 12 AAC 52.240 as proposed.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Tammy Lindemuth				x
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Ramsey Bell	x			

The motion passed with no further discussion.

On a motion duly made by James Henderson to amend 12 AAC 52.470(d) to read, "A pharmacist or pharmacist intern may dispense any quantity of a prescription drug order so long as the total quantity of dosage units dispensed does not exceed the total quantity of dosage units authorized by the prescriber, including refills." and to strike (d)(2), seconded by Ramsey Bell and approved unanimously, it was:

RESOLVED to amend 12 AAC 52.470(d) as proposed.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Tammy Lindemuth				x
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Ramsey Bell	x			

The motion passed with no further discussion.

On a motion duly made by Ashley Schaber to amend 12 AAC 52.585 related to patient counseling, seconded by Ramsey Bell and approved unanimously, it was:

RESOLVED to amend 12 AAC 52.585 as proposed.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Tammy Lindemuth				x
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Ramsey Bell	x			

The motion passed with no further discussion.

On a motion duly made by Ashley Schaber to amend 12 AAC 52.620 related to wholesale drug distributor licensure, seconded by James Henderson and approved unanimously, it was:

RESOLVED to amend 12 AAC 52.620 as proposed.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Tammy Lindemuth				x
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Ramsey Bell	x			

The motion passed with no further discussion.

On a motion duly made by Ashley Schaber to amend 12 AAC 52.696 related to outsourcing facility licensure, seconded by James Henderson and approved unanimously, it was:

RESOLVED to amend 12 AAC 52.696 as proposed.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Tammy Lindemuth				x
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Ramsey Bell	x			

The motion passed with no further discussion.

On a motion duly made by Ashley Schaber to amend 12 AAC 52.697 related to third-party logistic provider licensure, seconded by James Henderson and approved unanimously, it was:

RESOLVED to amend 12 AAC 52.697 as proposed.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Tammy Lindemuth				x
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Ramsey Bell	x			

The motion passed with no further discussion.

On a motion duly made by Ashley Schaber to create a new regulation section titled. "Facility Manager' to read, "(a) A facility manager of a wholesale drug distributor, outsourcing facility, or third-party logistics provider designated to replace the facility manager of a facility shall notify the board within 10 days of that designation, by submitting a completed change of facility manager notice on a form provided by the department. The outgoing facility manager shall also notify the board within 10 days on a form provided by the department. (b) A facility manager may be in charge of more than one location and may be designated as the facility manager for multiple facilities simultaneously.", seconded by Ramsey Bell and approved unanimously, it was:

RESOLVED to create a new regulation related for facility managers.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Tammy Lindemuth				x
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Ramsey Bell	x			

The motion passed with no further discussion.

Off record for break at 12:30 p.m.
On record from break at 12:44 p.m.

Agenda Item 7 **Public Comment** **Time: 12:45 p.m.**

No motions.

Agenda Item 6 **Legislation** **Time: 12:48 p.m.**

No motions.

Agenda Item 14 **Adjourn** **Time: 1:08 p.m.**

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: June 02, 2022

TO: Board of Pharmacy

THRU: Greg Francois, Chief Investigator

FROM: Michael Bowles, Investigator

RE: Investigative Report for the June 16, 2022 Meeting

The following information was compiled as an investigative report to the Board for the period of February 08, 2022 thru June 02, 2022; 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 - 36

Case Number	Violation Type	Case Status	Status Date
OUT OF STATE PHARMACY			
2022-000476	Violation of licensing regulation	Intake	05/23/2022
2022-000213	Falsified application	Complaint	03/14/2022
2022-000434	Violation of licensing regulation	Complaint	06/02/2022
2021-000111	Violation of licensing regulation	Monitor	03/22/2022
2021-000468	Violation of licensing regulation	Investigation	05/09/2022
2021-001208	Violation of licensing regulation	Investigation	03/14/2022
2022-000129	License application problem	Investigation	05/31/2022
2022-000215	Violation of licensing regulation	Investigation	05/31/2022
2022-000293	Violation of licensing regulation	Investigation	05/31/2022

PHARMACIST

2022-000485	Drug diversion	Intake	05/25/2022
2022-000503	Falsified application	Intake	06/01/2022
2021-001241	Unprofessional conduct	Complaint	02/03/2022
2021-001312	Fraud or misrepresentation	Complaint	02/03/2022
2022-000287	Negligence	Complaint	04/06/2022

PHARMACIST INTERN

2022-000435	Unlicensed practice or activity	Complaint	06/02/2022

PHARMACY

2021-001187	Violation of licensing regulation	Complaint	03/03/2022
2022-000424	Violation of licensing regulation	Complaint	05/26/2022
2021-000037	PDMP Violation	Monitor	01/21/2021
2021-000288	Falsified application	Monitor	01/11/2022
2021-000775	Compliance Inspection	Investigation	08/27/2021
2021-000776	Compliance Inspection	Investigation	08/27/2021
2021-000784	Compliance Inspection	Investigation	08/27/2021
2022-000187	Violation of licensing regulation	Investigation	04/11/2022
2022-000216	Violation of licensing regulation	Investigation	05/31/2022

PHARMACY TECHNICIAN

2019-000721	Falsified application	Monitor	03/22/2022
2019-000936	Falsified application	Investigation	02/11/2021
2022-000320	Contested license denial	Litigation Initiated	04/06/2022

WHOLESALE DRUG DEALER

2022-000446	Violation of licensing regulation	Intake	05/12/2022
2022-000491	Violation of licensing regulation	Intake	05/26/2022
2021-001195	Violation of licensing regulation	Complaint	12/06/2021
2022-000284	Violation of licensing regulation	Complaint	03/30/2022
2022-000354	Violation of licensing regulation	Complaint	04/28/2022

2021-000733	Falsified application	Investigation	03/14/2022
2021-000940	Violation of licensing regulation	Investigation	01/03/2022
2021-001079	PDMP Violation	Investigation	02/16/2022
2022-000294	Violation of licensing regulation	Investigation	05/31/2022

Closed - 34

Case #	Violation Type	Case Status	Closed	Closure
OUT OF STATE PHARMACY				
2022-000127	License application problem	Closed-Intake	05/26/2022	Review Complete
2022-000278	Violation of licensing regulation	Closed-Intake	03/30/2022	Review Complete
2022-000460	License application problem	Closed-Intake	05/18/2022	Review Complete
2021-001194	Violation of licensing regulation	Closed-Complaint	02/10/2022	No Action - No Violation
2022-000188	Violation of licensing regulation	Closed-Complaint	04/26/2022	No Action - No Violation
2021-000054	License application problem	Closed-Investigation	03/03/2022	License Action
2021-000944	Violation of licensing regulation	Closed-Investigation	03/22/2022	Application Denied
2021-001204	Violation of licensing regulation	Closed-Investigation	03/16/2022	Advisement Letter
PHARMACY				
2022-000030	Violation of licensing regulation	Closed-Intake	02/10/2022	Incomplete Complaint
2022-000389	Compliance Inspection	Closed-Intake	04/28/2022	Compliance
2022-000390	Compliance Inspection	Closed-Intake	04/28/2022	Compliance
2022-000391	Compliance Inspection	Closed-Intake	04/28/2022	Compliance
2022-000392	Compliance Inspection	Closed-Intake	04/28/2022	Compliance
2022-000393	Compliance Inspection	Closed-Intake	04/27/2022	Compliance
2022-000436	Compliance Inspection	Closed-Intake	05/12/2022	Compliance
2022-000437	Compliance Inspection	Closed-Intake	05/12/2022	Compliance
2022-000438	Compliance Inspection	Closed-Intake	05/12/2022	Compliance
2022-000439	Compliance Inspection	Closed-Intake	05/12/2022	Compliance
2021-001130	Unprofessional conduct	Closed-Complaint	03/09/2022	No Action - No Violation

2021-001125	Violation of licensing regulation	Closed-Investigation	03/02/2022	Advisement Letter
2022-000365	Compliance Inspection	Closed-Division Inspection	04/20/2022	Compliance
2022-000366	Compliance Inspection	Closed-Division Inspection	04/20/2022	Compliance
2022-000367	Compliance Inspection	Closed-Division Inspection	04/20/2022	Compliance
2022-000368	Compliance Inspection	Closed-Division Inspection	04/20/2022	Compliance

PHARMACY TECHNICIAN

2021-001128	Falsified application	Closed-Complaint	03/09/2022	No Action - No Violation
2021-001127	Falsified application	Closed-Investigation	03/02/2022	Advisement Letter

REGISTERED NURSE

2021-000380	Drug diversion	Closed-Intake	04/04/2022	Incomplete Complaint

WHOLESALE DRUG DEALER

2022-000128	License application problem	Closed-Intake	05/26/2022	Review Complete
2022-000326	Violation of licensing regulation	Closed-Intake	04/12/2022	Review Complete
2022-000282	Violation of licensing regulation	Closed-Complaint	05/23/2022	Review Complete
2021-000763	Violation of licensing regulation	Closed-Investigation	03/03/2022	License Action
2021-000938	Violation of licensing regulation	Closed-Investigation	03/03/2022	License Action
2021-000945	Violation of licensing regulation	Closed-Investigation	03/09/2022	License Action
2021-001210	Violation of licensing regulation	Closed-Investigation	03/22/2022	Advisement Letter

END OF REPORT

FLORIDA

http://www.leg.state.fl.us/statutes/index.cfm?App_mode=Display_Statute&Search_String=&URL=0400-0499/0465/Sections/0465.0235.html

465.0235 Automated pharmacy systems used by long-term care facilities, hospices, or state correctional institutions, or for outpatient dispensing.—

(1) A pharmacy may provide pharmacy services to a long-term care facility or hospice licensed under chapter 400 or chapter 429 or a state correctional institution operated under chapter 944 through the use of an automated pharmacy system that need not be located at the same location as the pharmacy.

(2) A community pharmacy, as defined in s. 465.003 and licensed in this state, may provide pharmacy services for outpatient dispensing through the use of an automated pharmacy system that need not be located at the same location as the community pharmacy if:

(a) The automated pharmacy system is under the supervision and control of the community pharmacy.

(b) The automated pharmacy system is housed in an indoor environment area and in a location to increase patients' access to their prescriptions, including, but not limited to, medical facilities or places of business where essential goods and commodities are sold or large employer workplaces or locations where access to a community pharmacy is limited.

(c) The community pharmacy providing services through the automated pharmacy system notifies the board of the location of the automated pharmacy system and any changes in such location.

(d) The automated pharmacy system has a mechanism that provides live, real-time patient counseling by a pharmacist, as defined in s. 465.003 and licensed in this state, before the dispensing of any medicinal drug.

(e) The automated pharmacy system does not contain or dispense any controlled substance listed in s. 893.03 or 21 U.S.C. s. 812.

(f) The community pharmacy maintains a record of the medicinal drugs dispensed, including the identity of the pharmacist responsible for verifying the accuracy of the dosage and directions and providing patient counseling.

(g) The automated pharmacy system ensures the confidentiality of personal health information.

(h) The community pharmacy maintains written policies and procedures to ensure the proper, safe, and secure functioning of the automated pharmacy system. The community pharmacy shall annually review the policies and procedures and maintain a record of such policies and procedures for a minimum of 4 years. The annual review must be documented in the community pharmacy's records and must be made available

to the board upon request. The policies and procedures must, at a minimum, address all of the following:

1. Maintaining the automated pharmacy system and any accompanying electronic verification process in good working order.

2. Ensuring the integrity of the automated pharmacy system's drug identifier database and its ability to identify the person responsible for making database entries.

3. Ensuring the accurate filling, stocking, restocking, and verification of the automated pharmacy system.

4. Ensuring the sanitary operation of the automated pharmacy system and the prevention of cross-contamination of cells, cartridges, containers, cassettes, or packages.

5. Testing the accuracy of the automated pharmacy system and any accompanying electronic verification process. The automated pharmacy system and accompanying electronic verification process must, at a minimum, be tested before the first use of the system, upon restarting the system, and after a modification of the system or electronic verification process which alters the filling, stocking, or restocking of the system or the electronic verification process.

6. Training of persons authorized to access, stock, restock, or use the system.

7. Conducting routine and preventative maintenance of the automated pharmacy system, including calibration of the system, if applicable.

8. Removing expired, adulterated, misbranded, or recalled medicinal drugs from the automated pharmacy system.

9. Preventing unauthorized persons from accessing the automated pharmacy system, including assigning, discontinuing, or modifying security access.

10. Identifying and recording persons responsible for filling, stocking, and restocking the automated pharmacy system.

11. Ensuring compliance with state and federal law, including, but not limited to, all applicable labeling, storage, and security requirements.

12. Maintaining an ongoing quality assurance program that monitors and records performance of the automated pharmacy system and any accompanying electronic verification process to ensure proper and accurate functioning, including tracking and documenting system errors. A community pharmacy must maintain such records for a minimum of 4 years and must make such records available to the board upon request.

(3) Medicinal drugs stored in bulk or unit of use in an automated pharmacy system servicing a long-term care facility, hospice, or correctional institution, or for outpatient dispensing, are part of the inventory of the pharmacy providing pharmacy services to that facility, hospice, or institution, or for outpatient dispensing, and medicinal drugs delivered by the automated pharmacy system are considered to have been dispensed by that pharmacy.

(4) The operation of an automated pharmacy system must be under the supervision of a pharmacist licensed in this state. To qualify as a supervisor for an automated pharmacy system, the pharmacist need not be physically present at the site of the automated pharmacy system and may supervise the system electronically. The pharmacist shall be required to develop and implement policies and procedures designed to verify that the medicinal drugs delivered by the automated pharmacy system are accurate and valid and that the machine is properly restocked.

(5) The Legislature does not intend for this section to limit the current practice of pharmacy in this state. This section is intended to allow automated pharmacy systems to enhance the ability of a pharmacist to provide pharmacy services in locations that do not employ a full-time pharmacist. This section does not limit or replace the use of a consultant pharmacist.

(6) The board may adopt rules governing the use of automated pharmacy systems. If adopted, such rules must include all of the following:

(a) Recordkeeping requirements.

(b) Security requirements.

(c) Labeling requirements that permit the use of unit-dose medications if the facility, hospice, or institution maintains medication-administration records that include directions for use of the medication and the automated pharmacy system identifies:

1. The dispensing pharmacy.
2. The prescription number.
3. The name of the patient.
4. The name of the prescribing practitioner.

History.—s. 3, ch. 2004-25; s. 92, ch. 2006-197; s. 119, ch. 2020-2; s. 1, ch. 2020-124.

ARIZONA

R4-23-677. Automated Prescription-dispensing Kiosk Permit

A. General provisions.

1. Only a person issued a Board permit under A.R.S. § 32-1929 to operate a pharmacy in
Arizona may apply to the Board under A.R.S. § 32-1930 for a permit to operate an
automated prescription-dispensing kiosk.
2. A pharmacy permittee described under subsection (A)(1) shall apply for a separate
permit for each automated prescription-dispensing kiosk to be operated.

3. To obtain an automated prescription-dispensing kiosk permit, a pharmacy permittee
shall submit a completed application, using a form available on the Board's website, and
the fee specified in R4-23-205.
4. A pharmacy permittee to which the Board issues an automated prescription-dispensing

kiosk permit shall designate a pharmacist in charge of the automated prescription-
dispensing kiosk.

5. A pharmacy permittee to which the Board issues an automated prescription-dispensing
kiosk permit shall not place the automated prescription-dispensing kiosk in a gas station
or convenience store.
B. Policies and procedures. A pharmacy permittee to which the Board issues an automated
prescription-dispensing kiosk permit shall:
1. Ensure policies and procedures are established for the appropriate performance and use
of the automated prescription-dispensing kiosk. The policies and procedures shall
address:
a. Maintaining a record of each transaction in a manner that attaches the record to
the permit number of the automated prescription-dispensing kiosk;
b. Controlling access to the automated prescription-dispensing kiosk;
c. Operating the automated prescription-dispensing kiosk;
d. Training personnel who use the automated prescription-dispensing kiosk;

e. Maintaining patient services when the automated prescription-dispensing kiosk
is not operating or the prescribed drug or device is not available;
f. Securing the automated prescription-dispensing kiosk against unauthorized removal of the kiosk or access to or removal of drugs or devices from the kiosk;
g. Assuring a patient receives the pharmacy services necessary for appropriate pharmaceutical care including consultation with a pharmacist;
h. Maintaining integrity of information in the system and patient confidentiality;
i. Stocking and restocking the automated prescription-dispensing kiosk;
j. Ensuring compliance with packaging and labeling requirements; and
k. Removing drugs and devices from the automated prescription-dispensing kiosk
without dispensing them and handling wasted or discarded drugs and devices;

2. Ensure the policies and procedures are implemented and complied with by all personnel using the automated prescription-dispensing kiosk;
3. Maintain the policies and procedures by:
a. Reviewing the policies and procedures biennially and making needed revisions, if any;
b. Documenting the review required under subsection (B)(3)(a);
c. Assembling the policies and procedures as a written or electronic manual; and
d. Making the policies and procedures available within the pharmacy permittee to which the Board issued an automated prescription-dispensing kiosk permit for reference by pharmacy personnel and inspection by the Board; and
4. Implement a quality assurance program to monitor compliance with the policies and
procedures and all state and federal law.
C. Change of ownership. An automated prescription-dispensing kiosk permittee shall comply
with R4-23-601(F).
D. An automated prescription-dispensing kiosk permittee shall renew the permit as specified
under R4-23-602(D).
E. The Board shall adhere to the time frames specified under R4-23-602(C) when processing an
initial or renewal application for an automated prescription-dispensing kiosk permit.

Historical Note

New Section made by final rulemaking at 25 A.A.R. 1012, effective June 1, 2019 (Supp. 19-2).

Division 006/143–Pharmacy Prescription Lockers

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Establishes new registration for Pharmacy Prescription Lockers (PPLs)

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Proposes rules that establish a new registration type for Pharmacy Prescription Lockers (PPL). Adds new Division 143 which contains requirements for the operation of a PPL by a PPL Affiliated Pharmacy.

Documents Relied Upon per ORS 183.335(2)(b)(D): None

Resources: Prescription lockers are the patient facing pick-up units that hold prescription, non-prescription drugs, devices and supplies already prepared by the pharmacy - Parata Wellspot Locker - Scriptcenter LS - iLocalbox

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): The agency sent out a fiscal impact request for estimated costs associated with compliance, implementation and operation of a PPL.

Cost of Compliance - (Stakeholders): On 1/24/2022 a fiscal impact request was sent to 1,419 interested party email addresses and 1,444 PIC email addresses. The agency received 1 response with the following estimates:

- Locker purchase: $40,000- $80,000
- Locker lease: $500-1,000 per month
- Surveillance systems: $10,000 initially, then $100-500 per month for data storage

Pharmacies are not required to operate a Pharmacy Prescription Locker (PPL). If a pharmacy chooses to operate a PPL, the PPL Affiliated Pharmacy will be required to apply and pay a registration fee of $225 for the PPL and be required to comply with all Oregon Administrative Rules and Oregon Revised Statutes. We do anticipate that licensed drug outlets may be financially impacted in order to comply with the proposed rules.

Pharmacies that choose to deploy lockers will generate revenue from prescription and over-the-counter drug sales to help offset the cost of compliance with these proposed rules.

OBOP/Other State Agencies/Units of Local Government/Public: Fiscal impact is estimated to be minimal for the agency and limited to administrative and compliance costs. There is no anticipated fiscal impact to other state agencies, units of local government or the public.

Cost of Compliance (including small businesses): There are approximately 113 small business drug outlet pharmacies registered with the board. It is not anticipated that the cost of compliance for small business would be different from that of a non-small business.

Describe how small businesses were involved in development of the rules: Small businesses were not involved with the development of the proposed rules.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): A RAC was not consulted for the development of these rules. The board held a technology forum during the August 2020 board meeting where vendors presented information and resources for the board's consideration prior to drafting proposed rules.

Racial Equity statement per ORS 183.335(2)(b)(F): (identifying how adoption of rule might impact one group of people differently than others) Large, urban, predominantly white communities usually have multiple pharmacies to choose from, but in smaller, rural, and lower socioeconomic areas, even within cities, it can be much more difficult to find an open pharmacy. The proposed rules may positively impact Oregonian's access to pick up prescriptions without having to physically visit an open pharmacy. No contact delivery/pick-up has become necessary for many health-related services due to the ongoing public health emergency.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Rules establish a new drug outlet type of Pharmacy Prescription Lockers (PPLs) and permit a pharmacy to operate a PPL.

Division 6
DEFINITIONS

855-006-0005
Definitions

(x) "Alarm system" means a device or series of devices, which emit or transmit an audible or remote visual or electronic alarm signal, which is intended to summon a response.

(x) "Audiovisual communication system" means a continuously accessible, two-way audiovisual link that allows audiovisual communication in real-time and that prevents unauthorized disclosure of protected health information.

(x) "Entry system" enables control of access to a secured area.

(x) "Still image capture" means a specific image captured electronically from a video or other image capture device.

(x) "Store and forward" means a video or still image record which is saved electronically for future review.

(x) "Surveillance system" means a system of video cameras, monitors, recorders, and other equipment used for surveillance.

NOTE: Board will motion all changes to Div 006 Definitions in one motion at end of policy discussions.

PROPOSE

Division 143
PHARMACY PRESCRIPTION LOCKER

855-143-0001
Purpose and Scope

The purpose of OAR 855-143 is to provide minimum requirements for the operation of a Pharmacy Prescription Locker (PPL) by a PPL Affiliated Pharmacy.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.527

855-143-0005
Definitions

The following words and terms, when used in OAR 855-143, have the following meanings, unless the context clearly indicates otherwise. Any term not defined in this section has the definition set out in OAR 855-006.

(1) "Pharmacy Prescription Locker Affiliated Pharmacy" or "PPL Affiliated Pharmacy" means a Retail Drug Outlet Pharmacy registered in Oregon that operates a Pharmacy Prescription Locker.

(2) "Pharmacy Prescription Locker" or "PPL" means an Oregon location registered as a Retail Drug Outlet Pharmacy Prescription Locker using a mechanical system that securely stores completed patient-specific prescription and non-prescription drugs, devices, and related supplies for pick up.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.527

855-143-0010
Registration: General

(1) Each PPL located in Oregon must be registered as a Retail Drug Outlet PPL.

(2) A controlled substance registration will not be issued for a Retail Drug Outlet PPL.

POLICY DISCUSSION: Controlled substances / DEA Policy & Liaison

(3) A Retail Drug Outlet PPL application must specify the PPL Affiliated Pharmacy and cannot operate without a PPL Affiliated Pharmacy that is registered by the board as a Retail Drug Outlet Pharmacy.

(4) Each registration renewal application must be accompanied by the annual fee and must contain the same information required in OAR 855-143-0015(2) and additional information requested by the board.

PROPOSED

(5) The initial and annual registration fee for pharmacies is set out in OAR 855-110.

(6) A Retail Drug Outlet PPL registration expires March 31, annually. If the annual registration fee referred to in OAR 855-110 is not paid by March 31 of the current year, a late fee as set out in OAR 855-110 must be included with the application for registration renewal.

(7) The registration is not transferable.

(8) The registration fee cannot be prorated.

(9) A PPL may not operate until a certificate of registration has been issued by the board.

(10) The Pharmacy registration and PPL registration must be on display at both the PPL Affiliated Pharmacy and at the PPL.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.225, ORS 689.305, ORS 689.527

855-143-0015
Registration: Application

(1) An application for registration of a new PPL must include a floor plan drawn to scale with the location of the:

(a) PPL at the facility;

(b) Surveillance system cameras; and

(c) Alarm system panel.

(2) The application for registration of new PPL must be approved by the Board prior to opening.

(3) The application must specify the location of the PPL and must indicate the owner, trustee, receiver, or other person applying for the registration. When an applicant is not the owner of the pharmacy, the application must indicate the owner and the applicant's affiliation with the owner:

(a) If the owner is a partnership or other multiple owners, the names of the partners or persons holding the five largest interests must be indicated on the application;

(b) If the owner is a corporation, the name filed must be the same as filed with the Secretary of State. The name of the corporation, the names of the corporation officers and the names of the stockholders who own the five largest interests must be indicated on the application.

(4) Upon request by the Board, the applicant must furnish such information as required by the Board regarding the partners, stockholders, or other persons not named in the application.

PROPOSED

(5) A certificate of registration will be issued upon Board approval of the application.

Statutory/Other Authority: ORS 475.035, ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.305, ORS 689.527

855-143-0020
Registration: Change of Owner, Location, or PPL Affiliated Pharmacy

(1) A change of location of the PPL Affiliated Pharmacy or location of the PPL requires:

(a) Submission of a new PPL application a minimum of 15 days prior to occurrence;

(b) Registration fee;

(c) Approval of the Board; and

(d) New certificate of registration.

(2) A change in the PPL Affiliated Pharmacy or ownership of the PPL requires:

(a) Submission of a new PPL application a minimum of 15 days prior to occurrence;

(b) Registration fee;

(c) Approval of the Board; and

(d) New certificate of registration.

(3) A change of ownership includes any change in the legal form of the business including additions or deletions of partners.

(4) A certificate of registration will be issued upon Board approval of the application.

(5) A PPL that has changed location or ownership must not operate until the new certificate of registration has been approved and issued.

Statutory/Other Authority: ORS 475.035, ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.305 ORS 689.527

855-143-0025
Registration: Closure

NOTE: Under review in Div 041/139 currently, will propose amendments at April 2022 board meeting to align Div 139 with any updates to rules in Div 041/139.

PROPOSED

A PPL Affiliated Pharmacy must notify the board a minimum of 15 days prior to discontinuing operation of a PPL. Notification must include the:

(a) Final disposition of drugs stored in the PPL including:

(A) Name and location where the drugs are transferred;

(B) Name and location where destruction occurred; and

(C) Name and location of the site that will store all records;

(b) Provide the board with:

(A) Oregon Board of Pharmacy state license(s); and

(B) Signed statement giving the effective date of closure.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.305, ORS 689.527

855-143-0030
Non-Resident Affiliated Pharmacies

(1) For the purpose of these rules, a non-resident pharmacy includes a PPL Affiliated Pharmacy located outside of Oregon and providing pharmacy services to a PPL located in Oregon.

(2) Each non-resident PPL Affiliated Pharmacy must be registered with the Oregon Board of Pharmacy as a Retail Drug Outlet Pharmacy.

(3) To qualify for registration under these rules, every non-resident PPL Affiliated Pharmacy must be registered and in good standing with the Board of Pharmacy in the pharmacy's state of residence.

(4) The Oregon licensed Pharmacist-in-Charge (PIC) of the non-resident PPL Affiliated Pharmacy is the PIC for each PPL.

(5) The PIC is responsible for ensuring that the PPL PIC self-inspection form is completed prior to February 1 each year.

(6) The PIC must comply with the requirements of OAR 855-019-0300.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.225, ORS 689.527

PROPOSED

855-143-0050
Personnel

(1) A PPL must have an Oregon licensed PIC at all times.

(2) Prior to utilizing a PPL, the Oregon licensed Pharmacist, Intern, Certified Oregon Pharmacy Technician and Pharmacy Technician must have completed a training program on the proper use of the PPL.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.527

855-143-0100
Security

(1) The PPL Affiliated Pharmacy, the PPL, Oregon licensed PIC of the PPL Affiliated Pharmacy and each Oregon licensed Pharmacist supervising the PPL is responsible for the security of the PPL including provisions for adequate safeguards against loss, theft or diversion of prescription and non-prescription drugs, devices, and related supplies, and records for such drugs, devices and related supplies.

(2) The PPL Affiliated Pharmacy must ensure the PPL:

(a) Is placed in a secure indoor location that is climate controlled and protected from the elements;

(b) Is securely fastened to a permanent structure so that it cannot be removed;

(c) Stores prescription and non-prescription drugs, devices, and related supplies in compliance with the provisions of OAR 855-139-0125;

(3) The PPL must be secured to prevent access when:

(a) There is no Oregon licensed Pharmacist supervising and authorizing access in real-time to the PPL; or

(b) There is no Pharmacist, Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician employed by the PPL Affiliated Pharmacy present at the PPL; or

(c) Any component of the PPL is not functioning.

(4) A record must be maintained with the name and Oregon license number of each person accessing the PPL.

(5) An Intern, Certified Oregon Pharmacy Technician, and Pharmacy Technician may only access the PPL when an Oregon licensed Pharmacist is supervising the licensee and has authorized access to the PPL in real-time.

PROPOSED

(6) Unlicensed personnel (e.g. vendor) may only access the PPL when escorted and continuously observed by a licensee who is authorized by the Oregon licensed Pharmacist who is supervising and authorizing access to the PPL in real-time.

(7) Minimum security methods must include a properly functioning:

(a) Alarm system at the PPL and real-time notification to an Oregon licensed Pharmacist of the PPL Affiliated Pharmacy if unauthorized access occurs;

(b) Electronic entry system that is controlled by an Oregon licensed Pharmacist and records the:

(A) Identification of the Oregon licensed Pharmacist authorizing access and securing the PPL;

(B) Identification of the Pharmacist, Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician accessing and securing the PPL; and

(C) Date and time of each activity; and

(c) Surveillance system that utilizes continuously accessible and recorded video between the PPL Affiliated Pharmacy and the PPL. The system must provide a clear view of the entire PPL including its access points.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.527

855-143-0120
Drug: Procurement

A PPL may only receive prescription, non-prescription drugs, devices, and related supplies from the PPL Affiliated Pharmacy.

Statutory/Other Authority: ORS 475.035, ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.527

855-139-0125
Drug: Storage

NOTE: Under review in Div 041/139 currently, will propose amendments at April 2022 board meeting to align Div 139 with any updates to rules in Div 041/139.

(1) A PPL must maintain proper storage of all drugs. This includes, but is not limited to the following:

(a) All drugs must be stored according to manufacturer's published or USP guidelines.

PROPOSED

(b) All drugs must be stored in appropriate conditions of temperature, light, humidity, sanitation, ventilation, and space.

(c) Appropriate storage conditions must be provided for, including during transfers between facilities and to patients.

(d) A PPL must quarantine drugs which are outdated, adulterated, misbranded or suspect. Cold Storage and Monitoring.

(2) A PPL must store all drugs at the proper temperature according to manufacturer's published guidelines (pursuant to FDA package insert or USP guidelines).

(a) All drug refrigeration systems must:

(A) Maintain refrigerated products between 2 to 8 °C (35 to 46 °F); frozen products between -25 to -10 °C (-13 to 14 °F); or as specified by the manufacturer.

(B) Utilize a centrally placed, accurate, and calibrated thermometer;

(C) Be dedicated to pharmaceuticals only;

(D) Be measured continuously and documented either manually twice daily to include minimum, maximum and current temperatures; or with an automated system capable of creating a producible history of temperature readings.

(b) A PPL must adhere to a monitoring plan, which includes, but is not limited to:

(A) Documentation of training of all personnel;

(B) Maintenance of manufacturer recommended calibration of thermometers;

(C) Maintenance of records of temperature logs for a minimum of three years;

(D) Documentation of excursion detail, including, but not limited to, event date and name of persons(s) involved in excursion responses;

(E) Documentation of action(s) taken, including decision to quarantine product for destruction, or determination by an Oregon licensed Pharmacist that it is safe for continued use. This documentation must include details of the information source;

(F) A written emergency action plan;

(G) Routine preventative maintenance and evaluation of refrigeration equipment and monitoring equipment; and

(H) Documentation and review of temperature recordings at least once every 28 days by the Oregon licensed Pharmacist at the time of in person physical inspection.

PROPOSED

368 **Statutory/Other Authority: ORS 689.205, ORS 689.325**
369 **Statutes/Other Implemented: ORS 689.155, ORS 689.527**
370
371
372 **855-139-0130**
373 **Drug: Loss**
374
375 **A PPL and its PPL Affiliated Pharmacy must:**
376
377 **(1) Ensure that disasters, accidents and emergencies which may affect the strength, purity, or labeling**
378 **of drugs or devices are reported to the board immediately.**
379
380 **(2) Ensure that confirmed significant drug loss or any loss related to suspected drug theft is reported**
381 **to the board within one business day.**
382
383 **Statutory/Other Authority: ORS 689.205, ORS 689.305, ORS 689.315**
384 **Statutes/Other Implemented: ORS 689.155, ORS 689.527**
385
386
387 **855-139-0150**
388 **Outlet: Sanitation**
389
390 **A PPL and its PPL Affiliated Pharmacy must ensure the PPL is kept clean.**
391
392 **Statutory/Other Authority: ORS 689.305**
393 **Statutes/Other Implemented: ORS 689.305, ORS 689.527**
394
395
396 **855-139-0155**
397 **Outlet: Minimum Equipment Requirements**
398
399 **(1) Each Oregon PPL must have the following:**
400
401 **(a) Appropriate equipment and supplies as required by Oregon Revised Statutes, Oregon**
402 **Administrative Rules, United States Code, Code of Federal Regulations, and standards adopted by**
403 **reference (e.g. USP) based on services offered by the PPL outlet;**
404
405 **(b) Appropriate equipment to maintain the proper storage of drugs;**
406
407 **(c) Signage in a location easily seen by the public at the PPL where prescription and non-prescription**
408 **drugs, devices, and related supplies are dispensed:**
409
410 **(A) Stating "The (insert name of PPL Affiliated Pharmacy) may be able to substitute a less expensive**
411 **drug which is therapeutically equivalent to the one prescribed by your doctor unless you do not**
412 **approve." The printing on this sign must be in block letters not less than one inch in height.**
413
414 **(B) Providing notification in each of the languages required in OAR 855-139-0410 of the right to free,**
415 **competent oral interpretation and translation services, including translated prescription labels, for**

PROPOSED

patients who are of limited English proficiency, in compliance with federal and state regulations if the pharmacy dispenses prescriptions for a patient's self-administration;

(C) Stating "This location is a Pharmacy Prescription Locker, supervised by an Oregon licensed Pharmacist from (insert name of PPL Affiliated Pharmacy, address, and telephone number)." The printing on the sign must be in block letters not less than one inch in height; and

(D) Providing notification of accurate hours of operation at each building entrance and each pharmacy entrance; and

(e) Accurate hours of operation on each telephone greeting and pharmacy-operated internet (e.g. website, social media, mobile applications).

(d) Additional equipment and supplies that are determined as necessary by the PPL Affiliated Pharmacy or PIC.

(2) Failure to have, use and maintain required equipment constitutes unprofessional conduct under ORS 689.405(1)(a).

Statutory/Other Authority: ORS 689.205, ORS 689.654
Statutes/Other Implemented: ORS 689.155, ORS 689.515, ORS 689.654, ORS 689.527

855-143-0200
Outlet: General Requirements

(1) The PPL Affiliated Pharmacy and its PIC are responsible for all operations and enforcing all policies and procedures of the PPL.

(2) A PPL Affiliated Pharmacy may operate more than one PPL.

(3) A PPL Affiliated Pharmacy must be less than 120 miles apart via the shortest surface street route from the PPL.

(4) A PPL and its PPL Affiliated Pharmacy must:

(a) Have the same owner; or

(b) Have a written contract that specifies:

(A) The services to be provided by each licensee and registrant;

(B) The responsibilities of each licensee and registrant; and

(C) The accountabilities of each licensee and registrant;

(c) Ensure each prescription and non-prescription drugs, devices, and related supplies are dispensed in compliance with OAR 855-019, OAR 855-025, OAR 855-031, OAR 855-041 and OAR 855-143;

PROPOSED

464 **(d) Ensure prescription and non-prescription drugs devices, and related supplies are not dispensed**
465 **from the PPL if an Oregon licensed Pharmacist is not available for patient consultation or if the PPL is**
466 **not operable and functioning in all aspects;**
467
468 **(e) Ensure that the PPL Affiliated Pharmacy prevents duplicate dispensing of a prescription;**
469
470 **(f) Comply with all applicable federal and state laws and rules;**
471
472 **(g) Ensure that PPL Affiliated Pharmacy has received and documented consent by the patient or**
473 **patient's agent for the patient's prescription and non-prescription drugs, devices, and related supplies**
474 **to be placed in the PPL;**
475
476 **(h) Ensure that there is an Oregon licensed PIC who is responsible for all operations and enforcing all**
477 **policies and procedures of the PPL;**
478
479 **(i) Designate in writing the Oregon licensed Pharmacists, Interns, Pharmacy Technicians and Certified**
480 **Oregon Pharmacy Technicians authorized to access the PPL;**
481
482 **(j) Utilize complete chain of custody tracking;**
483
484 **(k) Train the Oregon licensed Pharmacists, Interns, Pharmacy Technicians and Certified Oregon**
485 **Pharmacy Technicians in the operation of the PPL and document the training;**
486
487 **(l) Develop, implement and enforce a continuous quality improvement program for dispensing**
488 **services from a PPL designed to objectively and systematically:**
489
490 **(A) Monitor, evaluate, document the quality and appropriateness of patient care;**
491
492 **(B) Improve patient care; and**
493
494 **(C) Identify, resolve and establish the root cause of dispensing and DUR errors and prevent their**
495 **reoccurrence;**
496
497 **(m) Provide a toll-free telephone number that a patient, patient's agent or prescriber may use to**
498 **contact the Oregon licensed Pharmacist from the PPL Affiliated Pharmacy; and**
499
500 **(n) Develop, implement and enforce a process for an in person physical inspection of the PPL by an**
501 **Oregon licensed Pharmacist at least once every 28 days or more frequently as deemed necessary by**
502 **the Oregon licensed PIC of the PPL Affiliated Pharmacy. The inspection must utilize the PPL self-**
503 **inspection form, be documented, and records retained.**
504
505 **Statutory/Other Authority: ORS 689.205**
506 **Statutes/Other Implemented: ORS 689.155, ORS 689.527**
507
508
509 **855-143-0205**
510 **Outlet: Technology**
511

PROPOSED

512 **A PPL and its PPL Affiliated Pharmacy must:**
513
514 **(1) Utilize a shared computer system and have appropriate technology or interface to allow access to**
515 **information required to dispense a prescription and non-prescription drugs, devices, and related**
516 **supplies and counsel the patient or patient's agent;**
517
518 **(2) Utilize barcode, radio-frequency identification or quick response code technology for stocking,**
519 **destocking and dispensing of the PPL;**
520
521 **(3) Test the PPL and verify the unit is operable and functioning in all aspects in accordance with**
522 **minimum acceptable system or unit design specifications before dispensing prescription and non-**
523 **prescription drugs, devices, and related supplies and after an upgrade or change is made to the**
524 **system. The PPL Affiliated Pharmacy must make the results of such testing available to the board**
525 **upon request; and**
526
527 **(4) Develop, implement and enforce a plan for routine maintenance of the PPL.**
528
529 **(5) Develop, implement and enforce a plan for responding to and recovering from an interruption of**
530 **service where the PPL is not fully operational and functioning.**
531
532 **Statutory/Other Authority: ORS 689.205**
533 **Statutes/Other Implemented: ORS 689.155, ORS 689.527**
534
535
536 **855-139-0210**
537 **Outlet: Supervision**
538
539 **A PPL and its PPL Affiliated Pharmacy must:**
540
541 **(1) Ensure prescription and non-prescription drugs, devices, and related supplies are only dispensed at**
542 **the PPL if an Oregon licensed Pharmacist is available for patient consultation and the PPL is fully**
543 **operational.**
544
545 **(2) Ensure that stocking and destocking of prescription and non-prescription drugs, devices, and**
546 **related supplies in a PPL is completed under the supervision, direction and control of a pharmacist.**
547
548 **(3) Ensure that an Oregon licensed Pharmacist verifies and documents that:**
549
550 **(a) All prescription and non-prescription drugs, devices, and related supplies were correctly stocked**
551 **into the PPL;**
552
553 **(b) All prescription and non-prescription drugs, devices, and related supplies destocked from the PPL**
554 **were returned to the PPL Affiliated Pharmacy;**
555
556 **(c) Proper storage conditions were maintained during transfer per OAR 855-143-0125; and**
557
558 **(d) Records are maintained per OAR 855-143-0550.**
559

PROPOSED

Statutory/Other Authority: ORS 689.205, ORS 689.225
Statutes/Other Implemented: ORS 689.151, ORS 689.155,ORS 689.305, ORS 689.527

855-143-0215
Outlet: Pharmacist Utilization

A PPL and its PPL Affiliated Pharmacy must:

(1) Ensure prescription and non-prescription drugs, devices, and related supplies are not dispensed from the PPL if an Oregon licensed Pharmacist is not available for patient consultation or if the PPL is not operable and functioning in all aspects.

(2) Utilize an Oregon licensed Pharmacist to provide real-time consultation, counseling, or to accept the refusal of counseling from the patient or the patient's agent via audiovisual communication system:

(a) For each prescription and non-prescription drugs, devices, and related supplies being dispensed when counseling is required under OAR 855-019-0230

(b) When the patient or patient's agent requests consultation; and

(c) Document the interaction.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.527

855-143-0220
Outlet: Non-Prescription Drugs and Supplies

If non-prescription drugs and related supplies are placed in the PPL, the PPL and its PPL Affiliated Pharmacy must:

(1) Ensure that only an Oregon licensed Pharmacist verifies non-prescription drugs and related supplies that will be placed in the PPL; and

(2) Ensure that an Oregon-licensed Pharmacist is readily available to provide counseling or recommendations involving non-prescription drugs and related supplies.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.527

PROPOSED

608 **855-143-0225**
609 **Outlet: Controlled Substances**
610
611 **Controlled substances may not be stored in the PPL.**
612
613 **Statutory/Other Authority: ORS 689.205**
614 **Statutes/Other Implemented: ORS 689.155, ORS 689.527**
615
616
617 **855-143-0345**
618 **Dispensing: General Requirements**
619
620 **The PPL Affiliated Pharmacy must:**
621
622 **(1) Ensure prescription, prescription refill, and drug order must be correctly dispensed by the PPL in**
623 **accordance with the prescribing practitioner's authorization; and**
624
625 **(2) Ensure the PPL dispenses prescriptions accurately and to the correct party.**
626
627 **Statutory/Other Authority: ORS 689.205**
628 **Statutes/Other Implemented: ORS 689.155, ORS 689.527, ORS 689.527**
629
630
631 **855-143-0500**
632 **Policies and Procedures**
633
634 **(1) The Oregon licensed PIC of the PPL Affiliated Pharmacy and the PPL Affiliated Pharmacy drug**
635 **outlet is accountable for establishing, maintaining, and enforcing written policies and procedures for**
636 **the PPL. The written policies and procedures must be maintained at the PPL Affiliated Pharmacy and**
637 **must be available to the board upon request.**
638
639 **(2) The written policies and procedures must include at a minimum the responsibilities of the PPL**
640 **Affiliated Pharmacy and each PPL including;**
641
642 **(a) Security;**
643
644 **(b) Operation, testing and maintenance of the PPL;**
645
646 **(c) Sanitation and cleaning;**
647
648 **(d) Storage of drugs;**
649
650 **(e) Stocking and destocking;**
651
652 **(f) Dispensing;**
653
654 **(g) Preventing duplicate dispensing;**
655

PROPOSED

656 **(h) Oregon licensed Pharmacist supervision, direction and control of and control of licensed personnel**
657 **accessing the PPL;**
658
659 **(i) Documenting the identity, function, location, date and time of the licensed personnel accessing the**
660 **PPL;**
661
662 **(j) Utilization of Oregon licensed Pharmacist (i.e. Counseling);**
663
664 **(k) Recordkeeping;**
665
666 **(l) Patient consent and confidentiality;**
667
668 **(m) On-site inspection by an Oregon licensed Pharmacist;**
669
670 **(n) Continuous quality improvement;**
671
672 **(o) Plan for discontinuing and recovering services if PPL disruption occurs;**
673
674 **(p) Training: initial and ongoing; and**
675
676 **(q) Interpretation, translation and prescription reader services.**
677
678 **(3) If non-prescription drugs or supplies are placed in the PPL, the policies and procedures must**
679 **outline the process for the Oregon licensed Pharmacist counseling and advice.**
680
681 **(4) If compounded preparations are compounded at the PPL Affiliated Pharmacy and placed in the PPL**
682 **the policies and procedures must meet the requirements of OAR 855-045.**
683
684 **(5) A PPL Affiliated Pharmacy that provides prescription and non-prescription drugs, devices, and**
685 **related supplies through a PPL must review its written policies and procedures every 12 months,**
686 **revise them if necessary, and document the review.**
687
688 **Statutory/Other Authority: ORS 689.205**
689 **Statutes/Other Implemented: ORS 689.155, ORS 689.527**
690
691
692 **855-143-0550**
693 **Records: General Requirements**
694
695 **(1) The recordkeeping requirements OAR 855-143 are in addition to the requirements of other**
696 **recordkeeping rules of the board. Unless otherwise specified, all records and documentation required**
697 **by these rules, must be retained for three years and made available to the board for inspection upon**
698 **request. Records must be stored onsite for at least one year and may be stored, after one year, in a**
699 **secured off-site location if retrievable within three business days. Records and documentation may be**
700 **written, electronic or a combination of the two.**
701
702 **(2) All required records for the Drug Outlet PPL must be maintained by the PPL Affiliated Pharmacy.**
703

PROPOSED

704 **(3) Records retained by the PPL Affiliated Pharmacy must include, but are not limited to:**
705
706 **(a) Date, time and identification of each individual and activity or function performed on the PPL;**
707
708 **(b) Oregon licensed Pharmacist physical inspection of the PPL;**
709
710 **(c) Audiovisual communication system testing;**
711
712 **(d) Licensee training on the proper use of the PPL;**
713
714 **(e) Still image capture and store and forward images must be retained according to (1);**
715
716 **(f) Data and surveillance system data must be retained for 6 months; and**
717
718 **(g) Any errors or irregularities identified by the quality improvement program.**
719
720 **(4) Records of dispensing from a PPL must include the:**
721
722 **(a) Physical location of the PPL;**
723
724 **(b) Identification of the patient or patient's agent retrieving the prescription, non-prescription drugs,**
725 **and supplies;**
726
727 **(c) A digital image of the individual to whom the prescription was dispensed.**
728
729 **(d) Date and time of transaction;**
730
731 **(e) Each prescription number, patient name, prescriber name, drug name, strength, dosage form and**
732 **quantity;**
733
734 **(f) Each non-prescription drug and supply name, UPC or NDC number, and quantity; and**
735
736 **(g) Name of Oregon licensed Pharmacist or Oregon licensed Intern who provided counseling to the**
737 **patient or patient's agent, if required, documentation that the counseling was performed or that the**
738 **Pharmacist or Intern accepted the patient or patient's agent request not to be counseled.**
739
740 **(5) Records of stocking and destocking of prescriptions into or from a PPL must include the:**
741
742 **(a) Date and time;**
743
744 **(b) Each prescription number, patient name, prescriber name, drug name, strength, dosage form and**
745 **quantity;**
746
747 **(c) Each non-prescription drug and supply name, UPC or NDC number, and quantity;**
748
749 **(d) Name and Oregon license number of the person stocking or destocking prescription, non-**
750 **prescription drugs and supplies from the system; and**
751

PROPOSED

752 **(e) Identity of the Oregon licensed Pharmacist who verifies that the system has been accurately**
753 **stocked or destocked.**
754
755 **Statutory/Other Authority: ORS 689.205**
756 **Statutes/Other Implemented: ORS 689.155, ORS 689.508, ORS 689.527**
757
758
759 **855-139-0600**
760 **Prohibited Practices: General**
761
762 **A PPL may not:**
763
764 **(1) Allow unlicensed personnel, Oregon licensed Pharmacy Technicians or Certified Oregon Pharmacy**
765 **Technicians to ask questions of a patient or patient's agent which screen and/or limit interaction with**
766 **the Oregon licensed Pharmacist;**
767
768 **(2) Advertise or otherwise purport to operate as a pharmacy or to advertise or purport to provide**
769 **pharmacy services unless the person is registered with the board pursuant to ORS 689.305;**
770
771 **(3) Utilize a person to dispense or deliver a prescription and non-prescription drugs, devices, and**
772 **related supplies directly to the patient;**
773
774 **(4) Dispense drugs that require further manipulation by a prior to administration or dispensing (e.g.**
775 **reconstitution, compounding, vaccines); and**
776
777 **(5) Store or dispense controlled substances.**
778
779 **Statutory/Other Authority: ORS 475.035, ORS 689.205, ORS 689.305, ORS 689.315**
780 **Statutes/Other Implemented: ORS 689.155, ORS 689.527**
781
782
783 **855-143-0602**
784 **Prohibited Practices: Disclosure of Patient Information**
785
786 **A Retail Drug Outlet PPL may not:**
787
788 **(1) Allow a licensee or registrant of the board who obtains any patient information to disclose that**
789 **information to a third party without the consent of the patient except as provided in (2) of this rule.**
790
791 **(2) A licensee may disclose patient information:**
792
793 **(a) To the board;**
794
795 **(b) To a practitioner, Oregon licensed Pharmacist, Intern, Pharmacy Technician, or Certified Oregon**
796 **Pharmacy Technician, if disclosure is authorized by an Oregon-licensed Pharmacist who reasonably**
797 **believes that disclosure is necessary to protect the patient's health or well-being; or**
798
799 **(c) To a third-party when disclosure is authorized or required by law; or**

PROPOSED

800 **(d) As permitted pursuant to federal and state patient confidentiality laws; or**
801
802 **(e) To the patient or to persons as authorized by the patient.**
803
804 **(3) Allow a licensee or registrant of the board to access or obtain any patient information unless it is**
805 **accessed or obtained for the purpose of patient care.**
806
807 **Statutory/Other Authority: ORS 475.035, ORS 689.205, ORS 689.305,ORS 689.315**
808 **Statutes/Other Implemented: ORS 689.155, ORS 689.527**
809
810
811 **855-143-0650**
812 **Grounds for Discipline**
813
814 **The State Board of Pharmacy may impose one or more of the following penalties which includes:**
815 **suspend, revoke, or restrict the license of an outlet or may impose a civil penalty upon the outlet**
816 **upon the following grounds:**
817
818 **(1) Any of the grounds listed in ORS 689.405.**
819
820 **(2) Advertising or soliciting that may jeopardize the health, safety, or welfare of the patient including,**
821 **but not be limited to, advertising or soliciting that:**
822
823 **(a) Is false, fraudulent, deceptive, or misleading; or**
824
825 **(b) Makes any claim regarding a professional service or product or the cost or price thereof which**
826 **cannot be substantiated by the licensee.**
827
828 **Statutory/Other Authority: ORS 689.151, ORS 689.155, ORS 689.205, ORS 689.225**
829 **Statutes/Other Implemented: ORS 689.155, ORS 689.405, ORS 689.527**
830
831

PROPOSED

Division 006/019/041/139/143– RPH/Operation of a Pharmacy/RDSP/Lockers (Interpreters/Patient Records)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Adds requirements for use of interpreters and modifies patient record requirements

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Revisions to Division 006/019/041/139 are necessary to incorporate directives set forth in 2021 HB 2359, related to health care interpreters. Per 2021 HB 2359, pharmacists and interns must work with health care interpreters from health care interpreter registry operated by Oregon Health Authority to provide interpretation services. Modifies patient records requirements to include patient's sex assigned at birth current gender identification, and current chosen name.

Documents Relied Upon per ORS 183.335(2)(b)(D):

- 2021 HB 2359 and related statutes and OHA rules OAR XXX-XXX-XXXX related to health care interpreters

- Providing Inclusive Care and Services for the Transgender and Gender Diverse Community: A Pharmacy Resource Guide March 2021

Resources

- Redfern, Jan S., Jann, Michael W. "The evolving role of pharmacists in transgender health care." Transgender health 4.1 (2019): 118-130.https://www.liebertpub.com/doi/epdf/10.1089/trgh.2018.0038

- Cleveland Clinic: Why Deadnaming is Harmful

- EPIC: More Inclusive Care for Transgender Patients Using Epic

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): To be determined

OBOP/Other State Agencies/Units of Local Government/Public: No anticipated fiscal impact is expected for the agency, other state agencies, units of local government or the public.

Cost of Compliance (including small businesses): To be determined

Number/Type:

Reporting, Recordkeeping and Administrative Activities Cost:

Professional Services, Equipment/ Supplies, Labor Cost:

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No, A RAC was not consulted, proposed rules are a legislative directive of 2021 HB 2359 related to health care interpreters. Proposed rules are also designed to provide more inclusive care for transgender and gender diverse patients.

Racial Equity statement per ORS 183.335(2)(b)(F): (identifying how adoption of rule might impact one group of people differently than others) Patients from a variety of racial and ethnic backgrounds are of Limited English Proficiency. Approximately 222,000 Oregonians (1 out of every 17) cannot read the directions for their prescription medications provided in English. Interpreters offer a language and

cultural bridge between a Pharmacist and a LEP patient. Utilizing qualified interpreters will ensure that proper communication occurs to allow the LEP patient to achieve desired health outcomes. The ability to access an interpreter who can speak the patient's preferred language will have a positive impact on patients from a variety of racial and ethnic backgrounds who may have barriers to communication in English.

There is limited data about the health status and health needs of people who identify as lesbian, gay, bisexual or transgender (LGBT). In Oregon, approximately 20,000 Oregonians (1 out of every 171) identify as transgender. Sex assigned at birth is an important, structured variable that is used to facilitate effective patient care that is efficient, equitable, and patient-centered. Sex assigned at birth in a patient's medical record is often used to calculate medication dosages and screen for drug interactions for a patient's typical hormonal history and anatomy. The proposed rules regarding patient records are intended to provide pharmacists with the information they need for accurate dosage calculations and drug interaction screening while also recognizing the importance of recognizing patients by their chosen name and preferred gender identification.

Rules Summary per ORS 183.335(2)(a)(B) (Indicates the change to the rule and why): Proposed amendments are necessary to incorporate directives set forth in 2021 HB 2359, related to health care interpreters. Requires pharmacists and interns to work with health care interpreters from health care interpreter registry operated by Oregon Health Authority to provide interpretation services. In addition, procedural rule review modifying patient records requirements to provide pharmacists with hormonal history and anatomy for accurate drug dosing and interaction screening. Also provides pharmacies with the ability to identify patients by their chosen name and gender identification.

Division 6
DEFINITIONS

855-006-0005
Definitions

(x) "Certified health care interpreter" has the meaning given that term in ORS 413.550.

(x) "Health care interpreter" has the meaning given that term in ORS 413.550.

(x) "Health care interpreter registry" means the registry described in ORS 413.558 that is administered by the authority.

(x) "Individual with limited English proficiency" means a person who, by reason of place of birth or culture, communicates in a language other than English and prefers to communicate in a language other than English.

NOTE: Board will motion all changes to Div 006 Definitions in one motion at end of policy discussions.

Division 19
PHARMACISTS

855-019-0230

Counseling

(1) The pharmacist or intern ~~shall~~ **must** orally counsel the patient or patient's agent on the use of a drug or device as appropriate:

(a) The pharmacist or intern ~~shall~~ **must** counsel the patient on a new prescription and any changes in therapy, including but not limited to a change in directions or strength, or a prescription which is new to the pharmacy;

(b) Only the pharmacist or intern may accept a patient's or patient's agent's request not to be counseled. If, in their professional judgment, the pharmacist or intern believes that the patient's safety may be affected, the pharmacist or intern may choose not to release the prescription until counseling has been completed;

(c) ~~Effective July 1, 2008, t~~**T**he pharmacist or intern that provides counseling or accepts the request not to be counseled ~~shall~~ **must** document the interaction;

(d) A pharmacist ~~shall~~ **must** not allow non-pharmacist personnel to release a prescription that requires counseling, or accept the request not to be counseled;

(e) For a prescription delivered to a patient, except at a pharmacy or a pharmacy prescription locker, the pharmacist ~~shall~~ **must** offer in writing, to provide direct counseling and information about the drug, including information on how to contact the pharmacist;

(f) For each patient, the pharmacist or intern ~~shall~~ **must** determine the amount of counseling that is reasonable and necessary under the circumstance to promote safe and effective use or administration of the drug or device, and to facilitate an appropriate therapeutic outcome for that patient~~.~~**; and**

(g) When communicating (e.g. counseling, patient care services, billing) with a patient who prefers to communicate in a language other than English, the Pharmacist or Intern must work with a health care interpreter from the health care interpreter registry administered by the Oregon Health Authority under ORS 413.558 unless the Pharmacist is proficient in the patient's preferred language.

(2) Counseling on a refill prescription ~~shall~~ **must** be such as a reasonable and prudent pharmacist would provide.

(3) A pharmacist may provide counseling in a form other than oral counseling when, in their professional judgment, a form of counseling other than oral counseling would be more effective.

(4) A pharmacist or intern ~~shall~~ **must** initiate and provide counseling under conditions that maintain patient privacy and confidentiality.

(5) For a discharge prescription from a hospital, the pharmacist must ensure that the patient receives appropriate counseling.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151 & **ORS** 689.155

PROPOSED

Division 41
OPERATION OF PHARMACIES

855-041-1165
Patient Medical Record

A patient record system ~~shall~~ **must** be maintained by pharmacies for all patients for whom **a** prescription drug ~~orders are~~ **is** dispensed~~, except for those patients who the pharmacist has good reason to believe will not return to that pharmacy to obtain drugs~~. The patient record system ~~shall~~ **must** provide ~~for readily retrievable~~ information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a prescription drug order is presented for dispensing. The pharmacist ~~shall~~ **must** make a reasonable effort to obtain, record, and maintain the following information:

(1) Full name of the patient **and current chosen name** for whom the drug is intended;

(2) Address and telephone number of the patient;

(3) Patient's ~~age or~~ date of birth;

(4) Patient's **sex assigned at birth and current** gender **identification**;

POLICY DISCUSSION: Board direction

(5) Patient's preferred language for communication and prescription labeling;

(~~5~~**6**) Chronic medical conditions;

(~~6~~**7**) A list of all prescription drug orders obtained by the patient at the pharmacy maintaining the patient record showing the name of the drug or device, prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber;

(~~7~~**8**) Known allergies, drug reactions, and drug idiosyncrasies; and

(~~8~~**9**) If deemed relevant in the pharmacist's professional judgment:

(a) Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug; and

(b) Additional information such as chronic conditions or disease states of the patient, the patient's current weight, and the identity of any other drugs, including over-the-counter drugs, or devices currently being used by the patient which may relate to prospective drug review.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, 689.155 & 689.508

PROPOSED

855-041-0XXX
Dispensing: Interpretation

(1) Except as provided in subsection (2) of this section, a Pharmacist or Intern must work with a health care interpreter from the health care interpreter registry administered by the Oregon Health Authority under ORS 413.558 when communicating with a patient who prefers to communicate in a language other than English, unless the Pharmacist is proficient in the patient's preferred language.

(2) A Pharmacist or Intern who is otherwise required to work with a health care interpreter from the health care interpreter registry may work with a health care interpreter who is not listed on the health care interpreter registry only if the Pharmacist or Intern:

(a) Verifies that the Pharmacist or Intern has taken appropriate steps needed to obtain a health care interpreter from the health care interpreter registry in accordance with rules adopted by the authority under ORS 413.558; or

(b) Has offered the patient the services of a health care interpreter from the health care interpreter registry and the patient declined the offer and chose a different interpreter.

(3) A Pharmacist or Intern must provide personal protective equipment, consistent with established national standards, to health care interpreters providing services on-site at no cost to the health care interpreter and may not suggest to the health care interpreter that the health care interpreter should procure the health care interpreter's own personal protective equipment as a condition of working with the Pharmacist or Intern.

(4) A Pharmacist or Intern must maintain records of each patient encounter in which the Pharmacist or Intern worked with a health care interpreter from the health care interpreter registry. The records must include:

(a) The name of the health care interpreter;

(b) The health care interpreter's registry number; and

(c) The language interpreted.

Statutory/Other Authority: ORS 689.205, 2021 HB 2359
Statutes/Other Implemented: ORS 689.155, 2021 HB 2359

Division 139
REMOTE DISPENSING SITE PHARMACY

855-139-0555
Records: Patient

A patient record system must be maintained by pharmacies for all patients for whom a prescription drug is dispensed. The patient record system must provide information necessary for the dispensing Oregon licensed Pharmacist to identify previously dispensed drugs at the time a prescription is presented for

PROPOSED

168 dispensing. The pharmacist must make a reasonable effort to obtain, record, and maintain the following
169 information:
170
171 (1) Full name of the patient **and current chosen name** for whom the drug is intended;
172
173 (2) Address and telephone number of the patient;
174
175 (3) Patient's ~~age or~~ date of birth;
176
177 (4) Patient's **sex assigned at birth and current** gender **identification**;
178
179 **(5) Patient's preferred language for communication and prescription labeling;**
180
181 (~~5~~**6**) Chronic medical conditions;
182
183 (~~6~~**7**) A list of all prescription drug orders obtained by the patient at the pharmacy maintaining the
184 patient record showing the name of the drug or device, prescription number, name and strength of the
185 drug, the quantity and date received, and the name of the prescriber;
186
187 (~~7~~**8**) Known allergies, drug reactions, and drug idiosyncrasies; and
188
189 (~~8~~**9**) If deemed relevant in the pharmacist's professional judgment:
190
191 (a) Oregon licensed Pharmacist comments relevant to the individual's drug therapy, including any other
192 information peculiar to the specific patient or drug; and
193
194 (b) Additional information such as chronic conditions or disease states of the patient, the patient's
195 current weight, and the identity of any other drugs, including over-the-counter drugs, or devices
196 currently being used by the patient which may relate to prospective drug review.
197
198 Statutory/Other Authority: ORS 689.205
199 Statutes/Other Implemented: ORS 689.151, ORS 689.155 & ORS 689.508
200
201 **855-139-0XXX**
202 **Dispensing: Interpretation**
203
204 **(1) Except as provided in subsection (2) of this section, a Pharmacist or Intern from the RDSP Affiliated**
205 **Pharmacy must work with a health care interpreter from the health care interpreter registry**
206 **administered by the Oregon Health Authority under ORS 413.558 when communicating with a patient**
207 **who prefers to communicate in a language other than English, unless the Pharmacist is proficient in**
208 **the patient's preferred language.**
209
210 **(2) A Pharmacist or Intern who is otherwise required to work with a health care interpreter from the**
211 **health care interpreter registry may work with a health care interpreter who is not listed on the**
212 **health care interpreter registry only if the Pharmacist or Intern:**
213

PROPOSED

(a) Verifies that the Pharmacist or Intern has taken appropriate steps needed to obtain a health care interpreter from the health care interpreter registry in accordance with rules adopted by the authority under ORS 413.558; or

(b) Has offered the patient the services of a health care interpreter from the health care interpreter registry and the patient declined the offer and chose a different interpreter.

(3) A Pharmacist or Intern must provide personal protective equipment, consistent with established national standards, to health care interpreters providing services on-site at no cost to the health care interpreter and may not suggest to the health care interpreter that the health care interpreter should procure the health care interpreter's own personal protective equipment as a condition of working with the Pharmacist or Intern.

(4) A Pharmacist or Intern must maintain records of each patient encounter in which the Pharmacist or Intern worked with a health care interpreter from the health care interpreter registry. The records must include:

(a) The name of the health care interpreter;

(b) The health care interpreter's registry number; and

(c) The language interpreted.

Statutory/Other Authority: ORS 689.205, 2021 HB 2359
Statutes/Other Implemented: ORS 689.155, 2021 HB 2359

Division 143
PHARMACY PRESCRIPTION LOCKERS

NOTE: Will bring language for Division 143 Lockers to April Board meeting.

PROPOSED

Department of Commerce, Community
and Economic Development

Division of Corporations, Business
and Professional Licensing

Alaska Board of Pharmacy

Annual Report

Fiscal Year 2022

Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing
P.O. Box 110806
Juneau, Alaska 99811-0806
Email: *License@Alaska.Gov*

Alaska Board of Pharmacy

FY 2022 Annual Report

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Alaska Board of Pharmacy

FY 2022 Annual Report

Identification of the Board

Board Member	Duty Station	Date Appointed	Term Expires
Justin Ruffridge, PharmD Chair	Anchorage, AK	Mar 1, 2020	Mar 1, 2023
Ashley Schaber, PharmD Vice Chair	Anchorage, AK	Jul 1, 2021	Mar 1, 2024
James Henderson, RPh Secretary	Soldotna, AK	Mar 1, 2017	Mar 1, 2025
Leif Holm, PharmD	North Pole, AK	Mar 1, 2015	Mar 1, 2023
Ramsey Bell, PharmD	Eagle River, AK	Mar 1, 2022	Mar 1, 2026
Tammy Lindemuth Public Member	Anchorage, AK	Jan 24, 2018	Mar 1, 2025
Vacant Public Member			

Identification of the Board (continued)

Board Member	Duty Station	Date Appointed	Term Expires

Identification of Staff

Laura Carrillo, MPH - Executive Administrator
Department of Commerce, Community & Economic Development
Division of Corporations, Business and Professional Licensing
P.O. Box 110806
Juneau, Alaska 99811-0806
(907) 465-2550

Bradley Johnson - Occupational Licensing Examiner (since March 2022)
Department of Commerce, Community & Economic Development
Division of Corporations, Business and Professional Licensing
P.O. Box 110806
Juneau, Alaska 99811-0806
(907) 465-2550

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Department of Commerce, Community & Economic Development
Division of Corporations, Business and Professional Licensing
P.O. Box 110806
Juneau, Alaska 99811-0806
(907) 465-2550

-
Department of Commerce, Community & Economic Development
Division of Corporations, Business and Professional Licensing
P.O. Box 110806
Juneau, Alaska 99811-0806
(907) 465-2550

-
Department of Commerce, Community & Economic Development
Division of Corporations, Business and Professional Licensing
P.O. Box 110806
Juneau, Alaska 99811-0806
(907) 465-2550

Identification of Staff (continued)

-
Department of Commerce, Community & Economic Development
Division of Corporations, Business and Professional Licensing
P.O. Box 110806
Juneau, Alaska 99811-0806
(907) 465-2550

-
Department of Commerce, Community & Economic Development
Division of Corporations, Business and Professional Licensing
P.O. Box 110806
Juneau, Alaska 99811-0806
(907) 465-2550

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Juneau, Alaska 99811-0806
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P.O. Box 110806
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(907) 465-2550

-
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Division of Corporations, Business and Professional Licensing
P.O. Box 110806
Juneau, Alaska 99811-0806
(907) 465-2550

Identification of Staff

-
Department of Commerce, Community & Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
(907) 269-8160

-
Department of Commerce, Community & Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
(907) 269-8160

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(907) 269-8160

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550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
(907) 269-8160

Identification of Staff (continued)

-
Department of Commerce, Community & Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
(907) 269-8160

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Alaska Board of Pharmacy

FY 2022 Annual Report

Narrative Statement

The Board of Pharmacy "the board" optimistically submits this narrative statement highlighting its endeavors to promote the welfare and safety of the public through the effective regulation of the pharmacy profession and pharmaceutical supply chain in Alaska. As the ongoing COVID-19 pandemic continued affecting the operations, priorities, and goals of agencies providing critical care services to the public across the nation and the state, the Board of Pharmacy remained zealous in its efforts to safeguard the integrity of its profession while keeping patient safety at the forefront of its pursuits. In FY22, the Board of Pharmacy: published guidance to its licensees on scope of practice expansion authority to provide services related to the testing and treatment of COVID-19; expanded patient access to medications by extending supply-day thresholds for initial and refill prescriptions; and relaxed license qualification requirements using a barrier-reduction regulatory framework to scale-up pharmacy services and support the growth of the Alaskan economy.

FY21-22 marked the beginning of the board's first sunset audit since 2017, which both acknowledged the proliferation of regulatory projects drafted and implemented by the board and provided areas where improved regulatory oversight can be concentrated to further advance its profession and improve patient care. House Bill 306, sponsored by Representative Andi Story, which passed the legislature at the final hour of the FY22 session, extends the Board of Pharmacy through June 30, 2028. While not the full eight (8)-year period that would have extend the board through 2030, the six (6)-year extension is necessitated by the need to reassess the administration and oversight of the Prescription Drug Monitoring Program (PDMP), the state's controlled substance prescription database and interactive technological tool to assist providers in combating the opioid epidemic. As the PDMP affects a total of six (6) professions regulated by the State Medical Board, Board of Nursing, Board of Examiners in Optometry, Board of Veterinary Examiners, and Board of Dental Examiners, and the Board of Pharmacy, the legislature expects to see continued collaboration among these boards and their constituents.

The sunset audit also illuminated inherent statutory limitations that impose challenges on the board's ability to satisfy reporting requirements to the legislature and its ability to comply with federal grant deliverables. Driven by collaborative ownership of the program, the board chair of each PDMP-affected profession continued to convene its PDMP Chairs Group on a bi-weekly basis in FY21, which began in FY20 as a unified approach to discuss and identify barriers and challenges of the system and to strategize best approaches to, practices for, and priorities for PDMP data usage and dissemination. At the request of the legislature, DCCED - CBPL is procuring a consultant in FY23 to analyze the structure of the PDMP, assess effectiveness of program administration and regulation, and to provide recommendations on how the system can more aptly align with its legislative intent to support judicious prescribing and reduce diversion and abuse of federally-scheduled controlled substances.

Other relevant legislation that passed in FY22 include House Bill 145, an effort lead by the Alaska Pharmacist Association (AKPhA) with support from and collaboration with the board. HB 145 will update language to recognize pharmacists' existing ability to prescribe certain medications, such as vaccines and opioid overdose drugs--a bill that welcomes Alaska to a group of only five (5) states that recognize pharmacists' ability to independently prescribe. This law also acknowledges pharmacists as providers who are trained, qualified, and competent to render certain independent general health and wellness, disease prevention, and medication therapy services without entering into a cooperative practice agreement with a prescriber, and without facing insurance discrimination under Title 21. HB 145 further supports the effective regulation and expansion of pharmacy services by permitting pharmacy technicians to administer vaccinations under pharmacist supervision. Additionally, the board supported the Alaska State Veterinary Medical Association (AKVMA) and the Alaska Board of Veterinary Examiner's PDMP exemption bills, HB 91 and its companion bill, SB 132; however, these bills did not pass in FY22.

In tangential efforts, the Controlled Substances Advisory Subcommittee (CSAC) continues to be led by the Board of Pharmacy's chair or chair's delegate. In FY22, the CSAC continued discussing recently emerging substances of abuse, including kratom and gabapentin. This year, the CSAC decided to put forward a recommendation that Governor Dunleavy schedule kratom as a state-controlled substance to enable prosecution authority and to reduce the diversion and misuse of this substance.

Narrative Statement (continued)

On the regulatory front, the board held timely quarterly and special teleconference meetings to push forward a compilation of regulatory proposals, a bulk of which were crafted in FY2020 but forced into abeyance due to the pandemic, including language related to the license renewal of non-resident wholesale drug distributors, outsourcing facilities, and third-party logistics providers. These license categories were brought under the purview of the board to regulate in FY19, though proposed renewal language will likely be codified in FY23.

Additionally, the board implemented regulations in FY22 related to:

- Clarifying requirements for registration with and reporting to the PDMP, including delegate access.
- Establishing a timeframe for which pharmacists and pharmacies are to report to the board its status of dispensing/distributing federally-scheduled II – IV controlled substances within 10 days
- Clarifying duties for pharmacy technicians with national certification
- Support and facilitate expedited licensure for active duty military members and spouse of military members pursuing licensure as a technician, intern, or pharmacist
- Broaden qualifications for emergency permit issuance to quickly deploy adequate personnel for pharmacies and patients in need

In FY23, the board also intends to implement regulations to:

- Reduce barriers to initial licensure for individuals, including eliminating transcript and notary requirements for individuals and expanding acceptable formats of license verifications
- Reduce barriers to initial licensure for pharmacies and facilities, including eliminating inspection-report, fingerprint/background report requirements, and certified true copy requirements
- Remove onerous requirements to licensure renewal, including allowing attestations in lieu of original documents and removing requirements to provide certified true copies
- Create a comprehensive joint application for providers to submit a collaborative practice agreement application to the State Medical Board and Board of Pharmacy for approval.
- Draft regulations to support and correspond to statute changes as a result of HB145
- Develop a licensure process for entities involved in the manufacture of prescription drugs
- Implement regulations improving and expediting the license process for active duty military members and/or their spouse
- Amend regulations to improve access to telepharmacy services

The board is also excited to highlight developments and engagements of both new and existing partnerships with agencies sharing common goals to promote parity in health care, support accessibility of treatment to underserved and geographically-challenged areas and populations, and identify and address challenges and opportunities to support valued personnel within a demanding pharmaceutical infrastructure. FY22 efforts include:

- Collaborating with the National Association of Boards of Pharmacy (NABP) to delegate eligibility approval for MPJE and NAPLEX exams
- Participating in question development and reviews to ensure the validity and integrity of examinations required for licensure
- Coordinating a multi-agency rapid response network to address patients experiencing barriers to care due to sudden service closures
- Engaging in conversations with telehealth stakeholders to improve access to telepharmacy and stimulate the growth of these services within Alaska

While the board and its collaborators have made great strides in FY22, there is much more to be accomplished in the next fiscal year. The board is keyed in to anticipates changes with the Drug Supply Chain Security Act (DSCSA) effective in FY23 and stands ready to promulgate regulations needed to initiate an effective regulatory response for entities involved in the distribution of prescription drugs. In entering FY23, the board will continue its efforts to ensure a healthy Alaska through continued development of strategic plans, removal of barriers to and streamlining the process for licensure and renewal, exercise collaborative oversight of the PDMP, and nurture continued relationships with departments and organizations whose support is invaluable to the strengthening and advancement of its profession.

With gratitude,

Laura Carrillo, MPH
Executive Administrator

Alaska Board of Pharmacy

FY 2022 Annual Report

Budget Recommendations for FY 2023

Budget Recommendations section anticipates the board's fiscal priorities for the upcoming year. Please complete all parts of this section with details about anticipated meetings, conferences, memberships, supplies, equipment, to other board requests. Meeting expenses that are being funded through third-party reimbursement or direct booking must be identified separately from expenses paid through license fees (receipt-supported services or RSS). Be sure to explain any items listed as "other" so they may be tracked appropriately.

Board Meeting Date	Location	# Board	# Staff
September 22 - 23, 2022	Anchorage	2	1
▣ Airfare:			$ 2,000.00
▣ Hotel:			$ 1,200.00
▣ Ground:			$ 100.00
▣ Other: M&IE			$ 350.00
Total Estimated Cost:			$ 3,650.00

Board Meeting Date	Location	# Board	# Staff
November 17 - 18, 2022	Anchorage	2	1
▣ Airfare:			$ 2,000.00
▣ Hotel:			$ 1,200.00
▣ Ground:			$ 100.00
▣ Other: M&IE			$ 350.00
Total Estimated Cost:			$ 3,650.00

Board Meeting Date	Location	# Board	# Staff
February TBD, 2023	Anchorage	2	1
▣ Airfare:			$ 2,000.00
▣ Hotel:			$ 1,200.00
▣ Ground:			$ 100.00
▣ Other: M&IE			$ 350.00
Total Estimated Cost:			$ 3,650.00

Budget Recommendations for FY 2023 (continued)

Budget Recommendations section anticipates the board's fiscal priorities for the upcoming year. Please complete all parts of this section with details about anticipated meetings, conferences, memberships, supplies, equipment, to other board requests. Meeting expenses that are being funded through third-party reimbursement or direct booking must be identified separately from expenses paid through license fees (receipt-supported services or RSS). Be sure to explain any items listed as "other" so they may be tracked appropriately.

Board Meeting Date	Location	# Board	# Staff
May TBD, 2023	Anchorage	2	1

☒ Airfare:	$ 2,000.00
☒ Hotel:	$ 1,200.00
☒ Ground:	$ 100.00
☒ Other: M&IE	$ 350.00
Total Estimated Cost:	$ 3,650.00

Board Meeting Date	Location	# Board	# Staff

☒ Airfare:	
☒ Hotel:	
☒ Ground:	
☐ Other: M&IE	
Total Estimated Cost:	$ 0.00

Board Meeting Date	Location	# Board	# Staff

☐ Airfare:	
☐ Hotel:	
☐ Ground:	
☐ Other:	
Total Estimated Cost:	$ 0.00

Budget Recommendations for FY 2023 (continued)

Travel Required to Perform Examinations

☒ Not Applicable

Date	Location	# Board	# Staff

Description of meeting and its role in supporting the mission of the Board:

☐ Airfare:

☐ Hotel:

☐ Ground:

☐ Conference:

☐ Other:

Total Estimated Cost: $ 0.00

Travel Required to Perform Examinations

☒ Not Applicable

Date	Location	# Board	# Staff

Description of meeting and its role in supporting the mission of the Board:

☐ Airfare:

☐ Hotel:

☐ Ground:

☐ Conference:

☐ Other:

Total Estimated Cost: $ 0.00

Budget Recommendations for FY 2022 (continued)

(Rank in order of importance)

☒ #1 Rank in Importance or ☐ Not Applicable

Date	Location	# Board	# Staff
August 28-30, 2022	Oklahoma City, OK	1	1

Description of meeting and its role in supporting the mission of the Board:

This is an NABP District 6 – 8 meeting (Alaska is in district 7). This is a unique opportunity to round-table with district members on matters affecting today's pharmacy practice and an opportunity to engage in proactive discussions for tomorrow's pharmacists. Attendees will propose and resolve resolutions in an ongoing effort to support the practice of pharmacy.

Expenditure	License Fees (RSS)	Third-Party Reimbursement	Third-Party Direct Booked	Total
☒ Airfare:	$500.00			$500.00
☒ Hotel:	$2,500.00			$2,500.00
☒ Ground:	$100.00			$100.00
☒ Conference:				$0.00
☒ Other	$1,080.00			$1,080.00
Describe "Other" (break out all sections):	M&IE			
Net Total:	$ 4,180.00	$ 0.00	$ 0.00	$ 4,180.00

Budget Recommendations for FY 2022 (continued)

Out-of-State Meetings and Additional In-State Travel

#2 Rank in Importance

Date	Location	# Board	# Staff
May 11-13, 2023	Nashville, TN	1	1

Description of meeting and its role in supporting the mission of the Board:

119th Annual Meeting of the National Association of Boards of Pharmacy (NABP) – State boards, regulators, and stakeholders gain a deeper understanding of how NABP and the pharmacy regulatory boards work together to protect public health. Attendees have the opportunity to network and participate in business sessions to keep abreast of the salient issues affecting pharmacy practice and regulation.

Expenditure	License Fees (RSS)	Third-Party Reimbursement	Third-Party Direct Booked	Total
Airfare:	$500.00			$500.00
Hotel:	$2,500.00			$2,500.00
Ground:	$100.00			$100.00
Conference:	$400.00			$400.00
Other	$1,080.00	$1,500.00		$2,580.00
Describe "Other" (break out all sections):	M&IE, 3rd party conference scholarship opportunity			
Net Total:	$ 4,580.00	$ 1,500.00	$ 0.00	$ 6,080.00

Budget Recommendations for FY 2022 (continued)

Out-of-State Meetings and Additional In-State Travel

#3 Rank in Importance

Date	Location	# Board	# Staff
April 10-13, 2023	Atlanta, GA	1	2

Description of meeting and its role in supporting the mission of the Board:

National Rx Abuse and Heroin Summit – This conference supports the state's opioid response and the board's efforts to effectively administer the state's PDMP. Federal grant funds will be used to send 2 staff members to this conference to attend the PDMP track. License fees will be used to send 1 board member to attend the regulatory, policy, clinical, and/or law enforcement tracks to advance the board's efforts to protect public safety and to support the chair in its Controlled Substances Advisory Committee (CSAC) roll. The below cost reflects travel for 1 board member.

Expenditure	License Fees (RSS)	Third-Party Reimbursement	Third-Party Direct Booked	Total
Airfare:	$2,000.00			$2,000.00
Hotel:	$1,000.00			$1,000.00
Ground:	$100.00			$100.00
Conference:	$1,125.00			$1,125.00
Other	$170.00			$170.00
Describe "Other" (break out all sections):	M&IE			
Net Total:	$ 4,395.00	$ 0.00	$ 0.00	$ 4,395.00

Budget Recommendations for FY 2022 (continued)

Out-of-State Meetings and Additional In-State Travel

#4 Rank in Importance

Date	Location	# Board	# Staff
Sep 7, 2022	Online	1	

Description of meeting and its role in supporting the mission of the Board:

MPJE State-Specific Review – this is an opportunity for member boards to participate in review of current exam items to ensure the most valid and relevant questions are reflected in the Multi-State Jurisprudence Exam (MPJE), which is administered by the NABP. This exam is integral to assessing competency for licensure as a pharmacist. Participation in this workshop also allows for selection of new items for pre-testing, which is integral to the validity of MPJEs.

Expenditure	License Fees (RSS)	Third-Party Reimbursement	Third-Party Direct Booked	Total
☐ Airfare:				$0.00
☐ Hotel:				$0.00
☐ Ground:				$0.00
☐ Conference:				$0.00
☐ Other				$0.00
Describe "Other" (break out all sections):				
Net Total:	$ 0.00	$ 0.00	$ 0.00	$ 0.00

Budget Recommendations for FY 2022 (continued)

Out-of-State Meetings and Additional In-State Travel

#5 Rank in Importance

Date	Location	# Board	# Staff
TBD 2023	TBD	1	0

Description of meeting and its role in supporting the mission of the Board:

Compounding Pharmacy Compliance - The board, through their compounding subcommittee, has been working on advancing their compounding regulations over the last few years. This conference is an opportunity to netword with expertens in the compounding industry, analyze evolving regulations, strengthen compounding systems and processes, and gain insight into techniques to ensure accuracy and sterility. The overarching goal is patient safety.

Expenditure	License Fees (RSS)	Third-Party Reimbursement	Third-Party Direct Booked	Total
Airfare:	$800.00			$800.00
Hotel:	$600.00			$600.00
Ground:	$50.00			$50.00
Conference:	$450.00			$450.00
Other	$540.00			$0.00
Describe "Other" (break out all sections):	M&IE			
Net Total:	$ 2,440.00	$ 0.00	$ 0.00	$ 1,900.00

Budget Recommendations for FY 2022 (continued)

Out-of-State Meetings and Additional In-State Travel

#6 Rank in Importance

Date	Location	# Board	# Staff

Description of meeting and its role in supporting the mission of the Board:

Expenditure	License Fees (RSS)	Third-Party Reimbursement	Third-Party Direct Booked	Total
☐ Airfare:				$0.00
☐ Hotel:				$0.00
☐ Ground:				$0.00
☐ Conference:				$0.00
☐ Other				$0.00
Describe "Other" (break out all sections):				
Net Total:	$ 0.00	$ 0.00	$ 0.00	$ 0.00

Budget Recommendations for FY 2022 (continued)

Out-of-State Meetings and Additional In-State Travel

#7 Rank in Importance

Date	Location	# Board	# Staff

Description of meeting and its role in supporting the mission of the Board:

Expenditure	License Fees (RSS)	Third-Party Reimbursement	Third-Party Direct Booked	Total
☐ Airfare:				$0.00
☐ Hotel:				$0.00
☐ Ground:				$0.00
☐ Conference:				$0.00
☐ Other				$0.00
Describe "Other" (break out all sections):				
Net Total:	$ 0.00	$ 0.00	$ 0.00	$ 0.00

Budget Recommendations for FY 2022 (continued)

Out-of-State Meetings and Additional In-State Travel

#8 Rank in Importance

Date	Location	# Board	# Staff

Description of meeting and its role in supporting the mission of the Board:

Expenditure	License Fees (RSS)	Third-Party Reimbursement	Third-Party Direct Booked	Total
☐ Airfare:				$0.00
☐ Hotel:				$0.00
☐ Ground:				$0.00
☐ Conference:				$0.00
☐ Other				$0.00
Describe "Other" (break out all sections):				
Net Total:	$ 0.00	$ 0.00	$ 0.00	$ 0.00

Budget Recommendations for FY 2023 (continued)

Non-Travel Budget Requests

☐ Not Applicable ☐ Resources ☐ Examinations
☐ Membership ☐ Training ☐ Other

Product or Service	Provider	Cost Per Event

Description of item and its role in supporting the mission of the Board:

Non-Travel Budget Requests

☐ Not Applicable ☐ Resources ☐ Examinations
☐ Membership ☐ Training ☐ Other

Product or Service	Provider	Cost Per Event

Description of item and its role in supporting the mission of the Board:

Non-Travel Budget Requests

☐ Not Applicable ☐ Resources ☐ Examinations
☐ Membership ☐ Training ☐ Other

Product or Service	Provider	Cost Per Event

Description of item and its role in supporting the mission of the Board:

Budget Recommendations for FY 2023 (continued)

Other Items with a Fiscal Impact

☐ **Not Applicable**

Cost Per Event:

Number of Events:

Product or Service	Provider	Cost Per Event

Description of item and its role in supporting the mission of the Board:

Other Items with a Fiscal Impact

☐ **Not Applicable**

Cost Per Event:

Number of Events:

Product or Service	Provider	Cost Per Event

Description of item and its role in supporting the mission of the Board:

Other Items with a Fiscal Impact

☐ **Not Applicable**

Cost Per Event:

Number of Events:

Product or Service	Provider	Cost Per Event

Description of item and its role in supporting the mission of the Board:

Budget Recommendations for FY 2023 (continued)

Other Items with a Fiscal Impact

☐ **Not Applicable**

Cost Per Event:

Number of Events:

Product or Service	Provider	Cost Per Event

Description of item and its role in supporting the mission of the Board:

Other Items with a Fiscal Impact

☐ **Not Applicable**

Cost Per Event:

Number of Events:

Product or Service	Provider	Cost Per Event

Description of item and its role in supporting the mission of the Board:

Summary of FY 2022 Fiscal Requests

Board Meetings and Teleconferences:	$14,600.00
Travel for Exams:	$0.00
Out-of-State and Additional In-State Travel:	$16,555.00
Dues, Memberships, Resources, Training:	$0.00
Total Potential Third-Party Offsets:	- $ 1,500.00
Other:	$0.00
Total Requested:	$29,655.00

Legislative Recommendations - Proposed Legislation for FY 2023

☐ **No Recommendations**
The Board has no recommendations for proposed legislation at this time.

☒ **Recommendations**
The Board has the following recommendations for proposed legislation:

With the passage of HB 145 in FY2022 that overlap with changes the Board of Pharmacy previously identified in its FY2021 legislative recommendations, a number of intended statutory changes will be resolved. Common interest areas covered in HB 145 and to be effective 90 days subsequent to Governor Dunleavy's signature, include:

- Removal of “dosage form” from the definition of “equivalent drug product” in AS 08.80.480.
- Clarification of pharmacists’ ability to independently prescribe and administer vaccines and emergency medications under AS 08.80.168
- Expansion of pharmacist's ability to independent treat and monitor other conditions as needed
- Allowing pharmacist interns and pharmacy technicians, as supervised by a pharmacist, to prescribe vaccines and emergency medications under AS 08.80.168
- Recognition of pharmacists as providers under AS 21.36.090(d) to eliminate insurance reimbursement discrimination for services provided.

A summary of the Board of Pharmacy’s legislative recommendations it intends to pursue in FY2023 include:

Statutory area	Summary of Change	Citation
Moral character	Remove moral character requirement from applications for pharmacists via examination and reciprocity	AS 08.80.110(2), AS 08.80.145(3)
Registration of pharmacies	Repeal registration and introduce a licensure category	AS 08.80.158
Requirements for non-resident pharmacies	Include devices, require licensure	AS 08.80.159
Licenses not affected	Drug dispensing machines	AS 08.80.400
Prohibited terms	Add “apothecary”	AS 08.80.420
Powers and duties of the board	Regulate the practice of white and brown bagging; regulate kiosks as a separate license type	AS 08.80.030
Creation and membership of board; officers	Add a technician seat; remove one public member seat	AS 08.80.010
National criminal history record check	Require FBI fingerprints for pharmacist applicants	AS 12.62.400

Recommended amendments are include on the following page.

Legislative Recommendations (continued)

The Board of Pharmacy recommends REPEALING the following:

- AS 08.80.030(b)(10) - (Powers and Duties of the Board): "issue licenses to persons engaged in the manufacture and distribute of drugs and devices;"
- AS 08.80.110(2) - (Qualifications for Licensure by Examination): "furnish the board with at least two affidavits from reputable citizens that the applicant has known for at least one year attesting to the applicant's good moral character;"
- AS 08.80.145(3) - (Reciprocity; License Transfer): "is of good moral character"
- AS 08.80.145(5) - (Reciprocity; License Transfer): "or has met the internship requirements of this state"
- AS 08.80.160(10) - (Fees): "Registration or"

The Board of Pharmacy recommends AMENDING the following:

- AS 08.80.0310(a) - (Creation and Membership of Board; Officers): "There is created the Board of Pharmacy, composed of seven (or eight) members, five of whom shall be pharmacists licensed in the state
  who have been actively engaged in the practice of pharmacy in the state for a period of three years immediately preceding their appointment. One shall be a pharmacy technician licensed in the state for at least two years. One shall be a person with no direct final interest in the healthcare industry."
- AS 08.80.030(b)(14) - (Powers and Duties of the Board): "require that a licensed pharmacist dispensing federally-scheduled controlled substances in the state register with the controlled substance prescription database under AS 17.30200(o)"
- AS 08.80.030(b)(16) - (Powers and Duties of the Board): "license wholesale drug distributors, third-party logistics providers, outsourcing facilities, and manufacturers under AS 08.80.159, and pharmacies under AS 08.80.157 that are physically located outside the state"
- AS 08.80.159(a) - (Licensing and Inspection of Facilities Outside of the State): "Before shipping, mailing, mailing, distributing, or delivering prescription drugs to a licensee in the state or advertising in the state, a wholesale drug distributor, manufacturer, third-party logistics provider, or an outsourcing facility that is located outside of the state shall"
- AS 08.80.420(a) - (Certain Advertising Prohibited): "A person may not use or exhibit the title “pharmacist,” “assistant pharmacist,” or “druggist,” or the descriptive term “pharmacy,” “drug store,” “drug sundries,” “apothecary”, or other similar title or term containing the word “drug,” in any business premises, or in an advertisement through the media of press, or publication, or by radio or television, unless the business has a licensed pharmacist in regular and continuous employment."

The Board of Pharmacy recommends ADDING the following:

- AS 08.80.030(b)(17) - (Powers and Duties of the Board): "license and establish standards for automated prescription drug machines installed outside the premise of institutional facilities"
- AS 08.80.030(b)(18) - (Powers and Duties of the Board): "establish standards for the practice of white and brown bagging"
- AS 08.80.030(b)(19) - (Powers and Duties of the Board): "license Internet pharmacies providing services to residents in the State"

Regulation Recommendations - Proposed Regulations for FY 2023

☐ **No Recommendations**
The Board has no recommendations for proposed regulations at this time.

☒ **Recommendations**
The Board has the following recommendations for proposed regulations:

The Board of Pharmacy recommends AMENDMENTS to:

- 12 AAC 52.130 - (Registration of Pharmacies Located Outside of the State) to update the language from "registration" to "license"
- 12 AAC 52.865 - (Reporting and Reviewing PDMP Information) to incorporate language on ASAP (American Society for Automation in Pharmacy) reporting fields for veterinary prescriptions.
- 12 AAC 52.920 - (Disciplinary Guidelines) to clarify applicability to (C) and (D) is only to the extent the individual is licensed under this chapter (AS 08).

The Board of Pharmacy recommends NEW SECTIONS for:

- Automated dispensing machines and kiosks
- Inventory losses by wholesale drug distributors
- Manufacturer applications
- Internet pharmacies
- Inventory losses by wholesale drug distributors

The Board of Pharmacy acknowledges it must CREATE/UPDATE regulations by July 1, 2023 corresponding with HB 145:

- 12 AAC 52.992 - Re-title and replace term, "independent administration of" with "prescribe" wherever applicable and incorporate pharmacy technician requirements/standards
- 12 AAC 52.994 - Re-title and replace term, "independent administration of" with "prescribe" wherever applicable
- 12 AAC 52.240 - Update collaborative practice section to incorporate language for general health and wellness, disease prevention, and self-limiting conditions
- 12 AAC 52.460 - Remove "dosage form" ate collaborative practice section to incorporate language for general health and wellness, disease prevention, and self-limiting conditions
- 12 AAC 52.NEW - establish standards for monitoring of drug therapy

Regulation Recommendations (continued)

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Goals and Objectives

Part I
FY 2022's goals and objectives and how they were met:

In its FY2022 strategic plan, the Board of Pharmacy identified four (4) overarching goals inspired by (4) guiding principles in the focus areas of communication, administration, licensure, and regulation/enforcement. Each goal includes identification of strategies (objectives) to support and advance the board's guiding principle areas. This section highlights the board's progress with its 16 identified strategies.

ALASKA BOARD OF PHARMACY
2022 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** Encourage appropriate disclosure of information related to licensing and investigative processes. **1.3** Maximize communication channels through the Board of Pharmacy website and List Service. **1.4** Increase collaboration with health care boards and stakeholders to address issues affecting scope of practice and patient care.
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 licensure through online applications. **2.4** Exercise fiscal discipline through effective budget management.
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** Periodically review applications and forms for alignment with existing requirements.
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** Reduce adverse health outcomes during emergencies through prompt regulatory responses and board guidance. **4.4** Establish disciplinary guidelines and conduct random inspections to ensure safety protocols and competencies are met. **4.5** Establish a simple regulatory approach to expand licensure to active duty military personnel and spouse of military personnel. **4.6** Advocate for legislation as the pharmacy profession evolves and new opportunities for improved patient safety arise.

For more information, please visit the following resources:

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

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

Goals and Objectives (continued)

Part I (continued)
FY 2022's goals and objectives and how they were met:

The following table outlines the board's progress for strategies (objectives) 1.1 through 2.4.

GOAL/STRATEGY	MET BY
1.1: Improve customer service by providing timely updates to applicants and licensees.	• Consistently provided authorization codes for applicants to check their application/record status in real-time using MY LICENSE • Provided courtesy emails with visual aids on how to identify and act on authorization codes • Utilized a spreadsheet to track follow-up with in-process applicants • Provide MY LICENSE status updates and email status updates
1.2: Encourage appropriate disclosure of information related to licensing and investigative processes.	• Provide form #08-4752 (ProFit template) to applicants • Provide detailed instructions via MY LICENSE and via email
1.3: Maximize communication channels through the Board of Pharmacy website and List Service	• The board fulfilled this strategy by sending multiple notices: o Proposed PDMP regulations (08/31/2021) o PDMP fee reductions (09/17/2021) o CBPL COVID Joint Statement (11/12/2021) o November board meeting (11/17/2021) o Continuing Education Disciplinary Matrix (11/23/2021) o COVID-19 therapeutics (11/23/2021) o Proposed license fee reductions (01/31/2022) o Proposed regulations related to emergency permits, military licensing, and renewal applications (02/02/2022) o February board meeting (02/14/2022) o Board Disciplinary Matrix (02/24/2022) o Alaska Well-Being Index participation link (02/28/2022) o FDA discretion in clozapine REMS program (03/03/2022) o Phasing out of hard copy license certificates (03/17/2022) o Fee reductions effective date (05/05/2022) o 2022 – 2024 renewal extension (05/05/2022) • Updated FAQs site by removing obsolete material
1.4: Increase collaboration with health care boards and stakeholders to address issues affecting scope of practice and patient care.	• Continued to chair the Controlled Substance Advisory Subcommittee (CSAC) • Continued to participate in bi-weekly PDMP chairs meeting • Continued to participate in bi-weekly healthcare board chairs meeting • Issued a joint statement with the Board of Nursing and Board of Dental Examiners
2.1: Avoid delays in application processing by maintaining adequate staffing and exploring flexible retention strategies.	• Ongoing challenge; division continues to experience extensive vacancies • Telework option provided to support staff flexibility and retention
2.2: Maintain a proactive approach to licensing by consulting historical knowledge, researching national trends, and encouraging innovation in the planning process.	• Use of desk manual prepared by board's executive administrator • Use of policies and procedures provided by division leadership • Referring to examples of previous work product to ensure consistency
2.3: Automate licensure through online applications	• Not met; online application priorities suspended to accommodate and prioritize core licensing functions using existing methods to apply
2.4: Exercise fiscal discipline through effective budget management.	• The board participated in the division's fee analysis and made fee reductions effective towards the end of FY22.

Goals and Objectives (continued)

Part I (continued)
FY 2022's goals and objectives and how they were met:

The following table outlines the board's progress for strategies (objectives) 3.1 through 4.6.

GOAL/STRATEGY	MET BY
3.1: Adhere to established licensing standards by reviewing education, experience, and examination requirements.	• Continued use of application checklists
3.2: Periodically review applications and forms for alignment with existing requirements.	• Ongoing; the board's executive administrator is proactive with form updates and anticipates form updates necessitated by regulation changes

4.1: Routinely review effectiveness of regulations that reduce barriers to licensure without compromising patient health and safety.	The following areas have been approved by the board, released to the public for comments, or are pending adoption in FY2022:
	• The board is successful in continuing to work on and support the division's *Right Touch Regulations* initiative.
	  ○ Reducing barriers to licensure by eliminating onerous requirements, including authorization for release of records, affidavits of moral character for interns, inspection requirements, background reports and resumes for facilities
	  ○ Eliminating requirements made redundant by similar industry or employer requirements, including academic transcripts
	  ○ Streamlining application processing by delegating approval to the board's executive administrator
	• The board continued to work on broadening circumstances for which an applicant may qualify for an emergency permit

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.	• Continued facilitation of bi-weekly board chairs meeting • Active participation in discussions during FY22 legislative session • Provided continued education and outreach to providers • Updated website content and continued to make resources and reports available to users and the public • Launched a PDMP communications module to facilitate secure provider-to-provider collaboration
4.3: Reduce adverse health outcomes during emergencies through prompt regulatory responses and board guidance.	• The board did not promulgate emergency regulations in FY22; however, it did collaborate with the Department of Law to issue guidance on providing therapeutics for COVID-19 • The board collaborated with the Board of Nursing and Board of Dental Examiners to issue a joint statement
4.4: Establish disciplinary guidelines and conduct random inspections to ensure safety protocols and competencies are met.	• Board approved continuing education disciplinary matrix in early-FY22 • Board approved comprehensive disciplinary matrix in mid-FY22
4.5: Establish a simple regulatory approach to expand licensure to active duty military personnel and spouse of military personnel	• The board continued to work on developing and improving the license process for activity duty military members and/or their spouse; board approved language and released amendment for public comment in FY22
4.6: Advocate for legislation as the pharmacy profession evolves and new opportunities for improved patient safety arise	• The board supported HB 145 (expand pharmacist authority) • The board supported HB 91/SB132 (PDMP vet exemption)

Goals and Objectives (continued)

Part II
FY 2023's goals and objectives, and proposed methods to achieve them.
Describe any strengths, weaknesses, opportunities, threats and required resources:

The Board of Pharmacy's 2023 Strategic Plan is below:

ALASKA BOARD OF PHARMACY
2023 STRATEGIC PLAN

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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 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	Review professional fitness questions for applicability and update applications accordingly
		3.4	Develop a license application for manufacturers.
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	Establish disciplinary guidelines to ensure established safety protocols and competencies are met.
		4.4	Advocate for legislation as the pharmacy profession evolves and new opportunities for improved patient safety arise.
		4.5	Anticipate changes to the Drug Supply Chain Security Act and respond proactively.

For more information, please visit the following resources:

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

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

Goals and Objectives (continued)

Part II (continued)
FY 2023's goals and objectives, and proposed methods to achieve them.
Describe any strengths, weaknesses, opportunities, threats and required resources:

The Board of Pharmacy's SWOT analysis is below:

Strengths	Weaknesses	Opportunities	Threats
• Technologically adaptive • Use of diverse communication channels • Established licensing policies and procedures • Emergency preparedness regulations • Task list accountability and follow-up • Rapport with stakeholders (AKPhA, DHSS)	• Board member participation • Staff turnover	• Expedited online licensing through myAlaska • Expanded public comment opportunities	• Staff availability • Shifting priorities and lack of resources

Alaska Board of Pharmacy

FY 2022 Annual Report

Sunset Audit Recommendations

Date of Last Legislative Audit: 07/15/2021

Board Sunset Date: 06/30/2028

Audit Recommendation:
The board chair and DCBPL's director should improve procedures and training to ensure applicants meet requirements prior to licensure.

Action Taken:
Ensure use of existing checklists and proper use of the licensing system.

Next Steps:
Ongoing staff training.

Completed: ☐ No ■ Yes **If yes, date completed:** Ongoing

Audit Recommendation:
The board should adopt regulations for renewing outsourcing facilities and third-party logistics provider licenses.

Action Taken:
The board began drafting regulations for renewal of out-of-state facilities in 2020, adopting language during its November 2021 meeting. Amendments were released for public comment In February 2022.

Next Steps:
The board will be adopting renewal regulations for out-of-state facilities during its June 16, 2022 board meeting.

Completed: ■ No ☐ Yes **If yes, date completed:**

Audit Recommendation:
Applicable occupational boards and DCBPL's director should continue to coordinate efforts to improve the monitoring and enforcement of CSPD requirements.

Action Taken:
DCBPL's director is working on procuring an consultant to assess administration of the database. The board of pharmacy, its staff, and the PDMP manager continue to support the facilitation of PDMP meetings.

Next Steps:
Continued progress on actions already taken.

Completed: ■ No ☐ Yes **If yes, date completed:**

Sunset Audit Recommendations (continued)

Audit Recommendation:
DCCED commissioner should allocate sufficient resources to ensure licensees holding a DEA registration number are consistently recorded in DCBPL's licensing database.

Action Taken:
Training provided to staff on how to identify and enter DEA registration #s; development of checklists and instructional materials.

Next Steps:
Continued progress on actions already taken.

Completed: ☐ **No** ☐ **Yes** **If yes, date completed:** Ongoing

Audit Recommendation:
DCCED's commissioner should allocate sufficient resources to ensure the CSPD requirements are enforced.

Action Taken:
Continued resources to support affected boards; training materials provided and disseminated.

Next Steps:
Ongoing.

Completed: ☐ **No** ☐ **Yes** **If yes, date completed:**

Audit Recommendation:

Action Taken:

Next Steps:

Completed: ☐ **No** ☐ **Yes** **If yes, date completed:**

Sunset Audit Recommendations (continued)

Audit Recommendation:		
Action Taken:		
Next Steps:		
Completed: ☐ **No** ☐ **Yes**		**If yes, date completed:**

Audit Recommendation:		
Action Taken:		
Next Steps:		
Completed: ☐ **No** ☐ **Yes**		**If yes, date completed:**

Audit Recommendation:		
Action Taken:		
Next Steps:		
Completed: ☐ **No** ☐ **Yes**		**If yes, date completed:**

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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 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** Review professional fitness questions for applicability and update applications accordingly **3.4** Develop a license application for manufacturers.
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** Establish disciplinary guidelines to ensure established safety protocols and competencies are met. **4.4** Advocate for legislation as the pharmacy profession evolves and new opportunities for improved patient safety arise. **4.5** Anticipate changes to the Drug Supply Chain Security Act and respond proactively.

For more information, please visit the following resources:

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

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

DEA FORM 106

Report of Theft or Loss of Controlled Substances

OMB No. 1117-0001 (Exp. Date 7/31/2023)

U.S. Department of Justice
Drug Enforcement Administration
Diversion Control Division

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CBPL
JUNEAU

Type of Report: *(check one box only)* ☒ New Report ☐ Amendment Key *(prior report dated)*: 6OH4WCYR2X8

1. **DEA Registration Number:** BC3035614

Name of Business: COSTCO WHOLESALE CORPORATION

Address: 330 W. DIMOND BLVD

City. ANCHORAGE **State:** AK **ZIP Code:** 99515

Point of Contact: NICHELL MOORE

Email Address: W010PHM@COSTCO.COM **Phone No.:** 9072677116

Date of the Theft or Loss *(or first discovery of theft or loss)*: March 18, 2022 **Number of Thefts and Losses in the past 24 months:** 5

Principal Business of Registrant: CHAIN PHARMACY

2. **Type of theft or loss:** EMPLOYEE THEFT (OR SUSPECTED):

3. **Loss in Transit.** *(*Fill out this section only if there was a loss in transit, or hijacking of transport vehicle.)*

Name of Common Carrier: _____

Telephone Number of Common Carrier: _____ Package Tracking Number: _____

Have there been losses in transit from this same carrier in the past? ☐ No ☐ Yes *(If yes, how many, excluding this theft or loss?)*: _____

Was the package received and accepted by the consignee? ☐ No ☐ Yes *(If yes, the consignee is responsible for reporting the theft or loss.)*

If the package was accepted by the consignee, did it appear to be tampered with? ☐ No ☐ Yes

Name of Consignee / Supplier: _____

Enter the Name of Consignee (if reported by the supplier), or the Name of Supplier (if the package was accepted by the consignee).
If the consignee does not have a DEA Registration Number, e.g. if this was a shipment to a patient, or a nursing home emergency kit, enter "Patient" or "Nursing Home Kit."

DEA Registration Number of Consignee / Supplier: _____

Enter the DEA Registration Number of Consignee (if reported by the supplier), or DEA Registration Number of Supplier, (if the package was accepted by the consignee). If the controlled substances were shipped to a non-registrant, leave blank, unless a registered pharmacy shipped to an emergency kit held on site at a nursing home. In this case, the supplying pharmacy is required to report the theft or loss.

4. **If this was a robbery, were any people injured?** ☐ No ☐ Yes *(If yes, how many?)*: _____ Were any people killed? ☐ No ☐ Yes *(If yes, how many?)*: _____

5. **Purchase value to Registrant of controlled substances taken?:** $ 54

6. **Were any pharmaceuticals or merchandise taken?** ☒ No ☐ Yes *(Est. Value)*: _____

7. **Was theft reported to Police?** ☒ No ☐ Yes *(If yes, fill out the following information)*:

Name of Police Department: _____ Police Report number: _____

Name of Responding Officer _____ Phone No.: _____

8. **Which corrective measure(s) have you taken to prevent a future theft or loss?**

- ☐ Installed monitoring equipment (e.g. video camera).
- ☐ Increased employee monitoring (e.g. random drug tests).
- ☐ Installed metal bars or other security on doors or windows.
- ☐ Secured Controlled Substances within safe.
- ☐ Other (Please describe on last page).
- ☒ Provided security training to staff.
- ☐ Requested increased security patrols by Police.
- ☐ Hired security guards for premises.
- ☐ Terminated employee.

DEA FORM **106**

Report of Theft or Loss of Controlled Substances

OMB No 1117-0001 (Exp. Date 7/31/2023)

U.S. Department of Justice
Drug Enforcement Administration
Diversion Control Division

LIST OF CONTROLLED SUBSTANCES LOST

	Trade Name of Substance or Preparation	NDC Number	Name of Controlled Substance in Preparation	Dosage Strength	Dosage Form	Total Quantity Lost or Stolen
1	TESTOSTERONE CYP 200 MG/ML	00574082001	TESTOSTERONE CYPIONATE	200 MG/ML	VIAL (SDV,MDV (	3

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DEA FORM-106 *(Previous editions are obsolete.)*

Report of Theft or Loss of Controlled Substances

OMB No. 1117-0001 (Exp Date 7/31/2023)

U S. Department of Justice
Drug Enforcement Administration
Diversion Control Division

9. **What identifying marks, symbols, or price codes were on the labels of these containers that would assist in identifying the products?:**

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10. **If Official Controlled Substance Order Forms (DEA-222) were stolen, give numbers:**

Describe any other corrective measure(s) you have taken to prevent a future theft or loss:

Enter remarks, if required. Description of how theft or loss occurred. Attach a separate sheet, if necessary:

DURING MONTHLY CONTROL AUDIT DISCOVERED 3ML TESTOSTERONE MISSING

The foregoing information is correct to the best of my knowledge and belief: By signing my full name in the space below, I hereby certify that the foregoing information furnished on this DEA Form 106 is true and correct, and understand that this constitutes an electronic signature for purposes of this reporting requirement only.

Signature: NICHELL MOORE

Title: PHARMACY MANAGER

Date Signed: March 31, 2022

NOTICE: In accordance with the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this collection of information is 1117-0001 Public reporting burden for this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Freedom of Information: Please prominently identify any confidential business information per 28 CFR 16.8(c) and Exemption 4 of the Freedom of Information Act (FOIA). In the event DEA receives a FOIA request to obtain such information, DEA will give written notice to the registrant to obtain such information DEA will give written notice to the registrant to allow an opportunity to object prior to the release of information.

Privacy Act Information

AUTHORITY: Section 301 of the Controlled Substances Act of 1970 (PL 91-513).

PURPOSE. Reporting of unusual or excessive theft or loss of a Controlled Substance.

ROUTINE USES. The Controlled Substances Act authorizes the production of special reports required for statistical and analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated.

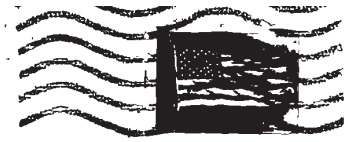
A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes

B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.

EFFECT Failure to report theft or loss of Controlled Substances may result in penalties under Section 402 and 403 of the Controlled Substances Act

C[illegible]
3[illegible] W. D[illegible]OND BLVD.
A[illegible]CE AK 99515
TELEPHONE: (907) 267-7116

ALASKAN FRONTIER
995-997
1 APR 2022 PM 1 L



Alaska State Board of Pharmacy
PO Box 110806
Juneau, AK
99811-0806

99811-080606

DEA FORM **106**

Report of Theft or Loss of Controlled Substances

OMB No 1117-0001 (Exp. Date 7/31/2023)

U S Department of Justice
Drug Enforcement Administration
Diversion Control Division

Type of Report: *(check one box only)* ☐ New Report ☑ Amendment Key *(prior report dated)*: 12/08/2021

RECEIVED Juneau DEC 21 2021 CBPL

1. **DEA Registration Number:** BC3035614

Name of Business: Costco Wholesale

Address: 330 W Dimond Blvd

City: Anchorage State: AK ZIP Code: 99515

Point of Contact: Nichell Moore

Email Address: w010phm@costco.com Phone No.: (907) 267-7116

Date of the Theft or Loss (*or first discovery of theft or loss*): 12/07/2021 Number of Thefts and Losses in the past 24 months: 3

Principal Business of Registrant: ☑ Pharmacy ☐ Practitioner ☐ Manufacturer ☐ Hospital/Clinic ☐ Distributor ☐ NTP ☐ Other (Specify) _____

2. **Type of Theft or Loss:** Employee Theft (or Suspected)

3. **Loss in Transit.** *(*Fill out this section only if there was a loss in transit, or hijacking of transport vehicle.)*

Name of Common Carrier: _____

Telephone Number of Common Carrier: _____ Package Tracking Number: _____

Have there been losses in transit from this same carrier in the past? ☐ No ☐ Yes *(If yes, how many, excluding this theft or loss?)*: _____

Was the package received and accepted by the consignee? ☐ No ☐ Yes *(If yes, the consignee is responsible for reporting the theft or loss.)*

If the package was accepted by the consignee, did it appear to be tampered with? ☐ No ☐ Yes

Name of Consignee / Supplier: _____

Enter the Name of Consignee (if reported by the supplier), or the Name of Supplier (if the package was accepted by the consignee)
If the consignee does not have a DEA Registration Number, e.g. if this was a shipment to a patient, or a nursing home emergency kit, enter "Patient" or "Nursing Home Kit"

DEA Registration Number of Consignee / Supplier: _____

Enter the DEA Registration Number of Consignee (if reported by the supplier), or DEA Registration Number of Supplier, (if the package was accepted by the consignee). If the controlled substances were shipped to a non-registrant, leave blank, unless a registered pharmacy shipped to an emergency kit held on site at a nursing home In this case, the supplying pharmacy is required to report the theft or loss

4. **If this was a robbery, were any people injured?** ☐ No ☐ Yes *(If yes, how many?)*: _____ Were any people killed? ☐ No ☐ Yes *(If yes, how many?)*: _____

5. **What is the total value of the controlled substances stolen or lost?:** $ $ 26.81
(This is the amount you paid for the controlled substances, not the retail value.)

6. **Was theft reported to Police?** ☑ No ☐ Yes *(If yes, fill out the following information)*:

Name of Police Department: _____ Police Report number: _____

Name of Responding Officer: _____ Phone No.: _____

7. **Which corrective measure(s) have you taken to prevent a future theft or loss?**

- ☐ Installed monitoring equipment (e.g. video camera).
- ☐ Increased employee monitoring (e.g. random drug tests).
- ☐ Installed metal bars or other security on doors or windows.
- ☐ Secured Controlled Substances within safe.
- ☑ Other (Please describe on last page).
- ☐ Provided security training to staff.
- ☐ Requested increased security patrols by Police.
- ☐ Hired security guards for premises.
- ☐ Terminated employee.

8. **Were any pharmaceuticals or merchandise taken?** ☑ No ☐ Yes *(Estimated Value)*:

DEA FORM **106**

Report of Theft or Loss of Controlled Substances

OMB No. 1117-0001 (Exp. Date 7/31/2023)

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U S. Department of Justice
Drug Enforcement Administration
Diversion Control Division

LIST OF CONTROLLED SUBSTANCES LOST OR STOLEN

	Trade Name of Substance or Preparation	NDC Number	Name of Controlled Substance in Preparation	Dosage Strength	Dosage Form	Total Quantity Lost or Stolen
Examples	**Desoxyn**	**00074-3377-01**	**Methamphetamine Hydrochloride**	**5 mg**	**Tablets**	**300**
	Demerol	**00409-1181-30**	**Meperidine Hydrochloride**	**50 mg/ml**	**Vial**	**150 ml**
	Robitussin A-C	**00031-8674-25**	**Codeine Phosphate**	**2 mg/cc**	**Liquid**	**5676 ml**
1	Phenergan VC with codeine	00121-0925-15	codeine	10mg	liquid	106ml
2.						
3.						
4.						
5.						
6						
7.						
8.						
9.						
10.						
11.						
12.						
13.						
14.						
15.						
16.						
17.						
18.						
19.						
20.						

Remarks: (Optional)

Do not believe that theft or diversion was involved. Preliminary research of possible mix up that it might have got mixed with a prometh w/codeine return to stock/rx somewhere or got spilled

Express Quantity in Dosage Units, or Milliliters for Liquids

DEA FORM **106**

Report of Theft or Loss of Controlled Substances

OMB No. 1117-0001 (Exp. Date 7/31/2023)

U.S. Department of Justice
Drug Enforcement Administration
Diversion Control Division

Form DEA-106 (10/23/2020) Pg. 3

LIST OF MAIL-BACK PACKAGES OR INNER LINERS LOST OR STOLEN

	Mail-Back Package	Inner Liner	Unique Identification Number(s)	Size of Inner Liner	Total Quantity Lost or Stolen
Examples	X		**MBP1106, MBP1108 – MBP1110, MBP1112**	**N/A**	**5**
		X	**CRL1007 – CRL1027**	**15 GALLON**	**21**
		X	**CRL1201**	**5 GALLON**	**1**
1.					
2					
3.					
4.					
5.					
6.					
7.					
8.					

Remarks: (Optional)

Express in Total Quantities

If you are an authorized Retail Pharmacy or Hospital/Clinic with an onsite Pharmacy and reporting a theft or loss at a Long-Term Care Facility (LTCF), provide name and address of LTCF.

Name of LTCF

Address, City, State, Zip Code

DEA FORM **106**

Report of Theft or Loss of Controlled Substances

OMB No. 1117-0001 (Exp. Date 7/31/2023)

U S. Department of Justice
Drug Enforcement Administration
Diversion Control Division

Describe any other corrective measure(s) you have taken to prevent a future theft or loss:

ran reports, checked shelves, outdates, returns, verify return to stock bottles match stock bottles, double check open and closed stock bottles for qty

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Enter remarks, if required. Description of how theft or loss occurred.

Do not believe that theft or diversion was involved. Preliminary research of possible mix up that it might have got mixed with a prometh w/codeine return to stock/rx somewhere or got spilled

The foregoing information is correct to the best of my knowledge and belief: By signing my full name in the space below, I hereby certify that the foregoing information furnished on this DEA Form 106 is true and correct, and understand that this constitutes an electronic signature for purposes of this reporting requirement only.

Signature: _____

Title: Pharmacy manager

Date Signed: 12/17/21

NOTICE: In accordance with the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this collection of information is 1117-0001. Public reporting burden for this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Freedom of Information: Please prominently identify any confidential business information per 28 CFR 16 8(c) and Exemption 4 of the Freedom of Information Act (FOIA). In the event DEA receives a FOIA request to obtain such information, DEA will give written notice to the registrant to obtain such information. DEA will give written notice to the registrant to allow an opportunity to object prior to the release of information

Privacy Act Information

AUTHORITY: Section 301 of the Controlled Substances Act of 1970 (PL 91-513)

PURPOSE: Reporting of unusual or excessive theft or loss of a Listed Chemical

ROUTINE USES The Controlled Substances Act authorizes the production of special reports required for statistical and analytical purposes Disclosures of information from this system are made to the following categories of users for the purposes stated:

A Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.

B State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes

EFFECT Failure to report theft or loss of Listed Chemicals may result in penalties under 21 U.S.C § 842 and § 843 of the Federal Criminal Code

DEA FORM **106**

Report of Theft or Loss of Controlled Substances

OMB No. 1117-0001 (Exp. Date 7/31/2023)

U.S. Department of Justice
Drug Enforcement Administration
Diversion Control Division

Type of Report: *(check one box only)* ☒ **New Report** ☐ **Amendment Key** ***(prior report dated)*:** 744A36EA5JDM

1. **DEA Registration Number:** AM3308916

Name of Business: ALASKA PSYCHIATRIC INST

Address: ALASKA PSYCHIATRIC INSTITUTE, 3700 PIPER STREET

City: ANCHORAGE **State:** AK **ZIP Code:** 995084677

Point of Contact: MEREDITH HOLLMAN

Email Address: API_PHARMACY_STAFF@ALASKA.GOV **Phone No.:** 9072697178

Date of the Theft or Loss (*or first discovery of theft or loss*): April 19, 2022 **Number of Thefts and Losses in the past 24 months:** 0

Principal Business of Registrant: HOSPITAL/CLINIC

2. **Type of theft or loss:** PACKAGING DISCREPANCY:

3. **Loss in Transit.** *(*Fill out this section only if there was a loss in transit, or hijacking of transport vehicle.)*

Name of Common Carrier: _____

Telephone Number of Common Carrier: _____ Package Tracking Number: _____

Have there been losses in transit from this same carrier in the past? ☐ No ☐ Yes *(If yes, how many, excluding this theft or loss?)*: _____

Was the package received and accepted by the consignee? ☐ No ☐ Yes *(If yes, the consignee is responsible for reporting the theft or loss.)*

If the package was accepted by the consignee, did it appear to be tampered with? ☐ No ☐ Yes

Name of Consignee / Supplier: _____

Enter the Name of Consignee (if reported by the supplier), or the Name of Supplier (if the package was accepted by the consignee).

If the consignee does not have a DEA Registration Number, e.g. if this was a shipment to a patient, or a nursing home emergency kit, enter "Patient" or "Nursing Home Kit."

DEA Registration Number of Consignee / Supplier: _____

Enter the DEA Registration Number of Consignee (if reported by the supplier), or DEA Registration Number of Supplier, (if the package was accepted by the consignee). If the controlled substances were shipped to a non-registrant, leave blank, unless a registered pharmacy shipped to an emergency kit held on site at a nursing home. In this case, the supplying pharmacy is required to report the theft or loss.

4. **If this was a robbery, were any people injured?** ☐ No ☐ Yes *(If yes, how many?)*: _____ Were any people killed? ☐ No ☐ Yes *(If yes, how many?)*: _____

5. **Purchase value to Registrant of controlled substances taken?:** $ 1

6. **Were any pharmaceuticals or merchandise taken?** ☒ No ☐ Yes *(Est. Value)*: _____

7. **Was theft reported to Police?** ☒ No ☐ Yes *(If yes, fill out the following information)*:

Name of Police Department: _____ Police Report number: _____

Name of Responding Officer: _____ Phone No.: _____

8. **Which corrective measure(s) have you taken to prevent a future theft or loss?**

- ☒ Installed monitoring equipment (e.g. video camera).
- ☐ Increased employee monitoring (e.g. random drug tests).
- ☐ Installed metal bars or other security on doors or windows.
- ☐ Secured Controlled Substances within safe.
- ☐ Other (Please describe on last page).
- ☐ Provided security training to staff.
- ☐ Requested increased security patrols by Police.
- ☐ Hired security guards for premises.
- ☐ Terminated employee.

DEA FORM **106**

Report of Theft or Loss of Controlled Substances

OMB No. 1117-0001 (Exp. Date 7/31/2023)

U.S. Department of Justice
Drug Enforcement Administration
Diversion Control Division

LIST OF CONTROLLED SUBSTANCES LOST

	Trade Name of Substance or Preparation	NDC Number	Name of Controlled Substance in Preparation	Dosage Strength	Dosage Form	Total Quantity Lost or Stolen
1	LORAZEPAM 1 MG TABLET	00904600860	LORAZEPAM	1 MG	TABLET	18

U.S. Department of Justice · Drug Enforcement Administration · Diversion Control Division

Report of Theft or Loss of Controlled Substances

OMB No. 1117-0001 (Exp Date 7/31/2023)

U.S. Department of Justice
Drug Enforcement Administration
Diversion Control Division

9. What identifying marks, symbols, or price codes were on the labels of these containers that would assist in identifying the products?:

EP 905/1

10. If Official Controlled Substance Order Forms (DEA-222) were stolen, give numbers:

N/A

Describe any other corrective measure(s) you have taken to prevent a future theft or loss:

Enter remarks, if required. Description of how theft or loss occurred. Attach a separate sheet, if necessary:

SEALED MANUFACTURER BOTTLE WAS OPENED UNDER SURVEILLANCE VIDEO FOR REPACKAGING. 100CT BOTTLE WAS DISCOVERED TO CONTAIN 82 TABLETS.

The foregoing information is correct to the best of my knowledge and belief: By signing my full name in the space below, I hereby certify that the foregoing information furnished on this DEA Form 106 is true and correct, and understand that this constitutes an electronic signature for purposes of this reporting requirement only.

Signature: MEREDITH HOLLMAN

Title: PHARMACIST

Date Signed: April 20, 2022

NOTICE: In accordance with the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this collection of information is 1117-0001. Public reporting burden for this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Freedom of Information: Please prominently identify any confidential business information per 28 CFR 16.8(c) and Exemption 4 of the Freedom of Information Act (FOIA). In the event DEA receives a FOIA request to obtain such information, DEA will give written notice to the registrant to obtain such information. DEA will give written notice to the registrant to allow an opportunity to object prior to the release of information.

Privacy Act Information

AUTHORITY: Section 301 of the Controlled Substances Act of 1970 (PL 91-513).

PURPOSE: Reporting of unusual or excessive theft or loss of a Controlled Substance.

ROUTINE USES: The Controlled Substances Act authorizes the production of special reports required for statistical and analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated:

A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.

B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.

EFFECT: Failure to report theft or loss of Controlled Substances may result in penalties under Section 402 and 403 of the Controlled Substances Act.

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JUNEAU

4/11/2022

Alaska State Board of Pharmacy
P.O. Box 110806
Juneau, AK 99811-0806
Fax: (907) 465-2974

RE: Pharmacy # 17435
1200 N MULDOON RD
ANCHORAGE, AK 99504
DEA # FAS754797
State License # 113861
Date of Loss Listed on Initial Notification: 4/5/2022

Number of Pages Attached (Including Cover Letter): 2

Dear Sir/Madam:

On 4/5/2022 an initial notification of a significant loss or theft of controlled substance was sent from the CVS pharmacy referenced above.

Enclosed is a DEA-106, Report of a Loss of Controlled Substances, which was submitted for the aforementioned loss/theft.

If you require additional information, please contact the Pharmacy Supervisor/District Leader:

Ryan Davis
Ryan.Davis@CVSCaremark.com

Very truly yours,

Donna Fracisco

Donna Fracisco, CPhT
Lead Coordinator, Drug Loss Program Team

DEA FORM **106**

Report of Theft or Loss of Controlled Substances

OMB No. 1117-0001 (Exp Date 7/31/2023)

U.S Department of Justice
Drug Enforcement Administration
Diversion Control Division

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Type of Report: *(check one box only)* ☒ New Report ☐ Amendment Key *(prior report dated)*: 1STFJKHMCH46

1. **DEA Registration Number:** FA5754797

Name of Business: ALASKA CVS PHARMACY, L L C.

Address: 1200 NO MULDOON RD

City: ANCHORAGE **State:** AK **ZIP Code:** 99504

Point of Contact: DONNA FRANCISCO

Email Address: DONNA.FRANCISCO@CVSHEALTH.COM **Phone No.:** 4013744322

Date of the Theft or Loss *(or first discovery of theft or loss)*: April 05, 2022 **Number of Thefts and Losses in the past 24 months:** 1

Principal Business of Registrant: CHAIN PHARMACY

2. **Type of theft or loss:** PACKAGING DISCREPANCY

3. **Loss in Transit.** *(Fill out this section only if there was a loss in transit, or hijacking of transport vehicle.)*

Name of Common Carrier: _____

Telephone Number of Common Carrier: _____ Package Tracking Number: _____

Have there been losses in transit from this same carrier in the past? ☐ No ☐ Yes *(If yes, how many excluding this theft or loss?)*: _____

Was the package received and accepted by the consignee? ☐ No ☐ Yes *(If yes, the consignee is responsible for reporting the theft or loss.)*

If the package was accepted by the consignee, did it appear to be tampered with? ☐ No ☐ Yes

Name of Consignee / Supplier: _____

Enter the Name of Consignee (if reported by the supplier), or the Name of Supplier (if the package was accepted by the consignee)
If the consignee does not have a DEA Registration Number, e.g. if this was a shipment to a patient, or a nursing home emergency kit, enter "Patient" or "Nursing Home Kit."

DEA Registration Number of Consignee / Supplier: _____

Enter the DEA Registration Number of Consignee (if reported by the supplier), or DEA Registration Number of Supplier (if the package was accepted by the consignee). If the controlled substances were shipped to a non-registrant, leave blank, unless a registered pharmacy shipped to an emergency kit held on site at a nursing home. In this case, the supplying pharmacy is required to report the theft or loss.

4. **If this was a robbery, were any people injured?** ☐ No ☐ Yes *(If yes, how many?)*: _____ **Were any people killed?** ☒ No ☐ Yes *(If yes, how many?)*: _____

5. **Purchase value to Registrant of controlled substances taken?** $ 123

6. **Were any pharmaceuticals or merchandise taken?** ☒ No ☐ Yes *(Est. Value)*: _____

7. **Was theft reported to Police?** ☒ No ☐ Yes *(If yes, fill out the following information)*:

Name of Police Department: _____ Police Report number: _____

Name of Responding Officer: _____ Phone No.: _____

8. **Which corrective measure(s) have you taken to prevent a future theft or loss?**

- ☐ Installed monitoring equipment (e.g. video camera).
- ☐ Increased employee monitoring (e.g. random drug tests).
- ☐ Installed metal bars or other security on doors or windows.
- ☐ Secured Controlled Substances within safe.
- ☒ Other (Please describe on last page).
- ☐ Provided security training to staff.
- ☐ Requested increased security patrols by Police.
- ☐ Hired security guards for premises.
- ☐ Terminated employee.

DEA FORM **106**

Report of Theft or Loss of Controlled Substances

OMB No. 1117-0001 (Exp Date 7/31/2023)

U.S. Department of Justice
Drug Enforcement Administration
Diversion Control Division

LIST OF CONTROLLED SUBSTANCES LOST

	Trade Name of Substance or Preparation	NDC Number	Name of Controlled Substance in Preparation	Dosage Strength	Dosage Form	Total C Lost or
1	OXYCODONE-ACETAMINOPHEN 5-325 MG TAB	53746020301	OXYCODONE HCL/ACETAMINOPHEN	5 MG-325 MG	TABLET	

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DEA FORM **106**

Report of Theft or Loss of Controlled Substances

OMB No 1117-0001 (Exp Date 7/31/2023)

U.S. Department of Justice
Drug Enforcement Administration
Diversion Control Division

9. **What identifying marks, symbols, or price codes were on the labels of these containers that would assist in identifying the products?:**

10. **If Official Controlled Substance Order Forms (DEA-222) were stolen, give numbers:**

Describe any other corrective measure(s) you have taken to prevent a future theft or loss

ALL LOSS PREVENTION POLICY AND PROCEDURES WILL BE REVIEWED WITH THE PHARMACY TEAM TO PREVENT FUTURE LOSSES. THIS INCLUDES DILIGENT INVENTORY MANAGEMENT AND DISPENSING STANDARDS. WE WILL ALSO REVIEW BACK COUNTING OF ALL NARCOTICS AT THE TIME OF DISPENSING TO ENSURE ACCURACY.

Enter remarks, if required. Description of how theft or loss occurred. Attach a separate sheet, if necessary.

OUR INVESTIGATION INTO THIS LOSS HAS RULED OUT ALL OTHER AVAILABLE CHOICE FOR "TYPES OF THEFT/LOSS." THIS IS AN UNKNOWN LOSS.

The foregoing information is correct to the best of my knowledge and belief. By signing my full name in the space below, I hereby certify that the foregoing information furnished on this DEA Form 106 is true and correct, and understand that this constitutes an electronic signature for purposes of this reporting requirement only.

Signature: DONNA FRANCISCO

Title: CPHT LEAD COORDINATOR DRUG LOSS PROGRAM

Date Signed: April 11, 2022

NOTICE: In accordance with the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this collection of information is 1117-0001. Public reporting burden for this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Freedom of Information: Please prominently identify any confidential business information per 28 CFR 16.8(c) and Exemption 4 of the Freedom of Information Act (FOIA). In the event DEA receives a FOIA request to obtain such information, DEA will give written notice to the registrant to obtain such information. DEA will give written notice to the registrant to allow an opportunity to object prior to the release of information.

Privacy Act Information

AUTHORITY: Section 301 of the Controlled Substances Act of 1970 (PL 91-513)

PURPOSE: Reporting of unusual or excessive theft or loss of a Controlled Substance.

ROUTINE USES: The Controlled Substances Act authorizes the production of special reports required for statistical and analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated:

A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.

B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.

EFFECT: Failure to report theft or loss of Controlled Substances may result in penalties under Section 402 and 403 of the Controlled Substances Act.

DEA FORM **106**

Report of Theft or Loss of Controlled Substances

OMB No. 1117-0001 (Exp. Date 7/31/2023)

U.S. Department of Justice
Drug Enforcement Administration
Diversion Control Division

Type of Report: *(check one box only)* ☒ **New Report** ☐ **Amendment Key** ***(prior report dated)*:** 72X56LT923V3

1. **DEA Registration Number:** BM8618463

Name of Business: MAT-SU REGIONAL MEDICAL CENTER

Address: 2500 S. WOODWORTH LOOP

City: PALMER **State:** AK **ZIP Code:** 99645

Point of Contact: GREGORY MICHAUD

Email Address: G.MICHAUD@MSRMC.COM **Phone No.:** 9078616760

Date of the Theft or Loss (*or first discovery of theft or loss*): May 15, 2022 **Number of Thefts and Losses in the past 24 months:** 4

Principal Business of Registrant: HOSPITAL/CLINIC

2. **Type of theft or loss:** EMPLOYEE THEFT (OR SUSPECTED):

3. **Loss in Transit.** *(*Fill out this section only if there was a loss in transit, or hijacking of transport vehicle.)*

Name of Common Carrier: _____

Telephone Number of Common Carrier: _____ Package Tracking Number: _____

Have there been losses in transit from this same carrier in the past? ☐ No ☐ Yes *(If yes, how many, excluding this theft or loss?)*: _____

Was the package received and accepted by the consignee? ☐ No ☐ Yes *(If yes, the consignee is responsible for reporting the theft or loss.)*

If the package was accepted by the consignee, did it appear to be tampered with? ☐ No ☐ Yes

Name of Consignee / Supplier: _____

Enter the Name of Consignee (if reported by the supplier), or the Name of Supplier (if the package was accepted by the consignee).

If the consignee does not have a DEA Registration Number, e.g. if this was a shipment to a patient, or a nursing home emergency kit, enter "Patient" or "Nursing Home Kit."

DEA Registration Number of Consignee / Supplier: _____

Enter the DEA Registration Number of Consignee (if reported by the supplier), or DEA Registration Number of Supplier, (if the package was accepted by the consignee). If the controlled substances were shipped to a non-registrant, leave blank, unless a registered pharmacy shipped to an emergency kit held on site at a nursing home. In this case, the supplying pharmacy is required to report the theft or loss.

4. **If this was a robbery, were any people injured?** ☐ No ☐ Yes *(If yes, how many?)*: _____ Were any people killed? ☐ No ☐ Yes *(If yes, how many?)*: _____

5. **Purchase value to Registrant of controlled substances taken?:** $ 1

6. **Were any pharmaceuticals or merchandise taken?** ☒ No ☐ Yes *(Est. Value)*: _____

7. **Was theft reported to Police?** ☒ No ☐ Yes *(If yes, fill out the following information)*:

Name of Police Department: _____ Police Report number: _____

Name of Responding Officer: _____ Phone No.: _____

8. **Which corrective measure(s) have you taken to prevent a future theft or loss?**

- ☐ Installed monitoring equipment (e.g. video camera).
- ☒ Increased employee monitoring (e.g. random drug tests).
- ☐ Installed metal bars or other security on doors or windows.
- ☐ Secured Controlled Substances within safe.
- ☐ Other (Please describe on last page).
- ☐ Provided security training to staff.
- ☐ Requested increased security patrols by Police.
- ☐ Hired security guards for premises.
- ☐ Terminated employee.

DEA FORM **106**

Report of Theft or Loss of Controlled Substances

OMB No. 1117-0001 (Exp. Date 7/31/2023)

U.S. Department of Justice
Drug Enforcement Administration
Diversion Control Division

LIST OF CONTROLLED SUBSTANCES LOST

	Trade Name of Substance or Preparation	NDC Number	Name of Controlled Substance in Preparation	Dosage Strength	Dosage Form	Total Quantity Lost or Stolen
1	HYDROCODONE-ACETAMINOPHEN 5-325 MG TAB	00406012362	HYDROCODONE BIT/ACETAMINOPHEN	5 MG-325 MG	TABLET	1

U.S. Department of Justice · Drug Enforcement Administration · Diversion Control Division

Report of Theft or Loss of Controlled Substances

OMB No. 1117-0001 (Exp Date 7/31/2023)

U.S. Department of Justice
Drug Enforcement Administration
Diversion Control Division

9. What identifying marks, symbols, or price codes were on the labels of these containers that would assist in identifying the products?:

M365 IP109

10. If Official Controlled Substance Order Forms (DEA-222) were stolen, give numbers:

Describe any other corrective measure(s) you have taken to prevent a future theft or loss:

Enter remarks, if required. Description of how theft or loss occurred. Attach a separate sheet, if necessary:

NURSE REMOVED TWO HYDROCODONE/APAP 5/325 TABS FROM THE OMNICELL AND PATIENT ONLY DESIRED A SINGLE TAB UPON ADMINSTRATION. THE NURSE DOCUMENTED THE ADMINISTRATION OF ONE TAB AND THEN DOCUMENTED THE RETURN OF THE SECOND TAB IN THE OMNICELL. THE PHARMACY TECHNICIAN UPON PERFORMING THEIR ROUNDS THEN EMPTIED THE RETURN BIN FROM THE OMNICELL BUT THE SINGLE TABLET OF HYDROCODONE/APAP WAS NOT IN THE BIN. MULTIPLE ATTEMPTS WERE MADE TO LOCATE THE MISSING TABLET, BUT IT COULD NOT BE FOUND.

The foregoing information is correct to the best of my knowledge and belief: By signing my full name in the space below, I hereby certify that the foregoing information furnished on this DEA Form 106 is true and correct, and understand that this constitutes an electronic signature for purposes of this reporting requirement only.

Signature: GREGORY MICHAUD

Title: DIRECTOR OF PHARMACY

Date Signed: May 16, 2022

NOTICE: In accordance with the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this collection of information is 1117-0001. Public reporting burden for this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Freedom of Information: Please prominently identify any confidential business information per 28 CFR 16.8(c) and Exemption 4 of the Freedom of Information Act (FOIA). In the event DEA receives a FOIA request to obtain such information, DEA will give written notice to the registrant to obtain such information. DEA will give written notice to the registrant to allow an opportunity to object prior to the release of information.

Privacy Act Information

AUTHORITY: Section 301 of the Controlled Substances Act of 1970 (PL 91-513).

PURPOSE: Reporting of unusual or excessive theft or loss of a Controlled Substance.

ROUTINE USES: The Controlled Substances Act authorizes the production of special reports required for statistical and analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated:

A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.

B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.

EFFECT: Failure to report theft or loss of Controlled Substances may result in penalties under Section 402 and 403 of the Controlled Substances Act.

DEA FORM **106**

Report of Theft or Loss of Controlled Substances

OMB No. 1117-0001 (Exp. Date 7/31/2023)

U.S. Department of Justice
Drug Enforcement Administration
Diversion Control Division

Type of Report: *(check one box only)* ☒ **New Report** ☐ **Amendment Key** ***(prior report dated)*:** 3NJL5Z4ETSVN

1. DEA Registration Number: BC2462822

Name of Business: CARR-GOTTSTEIN FOODS, CO.

Address: 10576 KENAI SPUR HIGHWAY

City: KENAI **State:** AK **ZIP Code:** 99611

Point of Contact: LUAN LE

Email Address: S1808C01@SAFEWAY.COM **Phone No.:** 9072836360

Date of the Theft or Loss (*or first discovery of theft or loss*): February 08, 2022 **Number of Thefts and Losses in the past 24 months:** 0

Principal Business of Registrant: CHAIN PHARMACY

2. Type of theft or loss: PACKAGING DISCREPANCY:

3. Loss in Transit. *(*Fill out this section only if there was a loss in transit, or hijacking of transport vehicle.)*

Name of Common Carrier: _____

Telephone Number of Common Carrier: _____ Package Tracking Number: _____

Have there been losses in transit from this same carrier in the past? ☐ No ☐ Yes *(If yes, how many, excluding this theft or loss?)*: _____

Was the package received and accepted by the consignee? ☐ No ☐ Yes *(If yes, the consignee is responsible for reporting the theft or loss.)*

If the package was accepted by the consignee, did it appear to be tampered with? ☐ No ☐ Yes

Name of Consignee / Supplier: _____

Enter the Name of Consignee (if reported by the supplier), or the Name of Supplier (if the package was accepted by the consignee).

If the consignee does not have a DEA Registration Number, e.g. if this was a shipment to a patient, or a nursing home emergency kit, enter "Patient" or "Nursing Home Kit."

DEA Registration Number of Consignee / Supplier: _____

Enter the DEA Registration Number of Consignee (if reported by the supplier), or DEA Registration Number of Supplier, (if the package was accepted by the consignee). If the controlled substances were shipped to a non-registrant, leave blank, unless a registered pharmacy shipped to an emergency kit held on site at a nursing home. In this case, the supplying pharmacy is required to report the theft or loss.

4. If this was a robbery, were any people injured? ☐ No ☐ Yes *(If yes, how many?)*: _____ Were any people killed? ☐ No ☐ Yes *(If yes, how many?)*: _____

5. Purchase value to Registrant of controlled substances taken?: $ 1

6. Were any pharmaceuticals or merchandise taken? ☒ No ☐ Yes *(Est. Value)*: _____

7. Was theft reported to Police? ☒ No ☐ Yes *(If yes, fill out the following information)*:

Name of Police Department: _____ Police Report number: _____

Name of Responding Officer: _____ Phone No.: _____

8. Which corrective measure(s) have you taken to prevent a future theft or loss?

- ☐ Installed monitoring equipment (e.g. video camera).
- ☐ Increased employee monitoring (e.g. random drug tests).
- ☐ Installed metal bars or other security on doors or windows.
- ☐ Secured Controlled Substances within safe.
- ☒ Other (Please describe on last page).
- ☐ Provided security training to staff.
- ☐ Requested increased security patrols by Police.
- ☐ Hired security guards for premises.
- ☐ Terminated employee.

DEA FORM **106**

Report of Theft or Loss of Controlled Substances

OMB No. 1117-0001 (Exp. Date 7/31/2023)

U.S. Department of Justice
Drug Enforcement Administration
Diversion Control Division

LIST OF CONTROLLED SUBSTANCES LOST

	Trade Name of Substance or Preparation	NDC Number	Name of Controlled Substance in Preparation	Dosage Strength	Dosage Form	Total Quantity Lost or Stolen
1	DEXTROAMP-AMPHET ER 25 MG CAP	00228306411	AMPHETAMINE ASPARTATE/AMPHETAMINE SULFATE/DEXTROAMP	25 MG	CAPSULE, SUST/	5

U.S. Department of Justice · Drug Enforcement Administration · Diversion Control Division

DEA FORM-106 *(Previous editions are obsolete.)*

Report of Theft or Loss of Controlled Substances

OMB No. 1117-0001 (Exp Date 7/31/2023)

U.S. Department of Justice
Drug Enforcement Administration
Diversion Control Division

9. What identifying marks, symbols, or price codes were on the labels of these containers that would assist in identifying the products?:

10. If Official Controlled Substance Order Forms (DEA-222) were stolen, give numbers:

Describe any other corrective measure(s) you have taken to prevent a future theft or loss:

MOVING FORWARD, THE PHARMACY WILL AUDIT THE WEEKLY DISPENSING REPORT AND CHECK ON HAND COUNTS FOR AMPHETAMINE ER 25MG. THIS WILL BE IN EFFECT INDEFINITELY OR UNTIL THE CAUSE OF THE LOSS HAS BEEN DETERMINED.

Enter remarks, if required. Description of how theft or loss occurred. Attach a separate sheet, if necessary:

DUE TO THE VARIANCE DISCOVERED AND THE FREQUENCY OF DISPENSING OF THIS PRODUCT, WE HAVE NO EVIDENCE TO SUPPORT ANY OTHER EXPLANATION FOR THIS LOSS.

The foregoing information is correct to the best of my knowledge and belief: By signing my full name in the space below, I hereby certify that the foregoing information furnished on this DEA Form 106 is true and correct, and understand that this constitutes an electronic signature for purposes of this reporting requirement only.

Signature: LUAN LE

Title: PHARMACIST

Date Signed: February 25, 2022

NOTICE: In accordance with the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this collection of information is 1117-0001. Public reporting burden for this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

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Privacy Act Information

AUTHORITY: Section 301 of the Controlled Substances Act of 1970 (PL 91-513).

PURPOSE: Reporting of unusual or excessive theft or loss of a Controlled Substance.

ROUTINE USES: The Controlled Substances Act authorizes the production of special reports required for statistical and analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated:

A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.

B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.

EFFECT: Failure to report theft or loss of Controlled Substances may result in penalties under Section 402 and 403 of the Controlled Substances Act.

From: Gregory Michaud
To: Carrillo, Laura N (CED)
Subject: MSRMC DEA 106 Filed
Date: Monday, April 11, 2022 2:40:22 PM
Attachments: DEA106_4-8-22_Ammended_4-11-22.pdf

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

Hi Laura,

I'm attaching a DEA 106 that we filed on Sat 4/9. We amended the 106 today 4/11 after there was no suspected diversion based on our investigation.

Let me know if you have any questions.

Thanks,
Greg

--
Gregory A. Michaud, PharmD, MBA, BCPS |Director of Pharmacy
Mat-Su Regional Medical Center
2500 S. Woodworth Loop | Palmer, Alaska, 99645
Phone # 907-861-6760 |Fax # 907-861-6731
Email g.michaud@msrmc.com

DEA FORM **106**

Report of Theft or Loss of Controlled Substances

OMB No. 1117-0001 (Exp. Date 7/31/2023)

U.S. Department of Justice
Drug Enforcement Administration
Diversion Control Division

Type of Report: *(check one box only)* ☐ **New Report** ☒ **Amendment Key** ***(prior report dated)*:** 3KWGVDIOPBR4

1. **DEA Registration Number:** BM8618463

Name of Business: MAT-SU REGIONAL MEDICAL CENTER

Address: 2500 S. WOODWORTH LOOP

City: PALMER **State:** AK **ZIP Code:** 99645

Point of Contact: GREGORY MICHAUD

Email Address: G.MICHAUD@MSRMC.COM **Phone No.:** 9078616760

Date of the Theft or Loss (*or first discovery of theft or loss*): April 08, 2022 **Number of Thefts and Losses in the past 24 months:** 4

Principal Business of Registrant: HOSPITAL/CLINIC

2. **Type of theft or loss:** EMPLOYEE THEFT (OR SUSPECTED):

3. **Loss in Transit.** *(*Fill out this section only if there was a loss in transit, or hijacking of transport vehicle.)*

Name of Common Carrier: _____

Telephone Number of Common Carrier: _____ Package Tracking Number: _____

Have there been losses in transit from this same carrier in the past? ☐ No ☐ Yes *(If yes, how many, excluding this theft or loss?)*: _____

Was the package received and accepted by the consignee? ☐ No ☐ Yes *(If yes, the consignee is responsible for reporting the theft or loss.)*

If the package was accepted by the consignee, did it appear to be tampered with? ☐ No ☐ Yes

Name of Consignee / Supplier: _____

Enter the Name of Consignee (if reported by the supplier), or the Name of Supplier (if the package was accepted by the consignee).

If the consignee does not have a DEA Registration Number, e.g. if this was a shipment to a patient, or a nursing home emergency kit, enter "Patient" or "Nursing Home Kit."

DEA Registration Number of Consignee / Supplier: _____

Enter the DEA Registration Number of Consignee (if reported by the supplier), or DEA Registration Number of Supplier, (if the package was accepted by the consignee). If the controlled substances were shipped to a non-registrant, leave blank, unless a registered pharmacy shipped to an emergency kit held on site at a nursing home. In this case, the supplying pharmacy is required to report the theft or loss.

4. **If this was a robbery, were any people injured?** ☐ No ☐ Yes *(If yes, how many?)*: _____ Were any people killed? ☐ No ☐ Yes *(If yes, how many?)*: _____

5. **Purchase value to Registrant of controlled substances taken?:** $ 1

6. **Were any pharmaceuticals or merchandise taken?** ☒ No ☐ Yes *(Est. Value)*: _____

7. **Was theft reported to Police?** ☒ No ☐ Yes *(If yes, fill out the following information)*:

Name of Police Department: _____ Police Report number: _____

Name of Responding Officer: _____ Phone No.: _____

8. **Which corrective measure(s) have you taken to prevent a future theft or loss?**

- ☐ Installed monitoring equipment (e.g. video camera).
- ☒ Increased employee monitoring (e.g. random drug tests).
- ☐ Installed metal bars or other security on doors or windows.
- ☐ Secured Controlled Substances within safe.
- ☒ Other (Please describe on last page).
- ☐ Provided security training to staff.
- ☐ Requested increased security patrols by Police.
- ☐ Hired security guards for premises.
- ☐ Terminated employee.

DEA FORM **106**

Report of Theft or Loss of Controlled Substances

OMB No. 1117-0001 (Exp. Date 7/31/2023)

U.S. Department of Justice
Drug Enforcement Administration
Diversion Control Division

LIST OF CONTROLLED SUBSTANCES LOST

	Trade Name of Substance or Preparation	NDC Number	Name of Controlled Substance in Preparation	Dosage Strength	Dosage Form	Total Quantity Lost or Stolen
1	OXYCODONE HCL 5 MG TABLET	00406055262	OXYCODONE HCL	5 MG	TABLET	1

U.S. Department of Justice · Drug Enforcement Administration · Diversion Control Division

Report of Theft or Loss of Controlled Substances

OMB No. 1117-0001 (Exp Date 7/31/2023)

U.S. Department of Justice
Drug Enforcement Administration
Diversion Control Division

9. What identifying marks, symbols, or price codes were on the labels of these containers that would assist in identifying the products?:

05 52, M (NDC 00406-0552-62)

10. If Official Controlled Substance Order Forms (DEA-222) were stolen, give numbers:

Describe any other corrective measure(s) you have taken to prevent a future theft or loss:

EDUCATED STAFF ON PROPER PROCEDURES FOR HANDLING OF CONTROLLED SUBSTANCES AND THE IMPORTANCE OF FOCUSING ON THE TASK TO ENSURE INADVERTANT LOSS DOES NOT OCCUR.

Enter remarks, if required. Description of how theft or loss occurred. Attach a separate sheet, if necessary:

NURSE REMOVED A SINGLE TABLET FROM MEDICATION DISPENSING CABINET AND THE TABLET WAS LOST DURING THE PROCESS OF REMOVING ADDITIONAL MEDICATIONS AND ADMINSTRATION TO THE PATIENT. EFFORTS WERE MADE TO FIND THE MISSING TABLET, BUT THESE WERE UNSUCCESSFUL. REVIEW OF VIDEO FOOTAGE CLEARLY SHOWS THE NURSE INADVERTANTLY DISPOSING OF THE TABLET IN THE TRASH ALONG WITH SOME PACKAGING MATERIALS. THE TRASH WAS REMOVED BY HOUSEKEEPING SHORTLY THEREAFTER AND DISPOSED OF, MAKING RETRIEVAL IMPOSSIBLE.

The foregoing information is correct to the best of my knowledge and belief: By signing my full name in the space below, I hereby certify that the foregoing information furnished on this DEA Form 106 is true and correct, and understand that this constitutes an electronic signature for purposes of this reporting requirement only.

Signature: GREGORY MICHAUD

Title: DIRECTOR OF PHARMACY

Date Signed: April 11, 2022

NOTICE: In accordance with the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this collection of information is 1117-0001. Public reporting burden for this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Freedom of Information: Please prominently identify any confidential business information per 28 CFR 16.8(c) and Exemption 4 of the Freedom of Information Act (FOIA). In the event DEA receives a FOIA request to obtain such information, DEA will give written notice to the registrant to obtain such information. DEA will give written notice to the registrant to allow an opportunity to object prior to the release of information.

Privacy Act Information

AUTHORITY: Section 301 of the Controlled Substances Act of 1970 (PL 91-513).

PURPOSE: Reporting of unusual or excessive theft or loss of a Controlled Substance.

ROUTINE USES: The Controlled Substances Act authorizes the production of special reports required for statistical and analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated:

A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.

B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.

EFFECT: Failure to report theft or loss of Controlled Substances may result in penalties under Section 402 and 403 of the Controlled Substances Act.

From:	Kenneth Dietz
To:	Carrillo, Laura N (CED)
Cc:	pharmacy.pcat
Subject:	(noencrypt) DEA Form #106 5/12/22 (date of loss 4/18/2022) SAFEWAY PHARMACY #1820 AK
Date:	Thursday, May 12, 2022 1:50:53 PM
Attachments:	image001.png 1820 041822 DEA 106 FORM.pdf

You don't often get email from kenneth.dietz@albertsons.com. Learn why this is important

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

Please see the attached DEA 106 Form filed for SAFEWAY PHARMACY #1820

Ken Dietz
Pharmacy Compliance and Analytics
Albertsons Companies
250 E Park Center Blvd
Boise, ID 83706
PCAT: 208-395-3200
Fax: 623-336-6099

Warning: All e-mail sent to this address will be received by the corporate e-mail system, and is subject to archival and review by someone other than the recipient. This e-mail may contain proprietary information and is intended only for the use of the intended recipient(s). If the reader of this message is not the intended recipient(s), you are notified that you have received this message in error and that any review, dissemination, distribution or copying of this message is strictly prohibited. If you have received this message in error, please notify the sender immediately.

DEA FORM **106**

Report of Theft or Loss of Controlled Substances

OMB No. 1117-0001 (Exp. Date 7/31/2023)

U.S. Department of Justice
Drug Enforcement Administration
Diversion Control Division

Type of Report: *(check one box only)* ☒ **New Report** ☐ **Amendment Key** ***(prior report dated)*:** 2SG9J9TFRDFQ

1. DEA Registration Number: BS8171643

Name of Business: SAFEWAY INC

Address: 3627 AIRPORT WAY

City: FAIRBANKS **State:** AK **ZIP Code:** 99709

Point of Contact: KEVIN LY

Email Address: S2754C01@SAFEWAY.COM **Phone No.:** 9073744060

Date of the Theft or Loss (*or first discovery of theft or loss*): May 01, 2022 **Number of Thefts and Losses in the past 24 months:** 0

Principal Business of Registrant: CHAIN PHARMACY

2. Type of theft or loss: PACKAGING DISCREPANCY:

3. Loss in Transit. *(*Fill out this section only if there was a loss in transit, or hijacking of transport vehicle.)*

Name of Common Carrier: _____

Telephone Number of Common Carrier: _____ Package Tracking Number: _____

Have there been losses in transit from this same carrier in the past? ☐ No ☐ Yes *(If yes, how many, excluding this theft or loss?)*: _____

Was the package received and accepted by the consignee? ☐ No ☐ Yes *(If yes, the consignee is responsible for reporting the theft or loss.)*

If the package was accepted by the consignee, did it appear to be tampered with? ☐ No ☐ Yes

Name of Consignee / Supplier: _____

Enter the Name of Consignee (if reported by the supplier), or the Name of Supplier (if the package was accepted by the consignee).

If the consignee does not have a DEA Registration Number, e.g. if this was a shipment to a patient, or a nursing home emergency kit, enter "Patient" or "Nursing Home Kit."

DEA Registration Number of Consignee / Supplier: _____

Enter the DEA Registration Number of Consignee (if reported by the supplier), or DEA Registration Number of Supplier, (if the package was accepted by the consignee). If the controlled substances were shipped to a non-registrant, leave blank, unless a registered pharmacy shipped to an emergency kit held on site at a nursing home. In this case, the supplying pharmacy is required to report the theft or loss.

4. If this was a robbery, were any people injured? ☐ No ☐ Yes *(If yes, how many?)*: _____ Were any people killed? ☐ No ☐ Yes *(If yes, how many?)*: _____

5. Purchase value to Registrant of controlled substances taken?: $ 908

6. Were any pharmaceuticals or merchandise taken? ☒ No ☐ Yes *(Est. Value)*: _____

7. Was theft reported to Police? ☒ No ☐ Yes *(If yes, fill out the following information)*:

Name of Police Department: _____ Police Report number: _____

Name of Responding Officer: _____ Phone No.: _____

8. Which corrective measure(s) have you taken to prevent a future theft or loss?

- ☐ Installed monitoring equipment (e.g. video camera).
- ☐ Increased employee monitoring (e.g. random drug tests).
- ☐ Installed metal bars or other security on doors or windows.
- ☐ Secured Controlled Substances within safe.
- ☒ Other (Please describe on last page).
- ☐ Provided security training to staff.
- ☐ Requested increased security patrols by Police.
- ☐ Hired security guards for premises.
- ☐ Terminated employee.

DEA FORM **106**

Report of Theft or Loss of Controlled Substances

OMB No. 1117-0001 (Exp. Date 7/31/2023)

U.S. Department of Justice
Drug Enforcement Administration
Diversion Control Division

LIST OF CONTROLLED SUBSTANCES LOST

	Trade Name of Substance or Preparation	NDC Number	Name of Controlled Substance in Preparation	Dosage Strength	Dosage Form	Total Quantity Lost or Stolen
1	TESTOSTERONE 30 MG/1.5 ML PUMP	45802061001	TESTOSTERONE	30 MG/ACTUATION	SOLUTION IN ME	270

U.S. Department of Justice · Drug Enforcement Administration · Diversion Control Division

Report of Theft or Loss of Controlled Substances

OMB No. 1117-0001 (Exp Date 7/31/2023)

U.S. Department of Justice
Drug Enforcement Administration
Diversion Control Division

9. What identifying marks, symbols, or price codes were on the labels of these containers that would assist in identifying the products?:

10. If Official Controlled Substance Order Forms (DEA-222) were stolen, give numbers:

Describe any other corrective measure(s) you have taken to prevent a future theft or loss:

THE PHARMACY WILL AUDIT TESTOSTERONE TD SOLN 30 MG EVERY MONTH FOR THE NEXT SIX MONTHS OR UNTIL THE CAUSE OF THE LOSS HAS BEEN DETERMINED.

Enter remarks, if required. Description of how theft or loss occurred. Attach a separate sheet, if necessary:

DUE TO THE VARIANCE DISCOVERED AND THE FREQUENCY OF DISPENSING OF THIS PRODUCT, WE HAVE NO EVIDENCE TO SUPPORT ANY OTHER EXPLANATION FOR THIS LOSS.

The foregoing information is correct to the best of my knowledge and belief: By signing my full name in the space below, I hereby certify that the foregoing information furnished on this DEA Form 106 is true and correct, and understand that this constitutes an electronic signature for purposes of this reporting requirement only.

Signature: KEVIN LY

Title: PHARMACY MANAGER

Date Signed: May 11, 2022

NOTICE: In accordance with the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this collection of information is 1117-0001. Public reporting burden for this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Freedom of Information: Please prominently identify any confidential business information per 28 CFR 16.8(c) and Exemption 4 of the Freedom of Information Act (FOIA). In the event DEA receives a FOIA request to obtain such information, DEA will give written notice to the registrant to obtain such information. DEA will give written notice to the registrant to allow an opportunity to object prior to the release of information.

Privacy Act Information

AUTHORITY: Section 301 of the Controlled Substances Act of 1970 (PL 91-513).

PURPOSE: Reporting of unusual or excessive theft or loss of a Controlled Substance.

ROUTINE USES: The Controlled Substances Act authorizes the production of special reports required for statistical and analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated:

A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.

B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.

EFFECT: Failure to report theft or loss of Controlled Substances may result in penalties under Section 402 and 403 of the Controlled Substances Act.

DEA FORM **106**

Report of Theft or Loss of Controlled Substances

OMB No. 1117-0001 (Exp. Date 7/31/2023)

U.S. Department of Justice
Drug Enforcement Administration
Diversion Control Division

Type of Report: *(check one box only)* ☒ **New Report** ☐ **Amendment Key** ***(prior report dated)*:** 4FW6G6P3K82W

1. **DEA Registration Number:** FC2432261

Name of Business: SAFEWAY, INC.

Address: 664 E PALMER WASILLA HWY

City: PALMER **State:** AK **ZIP Code:** 99645

Point of Contact: BEAU CRAIG

Email Address: S1739C01@SAFEWAY.COM **Phone No.:** 9077611460

Date of the Theft or Loss (*or first discovery of theft or loss*): March 21, 2022 **Number of Thefts and Losses in the past 24 months:** 0

Principal Business of Registrant: CHAIN PHARMACY

2. **Type of theft or loss:** PACKAGING DISCREPANCY:

3. **Loss in Transit.** *(*Fill out this section only if there was a loss in transit, or hijacking of transport vehicle.)*

Name of Common Carrier: _____

Telephone Number of Common Carrier: _____ Package Tracking Number: _____

Have there been losses in transit from this same carrier in the past? ☐ No ☐ Yes *(If yes, how many, excluding this theft or loss?)*: _____

Was the package received and accepted by the consignee? ☐ No ☐ Yes *(If yes, the consignee is responsible for reporting the theft or loss.)*

If the package was accepted by the consignee, did it appear to be tampered with? ☐ No ☐ Yes

Name of Consignee / Supplier: _____

Enter the Name of Consignee (if reported by the supplier), or the Name of Supplier (if the package was accepted by the consignee).

If the consignee does not have a DEA Registration Number, e.g. if this was a shipment to a patient, or a nursing home emergency kit, enter "Patient" or "Nursing Home Kit."

DEA Registration Number of Consignee / Supplier: _____

Enter the DEA Registration Number of Consignee (if reported by the supplier), or DEA Registration Number of Supplier, (if the package was accepted by the consignee). If the controlled substances were shipped to a non-registrant, leave blank, unless a registered pharmacy shipped to an emergency kit held on site at a nursing home. In this case, the supplying pharmacy is required to report the theft or loss.

4. **If this was a robbery, were any people injured?** ☐ No ☐ Yes *(If yes, how many?)*: _____ Were any people killed? ☐ No ☐ Yes *(If yes, how many?)*: _____

5. **Purchase value to Registrant of controlled substances taken?:** $ 4

6. **Were any pharmaceuticals or merchandise taken?** ☒ No ☐ Yes *(Est. Value)*: _____

7. **Was theft reported to Police?** ☒ No ☐ Yes *(If yes, fill out the following information)*:

Name of Police Department: _____ Police Report number: _____

Name of Responding Officer: _____ Phone No.: _____

8. **Which corrective measure(s) have you taken to prevent a future theft or loss?**

- ☐ Installed monitoring equipment (e.g. video camera).
- ☐ Increased employee monitoring (e.g. random drug tests).
- ☐ Installed metal bars or other security on doors or windows.
- ☐ Secured Controlled Substances within safe.
- ☒ Other (Please describe on last page).
- ☐ Provided security training to staff.
- ☐ Requested increased security patrols by Police.
- ☐ Hired security guards for premises.
- ☐ Terminated employee.

DEA FORM **106**

Report of Theft or Loss of Controlled Substances

OMB No. 1117-0001 (Exp. Date 7/31/2023)

U.S. Department of Justice
Drug Enforcement Administration
Diversion Control Division

LIST OF CONTROLLED SUBSTANCES LOST

	Trade Name of Substance or Preparation	NDC Number	Name of Controlled Substance in Preparation	Dosage Strength	Dosage Form	Total Quantity Lost or Stolen
1	DIPHENOXYLATE-ATROPINE 2.5-0.025 MG TABLE	00832059011	DIPHENOXYLATE HCL/ATROPINE SULFATE	2.5 MG-0.025 MG	TABLET	82

U.S. Department of Justice · Drug Enforcement Administration · Diversion Control Division

DEA FORM-106 *(Previous editions are obsolete.)*

Report of Theft or Loss of Controlled Substances

OMB No. 1117-0001 (Exp Date 7/31/2023)

U.S. Department of Justice
Drug Enforcement Administration
Diversion Control Division

9. What identifying marks, symbols, or price codes were on the labels of these containers that would assist in identifying the products?:

10. If Official Controlled Substance Order Forms (DEA-222) were stolen, give numbers:

Describe any other corrective measure(s) you have taken to prevent a future theft or loss:

BACK COUNT DIPHEN/ATROP TAB WHEN DISPENSING AND WRITE BACK COUNT ON STOCK BOTTLE, FOR THE NEXT THREE MONTHS OR UNTIL THE CAUSE OF LOSS IS DETERMINED.

Enter remarks, if required. Description of how theft or loss occurred. Attach a separate sheet, if necessary:

DUE TO THE VARIANCE DISCOVERED AND THE FREQUENCY OF DISPENSING OF THIS PRODUCT, WE HAVE NO EVIDENCE TO SUPPORT ANY OTHER EXPLANATION FOR THIS LOSS.

The foregoing information is correct to the best of my knowledge and belief: By signing my full name in the space below, I hereby certify that the foregoing information furnished on this DEA Form 106 is true and correct, and understand that this constitutes an electronic signature for purposes of this reporting requirement only.

Signature: BEAU CRAIG

Title: PHARMACIST

Date Signed: March 25, 2022

NOTICE: In accordance with the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this collection of information is 1117-0001. Public reporting burden for this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Freedom of Information: Please prominently identify any confidential business information per 28 CFR 16.8(c) and Exemption 4 of the Freedom of Information Act (FOIA). In the event DEA receives a FOIA request to obtain such information, DEA will give written notice to the registrant to obtain such information. DEA will give written notice to the registrant to allow an opportunity to object prior to the release of information.

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ROUTINE USES: The Controlled Substances Act authorizes the production of special reports required for statistical and analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated:

A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.

B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.

EFFECT: Failure to report theft or loss of Controlled Substances may result in penalties under Section 402 and 403 of the Controlled Substances Act.

From: 118th NABP Annual Meeting
To: Carrillo, Laura N (CED)
Subject: Delegates Approve Seven Resolutions at the 118th NABP Annual Meeting
Date: Thursday, May 26, 2022 2:02:11 PM

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

FOR IMMEDIATE RELEASE
May 26, 2022
Media Contact: Larissa Doucette
847/391-4405; help@nabp.pharmacy

Delegates Approve Seven Resolutions at the 118th NABP Annual Meeting

MOUNT PROSPECT, IL – Delegates from the member boards of pharmacy adopted seven resolutions during the 118th National Association of Boards of Pharmacy® (NABP®) Annual Meeting, held in Phoenix, AZ, on May 19-21, 2022. The resolutions addressed the following:

- convening a task force to amend the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy* to include a foundational definition of pharmacists as health care providers;
- conducting a survey of states and United States jurisdictions to collect data regarding pharmacy e-prescribing concerns and, if appropriate, convene a task

force to further study the issue and make recommendations for improving e-prescribing functionality;

- examining the development of a national standardized pharmacy jurisprudence examination for the state boards of pharmacy to assess competence for licensure;
- requesting that Food and Drug Administration (FDA) provide timely guidance to states regarding how the agency intends to assess state licensing statutes, regulations, and processes for consistency with the agency's *National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers* and that FDA focuses on issues impacting patient safety; and encouraging boards of pharmacy to provide public comment on the proposed rule;
- communicating with Drug Enforcement Administration (DEA) and Congress about the importance of state regulation of telepharmacy and the potential impact that DEA regulation could have on patient access to medications; and
- examining the feasibility of creating a system to allow efficient interstate portability through a multistate licensure compact.

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

The complete text of the resolutions will be available in the About section under Annual Meeting on the NABP website.

NABP is the independent, international, and impartial Association that assists its member boards in protecting the public health. Visit www.nabp.pharmacy to learn more.

-30-

Unsubscribe

This message was sent to **laura.carrillo@alaska.gov** from **NABPmeetings@nabp.pharmacy**

118th NABP Annual Meeting
National Association of Boards of Pharmacy
1600 Feehanville Dr
Mount Prospect, IL 60056

From: Janso, Lisa
Subject: District 7 Well-being Index for Pharmacy Personnel Reports
Date: Wednesday, May 11, 2022 12:35:33 PM
Attachments: image001.png
image002.png
image003.png
image004.png
image005.png
NABP Report - District 7 - May 2022.pdf

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

Good afternoon,

As previously noted, NABP is collaborating with APhA to make available the monthly Well-being Index (WBI) for Pharmacy Personnel Report. The May 2022 Report for District 7 states is attached.

A small bump in the number of assessors continues this month that is believed to be primarily due to promotion of the WBI tool at APhA2022. The overall distress percent ticked up again this month but is still just below 32% at 31.98%.

The reason a distress percent goes up or down when the number of assessors remains the same is reassessments. Current assessors may reassess as many times as they would like, and those reassessments will change the distress percent without changing the number of assessors. This month, 51% (n=8399) of all assessments are first/only time and 49% (n=8080) are reassessments. This month's report includes a slide that shows the number of first-time assessments, number of reassessments, number of unique reassessment assessors, and total reassessments for each state in your district.

As a reminder, each state's distress percent rank is expressed as "ranked X/52". If the state's rank is 5/52, it means that the state has the 5th highest distress percent of the 52 jurisdictions (50 states, DC, and Puerto Rico).

For your reference, the APhA/NASPA 2021 Pharmacy Workplace Survey Final Report was released late last week.

- The press release for the Final Report can be found here.
- The Final Report can be found here.

If you have any questions or would like to provide feedback on the WBI reports, please contact ExecOffice@nabp.pharmacy.

Best regards,

Lisa Janso, MS
Executive Committee Manager
847/391-4462

National Association of Boards of Pharmacy
1600 Feehanville Dr, Mount Prospect, IL 60056
www.nabp.pharmacy | ljanso@nabp.pharmacy

APhA

WELL-BEING index

Well-being Index For Pharmacy Personnel

State Report for State Boards of Pharmacy

NABP District Seven States

APRIL 2022

For Every Pharmacist. For All of Pharmacy.

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Available Pharmacists Positions vs Distress Percent

District Data from the Pharmacist Workforce Center

Year-end 2021 versus 2020

WELL-BEING
index
https://app.mywellbeingi
Invitation Code:
256

Availability of pharmacist positions (all settings) in District Seven with Comparison Distress Percent

Pharmacy Demand Report, through end of 2021, as reported by the Pharmacy Workforce Center*

	Number of Licensed Pharmacists as of Oct 2020	Total Availability of Positions In 2020	Distress Percent Pharmacists Only At end of 2020	Number of Licensed Pharmacists as of Oct 2021	Total Availability of Positions In 2021	Distress Percent Pharmacists Only At end of 2021
Alaska	1002	40	23.08% (n=18)	1002	73	26.67% (n=47)
Idaho	4082	84	25.93% (n=39)	3624	145	27.16% (n=47)
Montana	2111	35	52.38% (n=16)	2200	79	54.55% (n=17)
Oregon	8488	118	32.85% (n=68)	9006	271	33.33% (n=71)
Washington	10969	317	39.44% (n=92)	10969	444	39.16% (n=104)

*The Pharmacy Workforce Center has released the latest iteration of the Pharmacy Demand Report (PDR), containing data through the end of 2021. The PDR aims to provide an enhanced measurement of pharmacist demand in the U.S. To receive an email notification when the latest report is available, please complete the form at the bottom of the PDR homepage.

DISTRESS PERCENT CHANGES
National and District
March 2022 versus April 2022

Changes in Distress Levels

As of April 2022

State	Change in Distress % March 2022 April 2022	Distress % April 2022	State Rank for Distress Percent April 2022
Largest Increase in Distress Percent			
Oklahoma	1.76%	34.36%	21
Nevada	1.39%	58.06%	1
West Virginia	1.05%	44.72%	5
Rhode Island	0.87%	31.82%	34 (T)
South Dakota	0.83%	26.97%	46
Largest Decrease in Distress Percent			
North Dakota	-1.51%	33.33%	28 (Tie)
New Mexico	-1.45%	34.73%	20
Wyoming	-0.79%	32.60%	32
New Hampshire	-0.69%	29.79%	41
Connecticut	-0.67%	31.75%	36
NATIONAL	-0.07%	31.92%	----

Changes in Distress Levels – District Seven

As of April 2022

	Change in Distress % Mar 22 Vs Apr 22	Distress % Apr 2022	Distress % State Rank Apr 2022	Change in Distress % Feb 22 Vs Mar 22	Distress % State Rank Mar 2022	Distress % State Rank Feb 2022	Distress % State Rank Jan 2022	Distress % State Rank Dec 2021	Distress % State Rank Nov 2021	Distress % State Rank Sep 2021	Distress % State Rank Jul 2021	Distress % State Rank Apr 2021	Distress % State Rank May 2020	Distress % State Rank Apr 2020
Alaska	**-0.47%**	**31.88%**	**33**	9.09%	33	49	48	48	49	49	49	49	49	49
Idaho	**-0.30%**	**33.33%**	**27**	-0.01%	25	26	31	31	33	40	34	34	40	39
Montana	**No Change**	**40.63%**	**11**	No Change	11	12	10	10	10	10	12	12	19 (t)	24
Oregon	**0.01%**	**33.16%**	**29**	No Change	30	30	29	27 (t)	30	28	28	28	36	37
Washington	**-0.28%**	**40.87%**	**9**	No Change	10	10	12	11	11	12	11	11	12	13
Wyoming	**-0.79%**	**17.39%**	**52**	No Change	52	52	52	52	52	51	52	51	~	~

Note: Historic data from 2020/2021 has been removed to allow space for current month.
Refer to previous months' reports or contact ashaughnessy@aphanet.org for data.

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https://app.m org/signup
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For Every Pharmacist. For All of Pharmacy.

DISTRESS PERCENT MONTHLY REPORTS
State-Specific
March 2022 versus April 2022

PHARMACISTS WELL-BEING INDEX
STATE DISTRESS PERCENT*

APRIL 2022

As of April 6, 2022, the Alaska distress percent was 31.88% (ranked 33/52) with 49 assessors.

MARCH 2022

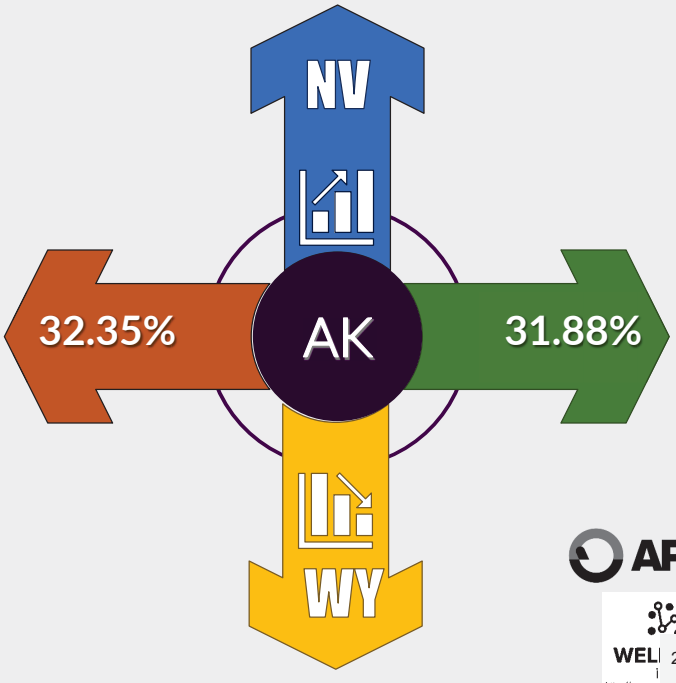
As of March 6, 2022, the Alaska distress percent was 32.35% (ranked 34/52) with 49 assessors.

STATE COMPARISON

As of April 6, 2022

Nevada is the highest at 58.06% (n=26)

Wyoming has the lowest 17.39% (n=16)



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WELL 262 NG

https://app.my... g/signup
Invitation Code: APhA

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

PHARMACISTS WELL-BEING INDEX
STATE DISTRESS PERCENT*

APRIL 2022

As of April 6, 2022, the Idaho distress percent was 33.33% (ranked 27/52) with 67 assessors.

MARCH 2022

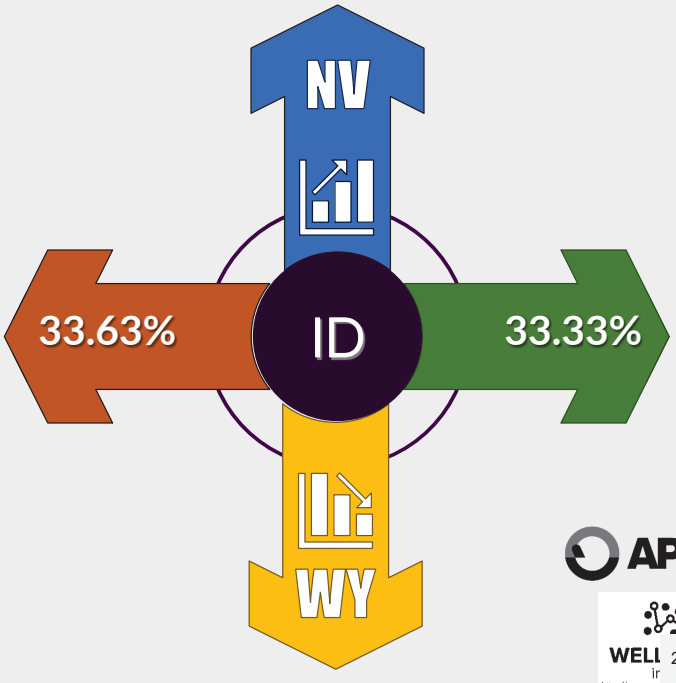
As of March 6, 2022, the Idaho distress percent was 33.63% (ranked 26/52) with 65 assessors.

STATE COMPARISON

As of April 6, 2022

Nevada is the highest at 58.06% (n=26)

Wyoming has the lowest 17.39% (n=16)



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

APhA

WELL 263 IG
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https://app.myw
Invitation Code: APhA

PHARMACISTS WELL-BEING INDEX
STATE DISTRESS PERCENT*

APRIL 2022

As of April 6, 2022, the Montana distress percent was 40.63% (ranked 11/52) with 26 assessors.

MARCH 2022

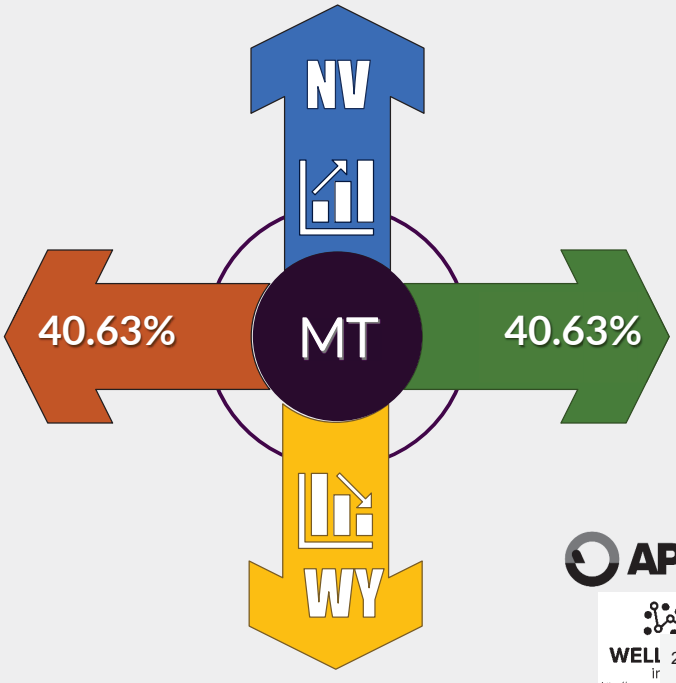
As of March 6, 2022, the Montana distress percent was 40.63% (ranked 11/52) with 26 assessors.

STATE COMPARISON

As of April 6, 2022

Nevada is the highest at 58.06% (n=26)

Wyoming has the lowest 17.39% (n=16)



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https://app.myw /signup
Invitation Code: APhA

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

PHARMACISTS WELL-BEING INDEX
STATE DISTRESS PERCENT*

APRIL 2022

As of April 6, 2022, the Oregon distress percent was 33.16% (ranked 29/52) with 94 assessors.

MARCH 2022

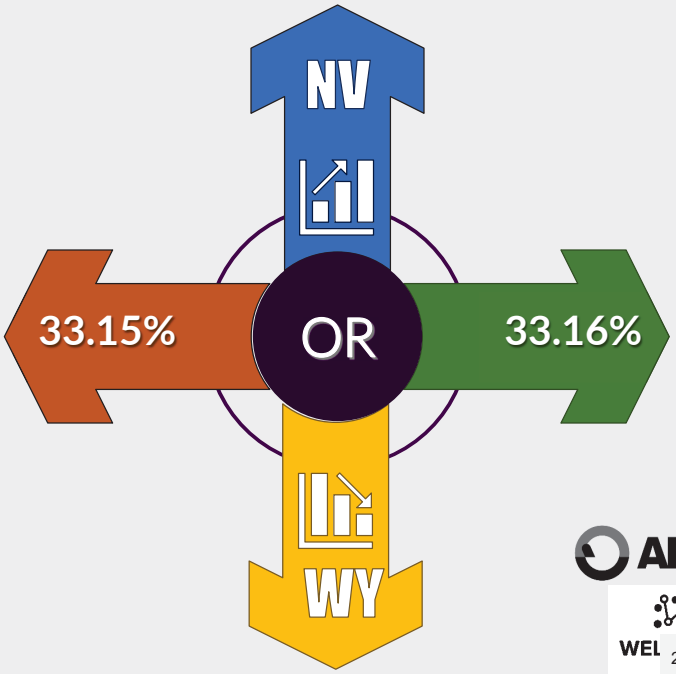
As of March 6, 2022, the Oregon distress percent was 33.15% (ranked 30/52) with 94 assessors.

STATE COMPARISON

As of April 6, 2022

Nevada is the highest at 58.06% (n=26)

Wyoming has the lowest 17.39% (n=16)



APhA

WEL 265 NG

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Invitation code: aphaa

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

PHARMACISTS WELL-BEING INDEX
STATE DISTRESS PERCENT*

APRIL 2022

As of April 6, 2022, the Washington distress percent was 40.87% (ranked 9/52) with 152 assessors.

MARCH 2022

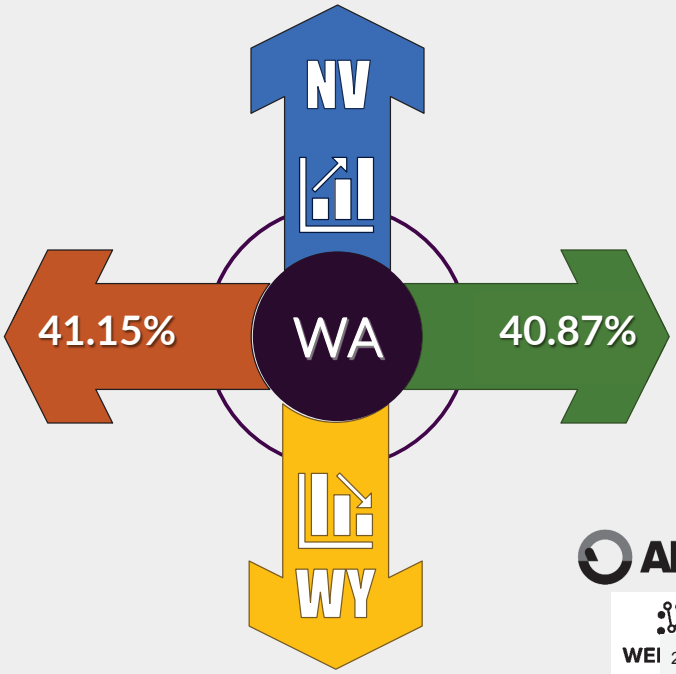
As of March 6, 2022, the Washington distress percent was 41.15% (ranked 10/52) with 150 assessors.

STATE COMPARISON

As of April 6, 2022

Nevada is the highest at 58.06% (n=26)

Wyoming has the lowest 17.39% (n=16)



APhA

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Invitation Code: APhA

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

PHARMACISTS WELL-BEING INDEX
STATE DISTRESS PERCENT*

APRIL 2022

As of April 6, 2022, the Wyoming distress percent was 17.39% (ranked 52/52) with 16 assessors.

MARCH 2022

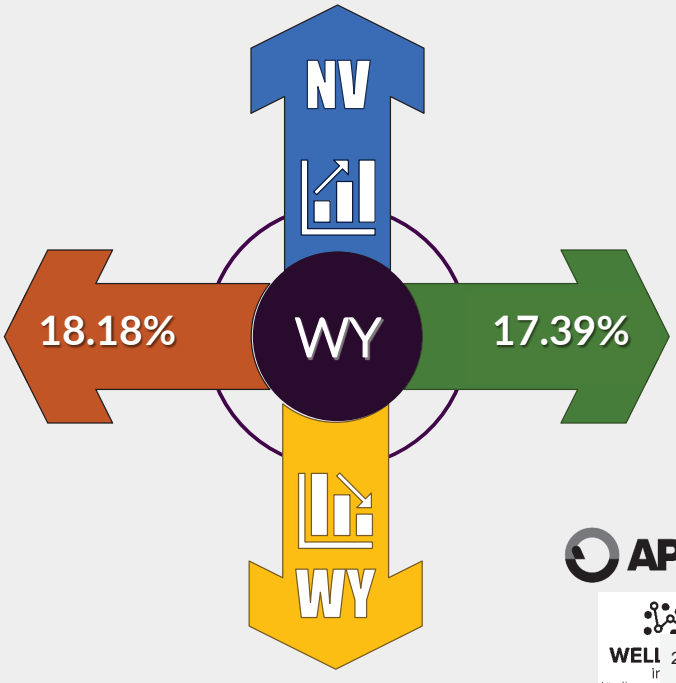
As of March 6, 2022, the Wyoming distress percent was 18.18% (ranked 52/52) with 15 assessors.

STATE COMPARISON

As of April 6, 2022

Nevada is the highest at 58.06% (n=26)

Wyoming has the lowest 17.39% (n=16)



APhA

WELL 267 IG
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https://app.myw /signup
Invitation Code: APhA

Distress Percent is the percentage of individuals with a Pharmacist 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*

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!

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
https://app.mywellbeingindex.org/signup
Invitation Code: APhA

Or Scan

You're committed to pharmacy.
We're committed to your well-b
www.pharmacist.com/wellbe

From:	IGA
To:	IGA
Cc:	IGA
Subject:	FDA's Compounding Quality Center of Excellence Upcoming Events
Date:	Tuesday, May 31, 2022 10:07:59 AM
Attachments:	image003.png image004.png

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

Hello-

The U.S. Food and Drug Administration's (FDA or Agency) Intergovernmental Affairs (IGA) team would like to share the following information with you.

FDA's Compounding Quality Center of Excellence is announcing upcoming events that aim to support the Outsourcing Facility industry to enhance the overall quality of compounded drugs.

Please contact CompoundingQualityCoE@fda.hhs.gov with any questions.

Thank you,

FDA Compounding Quality Center of Excellence

Content

- **2022 Annual Center of Excellence Outsourcing Facility Conference**
- **Virtual Instructor-led Trainings**
- **Self-guided Trainings**

2022 Annual Center of Excellence Outsourcing Facility Conference

Save the Date! The **2022 Annual Center of Excellence Outsourcing Facility Conference** is scheduled for September 6 - 8, 2022 and will be **virtual this year**. This year's theme is *The Shared Pursuit of Compounding Excellence.* Sessions will cover topics of interest that have been requested by outsourcing facilities and industry stakeholders.

Subscribe to receive an email announcement when registration opens.

Virtual Instructor-led Trainings

Virtual, instructor-led trainings (ILT) are available to Outsourcing Facilities and traditional compounders and regulators on a more limited basis. Each ILT offers an

opportunity to learn more about current good manufacturing practice (CGMP) regulations, ask questions, and engage with others from across the industry.

ILT courses are free to the public and offer continuing education (CE) credits to those who attend at least three days of the course.

We are excited to announce a new **Quality Management Systems** course launching this summer. Please see below for all upcoming course dates. Additional courses will be announced and open for registration in the Fall of 2022.

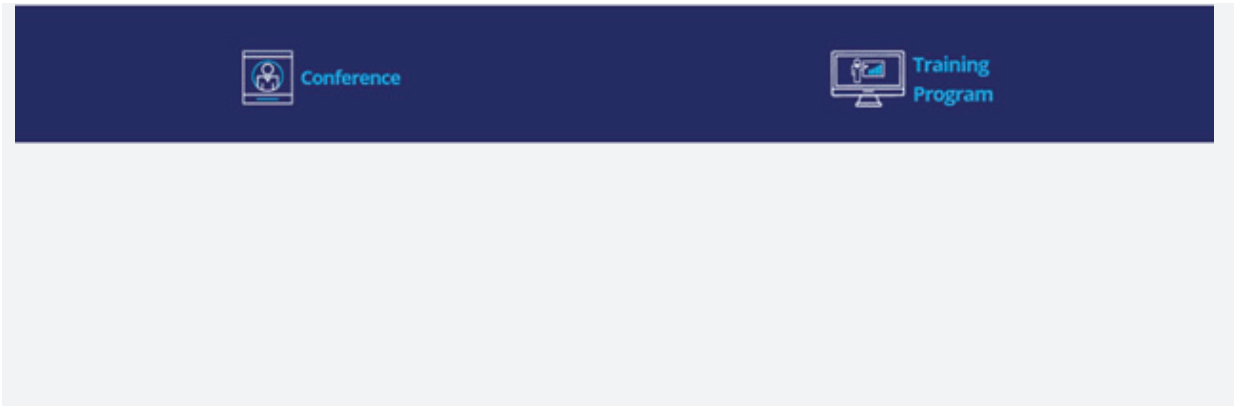
ILT Courses	Course Dates	Description
Quality Management Systems	July 11-14, 2022 August 22-25, 2022 September 26-29, 2022	Learn the fundamentals of an effective QMS that assures Quality, the critical role of senior management, and the impact of quality culture throughout an organization. The course will also explore the concepts of knowledge management, quality risk management, and data integrity. Practical activities will include case studies, inspectional observation and warning letter responses, quality culture assessments, and data integrity risk evaluations.

Self-guided Trainings

Our **on-demand training page** highlights **nine self-guided courses** that provide an overview of select CGMP regulations and policy topics, offering free continuing education to pharmacists, physicians, and nurses. The webpage also lists recent CDER webinars hosted on FDA's YouTube and FDA presentations related to compounding.

Please see a list of self-guided trainings below and learn more here.

Web-Based Training Courses
Regulatory Framework for Human Drug Compounding
Outsourcing Facility Guide
Investigations and CAPA
Supplier/Contractor Qualification and Management
Insanitary Conditions & Sterility Assurance
Personnel Gowning in Sterile Drug Production
Airflow
Aseptic Process Simulations (Media Fills)
Stability and Beyond Use Dates


Conference
Training
Program

From: FDA Intergovernmental Affairs
To: Board of Pharmacy (CED sponsored)
Subject: Weekly Digest for the Week of May 23, 2022
Date: Friday, May 27, 2022 12:48:34 PM

FDA

Intergovernmental Affairs

Weekly Digest for the Week of May 23, 2022

Good afternoon! The FDA Intergovernmental Affairs (IGA) team would like to bring to your attention the following announcements the Agency made during the week of **May 23, 2022**. If you have any questions on the below announcements, please reach out to us at IGA@fda.hhs.gov.

FDA Warnings and Recalls

- On May 27, 2022, the Food and Drug Administration **provided an update on additional steps it has taken that will lead to more infant formula on U.S. store shelves in the coming weeks and months. "We continue to work around the clock with our government partners and industry to ensure there's adequate infant formula available wherever and whenever parents and caregivers need it," said FDA Commissioner Robert M. Califf, M.D. "Steps like the one the agency is taking today means more infant formula will be available to parents and caregivers in the weeks and months ahead. We will not rest until our shelves are replete with safe and nutritious infant formula." Under the agency's recent increased flexibilities, Bubs Australia plans to provide at least 1.25 million cans of several varieties of its infant formula** such as stage 1 and 2 cans of Bubs Organic Grass Fed, Bubs Supreme A2 Beta-Casein Protein and Bubs Easy-digest Goat Milk, that will make at least 27.5 million full-size, 8-ounce bottles. Some of this product is currently in stock for transport and additional

product is being produced in the coming weeks and months. The U.S. Department of Health and Human Services is evaluating options for getting the products to the U.S. as quickly as possible. The company has information about the products and where to find product once in the U.S. on the Aussie Bubs website.

- The Food and Drug Administration provided an update on **steps it has taken that will lead to millions of bottles of specialized medical infant formula to help address immediate needs for infants with certain allergies or critical health conditions**, on May 26, 2022. This type of specialized medical infant formula is currently in short supply in the U.S. **"We have made tremendous progress, including notable steps in just the past week, which will allow us to immediately begin bringing specialty and infant formula products into the U.S. as quickly as possible," said FDA Commissioner Robert M. Califf, M.D. "We continue to work closely with our U.S. government partners and domestic and international manufacturers to identify additional formula product that will be available to parents and caregivers in the weeks and months ahead. It is our goal to ensure that hospitals, specialty pharmacies, and retail store shelves will begin seeing adequate supplies again in the coming weeks." About 500,000 additional cans of specialized medical formula manufactured by Danone's Nutricia business will be headed to the U.S.** These Neocate amino acid-based formula products -- some of which are already manufactured for the U.S. market and are made at facilities in Europe -- amounts to more than 5 million full-size, 8-ounce bottles. The U.S. Department of Health and Human Services and Danone continue to partner to evaluate options for getting the products to the U.S. as quickly as possible. The specialized medical formula is expected to be distributed through direct ordering, hospitals, health care professionals, pharmacies, healthcare product distributors and Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) local access points to ensure they get to the infants who rely on these products.

- On May 24, 2022, the Food and Drug Administration **announced that it will exercise enforcement discretion with respect to specific infant formula products to increase infant formula supplies in the United States.** The List of Companies Receiving Enforcement Discretion for Infant Formula will be updated on a regular basis. The FDA **has informed Kendal Nutricare that the agency is exercising enforcement discretion for the importation of certain infant formula** under the Kendamil brand. Under the agency's recent increased flexibilities regarding importation of certain infant formula products, the **company initially estimates that about 2 million cans of infant formula are expected to land on U.S. store shelves beginning in June.** The FDA is also announcing that **it is not objecting to the release of about 300,000 cans of EleCare amino acid-based infant formula previously produced at Abbott Nutrition's Sturgis, Michigan, facility to individuals needing urgent, life-sustaining supplies of this specialty formula on a case-by-case basis.** These products will undergo enhanced microbiological testing before release. You can find additional information here.

- On May 26, 2022, the Food and Drug Administration, along with CDC and state and local partners, are **investigating a multistate outbreak of *Salmonella* Senftenberg infections linked to certain Jif brand peanut butter products produced at the J.M. Smucker Company facility in Lexington, Kentucky.** J.M. Smucker Company has voluntarily recalled certain Jif brand peanut butter products that have the lot codes described below. Photo examples are

included below. **FDA has posted a list of additional recalls being conducted by companies that have used the recalled Jif peanut butter as an ingredient in the manufacturing of a new product (e.g., chocolate products) or in repackaging the product (e.g., snack cups).** This list will be updated as the agency receives notification of new recalls. As of May 25, 2022, CDC reports that of the 10 people interviewed, 10 (100%) reported eating peanut butter prior to becoming ill. Nine people reported brand information, and all nine (100%) reported eating different varieties of Jif brand peanut butter. FDA's investigation is ongoing and more information will be provided as it becomes available. Consumers, restaurants, and retailers should not eat, sell, or serve any recalled Jif brand peanut butter, including recalled products that contain the recalled Jif peanut butter. Consumers should also avoid feeding recalled peanut butter to pets or other animals, including wild birds. For more information, please click here.

COVID-19 Updates

- On May 20, 2022, the the Food and Drug Administration and HHS/ASPR **announced the authorization of an extension to the shelf-life from 12 months to 18 months for specific lots of the refrigerated Eli Lilly monoclonal antibody, bebtelovimab, which is currently authorized for emergency use.** FDA granted this extension following a thorough review of data submitted by Eli Lilly. As a result of this extension, some batches may be stored for an additional 6 months from the labeled date of expiry (see Table 1 here). This extension applies to all unopened vials of bebtelovimab that have been held in accordance with storage conditions detailed in the authorized Fact Sheet for Health Care Providers (PDF, 433 KB) and the EUA Letter of Authorization (PDF, 111 KB) for bebtelovimab. As required by the EUA, unopened vials of bebtelovimab injection, 175 mg/2 mL, must be stored under refrigerated temperature at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light.

- On May 19, 2022, the the Food and Drug Administration **issued a warning letter to Santhigram Kerala Ayurvedic Co. of U.S., Inc. for selling unapproved products with fraudulent claims to treat multiple diseases, including COVID-19.** The FDA also issued a warning letter to Ayuryoga, Inc. for selling unapproved products with fraudulent claims to treat multiple diseases. Consumers concerned about COVID-19 should consult with their health care provider.

- On May 17, 2022, the the Food and Drug Administration **revised the scope of authorization for Evusheld's EUA to include new information on hypersensitivity reactions and the risk of cross-hypersensitivity with COVID-19 vaccines and related clinical recommendations**. Clinicians should consider consulting an allergist-immunologist prior to administering Evusheld to individuals with a history of a severe allergic reaction (e.g., anaphylaxis) to a COVID-19 vaccine. For all individuals, Evusheld should be administered under the supervision of a health care provider with appropriate medical support to manage severe allergic reactions. In addition, everyone who receives Evusheld should be observed after injection for at least one hour to monitor for hypersensitivity reactions.

- COVID-19 testing updates:

- As of today, **436 tests and sample collection devices are authorized by the FDA under emergency use authorizations (EUAs).** These include 302 molecular tests and sample collection devices, 84 antibody and other immune response tests, 49 antigen tests, and 1 diagnostic breath test. There are 80 molecular authorizations and 1 antibody authorization that can be used with home-collected samples. There is 1 EUA for a molecular prescription at-home test, 2 EUAs for antigen prescription at-home tests, 17 EUAs for antigen over-the-counter (OTC) at-home tests, and 3 for molecular OTC at-home tests.

- The Food and Drug Administration has **authorized 27 antigen tests and 7 molecular tests for serial screening programs.** The FDA has also authorized 987 revisions to EUA authorizations.

REMINDERS:

- The Food and Drug Administration holds weekly **Virtual Town Halls on COVID Diagnostics, every Wednesday** – from 12:15 to 1:15 pm ET. For more information, click here.

RESOURCES:

- **Use this chart to find out if you're eligible for a COVID-19 vaccine booster and which one.**

- The Food and Drug Administration has created a consumer web site: **Know Your Treatment Options for COVID-19 - provides the latest information on treatment options in the battle against coronavirus disease**, including all FDA authorized and approved drug treatments, as well as how to get more information about them and others. The web site is updated regularly.

- FDA's Office of Minority Health and Health Equity (OMHHE) **Multilingual COVID-19 Resources**

- **FDA's Coronavirus Disease 2019 (COVID-19)** webpage provides the latest news and information.

- FDA's **COVID-19 Vaccines webpage** at www.fda.gov/covid19vaccines highlight new information as it becomes available

- The Food and Drug Administration's webpage - **A Closer Look at COVID-19 Diagnostic Testing** - provides health care providers and other public health professionals, including those who might purchase COVID-19 tests, with more technical information and resources.

- **Coronavirus Treatment Acceleration Program (CTAP)** information can be found here.

Devices

- The Food and Drug Administration will hold a **virtual public workshop entitled "Building Medical Device Supply Chain Resilience: A Healthcare and Public Health Ecosystem-Wide Collaboration," on June 7, 2022.** The purpose of the public workshop is to discuss ways to foster resiliency in the medical device supply chain and to seek input on the new Resilient

Supply Chain Program (RSCP). The RSCP aims to build upon a foundation of strong partnerships to improve supply chain resiliency through proactive communication, collaboration, and engagement with patient advocates, health care providers, distributors, group purchasing organizations, manufacturers, as well as key component and material suppliers. **If you wish to attend this Workshop, you must register by 4:00 p.m. on June 6, 2022.** Space is limited for the breakout sessions, so FDA may limit the number of participants from each organization. **If you wish to participate in the breakout sessions, registration must be completed by 4:00 p.m. on May 17, 2022.** You can find more information about the RSCP here.

- **A virtual meeting about Augmented Reality (AR) and Virtual Reality (VR) Medical Devices will be held on July 12-13, 2022,** the Food and Drug Administration announced. **At the meeting, the Patient Engagement Advisory Committee (the Committee) will discuss and make recommendation on factors to consider when evaluating the benefits, risks, and uncertainty for AR/VR devices.** The Committee will also discuss specific challenges related to vulnerable populations (for example, pediatric or cognitively impaired) who may use this technology. For additional details, please click here.

Drugs and Biologics

- On May 23, 2022, the the Food and Drug Administration **announced the availability of one final guidance and two draft guidances for blood establishments.** The final guidance, "Recommendations to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Components," removes the recommendations to defer indefinitely blood donors for: 1) geographic risk of possible exposure to bovine spongiform encephalopathy for time spent in the United Kingdom (U.K.) from 1980-1996 and for time spent in France and Ireland from 1980-2001, and 2) receipt of a blood transfusion in the U.K., France, and Ireland from 1980-present. The guidance also provides recommendations for requalification of individuals previously deferred for these geographic risk factors, provided they meet all other eligibility requirements. The draft guidance, "Blood Pressure and Pulse Donor Eligibility Requirements – Compliance Policy," describes the circumstances in which FDA does not intend to take regulatory action for a blood establishment's failure to comply with certain regulations for determining the eligibility of blood donors with blood pressure or pulse outside the specified limits. The draft guidance, "Compliance Policy Regarding Blood and Blood Component Donation Suitability, Donor Eligibility and Source Plasma Quarantine Hold Requirements," describes the conditions under which the FDA does not intend to take regulatory action for a blood establishment's failure to comply with certain requirements regarding donation suitability, donor eligibility, and quarantine hold for Source Plasma.

Foods

- On May 27, 2022, the Food and Drug Administration announced a webinar on **Tuesday, June 14, 2022, at 1:00 pm (ET) to discuss the recent draft guidance on lead action levels for juice.** The draft guidance, titled "Action Levels for Lead in Juice; Draft Guidance for Industry,"

issued in April provides action levels for lead in single-strength (ready to drink) apple juice and in other single-strength juices and juice blends. These draft action levels support the agency's broader effort to reduce exposure to arsenic, lead, cadmium, and mercury from foods, and advance our goals in the Closer to Zero action plan. During the webinar the FDA will provide an overview of the draft guidance and additional information, as well as answer stakeholder questions. To register for the webinar and to submit a question or brief comment related to this guidance in advance, please visit the registration page. Questions or comments must be submitted by Tuesday, May 31, 2022.

Veterinary Food and Medicine

- On May 26, 2022, the the Food and Drug Administration **posted warning letters to multiple companies illegally selling CBD products intended for use in food-producing animals.** Although the FDA does not know the current extent of CBD use in food-producing animals, the agency is taking steps regarding these unapproved and potentially unsafe products now to help protect animals and the safety of the food supply. The companies also sell CBD-containing unapproved new drugs for humans and adulterated human foods. Some of the products were marketed as dietary supplements even though CBD-containing products do not meet the definition of a dietary supplement.

- On May 23, 2022, the the Food and Drug Administration **announced the availability of a report drafted by the Reagan-Udall Foundation as part of a cooperative agreement.** The report summarizes key findings from a series of targeted conversations with stakeholders about the feasibility of establishing a voluntary public-private partnership to collect and analyze antimicrobial use data from food-producing animals. **The Foundation will host a virtual public forum on June 14, 2022, from 1:00 pm to 3:00 pm to present insights from the report and allow for questions from the public.** The FDA has also opened a docket to accept public comments through August 21, 2022.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 10, 12, 16, and 205

[Docket No. FDA–2020–N–1663]

RIN 0910–AH11

National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is proposing national standards for the licensing of prescription drug wholesale distributors (''wholesale distributors'' or ''wholesale drug distributors'') and third-party logistics providers (''3PLs''), as directed under the Drug Supply Chain Security Act (DSCSA) (Title II of the Drug Quality and Security Act). Pursuant to the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the DSCSA, the proposed rule would establish standards for all State and Federal licenses issued.

DATES: Submit either electronic or written comments on the proposed rule by June 6, 2022. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by March 7, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time on June 6, 2022. Electronic comments must be submitted on or before that date. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions in the following ways:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–N–1663 for ''National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

Submit comments on information collection issues under the Paperwork Reduction Act of 1995 to the Office of Management and Budget (OMB) at *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The title of this proposed collection is ''National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers.''

FOR FURTHER INFORMATION CONTACT: Aaron Weisbuch, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4261, Silver Spring, MD 20993, 301–796–3130. With regard to the information collection: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

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I. Executive Summary

A. Purpose of the Proposed Rule

The Drug Quality and Security Act (DQSA) was enacted on November 27, 2013. Title II of the DQSA, the Drug Supply Chain Security Act (DSCSA), includes provisions designed to strengthen the integrity of the pharmaceutical distribution supply chain. Among other measures, section 204 of the DSCSA amends section 503(e) of the FD&C Act (21 U.S.C. 353(e)), which requires licensure of prescription drug wholesale distributors (wholesale distributors or wholesale drug distributors or WDDs) and adds section 583 to the FD&C Act (21 U.S.C. 360eee–2), which requires FDA to establish by regulation national standards for the licensure of prescription drug wholesale distributors. Section 205 of the DSCSA adds section 584 to the FD&C Act (21 U.S.C. 360eee–3), which requires licensure of third-party logistics providers and requires FDA to establish, by regulation, national standards for the licensure of third-party logistics providers.

This proposed regulation, when finalized, will establish the national standards for the licensure of wholesale drug distributors and 3PLs required under sections 583 and 584 of the FD&C Act, as amended by the DSCSA. As required by statute, the standards, terms and conditions for licensure established by this regulation will apply to both Federal and State licenses (503(e)(1)(B), 583(b), and 584(a)(1)(A) of the FD&C Act).

As discussed in section X (Federalism), section 585(b)(1) of the FD&C Act (21 U.S.C. 360eee–4(b)(1)) preempts States and localities from establishing or continuing requirements for 3PL or WDD licensure that are different from the national standards and requirements applicable under sections 584 and 503(e) of the FD&C Act. However, the statutory provisions themselves do not establish these ''standards and requirements''; instead, this regulation, once effective, will establish them. Accordingly, State and local licensure requirements will be preempted only once this regulation, when finalized, takes effect; until such time, current licensing of WDDs and 3PLs may continue. As discussed below, this determination will help avoid supply chain disruption, based on licensing uncertainties, during the period between DSCSA's enactment and the effective date of this regulation. Avoiding such interim period supply chain issues accords with Congress's overall intent to secure and strengthen the supply chain, as evidenced by other FD&C Act provisions added by DSCSA that recognize State licensure of WDDs and 3PLs prior to this regulation becoming effective.

In addition, pursuant to section 585(c) of the FD&C Act (21 U.S.C. 360eee–4(c)), regulation of areas within the historical police powers of the States would be unaffected by this regulation, including prohibiting employees of WDDs and 3PLs from engaging in criminal activity related to prescription drugs, provided that the State requirements involved are not related to licensure of 3PLs or WDDs.

The requirements for state licensing of wholesale distributors are currently established under 21 CFR part 205, and FDA is now proposing the withdrawal of that regulation and for part 205 to be replaced with this proposed rule. Where a state from which a drug is being distributed has not established a licensing program in accordance with the regulation, the DSCSA establishes FDA as the licensing authority for wholesale distributor and 3PL licenses (sections 503(e)(1)(A)(i)(II) and 584(a)(1)(B) of the FD&C Act). When finalized, the national standards set forth in the proposed rule will provide greater assurance that these supply chain participants are sufficiently vetted and qualified to distribute products, further strengthening the supply chain and the safety of prescription drugs provided to American consumers.

When finalized, this proposed rule will also set forth the standards applicable to, and the requirements for approval of, third-party organizations involved in the licensure and inspection process (''approved organizations'' or ''AOs''). Sections 583(c) and 584(d)(2)(A) of the FD&C Act provide, respectively, that FDA may approve ''third-party accreditation'' or inspection services or programs to conduct inspections of facilities used by wholesale distributors seeking licensure and to review the qualifications of 3PLs for licensure. This proposed rule will also address the standards and requirements for approving such third-party accreditation or inspection services or programs.

Overall, this proposed rule is designed to ensure that the supply chain remains secure and that those prescription drugs subject to the DSCSA that are moving through the supply chain are properly stored, handled, and transported. These measures are intended to help protect American consumers from drugs that may be counterfeit, stolen, contaminated, or otherwise harmful.

For purposes of this proposed rule, FDA has defined ''entity'' or ''entities'' to mean a business organization, such as a corporation, company, association, firm, partnership, society, or joint stock company. Unless otherwise noted, the term ''3PL'' or ''third-party logistics provider'' in this proposed rule includes both the 3PL entity and the individual 3PL facilities requiring a license.

B. Summary of the Major Provisions of the Proposed Rule

FDA is proposing to replace the current part 205 with a new part 205 that will implement the licensure requirements of the DSCSA and govern licensure of 3PLs and wholesale distributors. When finalized, the new part 205 will replace the existing part 205 in its entirety. Subpart A will set forth the national licensing standards for State and Federal licenses issued to 3PLs pursuant to section 584 of the FD&C Act, and subpart C will set forth the national licensing standards for State and Federal licenses issued to wholesale distributors pursuant to sections 503(e) (as amended) and 583 of the FD&C Act. Subparts B and D will set forth the applicable standards and processes for approved organizations to perform licensure reviews and conduct inspections.

1. National Standards for the Licensure of Third-Party Logistics Providers

The DSCSA identifies 3PLs as separate members of the drug supply chain—distinct from wholesale drug distributors—and specifically precludes States from regulating 3PLs as wholesale distributors (585(b)(2) of the FD&C Act). FDA is required by section 584 of the FD&C Act to establish national standards for the licensure of 3PLs, and

the Agency is proposing those standards in subpart A of proposed part 205. When finalized, each facility of an entity meeting the definition of a 3PL in section 581(22) of the FD&C Act (21 U.S.C. 360eee(22)) will be required to be licensed by a State or Federal licensing authority in accordance with the standards articulated in subpart A of proposed part 205.

2. National Standards for the Licensure of Wholesale Drug Distributors

Prior to DSCSA's enactment, wholesale distributors engaging in interstate commerce were required to be licensed by the State in which they were operating pursuant to section 503(e)(2) of the FD&C Act (as then in effect). This section established minimum standards, terms, and conditions for licensing of wholesale distributors pre-DSCSA. As required by sections 503(e)(1)(B) (as amended by the DSCSA) and 583 of the FD&C Act, FDA is proposing to establish national standards, terms, and conditions through this rulemaking for the licensure of wholesale distributors that, when final, will apply to all State licensing programs as well as to the new Federal licensing program to be operated by FDA. These new standards would replace the previous standards set forth in current part 205.

3. Approval of Third Parties To Conduct Licensure Reviews and Inspections

In accordance with section 584(d)(2)(A) of the FD&C Act, FDA is proposing to establish a process by which third-party organizations will be approved by FDA to review a 3PL's qualifications for licensure. In addition, in accordance with section 583(c) of the FD&C Act, FDA is proposing to establish a process by which third-party organizations will be approved by FDA to conduct inspections of wholesale distributors for the purpose of licensure.

4. Conforming Changes

The regulation also proposes to amend 21 CFR 10.50(c) and 12.21(a)(2), which list statutory authorities that provide the opportunity for a formal evidentiary public hearing under 21 CFR part 12. Because the regulation proposes that wholesale distributors and 3PLs could request a formal evidentiary public hearing under part 12 for review of decisions affecting the denial, suspension, or revocation of 3PL or wholesale distributor licenses issued by the Secretary of Health and Human Services (Secretary), sections 503(e), 583, and 584 of the FD&C Act would be added to the list of statutory sections under which there is the opportunity for a hearing under §§ 10.50(c) and 12.21(a)(2), regarding such decisions. We are also proposing a conforming change to 21 CFR 16.1(b) to describe procedures for regulatory hearings that would add actions related to approved organizations under proposed §§ 205.19 and 205.33 respectively, including revocation or suspension of approval, to the list of actions for which a regulatory hearing under 21 CFR part 16 may be held.

C. Legal Authority

We are issuing this proposed rule under sections 301, 501, 502, 503(e), 582, 583, 584, 585, 701(a), and 704 of the FD&C Act (21 U.S.C. 331, 351, 352, 353(e), 360eee–1, 360eee–2, 360eee–3, 360eee–4, 371(a), and 374).

D. Costs and Benefits

In this rulemaking, we propose new national standards for the licensing of prescription drug wholesale distributors and third-party logistics providers as directed under the Drug Supply Chain Security Act, Title II of the Drug Quality and Security Act. If finalized, the rule would also establish a Federal licensing system for wholesale drug distributors and third-party logistics providers to use in the absence of a state licensure program that is consistent with the proposed national standards.

The standards for prescription drug wholesale distribution in the proposed rule would result in benefits to consumers and benefits to distributors from reducing the diversion of prescription drugs. Other monetized benefits include cost savings from reducing the frequency and quantity of licensure applications and cost savings from reducing state licensing standards in some states. We estimate that the annualized benefits over 10 years would range from $1.25 million to $31.50 million at a 7 percent discount rate, with a primary estimate of $10.66 million. We estimate that the annualized benefits would range from $1.26 million to $32.18 million at a 3 percent discount rate, with a primary estimate of $10.89 million.

We also expect that the proposed rule, if finalized, would impose costs on wholesale drug distributors, third-party logistics providers, states, approved organizations, and the Food and Drug Administration (FDA). Costs to wholesale drug distributors and third-party logistics providers include costs of learning about the rule, reporting to FDA, undergoing routine inspections, writing and revising standard operating procedures, and conducting background checks. Wholesale-drug distributors would also incur costs to furnish surety bonds to their state licensing authority to obtain or renew their licenses.

Costs to states include the time spent reading and understanding the rule, passing or revising the laws and regulations governing their licensure programs, and inspecting WDD and 3PL facilities. Approved organizations would incur legal, application, and training costs, as well as costs to inspect WDD and 3PL facilities. FDA costs include the costs to establish and operate a reporting database and a licensure program for wholesale drug distributors and third-party logistics providers and the costs to establish and operate an approval program for approved organizations.

We estimate that the annualized costs over 10 years would range from $13.21 million to $20.63 million at a 7 percent discount rate, with a primary estimate of $16.92 million. We estimate that the annualized costs over 10 years at a 3 percent discount rate would range from $12.83 million to $20.10 million, with a primary estimate of $16.47 million.

II. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation/ acronym	What it means
3PL	Third-Party Logistics Provider.
AO	Approved Organization.
CFR	Code of Federal Regulations.
DSCSA	Drug Supply Chain Security Act.
DQSA	Drug Quality and Security Act.
FDA or the Agency.	U.S. Food and Drug Administration.
FD&C Act	Federal Food, Drug, and Cosmetic Act.

III. Background

A. Introduction

The DSCSA (Title II of Pub. L. 113–54) was signed into law on November 27, 2013, to better protect the U.S. drug supply chain. FDA's implementation of the DSCSA includes many activities, including this proposed rule. Once final, this rule will establish national standards for licensure of wholesale distributors and 3PLs, as required by the DSCSA. For information on additional FDA activities related to the DSCSA, a web page describing FDA's implementation activities can be found at: *https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/default.htm.*

B. Need for the Regulation: The DSCSA and Establishment of National Standards for Licensure

The U.S. drug supply chain remains one of the safest in the world. However, the increasingly globalized nature of the supply chain brings with it complexities

that increase threats to the safety and security of the U.S. drug supply. A breach at any point in the supply chain carries potential for dangerous, and even deadly, outcomes for American consumers.

In passing the DSCSA, Congress recognized the need for national standards for the storage, handling, and transport of prescription drugs and directed FDA, in sections 583(a) and 584(d) of the FD&C Act, to establish such standards by regulation for WDDs and 3PLs, respectively. These national standards will help diminish opportunities for dangerous and criminal conduct affecting the supply of prescription drugs in the United States. When final, every U.S. wholesale distributor and 3PL facility will be held to these standards through the statute's licensure requirements. Where a State does not have a licensing program in accordance with the regulation, FDA will be the licensing authority.

This proposed rule, when finalized, will provide much needed certainty and clarity for wholesale distributors and 3PLs seeking licensure. In passing the DSCSA, Congress believed the existing system of different regulation regarding supply chain security by each state created a patchwork system of governance and that a uniform national standard would address this concern. See statements of Senator Mikulski (Ref 1), Congressmen Mathis (Ref 2) and Congressman Latta (Ref 3).

Requirements for wholesale distributors currently vary significantly across State lines, and many wholesale distributors and 3PLs have facilities in multiple States. Specifically, State requirements and standards for licensure can vary on topics such as the length of time for which records must be maintained; qualifications of facility managers and designated representatives; facility requirements; licensure duration; renewal procedures; exemptions from the definition of wholesale distribution; and inspection and approval requirements by certain, specific organizations in order to receive licensure in certain States. This proposed rule, when finalized will be an important first step in harmonizing these requirements, thus allowing for greater compliance and management of licensure.

Additionally, we note that commenters on FDA's draft guidance entitled ''The Effect of Section 585 of the FD&C Act on Drug Product Tracing and Wholesale Drug Distributor and Third-Party Logistics Provider Licensing Standards and Requirements: Questions and Answers'' (Ref 4) agreed that creation of a uniform national standard for licensure, through the issuance of these regulations, should be the goal of FDA (see, *e.g.,* Ref 5). Commenters noted that the patchwork of licensing standards was precisely the regulatory burden that the DSCSA was intended to eliminate. (see, *e.g.,* Ref 6) Comments added that tracking and complying with different standards in different States on a continuing basis would be very time consuming and add unnecessary costs to the distribution chain (see, *e.g.,* Ref 7).

We believe that the issuance of these regulations, when finalized, will provide far greater clarity to both States and regulated industry as to the requirements and expectations FDA has with respect to licensure. The publication of these regulations, when finalized, and the approach to preemption discussed in this document will reflect the national standard Congress intended, but will detail FDA's expectations with respect to licensure. This will allow for greater certainty in the logistics and distribution industry, and in the supply chain as a whole.

Since the passage of DSCSA, States have implemented disparate policies with respect to licensure of 3PLs. Some States repealed or eliminated 3PL as a licensure category, others are waiting for FDA to publish its regulations before determining how to proceed, some are licensing 3PLs under some other form of licensure, and some do not regulate 3PLs at all (Ref 8). These regulations, when finalized, will provide certainty and clarity in the logistics industry.

The Agency believes finalizing these proposed regulations is crucial to implementation of licensure of 3PLs as intended by DSCSA. Under section 582(a)(7) of the FD&C Act (21 U.S.C. 360eee–1(a)(7)), 3PLs are deemed licensed until the effective date of these regulations unless the Secretary has made a finding that the 3PL does not utilize good handling and distribution practices and publishes notice thereof. Until these regulations are issued, and the framework for licensure established, the Agency cannot institute the provisions and the goals of DSCSA—to further secure the supply chain by including 3PLs as an authorized member of the supply chain through the licensure provisions, which will ensure that they are appropriately credentialed, inspected, and therefore duly qualified to participate in the supply chain.

Theft and diversion of prescription drugs continue to be major issues, contributing to drug shortages and creating significant financial losses, the effects of which cascade throughout the supply chain to consumers. FDA has observed that these instances often involve products distributed by unlicensed wholesale distributors. FDA standards, oversight, and regulations, including to implement the requirements of DSCSA, will lessen and hopefully eliminate product diversion in the legitimate supply chain. According to the National Association of Boards of Pharmacy (NABP)'s 2013 report entitled ''Wholesale Drug Distribution: Protecting the Integrity of the Nation's Prescription Drug Supply,'' drug diverters and bad actors seek out gaps in the distribution and regulatory structure, specifically seeking out States whose licensure framework is less stringent (Ref. 9). This proposed rule, when finalized, and the preemption of inconsistent State provisions will remedy this forum shopping for drug diverters who seek to take advantage of the lack of uniform framework.

Additionally, NABP's 2013 report also contends that the so-called ''five percent rule'' is a policy that has been ripe for exploitation due to the policy being inconsistently legislated, interpreted, and enforced from State to State. This was a policy under which FDA had previously concluded that sales of prescription drugs by a retail pharmacy to licensed practitioners for office use would be considered to be minimal and not constitute wholesale distribution, if the total dollar volume of these sales does not exceed 5 percent of the total dollar volume of that retail pharmacy's annual prescription sales (see further discussion in ''Definitions'' section below). However, this interpretation was not codified. The NABP observed that ''pharmacies acting as wholesalers have been found to take advantage of the parameters set by some States [regarding minimal quantities] when it comes to drug distribution. Rather than dispensing the drugs as mandated, these pharmacies retain them to resell to wholesalers at an amount exceeding the specified quantity of prescription medications as permitted in certain States (often times 5% of annual sales). Some have gone as far as to sell their entire inventory into the gray market'' This proposed rule, when finalized, codifies the principle that the five percent rule only applies to pharmacy sales for office use. Sales above five percent for office use, or any sales to a wholesale distributor, require the pharmacy to become licensed and regulated as a wholesale distributor. This proposed rule will clarify this requirement and close a potential loophole that could lead to diversion of products and excessive sales from dispensers who are not licensed and registered as wholesale distributors

when they are engaging in wholesale distribution.

Unlicensed wholesale distribution has been a major source of diverted products both leaving and reentering the supply chain. Significant amounts of drug diversion involve wholesale distributors, either diverting the product themselves from the supply chain, or purchasing product that was diverted by another actor. The DSCSA, which requires uniform national standards for licensure of wholesale distributors, will cut down on these types of instances of diversion since supply chain trading partners are required to transact with only other trading partners who meet the strict requirements laid out in these regulations. There are many examples of diversion and criminal action by wholesale distributors under the current regulatory scheme, which these regulations, when finalized, will discourage, or possibly even prevent, in the future.

As an example, from 2007–2014, individuals involved with the Minnesota Independent Cooperative bought prescription drugs from a network of illegal and unlicensed sources and sold approximately $393 million worth of diverted prescription drugs to wholesalers and retail pharmacies throughout the United States. These individuals falsified transactional documents, as well as licensure documents, to enter into fraudulent transactions with dispensers and other wholesalers. In a 2008 example detailed in the indictment, the unlicensed individuals involved allegedly bought a truckload of stolen asthma inhalers for $662,000 and sold them through the Minnesota Independent Collective to another wholesaler for about $1 million (Ref 10). These regulations, when finalized, and the DSCSA requirements that trading partners only transact with authorized, licensed trading partners, and verify suspect and illegitimate product, will make these schemes far more difficult to achieve. Had DSCSA been the prevailing regulatory scheme at the time, other wholesale distributors and dispensers would have been deterred from doing business with the Minnesota Independent Collective because they were not an authorized trading partner.

In 2014, two individuals pleaded guilty to their involvement in a drug diversion and distribution scheme through an entity called Cumberland Distribution. Both defendants admitted that Cumberland Distribution purchased prescription drugs from individuals and entities that were not licensed to engage in the wholesale distribution of prescription drugs and were not authorized to distribute prescription drugs. Cumberland Distribution then distributed these products to dispensers. The prescription drugs were acquired through various networks of ''diverters'' who obtained prescription drugs from other unlawful sources. As a result, Cumberland Distribution could not lawfully resell the drugs. Pharmacies throughout the United States purchased these diverted prescription drugs from Cumberland Distribution under the guise that the products had been in the custody of licensed wholesale distributors or other authorized distributors since being sold by the original manufacturer (Ref 11). Under DSCSA, the licensure status of these purported wholesale distributors is easily searchable and verifiable, thus making diversion schemes, such as this, far more difficult to achieve. In addition to requiring FDA to establish national licensure standards, the DSCSA outlines critical steps for building an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States (section 582(g) of the FD&C Act). This system will enhance FDA's ability to protect American consumers from exposure to drugs that may be unfit for distribution and will increase efficiency in the detection and removal of potentially dangerous drugs from the U.S. drug supply chain.

The FD&C Act, as amended by DSCSA, requires FDA to establish national standards for the licensure of two critical members of the supply chain: wholesale drug distributors and 3PLs. It also requires that only those wholesale distributors and 3PL facilities licensed according to these national standards may engage in wholesale distribution or 3PL activities, respectively. Only licensed wholesale drug distributors and 3PLs whose facilities are so licensed will be considered ''authorized trading partners'' permitted under the FD&C Act, as amended by DSCSA, to engage in transactions related to the sale and distribution of certain prescription drugs with other members of the supply chain.

To create the standards proposed in the regulations, FDA conducted a comprehensive review of existing State standards for licensure including storing, handling, and holding prescription drugs, as well as other nationally recognized standards and model rules for wholesale distribution and logistics, such as those created by the NABP (Ref 12), Healthcare Distribution Alliance (Ref 13), World Health Organization (Ref 14), and the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S) (Ref 15). The Agency believes that the proposed standards align with existing practices and will help ensure that 3PL and wholesale distribution activities are undertaken in a manner that minimizes diversion and threats to the regulated supply chain.

C. Changes From the Prescription Drug Marketing Act (PDMA)

Prior to the DSCSA's enactment, the last comprehensive legislative action related to prescription drug distribution was the Prescription Drug Marketing Act of 1987 (PDMA) (Pub. L. 100–293). Among other things, the PDMA required wholesale distributors to obtain licenses from States in which they were operating (sec. 6 of the PDMA; also see FDA's 2001 Report to Congress on the PDMA (Ref 16)). Under the PDMA, FDA promulgated regulations that established minimum standards, terms, and conditions for licensure of wholesale distributors. The PDMA provided neither a specific definition of 3PL-type entities nor specific oversight over them; without a distinct regulatory framework for 3PLs, some States chose to regulate and license 3PLs as wholesale distributors, with some others choosing to license 3PLs as separate entities. The DSCSA requires that all wholesale distributor and 3PL licenses meet the standards established by FDA (sections 503(e)(1)(B) and 584(a) of the FD&C Act), and that 3PLs not be licensed as wholesale distributors (section 585(b)(2) of the FD&C Act).

If an entity owns a facility in which it is engaging in 3PL activities and wholesale distribution out of the same facility, the entity will be required to hold a 3PL license and a separate wholesale distributor license for the distinct functions they perform.

IV. Legal Authority

The Agency is proposing this rule under the authority to propose national standards for the licensing of wholesale distributors and 3PLs granted to it by various sections of the FD&C Act, including sections 301, 503(e), 582, 583, 584, 585, 701(a), and 704 (21 U.S.C. 331, 351, 352, 353(e), 360eee–1, 360eee–2, 360eee–3, 360eee–4, 371(a), and 374).

Section 503(e) requires wholesale distributors to be licensed according to the standards, terms, and conditions established by the Secretary, and section 583 requires FDA to establish by regulation national standards for the licensure of prescription drug wholesale distributors. Section 584 requires 3PLs to be licensed according to standards established in regulations promulgated

by FDA for the licensure of 3PLs. Section 301(t) prohibits the failure to comply with the requirements under sections 584 and 503(e). Section 301 also prohibits a number of actions concerning adulterated and misbranded drugs. Section 585 provides that states cannot implement licensing standards, requirements, or regulations that are inconsistent with, less stringent than, directly related to, or covered by the standards applicable under sections 503(e) and 584. Section 585 also precludes states from regulating 3PLs as wholesale distributors. To enforce these and other provisions of the FD&C Act, section 704 authorizes FDA to conduct inspections. Section 701(a) of the FD&C Act provides general authority to issue regulations for the efficient enforcement of the FD&C Act. By establishing national standards for the licensing of wholesale distributors and 3PLs, this rule, when finalized, is expected to aid in the efficient administration and enforcement of the FD&C Act, and in particular would help efficiently enforce the provisions relating to licensure of wholesale drug distributors and 3PLs.

V. Description of the Proposed Rule

The national standards for the licensure of 3PLs, required by section 584 of the FD&C Act, as amended by DSCSA, are set forth in subpart A of proposed part 205. The national standards for the licensure of wholesale distributors, required by sections 503(e) and 583 of the FD&C Act, as amended by DSCSA, are set forth in subpart C of proposed part 205. The process and standards for third-party accreditation programs to become approved by the Federal Government to evaluate the qualifications of 3PLs for licensure, as required by section 584(d) of the FD&C Act, are established in subpart B of proposed part 205. The process and standards for third-party accreditation and inspection services to become approved by the Federal Government to conduct inspections of wholesale distributors, as permitted by section 583(c) of the FD&C Act, are set forth in subpart D of proposed part 205.

A. Scope/Applicability (Proposed §§ 205.1 and 205.2)

In accordance with section 584 of the FD&C Act, FDA is proposing to establish the national standards for licensing by State and Federal licensing authorities set forth in subpart A of part 205 that would apply to 3PL facilities in any State (see proposed § 205.1). Furthermore, in accordance with section 503(e)(1) of the FD&C Act, FDA is proposing to establish the national standards for wholesale distributors set forth in subpart C of part 205 that would apply to wholesale distributors of prescription drugs in any State (see proposed § 205.1). The standards, terms, and conditions for licensure established under part 205, subparts A and C, once finalized, would apply to all State and Federal 3PL and wholesale distributor licenses.

All 3PL facilities are required to obtain a 3PL license for each facility of such 3PL. The FD&C Act, as amended by DSCSA, prohibits States from regulating 3PLs as wholesale distributors. A 3PL that also engages in wholesale distribution in the same facility in which it engages in 3PL activities must obtain a separate wholesale distribution license (see proposed § 205.1).

An entity is considered a wholesale distributor if the entity is engaged in the distribution of a drug subject to section 503(b) (relating to prescription drugs) of the FD&C Act (21 U.S.C. 353(b)), to a person other than a consumer or patient, with a few exclusions. Under section 201(g) of the FD&C Act (21 U.S.C. 321(g)), a drug includes a bulk drug substance, and under current FDA regulations, the term *bulk drug substance* means any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug. The term does not include intermediates used in the synthesis of such substances (21 CFR 203.3(e)). FDA believes that the distribution of bulk drug substances must have the same safeguards and provisions as the distribution of finished drug products. The same safeguards that prevent diversion and theft and secure the pharmaceutical distribution supply chain generally must include the transfer of bulk drug substances, as they are subject to the same concerns as the distribution of prescription drugs in finished dosage form.

FDA is proposing to establish the process and standards that would apply to any third-party accreditation or inspection services seeking to obtain or maintain approval by FDA to evaluate qualifications of 3PLs for licensure or to conduct inspections of wholesale distributors (see proposed § 205.1). Once finalized, proposed subparts B and D of part 205 would establish the process and standards for third-party accreditation and inspection services to become approved by the Secretary to review the qualifications of 3PLs for licensure, as required by section 584(d) of the FD&C Act, and to conduct inspections of wholesale distributors, as permitted by section 583(c) of the FD&C Act (see proposed § 205.2) (*i.e.,* to become ''approved organizations'').

B. Definitions (Proposed § 205.3)

By its terms, the definitions of terms in section 581 of the FD&C Act (21 U.S.C. 360eee) applies in subchapter H. However, because those terms are also used throughout section 503(e) of the FD&C Act (as amended by the DSCSA), FDA considers the definitions and interpretations contained in section 581 of the FD&C Act to apply to those terms when used in proposed part 205. Specifically, the definitions of the following terms contained in section 581 of the FD&C Act apply when used in proposed part 205: Affiliate, authorized, dispenser, illegitimate product, licensed, manufacturer, product, repackager, return, specific patient need, suspect product, third-party logistics provider, and wholesale distributor. In addition, FDA is proposing the definition of the following additional terms to help clarify the requirements. FDA believes that these proposed definitions align with existing law and regulations, as well as current industry practices.

- *3PL Activities:* Includes warehousing and ''other logistics services'' that are undertaken with respect to a product (as defined in proposed § 205.3(k)).
- *Change of Entity Ownership:* Recognizing that businesses often undergo changes in corporate structure through mergers, acquisitions, and other transactions, FDA proposes that ''change of entity ownership'' be defined to help ensure consistency with regard to how such changes will affect licensure. The definition describes the events that would constitute a change in ownership with respect to a partnership, unincorporated sole proprietorship, corporation, or limited liability company.
- *Co-Licensed Partner:* One of two or more entities that have entered into an agreement for the right to engage in the marketing of a prescription drug. The Agency believes this definition is in alignment with industry practice and existing laws.
- *Designated Representative:* An individual who is designated as the representative of the facility manager and, as such, is identified by the licensee as responsible for managing the daily operation of the establishment in compliance with licensure requirements and has the authority to implement corrective action when necessary. This individual is also responsible for ensuring that personnel are appropriately qualified, assigned, and

trained to accomplish their duties. The Agency believes this definition reflects current practices and understanding.

• *Entity or Entities:* A business organization, such as a corporation, company, association, firm, partnership, society, sole proprietorship, or joint stock company.

• *Facility:* A site at one general, permanent, physical location used to store or handle prescription drugs. For purposes of proposed part 205, a facility does not include a site, such as a corporate office or headquarters, where the sole activity conducted at the site is one of oversight, support, or business administrative function.

• *Key Personnel:* Any individual who has responsibility for managing the operations of the wholesale distributor, including any principal, owner, director, officer of the wholesale distributor, designated representatives, and other individuals who are authorized to enter areas where prescription drugs are held and are likely to handle those prescription drugs as a part their responsibilities within the operation.

○ Section 583(b)(5) of the FD&C Act, as amended by DSCSA, requires that FDA establish standards for the ''establishment and implementation of qualifications for key personnel'' of wholesale distributors. These key personnel must be sufficiently qualified and screened to carry out the important responsibilities that come with positions within a wholesale distribution company. FDA believes individuals who hold these positions must be held to a high standard of qualification as they are entrusted with important aspects of protecting the pharmaceutical distribution supply chain.

• *Minimal Quantities:* An annual dollar volume of prescription drugs sold by a retail pharmacy to licensed practitioners for office use that does not exceed 5 percent of the total dollar volume of that retail pharmacy's annual prescription sales.

○ Section 503(e)(4) of the FD&C Act excludes a number of activities from the definition of wholesale distribution. One excluded category, listed at section 503(e)(4)(E) of the FD&C Act, is ''the distribution of minimal quantities of a drug by a licensed retail pharmacy to a licensed practitioner for office use.'' FDA has previously considered what constitutes minimal quantities in determining when the practices of a retail pharmacy become wholesale drug distribution and thereby subject to licensure (see 64 FR 67720, December 3, 1999). For example, in preamble discussions around codifying provisions related to wholesale distribution, FDA proposed a minimal quantities limit, considered comments, and ultimately concluded that sales of prescription drugs by a retail pharmacy to licensed practitioners for office use would be considered to be minimal and not wholesale distribution, if the total dollar volume of these sales does not exceed 5 percent of the total dollar volume of that retail pharmacy's annual prescription sales.

○ The Agency continues to maintain its position that a 5-percent limit to what constitutes minimal quantities is sufficient ''to meet the needs of licensed practitioners who may not purchase enough prescription drugs to go through a wholesale distributor and thus may not otherwise be able to easily obtain drugs for office use'' (64 FR 67720 at 67748). We believe this standard is still relevant and is the industry standard. We note that in January 2013, the NABP passed a resolution that supports limiting the five percent rule to allow for transfer ''between pharmacies, or from pharmacy to or from pharmacies to practitioners, only for the purpose of dispensing or administration, but not for resale; and to prohibit the transfer, distribution, or sale of prescription drugs from pharmacies to wholesalers for resale'' (Ref 17). The transfer or sale from dispenser to dispenser for a specific patient need is already considered to not be wholesale distribution under the FD&C Act (see section 503(e)(4)). This NABP resolution accords with FDA's proposed definition of *minimal quantities.* We request comment on the codification of this 5 percent limit for office use and of the definition of *minimal quantities.*

○ Accordingly, a licensed retail pharmacy that distributes more than 5 percent of its annual sales to licensed practitioners is engaging in wholesale distribution, subject to all the requirements for wholesale distributors, unless its activities are otherwise excluded from the definition of wholesale distribution. The exemption for distributing minimal quantities of drugs by retail pharmacies to licensed practitioners for office use was ''not created to confer a special benefit on retail pharmacies, but to meet the legitimate need of licensed practitioners'' (64 FR 67720 at 67748). For purposes of section 503(e)(4)(E) of the FD&C Act, FDA is proposing to codify its position on ''minimal quantities'' in the proposed § 205.3(h) to mean the ''total annual dollar amount sold to licensed practitioners for office use does not exceed 5 percent of the total dollar volume of that retail pharmacy's annual prescription drug sales.''

○ The Agency also notes that this exclusion only applies to sales of prescription drugs from licensed pharmacies to licensed practitioners for office use. FDA understands that some States and other entities have expanded the applicability of this exclusion from the definition of wholesale distribution to allow for distribution from pharmacies to other entities outside of licensed practitioners for office use, but FDA notes that this practice is not allowed under current Federal law. The statutory language at section 503(e)(4)(E) of the FD&C Act specifically limits the exclusion to the distribution of minimal quantities of a drug between a licensed retail pharmacy and a licensed practitioner for office use. Unless a specific sale or transfer of a drug from one dispenser to another dispenser is outside of the definition of wholesale distribution because it is to a consumer or patient (*e.g.,* to fulfill a ''specific patient need,'' as defined at section 581(19) of the FD&C Act), a pharmacy that sells or trades prescription drugs to other pharmacies or other entities falls within the definition of wholesale distribution. Such activity is considered wholesale distribution under section 503(e)(4) of the FD&C Act, subject to all the requirements of wholesale distributors.

• *Other Logistics Services:* Services provided by entities that accept or transfer direct possession of products from that entity's facility within the United States and its territories on behalf of a trading partner (*e.g.,* manufacturer, wholesale distributor, dispenser), but that do not take ownership of the product or have the responsibility to direct a product's sale or disposition. It also includes services undertaken with respect to a product for a repackager that is acting on behalf of a manufacturer, wholesale distributor, or dispenser.

○ Under the DSCSA, the definition of 3PL includes entities that conduct ''other logistics services'' on behalf of a manufacturer, wholesale distributor, or dispenser of a product. The Agency recognizes that 3PLs may perform 3PL activities for repackagers and proposes to include in the definition of ''other logistics services'' those services undertaken with respect to a product for a repackager acting on behalf of a manufacturer, wholesale distributor, or dispenser.

○ Under this proposed definition, a common carrier that only transports a product, but does not take ownership of the product, is not conducting ''other logistic services.'' Similarly, an entity

that directs the sale or disposition of the product but does not take possession (such as a broker) would not be conducting ''other logistics services'' and does not meet the definition of a 3PL, but may be engaged in activities that meet the definition of a manufacturer or wholesale distributor.

• *Other Than a Consumer or Patient:* A person receiving the drug who is not (i) the individual identified as the recipient of the prescription drug, (ii) a dispenser fulfilling a specific patient need, or (iii) the clinical investigator, as defined in 21 CFR 312.3(b) (or any successor regulation).

○ FDA considers certain types of prescription drug distribution as outside the scope of ''wholesale distribution'' under section 503(e)(4) of the FD&C Act because they constitute ''the distribution of a drug'' to a ''consumer or patient,'' which is excluded from the definition of wholesale distribution. The first of these is the distribution to, or receipt by, the patient, who, for purposes of DSCSA, FDA considers to be the individual intended to take or be administered the prescription drug. This would typically be the individual whose name appears on the prescription.

○ FDA also considers the transfer or sale of a drug from one dispenser to another to fulfill a ''specific patient need'' to be outside the scope of wholesale distribution. Specific patient need is defined at section 581(19) of the FD&C Act as ''the transfer of a product from one pharmacy to another to fill a prescription for an identified patient.'' FDA would note, however, that a dispenser who transfers or sells a drug to a trading partner other than another dispenser, or to another dispenser where there is no specific patient need evidenced by a prescription, is distributing a drug to someone other than a consumer or patient, which, if not otherwise excluded under section 503(e)(4) of the FD&C Act, would be engaging in wholesale drug distribution requiring a wholesale distributor license.

○ Finally, FDA considers the sale or transfer of a drug for investigational or research purposes to an investigator, as defined in 21 CFR 312.3 (or any successor regulation), under an investigational new drug application (IND) submitted to FDA to be outside the scope of wholesale distribution because the drug is used for in vitro, clinical, or other research purposes under an IND.

○ For these reasons, FDA is proposing to exclude these types of transactions from the scope of wholesale distribution.

• *Product:* A prescription drug in a finished dosage form that is ready for administration to a patient without substantial further manufacturing (*e.g.,* capsules, tablets, lyophilized products before reconstitution).

○ The definition of ''product'' proposed here is broader and more inclusive than that used for purposes of product tracing detailed in section 582 of the FD&C Act as defined in section 581(13). As used in section 584 of the FD&C Act for purposes of licensure of a 3PL, the term ''product'' excludes active pharmaceutical ingredients intended for incorporation into a finished drug product but have yet to undergo substantial further manufacturing to become the finished dosage form for administration. Of note, for purposes of section 582 of the FD&C Act (21 U.S.C. 360eee–1), the definition for ''product'' excludes certain types of prescription drugs in finished dosage form (section 581(13) of the FD&C Act).

• *Significant Disciplinary Action:* Any action by a State or Federal licensing authority that would limit or prevent a 3PL from conducting 3PL activities, or would limit or prevent a wholesale distributor from distributing or facilitating the distribution of prescription drugs. This includes suspension or revocation of a 3PL or wholesale distributor license, State controlled substances license, or Drug Enforcement Administration (DEA) registration, and potentially includes other disciplinary actions such as a consent decree or final ruling of a State licensure board, depending on the impact on the 3PL's or wholesale distributor's legal ability to perform licensed activities.

• *Unfit for Distribution:* A prescription drug that has been identified as a drug whose sale would violate the FD&C Act. This definition includes prescription drugs identified as suspect or illegitimate (582(c)(4) of the FD&C Act); adulterated, including drugs rendered nonsaleable because conditions (such as return, recall, damage, or expiry) cast doubt on the drug's safety, identity, strength, quality, or purity (section 501 of the FD&C Act); or misbranded (section 502 of the FD&C Act (21 U.S.C. 352)).

○ FDA believes that prescription drugs unfit for distribution must be segregated from those that are fit for distribution to protect patients from receiving potentially defective or harmful prescription drugs and prevent the distribution of drugs that are unfit for distribution.

○ A wholesale distributor or 3PL could potentially identify a prescription drug as unfit for distribution through their own examination of incoming and outgoing shipments of prescription drugs as outlined by proposed 21 CFR 205.12(c)(1) for 3PLs and 205.26(c)(4) for wholesale distributors, through inventory review under proposed 21 CFR 205.12(c)(4)(i) for 3PLs and 205.26(c)(5)(i)(B) for wholesale distributors, through other internal means designed to detect product that is unfit for distribution, or be notified of a prescription drug's status as unfit for distribution by a trading partner or others.

• *Wholesale distribution:*

○ Section 503(e)(4) of the FD&C Act defines wholesale distribution as ''the distribution of a drug subject to [section 503(b) of the FD&C Act] to a person other than a consumer or patient, or receipt of a drug subject to [section 503(b) of the FD&C Act] by a person other than the consumer or patient.'' The definition then goes on to list 19 activities that are not considered wholesale distribution. Of these, FDA is providing clarification about several that may be causing some confusion for industry and the States.

○ Section 503(e)(4)(C) of the FD&C Act states that the distribution of a drug or an offer to distribute a drug for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the Public Health Service Act, does not constitute wholesale distribution. In addition to distribution of a drug during a declared public health emergency pursuant to section 319 of the Public Health Service Act, FDA considers the following circumstances to constitute emergency medical reasons and therefore be excluded from the definition of wholesale distribution: (1) The distribution of a drug to a first responder or other authorized individual administering prescription drugs to acutely ill or injured persons in an emergency situation and outside a healthcare facility, and (2) a long-term care facility receiving an emergency kit containing drugs for use in emergency situations to treat acutely ill or injured persons during hours of the day when necessary drugs cannot be obtained from a dispenser. Pursuant to 503(e)(4)(C) of the FD&C Act, this exclusion from the definition of wholesale distribution does not include distributing a drug during a shortage unless such shortage was caused by a public health emergency.

○ The exclusion at section 503(e)(4)(E) of the FD&C Act for the distribution of minimal quantities of prescription drugs by a licensed retail pharmacy to a licensed practitioner for

office use is discussed in the description of the term ''minimal quantities.''

○ Section 503(e)(4)(H) of the FD&C Act excludes ''the distribution of a drug by the manufacturer of such drug'' from wholesale distribution. Therefore, FDA considers the activities of a manufacturer, as defined at section 581(10) of the FD&C Act, when distributing its own drug, as excluded from the definition of wholesale distribution and not subject to the requirements that apply to wholesale distributors. FDA believes this is supported by the term ''wholesale distributor,'' which is defined at section 581(29) of the FD&C Act, in relevant part, as ''a person (other than a manufacturer, a manufacturer's co-licensed partner . . .) engaged in wholesale distribution.'' The Agency notes, however, that if Manufacturer A purchases and distributes Manufacturer B's drug, for which Manufacturer A has no affiliation and is not a co-licensed partner, Manufacturer A is engaged in wholesale distribution, subject to all the requirements for wholesale distributors.

C. National Standards for Third-Party Logistics Providers

1. 3PL Licensure

3PL facilities are required to be licensed in order to conduct activities in any State (section 584 of the FD&C Act). As such, the proposed regulation provides that a 3PL facility may not conduct 3PL activities unless it is licensed by the State from which it conducts 3PL activities, or by FDA if the State from which 3PL activities are conducted has not established a licensure program in accordance with the regulations, as set forth in section 584(a) of the FD&C Act (see proposed § 205.4(a)). In addition, the requirement in 584(a) of the FD&C Act that each facility of the 3PL must be licensed, such that a 3PL with multiple facilities in a single State will have multiple licenses from that State, is set forth in proposed § 205.4(b).

Under FDA's proposed regulation, if a 3PL owns or leases a facility serving as a warehouse for products, the State in which the facility is located will be considered the State from which the 3PL ''conducts activities'' and will be the State from which the 3PL must obtain a license for that facility under proposed § 205.4(a)(1). FDA understands there has been some confusion about whether an entity hired or contracted by another trading partner to provide labor, logistic, or administrative services for that trading partner in that trading partner's facility would be considered a 3PL. This could occur, for example, where a wholesale distributor hires a contractor to provide such support services from within the wholesale distributor's facility exclusively for that wholesale distributor. In this scenario, the contractor's activities from within the wholesale distributor's licensed facility would be captured by the wholesale distributor's license and obligations for compliance, and the facility would not be considered a 3PL or required to have a 3PL license. However, an entity that operates a facility in which it engages in wholesale distribution and performs 3PL activities on behalf of other trading partners for products it does not own or direct the sale or disposition of is required to obtain both a wholesale distributor and 3PL license for that facility.

Additionally, pursuant to section 584(a)(2) of the FD&C Act, if a product is distributed in interstate commerce, the 3PL must be licensed by the State into which the product is distributed if that State requires such license; however, section 584(a)(2) of the FD&C Act also provides that if the 3PL is licensed by FDA, as described in section 584(a)(1)(B), the 3PL is not required to obtain a license from the State into which the product is distributed (see proposed § 205.4(a)(3)). Finally, to ensure that a facility and those responsible for its operations meet the licensing standards, FDA proposes to require that 3PL licenses be facility- and owner-specific and not transferable to another establishment or owner (see proposed § 205.4(c)). 3PL licenses must be held at the licensed facility and must be made available to State, Federal, or other licensing authorities upon request (see proposed § 205.4(d)).

Section 584 states that the national licensing standards for 3PLs established by regulation take effect 1 year after the date such final regulation is published (section 584(d)(1) and (3) of the FD&C Act). National licensing standards for wholesale distributors established by regulation take effect 2 years after the date such final regulation is published (section 583(a) and (e)(3) of the FD&C Act). For several reasons, including those discussed below, FDA does not intend to enforce the licensing requirements for 3PLs until 2 years after the final regulation is published.

FDA recognizes that 1 year may be insufficient time for States to implement 3PL licensure programs, should they decide to implement such a program, and for 3PLs to apply for licensure under these programs. Setting up a state licensure program may require additional time. This is especially true in States that will require State legislative action to implement a licensure program, with some State legislatures only meeting biennially.

Considering these factors, FDA does not intend to enforce these requirements with respect to the national standards for licensure until 2 years after the regulation is finalized. This will help ensure there is time for States to establish or modify their licensure programs in accordance with the new standards and time for 3PLs to apply and obtain a new license.

For 1 year after the effective date of the final regulation, FDA also does not intend to enforce the requirements of section 582(b)(3), (c)(3), (d)(3), and (e)(3) of the FD&C Act with respect to a manufacturer, wholesale distributor, dispenser, or repackager who has as a trading partner a 3PL that is not licensed, unless the 3PL is not licensed because the Secretary or a state licensing body has made a finding that the 3PL does not utilize good handling and distribution practices and has published notice thereof.

2. General Application Requirements for Licensure

The general requirements that must be met for a State or Federal licensing authority to issue a license to a 3PL facility are proposed in § 205.5. As proposed, § 205.5(a) includes requirements applicable to the individual who submits the application and states that the applicant must submit all required information and pay any applicable licensing fee to be issued a license.

The information that would be required as part of a 3PL's application for licensure of a facility is set forth in proposed § 205.5(b). FDA believes this information is necessary for the licensing authority to assess whether the 3PL is in good standing and has the infrastructure and capabilities to fulfill its duties and obligations under these national standards for 3PL licensure. This includes disclosing whether the 3PL facility manager or designated representative has ever been convicted of a felony relating to prescription drug distribution (see proposed § 205.5(b)(7)). FDA believes that this information is crucial to protect the integrity of the prescription drug supply chain by ensuring that those responsible for the daily operations of a 3PL facility do not have a history of violating the FD&C Act. In addition, in its application for licensure renewal, under proposed § 205.7, a 3PL would be required to certify that the 3PL facility has continually met the requirements of § 205.5 and will inform the licensing authority of certain changes to

information if such changes have not already been submitted to the licensing authority (see proposed § 205.5(c)).

3. The Federal Licensure Process

Section 584(a)(1)(B) of the FD&C Act gives FDA the authority to license 3PLs directly if the State from which a 3PL conducts 3PL activities has not established a licensure requirement in accordance with the regulations. The process that FDA will use for issuing licenses to 3PLs is detailed in proposed § 205.6. While § 205.6 is only applicable to 3PLs obtaining a license from FDA, FDA suggests that States implement similar procedures. FDA intends to help stakeholders understand who the appropriate licensing authority is in the 3PL's State.

The FDA licensure process begins when a 3PL seeking licensure for a facility submits an application to FDA for review and consideration (see proposed § 205.6(a)). The DSCSA permits FDA to approve third-party organizations, referred to as approved organizations or AOs, to evaluate a 3PL's qualifications for licensure (section 584(d)(2)(A)–(B) and 584(e) of the FD&C Act). If FDA has approved one or more organizations to review a 3PL's qualifications for licensure, a 3PL should note the AO it prefers on its application. FDA generally intends to review a 3PL's qualifications for licensure only if the review cannot be completed by an FDA-approved AO. The licensure review consists of a review of all documents submitted in support of the application and an inspection of the facility pursuant to proposed § 205.16. FDA intends for the licensure application process to be electronic (see proposed § 205.6(a)) and to leverage existing technologies to streamline the licensure process.

While the DSCSA permits AOs to review a 3PL's qualifications for licensure and to recommend to FDA whether a 3PL should be licensed, the responsibility for determining whether a 3PL meets all applicable requirements and to issue the license remains with FDA (see proposed § 205.6(b)).

So as not to delay the licensure process, when reviewing an application, FDA intends to work with 3PLs to correct minor errors made on the application and communicate with the 3PL about additional information the Agency may need (see proposed § 205.6(c)). When FDA determines that a 3PL facility meets the applicable requirements and that none of the prohibited factors listed in proposed § 205.9(a)(1) are present, FDA will send the applicant an approval letter and a licensing certificate, effective on the date it is issued (see proposed § 205.6(d)).

FDA recognizes that a 3PL may have concerns about what happens to the status of its license if the AO that reviewed its qualifications for licensure has disciplinary sanctions taken against it that affect its approval status or if it is otherwise no longer considered an approved AO. While a 3PL facility should not be penalized for the actions of the AO that reviews its qualifications for licensure, FDA must ensure that the AO's review and findings provide a reliable basis for licensing decisions.

As such, FDA is proposing that the approval status of the AO that performed the licensure review for a 3PL facility will not automatically affect the licensure of a licensed 3PL facility that is otherwise in good standing (see proposed § 205.6(e)). Rather, in the event that an AO has disciplinary sanctions taken against it, ends its business, or is otherwise no longer considered an approved AO, the license of any 3PL facility reviewed by that AO will be subject to appropriate action in accordance with § 205.9 and other applicable statutes or regulations. FDA may verify the 3PL's compliance status and review the facts in that situation to determine the potential effect, if any, on the licensure of 3PL facilities reviewed by that AO.

FDA intends to publish additional guidance regarding the process and procedures related to obtaining and maintaining a 3PL license issued by FDA.

4. Changes to Information, Location, or Ownership of a Licensed 3PL

For the licensing authority to effectively carry out its responsibilities, a 3PL must keep its license information current and report any changes in information, including those that may significantly affect operations such as changes in location or ownership, to the licensing authority. Presently, the reporting requirements for these types of changes vary by State. FDA is proposing in § 205.7 that changes to certain information, including, for example, any changes in information submitted as part of an application for licensure, be submitted electronically to the licensing authority within 30 calendar days of the change (see proposed § 205.7(a)). Additionally, because a license is facility- and-owner specific (see proposed § 205.4(c)), the Agency is proposing that changes in the location or the ownership of a facility will require a new license (see proposed § 205.7(b) and (c)).

5. Expiration and Renewal of Licenses

The DSCSA requires that the regulations establishing national standards for 3PLs provide that a 3PL license expires 3 years after the date of issuance, with the option for renewal for additional 3-year periods (section 584(d)(2)(H) of the FD&C Act). FDA is proposing to implement this requirement under proposed § 205.8 by saying that all 3PL licenses, whether newly issued or renewed by the licensing authority, expire 3 years from the date of issuance or renewal. FDA also proposes that 3PLs may not submit renewal applications more than 90 days prior to the license's date of expiration to ensure that licenses are renewed based on current information. While we do not anticipate lengthy administrative delays by the licensing authority, if a 3PL files an application for a license renewal within the appropriate time period and there is an administrative delay reviewing the license application that causes the 3PL license to lapse, the 3PL will not be penalized for that administrative delay. In this scenario, the 3PL's license will be considered valid during the period of the administrative delay (see proposed § 205.8).

The Agency understands that at the time a final rule covering these proposed national standards goes into effect, there are likely to be 3PLs with existing licenses under State law. Nevertheless, 3PLs with existing State licenses must obtain new licenses in accordance with section 584(a) of the FD&C Act. These national licensing standards serve an important function of ensuring consistency across the domestic market. However, as described above, FDA does not intend to enforce the requirements with respect to the national standards for licensure of 3PLs until 2 years after the regulation is finalized. FDA's proposed requirements are further detailed in proposed § 205.16, which discusses the required inspections prior to licensure.

6. Licensure Denial, Suspension, Reinstatement, and Revocation—Notice and Opportunity To Request a Hearing

The standards for licensure denial are set forth in proposed § 205.9.

Proposed § 205.9(a)(1) enumerates 9 circumstances under which the licensing authority would be required to deny a 3PL's request for licensure or license renewal. FDA believes that this list will help 3PLs focus on good storage practices outlined by FDA that are necessary to protect the integrity of the products in the pharmaceutical distribution supply chain. To avoid

denial or delays of their applications, 3PLs should ensure that they address the reasons for denial of a license outlined in proposed § 205.9(a)(1) when they file for licensure.

Proposed § 205.9(a)(2) details the process afforded to 3PLs whose applications for licensure have been denied. FDA is proposing to provide applicants with the opportunity to provide additional information for reconsideration of the denial. If the licensing authority denies a 3PL's request for licensure after reconsideration, the 3PL will receive a notice of opportunity to request a hearing under existing FDA hearing procedures. FDA requests comment regarding the reconsideration and appeal process outlined in this regulation for 3PLs whose applications for licensure have been denied.

The proposed standards for suspending a 3PL license are set forth in § 205.9(b) and (c) and are based on the severity of risk posed to the public health. Under most circumstances, we anticipate that a 3PL would have the opportunity for a hearing before licensure suspension. However, under certain circumstances that involve repeated conduct detrimental to the public health or refusal to correct significant issues that could lead to the dissemination of illegitimate product, the Agency may suspend a license immediately while giving the 3PL an opportunity to request a hearing. Under proposed § 205.9(b), a 3PL's license may also be suspended after the 3PL receives a notice of opportunity to request a hearing. A suspended 3PL must cease all 3PL activities until their license is re-instated. This provision applies when the licensing authority has a reasonable belief that the 3PL is not in compliance with licensure requirements. FDA is proposing for § 205.9(b) to require the licensing authority to notify the 3PL in writing of the intent to suspend its license. A 3PL will have 30 days from the date listed on the notice of intent to suspend a license to provide additional information to the licensing authority so it may reconsider its decision.

If reconsideration is not sought or is denied, the licensing authority will inform the 3PL in writing of its formal intent to proceed with license suspension. The notice will contain a statement informing the 3PL that it can request a hearing on the question of whether there are sufficient grounds for suspension. The 3PL will have 10 days from the date on the notice to inform the licensing authority of its intent to request a hearing; otherwise the opportunity for a hearing will be waived and the license suspended. FDA believes this process will afford 3PLs a sufficient opportunity to present information and attempt to remedy noncompliance issues which may threaten the safety of products in the supply chain. FDA requests comment regarding this reconsideration and appeal process.

Proposed § 205.9(c) allows for license suspension prior to opportunity for hearing and effective immediately if the 3PL's noncompliance poses an imminent threat to public safety. For example, if a 3PL is warehousing or shipping illegitimate product, and once made aware, corrective actions to protect the public health from the threat of these products are not taken, the 3PL's license could be suspended immediately. Another example could be a scenario where the conditions under which drugs are held or warehoused cause the product to be illegitimate and the 3PL refuses to correct the conditions or continues to ship these illegitimate products. Under the proposed regulation, in such a situation, the licensing authority will inform the 3PL in writing that its license is suspended. The notice will also contain a statement informing the 3PL that it may request a hearing and that a hearing, if granted, will be afforded within 10 days upon the receipt of the 3PL's request for hearing. The 3PL has 10 days from the date on the notice of suspension to request a hearing; otherwise its opportunity for a hearing will be waived. FDA believes that this limits the amount of time a 3PL license would be suspended while providing a reasonable amount of time both for the 3PL to review the notice of suspension and collect the necessary information to demonstrate that its license should not be suspended, and for FDA to consider a request for a hearing and to schedule and prepare for a hearing, if the hearing request is granted. FDA believes immediate suspension of a 3PL license is crucial in cases where continued operation of the 3PL presents an imminent threat to public safety and the pharmaceutical supply chain.

Under proposed § 205.9(d), a 3PL's suspended license may be reinstated if the 3PL can demonstrate to the licensing authority that it is in compliance with regulation requirements.

Under the proposed rule, the process outlined at 21 CFR 10.75 is the default for appeals regarding a denied application for a 3PL license, and the hearing process outlined at 21 CFR part 16 is the default for appeals regarding a suspended or revoked 3PL license. However, the 3PL may request any of the procedures in 21 CFR parts 10 through 16. FDA believes that this proposed approach is consistent with current practice and suggests that States develop comparable processes.

The standards for revoking a 3PL license are set forth in proposed § 205.9(e). The licensing authority will revoke a license if it finds that a 3PL whose license has been suspended is unable or refuses to comply with the licensing requirements. The requirements governing the revocation of a 3PL license are set forth in proposed § 205.9(e)(2) through (5) and mirror those outlined in § 205.9(b)(2) through (7) for licensure suspension, with one exception: When the licensing authority informs the 3PL of its intent to revoke a license, the 3PL is given no opportunity for reconsideration since it already had an opportunity to rectify deficiencies while its license was suspended.

In addition, where a 3PL fails to timely renew its application, the license will be considered expired and a 3PL will need to submit an application for new licensure because the licensing authority may be unable to confirm that the 3PL continues to meet all necessary licensure requirements (see proposed § 205.9(f)).

FDA is also proposing to terminate a 3PL's license upon request from the 3PL when the request includes a notice of the 3PL's intent to discontinue its activities and a waiver of an opportunity for a hearing. The 3PL will be required to apply for a new license should it decide to resume 3PL activities (see proposed § 205.9(g)).

7. Good Storage Practices for 3PL Facilities

The DSCSA charges FDA with creating national standards for the licensure of 3PL facilities, including the requirement that 3PLs comply with storage practices as determined by the Secretary (see section 584(d)(2)(C) of the FD&C Act). Those requirements are detailed in proposed § 205.10. FDA considers the requirement that ''each facility of such [3PL]'' be licensed ''in accordance with the regulations'' (section 584(a) of the FD&C Act) to mean that 3PLs without a facility are not required to be licensed. Section 584 of the FD&C Act provides that FDA will establish licensure standards that include requirements relating to storage of product. These standards address issues regarding access and maintenance that presuppose the existence of a physical facility where product is maintained. As such, the requirements apply to each 3PL facility that is owned, rented, or leased by the 3PL. If the 3PL shares the same name and location as another trading partner

(for example, a wholesale distributor), each entity must be separately licensed and must have separate systems and processes in place for their separate functions (see proposed § 205.10(b)).

The requirements for 3PL facilities regarding how products will be stored and adequate security maintained are set forth in proposed § 205.10(c). This provision includes requirements for storage of nonsaleable products within the 3PL facility. If the facility is in possession of a suspect product, the facility must have clearly defined areas in which to quarantine the suspect product until the product is dispositioned (section 584(d)(2)(C)(i) of the FD&C Act).

FDA is also proposing to require that 3PLs keep illegitimate product and other products unfit for distribution in a clearly defined and designated area, separate from saleable products, until dispositioned so the illegitimate or otherwise unfit product is not inadvertently combined with saleable products (see proposed § 205.10(c)(2)). An illegitimate product poses as great a risk to public health, if not a greater risk, as a suspect product because a product is illegitimate when there is credible evidence shows that the product is counterfeit, diverted, stolen, intentionally adulterated such that the product would result in serious adverse health consequences or death to humans, is the subject of a fraudulent transaction, or appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans (section 581(8) of the FD&C Act). As such, it is counter to public health to store products that are unfit for distribution alongside saleable product. Furthermore, it would be illogical to move suspect product that has been determined to be illegitimate out of quarantine and into another area to be potentially stored with saleable product.

8. Personnel Requirements Necessary for Good Storage Practices

Ensuring that 3PL personnel are appropriately qualified is integral to establishing good storage practices (section 584(d)(2)(C) of the FD&C Act). For this reason, proposed § 205.10(b)(3) requires that a 3PL facility must be designed in such a manner that only personnel who possess appropriate and verifiable experience and training will have access to areas in which products are held. While not proposed to be required in part 205, FDA believes that a best practice in order to maintain the security of prescription drug products, would be for a 3PL to screen personnel who work in areas of its facility where prescription drug products are held for records of Federal or State criminal convictions relating to the possession, control, or distribution of prescription drugs. While also not proposed to be required in part 205, FDA believes it would be a best practice for a firm to request that employees state that they are not engaged in and will not engage in the illegal use of controlled substances while serving in their capacity within the 3PL.

FDA also proposes requiring that 3PLs maintain and make available to the licensing authority certain information about their facilities' managers and designated representatives (see proposed § 205.11). Furthermore, FDA is establishing specific employee qualifications with respect to facility managers or designated representatives that are necessary to effect good storage practices (see proposed § 205.11(b)). Specifically, FDA is proposing to require that a facility manager or designated representative of the facility manager serve in either capacity for only one facility at any one time (see proposed § 205.11(b)(2)). FDA believes that a facility manager or designated representative of the facility manager must be accountable for all operations of a 3PL facility. That facility manager or designated representative must be present within the facility, and must be familiar with the day-to-day operations of that facility. FDA believes that the best way to ensure the accountability and familiarity required for compliance is for a designated representative or facility manager to serve only one facility at a time. This is to ensure that the facility manager or designated representative is actively engaged in managing the daily operations of the facility and that they remain aware of any non-compliance issues that may arise. To ensure the qualified designated representative can fulfill their obligations to manage and carry out daily operations, FDA proposes to require that a 3PL provide its designated representative with adequate authority and the necessary resources (see proposed § 205.11(c) and (d)). FDA believes that establishing these requirements will help ensure that the products handled by a 3PL are properly safeguarded to protect the supply chain and the public health.

Section 584(d)(2)(E) and (F) of the FD&C Act requires mandatory background checks for facility managers or the designated representatives of facility managers to ensure that neither the 3PL's facility manager nor the designated representative has engaged in the prohibited behaviors outlined in proposed § 205.11(e). Additionally, FDA is outlining other activities which may lead to the denial of licensure in proposed § 205.11(f). They are not bars to licensure, but they are factors that may be considered by licensure authorities when reviewing an application for licensure to determine whether the 3PL has storage practices sufficient to maintain adequate security over the facility. FDA requests comment on this section of the regulation and the scenarios outlined therein.

Requiring that individuals with significant authority over 3PL activities be subject to a criminal background check adds an additional layer of safety and security to the supply chain (see proposed § 205.11(g)). Theft of product by personnel who have direct access to areas where products are stored is a known problem across the healthcare industry; the background checks required by section 584(d)(2)(F) of the FD&C Act that FDA is proposing here are necessary precautions to prevent the potential theft, loss, or abuse of prescription drugs.

FDA suggests an additional best practice for a 3PL to utilize when staffing their operation. This best practice, related to staff who work within a 3PL, is designed to ensure security within a 3PL. FDA recommends to 3PLs that the individuals who work within their operation and have access to prescription drugs should not have a record of criminal activity involving violations of the FD&C Act or other laws involving prescription drugs.

When screening personnel who work in areas of a 3PL facility where products are held, including the facility manager or designated representative, FDA recommends that a 3PL consider whether such personnel have (1) engaged in a pattern of violating the requirements of section 584 of the FD&C Act that present a threat of serious adverse health consequences or death to humans; (2) been found to have committed or facilitated commission of any prohibited acts under the FD&C Act or violated or facilitated any violations of any of the regulations in this part or analogous provisions of the State licensing authority, as applicable; (3) been convicted of any violation of Federal, State, or local laws relating to drug samples, wholesale or retail drug distribution, distribution of controlled substances, or third-party logistics services; or (4) been convicted of any felony under Federal, State, or local laws involving or related to prescription drugs. FDA believes that 3PLs should consider an applicant's history of violations of the FD&C Act, or other

laws involving prescription drugs, when making staffing decisions.

9. Required Written Policies and Procedures

Section 584(d)(2)(C)(iii) of the FD&C Act enumerates certain types of written policies and procedures that FDA regulations must require, and tasks FDA with defining the content with more specificity. Those written policies and procedures are set out in proposed § 205.12. All 3PLs would be expected to establish, maintain, and follow the written policies and procedures set forth in these proposed subsections for each 3PL facility, to the extent that the requirements of those sections are relevant to the scope of their specific 3PL activities. Under the proposed regulation, all written policies and procedures will be made available to the licensing authority upon request, and the licensing authority will be permitted to have access to and copy records of the 3PL to ensure that the 3PL facility is following its written policies and procedures (see proposed § 205.12(a)). Written policies and procedures include those that are stored and maintained electronically.

FDA is implementing the statutory requirements listed in section 584(d)(2)(C)(iii) of the FD&C Act through proposed § 205.12(c)(1) through (6). Under these requirements, 3PLs must maintain written policies and procedures to address a product's receipt, security, storage, inventory, shipment, and distribution. Proposed § 205.12(c)(1) through (6) details the specific elements that such written policies and procedures must contain. Such elements are necessary to maintain supply chain integrity and align with current industry practices to protect the integrity of the drugs that are distributed through the supply chain.

To ensure good storage practices, FDA is also proposing to require that 3PLs establish written policies and procedures for handling not only expired product as required in section 584(d)(2)(C)(iii)(VI) of the FD&C Act, but also products that are unfit for distribution (see proposed § 205.12(f)). Furthermore, any drug unfit for distribution should be segregated and returned or destroyed to prevent its distribution to the patient (see proposed § 205.12(f)(1)). These requirements will ensure that drugs, the distribution of which would violate the FD&C Act and which may not be fit for consumption by American consumers for a variety of reasons, are not distributed into the supply chain. FDA believes that these proposed standards align with current industry practices.

Similarly, to further ensure the safety and efficacy of drug products, FDA is proposing that 3PLs maintain written policies and procedures related to the storage, inventory, and disposition of both suspect and illegitimate products. In the case of a suspect product, the written policies and procedures must include the procedure for quarantine or destruction of the product if directed to do so by the product's manufacturer, wholesale distributor, dispenser, or an authorized government agency. In the instance of an illegitimate product, written policies and procedures must be in place to ensure that illegitimate product is appropriately dispositioned as directed by the respective manufacturer, wholesale distributor, dispenser, or authorized government agency. This may include segregation in a clearly defined, designated area from which the product may be dispositioned. FDA believes that these proposed standards align with current industry practices and will give 3PLs a clear roadmap for dealing with potentially difficult situations involving suspect and illegitimate product.

Finally, FDA views it as a best practice for a 3PL to establish written policies and procedures to ensure that it only engages in 3PL activities on behalf of authorized trading partners with respect to a product. DSCSA requires that all other entities that accept or transfer direct possession or ownership in the supply chain are only permitted to do business with other authorized trading partners (section 582 of the FD&C Act). FDA believes that, to further ensure supply chain security and integrity, it is important that 3PLs also only do business with other authorized trading partners. 3PLs that engage in transactions with non-authorized trading partners may expose the supply chain to potentially harmful or substandard product. FDA notes that 3PLs are included in the wholesale distributor and third-party logistics provider reporting public database (available at *https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm423749.htm*) which allows manufacturers, wholesale distributors, repackagers, and dispensers to determine if the 3PL is authorized. Similarly, 3PLs should include using the publicly available information regarding other trading partners in their written policies and procedures to ensure they are doing business with only authorized trading partners.

10. Recordkeeping and List of Trading Partners

The maintenance, availability, and accuracy of the records made available for inspection under section 584(d)(2)(D) of the FD&C Act is critical to demonstrate that 3PLs are acting in compliance with relevant laws and regulations and to ensure their records can be relied upon to identify any potential risk to the public health. As such, FDA is proposing to require that all records be securely stored, with procedures in place to restrict access and protect record integrity, and that any alterations made to records be signed and dated while preserving the original information contained in the record (see proposed § 205.13(a)). These records can be stored and maintained electronically. These records maintenance requirements will allow for greater confidence in both the information that is preserved at the facility and the information potentially disseminated to other trading partners.

FDA is proposing that all records must be retained for a minimum of 3 years, except for records related to suspect and illegitimate products, product quality complaints, and destroyed, returned, and recalled products, which each must be retained for a minimum of 6 years (see proposed § 205.13(b)). Such record retention is necessary not only to ensure 3PLs are complying with the FD&C Act, but also to ensure that there is consistency and continuity in the access to the information across the records required pursuant to sections 582, 583, and 584 of the FD&C Act. The DSCSA requires that, upon the licensing authority's request, 3PLs provide the licensing authority with a list of the trading partners (manufacturers, wholesale distributors, and dispensers) for which the 3PL conducts 3PL activities (section 584(d)(2)(G) of the FD&C Act). This requirement would be codified in proposed § 205.14 and would also include repackagers for which the 3PL provides services when those repackagers are acting on behalf of a manufacturer, wholesale distributor, or dispenser of a product, as explained in the definition of *other logistics services* at § 205.3(i).

11. Annual and Other Reporting to FDA

Under DSCSA, 3PLs must report certain information to FDA to be considered an authorized trading partner (sections 581(2)(C) and 584(b) of the FD&C Act). The annual reporting requirements for 3PLs went into effect on November 27, 2014. Proposed § 205.15 clarifies the statutorily

prescribed annual reporting requirements and proposes the collection of additional information to provide complete and useful information about 3PLs that can be used by FDA, States, and trading partners.

The DSCSA requires 3PLs to report to FDA for each facility: (1) The State by which the facility is licensed; (2) the facility's license number; (3) the facility's name and address; and (4) all trade names under which the facility conducts business (section 584(b) of the FD&C Act). If a facility conducts more than one type of activity, such as 3PL activities and wholesale distribution activities, the facility must be licensed as both a wholesale distributor and a 3PL and must report to FDA separately as a wholesale distributor and a 3PL (section 503(e)(2) of the FD&C Act).

FDA is proposing to require that 3PLs use an electronic system provided by FDA for reporting (see proposed § 205.15(a)). This electronic system will increase efficiency by providing uniformity in the content and format of reports, thereby making the information easier to process. FDA is proposing that the annual reporting schedule require all 3PLs to report each calendar year between January 1st and March 31st, although an entity may update information at any time (see proposed § 205.15(b)). For example, if a 3PL chooses to update a license on December 15, 2019, that 3PL will still have to report during the January 1, 2020 through March 31, 2020 annual reporting period.

The specific information that 3PLs must electronically report to FDA is set forth in proposed § 205.15(c). The DSCSA requires that 3PLs report the name and address of each facility (section 584(b)(2) of the FD&C Act). In fulfilling this requirement, the 3PL must provide the address that is associated with the State or Federal license. Licensed entities are also required to report to FDA the State by which they are licensed and the license number (section 584(b)(1) of the FD&C Act). In addition, FDA is proposing to require that the reported company name be identical to the official company name appearing on the license (see proposed § 205.15(c)(2)). Maintaining an account in FDA's electronic system for each 3PL facility license during the reporting period is integral to FDA's ability to provide oversight, as each facility of a 3PL must be licensed in order for the 3PL to conduct 3PL activities.

In addition to the requirements specified in the statute, FDA is proposing to require an additional data element that FDA views as important to the Agency, the States, and trading partners. This additional information will inform other trading partners that the 3PL is in fact an authorized trading partner with whom they can do business. To this end, FDA is proposing to require that 3PLs provide the date each State license expires. This information is essential for determining that licensure status for each 3PL facility is current.

Also, in addition to the physical address, which is required to be reported by statute, FDA believes that it would be a best practice for 3PLs to submit a unique facility identifier (UFI) that corresponds with the facility name and facility address. The UFI for a 3PL facility is useful to FDA when identifying and confirming certain business information. To be most helpful to FDA and other trading partners, a 3PL should obtain a separate UFI for each *physical* address that the 3PL is reporting since each 3PL facility must meet the 3PL requirements, and licensure is facility specific. FDA also believes that it would be a best practice for 3PLs to submit the contact information of an individual who will interact with FDA, including that individual's name, telephone number, and email address. FDA recommends as a best practice that the 3PL designate a contact person who is familiar with the daily operations of the 3PL facility, such as the designated representative, to ensure efficient processing of inquiries and minimize the impact inquiries may have on the daily operations of the facility.

It is important for other trading partners and FDA to know whether a 3PL has had a license revoked or suspended or whether a 3PL has had any other significant disciplinary actions taken against them that limits the ability of a facility to conduct drug-related business. As such, 3PLs must report significant disciplinary actions to FDA. This will involve providing a DEA registration number or State controlled substance license number when there is a significant disciplinary action issued by the DEA or the State controlled substance licensing authority that would limit the ability of the 3PL facility to conduct 3PL activities related to the distribution of controlled drug substances that meet the definition of product, as defined at § 205.3(k). In such a situation, information about the DEA registration or State controlled substance license is important because the disciplinary action would likely be associated with that specific license or registration.

A *significant disciplinary action* is defined in the proposed regulation as an action that limits the ability of a facility to conduct 3PL activities related to the distribution of prescription drug products. FDA proposes that, within 30 calendar days after a significant disciplinary action is imposed or taken by a State or Federal government, 3PLs must report the type of disciplinary action, the date the action was taken, and the State where the disciplinary action occurred, as well as submit any documents associated with the disciplinary action, including a final ruling by the relevant State or Federal agency or board or a consent decree.

Finally, FDA is proposing to require a 3PL to report to FDA within 30 calendar days of ceasing warehousing or other logistics services that it is going out of business or voluntarily withdrawing a 3PL license from a State. FDA believes reporting this information is essential for the information in the public database to be complete, accurate, and useful for FDA, the States, and trading partners.

To ensure efficient enforcement of FD&C Act requirements and to make public the voluntary information provided by each 3PL facility, FDA proposes adding 3PL licensure to the public database to make information about 3PLs available on FDA's website. Having the license status of 3PLs in one publicly available database will help FDA, trading partners, and other stakeholders determine whether 3PLs are properly licensed and authorized.

12. Inspection Provisions

Section 584(d)(2)(D) of the FD&C Act requires that the regulations provide for periodic inspections of 3PL facilities to ensure compliance with the national standards and directs FDA to determine the intervals at which periodic inspections of a 3PL will be conducted by the licensing authority to ensure a facility's compliance with the law and this regulation. To this end, FDA is proposing to require that a physical inspection of a 3PL facility be conducted prior to issuance of the initial license and routinely once every 3 years thereafter (see proposed § 205.16(a) and (b)). The regulation proposes allowing the licensing authority, or an AO, as determined by the licensing authority, to conduct physical inspections (see proposed § 205.16(a)). As used in part 205, subparts A and B, *licensing authority* means the State licensing authority or FDA. When developing the timeframes for inspections, FDA sought to balance the risk to the supply chain while considering FDA's and State agencies' resource constraints. FDA is proposing to require that the physical inspection of a 3PL facility warehouse space include

the paper and electronically stored records detailing the processes related to all 3PL activities (see proposed § 205.16(c)). FDA has authority to require that an inspection of a 3PL warehouse include the 3PL's records, files, and processes related to product warehousing. Section 704(a)(1) of the FD&C Act (21 U.S.C. 374(a)(1)) states that ''in the case of any . . . warehouse . . . in which prescription drugs . . . are held, inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities).'' This authority directly applies to FDA's ability to inspect a 3PL's facility warehouse space for relevant records and files to ensure compliance with the FD&C Act. FDA also proposes to require that 3PLs permit inspections at reasonable times and that the licensing authority conduct its inspection in a reasonable manner (see proposed § 205.16(c) and (d)).

D. Approved Organizations for 3PLs

1. Approval and Utilization of Outside Organizations in the Licensure Process

The DSCSA requires that regulations codified by FDA establish a process by which a third-party organization approved by FDA shall, upon a 3PL's request, ''issue a license'' to each 3PL facility that meets the requirements for licensure (section 584(d)(2)(A) of the FD&C Act). However, in situations where a State has not established a licensure program in accordance with the regulations, the DSCSA charges FDA with issuing 3PL licenses, provided the applicable requirements for licensure are met (section 584(a)(1)(B) of the FD&C Act). Accordingly, FDA interprets the language of 584(d)(2)(A) of the FD&C Act to mean that a third-party organization approved by FDA—an AO—will conduct a review of the 3PL's qualifications for licensure and issue a report to FDA regarding whether the 3PL ''demonstrates that all applicable requirements for licensure . . . are met,'' which FDA can rely on when issuing a license per section 584(e) of the FD&C Act.

The DSCSA allows States and FDA to approve organizations for purposes of licensure review and periodic inspection. Proposed §§ 205.17, 205.18, and 205.19 contain the process that FDA will use to approve organizations and the qualifications to become an AO. FDA suggests that States that choose to rely on AOs for licensure reviews have in place the same or similar processes for approved organizations to conduct licensure reviews and for decisions affecting the approval status of those organizations.

The scope of work AOs would be tasked with performing and the standards an AO must meet to become approved are detailed in subpart B of proposed part 205. The proposed rules also set forth the process by which FDA will approve organizations to review the qualifications of 3PL facilities for licensure, which we refer to as a ''licensure review.''

A licensure review consists of performing a review of all documents submitted to the licensing authority in support of an application for 3PL licensure and conducting an inspection of the facility as directed by the licensing authority. If a review of documentation supports licensure of the 3PL facility, the facility will then be inspected by an AO, as directed by FDA. FDA is proposing that the AO's licensure review be completed within 90 days upon receiving notice from the Agency to conduct the licensure review. FDA believes that this 90-day timeframe is sufficient for an AO to perform the work with which they are tasked while also ensuring that there are no undue delays in the licensure process. Upon completion of the licensure review, the AO would then provide FDA with a licensure review report within 7 days (see proposed § 205.17(b)), with a copy sent to the 3PL facility. As proposed, using the report submitted by the AO, FDA would make the final determination as to whether a 3PL facility should be issued a license. The process that AOs should follow when conducting routine inspections of 3PL facilities mirrors the process for licensure review and is detailed in proposed § 205.17(c).

It is important that FDA can verify an AO's continued compliance with the approval requirements. Therefore, to keep its approval, FDA is proposing to require that an AO maintain certain records for a period of at least 5 years and these records must be readily available to FDA upon request. Unless specified by statute, we believe it is reasonable for the required length of maintenance of records to align with the length of the entity's licensure term. In addition, to ensure public safety, FDA is proposing to require that AOs report potential violations at 3PL facilities to FDA within 24 hours of discovery (see proposed § 205.17(f)). The general qualifications for approval of AOs are set out in proposed § 205.18.

To become and remain approved, FDA is proposing to require that an organization, and those employed by the organization, abide by certain requirements that are intended to secure against conflicts of interest, promote professional business practices, and protect non-public information (see proposed § 205.18(a)).

FDA is proposing to allow AOs to hire outside contractors to conduct licensure reviews or licensure review-related activities. Under FDA's proposed regulation, AOs who decide to use outside contractors must ensure that the contractors not only effectively carry out the licensure review or licensure review-related activities in a manner consistent with this proposed regulation to ensure public health, but the AO must also ensure that the contractors properly protect all non-public information.

For an AO to maintain approval, FDA proposes to require that the AO ensures contractors abide by all applicable confidentiality agreements, that the AOs have policies and procedures in place to ensure the contractors abide by these proposed standards, and that the contractors have the necessary training and expertise to carry out licensure reviews (see proposed § 205.18(b)(1)). Also, before a contractor hired by an AO may perform a licensure review of a 3PL facility, the 3PL must have entered into an agreement with the AO giving the AO permission to share with contractors the 3PL's confidential commercial information (see proposed § 205.18(b)(2)). If such consent is not provided by the 3PL facility, the AO must perform the licensure review itself. FDA believes that this approach is reasonable given that it is the AO's decision to work with contractors and, under this proposed regulation, the ultimate responsibility for the licensure review rests with the AO.

In addition, so FDA may keep track of which organization is responsible for each licensure review, FDA proposes that AOs must submit to FDA a list of the contractors used by the organization each year and the AO must certify that such contractors comply with the applicable requirements (see proposed § 205.18(b)(3)). Finally, to ensure that the standards set forth in this regulation are followed and that lines of responsibility are clear, FDA proposes to require that the AOs remain responsible for all the work performed by outside contractors (see proposed § 205.18(b)).

FDA proposes to prohibit contractors from subcontracting licensure review or licensure review-related activities (see proposed § 205.18(b)(1)(ii)). Limiting the ability of contractors to further delegate their responsibility ensures that FDA will have accurate information about who is conducting licensure reviews, that those responsible for the licensure reviews have the necessary

qualifications, and that their conduct is governed by this proposed regulation.

The proposed process that FDA will use to approve organizations, including the application process, as well as the process for suspending or revoking an organization's approval, are set forth in proposed § 205.19. To ensure compliance with DSCSA, FDA is proposing that organizations seeking approval by FDA must first electronically submit to FDA an application demonstrating the organization's ability to assess compliance with all 3PL requirements detailed in proposed § 205.19 (see proposed § 205.19(a) and (b)). Organizations must also provide training that their employees must pass before they may conduct licensure reviews (see proposed § 205.19(c)). To verify information contained in the application and further ensure compliance with the proposed regulation, FDA proposes that, before an AO may conduct its first licensing review, it must be audited by FDA (see proposed § 205.19(d)). A new approval will be valid for 5 years (see proposed § 205.19(e)).

If an organization's request for approval is denied, the organization may issue a request for reconsideration under 21 CFR 10.75 (see proposed § 205.19(f)). In addition, to ensure compliance and protect public health, FDA proposes that an AO may have its approval suspended if it does not maintain the standards outlined in this part (see proposed § 205.19(g)). A suspended AO must cease all 3PL licensure review including any pending inspections of 3PL facilities. A suspended AO must notify any 3PLs under a pending licensure review by the AO, of the AO's suspension within 7 calendar days (see proposed § 205.19(g)(5)). While most suspensions will happen only after notice and opportunity to request a hearing, under the proposed regulations, FDA reserves the ability to suspend approval prior to a hearing if there is a reasonable probability that the organization's noncompliance will cause imminent and serious adverse health consequences or death to humans (see proposed § 205.19(h)).

Furthermore, FDA proposes that a suspended approval can be reinstated if the issue is resolved within 1 year from the date of suspension (see proposed § 205.19(i)), though it may be revoked if the organization fails to rectify the situation that resulted in the suspension (see proposed § 205.19(j)). FDA believes that 1 year provides the AO enough time to remedy most situations. An AO's approval may also be reinstated on a conditional basis. If the AO is conditionally reinstated, they will enter a three-year probationary period, during which if any material deficiencies arise, their license will be subject to immediate revocation (see proposed § 205.19(i)(2)).

FDA also proposes to permit an AO to voluntarily withdraw its approval, but it must inform FDA of any facilities with pending reviews (see proposed § 205.19(l)). To further ensure that pending licensure reviews are not overlooked, under FDA's proposed regulation, an AO whose approval has been suspended, revoked, or voluntarily withdrawn has the responsibility to report this information to those 3PL facilities with pending licensure reviews (see proposed § 205.19(m)); this will stop the clock on the 90-day licensure review while the 3PL applies for licensure review from another AO or FDA. Also, to ensure that the AOs continue to meet the standards put forth in this subpart, and part 205 generally, under the proposed regulations, an AO must inform FDA of any changes to information that was submitted as part of its application for approval (see proposed § 205.19(n)(1)). Since the approval of an organization is nontransferable, changes in ownership also require an AO to submit a new application to FDA (see proposed § 205.19(n)(2)). Finally, as an additional assurance that an AO continues to comply with the provisions of this part, FDA proposes to require that AO's remain subject to periodic audits by FDA (see proposed § 205.19(o)).

E. National Standards for Wholesale Distributors

1. Requirement That Wholesale Distributors Be Licensed

To implement section 503(e)(1) of the FD&C Act, FDA is proposing to codify at § 205.20(a) the requirement that a wholesale distributor be licensed by the State from which the drug is distributed, or by FDA if the State from which the drug is distributed has not established a licensure requirement in accordance with the standards proposed herein, as well as by the State into which the drug is distributed if that State requires such a license. This requirement is consistent with how States currently license wholesale distributors.

FDA anticipates that, for the purposes of annual reporting, a wholesale distributor who maintains multiple licenses to engage in wholesale distribution, will be able to report their required information aggregately for all their licenses (section 503(e)(2) of the FD&C Act). FDA believes this approach will increase efficiency for both wholesale distributors and the Agency, ensure that licenses for wholesale distribution facilities will be granted to qualified firms, and ensure records related to their facilities will be maintained in an organized fashion.

In addition, FDA proposes to set the licensure term for wholesale distributors at 2 years (see proposed § 205.20(b)). FDA considered current State requirements, as well as the potential impacts on State and Agency resources, to determine the term for licensure. Ultimately, the Agency believes that 2 years aligns with current practices, does not place an undue burden on State or FDA resources, and provides adequate protection to American consumers because it ensures that renewals will be based on current information and operations.

2. Surety Bonds

Wholesale distributors are required to obtain a surety bond to be licensed and engage in wholesale distribution (section 583(b)(3) of the FD&C Act). FDA is proposing to establish the terms of this requirement in proposed § 205.21. To receive or renew a license, a surety bond of $100,000, or $25,000 if applicable (for wholesale distributors with annual gross receipts of $10,000,000 or less), must be in place at the time the wholesale distributor's application for licensure or licensure renewal is submitted to the licensing authority (see proposed § 205.21(b)). The surety bond is intended to ensure compliance with DSCSA and that any administrative penalties levied by the licensing authorities are paid. DSCSA also permits the furnishing of ''other equivalent means of security acceptable to the State'' in lieu of a bond (section 583(b)(3)(A)(i) of the FD&C Act). It would be up to the State licensing authority to determine what, if anything, would constitute an equivalent means of security to a surety bond. Where FDA is the licensor, the wholesale distributor would need to furnish a surety bond to satisfy the bond requirement as other equivalent means of security appear to be specifically reserved for the States.

While a bond is required before a wholesale distributor may acquire the necessary license, section 583(b)(3)(B) of the FD&C Act provides a set of circumstances under which the surety bond requirement will be waived. FDA is proposing to codify at § 205.21(b)(3) the DSCSA requirement that if a wholesale distributor can prove it has the necessary bond for the State where the facility is located (*e.g.,* by providing a copy of the existing security bond

agreement), the requirement for an additional surety bond for another State is waived. In this situation, the wholesale distributor does not have to acquire an additional bond to satisfy the non-resident licensure requirements of the State into which the wholesale distributor plans to distribute. However, it remains unclear if and how this waiver should apply when an equivalent means of security to the surety bond are used. FDA requests comment specifically related to the waiver to the surety bond requirement and whether that waiver should apply to scenarios where some other equivalent means of security is used in lieu of a surety bond.

The terms that a surety bond must include are outlined in proposed § 205.21(c). FDA proposes to require not only that the terms cover the liability requirements related to administrative penalties, but also that the bond remain in full force for 1 year after the license expires and that the surety company guarantee payment within 30 days of receiving notice from the licensing authority. FDA also proposes permitting licensing authorities to make claims against the surety bond for 1 year after the wholesale distributor's license expires or within 60 days after an administrative or legal proceeding has concluded, whichever is longer. These timeframes seek to ensure that the rights of the different parties involved in a potential claim will be adequately protected. This is particularly important with respect to the waiver because it allows the affected States equal access to the surety bond and ensures consistent standards across States.

The implications of termination or lapse in coverage of a surety bond are detailed in proposed § 205.21(d). A wholesale distributor may cancel its surety bond, but FDA proposes to require that it give all impacted licensing authorities 30 days' prior notice before such cancellation take effect. Such notice is necessary because a wholesale distributor's license will be suspended upon the cancellation of the surety bond unless the wholesale distributor acquires a new bond before to the old bond is cancelled. FDA proposes that a license will be suspended if a licensing authority discovers a lapse in bond coverage.

FDA also proposes to require that the surety bond permit actions to be brought by either a State or Federal licensing authority (see proposed § 205.21(e)), provide the contact information for the surety company (see proposed § 205.21(f)), and name the specific parties to the surety bond (see proposed § 205.21(h)).

3. General Requirements for Licensure

This section includes the requirements for the application. FDA notes that the applicant would have to demonstrate compliance with the requirements as set forth in subpart C, including a satisfactory inspection, as described in proposed § 205.28, and criminal background checks for facility managers and designated representatives, as described in proposed § 205.25, to be granted a wholesale distributor license.

The general application requirements that must be met for a State or Federal licensing authority to issue a wholesale distributor license are set forth in proposed § 205.22. The requirements applicable to the individual who submits the licensure application are detailed in proposed § 205.22(a). FDA proposes to require that the applicant submit all required information and pay a licensing fee in order to be considered for licensure. FDA believes these general requirements align with current industry practices.

FDA is proposing at § 205.22(b) to require that the applicant provide the surety bond or other equivalent means of security acceptable to the State, required by section 583(b)(3) of the FD&C Act and detailed in proposed § 205.21, as part of the wholesale distributor's application for a license.

The information that the licensing authority will require as part of a wholesale distributor's initial application for licensure and renewal applications is set forth in proposed § 205.22(c) and (d). This information is necessary for the licensing authority to assess whether the wholesale distributor is in good standing and has the infrastructure and capabilities to fulfill the duties and obligations of licensure. For example, FDA is proposing to require that a wholesale distributor inform FDA if it has received any citations for violating requirements for licensure or received any significant disciplinary actions within the past 7 years (see proposed § 205.22(c)(8)). FDA believes this information is necessary to ensure the wholesale distributor can demonstrate that it has not engaged in a pattern of violating the standards for licensure. The DSCSA defines prohibited persons, in part, as licensees who have ''engaged in a pattern of violating the requirements of this section, or State requirements for licensure, that presents a threat of serious adverse health consequences or death to humans'' (section 583(d) of the FD&C Act). Therefore, this information is necessary to demonstrate that a wholesale distributor is not prohibited from receiving or maintaining licensure for wholesale distribution.

Finally, FDA proposes to require that a wholesale distributor's license be readily retrievable at the facility, and that the facility permit State or Federal inspectors, or others acting on behalf of the licensing authority, to inspect the license (see proposed § 205.22(e)).

4. The Federal Licensure Process

Section 503(e) of the FD&C Act, as amended by DSCSA, requires FDA to license wholesale distributors directly if the State in which it engages in wholesale distribution has not established a licensing requirement (section 503(e)(1) of the FD&C Act). Proposed § 205.23 details the process that FDA will use when issuing licenses to wholesale distributors. While this section is only applicable to wholesale distributors obtaining a license from FDA, FDA suggests States implement similar procedures to ensure that all wholesale distributor licenses issued are consistent with the proposed regulation pursuant to section 503(e)(1)(B) of the FD&C Act. FDA plans to make information available to clarify who is the appropriate licensing authority in the wholesale distributor's State. FDA believes this streamlined process for application will allow for greater clarity and harmonization across the industry.

For wholesale distributor license applications submitted to FDA, FDA proposes that the wholesale distributor submit the application electronically, including the information outlined in proposed §§ 205.21 and 205.22, along with additional supporting documentation (see proposed § 205.23(a)(1)). The DSCSA authorizes FDA's use of third-party organizations—AOs—to conduct inspections of wholesale distributors required under section 583(c) of the FD&C Act. If FDA has approved one or more AOs to inspect wholesale distributors, the wholesale distributor should note the AO it prefers to conduct its inspection on the application submitted to FDA (see proposed § 205.23(a)(2)). If no AO has been approved, FDA will conduct the inspection (see proposed § 205.23(a)(3)). Furthermore, submission of the application to FDA will not be considered complete until FDA receives all pertinent information and fees (see proposed § 205.23(a)(5)).

While the DSCSA permits AOs to conduct inspections of wholesale distributors applying for licensure, the responsibility of determining whether a wholesale distributor meets all the applicable requirements set forth in this proposed regulation remains with FDA (see proposed § 205.23(b)). To avoid

delays in the licensure process, FDA intends to work with wholesale distributors to correct minor errors made on the application (*e.g.,* missing written policies and procedures) and communicate with the wholesale distributor about additional information the Agency may need to process and review the application (see proposed § 205.23(c)). If the wholesale distributor meets the requirements outlined in this proposed part and none of the prohibited factors listed in proposed § 205.30(a)(1) are present, FDA will approve the application and send an approval letter and license certificate (see proposed § 205.23(d)).

FDA recognizes that a wholesale distributor may have concerns about what happens to the status of its license if disciplinary sanctions are taken against the approval status of the AO that conducted its inspection when applying for licensure or if the organization is otherwise no longer considered an approved AO. While FDA believes that a wholesale distributor should not be penalized for the actions of the AO, FDA must ensure that the AO's review and findings provide a reliable basis for licensing decisions. As such, FDA is proposing that, if the wholesale distributor is otherwise in good standing, a change in the approval status of the AO that conducted the inspection of the wholesale distributor will not automatically affect the licensure of a licensed wholesale distributor (see proposed § 205.23(e)). Rather, in the event that an AO has disciplinary sanctions taken against it, ends its business, or is otherwise no longer considered an approved AO, the license of any wholesale distributor reviewed by that AO will be subject to appropriate action in accordance with § 205.30 and other applicable statutes or regulations. FDA may verify the wholesale distributor's compliance status and review the facts in that situation to determine the potential effect, if any, on the licensure of wholesale distributors inspected by that AO.

5. Changes to Information, Ownership, or Location of Licensed Wholesale Distributors

FDA recognizes that information about a business can change over time. However, for the licensing authority to effectively carry out its responsibilities, license information must remain current and changes in information previously submitted must be reported to the licensing authority. Currently, the reporting requirements for these types of changes vary by State. FDA is proposing the establishment of specific timeframes for reporting changes (see proposed § 205.24) and believes that standardizing the timeframes will help make reporting business-related changes less burdensome for industry and licensing authorities. FDA is proposing that the wholesale distributor submit changes to certain information, such as the information submitted with a surety bond or as part of an application for licensure, to the licensing authority within 30 calendar days of the date the change became effective (see proposed § 205.24(a)). Significant changes, such as changes in location or changes to the person engaged in wholesale distribution, require the added scrutiny that comes with an inspection or review of an application for a new license to ensure that the entity will be able to continue to meet the standards for licensure in its new location or under its new management. For this reason, FDA is proposing that changes in location or changes to the person engaged in wholesale distribution will require an inspection or new license (see proposed § 205.24(b) and (c)). FDA recognizes that the ownership of a facility from which a wholesale distributor leases the facility and conducts wholesale distribution may change without the wholesale distribution operation changing in any meaningful way. If that change does not impact the wholesale distribution operation, the wholesale distributor will not need to apply for a new license. As described in proposed § 205.24(b)(1), the date the change of location takes place is the date the new location begins receiving prescription drugs.

6. Prohibited Persons and Qualifications for Key Personnel

The FD&C Act, as amended by DSCSA, requires FDA to establish and implement standards for the qualifications of wholesale distributors' key personnel (section 583(b)(5) of the FD&C Act). As discussed above and proposed at § 205.3(g), FDA considers key personnel to include individuals with responsibility for managing the operations of the wholesale distributor, including any principal, owner, director, officer of the wholesale distributor, facility manager or designated representative, or other individuals who are authorized to enter into areas where prescription drugs are held and are likely to handle those prescription drugs as a part of their responsibilities within the operation. FDA believes the qualifications for key personnel proposed in § 205.25 are necessary to ensure that all the individuals who are responsible for operating the wholesale distributor's facility are appropriately qualified to carry out their duties and that the wholesale distributor meets the national standards.

Proposed § 205.25(a) lists conduct that prohibits a wholesale distributor from obtaining licensure. Proposed § 205.25(b) establishes the basic standards for key personnel working within a wholesale distribution facility. Key personnel must have the appropriate education, background, training, and experience necessary to carry out their assigned functions within the operation. No one within the facility should carry out the responsibilities of key personnel without the proper training and expertise.

As a part of FDA's responsibility to establish and implement standards for the qualifications of wholesale distributors' key personnel, FDA is proposing that wholesale distributors and their key personnel meet certain other qualifications. Licensure may be denied if a wholesale distributor or any of their key personnel do not meet the standards for qualification as outlined in proposed § 205.25(c).

Key personnel working for a wholesale distributor hold critical positions of trust for protecting the security of the prescription drug supply chain. FDA believes it would be a best practice for a firm to require that all employees not engage in the illegal use of controlled substances while serving in their capacity in the wholesale distribution operation and request that all employees so state.

FDA is proposing to require wholesale distributors to establish and implement written policies and procedures to ensure that their key personnel meet the qualifications contained in this proposed section (see proposed § 205.25(e)) and to maintain certain information about their key personnel that demonstrates they are qualified to carry out the duties assigned to them (see proposed § 205.25(b)), including having the proper education and training (see proposed § 205.25(e)(3)). Proposed § 205.25(f) also limits a facility manager or designated representative to hold that position at one facility at a time. This is to ensure that the facility manager or designated representative is actively engaged in managing the daily operations of the facility and that they remain aware of any non-compliance issues that may arise.

The FD&C Act, as amended by DSCSA, specifically requires licensure standards to include mandatory background checks and fingerprinting of wholesale distributor facility managers and their designated representatives

(section 583(b)(4) of the FD&C Act). Entrusting individuals with the responsibility of distributing prescription drugs prior to a criminal background check may jeopardize the integrity of the drug supply chain and leave the public exposed to unnecessary harm posed by the possible introduction of drugs that are unsafe. FDA is proposing to codify at § 205.25(g) the requirement for facility managers and their designated representatives to submit a full set of fingerprints to conduct local and national criminal background checks. The background check, when completed, must demonstrate that the facility manager or designated representative has no history of criminal convictions pursuant to proposed § 205.25(a).

FDA suggests, when a wholesale distributor staffs its operation, it is a best practice that the individuals who work within their operation and have access to prescription drugs not have a record of criminal activity involving violations of the FD&C Act or other laws involving prescription drugs. This best practice is recommended to help ensure security within a wholesale distributor.

When screening personnel who work in areas of a facility where prescription drugs are held, including the facility manager or designated representative, FDA recommends that a wholesale distributor consider whether such personnel have (1) engaged in a pattern of violating the requirements of section 583 of the FD&C Act that present a threat of serious adverse health consequences or death to humans; (2) been found to have committed or facilitated commission of any prohibited acts under the FD&C Act or violated or facilitated any violations of any of the regulations in this part or analogous provisions of the State licensing authority, as applicable; (3) been convicted of any violation Federal, State, or local laws relating to drug samples, wholesale or retail drug distribution, distribution of controlled substances, or 3PL services; or (4) been convicted of any felony under Federal, State, or local laws involving or related to prescription drugs. FDA believes that wholesale distributors should consider an applicant's history of violations of the FD&C Act or other laws involving prescription drugs when making staffing decisions.

7. Wholesale Distributor Storage and Handling of Prescription Drugs, and Required Policies and Procedures

The DSCSA charges FDA with creating national standards for the storage and handling of prescription drugs by wholesale distributors, including facility requirements (section 583(b)(1) of the FD&C Act). To ensure confidence that the prescription drug delivered maintains its quality and integrity throughout the distribution process, FDA believes that wholesale distributors should establish and maintain quality systems that encompass the organizational structure, account for potential vulnerabilities or threats to the systems, and clearly articulate the procedures and processes for all wholesale distribution activity. A proper quality system should be fully documented, and the effectiveness of the system should be continually monitored to ensure the quality is maintained. This includes ensuring that facilities and equipment are properly maintained for their purposes of storing and distributing prescription drugs; that personnel are properly qualified, screened, and trained for their positions; and that documentation is comprehensive. Regular management review of all aspects of the quality systems in place is important for maintaining these high standards. FDA proposes § 205.26, which establishes basic requirements that will assist wholesale distributors in achieving these goals.

Although the FD&C Act permits an entity to be more than one type of trading partner so long as it complies with all the applicable requirements (section 582(a)(1) of the FD&C Act), FDA believes that the processes and functions of each type of entity need to be kept separate for the licensing authority to ensure the entity is complying with all the applicable requirements. Accordingly, FDA is proposing that any wholesale distributor's facility that is also licensed or registered as another trading partner and operating from the same address must have separate systems and processes in place for their separate functions (see proposed § 205.26(a)).

FDA believes that proper storage and handling of prescription drugs inherently requires the establishment of standards that address physical requirements for the facility space in which drugs are stored and handled, along with standards that address the manner in which drugs are to be securely stored and handled within the facility of a wholesale distributor. In § 205.26(b), FDA proposes the following requirements with regard to standards placed on the wholesale distributor's facility. FDA believes these facility requirements will ensure that their establishments are appropriate for the distribution (including storage) of prescription drugs.

The facility must be of a suitable size, configuration, and design to ensure proper storage, maintenance, and cleanliness (see proposed § 205.26(b)(1)(ii) through (iv)). The facility must also be equipped with clearly defined areas that separate drugs that are unfit for distribution, from those that are saleable to avoid potential mistakes when distributing the prescription drugs (see proposed § 205.26(b)(1)(vi)).

The facility must be sufficiently secure to protect the prescription drugs in the supply chain from possible theft or diversion (see proposed § 205.26(b)(2)). Facilities must protect against unauthorized entry and ensure that the premises are well lit and not vulnerable to intrusion (see proposed § 205.26(b)(2)(i) through (iii)). Entry and access to areas where prescription drugs are held within the facility must be limited to those who have the appropriate experience and training needed to conduct wholesale distribution (see proposed § 205.26(b)(2)(iv)). These basic security requirements will help wholesale distributors protect and safeguard the prescription drugs maintained in their facility.

A wholesale distributor has the responsibility of ensuring that prescription drugs are stored under proper conditions to maintain the safety and effectiveness of the drugs it distributes. Accordingly, a wholesale distributor's facility must maintain appropriate equipment (*e.g.,* refrigeration and air conditioning equipment) in good working order to ensure that prescription drugs are properly stored in the facility (see proposed § 205.26(b)(3)). To this end, FDA is proposing to require that a wholesale distributor establish written procedures to ensure that its equipment is installed and maintained by qualified individuals (see proposed § 205.26(b)(3)(i)). Written policies and procedures include those that are stored and maintained electronically. Upon inspection, a wholesale distributor must demonstrate and verify that its equipment is in working order and has been periodically assessed in accordance with the wholesale distributor's written procedures to ensure the equipment's continued functionality (see proposed § 205.26(b)(3)(i)), which is critical in ensuring that those drugs retain their safety and effectiveness throughout the supply chain.

Additionally, a wholesale distributor must regularly conduct and document facility assessments to make sure that drugs are properly stored in accordance

with their labeling (see proposed § 205.26(b)(4)).

FDA expects that, as a crucial part of the creation of a quality system, wholesale distributors will establish, maintain, and follow written policies and procedures regarding the safeguarding of the prescription drugs within their control. Proposed § 205.26(c) outlines several requirements for maintaining written policies and procedures to ensure that the requirements are carried out properly and consistently. Wholesale distributors are not limited to establishing written policies and procedures for the stated functions in proposed § 205.26(c), as a wholesale distributor may wish to establish written policies and procedures pertaining to other aspects of wholesale distribution and staffing of their facilities. The purpose of requiring written policies and procedures is to assist staff and management at a wholesale distribution facility to determine the processes required to ensure safe storage and distribution of prescription drugs.

Proposed § 205.26(c) includes the requirement that wholesale distributors establish and follow written policies and procedures to ensure that a wholesale distributor: (1) Only does business with other authorized trading partners (see proposed § 205.26(c)(1)); (2) properly maintains equipment in good working order as outlined in proposed § 205.26(b)(3) (see proposed § 205.26(c)(2)); (3) transports prescription drugs in a manner designed to avoid breakage and exposure (see proposed § 205.26(c)(3)); (4) inspects shipping containers for suspect or illegitimate products, as well as other quality issues that may render the prescription drug unfit for distribution (see proposed § 205.26(c)(4)); (5) stores and handles the prescription drugs they warehouse and distribute in accordance with the prescription drug's labeling (see proposed § 205.26(c)(5)); (6) properly retains, returns, or destroys drugs removed from the supply chain depending on the proper disposition of the prescription drug (see proposed § 205.26(c)(6)); and (7) is prepared to protect against reasonably foreseeable crises that could affect security or operations at the facility (see proposed § 205.26(c)(7)).

8. Recordkeeping

Proper recordkeeping is essential to the timely identification, recording, and reporting of issues arising within the supply chain. Section 583(b)(2) of the FD&C Act requires FDA to create national standards for establishing and maintaining records pertaining to the distribution of prescription drugs. FDA is proposing in § 205.27(a) that these records include documentation pertaining to the security, storage, handling, inventory, shipping, sale, purchase, trade, delivery, and receipt of prescription drugs, as well as policies, procedures, instructions, contracts, data, inspection reports, and any other documentation related to compliance with this part, such as invoices, purchase orders, packing slips, and shipping records. These records could be stored and maintained electronically. These records maintenance requirements will allow for greater confidence in the information preserved at the facility and potentially disseminated to other trading partners.

The maintenance, availability, and accuracy of the records made available for inspection under section 583(b)(6) of the FD&C Act are critical to ensure that wholesale distributors are acting in compliance with this proposed regulation and that the records can be relied upon to identify any potential risk to the public health. As such, FDA is proposing to require that all records be securely stored, and that any alterations made to records be signed and dated, while preserving the original information contained in the record (see proposed § 205.27(b)). This is intended to ensure that all records related to the distribution of prescription drugs provide transparency and accurately reflect the activities of the wholesale distributor. FDA also believes that reliability of the records is contingent on having processes and procedures in place that restrict access to and protect the integrity of the data. To this end, FDA is proposing to require in § 205.27(c) that wholesale distributors implement written policies and procedures to protect the integrity of their records.

Under proposed § 205.27(d), all records would be retained for a period of 3 years, except records related to suspect and illegitimate products, prescription drug quality complaints, and destroyed, returned, and recalled prescription drugs, which would need to be retained for a period of 6 years. Such record retention is necessary to ensure compliance and consistent enforcement of the various record keeping requirements of sections 582, 583, and 584 of the FD&C Act.

9. Inspections

Section 583(b)(6) of the FD&C Act directs FDA to establish national standards for a mandatory physical inspection of any facility used in wholesale distribution within a reasonable time frame from the initial application (section 583(b)(6) of the FD&C Act). FDA believes that it is imperative for the mandatory physical inspection to take place prior to issuing an initial license to a wholesale distributor to ensure that only those wholesale distributors who have the ability to properly store, handle, and distribute prescription drugs in accordance with the national standards are licensed. Accordingly, in proposed § 205.28(a), wholesale distributors are required to undergo a physical inspection before the licensing authority issues the initial license. As used in subpart C, *licensing authority* means the State licensing authority or FDA. To satisfy the inspection requirement, section 583(c) of the FD&C Act permits the licensing authority to conduct the inspection or accept an inspection by the State in which the facility is located or by a third-party accreditation or inspection service approved by the licensing authority in accordance with these standards. FDA has codified this provision at proposed § 205.28(a)(1) and (2). Additionally, FDA believes that section 583(c) can be applied to State licensure of non-resident wholesale distributors to ship into a State and proposes that a State into which a drug is distributed may use the same methods to satisfy the inspection requirement for non-resident wholesale distributors (see proposed § 205.28(a)(1)(iii)). FDA believes that requiring a satisfactory inspection prior to licensure will ensure that only wholesale distributors with appropriate facilities and equipment for storing and distributing prescription drugs are granted a license to participate in the supply chain.

FDA is proposing to require that the physical inspection of wholesale distributor facilities include the facility itself, processes related to all wholesale distribution activities, and paper and electronically stored records; that wholesale distributors permit inspections at reasonable times; and that the licensing authority conduct its inspection in a reasonable manner (see proposed § 205.28(b) and (c)). FDA believes that authentication of records during an inspection is important to maintain confidence in documentation preserved by the wholesale distributor, which may contain information about nonsaleable prescription drugs or be disseminated to other trading partners.

FDA proposes that a wholesale distributor be required to make records available during inspections, including records that are held offsite in the normal course of business. The failure of a wholesale distributor to produce

records in a timely manner during an inspection can significantly affect the licensing authority's ability to complete the inspection. Therefore, FDA is proposing that a wholesale distributor be required to provide offsite records within 2 business days of a request for such records by a State or Federal official, or sooner if necessitated by the duration of the inspection (see proposed § 205.28(b)). FDA also proposes the requirement that a wholesale distributor cooperate with the State or Federal licensing authority, or the AO conducting the inspection, at reasonable times, within reasonable limits, and in a reasonable manner to achieve the objective of the inspection (see proposed § 205.28(c)).

Finally, FDA believes routine inspections are an essential tool to ensure that wholesale distributors continue to comply with the national standards after obtaining their initial wholesale distributor license and move to renew that license. Accordingly, FDA is proposing to require that wholesale distributors undergo routine inspections at least once every 3 years (see proposed § 205.28(d)). In developing the inspection timeframes, FDA sought to balance the risk to the supply chain with FDA's and State licensing authorities' resource constraints. These routine inspections allow FDA or the licensing authority to ensure that wholesale distributors maintain the levels of quality storage and maintenance of prescription drugs at their facilities expected by FDA to safeguard the supply chain.

10. Annual and Other Reporting to FDA

Under DSCSA, wholesale distributors must report certain information to FDA as part of the requirement to be considered an authorized trading partner (sections 581(2)(B) and 503(e)(2)(A) of the FD&C Act). The annual reporting requirements for wholesale distributors went into effect on January 1, 2015, and FDA has published draft industry guidance that communicates draft Agency expectations for annual reporting while these regulations are being developed (79 FR 73083, December 9, 2014, and 82 FR 3004, January 10, 2017). Proposed § 205.29 clarifies the statutorily prescribed annual reporting requirements.

The DSCSA requires that any wholesale distributor who owns or operates an establishment that engages in wholesale distribution report to FDA on an annual basis: (1) The State in which the wholesale distributor is licensed; (2) the identification number of its wholesale distributor's license; (3) the name, address, and contact information for the wholesale distributor; (4) all trade names under which the licensed wholesale distributor conducts business; and (5) any significant disciplinary actions taken against the wholesale distributor (section 503(e)(2)(A) of the FD&C Act).

FDA is proposing to require that wholesale distributors use an electronic reporting system provided by FDA (see proposed § 205.29(a)). This electronic system will increase efficiency by providing uniformity in report content and format, making the information easier to process for regularly updating the public database (section 503(e)(2)(B) of the FD&C Act). In addition, FDA believes having the license status of wholesale distributors in one publicly available database would be helpful for FDA, trading partners, and other stakeholders in determining whether wholesale distributors are authorized, as defined in section 581(2)(B) of the FD&C Act. Reporting information for each wholesale distributor in FDA's electronic system during the reporting period is integral to FDA's ability to provide oversight, as wholesale distributors are prohibited from distributing product without a license.

FDA proposes that the annual reporting schedule will require all wholesale distributors to report each calendar year between January 1st and March 31st, although an entity may update information at any time (see proposed § 205.29(b)). For example, if a wholesale distributor chooses to update a license on December 15, 2019, that wholesale distributor will still have to report during the January 1, 2020, through March 31, 2020, annual reporting period.

The specific information that wholesale distributors must electronically report to FDA is set forth in proposed § 205.29(c). The DSCSA requires licensed entities to report to FDA each State by which they are licensed and each license number (section 503(e)(2)(A)(i)(I) of the FD&C Act). FDA is proposing that the wholesale distributor also submit the expiration date of its State licenses (see proposed § 205.29(c)). The submission of the wholesale distributor's license expiration date is paramount to FDA's ability to establish and maintain a public database identifying each authorized wholesale distributor as required by section 503(e)(2)(B) of the FD&C Act. If a wholesale distributor's license expires, it is no longer an authorized trading partner, and FDA will remove it from the public database until the license is renewed or a new license issued. Similarly, FDA is proposing that a wholesale distributor be required to report to FDA within 30 calendar days that it has gone out of business or voluntarily withdrawn a wholesale distributor's license from a State (see proposed § 205.30(e)). Again, FDA believes that requiring a wholesale distributor to report this information about the status of its license is essential for FDA to comply with the requirements under section 503(e)(2)(B) of the FD&C Act and to ensure that the database is accurate and helpful for the States and trading partners.

The DSCSA also requires that wholesale distributors report the name, address, and contact information for each facility at which, and all the trade names under which, the wholesale distributor conducts business (section 503(e)(2)(A)(i)(II) of the FD&C Act). In implementing this requirement, FDA is proposing to require the wholesale distributor to provide the company name that is identical to the official company name appearing on the license, along with the full business address that is associated with the State or Federal license (see proposed § 205.29(c)(2)).

Additionally, FDA is requesting that wholesale distributors submit a UFI that corresponds with the facility name and facility address. The UFI for a wholesale distributor's facility is useful to FDA in identifying and confirming certain business information. A wholesale distributor should obtain a separate UFI for each physical address it reports. FDA has published guidance on annual reporting that can assist wholesale distributors if they require additional information regarding the UFI reporting recommendation.

In addition, FDA believes the wholesale distributor's contact information should include someone familiar with the daily operations of the wholesale distributor's facility and who has the authority to act on inquiries to ensure efficient processing of inquiries and minimize the impact inquiries may have on the facility's daily operations. Therefore, wholesale distributors must submit the contact information of the facility manager or designated representative, including that individual's name, telephone number, and email address, with its annual reporting requirements pursuant to section 503(e)(2)(A)(i)(II) of the FD&C Act.

DSCSA requires a wholesale distributor to report to FDA any significant disciplinary action taken by a State or Federal government against the wholesale distributor (section 503(e)(2) of FD&C Act). A *significant disciplinary action* is defined in the

proposed regulation, in relevant part, as any action by a State or Federal licensing authority that limits or prevents a wholesale distributor from distributing or facilitating the distribution of prescription drugs (see proposed § 205.3(l)). FDA proposes that wholesale distributors report during the reporting period to FDA all significant disciplinary actions that occurred during the preceding 12-month period (see proposed § 205.29(d)(1)). After the reporting period, FDA proposes that within 30 calendar days after a significant disciplinary action is imposed or taken by a State or Federal government, wholesale distributors report the type of disciplinary action, the date the action was taken, and the State where the disciplinary action occurred, as well as submit any documents associated with the disciplinary action, including a final ruling by the relevant State or Federal agency or board or a consent decree (see proposed § 205.29(c)(4) and (d)). While wholesale distributors do not ordinarily have to report DEA registration numbers or State controlled substances licenses to FDA for annual reporting purposes, FDA suggests that such information be provided as part of its report under section 503(e)(2)(A)(ii) of the FD&C Act when there is a significant disciplinary action issued by the DEA or the State controlled substances licensing authority that would limit the ability of the wholesale distributor to distribute controlled drug substances. In such a situation, information about the DEA registration or State controlled substance license should be reported since the disciplinary action is reported under that specific license or registration.

11. Licensure Denial, Suspension, Reinstatement and Revocation—Notice and Opportunity To Request a Hearing

The standards for licensure denial are set forth in proposed § 205.30. Proposed § 205.30(a)(1) lists 10 circumstances under which a licensing authority will be required to deny a wholesale distributor's request for licensure or licensure renewal. FDA believes that these reasons requiring denial will ensure wholesale distributors focus on good storage practices outlined by FDA and are necessary to protect the integrity of the products in the pharmaceutical distribution supply chain. Wholesale distributors should seek to ensure that these reasons outlined in proposed § 205.30(a)(1) are addressed when the wholesale distributor files for licensure to avoid denial or delays of their application.

Proposed § 205.30(a)(2) through (5) details the process afforded to wholesale distributors whose applications for licensure have been denied. FDA is proposing to give applicants the opportunity to provide additional information for reconsideration of the denial. If the licensing authority denies a wholesale distributor's request for licensure after reconsideration, the wholesale distributor will receive a notice of opportunity to request for hearing under existing FDA hearing procedure. FDA requests comment regarding the reconsideration and appeal process outlined in this regulation for wholesale distributors whose applications for licensure have been denied.

The proposed standards for suspending a wholesale distributor's license are set forth in § 205.30(b) and (c). A suspended wholesale distributor must cease all receipt and distribution of prescription drugs until their license is re-instated. The proposed standards for suspension are based on the severity of risk posed to the public health. For example, under proposed § 205.30(b), a wholesale distributor's license may be suspended only after the wholesale distributor receives a notice of opportunity for hearing. If the licensing authority has a reasonable belief that the wholesale distributor is not in compliance with licensure requirements and such noncompliance threatens the quality of the product or threatens public safety, the licensing authority is required to notify the wholesale distributor in writing of the intent to suspend its license. A wholesale distributor will have 30 days upon the date of the notice of intent to suspend a license to provide additional information to the licensing authority so it may reconsider its decision to suspend the wholesale distributor license. If reconsideration is not sought, or if reconsideration is denied, the licensing authority will inform the wholesale distributor in writing of its formal intent to proceed with license suspension. The notice will contain a statement informing the wholesale distributor that it has an opportunity to request a hearing on the question of whether there are sufficient grounds for suspension. The wholesale distributor will have 10 days after the date of the notice to inform the licensing authority of its intent to request a hearing; otherwise the opportunity for a hearing will be waived and the license suspended. FDA requests comment regarding this reconsideration and appeal process.

Proposed § 205.30(c) allows for suspension prior to notice and opportunity for a hearing and for suspension to be effective immediately if the wholesale distributor's noncompliance poses an imminent threat to public safety. For example, if a wholesale distributor is distributing illegitimate product, and once made aware, does not take corrective actions to protect the public from the threat of these products, its license could be suspended immediately. Another example would be a scenario where the conditions under which drugs are held cause the product to be illegitimate and the wholesale distributor refuses to correct the conditions or continues to ship these illegitimate products. Under the proposed regulation, if the licensing authority proceeds with suspension in such a situation, the licensing authority will inform the wholesale distributor in writing that its license is suspended. The notice will also contain a statement informing the wholesale distributor that it may request a hearing and that hearing, if granted, will be afforded within 10 days of the receipt of the wholesale distributor's request for hearing. The wholesale distributor has 10 days from the date on the notice of suspension to request a hearing; otherwise its opportunity for a hearing will be waived. FDA believes that this limits the amount of time a wholesale distributor's license would be suspended while providing a reasonable amount of time both for the wholesale distributor to review a notice of suspension and collect the necessary information to demonstrate that its license should not be suspended, and for FDA to consider the hearing request, and to schedule and prepare for a hearing, if the hearing request is granted. FDA believes immediate suspension of a wholesale distributor's license is crucial in cases where continued operation of the wholesale distributor presents an imminent threat to public safety and the pharmaceutical supply chain.

Under proposed § 205.30(d), a wholesale distributor's suspended license may be reinstated if the wholesale distributor can demonstrate to the licensing authority that it is in compliance with this proposed regulation.

Under the proposed rule the process outlined at § 10.75 is the default for appeals related to a denied application for a wholesale distributor license, and the hearing process outlined at 21 CFR part 16 is the default for appeals related to a suspended or revoked wholesale distributor license. However, the wholesale distributor may request any of the procedures contained in 21 CFR parts 10 through 16. FDA believes that

this proposed approach is consistent with current practice and suggests that States develop comparable processes.

The standards for revoking a wholesale distributor license are set forth in proposed § 205.30(e). The licensing authority will revoke a license if it finds that a wholesale distributor whose license has been suspended is unable or refuses to comply with the licensing requirements. The requirements governing the revocation of a wholesale distributor license are set forth in proposed § 205.30(e)(2) through (4) and mirror the process outlined in § 205.30(b)(2) through (7), with one exception: When the licensing authority informs the wholesale distributor of its intent to revoke a license, the wholesale distributor is given no opportunity for reconsideration since it already had an opportunity to rectify deficiencies while its license was suspended.

In addition, where a wholesale distributor fails to timely renew its application, the license will be considered expired and the wholesale distributor will need to submit an application for new licensure if it seeks to resume wholesale distribution activities, because the licensing authority may be unable to confirm that the wholesale distributor continues to meet all necessary licensure requirements (see proposed § 205.30(f)). If a wholesale distributor's license expires, it must cease receipt and distribution of prescription drugs until their license has been re-instated.

FDA is also proposing that the licensing authority will terminate a wholesale distributor's license upon request from the wholesale distributor when the request includes a notice of the wholesale distributor's intent to discontinue its activities and a waiver of an opportunity for a hearing. The wholesale distributor will be required to apply for a new license should it decide to resume wholesale distribution activities (see proposed § 205.30(g)).

F. Approved Organizations for Wholesale Distributors

1. Approval of Outside Organizations and Utilization of Such Organizations in the Licensure Process

The FD&C Act, as amended by DSCSA, allows the Federal or State licensing authority to accept inspections of wholesale distributors conducted by third-party accreditation or inspection services they have approved to be part of the licensure process (section 583(c) of FD&C Act). Subpart D of the proposed rules defines the scope of work these approved organizations (AOs) would be tasked with performing, as well as the standards an AO must meet to become approved by FDA. Additionally, this subpart will explain the circumstances in which an inspection conducted by an AO may be used, what activities the AOs have the authority to conduct and are expected to conduct, and the qualifications that each third-party organization must possess to become approved by FDA. FDA suggests that States that choose to rely on AOs to conduct inspections have in place the same or similar qualifications and processes for approved organizations to conduct those inspections and for decisions affecting the approval status of those organizations.

FDA proposes that an AO must complete an inspection no more than 90 days after receiving notice from the licensing authority to conduct an inspection (see proposed § 205.31(b)). FDA believes this allows AOs sufficient time to perform the work with which they are tasked while also ensuring that the wholesale distributor's activities are not significantly delayed or otherwise impacted due to delays in the inspection process. Upon completion of the inspection, the AO would then provide FDA with a report based on the inspection within 7 days (see proposed § 205.31(b)(2) and (3)), with copy of the report to the wholesale distributor facility (see proposed § 205.31(b)(3)). Using the report submitted by the AO, FDA makes the final determination as to whether a wholesale distributor facility should be issued a license.

It is important that FDA be able to verify an AO's continued compliance with the requirements of the proposed regulation. Therefore, to become an AO and keep its approval, FDA is proposing to require that an AO maintain certain records for a period of at least 5 years and make these records readily available to FDA upon request (see proposed § 205.31(c)). In addition, to ensure public safety, FDA is proposing to require that AOs report certain observations at wholesale distributor facilities to FDA immediately (see proposed § 205.31(c)(4)). The general qualifications for approval are set out in proposed § 205.32.

To become and remain approved, FDA is proposing to require that an organization, and those employed by the organization, abide by certain guidelines intended to secure against conflicts of interest, promote professional business practices, and protect non-public information (see proposed § 205.32(a)).

FDA is proposing to allow AOs to hire outside contractors to conduct inspections. Under FDA's proposed regulation, AOs who decide to use outside contractors must ensure that they effectively carry out the inspection in a manner consistent with this proposed regulation to protect public health, conform to conflict of interest provisions, and properly protect all non-public information (see proposed § 205.32(b)). For an AO to maintain approval, FDA proposes to require that the AO ensure contractors abide by all applicable confidentiality agreements, the AO has policies and procedures in place to ensure the contractors abide by these proposed standards, and the contractors have the necessary training and expertise to carry out inspections of wholesale distributor facilities (see proposed § 205.32(b)(1)).

Before a contractor hired by an AO may perform an inspection of a wholesale distributor, the wholesale distributor must have entered into an agreement with the AO giving the AO permission to share with contractors the wholesale distributor's confidential commercial information (see proposed § 205.32(b)(2)). If such consent is not provided by the wholesale distributor, the AO will perform the inspection itself, without the use of contractors. FDA believes that this approach is reasonable given that it is the AO's decision to work with contractors and, under this proposed regulation, the ultimate responsibility for the inspection and the protection of the wholesale distributor's information rests with the AO.

In addition, FDA proposes that AOs must submit to FDA a list of the contractors used by the organization and must certify that such contractors comply with the applicable regulations (see proposed § 205.32(b)(3)). Finally, to ensure that the standards set forth in this subpart are followed, FDA proposes to require that the AOs remain responsible for all the work performed by outside contractors (see proposed § 205.32(b)).

FDA proposes that to maintain their approved status, AOs must prohibit contractors from subcontracting their inspection duties (see proposed § 205.32(b)(1)(ii)). Limiting the ability of contactors to further delegate their responsibility ensures that FDA will have accurate information about who is conducting inspections, that those responsible for the inspections have the necessary qualifications, and that their conduct is governed by this proposed regulation.

The proposed process that FDA will use to approve organizations, including the application process, as well as the process for suspending or revoking an organization's approval, are set forth in proposed § 205.33. FDA is proposing that organizations seeking approval by

FDA must electronically submit to FDA an application demonstrating the organization's ability to assess compliance with all wholesale distributor requirements detailed in proposed part 205 (see proposed § 205.33(a) and (b)), and employees must complete the necessary training as directed by FDA (see proposed § 205.33(c)). To verify information contained in the application and ensure compliance with the proposed regulation, FDA proposes that, before an AO may conduct its first inspection, a newly approved organization must be audited by FDA (see proposed § 205.33(d)). A new approval will be valid for 5 years (see proposed § 205.33(e)).

If an organization's request for approval is denied, the organization may submit a request for reconsideration under § 10.75 (see proposed § 205.33(f)). In addition, FDA proposes that an AO may have its approval suspended if it does not maintain the standards outlined in this section (see proposed § 205.33(g)). A suspended AO must cease all inspections of wholesale distributors. A suspended AO must notify any wholesale distributors with a pending inspection to be performed by the AO of the AO's suspension within 7 calendar days (see proposed § 205.33(g)(5). While most suspensions will happen only after notice and opportunity to request a hearing, under the proposed regulations, FDA reserves the ability to suspend approval prior to a hearing if there is a reasonable probability that the organization's noncompliance will cause imminent and serious adverse health consequences or death to humans (see proposed § 205.33(h)).

Furthermore, FDA proposes that a suspended approval can be reinstated if the issue is resolved within 1 year from the date of suspension (see proposed § 205.33(i)), though it may be revoked if the organization fails to rectify the situation that resulted in the suspension (see proposed § 205.33(j)). FDA believes that 1 year provides the AO enough time to remedy most situations. An AO's approval may also be reinstated on a conditional basis. If the AO is conditionally reinstated, they will enter a three-year probationary period, during which if any material deficiencies arise, their approval will be subject to immediate revocation (see proposed § 205.33(i)(2)).

FDA also proposes to permit an AO to voluntarily withdraw its approval or otherwise cease operations as an AO under this part, but it must inform FDA of any facilities with pending inspections (see proposed § 205.33(l)). To further ensure that pending inspections are not overlooked, under FDA's proposed regulation, an AO whose approval has been suspended or revoked has the responsibility to report this information to those wholesale distributors that have pending inspections (see proposed § 205.33(m)); this will stop the clock on the 90-day licensure review while the wholesale distributor applies for inspection from another AO or FDA. Also, to ensure wholesale distributors continue to comply with the provisions of this part, and to ensure that AOs remain able to assess compliance with the wholesale distributor requirements, an AO must inform FDA of any changes to information that was submitted as part of its application for approval (see proposed § 205.33(n)(1)). Since the approval of an organization is nontransferable, changes in ownership require an AO to submit a new application to FDA (see proposed § 205.33(n)(2)). Finally, as an additional assurance that an AO continues to comply with the provisions of this part, FDA proposes to require that AOs remain subject to periodic audits by FDA (see proposed § 205.33(o)).

VI. Proposed Effective/Compliance Dates

Section 584 of the FD&C Act states that the national licensing standards for 3PLs established by regulation take effect 1 year after the date such final regulation is published (section 584(d)(1) and (3) of the FD&C Act), and that national licensing standards for wholesale distributors established by regulation take effect 2 years after the date such final regulation is published (section 583(a) and (e)(3) of the FD&C Act). For several reasons, FDA does not intend to enforce the 3PL requirements until 2 years after the final regulation is published.

FDA recognizes that 1 year may be insufficient time for States to implement 3PL licensure programs, should they decide to implement such programs, and for 3PLs to apply for licensure under these programs. Setting up a state licensure program may require additional time. This is especially true in States that will require State legislative action to implement a licensure program, with some State legislatures only meeting biennially.

As the DSCSA states that the national standards for prescription drug wholesale distributors established by regulation pursuant to section 583 of the FD&C Act will take effect 2 years after the date such final regulation is published (section 583(a) and (e) of the FD&C Act), the national standards for licensing wholesale distributors in subpart C will be effective 2 years after the date the final rule is published.

Although the DSCSA states that the national licensing standards for 3PLs established by regulation pursuant to section 584 of the FD&C Act will take effect one year after the date such final regulation is published (section 584(d)(1) and (3) of the FD&C Act), as noted, FDA does not intend to enforce requirements with respect to the national standards for licensure of 3PLs until *2* years after the regulation is finalized, in order to provide States with the opportunity to establish or modify their licensure programs in accordance with the new standards and time for 3PLs to apply and obtain a new license. For 1 year after the effective date of the final regulation, FDA also does not intend to enforce the requirements of section 582(b)(3), (c)(3), (d)(3), and (e)(3) of the FD&C Act with respect to a manufacturer, wholesale distributor, dispenser, or repackager who has as a trading partner a 3PL that is not licensed, unless the 3PL is not licensed because the Secretary or a state licensing body has made a finding that the 3PL does not utilize good handling and distribution practices and the Secretary has published notice thereof.

VII. Preliminary Economic Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We believe that this proposed rule is a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed rule could impose significant, although uncertain, new economic burdens on small entities, we find that the proposed rule will have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing

''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $158 million, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

In this rulemaking, we propose new national standards for the licensing of prescription drug wholesale distributors and third-party logistics providers as directed under the Drug Supply Chain Security Act, Title II of the Drug Quality and Security Act. If finalized, the rule would also establish a Federal licensing system for wholesale drug distributors and third-party logistics providers to use in the absence of a state licensure program that is consistent with the proposed national standards.

This rulemaking is being published in conjunction with the proposed rule entitled ''Certain Requirements Regarding Prescription Drug Marketing'' (or part 203), published elsewhere in this issue of the **Federal Register**. We include the benefits and costs of part 203 in this economic analysis and, unless otherwise specified, references to the ''proposed rule'' in this analysis encompass both proposed rules.

We summarize the benefits and costs of the proposed rule in table 1. The standards for prescription drug wholesale distribution in the proposed rule would result in benefits to consumers and benefits to distributors from reducing the diversion of prescription drugs. Other monetized benefits include cost savings from reducing the frequency and quantity of licensure applications and cost savings from reducing state licensing standards in some states. We estimate that the annualized benefits over 10 years would range from $1.25 million to $31.50 million at a 7 percent discount rate, with a primary estimate of $10.66 million. We estimate that the annualized benefits would range from $1.26 million to $32.18 million at a 3 percent discount rate, with a primary estimate of $10.89 million.

We also expect that the proposed rule, if finalized, would impose costs on wholesale drug distributors, third-party logistics providers, states, approved organizations, and the Food and Drug Administration (FDA). Costs to wholesale drug distributors and third-party logistics providers include costs of learning about the rule, reporting to FDA, undergoing routine inspections, writing and revising standard operating procedures, and conducting background checks. Wholesale-drug distributors would also incur costs to furnish surety bonds to their state licensing authority to obtain or renew their licenses.

Costs to states include the time spent reading and understanding the rule, passing or revising the laws and regulations governing their licensure programs, and inspecting WDD and 3PL facilities. Approved organizations would incur legal, application, and training costs, as well as costs to inspect WDD and 3PL facilities. FDA costs include the costs to establish and operate a reporting database and a licensure program for wholesale drug distributors and third-party logistics providers and the costs to establish and operate an approval program for approved organizations.

We estimate that the annualized costs over 10 years would range from $13.21 million to $20.63 million at a 7 percent discount rate, with a primary estimate of $16.92 million. We estimate that the annualized costs over 10 years at a 3 percent discount rate would range from $12.83 million to $20.10 million, with a primary estimate of $16.47 million.

TABLE 1—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF THE PROPOSED RULE

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Benefits:							
Annualized Monetized ($ millions/year)	$10.66	$1.25	$31.50	2020	7	10	There is a high degree of uncertainty in the magnitude of benefits.
	10.89	1.26	32.18	2020	3	10	
Qualitative.							
Costs:							
Annualized Monetized ($ millions/year)	16.92	13.21	20.63	2020	7	10	
	16.47	12.83	20.10	2020	3	10	
Qualitative.							
Transfers:							
Federal Annualized Monetized ($ millions/year)	0.12	0.09	0.14	2020	7	10	
	0.11	0.08	0.14	2020	3	10	
	From: States			To: Firms			
Other Annualized Monetized ($ millions/year)	.....	.....	.....	.....	.....	.....	
	From:			To:			

Effects:
State, Local, or Tribal Government: Annualized net costs to states over 10 years ranging from $0.62 million to $1.44 million at a 7 percent discount and from $0.58 million to $1.38 million at a 3 percent discount rate.
Small Business: Quantified effects of more than 1 percent of average annual revenues for small 3PL firms. Unquantified effects are uncertain.
Wages: No estimated effect.
Growth: No estimated effect.

We have developed a comprehensive Preliminary Economic Analysis of Impacts (PRIA) that assesses the impacts of the proposed rule. The full preliminary analysis of economic impacts is available in the docket for this proposed rule (Ref 18) and at *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

VIII. Analysis of Environmental Impacts

FDA has carefully considered the potential environmental effects of this action and has concluded, under 21 CFR 25.30(h), that this action is of a type that does not individually or cumulatively have a significant effect on the human environment.

IX. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). A description of these provisions is given in the Description section of this document with an estimate of the annual reporting, recordkeeping, and third-party disclosure burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Requirements to Obtain a License to Distribute Drugs, Annual Reporting and Recordkeeping for Procedures, for Third-Party Logistics Providers and Prescription Drug Wholesale Distributors to Obtain a License to Distribute Drugs; 21 CFR part 205; OMB Control Number 0910–0251—Reinstatement

Description: The proposed rule would establish standards, terms, and conditions for the licensing of 3PLs and prescription drug wholesale distributors by State or Federal licensing authorities, including process for the revocation, reissuance, and renewal of such licenses. Sections 584 and 583 of the FD&C Act (21 U.S.C. 360eee–3, 360eee–2)) as added by the DSCSA (Title II of Pub. L. 113–54) requires FDA to issue regulations on national standards for the licensing of 3PLs and wholesale distributors. Accordingly, FDA is proposing requirements for licensing of wholesale distributors and third-party logistics providers. The proposed rule outlines these requirements, including information collection provisions, that 3PLs and wholesale distributors must meet to obtain a license. The licensing authority is the State, from which the 3PLs distribute drug or the State from which wholesale distributors distribute drug. However, if a State does not establish the licensure programs for 3PLs or wholesale distributors consistent with these regulations, FDA will issue the licenses to 3PLs or wholesale distributors in that State. In addition, States may require that a 3PL or a wholesale distributor obtain a license to ship drugs into that State. The FD&C Act does not require that States issue these types of licenses. However, if a State chooses to implement such a licensure requirement, the State must ensure that it is consistent with these regulations, and any wholesale distributor or 3PL wishing to ship products into that State must have a license.

Proposed part 205, subpart A, would set forth the national licensing standards for State and Federal licenses issued to 3PLs pursuant to section 584 of the FD&C Act (21 U.S.C. 360eee–3). Proposed part 205, subpart C, would set forth the national licensing standards for State and Federal licenses issued to wholesale distributors pursuant to sections 503(e) and 583 of the FD&C Act (21 U.S.C. 353(e) and 21 U.S.C. 360eee–2)) and replaces the existing regulations in proposed part 205 that outlined guidelines for State licensing of wholesale distributors that were developed under the Prescription Drug Marketing Act of 1987 (Pub. L. 100–293).

In addition, the FD&C Act, as amended by DSCSA, allows FDA to approve ''third party accreditation'' entities to evaluate the qualifications of 3PLs for licensure or inspect wholesale distributors facilities on behalf of FDA. These organizations are referred to in this proposed rule as approved organizations or ''AOs.'' The application to become an AO is the same whether the AO will be evaluating the qualifications of 3PLs for licensure, inspecting wholesale distributors facilities, or both. Subparts B and D of the proposed rule outline the qualifications for AOs to perform licensure reviews/inspections for 3PL facilities and inspections of wholesale distributors respectively.

Description of Respondents: Respondents to the information collection are third-party logistics providers and wholesale distributors in any State and any entity engaging in wholesale distribution of prescription drugs in any State. We are proposing that these respondents submit applications for licensure and maintain records of procedures and documents pertaining to licensure review, inspections, policies, and training.

The DSCSA establishes 3PLs as members of the drug supply chain, which are distinct from wholesale drug distributors, and specifically precludes States from regulating 3PLs as wholesale distributors (section 585(b)(2) of the FD&C Act (21 U.S.C. 360eee–4(b)(2)). FDA is required by section 584 of the FD&C Act (21 U.S.C. 360eee–3) to establish national standards for the licensure of 3PLs and is proposing those standards in part 205, subpart A. When the proposed rule is finalized, we will require that each facility of an entity that meets the definition of a 3PL in section 581(22) of the FD&C Act (21 U.S.C. 360eee(22)) be licensed by the State or FDA in accordance with the standards articulated in proposed part 205, subpart A.

Proposed part 205, subpart C, of the proposed rule, §§ 205.20 through 205.30, establishes the national standards for the licensure of wholesale drug distributors. When the proposed rule is finalized, we will require that each wholesale distributor be licensed by the State or FDA in accordance with the standards in proposed part 205, subpart C.

Proposed part 205, subpart B (§§ 205.17 through 205.19), and subpart D (§§ 205.31 through 205.33), of the proposed rule describe the content requirements, application process, and reporting schedules to become an approved organization to conduct licensure review/inspections for 3PL facilities or conduct inspections of wholesale distributors. Although the work differs among licensure review and inspection for 3PLs and wholesale distributors, FDA believes that the same entities will apply to conduct licensure reviews and inspection of both types of entities. In addition, the submission of an application to become an AO is the same in subparts B and D. Because of this, we are combining the discussions of AOs for 3PLs and wholesale distributors, and the resulting burden estimates.

The national licensure standards FDA is proposing are intended to help ensure that the supply chain remains secure and that those finished prescription drug products subject to the DSCSA moving through the supply chain are properly stored, handled, and transported. These measures are

intended to help protect U.S. consumers from drugs that may be counterfeit, stolen, contaminated, or otherwise harmful. The required information collection to comply with the proposed rule is necessary for the States or FDA to assess the ability of 3PLs or wholesale distributors to properly maintain drug quality and security while the drug products are under their possession or control.

We estimate the burden of the information collection as follows:

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN [1]

Proposed 21 CFR part 205 section; IC activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Subpart A (3PLs):					
§§ 205.5 and 205.6; application and process requirements	459	1	459	2	918
§ 205.7; changes to licensure	6	1	6	1	6
§ 205.8; expiry and renewal of licensure	149	1	149	1	149
§ 205.9; denials, suspensions, reinstatements, revocations	35	1	35	1	35
§ 205.11; personnel list	459	1	459	.5	230
§ 205.15; annual reports	459	1	459	.25	115
Subpart B (Approved Organizations for 3PLs):					
§ 205.17; licensure review and inspection reports of 3PL facilities	6	15	90	5	450
§ 205.19; applications, denials, revocations, suspensions, renewals, reinstatements for AO status	3	1	3	2	6
Subpart C (WDD Standards):					
§§ 205.22 and 205.23; application and process requirements for licensure	1,951	1	1,951	2	3,902
§ 205.24; changes to WDD information	39	1	39	1	39
§ 205.26; confirmation of theft or loss of Rx drug	25	1	25	.5	13
§§ 205.29 and 205.30; denials, suspensions, reinstatements, revisions, and terminations—requests for hearing	38	1	38	1	38
§ 205.29(a)—WDD annual reports	1,951	1	1,951	1	1,951
Subpart D (Approved Organizations for WDDs):					
§§ 205.32 and 205.33; documentation of qualifications and disclosures to FDA	6	31	186	5	930
Total			5,890		

[1] There are no capital costs or operating and maintenance costs associated with the information collection.

TABLE 4—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Proposed 21 CFR part 205 section; IC activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Subpart A (3PLs):					
205.4; general requirements (retrievable records)	459	1	459	.5	230
205.12; written procedures	459	1	459	21	9,639
205.13; record and document maintenance	459	1	459	1	459
205.14; list of trading partners	459	1	459	2	918
Subpart B (Approved Organizations for 3PLs):					
205.17; licensure review and inspection records	6	15	90	2	180
205.19; written procedures, policies, training records	6	1	6	3	18
Subpart C (WDD Standards):					
205.21; surety bond	1,951	1	1,951	1	1,951
205.25; personnel records	1,951	1	1,951	1	1,951
205.26; facility records	1,951	1	1,951	1	1,951
205.28; inspection records	1,951	1	1,951	1	1,951
Subpart D (Approved Organizations for WDDs):					
205.31; records demonstrating qualification status	6	1	6	1	6
Total			9,742		19,254

[1] There are no capital costs or operating and maintenance costs associated with the information collection.

Reporting Burden

Among the reporting requirements found in proposed part 205 are content and format provisions pertaining to issuance, changes, expiry, renewal, and annual reports for 3PLs, as well as WDDs, as reflected above in table 3. The proposed regulations also prescribe procedural steps and reporting schedules for submitting information regarding licensure, changes to

licensure, reinstatement, and annual reporting, including requisite reporting timeframes. Consistent with our PRIA, we estimate that 459 3PL facilities and 1,951 WDDs will become subject to the reporting requirements described in proposed part 205, where we ascribe specific burden associated with the provisions found in table 3. Because we currently lack specific submission data regarding the proposed reporting requirements, we rely on our experience with similar information collection as the primary basis for our estimates. However, we invite specific comment from potential respondents regarding burden estimates we ascribe to the reporting elements found in the proposed regulations, along with a discussion of the basis for their computation.

Recordkeeping Burden

As set forth in the proposed regulations, 3PLs and WDDs must maintain records documenting procedures, management practice, policies, training, and personnel, among others. Under proposed § 205.4, all records are subject to FDA inspection and must be made available upon request in the format prescribed by the proposed regulations. Additional specific recordkeeping practice elements are also enumerated in the proposed regulations. Consistent with our PRIA, we estimate that 459 3PLs and 1,951 WDDs will become subject to these requirements, if the proposed rule is finalized. These provisions are reflected above in table 4, along with an estimated number of annual records and recordkeeping hours we attribute to the corresponding activity. As with the proposed reporting requirements, we currently lack specific data regarding recordkeeping associated with the proposed regulations. We invite specific comment from potential respondents regarding burden estimates we ascribe to the recordkeeping activities, along with a discussion of the basis for their computation.

To ensure that comments on information collection are received, OMB recommends that written comments be submitted through *reginfo.gov* (see **ADDRESSES**). All comments should be identified with the title of the information collection.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), we have submitted the information collection provisions of this proposed rule to OMB for review. These information collection requirements will not be effective until FDA publishes a final rule, OMB approves the information collection requirements, and the rule goes into effect. FDA will announce OMB approval of these requirements in the **Federal Register**.

X. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132, ''Federalism'' (64 FR 43255, August 10, 1999). This Executive order sets forth principles and criteria that agencies must adhere to in formulating and implementing policies that have federalism implications, defined in section 1(a) of the order as including regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' Section 4(a) of the Executive order requires agencies to ''construe . . . a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' The DSCSA added to the FD&C Act an express preemption provision under section 585, which addresses state licensure of WDDs and 3PLs in section 585(b)(1).

A. Scope of Preemption

FDA interprets section 585(b)(1) of the FD&C Act as preempting States and localities from establishing or continuing requirements for 3PL or WDD licensure that are different from the standards and requirements applicable under sections 584 and amended 503(e) of the FD&C Act. In other words, States and local governments may not establish or continue licensure requirements for 3PLs or WDDs unless those State requirements are the same as Federal requirements; different requirements are preempted.

As noted above, a draft guidance issued in October 2014 (Ref. 4) proposed a different preemption interpretation under which States and localities could impose requirements on 3PL and WDD licensure that were different from Federal requirements so long as those requirements did not fall below the minimum Federal standards. Several stakeholders commented that the agency's interpretation of section 585(b)(1) was too narrow. Instead, they argued Congress intended to preempt all state licensure laws not identical to Federal licensure standards, *i.e.,* that Congress wanted the Federal system to provide both a ''floor'' and a ''ceiling'' when it came to the issue of preemption.

FDA has reconsidered its earlier proposed interpretation and determined that its current interpretation—that the Federal requirements will establish both a ''floor'' and a ''ceiling''—is more consistent with the language of the statute, Congressional purpose, and policy considerations. Section 585(b)(1) provides for the preemption of any state requirements that are, among other things, ''inconsistent with'' or ''covered by'' Federal requirements—which suggests both a floor and a ceiling. Furthermore, the fundamental purpose of the DSCSA provisions was to strengthen the security and integrity of the drug supply chain through uniform national requirements (Refs 2, 3, 18), including with respect to licensure (see *e.g.,* section 583(b)). In contrast, under the interpretation proposed in our October 2014 draft guidance, 3PLs and WDDs could be required to comply with a patchwork of State and local licensure requirements, which would undermine the goal of national uniformity and could create barriers to the statute's implementation and administrability. That approach would not create the intended uniformity in national policy because States and localities would not be preempted from establishing unique or disparate requirements.

Accordingly, FDA is withdrawing, as of the date of publication of this proposed rule, that portion of the October 2014 draft guidance addressing preemption with respect to WDD/3PL licensure.

B. Effective Date of Preemption

Section 585(b)(1) provides that it is effective ''[b]eginning on the date of enactment of the Drug Supply Chain Security Act [November 27, 2013].'' However, that provision applies only to state requirements that are inconsistent with the national standards and requirements applicable under sections 584 and 503(e) of the FD&C Act. Those national standards will be established by this regulation, once finalized and effective. Thus, by its very terms, section 585(b)(1) has no current application. Accordingly, State and local licensure requirements will be preempted only once this regulation, when finalized, takes effect; until such time, current State and local licensing of WDDs and 3PLs may continue.

We believe that this result is dictated by the terms of the statute. However, even if the statute were considered ambiguous, this interpretation is consistent with the statutory framework and purposes. Other provisions added

by the DSCSA recognized state licensure of WDDs and 3PLs before the effective date of this regulation. For example, DSCSA requires both WDDs and 3PLs to report their state licensure, beginning January 1, 2015, for WDDs and November 27, 2014, for 3PLs (see sections 503(e)(2)(A) and section 584(b)). Because these reporting requirements apply during the period between DSCSA's enactment and the effective date of Federal licensing standards, they suggest that Congress intended to preserve the status quo in terms of permitting state licensure during this interim period. Indeed, if state licensing were viewed as preempted during this interim period, there could be no valid state licensure for 3PLs and WDDs to report, rendering this reporting provision meaningless. In addition, section 582(a)(6) expressly recognizes state WDD licensure during the period between DSCSA's enactment and the effective date of Federal licensure regulations, and section 582(a)(7) similarly deems 3PLs to be ''licensed'' during this time, including by acknowledging and accommodating state licensure of 3PLs.

Further, the WDD licensure rules take effect two years after publication of the final rule, per section 583(e)(3), and the 3PL rules take effect one year after publication of the final rule, per section 584(d)(3)(C). Thus, despite the reference to DSCSA's enactment date in section 585(b)(1), the statute also expressly provides that the Federal licensure standards will not be effective until several years after DSCSA's enactment.

The interpretation is also supported by reading the provisions of a statute as an integrated whole, consistent with its fundamental purpose. As noted, the purpose is to strengthen the security and integrity of the drug supply chain through uniform national requirements, including with respect to licensure. This purpose would be frustrated if the statute were implemented in a manner that could lead to supply chain disruption, due to licensing uncertainties, while the national licensure standards are pending. Thus, Congress included in the DSCSA provisions which recognize state licensure of WDDs and 3PLs prior to the effective date of Federal licensing standards. If preemption under section 585(b)(1) were construed to preempt states from continuing to license WDDs and 3PLs even before Federal standards are in place, there could be confusion whether these supply chain entities have valid licensure, to the detriment of supply chain operations. Accordingly, we believe that read as a whole, the statute can be reasonably interpreted as providing for preemption to apply only upon the effective date of this regulation, once finalized.

XI. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively determined that the rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. The Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

XII. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

* 1. 159 Cong. Rec. S8028 (2013) (Statement of Senator Barbara Mikulski); available at: *https://www.congress.gov/113/crec/2013/11/14/CREC-2013-11-14-pt1-PgS8027-6.pdf.*

* 2. 159 Cong. Rec. H5964 (2013) (Statement of Representative James Matheson); available at: *https://www.congress.gov/113/crec/2013/09/28/CREC-2013-09-28-pt1-PgH5946-2.pdf.*

* 3. 159 Cong. Rec. H5962 (2013) (Statement of Representative Robert Latta); available at: *https://www.congress.gov/113/crec/2013/09/28/CREC-2013-09-28-pt1-PgH5946-2.pdf.*

* 4. FDA, Guidance for Industry: ''Draft Guidance for Industry on The Effect of Section 585 of the FD&C Act on Drug Product Tracing and Wholesale Drug Distributor and Third-Party Logistics Provider Licensing Standards and Requirements: Questions and Answers'' October 2014, (available at *https://www.fda.gov/media/89954/download*), accessed December 14, 2021.

* 5. Ducca, A., Healthcare Distribution Management Association, Public comment letter Document ID: FDA–2014–D–1411–0012, submitted on December 24, 2014, to Docket No. FDA–2014–D–1411 pertaining to the ''Draft Guidance for Industry on The Effect of Section 585 of the FD&C Act on Drug Product Tracing and Wholesale Drug Distributor and Third-Party Logistics Provider Licensing Standards and Requirements: Questions and Answers; Availability,'' October 8, 2014 (available at *https://www.regulations.gov/document?D=FDA-2014-D-1411-0012*), accessed December 14, 2021.

* 6. Ventimiglia, V., Pharmaceutical Distribution Security Alliance, Public comment letter Document ID: FDA–2014–D–1411–0007, submitted on December 24, 2014, to Docket No. FDA–2014–D–1411 pertaining to the ''Draft Guidance for Industry on The Effect of Section 585 of the FD&C Act on Drug Product Tracing and Wholesale Drug Distributor and Third-Party Logistics Provider Licensing Standards and Requirements: Questions and Answers; Availability,'' October 8, 2014 (available at *https://www.regulations.gov/document?D=FDA-2014-D-1411-0007*), accessed December 14, 2021.

* 7. Rouse O'Neill, L., Health Industry Distributors Alliance, Public comment letter Document ID: FDA–2014–D–1411–0013, submitted on December 24, 2014, to Docket No. FDA–2014–D–1411 pertaining to the ''Draft Guidance for Industry on The Effect of Section 585 of the FD&C Act on Drug Product Tracing and Wholesale Drug Distributor and Third-Party Logistics Provider Licensing Standards and Requirements: Questions and Answers; Availability,'' October 8, 2014 (available at *https://www.regulations.gov/document?D=FDA-2014-D-1411-0013*), accessed December 14, 2021.

8. Gallenagh, E.A, L.F. Hirsch, and K.L. Palmer, ''Title II—Licensure of Wholesale Distributors and 3PLs,'' presented at Food and Drug Law Institute's Drug Quality Security Act Conference, November 15, 2017 (available at *https://www.fdli.org/wp-content/uploads/2017/11/DQSA-Hrisch-B.pdf*), accessed December 14, 2021.

9. National Association of Boards of Pharmacy, ''Wholesale Drug Distribution: Protecting the Integrity of the Nation's Prescription Drug Supply,'' August 2013 (available at *https://nabp.pharmacy/wp-content/uploads/2016/07/wholesale-drug-distribution-protecting-the-integrity-of-the-nations-prescription-drug-supply.pdf*), accessed December 14, 2021.

10. United States Department of Justice, ''Three California Men and Minnesota Corporation Indicted in Nationwide Prescription Drug Diversion Scheme,'' May 2015 (available at *https://www.justice.gov/opa/pr/three-california-men-and-minnesota-corporation-indicted-nationwide-prescription-drug*), accessed December 14, 2021.

* 11. United States Department of Justice, ''Two Plead Guilty In Prescription Drug Diversion Scheme,'' May 2014 (available at *https://www.justice.gov/usao-mdtn/pr/two-plead-guilty-prescription-drug-diversion-scheme*), accessed December 14, 2021.

12. National Association of Boards of Pharmacy, ''Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy'' (available at *https://*

nabp.pharmacy/publications-reports/resource-documents/model-pharmacy-act-rules/), accessed December 14, 2021.

13. Healthcare Distributors Alliance, ''HDA Model Licensure Standards for Third-Party Logistics Providers for FDA Consideration,'' February 2015 (available at *https://www.hda.org/~/media/pdfs/government-affairs/2015-02-10-traceability-resource-3pl-licensure-model.ashx*), accessed December 14, 2021.

* 14. World Health Organization, ''Annex 5: WHO good distribution practices for pharmaceutical products,'' 2010 (available at *https://www.who.int/medicines/areas/quality_safety/quality_assurance/GoodDistributionPracticesTRS957Annex5.pdf*)), accessed December 14, 2021.

15. National Association of Boards of Pharmacy and the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S) (available at *https://www.picscheme.org/*), accessed December 14, 2021.

* 16. U.S. Food and Drug Administration, ''Prescription Drug Marketing Act, Report to Congress,'' June 2001 (available at *https://wayback.archive-it.org/7993/20170405002846/https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendmentstotheFDCAct/PrescriptionDrugMarketingActof1987/ucm203148.htm*), accessed December 14, 2021.

17. National Association of Boards of Pharmacy, ''Prescription Medication Distribution—The Five Percent Rule for Resale (Resolution 109–2–13),'' June 2013 (available at *https://nabp.pharmacy/news/news-releases/prescription-medication-distribution-the-five-percent-rule-for-resale-resolution-109-2-13/*), accessed December 14, 2021.

18. FDA, ''National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers; Preliminary Regulatory Impacts Analysis,'' (available at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm*).

List of Subjects

21 CFR Part 10

Administrative practice and procedure, News media.

21 CFR Parts 12 and 16

Administrative practice and procedure.

21 CFR Part 205

Intergovernmental relations, Prescription drugs, Reporting and recordkeeping requirements, Security measures, Warehouses.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, we propose that 21 CFR parts 10, 12, 16, and 205 be amended as follows:

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

■ 1. The authority citation for part 10 continues to read as follows:

Authority: 5 U.S.C. 551–558, 701–706; 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–397, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

■ 2. In § 10.50, add paragraph (c)(21) to read as follows:

§ 10.50 Promulgation of regulations and orders after an opportunity for a formal evidentiary public hearing.

* * * * *

(c) * * *

(21) Sections 503(e), 583, and 584 on denial, suspension, or revocation of third-party logistics provider licenses or wholesale distributor licenses.

PART 12—FORMAL EVIDENTIARY PUBLIC HEARING

■ 3. The authority citation for part 12 continues to read as follows:

Authority: 21 U.S.C. 141–149, 321–393, 467f, 679, 821, 1034; 42 U.S.C. 201, 262, 263b–263n, 264; 15 U.S.C. 1451–1461; 5 U.S.C. 551–558, 701–721; 28 U.S.C. 2112.

■ 4. In § 12.21, revise paragraphs (a) introductory text and (a)(2) to read as follows:

§ 12.21 Initiation of a hearing involving the issuance, amendment, or revocation of an order.

(a) A proceeding under section 503(e); 505(d) or (e); 512(d), (e), (m)(3) or (4); 515(g)(1); 583; or 584 of the Federal Food, Drug, and Cosmetic Act, or section 351(a) of the Public Health Service Act, may be initiated—

* * * * *

(2) By a petition in the form specified elsewhere in this chapter, *e.g.,* § 205.9 for licenses for third-party logistics providers, § 205.30 for licenses for wholesale distributors, § 314.50 for new drug applications, § 514.1 for new animal drug applications, § 514.2 for applications for animal feeds, or § 601.3 for licenses for biologic products; or

* * * * *

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

■ 5. The authority citation for part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

■ 6. In § 16.1:

■ a. Designate the 16 undesignated paragraphs immediately following paragraph (b)(1) as paragraphs (b)(1)(i) through (xvi).

■ b. In paragraph (b)(2):

■ i. Remove ''§§ '' and ''§ '' everywhere they appear and add ''Sections'' and ''Section'' in their places, respectively;

■ ii. Designate the first 14 undesignated paragraphs immediately following paragraph (b)(2) as paragraphs (b)(2)(i) through (xiv);

■ iii. Add paragraphs (b)(2)(xv) and (xvi); and

■ iv. Designate the last 23 undesignated paragraphs as paragraphs (b)(2)(xvii) through (xxxix).

The additions read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(2) * * *

(xv) Section 205.19, relating to revocation or suspension of approval for an approved organization to conduct licensure reviews for third-party logistics provider applicants.

(xvi) Section 205.33, relating to revocation or suspension of approval for an approved organization to conduct inspections of wholesale distributors.

* * * * *

■ 7. Revise part 205 to read as follows:

PART 205—NATIONAL STANDARDS FOR THIRD-PARTY LOGISTICS PROVIDERS AND PRESCRIPTION DRUG WHOLESALE DISTRIBUTORS

Sec.
205.1 Scope.
205.2 Purpose.
205.3 Definitions.

Subpart A—Third-Party Logistics Providers Licensure Standards

205.4 Requirement that third-party logistics providers be licensed.
205.5 General application requirements for licensure.
205.6 Federal licensure process.
205.7 Changes to information, location, or ownership of a licensed 3PL.
205.8 Expiry and renewal.
205.9 Licensure denial, suspension, reinstatement, revocation, and voluntary termination: notice and opportunity to request a hearing.
205.10 Good storage practices for 3PL facilities.
205.11 Personnel requirements necessary for good storage practices.
205.12 Required written policies and procedures.
205.13 Recordkeeping and document maintenance.
205.14 3PLs must provide upon request a list of trading partners.
205.15 Requirements for initial and annual reporting to the Food and Drug Administration.
205.16 Inspections.

Subpart B—Approved Organizations for 3PLS

205.17 Use of approved third-party organizations.

205.18 General qualifications of approved organizations.
205.19 Process and procedures for approval by the Food and Drug Administration.

Subpart C—Wholesale Distributors Licensure Standards

205.20 Requirement that prescription drug wholesale distributors be licensed.
205.21 Surety bond requirement.
205.22 General application requirements for licensure.
205.23 Federal licensure process.
205.24 Changes to information, operation, location, or ownership of a wholesale distributor.
205.25 Prohibited persons and qualifications for key personnel.
205.26 National standards for the storage and handling of prescription drugs for wholesale distribution.
205.27 Standards for the establishment and maintenance of records of the distribution of prescription drugs.
205.28 Inspections.
205.29 Requirements for initial and annual reporting to the Food and Drug Administration.
205.30 Licensure denial, suspension, reinstatement, revocation, and voluntary termination—notice and opportunity to request a hearing.

Subpart D—Approved Organizations for Wholesale Distributors

205.31 Use of approved third-party organizations.
205.32 General qualifications of approved organizations.
205.33 Process and procedures for approval by the Food and Drug Administration.

Authority: 21 U.S.C. 351, 352, 353, 360eee–2, 360eee–3, 360eee–4, 371, 374.

§ 205.1 Scope.

(a) This part applies to the licensure of third-party logistics providers (3PLs) in any State and to any entity engaging in wholesale distribution of prescription drugs in any State. The standards established under subpart A of this part will apply to all State and Federal licenses described under sections 503(e)(5) and 584 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(e)(5) and 360eee–3). The standards established under subpart C of this part will apply to all State and Federal licenses described under sections 503(e)(1) and 583 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(e)(1) and 360eee–2).

(b) A facility or entity that conducts 3PL activities must obtain a 3PL license for each facility as described in this part and is not required to obtain a license as a wholesale distributor unless it is also conducting wholesale distribution activities, in which case, the entity or facility must obtain both a 3PL license as described in subpart A of this part and a wholesale distributor license as described in subpart C of this part. Unless otherwise noted, the term ''3PL'' or ''third-party logistics provider'' in this part applies to both the entity and the individual facilities requiring a license.

(c) Subpart B of this part applies to any third-party organization seeking to obtain or maintain approval by the Food and Drug Administration (FDA or the Agency) to evaluate the qualifications of 3PLs for licensure. Subpart D of this part applies to any third-party organization seeking to obtain or maintain approval by the Food and Drug Administration to conduct inspections of wholesale distributors.

§ 205.2 Purpose.

The purpose of this part is to establish standards, terms, and conditions for the licensing of 3PLs and prescription drug wholesale distributors by State or Federal licensing authorities, including a process for the revocation, reissuance, and renewal of such licenses. This part also establishes the process and standards the Food and Drug Administration will use to approve third-party organizations to evaluate the qualifications of 3PLs for licensure and conduct inspections of wholesale distributor facilities.

§ 205.3 Definitions.

The definitions and interpretations of terms contained in section 581 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360eee) apply to those terms when used in this part. The following terms are also defined for purposes of this part:

(a) *3PL activities* means the provision or coordination of warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, while not taking ownership of the product, nor having the responsibility to direct the sale or disposition of the product.

(b) *Change of entity ownership* means:

(1) *Partnership.* In the case of a partnership, the removal, addition, or substitution of a partner.

(2) *Unincorporated sole proprietorship.* In the case of an unincorporated sole proprietorship, the transfer of title and property to another party.

(3) *Corporation.* In the case of a corporation, the merger of the licensed corporation into another corporation or the consolidation of two or more corporations, resulting in the creation of a new corporation. Transfer of corporate stock or the merger of another corporation into the licensed corporation does not constitute change of entity ownership.

(4) *Limited liability company (LLC).* In the case of an LLC, the merger of the licensed LLC into another LLC or the consolidation of two or more LLCs, resulting in the creation of a new LLC. Transfer of company stock or the merger of another LLC into the licensed LLC does not constitute change of ownership.

(c) *Co-licensed partner* means one of two or more entities that have entered a written agreement for the right to engage in the marketing of a prescription drug.

(d) *Designated representative* means an individual who is designated as the representative of the facility manager and is responsible for managing the daily operations of the wholesale distributor or 3PL facility.

(e) *Entity* or *entities* means a business organization, such as a corporation, company, association, firm, partnership, society, sole proprietorship, or joint stock company.

(f) *Facility* means an establishment, warehouse, structure, or structures under common ownership at one general, permanent, physical location used for distribution, including storage and handling, of prescription drugs.

(g) *Key personnel* means any individual who has responsibility for managing the operations of the wholesale distributor, including any principal, owner, director, officer of the wholesale distributor, facility manager, or designated representative, or other individuals who are authorized to enter areas where prescription drugs are held and are likely to handle those prescription drugs as a part their responsibilities within the operation.

(h) *Minimal quantities* means the total annual dollar volume of prescription drugs sold by a retail pharmacy to licensed practitioners for office use does not exceed 5 percent of the total dollar volume of that retail pharmacy's annual prescription drug sales.

(i) *Other logistics services* include services provided by entities that accept or transfer direct possession of products from that entity's facility within the United States and its territories on behalf of a trading partner (*e.g.,* manufacturer, wholesale distributor, dispenser) but that do not take ownership of the product nor have the responsibility to direct a product's sale or disposition. ''Other logistics services'' also means services undertaken with respect to a product for a repackager acting on behalf of a manufacturer, wholesale distributor, or dispenser.

(j) *Other than a consumer* or *patient* means the person receiving the drug is not:

(1) The individual identified as the recipient of the prescription drug;

(2) A dispenser fulfilling a specific patient need as defined in section 581(19) of the Federal Food, Drug, and Cosmetic Act; or

(3) The clinical investigator, as defined in § 312.3(b) of this chapter.

(k) *Product* means a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing (*e.g.,* capsules, tablets, lyophilized products before reconstitution).

(l) *Significant disciplinary action* means any action by a State or Federal licensing authority that limits or prevents a 3PL from conducting 3PL activities related to the distribution of prescription drugs, or limits or prevents a wholesale distributor from distributing, as that term is defined in section 581(5) of the Federal Food, Drug and Cosmetic Act, or facilitating the distribution of prescription drugs. This includes the revocation or suspension of a 3PL or wholesale distributor license, or of a registration with the Drug Enforcement Administration.

(m) *Unfit for distribution* means a prescription drug that has been identified as a drug whose sale would violate the Federal Food, Drug, and Cosmetic Act. This includes prescription drugs identified as suspect or illegitimate pursuant to section 582(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360eee–1(c)); adulterated pursuant to section 501 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351), including drugs rendered nonsaleable because conditions such as return, recall, damage, or expiry cast doubt on the drug's safety, identity, strength, quality, or purity; or misbranded pursuant to section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352).

(n) *Wholesale distribution* means the distribution of a drug subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)) to a person other than a consumer or patient, or receipt of a drug subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act by a person other than the consumer or patient, but does not include:

(1) Intracompany distribution of any drug between members of an affiliate or within a manufacturer;

(2) The distribution of a drug or an offer to distribute a drug among hospitals or other health care entities that are under common control;

(3) The distribution of a drug or an offer to distribute a drug for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the Public Health Service Act (42 U.S.C. 247d), except that, for purposes of this paragraph (n)(3), a drug shortage not caused by a public health emergency will not constitute an emergency medical reason;

(4) The dispensing of a drug pursuant to a prescription executed in accordance with section 503(b) of the Federal Food, Drug, and Cosmetic Act;

(5) The distribution of minimal quantities of a drug by a licensed retail pharmacy to a licensed practitioner for office use;

(6) The distribution of a drug or an offer to distribute a drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(7) The purchase or other acquisition by a dispenser, hospital, or other health care entity of a drug for use by such dispenser, hospital, or other health care entity;

(8) The distribution of a drug by the manufacturer of such drug;

(9) The receipt or transfer of a drug by an authorized 3PL, provided that such 3PL does not take ownership of the drug;

(10) A common carrier that transports a drug, provided that the common carrier does not take ownership of the drug;

(11) The distribution of a drug, or an offer to distribute a drug by an authorized repackager that has taken ownership or possession of the drug and repacks it in accordance with section 582(e) of the Federal Food, Drug, and Cosmetic Act;

(12) Saleable drug returns when conducted by a dispenser;

(13) The distribution of a collection of finished medical devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user (referred to in paragraphs (n)(13)(i) through (iv) of this section as a *medical convenience kit*) if:

(i) The medical convenience kit is assembled in an establishment that is registered with the Food and Drug Administration as a device manufacturer in accordance with section 510(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(b)(2));

(ii) The medical convenience kit does not contain a controlled substance that appears in a schedule contained in the Controlled Substances Act;

(iii) In the case of a medical convenience kit that includes a product, the person that manufactures the kit:

(A) Purchased such product directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer; and

(B) Did not alter the product's primary container or label as purchased from the manufacturer or wholesale distributor;

(iv) In the case of a medical convenience kit that includes a product, the product is:

(A) An intravenous solution intended for the replenishment of fluids and electrolytes;

(B) A product intended to maintain the equilibrium of water and minerals in the body;

(C) A product intended for irrigation or reconstitution;

(D) An anesthetic;

(E) An anticoagulant;

(F) A vasopressor; or

(G) A sympathomimetic;

(14) The distribution of an intravenous drug that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);

(15) The distribution of an intravenous drug used to maintain the equilibrium of water and minerals in the body (such as dialysis solutions);

(16) The distribution of a drug that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;

(17) The distribution of medical gas, as defined in section 575 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ddd);

(18) Facilitating the distribution of a product by providing solely administrative services, including processing of orders and payments; or

(19) The transfer of a product by a hospital or other health care entity, or by a wholesale distributor or manufacturer operating at the direction of the hospital or other health care entity, to a repackager as described in section 581(16)(B) of the Federal Food, Drug, and Cosmetic Act and registered under section 510 of the Federal Food, Drug, and Cosmetic Act for the purpose of repackaging the drug for use by that hospital or other health care entity, and other health care entities that are under common control, if ownership of the drug remains with the hospital or other health care entity at all times.

Subpart A—Third-Party Logistics Providers Licensure Standards

§ 205.4 Requirement that third-party logistics providers be licensed.

(a) No 3PL may conduct 3PL activities unless each facility of the 3PL is licensed:

(1) By the State from which the 3PL conducts 3PL activities; or

(2) If the State from which the 3PL conducts 3PL activities has not established a licensure requirement in accordance with the standards set forth in this part, by the Food and Drug Administration; and

(3) If the product is distributed interstate, by the State into which the 3PL distributes the product if such licensure is required by that State, and the 3PL is not licensed by the Food and Drug Administration under § 205.6.

(b) Each facility owned, leased, or rented by a 3PL must have a separate license.

(c) Licenses are facility- and owner-specific and are not transferable.

(d) The 3PL must maintain its license at the licensed facility in a readily retrievable manner and must permit inspection of the license by any official, agent, or employee of the licensing authority or of any Federal, State, or local agency engaged in enforcement of laws relating to the distribution of prescription drugs.

§ 205.5 General application requirements for licensure.

(a) *Applicant requirements.* An individual who submits an application on behalf of a 3PL for a license issued pursuant to this subpart must:

(1) Be 18 years of age or older;

(2) Submit an affidavit that such individual's ownership or management of or employment by the 3PL would not preclude the 3PL from receiving or maintaining a license under § 205.11(f);

(3) Submit all application information required in the form required by the licensing authority; and

(4) Pay any licensing fees that are required by the licensing authority pursuant to section 584(c) of the Federal Food, Drug, and Cosmetic Act.

(b) *General requirements for licensure application.* The State or Federal licensing authority will require the following information from each 3PL facility as part of the initial application for the license described in § 205.4 and as part of any renewal of such license:

(1) The name and title of the individual who submits the application for licensure on behalf of the 3PL;

(2) The name of the 3PL as it should appear on the license, full business address of the facility, and telephone number;

(3) All trade or business names used by the 3PL, including prior trade or business names, within the past 7 years;

(4) Name, email address, and telephone number of the 3PL's facility manager or designated representative;

(5) The type of ownership or operation of the business entity, such as a partnership, corporation, limited liability company, or sole proprietorship;

(6) The name of any owners or operators of the 3PL, including:

(i) If a sole proprietorship, the full name of the sole proprietor and the name of the business entity;

(ii) If a partnership, the name of each partner and the name of the partnership;

(iii) If a corporation, the corporate names, the names of any subsidiaries and affiliates, the name and title of each corporate officer and director, and the State of incorporation; and

(iv) If a limited liability company, the name of the limited liability company, including any subsidiaries and affiliates, the name of each member, and the State in which the limited liability company was organized; and

(7) Whether the 3PL facility manager or designated representative has ever been convicted of a felony relating to prescription drug distribution, including a conviction under section 301(i) or (k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(i) or (k)) or 18 U.S.C. 1365, relating to product tampering, together with details concerning any such events.

(c) *General requirements for renewal applications.* On the renewal application provided by the State or Federal licensing authority, the 3PL must:

(1) Certify that the 3PL has continued to meet all the standards and complied with the requirements in this subpart since the previous license was issued; and

(2) Inform the applicable licensing authority of any changes to information previously submitted pursuant to paragraph (b) of this section or § 205.6(a)(2) for which a notification was not already submitted to the licensing authority under § 205.7.

§ 205.6 Federal licensure process.

(a) *Procedures for filing an FDA application for a 3PL license.* (1) Each 3PL facility must electronically submit an application to the Food and Drug Administration for a license to conduct 3PL activities in a State if the State does not have a 3PL licensure program consistent with the standards set forth in this section. The application must include the information specified in § 205.5, along with supporting documentation that demonstrates the applicant's storage practices are sufficient to ensure the continued safety, identity, strength, quality, and purity of the products in the facility.

(2) If one or more organizations have been approved by the Food and Drug Administration to conduct a review of a 3PL's qualifications for licensure pursuant to § 205.17, the 3PL will indicate in its application to the Food and Drug Administration which approved organization (AO) it prefers to conduct its licensure review. If there is no organization approved by the Food and Drug Administration to conduct licensure review, the Food and Drug Administration will conduct the review, as described in § 205.17(b). Licensure review must consist of:

(i) Review of all documents submitted in support of the application for 3PL licensure; and

(ii) Inspection of the facility, as directed by the licensing authority pursuant to § 205.16(a) or (b).

(3) The applicant, or the applicant's agent or other authorized official, must sign the application.

(4) An application for a 3PL license will not be considered as filed until the Food and Drug Administration has received all pertinent information and fees.

(b) *Determination that licensing requirements have been met.* The Food and Drug Administration, not an AO, will determine whether the 3PL meets all the applicable requirements set forth in this part.

(c) *Notification of easily correctable deficiencies.* The Food and Drug Administration will make every reasonable effort to promptly communicate to applicants easily correctable deficiencies found in an application when those deficiencies are discovered, particularly deficiencies concerning storage, handling, distribution, or recordkeeping issues. The Food and Drug Administration will also promptly inform applicants of its need for more data or information or for changes in the application needed to facilitate the Agency's review.

(d) *Issuance of 3PL license by FDA.* Approval of a 3PL license application or issuance of a 3PL license constitutes a determination by the Food and Drug Administration that, based upon the information provided and reviewed, the 3PL meets the applicable requirements to be licensed under section 584 of the Federal Food, Drug, and Cosmetic Act. The Food and Drug Administration will approve an application and send the applicant an approval letter and license certificate if none of the reasons in § 205.9(a)(1) for refusing to approve the application applies. Applicable requirements for the maintenance of 3PL facilities to conduct 3PL activities will include but not be limited to the good storage practices set forth under § 205.10. A license is effective on the date of issuance of the license certificate.

(e) *Validity of 3PL license.* Licenses issued to 3PL facilities will remain valid until the date of expiration, unless suspended or revoked.

§ 205.7 Changes to information, location, or ownership of a licensed 3PL.

(a) Any change to any information required in this subpart, including changes to any information required pursuant to §§ 205.5, 205.6, 205.11, and 205.15, must be submitted electronically to the licensing authority within 30 calendar days after such change is effective, except where otherwise provided in this subpart.

(b) Any change in the location of a facility at which 3PL activities are conducted will require a new license and inspection of the new facility prior to its beginning operations.

(1) The application for a new license required by § 205.5 must be submitted no later than 90 calendar days prior to beginning operations at the new location.

(2) On the date the change of location takes place, the license for the original facility is void.

(c) Any change in the entity engaged in 3PL activities in a facility will require a new license prior to beginning operations.

(1) The application for a new license required by § 205.5 must be submitted no later than 30 calendar days prior to the change in ownership.

(2) A new inspection of the facility may also be required at the licensing authority's discretion.

(3) A 3PL can continue to operate under the original license for 30 calendar days after the change of ownership occurs or until the license application of the new owner is approved, whichever is sooner.

§ 205.8 Expiry and renewal.

Any license issued or renewed pursuant to § 205.5 or § 205.6 will expire 3 years after the date issued. A 3PL renewal application will not be accepted more than 90 calendar days before the date of expiration. A 3PL will not be penalized for administrative delay on the part of the licensing authority in issuing a new license. A license will be considered valid during the period of the administrative delay if the 3PL timely submitted the renewal application.

§ 205.9 Licensure denial, suspension, reinstatement, revocation, and voluntary termination: notice and opportunity to request a hearing.

(a) *Denial of application for licensure.* (1) The licensing authority will refuse to approve or renew a 3PL license application for any of the following reasons:

(i) The facilities and controls used for the receipt, security, storage, inventory, shipment, or distribution of the product are inadequate to facilitate safe operations pursuant to § 205.10(b).

(ii) The methods or procedures to be used in the receipt, security, storage, inventory, shipment, or distribution of the product do not comply with the requirements for good storage practices in § 205.10.

(iii) The personnel employed by the applicant do not meet the requirements necessary for good storage practices in § 205.11.

(iv) There is insufficient information in the written policies and procedures required in § 205.12 to determine whether the methods or procedures to be used in the receipt, security, storage, inventory, shipment, or distribution of the product comply with the requirements for good storage practices in § 205.10, or to determine whether the facilities and controls to be used in the receipt, security, storage, inventory, shipment, or distribution of the product facilitate safe operations.

(v) The methods or procedures to be used in the receipt, storage, handling, or distribution of the product do not comply with the requirements for adequate recordkeeping in § 205.10 or § 205.13.

(vi) The application contains an untrue statement of material fact.

(vii) The applicant does not permit a properly authorized officer or employee of FDA, a State licensing authority, or an organization approved by the Food and Drug Administration pursuant to § 205.17 an adequate opportunity to inspect the facilities, controls, and any records relevant to the application.

(viii) For renewal applications, failure to report to the licensing authority any pertinent change of information required in § 205.5 or § 205.7.

(ix) For renewal applications, failure to comply with any of the requirements for annual reporting in § 205.15.

(2) If a 3PL's application fails to demonstrate that the 3PL meets the requirements for licensure set forth in this part, the licensing authority will provide written notice to the applicant that its license application may be denied, setting forth the grounds for the denial and an opportunity to demonstrate that the 3PL meets the requirements for licensure.

(3) The notice will inform the applicant of its right to provide additional information and request reconsideration of the denial by the licensing authority within 14 calendar days of the date of the licensing authority's written notice.

(4) If no reconsideration is sought or if, upon reconsideration, the licensing authority denies the applicant's request for licensure, the licensing authority will provide the applicant written notice of the denial and will provide the applicant notice of the opportunity to request a hearing.

(5) The applicant who wishes to request a hearing has 10 calendar days after the date of the notice of denial to submit a written notice of participation and request for a hearing. The applicant who fails to submit a written notice of participation and request for a hearing within 10 calendar days waives the opportunity for a hearing.

(6) Parts 10 through 16 of this chapter apply to 3PL licenses issued by the Food and Drug Administration under section 584 of the Federal Food, Drug, and Cosmetic Act.

(b) *Suspension of license after notice and opportunity to request a hearing.* (1) The licensing authority may move to suspend a license if the licensing authority has a reasonable belief that the licensee has failed to comply with any of the standards for receiving and maintaining licensure described in this subpart.

(2) The licensing authority will provide written notice of intent to suspend a 3PL license setting forth the grounds for the suspension pursuant to this part, including what information would be required to demonstrate or achieve compliance. The notice will inform the applicant of its right to provide additional information, request reconsideration of the suspension by the licensing authority, and demonstrate or achieve compliance before suspension.

(3) Each 3PL license holder has 30 calendar days from the date of the notice of intent to suspend to present, in writing, comments and information bearing on the initial decision.

(4) If no comments or information are received within 30 calendar days or if, upon reconsideration, the licensing authority believes the 3PL license should still be suspended, the licensing authority will provide the 3PL a second written notice of the intent to suspend, informing the 3PL of the opportunity to request a hearing on the question of whether there are grounds for suspension.

(5) The written notice will contain a statement that the 3PL will be afforded an opportunity to request a hearing.

(6) The 3PL must submit a written notice of participation and request a hearing in writing within 10 calendar days after the date of notice of the intent to suspend. A 3PL that fails to submit

a written notice of participation and request for hearing within 10 calendar days waives the opportunity for a hearing and the license will be suspended.

(7) Parts 10 through 16 of this chapter apply to 3PL licenses issued by the Food and Drug Administration under section 584 of the Federal Food, Drug, and Cosmetic Act.

(8) If a 3PL's license is suspended and the 3PL does not demonstrate or achieve compliance to the licensing authority's satisfaction within the time period indicated in the notice of suspension, the licensing authority will move to revoke the 3PL's license.

(c) *Immediate suspension of license.* (1) The licensing authority may suspend a license effective immediately if the licensing authority reasonably believes that the licensee has failed to comply with any of the standards for receiving and maintaining licensure described in this subpart and that the nature of the noncompliance at issue would reasonably be expected to cause an imminent threat to public health.

(2) The licensing authority will provide the 3PL with written notice of immediate suspension of its license setting forth the grounds for the immediate suspension pursuant to this part, including what information would be required to demonstrate compliance, and the opportunity to request a hearing within 10 calendar days of the 3PL's request for such hearing.

(3) The 3PL must submit a written notice of participation and request a hearing in writing within 10 calendar days after the date of the written notice of immediate suspension. A 3PL that fails to submit a written notice of participation and request for hearing within 10 calendar days after the date of the written notice waives the opportunity for a hearing.

(4) Parts 10 through 16 of this chapter apply to 3PL licenses issued by the Food and Drug Administration under section 584 of the Federal Food, Drug, and Cosmetic Act.

(5) If a 3PL's license is suspended and the 3PL does not demonstrate or achieve compliance to the licensing authority's satisfaction within the time period indicated in the notice of suspension, the licensing authority will move to revoke the 3PL's license.

(d) *Reinstatement of suspended licenses.* The licensing authority may reinstate a previously suspended license upon a 3PL's showing of compliance with requirements in this part and upon such inspection and examination as the licensing authority may require.

(e) *Revocation.* (1) If compliance is not demonstrated or achieved to the licensing authority's satisfaction within the time period indicated in the notice of suspension, the licensing authority will move to revoke the 3PL's license.

(2) The licensing authority will notify the 3PL of the intent to revoke the 3PL's license, setting forth the grounds for the revocation and offering an opportunity to request a hearing on the proposed revocation.

(3) The written notice will contain a statement that the 3PL may request a hearing.

(4) The 3PL must submit a written notice of participation and request a hearing within 10 calendar days after the date of the notice of revocation. A 3PL that fails to submit a written notice of participation and request for hearing within 10 calendar days waives the opportunity for a hearing.

(5) Parts 10 through 16 of this chapter apply to 3PL licenses issued by the Food and Drug Administration under section 584 of the Federal Food, Drug, and Cosmetic Act.

(f) *Nonrenewal.* If a license is suspended and the 3PL does not submit a renewal application by the date of expiration of the suspended license, the license will be considered expired. A 3PL may not conduct 3PL activities with an expired license and must submit a new application for licensure if it wishes to conduct 3PL activities.

(g) *Voluntary termination of licensure upon request by the 3PL.* The licensing authority will terminate a 3PL facility's license upon the 3PL's request, which includes a notice of intent to discontinue its 3PL activities and waive opportunity for a hearing. A 3PL facility that voluntarily terminates licensure must obtain a new license before resuming 3PL activities.

(1) If a 3PL facility that has had its license revoked wishes to apply for a new license, that facility must submit a new license application, which may include an inspection if required by the licensing authority under § 205.16.

(2) [Reserved]

§ 205.10 Good storage practices for 3PL facilities.

(a) A facility owned, rented, or leased by a 3PL for the purpose of conducting 3PL activities must meet the storage practices for facilities required in paragraphs (b) through (d) of this section.

(b) A facility to which a 3PL license has been issued in the same name and at the same address as another trading partner, such as a wholesale distributor, must maintain separate systems and processes for products that are specific to the 3PL.

(c) A facility owned, leased, or rented by a 3PL in which 3PL activities are conducted must have suitable storage practices in place for such facility, as demonstrated by the following:

(1) *General requirements.* The facility is:

(i) Not a personal residence;

(ii) Of a suitable size, construction, and configuration to ensure proper storage and distribution of all products warehoused at the facility, including lighting, ventilation, temperature, sanitation, humidity, space, equipment, and secure conditions where products are stored;

(iii) Of a suitable size, construction, and configuration to facilitate cleaning, maintenance, proper logistics, and distribution operations, and to provide protection from intrusion; and

(iv) Maintained in a clean and orderly condition, free from infestation of any kind.

(A) A cleaning program schedule must be maintained, documented, and followed.

(B) A pest control program, which is designed to ensure that the facility is free from infestation, must be in place, and pest control records must be kept.

(2) *Areas to handle separation of products that are unfit for distribution.* The facility has:

(i) Clearly defined, designated areas separate from saleable products to quarantine suspect product, illegitimate product, and other products that are unfit for distribution until dispositioned.

(ii) Clearly defined, designated areas to handle separation of products that are returned, recalled, or expired.

(iii) For returned or recalled products, clearly defined, designated areas separate from saleable products to handle returned or recalled product.

(iv) For expired products, clearly defined, designated areas separate from saleable products from which expired product may be returned to the manufacturer or repackager or destroyed.

(3) *Security of premises.* The facility is:

(i) Designed so that designated areas of the facility where products are held are accessible only to personnel, regardless of employee or contractor status, position title, or ownership interest, who possess appropriate and verifiable experience and training necessary to safely and lawfully engage in 3PL activities; and

(ii) Equipped with adequate security to protect from vulnerabilities and potential breaches. Adequate security must include precautions taken to ensure that:

(A) The facility is secure from unauthorized entry;

(B) Access from outside the premises is limited, well controlled, and documented;

(C) The outside perimeter of the premises is well lit;

(D) The facility is equipped with an alarm system to detect and notify appropriate personnel of entry after hours; and

(E) The facility is equipped with a security system that provides suitable protection against theft and diversion of products.

(4) *Facility assessments.* Facility assessments, including temperature mapping and other assessments designed to ensure products are properly stored in accordance with their labeling, must be regularly conducted and documented.

(5) *Equipment.* Equipment must be utilized and maintained in good repair and must be suitable for 3PL activities, as demonstrated by the following:

(i) The 3PL must be able to demonstrate that all equipment has been calibrated, as applicable, and validated at regular intervals to achieve the intended results accurately, consistently, and in a manner that can be reproduced by qualified individuals following approved procedures;

(ii) The 3PL must use appropriate manual, electromechanical, or electronic temperature and humidity recording equipment or logs to document proper storage of products; and

(iii) The monitoring equipment must alert appropriate personnel in a timely manner of any deviations from the intended storage conditions.

(d) In addition to the requirements set forth in this subpart, products must be handled and stored in accordance with all applicable Federal and State laws.

§ 205.11 Personnel requirements necessary for good storage practices.

(a) The 3PL must maintain a list of officers, directors, managers, and designated representatives; a description of their duties; and a summary of their qualifications. This list must be available for review by the State or Federal licensing authority.

(b) Qualifications for the 3PL's facility manager or designated representative of such facility manager must include that the individual:

(1) Has the education, background, training, and experience necessary to perform such individual's assigned functions;

(2) Serves as the facility manager or designated representative of such facility manager for only one facility at a time; and

(3) Is actively involved in and responsible for managing the daily operations of the 3PL facility.

(c) The 3PL must provide the facility manager or designated representative adequate authorities and resources to effectively manage the 3PL's daily operations in accordance with the standards in this part.

(d) The facility manager or designated representative is responsible for managing all the daily operations of the 3PL facility, including those duties delegated to other personnel.

(e) A 3PL is prohibited from obtaining or maintaining licensure if the 3PL employs a facility manager or designated representative who has been:

(1) Convicted of any felony violation of section 301(i) or (k) of the Federal Food, Drug, and Cosmetic Act; or

(2) Convicted of any violation of 18 U.S.C. 1365, relating to product tampering.

(f) Licensure may also be denied when storage practices are not sufficient to maintain adequate security because a facility manager or designated representative of such facility manager has been:

(1) Found to have delayed or otherwise impeded an inspection by the Federal or State licensing authority or an approved third-party inspector, or if an inspector, after reasonable efforts, was unable to gain access to an establishment or a location to carry out the inspection required under § 205.16 as permitted by section 704(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a));

(2) Found to have omitted material information or furnished false or fraudulent information in an application made in connection with the distribution of prescription drugs; or

(3) Subject to licensure suspension or revocation by Federal, State, or local government for any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances.

(g) Any facility manager or designated representative will be subject to criminal background checks. The results of the background checks must demonstrate no history of criminal convictions pursuant to paragraph (e) of this section.

§ 205.12 Required written policies and procedures.

(a) *General requirements for written policies and procedures.* Every 3PL must establish, maintain, and follow written policies and procedures as described in this section and relevant to the scope of their 3PL activities. The written policies and procedures must clearly delineate the responsibilities of the 3PL and any contractors used to fulfill any of the 3PL's duties. The written policies and procedures must also describe a system by which the 3PL will monitor all processes and, if deviations occur, document and investigate to determine the root cause of the deviation in a timely manner. Such written policies and procedures must be made available to the licensing authority upon request, and the licensing authority may copy records to ensure the 3PL is following written policies and procedures.

(1) Written policies and procedures must include, but are not limited to, the following:

(i) Documentation pertaining to receipt, security, storage, handling, inventory, shipment, and distribution of products, including written policies and procedures for identifying, recording, and reporting confirmed losses, thefts, diversions, and products unfit for distribution; and

(ii) Documentation pertaining to all policies, procedures, instructions, contracts, data, inspection reports, and any other documentation related to compliance with this part.

(b) *Personnel.* The 3PL must establish, maintain, and follow written policies and procedures that ensure the qualifications of personnel are met, maintained, and documented as required in § 205.11. These written policies and procedures must be available for review by the State or Federal licensing authority, as provided in § 205.13.

(c) *Written policies and procedures.* The 3PL must maintain written policies and procedures to address receipt, security, storage, inventory, shipment, and distribution of the product.

(1) *Receipt.* The 3PL must establish, maintain, and follow written policies and procedures providing for the inspection of all shipping containers in accordance with the following standards:

(i) *Incoming shipments.* Upon receipt, each shipping container must be visually examined for identity and for conditions that would suggest the product may be unfit for distribution.

(ii) *Outgoing shipments.* Each outgoing shipment must be properly inspected for identity of the product and to ensure that there is no shipment of product that is unfit for distribution.

(2) *Security.* The 3PL must establish, maintain, and follow written policies and procedures that provide for the secured storage of products and preserve the integrity of the 3PL's data and records.

(3) *Storage.* The 3PL must establish, maintain, and follow written policies and procedures that ensure products are stored at appropriate temperatures and under appropriate conditions, in accordance with the requirements in the products' labeling, to preserve their identity, strength, quality, and purity.

(4) *Inventory.* The 3PL must establish, maintain, and follow written policies and procedures related to inventory controls that:

(i) Ensure the facility's stock is inventoried regularly to protect against diversion and against distribution of product that may be unfit for distribution;

(ii) Contain procedures to identify, investigate, document, and correct stock errors, inaccuracies, and irregularities, including product theft, loss, or diversion;

(iii) Identify, record, and report confirmed product losses or theft immediately to the owner of the products and relevant authorities; and

(iv) Ensure that the 3PL can trace the receipt and outbound distribution of a product, as well as maintain supply and inventory records.

(5) *Shipment.* The 3PL must establish, maintain, and follow written policies and procedures providing for the transportation of products in accordance with the following standards:

(i) Products must be transported in a manner that will:

(A) Protect against breakage, contamination, adulteration, and theft;

(B) Prevent exposure to conditions that may compromise their quality and integrity; and

(C) Ensure that deviations from storage requirements during transport are promptly identified, investigated, documented, and reported to the trading partner from whom the product was received and to the manufacturer to determine if further commercial distribution is appropriate.

(ii) A 3PL that outsources transportation of products to a transportation provider, such as a common carrier, remains responsible for compliance with this part while the products are in transit to the intended trading partner. Arrangements for transportation by a transportation provider must be documented and carried out in accordance with the requirements in this section.

(6) *Distribution.* The 3PL must establish, maintain, and follow written policies and procedures related to the distribution of products that:

(i) Ensure products are distributed at appropriate temperatures and under appropriate conditions in accordance with the requirements in the products' labeling to preserve their identity, strength, quality, and purity; and

(ii) Protect against diversion and against distribution of products that may be unfit for distribution.

(d) *Recalled products.* The 3PL must establish, maintain, and follow written policies and procedures to support manufacturer recalls.

(e) *Preparing for foreseeable crises.* The 3PL must establish, maintain, and follow written policies and procedures to prepare for, protect against, and address any reasonably foreseeable crises that could affect security or operations (such as strike, fire, or flood).

(f) *Products that are unfit for distribution.* The 3PL must establish, maintain, and follow written policies and procedures for handling products that are adulterated, misbranded, or otherwise unfit for distribution, as well as returned products, that:

(1) Require such products to be physically segregated from other products and dispositioned as directed by the applicable manufacturer, wholesale distributor, dispenser, or an authorized government agency and in accordance with all applicable State and Federal laws;

(2) Identify a contact person responsible for communicating with the manufacturer, wholesale distributor, dispenser, or an authorized government agency regarding nonsaleable and returned products;

(3) Include procedures to prevent products unfit for distribution from entering the supply chain through the 3PL's disposition of nonsaleable products; and

(4) Require the 3PL to document the disposition of all nonsaleable and returned products, and maintain such records for inventory accountability.

(g) *Suspect product.* The 3PL must establish, maintain, and follow written policies and procedures to quarantine or destroy a suspect product if directed to do so by the product's manufacturer, wholesale distributor, dispenser, or an authorized government agency.

(h) *Illegitimate product.* The 3PL must establish, maintain, and follow written policies and procedures to store illegitimate product in a clearly defined, designated area from which the product may be dispositioned as directed by the respective manufacturer, wholesale distributor, dispenser, or an authorized government agency.

§ 205.13 Recordkeeping and document maintenance.

(a) *Maintenance, availability, and accuracy of records and written policies and procedures.* All required records and written policies and procedures outlined in § 205.12 must:

(1) Be readily retrievable and made available to licensing authorities upon request;

(2) Be securely stored from unauthorized access or modifications;

(3) Contain only alterations signed and dated by the individual who made the alteration. Such alteration must preserve the original information and document the reason for the alteration; and

(4) Accurately reflect the name of the 3PL as it appears on the 3PL facility's license, which must match the information that is reported to the Food and Drug Administration pursuant to the Food and Drug Administration reporting requirements at § 205.15.

(b) *Record and document retention.* (1) Except for the records listed in paragraph (b)(2) of this section, all records and written policies and procedures required to be maintained by this part must be retained for a period of 3 years.

(2) Records of suspect and illegitimate products and destroyed, returned, and recalled products must be retained for a period of 6 years.

§ 205.14 3PLs must provide upon request a list of trading partners.

A list of all manufacturers, wholesale distributors, repackagers, and dispensers for which the 3PL conducts 3PL activities must be readily retrievable and made available to regulatory authorities upon request.

§ 205.15 Requirements for initial and annual reporting to the Food and Drug Administration.

(a) *Electronic reporting requirement.* The 3PL must report electronically to the Food and Drug Administration using a secure mechanism in a format the Food and Drug Administration can review, process, and archive. Information reported will be included in the Food and Drug Administration's public database for 3PLs to the extent allowable by law.

(b) *Reporting periods*—(1) *Initial reporting.* Any entity that owns or operates a facility that conducts 3PL activities must report to the Food and Drug Administration within 30 calendar days of obtaining an initial State or Federal 3PL license.

(2) *Annual reporting.* Any entity that owns or operates a facility that is licensed to engage in 3PL activities must report to the Food and Drug Administration each calendar year between January 1 and March 31.

(c) *Required information.* Information reported for each 3PL facility separately

licensed by the licensing authority must include:

(1) A complete list of States by which the 3PL facility is licensed, including the corresponding identification number and the expiration date of each such license;

(2) Name of company as it appears on the license and full business address; and

(3) All trade names or business names under which the 3PL conducts business.

(d) *Timing for significant disciplinary action reporting*—(1) *Initial reporting.* The 3PL must report to the Food and Drug Administration any significant disciplinary actions that occurred in the previous 12 months.

(2) *Subsequent reporting.* The 3PL must, within 30 calendar days of a final action taken by a State or Federal licensing authority, report significant disciplinary actions to the Food and Drug Administration.

(e) *Reporting voluntary withdrawal of a State license.* The 3PL must report to the Food and Drug Administration that it has withdrawn its license in a State within 30 calendar days after such withdrawal, including the reasons for the voluntary withdrawal of licensure.

§ 205.16 Inspections.

(a) A physical inspection of a facility owned, rented, or leased by a 3PL for conducting 3PL activities must be conducted prior to issuance of the initial license by the licensing authority.

(1) Where the State is the licensing authority, the State may conduct the inspection or may accept an inspection by a third-party accreditation or inspection service approved by the State licensing authority. If the facility is out of state, the State may conduct the inspection or may accept an inspection by the State in which the facility is located.

(2) Where the Food and Drug Administration is the licensing authority, the Food and Drug Administration may conduct the inspection or may accept an inspection by an organization approved by the Food and Drug Administration under § 205.18.

(b) Routine inspections must be conducted thereafter once every 3 years by the licensing authority, a third-party approved organization or inspection service approved by the Food and Drug Administration under § 205.18, or the State licensing the 3PL.

(c) Records described in § 205.12(a)(1) that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means must be readily available for inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable must be made available for inspection within 2 business days of a request by a State or Federal official, or sooner if necessitated by the duration of the inspection.

(d) The 3PLs must permit the Federal or State licensing authority and third-party approved organizations or inspection services approved by the Food and Drug Administration or the State to enter and inspect their facilities and to audit their records and written operating procedures.

Subpart B—Approved Organizations for 3PLS

§ 205.17 Use of approved third-party organizations.

(a) A third-party organization that has been approved by the Food and Drug Administration pursuant to § 205.18 (or ''approved organization'' (AO)) may conduct licensure review of a 3PL's qualifications for licensure and may conduct inspections of 3PLs at the periodic intervals specified in § 205.16, as directed by the Food and Drug Administration.

(b) If an organization has been approved by the Food and Drug Administration to conduct licensure review, the AO will:

(1) Conduct the licensure review, which consists of:

(i) Reviewing all documents submitted in support of the application for 3PL licensure; and

(ii) Inspecting the facility, as directed by the licensing authority;

(2) Complete the licensure review within a timeframe not to exceed 90 calendar days after receiving notice to conduct a licensure review from the Food and Drug Administration;

(3) Based on the licensure review, write a detailed document including any findings and observations in support of the AO's recommendation to the Food and Drug Administration to grant or deny licensure; and

(4) Send the original document to the Food and Drug Administration, with a copy to the 3PL, within 7 calendar days of completing the licensure review.

(c) When conducting routine inspections at periodic intervals, the AO will:

(1) Complete the inspection within a timeframe not to exceed 90 calendar days after receiving notice to conduct an inspection from the Food and Drug Administration;

(2) Based on the inspection, write a detailed document including any findings and observations in support of the AO's recommendation to the Food and Drug Administration regarding a 3PL's licensure; and

(3) Send the original document to the Food and Drug Administration, with a copy to the 3PL, within 7 calendar days of completing the inspection.

(d) To maintain approval, an organization approved by the Food and Drug Administration must:

(1) Maintain records that support the AO's initial and continuing qualifications for approval for a minimum of 5 years;

(2) Maintain the following records related to licensure reviews for a minimum of 5 years:

(i) Supporting documentation reviewed as part of a licensure review;

(ii) Licensure review and inspection reports;

(iii) Correspondence with the Food and Drug Administration and the 3PL associated with a licensure review; and

(iv) Information on the identity and qualifications of all AO personnel who contributed to the licensure review, including a certification that such personnel have complied with all applicable requirements set forth in subpart A of this part and are free of any conflicts of interest, as set forth at 5 CFR part 2635 and 18 U.S.C. 208.

(e) Records maintained by the AO must:

(1) Be readily retrievable and made available to Federal licensing authorities upon request;

(2) Be maintained and protected in accordance with all applicable laws, including those regarding protection of personal identifying information and confidential commercial information;

(3) Be secure from unauthorized access or modifications; and

(4) Contain only alterations signed and dated by the individual who made the alteration. Such alteration must preserve the original information and document the reason for the alteration.

(f) An AO must report to the Food and Drug Administration within 24 hours of discovering any evidence or observations of potential violations found at a 3PL facility during an inspection of the facility that could pose an imminent threat to the public health. Reports must be made in the manner prescribed by the Food and Drug Administration.

§ 205.18 General qualifications of approved organizations.

(a) To become and remain an AO, the organization and anyone employed by the organization, including contractors used by the organization:

(1) Must not be a current Federal or State government employee;

(2) Must not engage in prescription drug-related activities, excluding

participation in the Agency's AO program and related activities, but including and not limited to manufacturing, wholesale distribution, repackaging, relabeling, dispensing, or 3PL activities;

(3) Must disclose to the Food and Drug Administration any participation or financial interest in entities that participate in the design, manufacture, promotion, or sale of articles or activities that are predominantly FDA-regulated or are expected to result in FDA-regulated articles;

(4) Must not be owned or controlled by, or have any organizational, material, or financial affiliation with, any of the entities engaged in manufacturing, wholesale distribution, repackaging, relabeling, dispensing, 3PL activities, or the design, manufacture, promotion, or sale of prescription drugs as defined in section 581(12) of the Federal Food, Drug, and Cosmetic Act;

(5) Must enter and abide by a written agreement with the applicant before data and information otherwise exempt from public disclosure may be disclosed to the AO or a contractor;

(6) Must operate in accordance with professional and ethical business practices and applicable legal requirements, which include, but are not limited to:

(i) Protecting against conflicts of interest as set forth in 5 CFR part 2635 and 18 U.S.C. 208;

(ii) Ensuring that the personnel employed or contracted by the AO who are working on licensure reviews have sufficient education, training, knowledge, and experience to conduct licensure reviews of 3PLs;

(iii) Treating received information, records, and reports that qualify as confidential commercial information as described at 5 U.S.C. 552(b)(4) according to applicable requirements for such information;

(iv) Maintaining appropriate security and protection, physical and electronic, of any information received in relation to licensure reviews to preserve confidentiality and ensure that the release of any information is limited to authorized disclosures to either the Food and Drug Administration or the 3PL facility;

(v) Reporting information to the Food and Drug Administration and entities for which licensure reviews were conducted that accurately reflects data reviewed, inspectional observations made, and other matters that relate to compliance with the Federal Food, Drug, and Cosmetic Act; and

(vi) Promptly responding to and attempting to resolve any complaints regarding activities for which it is approved by the Food and Drug Administration; and

(7) Must establish and maintain policies, procedures, and documentation to demonstrate that, at the time of application and throughout their tenure as an AO, the applicant has satisfied and can continue to satisfy the requirements to qualify as an AO capable of assessing compliance with all 3PL requirements. Such policies, procedures, and documentation must include, but are not limited to:

(i) AO program administration;

(ii) Disciplinary actions and corrective measures;

(iii) Recordkeeping and confidentiality;

(iv) Use of contractors; and

(v) Personnel qualifications and ongoing training.

(b) If an AO elects to use contractors for licensure reviews or licensure review-related activities, the AO remains responsible for the work of the contractors at all times.

(1) AOs that use contractors to conduct licensure reviews must abide by the confidentiality agreements between the Food and Drug Administration and the AO and have policies and procedures in place to ensure the contractor's continuing compliance with this part, as well as competence and qualifications to conduct licensure reviews. Such policies and procedures must ensure that contractors:

(i) Meet the qualifications set forth in paragraph (a) of this section;

(ii) Do not subcontract their licensure review duties, and that contractors are removed if such requirement is violated;

(iii) Abide by the policies and procedures of the AO, as set forth in § 205.19(b); and

(iv) Complete and pass the same training required by the AO, as set forth in § 205.19(c).

(2) If an AO elects to use contractors to conduct licensure reviews, the AO must receive and keep a record of written consent from the 3PL to share confidential commercial information with contractors by which a licensure review is being conducted.

(3) AOs that elect to use contractors must submit to the Food and Drug Administration a list of contractors used by the organization, accompanied by a statement from the organization certifying that such contractors meet the requirements of this subpart.

§ 205.19 Process and procedures for approval by the Food and Drug Administration.

(a) *Application.* An application to become an AO must be completed and submitted electronically to the Food and Drug Administration in a format the Food and Drug Administration can review, process, and archive.

(b) *Required application information.* Policies, procedures, and documentation as required by § 205.18(a)(7) must accompany the application.

(c) *Training.* Organizations must provide training as prescribed by the Food and Drug Administration, and any individual who conducts licensure reviews or supervises individuals who conduct licensure reviews is required to undergo and pass the prescribed training.

(1) If an individual does not pass training, that person must wait 30 days before retaking the training and may be required to show proof of additional education or experiential learning to demonstrate competence before retaking the training evaluation.

(2) To maintain approval, individuals employed by the AO and conducting licensure reviews or supervising those who conduct licensure reviews must undergo and pass annual training as prescribed by the Food and Drug Administration. Failure to complete and pass annual training may result in suspension of approval of the AO.

(3) The Food and Drug Administration may require additional training. If such additional training is required, AOs will be given a set time period during which training must be completed and passed to maintain approval.

(d) *Auditing.* Prior to conducting licensure reviews, an AO must undergo an onsite audit by the Food and Drug Administration. The Food and Drug Administration may also conduct random, periodic audits, as well as for-cause audits, of an AO, as set forth in paragraph (o) of this section.

(e) *Duration of approval and renewal process.* (1) The Food and Drug Administration approval to conduct licensure reviews is valid for a period of 5 years.

(2) AOs may submit a renewal application to the Food and Drug Administration 6 months prior to the expiration date, but no later than 3 months prior to the expiration date, to renew the approval.

(i) If a renewal application is submitted less than 3 months before the date of expiration, the AO's approval will expire if approval is not renewed prior to the date of expiration.

(ii) Upon expiration of the AO's approval, the AO must cease conducting any licensure review or inspection-related activities.

(f) *Denial of approval.* If an organization does not meet all of the Food and Drug Administration's standards detailed in §§ 205.17 and 205.18 for becoming an AO, the Food and Drug Administration will deny approval of the application in writing. Requests for review and reconsideration of a denial of approval must be submitted to the Food and Drug Administration within 30 calendar days of the date of the Food and Drug Administration's decision to deny the application. If, upon reconsideration, the Food and Drug Administration denies the applicant's request for approval, the Food and Drug Administration will provide the applicant written notice of the denial and an opportunity to appeal pursuant to § 10.75 of this chapter.

(g) *Suspension of approval after notice and opportunity to request a hearing.* (1) The Food and Drug Administration may suspend approval of an organization after an opportunity to request a hearing when there is a reasonable probability that the organization's noncompliance will negatively impact public health.

(2) If an AO fails to maintain the Food and Drug Administration's standards pursuant to §§ 205.17 and 205.18, the Food and Drug Administration will give written notice of the intent to suspend the organization's approval, including the grounds for the suspension, and the AO will have 30 days to provide additional information to the Food and Drug Administration for reconsideration.

(3) If, upon reconsideration, the Food and Drug Administration still believes the AO's approval should be suspended, the Food and Drug Administration will issue the AO a written formal notice of intent to suspend, along with notice of the opportunity to request a hearing pursuant to part 16 of this chapter.

(4) An AO that wishes to request a hearing has 10 calendar days after the date of the formal notice of intent to suspend to submit a written notice of participation and request for a hearing. An AO that fails to submit a written notice of participation and request for a hearing within 10 calendar days from the date of the notice waives the opportunity for a hearing.

(5) A suspended AO must notify any 3PLs under a pending licensure review by the AO of the AO's suspension within 7 calendar days.

(h) *Immediate suspension of approval.* (1) When there is a reasonable probability that the organization's noncompliance will cause imminent and serious adverse health consequences or death to humans, the Food and Drug Administration will suspend an AO's approval effective immediately.

(2) In such a situation, the Food and Drug Administration will provide the AO a written notice of immediate suspension, along with notice and opportunity to request a hearing pursuant to part 16 of this chapter within 14 calendar days of the AO's request for such hearing.

(3) An AO that wishes to request a hearing has 10 calendar days after the date of the formal notice of suspension to submit a written notice of participation and request for a hearing. An AO that fails to submit a written notice of participation and request for a hearing within 10 calendar days waives the opportunity for a hearing.

(i) *Reinstatement of approval.* (1) An organization's approval may be reinstated if the Food and Drug Administration determines that the suspended organization has rectified the issues leading to the suspension and can meet the standards set forth in this subpart. The organization must rectify the issues and come into compliance with the standards set forth in this subpart within 1 year from the date of suspension. If the issues have not been rectified within 1 year, or if the organization otherwise has failed to come into compliance with the standards set forth in this subpart within such time period, the Food and Drug Administration may revoke the AO's approval subject to the provisions of this part.

(2) An organization whose approval has been reinstated on a conditional basis will be subject to a 3-year probationary period, and if any material deficiencies arise during that period, the organization's approval will be revoked.

(j) *Revocation of approval.* (1) The Food and Drug Administration may revoke approval of an organization whose approval has been suspended pursuant to paragraphs (g) and (h) of this section:

(i) If an organization fails to demonstrate its intent to rectify the issues leading to the suspension within 6 months from the date of suspension; or

(ii) If the Food and Drug Administration determines that the organization failed to rectify the issues leading to the suspension to the Agency's satisfaction within 1 year of the date of suspension.

(2) The Food and Drug Administration will give written notice of the intent to revoke the organization's approval, including the grounds for the revocation, and an opportunity to request a hearing pursuant to part 16 of this chapter.

(3) The AO must submit a written notice of participation and request a hearing within 10 calendar days after the date of the notice of revocation. An AO that fails to submit a written notice of participation and request for hearing within 10 calendar days waives the opportunity for a hearing.

(4) An organization whose approval has been revoked that wishes to reapply to be an AO must submit a new application to the Food and Drug Administration.

(k) *Requests for reconsideration of Agency decision.* (1) The Food and Drug Administration will follow the process outlined at § 10.75 of this chapter to review matters relating to denial of approval, including review of the organization's application.

(2) The Food and Drug Administration will follow the process outlined at part 16 of this chapter to review matters relating to a suspension or revocation action, including review of the organization's application and administrative file.

(3) The Food and Drug Administration's decision after a request for reconsideration of denial, suspension, or revocation constitutes a final Agency action under 5 U.S.C. 702.

(l) *Voluntary withdrawal of approval.* (1) An organization wishing to voluntarily withdraw its approval, including but not limited to when an AO goes out of business, must notify the Food and Drug Administration in writing at least 6 months prior to the date the organization intends for the withdrawal to become effective.

(i) If an AO determines it will be withdrawing its approval with the Food and Drug Administration in less than 6 months, it must notify the Food and Drug Administration immediately of its intent to withdraw, and such notification must inform the Food and Drug Administration of the date the organization will cease business operations.

(ii) [Reserved]

(2) No later than 7 calendar days after notifying FDA, the organization must notify any facilities with pending reviews that it intends to withdraw its approval with the Food and Drug Administration and must provide the date on which the withdrawal is effective.

(m) *AO-required notifications to 3PLs.* The AO must, within 7 calendar days of the date of suspension, revocation, or voluntary withdrawal of approval, notify those 3PL facilities that have pending licensure reviews of the AO's suspension or revocation. This

notification must inform the 3PL facility that it must apply for licensure review with another AO, or the Food and Drug Administration if no other AO is available to conduct the licensure review.

(n) *Change of operation or ownership.* (1) The AO must report to the Food and Drug Administration within 30 calendar days any changes to the information submitted in the application for approval.

(2) Approval is not transferable.

(i) Changes in ownership of an AO require the organization to submit a new application to the Food and Drug Administration.

(ii) Such application must be submitted to the Food and Drug Administration no later than 30 calendar days prior to the date of the change of ownership.

(iii) No later than 30 calendar days before the date of the change of ownership, the AO must notify any 3PL facilities with pending applications of the pending change in ownership.

(iv) On the date the change of ownership takes place, the original approval is void.

(o) *Monitoring by the Food and Drug Administration.* (1) AOs are subject to audits by the Food and Drug Administration to ensure compliance with the Food and Drug Administration's requirements for approval.

(2) If an AO refuses to cooperate with the Food and Drug Administration's audit, the organization's approval may be suspended pursuant to paragraph (g)(1) of this section.

Subpart C—Wholesale Distributors Licensure Standards

§ 205.20 Requirement that prescription drug wholesale distributors be licensed.

(a) No wholesale distributor may engage in wholesale distribution of a prescription drug unless the person is licensed:

(1) By the State from which the drug is distributed; or

(2) If the State from which the drug is distributed has not established a licensure requirement in accordance with the standards set forth in this part, by the Food and Drug Administration; and

(3) If the drug is distributed interstate, by the State into which the drug is distributed if such licensure is required by that State.

(b) Any license issued or renewed pursuant to this section will expire 2 years after the date on which the license was issued. A wholesale distributor may submit a renewal application up to 90 calendar days before the date of expiration. A license will be considered valid during any period of the administrative delay on the part of the licensing authority, if the wholesale distributor timely submitted the renewal application.

§ 205.21 Surety bond requirement.

(a) *Surety bond compliance.* No wholesale distributor will be licensed under this section unless the wholesale distributor has furnished a bond, or other equivalent means of security acceptable to the State if the State is the licensing authority, that complies with the requirements of this section.

(b) *Surety bond requirements.* (1) For the issuance or renewal of a wholesale distributor license, an applicant that is not a government-owned and -operated wholesale distributor must submit to the licensing authority a surety bond from an authorized surety company of $100,000 or other equivalent means of security acceptable to the State. The term of the initial surety bond must be effective on the date that the application is submitted to the licensing authority.

(2) The licensing authority may accept a surety bond from an authorized surety company in the amount of $25,000 if the annual gross receipts of the previous tax year for the wholesale distributor are $10,000,000 or less.

(3) If a wholesale distributor can provide evidence that it possesses the required bond in the State where the wholesale distributor is located, the requirement for a bond in another State for a non-resident wholesale distributor license will be waived.

(c) *Terms of the surety bond.* (1) The terms of the bond submitted by a wholesale distributor must on its face reflect the requirements of this section, including meeting the requirements of liability coverage ($100,000 or $25,000, as applicable), as well as the responsibilities of the surety company and wholesale distributor as set forth in this section.

(2) The bond must be continuous and remain in full force and effect, running concurrently with the license period and for every succeeding licensing period for which the wholesale distributor may be licensed. The bond must remain in full force and effect until 1 year after the license expires, after which liability for license administrative fees ceases except as to any liability or indebtedness incurred or accrued before the termination date.

(3) The bond must guarantee that after receiving written notice from the licensing authority containing sufficient evidence to establish the surety's liability under the bond, the surety company will pay within 30 calendar days any administrative fines or penalties imposed by the licensing authority on the wholesale distributor holding the surety bond in that State. This includes any fees and costs incurred by the licensing authority regarding that license authorized by law and which the wholesale distributor fails to pay within 30 calendar days after the fine or costs become final. Any such claim may be made directly to the surety company and need not be preceded by the filing of any action in a proper court.

(4) The licensing authority may make a claim against the surety bond until 1 year after the date of expiration on the wholesale distributor's license or until 60 calendar days after any administrative or legal proceeding, which involved the wholesale distributor, is concluded, including any appeal, whichever occurs later.

(d) *Cancellation of a bond and lapse of surety bond coverage.* (1) A wholesale distributor may cancel its surety bond and must provide written notice 30 calendar days before the effective date of the cancellation to all applicable licensing authorities and the surety company.

(2) Cancellation of a surety bond is grounds for suspension of the wholesale distributor's license unless the wholesale distributor provides a new bond before the effective date of the bond's cancellation. If a new surety bond is provided before the effective date of the bond's cancellation, the liability of the surety company continues until the cancellation date. Otherwise, the liability of the surety company continues for 1 year after the date of cancellation, after which liability ceases except as to any liability or indebtedness incurred or accrued before the cancellation date.

(3) The wholesale distributor must immediately notify the licensing authority if there is a lapse in the wholesale distributor's surety coverage.

(4) If the licensing authority discovers a lapse in bond coverage that has not been previously disclosed by the wholesale distributor, the wholesale distributor's license will be suspended pursuant to § 205.30.

(e) *Actions under the surety bond.* The bond must provide that actions under the bond may be brought by a State or Federal licensing authority.

(f) *Required surety company information on the surety bond.* The bond must provide the surety company's name, street address or post office box number, city, State, and zip code.

(g) *Change of surety company.* A wholesale distributor that obtains a replacement surety bond from a different surety company to cover the remaining term of a previously obtained bond must submit the new surety bond to the licensing authority 30 calendar days prior to the expiration of the previous surety bond. There must be no gap in the coverage of the surety bond periods.

(h) *Parties to the surety bond.* The surety bond must name the wholesale distributor as Principal, the licensing authority as obligee, and the surety company (and its heirs, executors, administrators, successors, and assignees, jointly and severally) as surety.

§ 205.22 General application requirements for licensure.

(a) *Applicant requirements.* An individual who submits an application on behalf of a wholesale distributor for a license issued pursuant to this subpart must:

(1) Be 18 years of age or older;

(2) Submit an affidavit that their ownership or management of or employment by the entity would not preclude the entity from receiving or maintaining a license under § 205.25(a);

(3) Submit all application information required in the form required by the licensing authority; and

(4) Pay any licensing fees that are required by the licensing authority pursuant to section 503(e)(3) of the Federal Food, Drug, and Cosmetic Act.

(b) *Surety bond requirement.* The wholesale distributor must furnish a bond, or other equivalent means of security acceptable to the State, with the application for licensure in accordance with the surety bond requirements in § 205.21.

(c) *General requirements for licensure application.* The State or Federal licensing authority will require the following information from each wholesale distributor as part of the initial application for the license described in this section and as part of any renewal of such license:

(1) The name and title of the individual who submits the application for licensure on behalf of the wholesale distributor;

(2) The name of the wholesale distributor as it should appear on the license and the full business address and telephone number of the wholesale distributor;

(3) All trade or business names used by the wholesale distributor, including prior trade or business names, within the past 7 years;

(4) Name, email address, and telephone number of the designated representative or facility manager for the wholesale distributor;

(5) The type of ownership or operation of the business entity, such as a partnership, corporation, limited liability company, or sole proprietorship;

(6) The name of any owners or operators of the wholesale distributor, including:

(i) If a sole proprietorship, the full name of the sole proprietor and the name of the business entity;

(ii) If a partnership, the name of each partner and the name of the partnership;

(iii) If a corporation, the corporate names, the names of any subsidiaries and affiliates, the name and title of each corporate officer and director, and the State of incorporation; and

(iv) If a limited liability company, the name of the limited liability company, including any subsidiaries and affiliates, the name of each member, and the State in which the limited liability company was organized;

(7) Whether the wholesale distributor has ever been convicted of a felony relating to wholesale drug distribution, a felony conviction of section 301(i) or (k) of the Federal Food, Drug, and Cosmetic Act, or a felony conviction of 18 U.S.C. 1365, relating to product tampering, together with details concerning any such events; and

(8) Whether the wholesale distributor has received any citations for violating requirements for licensure within the past 7 years or has received any significant disciplinary actions within the past 7 years that presented a threat of serious adverse health consequences or death to humans, together with details concerning any such events.

(d) *General requirements for licensure renewal.* To renew a license, the wholesale distributor must submit the following to the renewing licensing authority:

(1) Certification that the wholesale distributor has continued to meet all the standards and complied with the requirements in this subpart since the previous license was issued; and

(2) Information about any changes to information previously submitted under this section, or § 205.21, or § 205.23(c) for which a notification was not already submitted to the licensing authority under § 205.24.

(e) *License availability requirement.* The wholesale distributor must maintain its license in a readily retrievable manner and must permit inspection of the license by any official, agent, or employee of the licensing authority or of any Federal, State, or local agency engaged in enforcement of laws relating to the distribution of prescription drugs.

§ 205.23 Federal licensure process.

(a) *Procedures for filing an FDA application for a wholesale distributor license.* (1) All wholesale distributors must electronically submit an application to the Food and Drug Administration for a license to engage in wholesale distribution if the State does not have a licensing program for wholesale distributors consistent with the standards set forth in this section. The application must include the information in §§ 205.21 and 205.22, along with a surety bond and supporting documentation that demonstrates the applicant's ability to comply with requirements intended to ensure the continued safety, identity, strength, quality, and purity of the prescription drugs.

(2) If one or more organizations have been approved by the Food and Drug Administration under § 205.32 to conduct inspections of wholesale distributors, the wholesale distributor will indicate in its application to the Food and Drug Administration which AO it prefers to conduct its inspection.

(3) If there is no organization approved by the Food and Drug Administration to conduct inspections for wholesale distributors, the Food and Drug Administration will conduct the inspection, as described in § 205.28(b).

(4) The applicant, or the applicant's agent or other authorized official, must sign the application.

(5) An application for a wholesale distributor license will not be considered as filed until the Food and Drug Administration has received all required information and fees.

(b) *Determination that licensing requirements have been met.* The Food and Drug Administration, not an AO, will determine whether the wholesale distributor meets all the applicable requirements set forth in this part.

(c) *Notification of easily correctable deficiencies.* The Food and Drug Administration will make reasonable efforts to promptly communicate to applicants easily correctable deficiencies found in an application when those deficiencies are discovered. The Food and Drug Administration will also promptly inform applicants if more data or information is needed to facilitate the Agency's review.

(d) *Issuance of wholesale distributor license by FDA.* Approval of a wholesale distributor license application or issuance of a wholesale distributor license constitutes a determination by the Food and Drug Administration that, based upon information received, the

wholesale distributor meets the applicable requirements to be licensed under sections 503(e)(1) and 583 of the Federal Food, Drug, and Cosmetic Act. The Food and Drug Administration will approve an application and send the applicant an approval letter and license certificate if none of the reasons in § 205.30(a)(1) for refusing to approve the application applies. Applicable requirements for wholesale distributors to engage in wholesale distribution must include but not be limited to the good storage practices set forth under § 205.26. A license is effective on the date of issuance of the license certificate.

(e) *Validity of a wholesale distributor license.* Licenses issued to a wholesale distributor will remain valid until the date of expiration, unless suspended or revoked.

§ 205.24 Changes to information, operation, location, or ownership of a wholesale distributor.

(a) Any change to any information required in this subpart, including changes to any information required pursuant to §§ 205.21, 205.22, and 205.25, must be submitted electronically to the licensing authority within 30 calendar days after such change is effective, except where otherwise provided in this subpart.

(b) Any change in the location of a wholesale distributor at which wholesale distribution occurs will require an inspection of the new facility prior to the wholesale distributor beginning operations at the new facility.

(1) On the date the change of location takes place, the wholesale distributor may not engage in wholesale distribution at the original facility.

(2) [Reserved]

(c) Any change in the person engaged in wholesale distribution will require a new license prior to beginning operations.

(1) The application for a new license required by § 205.23 must be submitted no later than 30 calendar days prior to the change in ownership.

(2) A new inspection of the wholesale distributor will be performed within a reasonable time.

(3) A wholesale distributor can continue to operate under the original license for 30 calendar days after the change of ownership occurs or until the license application of the new owner is approved, whichever is sooner.

§ 205.25 Prohibited persons and qualifications for key personnel.

(a) A wholesale distributor is prohibited from obtaining or maintaining licensure if the wholesale distributor has been:

(1) Convicted of any felony for violation of section 301(i) or (k) of the Federal Food, Drug, and Cosmetic Act;

(2) Convicted of any felony violation of 18 U.S.C. 1365 relating to product tampering; or

(3) Cited on two or more occasions within the previous 7 years for violating one or more of the requirements of section 583 or section 503(e) of the Federal Food, Drug, and Cosmetic Act or State requirements for licensure in such a way that presents a threat of serious adverse health consequences or death to humans.

(b) All key personnel must have the education, background, training, and experience necessary to perform his or her assigned functions.

(c) Licensure may also be denied when an applicant wholesale distributor or any of their key personnel has been:

(1) Found to have delayed or otherwise impeded an inspection by the Federal or State licensing authority or an approved third-party inspector, or an inspector, after reasonable efforts, was unable to gain access to an establishment or a location to carry out the inspection required under § 205.28, as permitted by section 704(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a));

(2) Found to have omitted material information or furnished false or fraudulent information in an application made about the distribution of prescription drugs; or

(3) Subject to licensure suspension or revocation by Federal, State, or local government for any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances.

(d) The wholesale distributor must maintain a list of officers, directors, facility managers, designated representatives, and other key personnel in charge of wholesale distribution, including storage and handling, and include a description of their duties and a summary of their qualifications. This list must be available for review by the State or Federal licensing authority.

(e) The wholesale distributor must establish and implement written policies and procedures designed to ensure that the qualifications of key personnel as required in this section are met, maintained, and documented. These written policies and procedures must be available for review by the State or Federal licensing authority, as provided in § 205.27. These policies and procedures must identify the personnel at the wholesale distributor's facility who are responsible for the following actions:

(1) Implementing and maintaining all facility and personnel requirements;

(2) Ensuring that the facility complies with all licensure and reporting requirements; and

(3) Ensuring that key personnel receive initial and regular training to ensure competence relevant to their job functions.

(f) In addition to the qualifications for key personnel in paragraphs (a) through (e) of this section, a facility manager or designated representative must have the following qualifications to carry out those responsibilities:

(1) Serves as the facility manager or designated representative of such facility manager for only one facility at any one time;

(2) Is actively involved in and responsible for managing the daily operations of the wholesale distributor facility; and

(3) Remains responsible for all facility manager or designated representative duties that are delegated to other personnel at the facility.

(g) Any facility manager or designated representative, prior to their association, employment, or contracting with the wholesale distributor as a facility manager or designated representative, must submit a full set of fingerprints for purposes of conducting local and national criminal background checks. The results of the background checks must demonstrate no history of criminal convictions pursuant to paragraph (a) of this section.

§ 205.26 National standards for the storage and handling of prescription drugs for wholesale distribution.

Any facility owned, rented, or leased by a wholesale distributor for engaging in wholesale distribution must meet the facility requirements in paragraphs (a) and (b) of this section, and the wholesale distributor must establish, maintain, and follow policies and procedures as set forth in paragraph (c) of this section.

(a) A wholesale distributor to which a license has been issued in the same name and at the same address as another authorized trading partner, such as a 3PL, must maintain separate systems and processes for the distribution of drugs that are specific to the wholesale distributor.

(b) The facility the wholesale distributor owns, leases, or rents for purposes of engaging in wholesale distribution must be suitable for the storage and handling of prescription drugs, as demonstrated by the following:

(1) *General requirements.* The facility is:

(i) Not a personal residence;

(ii) Of a suitable size, construction, and configuration designed to ensure proper distribution, including storage and handing, of all prescription drugs stored at or distributed from the facility;

(iii) Of a suitable size, construction, and configuration to facilitate cleaning, maintenance, and proper wholesale distribution operations;

(iv) Maintained in a clean and orderly condition, free from infestation of any kind;

(v) Equipped with sufficient lighting, ventilation, temperature, sanitation, humidity, space, equipment, and secure conditions for prescription drug storage; and

(vi) Equipped with clearly defined designated areas that separate saleable prescription drugs from prescription drugs that are unfit for distribution.

(2) *Security of premises.* The facility must be equipped with adequate security to prevent breaches. Adequate security includes ensuring that:

(i) The facility is secure from unauthorized entry;

(ii) Access from outside the premises is limited, well controlled, and documented;

(iii) The outside perimeter of the premises is well lit;

(iv) Entry into areas where prescription drugs are held is limited to key personnel who possess appropriate and verifiable experience and training necessary to safely and lawfully engage in the distribution of prescription drugs, as described in § 205.25, and to staff for purposes of maintenance and cleaning; and

(v) The facility is equipped with a security system that protects against theft and diversion of prescription drugs and accidental or unsanctioned modifications to data, including an alarm system to detect and notify appropriate personnel of any unauthorized entry.

(3) *Equipment.* The facility must have equipment that ensures prescription drugs are properly stored, including cold storage, refrigerators, temperature and humidity devices, and air handling units. All equipment utilized must be maintained in good repair and must be suitable for the distribution, including receipt, storing, and handling, warehousing, holding, displaying, or transporting of prescription drugs, as demonstrated by the following:

(i) All equipment must be installed, maintained, and repaired by qualified individuals following written procedures established by the wholesale distributor. The wholesale distributor must be able to demonstrate that all equipment has been calibrated, as applicable, and validated at regular intervals to achieve the intended results accurately, consistently, and in a manner that can be reproduced by qualified individuals following the wholesale distributor's written procedures. Such actions must be documented;

(ii) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment or logs must be used to document proper storage of prescription drugs; and

(iii) Monitoring equipment must immediately alert appropriate personnel of any deviations from the required storage conditions.

(4) *Facility assessments.* Facility assessments, including temperature mapping and other assessments designed to ensure prescription drugs are properly stored in accordance with their labeling, must be regularly conducted and documented.

(c) Every wholesale distributor must establish, maintain, and follow written policies and procedures for each of the requirements described in this section that are relevant to the scope of the wholesale distributor's activities involving prescription drugs at the facility. The written policies and procedures must describe a system by which the wholesale distributor will monitor all processes, and, if deviations occur, promptly document and investigate to determine the root cause of the deviation. If a wholesale distributor uses a contractor to carry out any of its duties, the wholesale distributor remains responsible for compliance with this subpart and must ensure that the contractor abides by the applicable written policies and procedures. The written policies and procedures must clearly describe the responsibilities of the wholesale distributor and any contractors used to fulfill the wholesale distributor's duties. Such arrangements must be documented and carried out in accordance with the requirements of this section.

(1) *Authorized trading partners.* The wholesale distributor must ensure that it conducts business only with other authorized trading partners as defined in section 581(2) and (23) of the Federal Food, Drug, and Cosmetic Act.

(2) *Facility and equipment maintenance management.* The wholesale distributor must ensure that the facility requirements in paragraph (b) of this section are met.

(3) *Transportation.* The wholesale distributor must ensure prescription drugs are transported in a manner that:

(i) Protects against breakage, contamination, adulteration, and theft;

(ii) Prevents exposure to conditions that may compromise prescription drug identity, strength, quality, or purity; and

(iii) Ensures that deviations from storage requirements during transport are identified, investigated, documented, corrected, and reported no later than 24 hours after discovery to the authorized trading partner from which the prescription drug was received, and to the manufacturer to determine if further commercial distribution is appropriate.

(4) *Examination of shipping containers.* The wholesale distributor must ensure that all shipping containers are examined in accordance with the following standards:

(i) *Incoming shipments.* Upon receipt, each shipping container must be visually examined for identity and to prevent the acceptance of prescription drugs that are unfit for distribution. This examination must be adequate to detect conditions that would suggest that the prescription drug may be unfit for distribution, such as alterations made or damage to the shipping container.

(ii) *Outgoing shipments.* Each outgoing shipment must be properly inspected for identity of the prescription drug to ensure that there is no shipment of a prescription drug that has been damaged in storage or held under improper conditions and to prevent the introduction or further shipment of any prescription drug that is unfit for distribution, including through the wholesale distributor's processing of returned or recalled drugs.

(5) *Storage and handling.* The wholesale distributor must ensure that prescription drugs are stored at appropriate temperatures and under appropriate conditions in accordance with the drugs' labeling, except that if no storage requirements are established in the drug's labeling, the drug may be held at controlled room temperature to preserve the drug's identity, strength, quality, and purity.

(i) *Inventory management.* The wholesale distributor must:

(A) Ensure compliance with the requirements of section 582(c) of the Federal Food, Drug, and Cosmetic Act;

(B) Ensure that the facility's stock is inspected regularly to protect against drug diversion and distribution of prescription drugs that are unfit for distribution;

(C) Investigate, document, and correct any stock irregularities, including theft, loss, or diversion of prescription drugs, in accordance with section 582(c) of the Federal Food, Drug, and Cosmetic Act, as applicable;

(D) Ensure that any prescription drug that appears to be unfit for distribution

is removed from saleable stock and handled appropriately according to the requirements in paragraphs (c)(5)(ii) through (iv) of this section;

(E) Immediately report any confirmed losses or theft of prescription drugs to the manufacturer of the drug and the Food and Drug Administration; and

(F) Ensure that records related to the actions required in paragraphs (c)(5)(i) through (iv) of this section are kept according to § 205.27.

(ii) *Handling of prescription drugs.* The wholesale distributor must ensure that only prescription drugs fit for distribution are further distributed or transferred.

(A) Any prescription drug that appears to be unfit for distribution must be stored in a secure area clearly defined for such use and physically segregated from saleable drugs, or electronically segregated, if appropriate, until the wholesale distributor determines by thorough examination that such drugs are fit for human use or nonsaleable.

(B) Any prescription drug found to be adulterated, misbranded, or otherwise unfit for distribution must be stored in a secure area clearly defined for such use and physically or electronically segregated from saleable drugs until they are returned to the supplier or destroyed in accordance with the standards in paragraph (c)(6) of this section.

(C) If a prescription drug is determined to be a suspect or illegitimate product, those suspect or illegitimate products must be handled according to the requirements of section 582(c)(4) of the Federal Food, Drug, and Cosmetic Act.

(iii) *Returned prescription drugs.* All returned prescription drugs must be stored in a secure area clearly defined for such use and physically segregated from saleable prescription drugs, until the wholesale distributor determines by thorough examination that such drugs are saleable or nonsaleable.

(A) *Saleable returns.* Prescription drugs may be returned to saleable stock only if the conditions under which the drug has been returned do not cast doubt on the drug's safety, identity, strength, quality, or purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale distributor must consider, among other things, the conditions under which the drug has been held, stored, or shipped.

(B) *Nonsaleable returns.* If the conditions under which the prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, drugs may be returned to the manufacturer or repackager, to the wholesale distributor from which such drug was purchased, or to an individual acting on behalf of such an entity, including a returns processor, or may be destroyed in a timely manner and in accordance with paragraph (c)(6) of this section and all applicable Federal and State laws.

(iv) *Recalled drugs.* Recalled prescription drugs must be handled as instructed by the manufacturer in the recall notice, which may require that the recalled drugs be stored in a secure area clearly defined for such purpose and physically segregated from saleable drugs until they are returned to the manufacturer or repackager, to the wholesale distributor from which such drug was purchased, or to an individual acting on behalf of such an entity, including a returns processor, or destroyed in accordance with the standards in paragraph (c)(6) of this section.

(6) *Disposition of drugs.* The wholesale distributor must establish, maintain, and follow written policies and procedures that ensure that prescription drugs removed from the pharmaceutical distribution supply chain because they are determined to be unfit for distribution are retained for further examination, returned to the manufacturer or repackager, returned to the wholesale distributor from which such drug was purchased, or returned to an individual acting on behalf of such an entity, including a returns processor, or destroyed in accordance with all applicable Federal and State laws and the following standards:

(i) *Quarantine and transfer for further examination.* The wholesale distributor must establish and maintain records for prescription drugs retained in quarantine and subsequently transferred to a manufacturer or regulatory or law enforcement agency for further additional physical examination or laboratory analysis.

(ii) *Return the drugs.* The wholesale distributor must establish and maintain records for the return of prescription drugs to the manufacturer, repackager, or wholesale distributor from which the wholesale distributor acquired the drugs, including when returned using a returns processor or reverse logistics provider to return the drugs.

(iii) *Destroy.* When prescription drugs are authorized for destruction, the wholesale distributor must:

(A) Destroy all containers, labels, and packaging to ensure that such items cannot be used in counterfeiting activities;

(B) Ensure that the destruction of prescription drugs, containers, labels, and packaging are witnessed; and

(C) Establish and maintain records for destroyed drugs and the witnessing thereof.

(7) *Preparation for foreseeable crises.* The wholesale distributor must prepare for, protect against, and address any reasonably foreseeable crises that could affect security or operation of the facility such as strike, fire, flood, or other natural disaster, or other situations of local, State, or national emergency.

§ 205.27 Standards for the establishment and maintenance of records of the distribution of prescription drugs.

(a) *Required records.* Required records include, but are not limited to, the following:

(1) Documentation pertaining to distribution, including storage and handling, security, inventory, transport, and shipping of prescription drugs, including written policies and procedures for identifying, recording, and reporting confirmed losses, thefts, and diversions, and prescription drugs that are unfit for distribution;

(2) All policies, procedures, instructions, contracts, data, inspection reports, and any documentation related to compliance with this subpart; and

(3) Invoices, purchase orders, packing slips, shipping records, and any other records of the distribution of prescription drugs.

(b) *Maintenance, availability, and accuracy of records.* Records must:

(1) Accurately reflect the name of the wholesale distributor as it appears on the wholesale distributor license and must match the information that is reported to the Food and Drug Administration pursuant to the Food and Drug Administration reporting requirements at § 205.29;

(2) Be readily retrievable and made available to regulatory authorities upon request;

(3) Be securely stored and protected from unauthorized access or modifications; and

(4) Contain only alterations signed and dated by the individual who made the alteration. Such alteration must preserve the original information and document the reason for the alteration.

(c) *Written policies and procedures.* Written policies and procedures must be implemented by the wholesale distributor to protect the integrity of records.

(d) *Record retention.* (1) Except for the records listed in paragraph (d)(2) of this section, all records required to be maintained by this subpart must be retained for a period of 3 years.

(2) Records of investigation of suspect and illegitimate products and of destroyed, nonsaleable returned, and recalled prescription drugs must be retained for a period of 6 years.

§ 205.28 Inspections.

(a) A facility to be used in wholesale distribution must undergo a physical inspection prior to issuance of the initial license by the Federal or State licensing authority.

(1) Where the State is the licensing authority, such inspection may be conducted by:

(i) The State in which the facility to be licensed is located; or

(ii) A third-party accreditation or inspection service approved by the State licensing the wholesale distributor; or

(iii) If the facility is located out of State, the State issuing the license may conduct the inspection or may accept an inspection by the State in which the facility is located or by a third party, as described in paragraph (a)(1)(ii) of this section.

(2) Where the Food and Drug Administration is the licensing authority, the Food and Drug Administration may conduct the inspection or may accept an inspection conducted by an organization approved by the Food and Drug Administration under § 205.32.

(b) Records described in § 205.27 that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means must be readily available for inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable must be made available for inspection within 2 business days of a request by a State or Federal official, or sooner if necessitated by the duration of the inspection.

(c) Wholesale distributors must permit the appropriate Federal, or State licensing authority and State- or FDA-approved third-party inspection services to enter and inspect their premises and to audit their records and written operating procedures.

(d) To ensure compliance with this subpart, routine inspections will be conducted once every 3 years by the licensing authority, or a third-party accreditation or inspection service approved by the Food and Drug Administration or the State licensing the wholesale distributor.

§ 205.29 Requirements for initial and annual reporting to the Food and Drug Administration.

(a) *Electronic reporting requirement.* The wholesale distributor must report electronically to the Food and Drug Administration using a secure mechanism in a format the Food and Drug Administration can review, process, and archive pursuant to section 503(e)(2)(A) of the Federal Food, Drug, and Cosmetic Act. Information reported will be included in the Food and Drug Administration's public database for wholesale distributors pursuant to section 503(e)(2)(B) of the Federal Food, Drug, and Cosmetic Act.

(b) *Reporting periods*—(1) *Initial reporting.* Any entity that owns or operates an establishment that engages in wholesale distribution must report within 30 calendar days of obtaining an initial State or Federal wholesale distributor license.

(2) *Annual reporting.* Any entity that is licensed to engage in wholesale distribution must report to the Food and Drug Administration each calendar year between January 1 and March 31.

(c) *Required information.* Information to be reported for each wholesale distributor must include:

(1) A complete list of States where the wholesale distributor is licensed, including the corresponding identification number and the expiration date of each such license;

(2) Name of company as it appears on the license, full business address, and contact information for the facility manager or designated representative of the wholesale distributor;

(3) All trade names or business names under which the wholesale distributor conducts business; and

(4) Any significant disciplinary actions by any State or Federal Agency taken against the wholesale distributor license related to the distribution of prescription drugs, including the State where the disciplinary action occurred, date of final action, type of disciplinary action, description of the violation, and documents associated with the disciplinary action.

(d) *Timing of significant disciplinary action reporting*—(1) *Initial reporting.* The wholesale distributor must report to the Food and Drug Administration any significant disciplinary actions, including but not limited to revocation or suspension of a wholesale distributor license by a State or Federal licensing authority, which occurred in the 12 months prior to obtaining licensure.

(2) *Subsequent reporting.* The wholesale distributor must, within 30 calendar days after a final action taken by a State or Federal licensing authority, report significant disciplinary actions to the Food and Drug Administration.

(e) *Other reports*—(1) *Closure of a facility.* The wholesale distributor must report to the Food and Drug Administration that a facility has ceased operations within 30 calendar days after it has stopped operating as a wholesale distributor.

(2) *Voluntary withdrawal of a State license.* The wholesale distributor must report to the Food and Drug Administration that it has withdrawn its license in a State within 30 calendar days after such withdrawal, including any reasons for the voluntary withdrawal of licensure.

§ 205.30 Licensure denial, suspension, reinstatement, revocation, and voluntary termination—notice and opportunity to request a hearing.

(a) *Denial of application for licensure.* (1) The licensing authority will refuse to approve a wholesale distributor license application for any of the following reasons:

(i) The methods or procedures to be used in the distribution of the prescription drug, including receipt, storage, and handling, are inadequate to preserve its safety, identity, strength, quality, or purity.

(ii) The facilities and controls used for the distribution of the prescription drug, including receipt, storage, and handling, are inadequate to preserve its safety, identity, strength, quality, or purity.

(iii) The methods or procedures to be used in the distribution of the prescription drug, including receipt, storage, and handling, do not comply with the requirements for good storage practices in § 205.26.

(iv) The personnel employed by the applicant do not meet the requirements necessary for good storage practices in § 205.25.

(v) There is insufficient information in the written policies and procedures required under § 205.26(c) to determine whether the methods or procedures to be used in the distribution of the prescription drug, including receipt, storage, and handling, comply with the requirements for good storage practices in § 205.26 and preserve the safety, identity, strength, quality, or purity of the prescription drug.

(vi) The methods or procedures to be used in the distribution of the prescription drug, including receipt, storage, and handling, do not comply with the requirements for adequate recordkeeping in § 205.27.

(vii) The application contains an untrue statement of material fact.

(viii) The applicant does not permit a properly authorized officer or employee of the Food and Drug Administration, a State licensing authority, or an AO approved by the Food and Drug Administration pursuant to § 205.32 an adequate opportunity to inspect the

facilities, controls, and any records relevant to the application.

(ix) For renewal applications, the applicant fails to report to the licensing authority any pertinent change of information required in § 205.21, § 205.22, or § 205.24.

(x) For renewal applications, the applicant fails to report to the Food and Drug Administration any of the requirements for annual reporting in § 205.29.

(2) If review of a wholesale distributor's application fails to demonstrate that the wholesale distributor meets the requirements for licensure set forth in § 205.22 and paragraph (a)(1) of this section, the licensing authority will provide written notice to the applicant that its license application may be denied, setting forth the grounds for the denial and providing an opportunity to demonstrate that the wholesale distributor meets the requirements for licensure.

(3) The notice will inform the applicant of its right to provide additional information and request reconsideration of the denial by the licensing authority within 14 calendar days of the date of the licensing authority's written notice.

(4) If no reconsideration is sought, or, if upon reconsideration, the licensing authority denies the applicant's request for licensure, the licensing authority will provide the applicant written notice of the denial and will provide the applicant notice of the opportunity to request a hearing.

(5) The applicant who wishes to request a hearing has 10 calendar days after the date of the notice of denial to submit a written notice of participation and request for a hearing. The applicant who fails to submit a written notice of participation and request for a hearing within 10 calendar days waives the opportunity for a hearing.

(6) Parts 10 through 16 of this chapter apply to wholesale distributor licenses issued by the Food and Drug Administration under sections 503(e) and 583 of the Federal Food, Drug, and Cosmetic Act.

(b) *Suspension of license after notice and opportunity to request a hearing.* (1) The licensing authority may move to suspend a license if the licensing authority has a reasonable belief that the licensee has failed to comply with any of the standards for receiving and maintaining licensure described in this subpart and that the nature of the noncompliance at issue would likely compromise the quality of product or threaten public safety.

(2) The licensing authority will provide written notice of the intent to suspend a wholesale distributor license setting forth the grounds for the suspension pursuant to this part, including what information would be required to demonstrate or achieve compliance. The notice will inform the applicant of its right to provide additional information, request reconsideration of the suspension by the licensing authority, and demonstrate or achieve compliance before suspension.

(3) Each wholesale distributor license holder has 30 calendar days from the date of the notice of intent to suspend to present, in writing, comments and information bearing on the initial decision.

(4) If no comments or information is received within 30 calendar days or, if upon reconsideration, the licensing authority believes the wholesale distributor license should still be suspended, the licensing authority will provide the wholesale distributor a second written notice of the intent to suspend, informing the wholesale distributor of the opportunity to request a hearing on the question of whether there are grounds for suspension.

(5) The wholesale distributor must submit a written notice of participation and request a hearing in writing within 10 calendar days after the date of the notice of the intent to suspend. A wholesale distributor that fails to submit a written notice of participation and request for hearing within 10 calendar days waives the opportunity for a hearing.

(6) Parts 10 through 16 of this chapter apply to wholesale distributor licenses issued by the Food and Drug Administration under sections 503(e) and 583 of the Federal Food, Drug, and Cosmetic Act.

(7) If a wholesale distributor's license is suspended and the wholesale distributor does not demonstrate or achieve compliance to the licensing authority's satisfaction within the time period indicated in the notice of suspension, the licensing authority will move to revoke the wholesale distributor's license.

(c) *Immediate suspension of license.* (1) The licensing authority may suspend a license effective immediately if the licensing authority reasonably believes that the licensee has failed to comply with any of the standards for receiving and maintaining licensure described in this subpart and that the nature of the noncompliance at issue would reasonably be expected to cause an imminent threat to public health.

(2) The licensing authority will provide the wholesale distributor with written notice of immediate suspension of its license setting forth the grounds for the suspension pursuant to this part, including what information would be required to demonstrate compliance, and the opportunity to request a hearing within 10 calendar days of the wholesale distributor's request for such hearing.

(3) The wholesale distributor must submit a written notice of participation and request a hearing in writing within 10 calendar days after the date of the written notice of immediate suspension. A wholesale distributor that fails to submit a written notice of participation and request for hearing within 10 calendar days from the date of the written notice waives the opportunity for a hearing.

(4) Parts 10 through 16 of this chapter apply to wholesale distributor licenses issued by the Food and Drug Administration under sections 503(e) and 583 of the Federal Food, Drug, and Cosmetic Act.

(5) If a wholesale distributor's license is suspended and the wholesale distributor does not demonstrate or achieve compliance to the licensing authority's satisfaction within the time period indicated in the notice of suspension, the licensing authority will move to revoke the wholesale distributor's license.

(d) *Reinstatement of suspended licenses.* The licensing authority may reinstate a previously suspended license upon a wholesale distributor's showing of compliance with requirements in this part and upon such inspection and examination as the licensing authority may require.

(e) *Revocation.* (1) If compliance is not demonstrated or achieved to the licensing authority's satisfaction within the time period indicated in the notice of suspension, the licensing authority will move to revoke the wholesale distributor's license.

(2) The licensing authority will notify the wholesale distributor of the intent to revoke the wholesale distributor's license, setting forth the grounds for the revocation and offering an opportunity to request a hearing on the proposed revocation.

(3) The wholesale distributor must submit a written notice of participation and request a hearing within 10 calendar days after the date of the notice of revocation. A wholesale distributor that fails to submit a written notice of participation and request for hearing within 10 calendar days waives the opportunity for a hearing.

(4) Parts 10 through 16 of this chapter apply to wholesale distributor licenses issued by the Food and Drug Administration under sections 503(e)

and 583 of the Federal Food, Drug, and Cosmetic Act.

(f) *Nonrenewal.* If a license renewal application is not submitted by the date of expiration of the license, the license will be considered expired. A wholesale distributor may not engage in wholesale distribution with an expired license and must submit a new application for licensure.

(g) *Voluntary termination of licensure upon request by the wholesale distributor.* The licensing authority will terminate a wholesale distributor's license upon the wholesale distributor's request, which will include a notice of intent to discontinue prescription drug wholesale distribution and waive opportunity for a hearing. A wholesale distributor that voluntarily terminates licensure must obtain a new license before resuming wholesale distribution.

(1) If a wholesale distributor that has had its license revoked wishes to apply for a new license, the wholesale distributor must submit a new license application, which may include an inspection if required by the licensing authority under § 205.28(a).

(2) [Reserved]

Subpart D—Approved Organizations for Wholesale Distributors

§ 205.31 Use of approved third-party organizations.

(a) A third-party organization that has been approved by the Food and Drug Administration pursuant to § 205.32 (''approved organization'' (AO)) may be used to conduct initial and routine inspections of the wholesale distributor's facility, as directed by the Food and Drug Administration.

(b) If an organization has been approved by the Food and Drug Administration to conduct inspections, the AO must:

(1) Complete inspections within a timeframe not to exceed 90 calendar days after receiving notice from the Food and Drug Administration to conduct an inspection;

(2) Based on the inspection, write a detailed document including a summary of the AO's findings; and

(3) Send the original document to the Food and Drug Administration, with a copy to the wholesale distributor, within 7 calendar days of completing the inspection.

(c) To become an AO, and to maintain its approval, an organization seeking the Food and Drug Administration's approval and current AOs must:

(1) Maintain records, including those that support the AO's initial and continuing qualifications for approval, for a minimum of 5 years.

(2) Maintain the following records of inspections submitted to the licensing authority for a minimum of 5 years:

(i) Copies of the records and supporting documentation reviewed as part of an inspection;

(ii) Inspection reports;

(iii) Correspondence with the Food and Drug Administration and the wholesale distributor associated with an inspection; and

(iv) Information on the identity, conflict of interest certification/compliance statement, and qualifications of all AO personnel who contributed to the inspection.

(3) Records maintained by the AO must:

(i) Be readily retrievable and made available to Federal licensing authorities upon request;

(ii) Be secure from unauthorized access or modifications; and

(iii) Contain only alterations signed and dated by the individual who made the alteration. Such alteration must preserve the original information and document the reason for the alteration.

(4) An AO must immediately report to the Food and Drug Administration the discovery of any evidence or observations of potential violations found at a wholesale distributor facility during an inspection of the facility that could pose imminent and serious adverse health consequences or death to humans. Reports must be made in the manner prescribed by the Food and Drug Administration.

§ 205.32 General qualifications of approved organizations.

(a) To become and remain an AO, the organization and anyone employed by the organization, including contractors used by the organization:

(1) Must not be a current Federal or State government employee;

(2) Must not engage in prescription drug-related activities, excluding participation in the Agency's AO program and related activities, but including and not limited to manufacturing, wholesale distribution, repackaging, relabeling, dispensing, or 3PL activities;

(3) Must disclose to the Food and Drug Administration any participation or financial interest in entities that participate in the design, manufacture, promotion, or sale of articles or activities that are predominantly Food and Drug Administration-regulated or are expected to result in Food and Drug Administration-regulated articles;

(4) Must not be owned or controlled by, or have any organizational, material, or financial affiliation with, any of the entities engaged in manufacturing, wholesale distribution, repackaging, relabeling, dispensing, 3PL activities, or the design, manufacture, promotion, or sale of prescription drugs as defined in section 581(12) of the Federal Food, Drug, and Cosmetic Act;

(5) Must enter and abide by a written agreement with the applicant before data and information otherwise exempt from public disclosure may be disclosed to the AO or the contractor;

(6) Must operate in accordance with professional and ethical business practices, which include:

(i) Protecting against conflicts of interest as set forth in 5 CFR part 2635 and 18 U.S.C. 208;

(ii) Ensuring that the personnel employed or contracted by the AO who are working on inspections have sufficient education, training, knowledge, and experience to conduct inspections of wholesale distributors;

(iii) Protecting against unauthorized disclosure of nonpublic information received, records, reports, and recommendations and maintaining appropriate security and protection of such information;

(iv) Maintaining appropriate security and protection, physical and electronic, of any information received in relation to inspections;

(v) Reporting information to the Food and Drug Administration and entities for which licensure reviews were conducted that accurately reflects data reviewed, inspectional observations made, and other matters that relate to or may influence compliance with the Federal Food, Drug, and Cosmetic Act; and

(vi) Promptly responding to and attempting to resolve any complaints regarding activities for which it is approved by the Food and Drug Administration; and

(7) Must establish and maintain policies, procedures, and documentation to demonstrate that, at the time of application, and throughout their tenure as an AO, the applicant has and can continue to satisfy the requirements to qualify as an AO capable of assessing compliance with all wholesale distributor requirements. Such policies, procedures, and documentation must include, but are not limited to:

(i) AO program administration;

(ii) Disciplinary actions and corrective measures;

(iii) Recordkeeping and confidentiality;

(iv) Use of contractors; and

(v) Personnel qualifications and ongoing training.

(b) If an AO elects to use contractors for inspections, the AO remains

responsible for the work of the contractors at all times.

(1) AOs that use contractors to conduct inspections must have policies and procedures in place to ensure the contractor's continuing compliance with this part, as well as competence and qualifications to conduct inspections. Such policies and procedures must ensure that contractors:

(i) Meet the qualifications set forth in paragraph (a) of this section;

(ii) Do not subcontract their inspection duties, and that contractors are removed if such requirement is violated;

(iii) Abide by the policies and procedures of the AO, as set forth in § 205.33(b); and

(iv) Complete and pass the same training required by the AO, as set forth in § 205.33(c).

(2) If an AO elects to use contractors to conduct inspections, the AO must receive and keep a record of written consent from the wholesale distributor to share confidential commercial information with contractors for which an inspection is being conducted.

(3) AOs that elect to use contractors must submit to the Food and Drug Administration a list of contractors used by the organization, accompanied by a statement from the organization certifying that such contractors meet the requirements of this subpart.

§ 205.33 Process and procedures for approval by the Food and Drug Administration.

(a) *Application.* An application to become an AO must be completed and submitted electronically to the Food and Drug Administration in a format the Food and Drug Administration can renew, process, and archive.

(b) *Required application information.* Policies, procedures, and documentation as required by § 205.32(a)(7) must accompany the application.

(c) *Training.* Organizations must provide training and any individual who conducts inspections or supervises individuals who conduct inspections is required to undergo and pass the prescribed training.

(1) If an individual does not pass training, that person must wait 30 days before retaking the training, and may be required to show proof of additional education or experiential learning to demonstrate competence before retaking the training evaluation.

(2) To maintain approval, individuals employed by the AO and conducting inspections or supervising those who conduct inspections must undergo and pass annual training as prescribed by the Food and Drug Administration. Failure to complete and pass annual training may result in suspension of approval.

(3) The Food and Drug Administration may require additional training. If such additional training is required, AOs will be given a set time period during which training must be completed and passed to maintain approval.

(d) *Auditing.* Prior to conducting its first inspection, an AO must undergo an onsite audit by the Food and Drug Administration. The Food and Drug Administration may also conduct random, periodic audits, as well as for-cause audits, of an AO, as set forth in paragraph (o) of this section.

(e) *Duration of approval and renewal process.* (1) The Food and Drug Administration approval to conduct inspections is valid for a period of 5 years.

(2) AOs must submit a renewal application to the Food and Drug Administration no later than 6 months prior to the expiration date to renew its approval.

(i) If a renewal application is submitted less than 6 months before the date of expiration, the AO's approval will expire if approval is not renewed prior to the date of expiration.

(ii) Upon expiration of the AO's approval, the AO must cease conducting any inspection-related activities.

(f) *Denial of approval.* If an organization does not meet all of the Food and Drug Administration's standards detailed in §§ 205.31 and 205.32 for becoming an AO, the Food and Drug Administration will deny the application in writing. Requests for review and reconsideration of a denial of an application must be submitted to the Food and Drug Administration within 30 calendar days of the date of the Food and Drug Administration's decision. If, upon reconsideration, the licensing authority denies the applicant's request for approval, the licensing authority will provide the applicant written notice of the denial and an opportunity to appeal pursuant to § 10.75 of this chapter.

(g) *Suspension of approval after notice and opportunity to request a hearing.* (1) The Food and Drug Administration may suspend approval of an organization after opportunity to request a hearing when there is a reasonable probability that the organization's noncompliance will negatively impact public health.

(2) If an AO fails to maintain the Food and Drug Administration's standards pursuant to §§ 205.31 and 205.32, the Food and Drug Administration will give written notice of the intent to suspend the organization's approval, including the grounds for the suspension, and the AO will have 30 days after the date of the notice to provide additional information to the Food and Drug Administration for reconsideration.

(3) If no additional information is provided or, if upon reconsideration, the Food and Drug Administration still believes the AO's approval should be suspended, the Food and Drug Administration will issue the AO a formal written notice of intent to suspend, along with notice of the opportunity to request a hearing pursuant to part 16 of this chapter.

(4) An AO that wishes to request a hearing has 10 calendar days after the date of the formal notice of intent to suspend to submit a written notice of participation and request for a hearing. An AO that fails to submit a written notice of participation and request for a hearing within 10 calendar days from the date of the notice waives the opportunity for a hearing.

(5) A suspended AO must notify any wholesale distributors with a pending inspection to be performed by the AO of the AO's suspension within 7 calendar days.

(h) *Immediate suspension of approval.* (1) When there is a reasonable probability that the organization's noncompliance will cause imminent and serious adverse health consequences or death to humans, the Food and Drug Administration will suspend an AO's approval effective immediately.

(2) In such a situation, the Food and Drug Administration will provide the AO a written notice of immediate suspension, along with notice and opportunity to request a hearing pursuant to part 16 of this chapter within 14 calendar days of the AO's request for such hearing.

(3) An AO that wishes to request a hearing has 10 calendar days after the date of the formal notice of suspension to submit a written notice of participation and request for a hearing. An AO that fails to submit a written notice of participation and request for a hearing within 10 calendar days waives the opportunity for a hearing.

(i) *Reinstatement of approval.* (1) An organization's approval may be reinstated if the Food and Drug Administration determines that the suspended organization has rectified the issues leading to the suspension and can meet the standards set forth in this subpart. Pursuant to this paragraph (i), the organization must rectify the issues and come into compliance with the Food and Drug Administration's

standards within 1 year from the date of suspension. If the issues have not been rectified within 1 year, the Food and Drug Administration may revoke the AO's approval subject to the provisions of this part.

(2) An organization whose approval has been reinstated on a conditional basis will be subject to a 3-year probationary period, and if any material deficiencies arise during that period, the organization's approval may be revoked.

(j) *Revocation of approval.* (1) The Food and Drug Administration may revoke approval of an organization whose approval has been suspended pursuant to paragraphs (g) and (h) of this section:

(i) If an organization fails to demonstrate intent to comply with the issues leading to the suspension within 6 months from the date of suspension; or

(ii) If the Food and Drug Administration determines that the organization failed to rectify the issues leading to the suspension to the Agency's satisfaction within 1 year of the date of suspension.

(2) The Food and Drug Administration will give written notice of the intent to revoke the organization's approval, including the grounds for the revocation, and an opportunity to request a hearing pursuant to part 16 of this chapter.

(3) The AO must submit a written notice of participation and request a hearing within 10 calendar days after the date of the notice of revocation. An AO that fails to submit a written notice of participation and request for hearing within 10 calendar days waives the opportunity for a hearing.

(4) An organization whose approval is revoked that wishes to reapply to be an AO must submit a new application to the Food and Drug Administration.

(k) *Requests for reconsideration of Agency decision.* (1) The Food and Drug Administration will follow the process outlined at § 10.75 of this chapter to review matters relating to denial of approval, including review of the organization's application.

(2) The Food and Drug Administration will follow the process outlined at part 16 of this chapter to review matters relating to a suspension or revocation action, including review of the organization's application and administrative file.

(3) The Food and Drug Administration's decision after request for reconsideration of denial, suspension, or revocation constitutes a final Agency action under 5 U.S.C. 702.

(l) *Voluntary withdrawal of approval.* (1) An organization wishing to voluntarily withdraw its approval, including but not limited to when an AO goes out of business, must notify the Food and Drug Administration in writing at least 6 months prior to the date the organization intends for the withdrawal to become effective.

(i) If an AO determines it will be withdrawing its approval with the Food and Drug Administration in less than 6 months, it must notify the Food and Drug Administration immediately of its intent to withdraw, and such notification must inform the Food and Drug Administration of the date the organization will cease business operations.

(ii) [Reserved]

(2) No later than 7 calendar days after notifying the Food and Drug Administration, the organization must notify any facilities with pending inspections that it intends to withdraw its approval with the Food and Drug Administration and must provide the date on which the withdrawal is effective.

(m) *AO-required notifications to wholesale distributors.* The AO must, within 7 calendar days of the date of suspension, revocation, or voluntary withdrawal of approval, notify those wholesale distributor facilities that have pending inspections of the AO's suspension or revocation. This notification must inform the wholesale distributor facility that it must apply for inspection with another AO, or the Food and Drug Administration if no other organization is approved.

(n) *Change of operation or ownership.* (1) The AO must report to the Food and Drug Administration within 30 calendar days any changes to the information submitted with its application for approval.

(2) Approval is not transferable.

(i) Changes in ownership of an AO require the organization to submit a new application to the Food and Drug Administration.

(ii) Such application must be submitted to the Food and Drug Administration no later than 30 calendar days prior to the date of the change of ownership.

(iii) No later than 30 calendar days before the date of the change of ownership, the AO must notify any wholesale distributor facilities with pending applications of the pending change in ownership.

(iv) On the date the change of ownership takes place, the original approval is void.

(o) *Monitoring by the Food and Drug Administration.* (1) AOs are subject to both periodic and for-cause audits by the Food and Drug Administration to ensure compliance with the Food and Drug Administration's requirements for approval in this part.

(2) If an AO refuses to cooperate with the Food and Drug Administration's audit, the organization's approval may be suspended.

Dated: January 24, 2022.

Janet Woodcock,

Acting Commissioner of Food and Drugs.

[FR Doc. 2022–01929 Filed 2–3–22; 8:45 am]

BILLING CODE 4164–01–P

Position Template Motion

I (board member name), move to assign the authoring of a position statement regarding (topic) to (assigned board member). This position statement will be:

1. Placed on the agenda for board review/approval during the (meeting date).

2. Added to the position statement page

3. Sent out via the ListService.

Reminder to boards: position statements do not have the force of law; they cannot change a law, create a law, or enforce a law. Position statements only serve as the board's official position on a topic and should be accurate and relevant, appropriate to the scope of practice for the profession, and align with the intent of an existing statute or regulation. Position statements should be in place to provide clarity to licensees and the public to support the board's mission and protect the public.

From: Chambers, Sara C (CED)
To: CED CBPL
Subject: preliminary look at 2022 legislation
Date: Friday, May 20, 2022 11:10:30 AM
Attachments: image001.png

Congratulations, CBPL! We did it—2022 legislative session is in the books! Below is a preliminary look at the bills that passed, a summary of what they do, what next steps are needed, and links to the bill content.

Please feel welcome to share this email message with your board members, especially if your licensing program is impacted and regulations may be needed. It will take a little time to unpack every nuance, so executive administrators and board members should start reading through at your soonest convenience and compiling questions. Glenn and I will be helping with implementation of all of these, so thank you for your excellent questions and ideas…and your patience with our research and responses.

BILL #	SHORT TITLE	EFFECTIVE DATE	POTENTIALLY AFFECTED PROGRAM(S)	LINK	DESCRIPTION	EFFECTIVE	REQUIRES REGULATIONS	ADDS NEW PERSONNEL	CREATES NEW LICENSE TYPE(S)
HB 44	PRACTICE OF ACCOUNTING; LICENSURE	2/9/2022	CPA	www.akleg.gov/basis/Bill/Detail/32?Root=HB 44	Updated CPA statutes with national standards and accepted industry terminology	90 days after Gov signs	Yes - 1/1/2023	No	No
HB 85	FINANCIAL INSTITUTIONS; LIABILITY	5/12/2022	BL	www.akleg.gov/basis/Bill/Detail/32?Root=hb+85	Exempts banks from having to obtain a business license	Immediate	No	No	No
HB 99	PHYSICAL/OCCUPATIONAL THERAPY BD/PRACTICE	5/16/2022	PHY	www.akleg.gov/basis/Bill/Detail/32?Root=hb+99	Modernizes PHY statutes and updates professional titles	90 days after Gov signs	Yes - 1/1/2023	No	No - but does change title of some existing license types
HB 145	EXPAND PHARMACIST AUTHORITY	5/16/2022	PHA	www.akleg.gov/basis/Bill/Detail/32?Root=hb+145	Allows pharmacists to provide patient care services without a collaborative practice agreement with a prescribing practitioner	90 days after Gov signs	Yes - 7/1/2023	No	No
HB 265	HEALTH CARE SERVICES BY TELEHEALTH	5/18/2022	All health care as defined in bill; Primarily MED and NUR	www.akleg.gov/basis/Bill/Detail/32?Root=hb+265	Expands & clarifies telehealth capacity and controlled substance prescribing for Alaska-licensed health care providers and for physicians licensed in another state	Immediate	Yes - 7/1/2023	No	No
HB 306	EXTEND BOARD OF PHARMACY	5/18/2022	PHA	www.akleg.gov/basis/Bill/Detail/32?Root=hb 306	Extends the PHA board to 6/30/2028	Immediate	No	No	No
HB 392	EXPAND ADV. PRAC. REG. NURSE AUTHORITY	5/17/2022	NUR & MED	www.akleg.gov/basis/Bill/Detail/32?Root=hb+392	Allows APRNs & PAs to sign or revoke DNRs, death certs, and issue life-sustaining procedures	90 days after Gov signs	Yes - 7/1/2023	No	No
HB 402	IDENTIFICATION OF CONTRACTOR IN ADS	5/17/2022	CON	www.akleg.gov/basis/Bill/Detail/32?Root=hb 402	Allows contractors to put website on ad instead of all other info	90 days after Gov signs	No	No	No
SB 9	ALCOHOLIC BEVERAGE CONTROL; ALCOHOL REG	5/16/2022	BL	www.akleg.gov/basis/Bill/Detail/32?Root=sb+9	Updates the BL exemption for licensed alcohol businesses	1/1/2024	No	No	No
SB 45	AGE FOR NICOTINE/E-CIG; TAX E-CIG	5/18/2022	BL	www.akleg.gov/basis/Bill/Detail/32?Root=sb+45	Makes 21 the minimum age for tobacco & nicotine products	1/1/2023	No	No	No
SB 173	DENTIST SPEC. LICENSE/RADIOLOGIC EQUIP	5/18/2022	DEN	www.akleg.gov/basis/Bill/Detail/32?Root=sb+173	Moves DEN radiological equipment to DOH; Reestablishes DEN specialties; and includes HB 111 (dental hygienist advanced practice permit)	1/1/2023 and 7/1/2023 (depending on section)	Yes - 7/1/2023	Yes	Yes
SB 186	EXTEND BOARD OF EXAMINERS IN OPTOMETRY	5/16/2022	OPT	www.akleg.gov/basis/Bill/Detail/32?Root=sb+186	Extends the OPT board to 6/30/2028	Immediate	No	No	No
SB 193	EXTEND BOARD OF CHIROPRACTIC EXAMINERS	5/17/2022	CHI	www.akleg.gov/basis/Bill/Detail/32?Root=sb+193	Extends the CHI board to 6/30/2027 & requires audit report within 1 year of effective date	Immediate	No	No	No
SB 222	EXTEND PT & OCCUPATIONAL THERAPY BOARD	5/5/2022	PHY	www.akleg.gov/basis/Bill/Detail/32?Root=sb+222	Extends the PHY board to 6/30/2030	Immediate	No	No	No

Please also note that while it is not specifically mentioned, the FY23 budget passed and included our fiscal requests. We will update individual boards in the coming weeks leading up to FY23 if there is anything exceptionally noteworthy relating to their program.

Thank you for your help the last 120+ days as we accomplished this goal together.

Happy Friday,

Sara Chambers
Division Director

Alaska Division of Corporations, Business and Professional Licensing
Inspiring public confidence through balanced regulation of competent professional and business services
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P.O. Box 110806, Juneau, AK 99811-0806
commerce.alaska.gov/web/cbpl
Phone: (907) 465-2144
FAX: (907) 465-2974

SENATE CS FOR HOUSE BILL NO. 306(FIN)

IN THE LEGISLATURE OF THE STATE OF ALASKA

THIRTY-SECOND LEGISLATURE - SECOND SESSION

BY THE SENATE FINANCE COMMITTEE

Offered: 5/18/22
Referred: Today's Calendar

Sponsor(s): REPRESENTATIVES STORY, Josephson

A BILL

FOR AN ACT ENTITLED

"An Act extending the termination dates of the Board of Pharmacy and the Alcoholic Beverage Control Board; and providing for an effective date."

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

*** Section 1.** AS 08.03.010(c)(16) is amended to read:

(16) Board of Pharmacy (AS 08.80.010) - June 30, **<u>2028</u>** [2022];

*** Sec. 2.** AS 44.66.010(a)(1) is amended to read:

(1) Alcoholic Beverage Control Board (AS 04.06.010) - June 30, **<u>2027</u>** [2022];

*** Sec. 3.** The uncodified law of the State of Alaska is amended by adding a new section to read:

EXEMPTION FROM AS 44.66.050(e). Sections 1 and 2 of this Act are exempt from the provision of AS 44.66.050(e) that prohibits a bill from continuing or reestablishing more than one board or commission.

*** Sec. 4.** This Act takes effect immediately under AS 01.10.070(c).

(LIMITED RUN SHOWING ALL ADDITIONAL SPONSORSHIPS)

CS FOR HOUSE BILL NO. 145(HSS)

IN THE LEGISLATURE OF THE STATE OF ALASKA

THIRTY-SECOND LEGISLATURE - SECOND SESSION

BY THE HOUSE HEALTH AND SOCIAL SERVICES COMMITTEE

Offered: 4/26/21
Referred: Rules

Sponsor(s): REPRESENTATIVES SNYDER, Tarr, Kreiss-Tomkins, Ortiz, Schrage, Fields, Story, Spohnholz, Josephson

SENATORS Gray-Jackson, Costello

A BILL

FOR AN ACT ENTITLED

"An Act relating to the Board of Pharmacy; relating to health care services provided by pharmacists and pharmacy technicians; and relating to the practice of pharmacy."

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(12) establish standards for the independent **prescribing and** administration [BY A PHARMACIST] of vaccines and related emergency medications under AS 08.80.168, including the completion of an immunization training program approved by the board;

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

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

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

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

*** Sec. 2.** AS 08.80.045 is amended by adding a new subsection to read:

(c) Except as otherwise provided in a regulation under (b) of this section, a pharmacist may prescribe, dispense, and administer nonprescription drugs or devices.

*** Sec. 3.** AS 08.80.155 is amended to read:

Sec. 08.80.155. Emergency permit. The board shall adopt regulations regarding the issuance of an emergency permit to practice **under this chapter** [PHARMACY].

*** Sec. 4.** AS 08.80.168(a) is amended to read:

(a) A pharmacist may independently **prescribe and** administer a vaccine and related emergency medication if the pharmacist has completed an immunization training program approved by the board and otherwise complies with the standards established by the board under AS 08.80.030(b).

*** Sec. 5.** AS 08.80.168(b) is amended to read:

(b) A pharmacist may independently **prescribe and administer** [DISPENSE] an opioid overdose drug if the pharmacist has completed an opioid overdose drug training program approved by the board and otherwise complies with the standards established by the board under AS 08.80.030(b).

*** Sec. 6.** AS 08.80.168 is amended by adding a new subsection to read:

(d) A pharmacy technician working under the immediate supervision of a pharmacist who meets the requirements of (a) of this section may administer a vaccine or related emergency medication if the pharmacy technician is authorized by the board to do so.

*** Sec. 7.** AS 08.80.297(a) is amended to read:

(a) A pharmacist **or person acting at the direction of a pharmacist** shall disclose the price of filling any prescription when requested by the consumer.

*** Sec. 8.** AS 08.80 is amended by adding a new section to article 3 to read:

Sec. 08.80.337. Other patient care services. (a) A pharmacist may, under a collaborative practice agreement with a written protocol approved by a practitioner,

provide patient care services.

(b) A pharmacist may independently provide patient care services for

(1) general health and wellness;

(2) disease prevention; or

(3) a condition that

(A) is minor and generally self limiting;

(B) has a test that is used to guide diagnosis or clinical decision-making and the test is waived under 42 U.S.C. 263a (Clinical Laboratory Improvement Amendments of 1988); or

(C) falls under a statewide standing order from the chief medical officer in the Department of Health and Social Services.

(c) This section does not authorize a pharmacist to prescribe a prescription drug that the pharmacist is not otherwise authorized to prescribe.

(d) In this section, "patient care services" means medical care services given in exchange for compensation intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process.

*** Sec. 9.** AS 08.80.480(12) is amended to read:

(12) "equivalent drug product" means a drug product that has the same established name, active ingredients, strength or concentration, [DOSAGE FORM,] and route of administration and that is formulated to contain the same amount of active ingredients in the same dosage form and to meet the same compendia or other applicable standards for strength, quality, purity, and identity, but that may differ in characteristics such as shape, scoring configuration, packaging, excipients including colors, flavors, preservatives, and expiration time;

*** Sec. 10.** AS 08.80.480(30) is amended to read:

(30) "practice of pharmacy" means the interpretation, evaluation, and dispensing of prescription drug orders in the patient's best interest; participation in drug and device selection, drug administration, drug regimen reviews, and drug or drug-related research; provision of patient counseling and the provision of those acts or services necessary to provide pharmaceutical care; the **independent prescribing,**

dispensing, and administration of [VACCINES AND RELATED EMERGENCY MEDICATION; THE INDEPENDENT DISPENSING OF OPIOID OVERDOSE] drugs **in accordance with AS 08.80.168**; the responsibility for compounding and labeling of drugs and devices except labeling by a manufacturer, repackager, or distributor of nonprescription drugs and commercially packaged legend drugs and devices; proper and safe storage of drugs and devices; and maintenance of proper records for them;

*** Sec. 11.** AS 21.36.090(d) is amended to read:

(d) Except to the extent necessary to comply with AS 21.42.365 and AS 21.56, a person may not practice or permit unfair discrimination against a person who provides a service covered under a group health insurance policy that extends coverage on an expense incurred basis, or under a group service or indemnity type contract issued by a health maintenance organization or a nonprofit corporation, if the service is within the scope of the provider's occupational license. In this subsection, "provider" means a state licensed physician, physician assistant, dentist, osteopath, optometrist, chiropractor, advanced practice registered nurse, **pharmacist,** naturopath, physical therapist, occupational therapist, marital and family therapist, psychologist, psychological associate, licensed clinical social worker, licensed professional counselor, or certified direct-entry midwife.

*** Sec. 12.** AS 21.42 is amended by adding a new section to read:

Sec. 21.42.440. Coverage for costs of services provided by pharmacists. A policy, contract, or prepaid plan for individual or group health insurance issued or delivered in the state that provides coverage for services within the scope of practice of a pharmacist licensed under AS 08.80 must provide for coverage of and reimbursement for the services if performed by a pharmacist for a person covered under the policy, contract, or plan.

HOUSE CS FOR SENATE BILL NO. 132(HSS)

IN THE LEGISLATURE OF THE STATE OF ALASKA

THIRTY-SECOND LEGISLATURE - SECOND SESSION

BY THE HOUSE HEALTH AND SOCIAL SERVICES COMMITTEE

Offered: 5/9/22
Referred: Labor and Commerce

Sponsor(s): SENATORS HOLLAND, Gray-Jackson, Hughes, Reinbold, Bishop, Begich, Shower, Myers, Micciche, Costello, Wilson

REPRESENTATIVES Prax, Tilton, Carpenter, Gillham, McCabe, Johnson, Cronk, McKay, Kaufman, Kurka, McCarty, Schrage

A BILL

FOR AN ACT ENTITLED

"An Act relating to the controlled substance prescription database."

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

*** Section 1.** AS 17.30.200(k) is amended to read:

(k) In the regulations adopted under this section, the board shall provide

(1) that prescription information in the database shall be purged from the database after two years have elapsed from the date the prescription was dispensed;

(2) a method for an individual to challenge information in the database about the individual that the person believes is incorrect or was incorrectly entered by a dispenser;

(3) a procedure and time frame for registration with the database;

(4) that a practitioner review the information in the database to check a patient's prescription records before dispensing, prescribing, or administering a schedule II or III controlled substance under federal law to the patient; the regulations must provide that a practitioner is not required to review the information in the

database before [DISPENSING, PRESCRIBING, OR ADMINISTERING]

(A) **dispensing, prescribing, or administering** a controlled substance to a person who is receiving treatment

(i) in an inpatient setting;

(ii) at the scene of an emergency or in an ambulance; in this sub-subparagraph, "ambulance" has the meaning given in AS 18.08.200;

(iii) in an emergency room;

(iv) immediately before, during, or within the first 48 hours after surgery or a medical procedure;

(v) in a hospice or nursing home that has an in-house pharmacy; [OR]

(B) **dispensing, prescribing, or administering** a nonrefillable prescription of a controlled substance in a quantity intended to last for not more than three days**; or**

(C) prescribing a controlled substance if the practitioner is a veterinarian.

*** Sec. 2.** AS 17.30.200(t) is amended to read:

(t) A practitioner or a pharmacist is not required to comply with the requirements of (a) and (b) of this section if

(1) the practitioner is a veterinarian licensed under AS 08.98 who is dispensing a prescription of a controlled substance in a quantity intended to last for not more than three days or who did not dispense a controlled substance during the daily reporting period; or

(2) a controlled substance is

(A) [(1)] administered to a patient at

(i) [(A)] a health care facility; or

(ii) [(B)] a correctional facility; **or**

(B) [(2)] dispensed to a patient for an outpatient supply of 24 hours or less at a hospital

(i) [(A)] inpatient pharmacy; or

1 **(ii)** [(B)] emergency department.

2 * **Sec. 3.** AS 17.30.200(u) is amended by adding a new paragraph to read:

3 (6) "practitioner" means

4 (A) a physician, dentist, advanced practice registered nurse,
5 optometrist, scientific investigator, veterinarian, or other person licensed,
6 registered, or otherwise permitted to distribute, dispense, conduct research with
7 respect to, or to administer or use in teaching or chemical analysis a controlled
8 substance in the course of professional practice or research in the state;

9 (B) a pharmacy, hospital, or other institution licensed,
10 registered, or otherwise permitted to distribute, dispense, conduct research with
11 respect to, or to administer a controlled substance in the course of professional
12 practice or research in the state.

Steps in the Board Regulation Adoption Process

Day 1

1
At an open meeting, the board votes on language to change regulations. This motion is forwarded to the Division Regulations Specialist for drafting.

Day 30

2
Once drafting is complete, the board holds another public meeting to edit or approve draft for public notice.

3
Approved language is reviewed by Division attorney.

4
Department of Law opens file.

Day 45

5
Division publishes and distributes public notice, additional regulation notice information, and proposed regulation to all licensees and interested parties. Public notice posted in newspaper and on Alaska Online Public Notice System

6
Public comment period and/or hearing (if applicable).

Day 65

7
Division Regulations Specialist compiles answers to questions and posts FAQ on the program web page.

Day 75

8
Regulations Specialist compiles public comments for distribution to board.

Day 90

9
Board holds an open meeting to review public comments, make minor changes, and adopt regulations. Substantive changes may require additional drafting and public notice (Step 2).

10
Division submits final regulation package to Department of Law for review and approval, and to the Governor's office.

11
Agency attorney reviews regulation

12
Regulations attorney reviews and either approves or disapproves regulation

Day 110

13
Unless returned by the Governor, Lt. Governor's office files approved regulation; regulations become effective in 30 days

Day 150

Once Regulations Are Effective

14a
Agency posts summary on Alaska Online Public Notice System

14b
Regulation published in Alaska Administrative Code

14c
Forms & FAQ updated on program web page

All timeframes are estimated, dependent upon staff and attorney workflow and board scheduling.

Updated by Law on August 2015 - Adapted by CBPL December 2018

Steps in the Regulation Process for a Board and Commission (board)[1]

Beginning the Process

1. At an open meeting, the board initiates and votes on proposed regulation changes.

2. **Reason:** Identify the reason for the proposed action, such as compliance with new or changed state law. If applicable, identify the law, order, decision, or other action of the federal government, or federal or state court, if that is the basis for the proposed action. The description need only be a sentence or two.

3. **Cost information:** In the meeting minutes there must be estimated costs in the aggregate to comply with the proposed action to:

    - A private person
    - Another state agency
    - A municipality

    Cost information is described simply as an estimate of annual costs within the board's ability to determine due to its familiarity with the regulated community.

    Example: The Board of Chiropractic Examiners is proposing to add three CE credits to their continuing competency requirements for a biennial license renewal. The proposal may cost

    - A private person: $50 per applicant/licensee
    - Another state agency: None known
    - A municipality: None known

4. Within 10 days of the meeting, board staff must transmit board minutes[2] or an excerpt of the minutes, draft language or proposals, and a completed Regulations FAQ Worksheet for the proposed regulation changes requested by the board to the Regulations Specialist.

What comes next: Regulations Specialist

5. The Regulations Specialist determines if there is authority in statute to adopt the proposed regulation changes.

6. The Regulations Specialist prepares a draft of regulation changes, using the Department of Law's *Drafting Manual for Administrative Regulations* for conformity and style, and works with board staff before submitting the final draft to the board for review/approval. In some instances the draft regulation changes will be reviewed by an AAG before the final draft is submitted to the board for review/approval.

7. Once completed, the draft proposed regulation changes are presented to the board at its next public meeting to review and approve the final draft, amends if needed, and requests that the approved draft be finalized and public noticed.

Public Notice

8. NOTE: The board must **always** provide an opportunity for submission of written comments in the regulation-adoption process. Also, the board should determine if it wants to hold a public hearing on the proposed regulation changes at its next meeting. If it does, the location, date and time of the hearing needs to be included in the public notice. Public hearings are usually held in conjunction with a regularly-scheduled meeting of the board and are always recorded. Oral public hearing is optional; however, answering the following questions will help the board determine if an oral public hearing is needed:

    - Are the regulations controversial and is there likely to be substantial public interest in them?
    - Would those most affected by the regulations be better able to participate if an oral hearing were held?
    - Would the board benefit from a face-to-face or teleconferenced opportunity to receive comments on the proposed regulations from interested persons?

9. Regulations Specialist sends notice to Alaska Dispatch News (or other newspapers if warranted) for publication, all interested parties, and licensees, if warranted. The Regulations Specialist posts the notice on the Alaska Online Public Notice System, electronically transmits a copy of the notice and proposed regulation changes to all incumbent legislators and the Legislative Affairs Agency, House & Senate Labor & Commerce Committees, Legislative Council, Lt. Governor, Governor, and Department of Law (Law). It is also emailed to board members and affected staff, including the commissioner's office. Public notice will be posted on the board's webpage.

Comment Period

10. The Regulations Specialist or board staff shall make a good faith effort to answer relevant questions received at least 10 days before the end of the public comment period. Questions must be in writing or asked at the legally noticed public meeting. The Regulations Specialist or board staff shall answer questions in writing and make the questions and answers available on the Alaska Online Public Notice System and the board's webpage. FAQs will be posted on the board's webpage and updated when relevant questions are answered. The Regulations Specialist or board staff may, but are not required to, answer written questions received after the 10-day cutoff date.

11. After the comment deadline (at least 30 days in duration), comments received on proposed regulation changes are compiled and copied by the Regulations Specialist and given to board staff to include in the board packets for the next open board meeting to be considered prior to adopting. Comments received after the deadline should not be forwarded to the board and comments should not be taken at the board meeting from the public prior to adoption unless a hearing was noticed and the comments are heard by the board during the comment period.

Adoption

12. The board's options regarding the proposed regulation changes at its next meeting are:

a. It can adopt the proposed regulation changes as written/publicly noticed, amend, and adopt them; or
b. Choose to take no action on them.
c. Substantive changes may require additional drafting and public notice (**see** Step 7 above).

13. When making a motion to adopt the regulations, the board is required to state on the record that it has reviewed any comments received, and considered the cost to private persons of the regulatory action being taken.

14. When regulation changes are adopted:

    a. The chair signs the adoption/certification order; and
    b. The board staff signs an affidavit of board action and/or affidavit of oral hearing (if applicable) and attaches it to the relevant minutes or an excerpt of the minutes and forwards to the Regulations Specialist.

Finalizing the regulation change process

15. Regulations Specialist prepares the final regulation package for transmittal to Department of Law for final review/approval, which includes the adopted regulations, certain affidavits, and other appropriate documents.

16. Assigned agency attorney reviews the regulations.

17. Regulations attorney reviews and either approves or disapproves regulation changes. Law reviews and will occasionally make edits. (On rare occasions, this may require the edited version to be re-adopted by the board at a subsequent meeting.) At the same time, the adopted regulations are submitted to the governor for review. The governor has 30 days to review the regulations under AS 44.62.040(c), and return the regulation for specified reasons.

18. Unless returned by the governor, when the governor and Law's review are complete, the adopted regulations are forwarded to the Lt. Governor for filing. Regulation changes are effective 30 days after filing unless a later effective date is specified in the adoption order.

Once regulations are effective

19. Agency posts summary of approved regulation changes on Alaska Online Public Notice System.

20. Agency updates statutes and regulations board webpage.

21. Regulation published in Alaska Administrative Code.

[1] The process may take six months to a year or longer to complete. It may be expedited if a board meets often or holds a teleconference following the written comment period to adopt the final regulations. Department of Law workload also plays a big part in the timeframe.

[2] Board minutes reflecting concisely what the project entails plays an important part in getting a project rolling. This is true for the initial stages and the final motion adopting the regulations following the public comment period due to the relevant minutes or an excerpt of the minutes being forwarded to the Department of Law with the final project.

MEMORANDUM

State of Alaska
Department of Law

To: The Honorable Kevin Meyer
Lieutenant Governor

From: Rebecca Polizzotto RCP
Chief Assistant Attorney General
and Regulations Attorney
Legislation and Regulations Section

Date: May 31, 2022

File No.: 2022200056

Tel. No.: 907-465-3600

Re: DCCED; Board of Pharmacy: amendment to 12 AAC 52 - licensing; emergency permits; license renewal; definitions

The Department of Law has reviewed the attached regulations of the Department of Commerce, Community, and Economic Development against the statutory standards of the Administrative Procedure Act. Based upon our review, we find no legal problems. This memorandum constitutes the written statement of approval under AS 44.62.060(b) and (c) that authorizes your office to file the attached regulations.

The Department of Commerce, Community, and Economic Development adopted these regulations after the close of the public comment period. These regulations amend 12 AAC 52 to allow for temporary military courtesy licenses and emergency permits. Additionally, updates are made to the standards for license renewal and the duties of the executive administer.

Both the February 3, 2022 public notice and the March 31, 2022 adoption order state that this action is not expected to require an increased appropriation. Therefore, a fiscal note under AS 44.62.195 is not required.

A number of technical edits are suggested to these regulations in accordance with AS 44.62.125. None of these edits are substantive in nature.

RCP:bws

cc w/ enclosures: Jun Maiquis, Regulations Contact
Department of Commerce, Community, and Economic Development

Harriet Milks, Senior Assistant Attorney General
Department of Law

ORDER CERTIFYING THE CHANGES TO REGULATIONS OF THE BOARD OF PHARMACY

The attached six pages of regulations, dealing with temporary military courtesy licenses, emergency permit, license renewal, and duties of executive administrator, are hereby certified to be a correct copy of the regulation changes that the Board of Pharmacy adopted at its March 25, 2022 teleconference meeting, under the authority of AS 08.01.062, AS 08.01.063, AS 08.01.100, AS 08.80.005, AS 08.80.030, AS 08.80.147, AS 08.80.150, AS 08.80.155, AS 08.80.157, AS 08.80.165, AS 08.80.261, and AS 08.80.270, 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: _____

Laura Carrillo Digitally signed by Laura Carrillo Date: 2022.03.31 00:51:09 -08'00'

Laura Carrillo, Executive Administrator
Alaska Board of Pharmacy

FILING CERTIFICATION

I, Kevin Meyer, Lieutenant Governor for the State of Alaska, certify that on _____, 2022 at _____.m., I filed the attached regulations according to the provisions of AS 44.62.040 – 44.62.120.

_____
Kevin Meyer, Lieutenant Governor

Effective: _____;

Register: _____.

Chapter 52. Board of Pharmacy.

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

12 AAC 52.105. Temporary military courtesy license. (a) The board ~~shall~~ will issue a temporary military courtesy license to an active duty military member or spouse of an active duty military member of the armed forces of the United States to practice as a pharmacist, pharmacy intern, or pharmacy technician who meets the requirements of AS 08.01.063 and this section ~~within~~ not later than 30 days after the board receives a completed application.

(b) An applicant for a temporary military courtesy license under this section ~~must~~

(1) must submit a completed application on a form provided by the department;

(2) must pay the temporary license application fee and license ~~fees~~ fee for a temporary set out under 12 AAC 02.105;

(3) must submit a copy of the applicant's P(A) ~~military identification or military dependent identification card and a copy of~~ current active duty military orders showing assignment to a duty station in this state; or P(B) if the applicant is the spouse of an active duty military member, the applicant's spouse's current active duty military orders showing assignment to a duty station in this state;

(4) must submit verification on a form provided by the department that the applicant is currently licensed in another licensing jurisdiction and the applicant's license in the other jurisdiction is not suspended, revoked, or otherwise restricted except for failure to apply for renewal or failure to obtain the required continuing education requirements; and

(5) may not have been convicted of a felony or another crime that affects the applicant's ability to practice as a pharmacist, pharmacy intern, or pharmacy technician competently and safely, as determined by the board.

(c) A temporary military courtesy license issued to an active duty military ~~personnel~~ member or spouse of an active duty military ~~personnel~~ member under this section will be issued for a period of 180 days and may be renewed

for one additional period ~~specified by~~ the board, ~~not to exceed 180 days~~.

(d) For an applicant applying for licensure under this section as a pharmacy technician, the board will accept ~~as substantially equivalent~~ any training completed while in the United States armed forces to work as a pharmacy technician or any technician license issued by another jurisdiction.

(e) While practicing under a temporary military courtesy license issued under this section, the holder of the temporary military courtesy license must comply with the standards of practice set out in AS 08.80 and this chapter.

(f) The board may refuse to issue a temporary military courtesy license for the same reasons that it may deny, suspend, or revoke a license under AS 08.80.261. (Eff. ____/____/_____, Register _____)

Authority:	AS 08.01.062	AS 08.80.005	AS 08.80.150
	AS 08.01.063	AS 08.80.030	AS 08.80.261

12 AAC 52.110 is amended to read:

12 AAC 52.110. Emergency permit [LICENSURE] to practice as a pharmacist, pharmacy intern, or pharmacy technician. (a) **An emergency permit ~~may be issued~~ to practice as a pharmacist, pharmacy intern, or pharmacy technician ~~in an urgent situation, as determined by the board~~ if the applicant** [IF THE BOARD DETERMINES THAT AN EMERGENCY EXISTS REQUIRING THE PROVISION OF LICENSED COVERAGE IN A PHARMACY THAT IS TEMPORARILY WITHOUT THE SERVICES OF A PHARMACIST DUE TO DEATH, ILLNESS, OR OTHER EMERGENCY CIRCUMSTANCES, THE BOARD MAY ISSUE AN EMERGENCY PHARMACIST, PHARMACY INTERN, OR PHARMACY TECHNICIAN PERMIT TO AN APPLICANT WHO]

~~DOL File#2022200056~~

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

(2) pays the emergency permit fee required in 12 AAC 02.310;

((Please retain/ incorporate/remove brackets for circled language)))

((board/D.L.)) confirms [SUBMITS VERIFICATION]

(3) ~~submits primary source verification~~ [ON A FORM PROVIDED BY THE DEPARTMENT] that the applicant ~~is currently licensed~~ in another licensing jurisdiction and the applicant's license in the other jurisdiction is not suspended, revoked, or otherwise restricted except for failure to apply for renewal or failure to obtain ~~the required~~ continuing education requirements;

((board/D.L.)) holds a license [IS CURRENTLY LICENSED]

((board/D.L.)) mandatory [THE REQUIRED]

(4) repealed 10/31/2019; and

(5) has not been convicted of a felony or another crime that affects the applicant's ability to practice pharmacy competently and safely.

(b) An emergency permit [UNDER (a) OF THIS SECTION] is nonrenewable, and is valid for **120 consecutive** [90] days or until the **urgent situation is determined by the board to** [EMERGENCY CIRCUMSTANCES] no longer exist, whichever is **sooner** [SHORTER].

(c) Repealed 11/19/2020.

(d) **Repealed** ____/____/_____ [IN AN URGENT SITUATION, THE BOARD MAY ISSUE AN EMERGENCY COURTESY LICENSE TO PRACTICE AS A PHARMACIST, PHARMACY INTERN, OR PHARMACY TECHNICIAN TO AN APPLICANT WHO MEETS THE REQUIREMENTS OF THIS SECTION. THE BOARD MAY RESTRICT THE LICENSE TO ONLY THOSE SERVICES REQUIRED TO RESPOND TO THE URGENT SITUATION. THE LICENSEE MAY NOT PRACTICE AS A PHARMACIST, PHARMACY INTERN, OR PHARMACY TECHNICIAN OUTSIDE THE SCOPE OF THE LIMITED PURPOSE FOR WHICH THE EMERGENCY COURTESY LICENSE IS ISSUED].

(e) **Repealed** ____/____/_____ [AN APPLICANT FOR AN EMERGENCY COURTESY LICENSE UNDER THIS SECTION MUST SUBMIT TO THE DEPARTMENT A

COMPLETED APPLICATION ON A FORM PROVIDED BY THE DEPARTMENT. A COMPLETE APPLICATION INCLUDES THE APPLICABLE APPLICATION AND LICENSING FEES ESTABLISHED IN 12 AAC 02.105].

(f) **Repealed** ____/____/_____ [AN EMERGENCY COURTESY LICENSE ISSUED UNDER THIS SECTION IS VALID FOR THE PERIOD SPECIFIED BY THE BOARD AND MAY NOT EXCEED 120 CONSECUTIVE DAYS. AN EMERGENCY COURTESY LICENSE MAY BE RENEWED FOR ONE ADDITIONAL PERIOD SPECIFIED BY THE BOARD, NOT TO EXCEED 120 CONSECUTIVE DAYS].

(g) The board will not issue, and an emergency **permit** [COURTESY LICENSE] holder may not use, an emergency **permit** [COURTESY LICENSE] as a substitute for a temporary license or other license required under AS 08.80.

(h) While practicing under an emergency **permit** [COURTESY LICENSE ISSUED UNDER THIS SECTION], the holder of the emergency courtesy license must comply with the standards of practice set out in AS 08.80 and this chapter.

(i) The board may refuse to issue an emergency **permit** [COURTESY LICENSE] for the same reasons that it may deny, suspend, or revoke a license under AS 08.80.261.

(j) In this section, "urgent situation" means a health crisis requiring an increased availability of pharmacists, pharmacy interns, [.] or pharmacy technicians. (Eff. 1/16/98, Register 145; am 1/17/2007, Register 181; am 8/12/2007, Register 183; am 10/31/2019, Register 232; am 11/19/2020, Register 236; am ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.155

12 AAC 52.300 is amended to read:

12 AAC 52.300. License renewal. (a) Pharmacy, **remote pharmacy,** wholesale drug

distributor, **outsourcing facility, third-party logistics provider, pharmacist, pharmacy technician,** and drug room licenses ~~expire on June 30 of even-numbered years, unless extended due to an emergency or extenuating circumstance as determined by the board~~.

(b) An applicant for renewal of a pharmacy, wholesale drug distributor, **outsourcing facility, third-party logistics provider,** or drug room license **must** [SHALL] submit **on or before the license expiration date**

(1) a completed renewal application **on a form provided by the department**;

(2) the license renewal fees required in 12 AAC 02.310; and

(3) **an attestation that** a [COMPLETED] self-inspection of the premises **using the** [QUESTIONNAIRE ON A] form provided by the department **was completed within the last two years or since the last time the license or registration was initially issued. The self-inspection must be retained, and available upon request, for the duration of the licensing period in which it was completed**.

(c) An applicant for renewal of a pharmacist or pharmacy technician license shall submit on or before the license expiration date

(1) a completed renewal application **on a form provided by the department**;

(2) the license renewal fees required in 12 AAC 02.310; and

(3) an attestation that the applicant has met all continuing education requirements of 12 AAC 52.320 – 12 AAC 52.350;

(4) repealed 4/3/2020.

(d) A pharmacy that has changed its name, physical address, or ownership since the date it was first issued or last renewed is not eligible for renewal.

(e) A wholesale drug distributor that has changed its name, physical address, ownership, or facility manager is not eligible for renewal if the change occurred 30 days

after the date a renewal application is submitted to the board.

(f) An outsourcing facility or third-party logistics provider that has changed its name, physical address, ownership, or facility manager is not eligible for renewal.

(g) All renewal applications will be administratively processed and will not require board review unless the executive administrator has reason to believe that renewing the license poses an immediate threat to public health or safety. (Eff. 1/16/98, Register 145; am 2/26/2000, Register 153; am 5/5/2000, Register 154; am 5/26/2006, Register 178; am 4/3/2020, Register 234; am 8/30/2020, Register 235; am ____/____/_____, Register _____)

Authority: AS 08.01.100 AS 08.80.030 AS 08.80.157

AS 08.80.005 AS 08.80.147 AS 08.80.165

12 AAC 52.993 is amended by adding a new paragraph to read:

(6) review and approve applications for licensure or registration as long as the applicant meets the requirements established for the license type for which they are applying. (Eff. 10/31/2019, Register 232; am ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.270

((Conversion to Bylaws 12 AAC 52.110))

12 AAC 52.140(c) is repealed:

(c) Repealed ___/___/_____. (Eff. 1/16/98, Register 145; am 2/15/2006, Register 177; am 1/17/2007, Register 181; am ___/___/_____)

((bold)) Authority: AS 08.80.005 AS 08.80.030

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

BRIEF DESCRIPTION: The Board of Pharmacy proposes to update regulations regarding its qualifications and requirements to apply for an emergency permit and renewal application requirements for pharmacists, pharmacy technicians, pharmacies, outsourcing facilities, wholesale drug distributors, and third-party logistics providers. It also proposes to repeal the emergency courtesy license, update duties of its executive administrator as it relates to renewal application processing, and establish temporary courtesy licenses for an active duty military member or their spouse.

The Board of Pharmacy (Board) proposes to adopt regulation changes in Title 12, Chapter 52 of the Alaska Administrative Code including the following:

1. **12 AAC 52.105. Temporary military courtesy licenses,** is a proposed new section that establishes temporary courtesy licenses for an active duty military member or spouse of an active duty military member of the armed forces of the United States to practice as a pharmacist, pharmacy intern, or pharmacy technician. The proposed regulations will allow for an expedited temporary licensing pathway for those in the military and their spouse.

2. **12 AAC 52.110. Emergency permit to practice as a pharmacist, pharmacy intern, or pharmacy technician,** is proposed to amend the emergency permit language as the intent was duplicative to the emergency courtesy license option.

3. **12 AAC 52.300. License renewal,** is proposed to update language to be all inclusive of pharmacy license and registration types; clarifies renewal must be on department form; replaces copy of inspection report for pharmacies or facilities with an attestation; clarifies eligibility for renewal or new application required if there is a change; and adds administrative and executive administrator processing language.

4. **12 AAC 52.993. Executive administrator,** is proposed to amend the executive administrator's duties by adding the ability to review and approve licenses or registrations as long as the applicant meets the requirements of the established checklist as codified in the regulations; clarifies role of executive administrator; creates efficiencies by allowing task delegation of the board to staff.

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 Jun Maiquis, 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/205318, and using the comment link. **The comments must be received not later than 4:30 p.m. on March 8, 2022.** Comments received after this deadline will not be considered by the Board.

You may submit written questions relevant to the proposed action to Jun Maiquis, 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. The Board may, but is not required to, answer written questions received after the 10-day cut-off date and before the end of the comment period.

If you are a person with a disability who needs a special accommodation in order to participate in this process, please contact Jun Maiquis at (907) 465-2537 or RegulationsAndPublicComment@alaska.gov not later than March 1, 2022 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 Jun Maiquis at (907) 465-2537 or RegulationsAndPublicComment@alaska.gov, or go to https://www.commerce.alaska.gov/web/portals/5/pub/PHA-0222.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.** Written comments and questions received are public records and are subject to public inspection.

Statutory Authority: AS 08.01.062; AS 08.01.063; AS 08.01.100; AS 08.80.005; AS 08.80.030; AS 08.80.147; AS 08.80.150; AS 08.80.155; AS 08.80.157; AS 08.80.165; AS 08.80.261; AS 08.80.270
Statutes Being Implemented, Interpreted, or Made Specific: AS 08.01.062; AS 08.01.063; AS 08.01.100; AS 08.80.005; AS 08.80.030; AS 08.80.147; AS 08.80.150; AS 08.80.155; AS 08.80.157; AS 08.80.165; AS 08.80.261; AS 08.80.270

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

DATE: 2/2/22

Jun Maiquis, Regulations Specialist
Division of Corporations, Business and
Professional Licensing

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.

ADDITIONAL REGULATION NOTICE INFORMATION
(AS 44.62.190(d))

1. **Adopting agency:** Board of Pharmacy – Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing.

2. **General subject of regulation:** Temporary military courtesy licenses, emergency permit, license renewal, and executive administrator.

3. **Citation of regulation:** 12 AAC 52.105, 12 AAC 52.110, 12 AAC 52.300, and 12 AAC 52.993.

4. **Department of Law file number:** To be assigned.

5. **Reason for the proposed action:** Update and clarification of current regulations, and to implement statutory changes made under Sections 1 and 2, Chapter 29, SLA 2021 (SB 21).

6. **Appropriation/Allocation:** Corporations, Business and Professional Licensing – #2360.

7. **Estimated annual cost to comply with the proposed action to:**
   A private person: $100 application fee and $100 temporary military courtesy license fee.
   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 2022 or in subsequent years.

9. **The name of the contact person for the regulation:**
   Laura Carrillo, 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: laura.carrillo@alaska.gov

10. **The origin of the proposed action:** Board of Pharmacy.

11. **Date:** 2/2/22 **Prepared by:** _____
    Jun Maiquis
    Regulations Specialist

AFFIDAVIT OF NOTICE OF PROPOSED REGULATION AND FURNISHING OF ADDITIONAL INFORMATION

I, Jun Maiquis, Regulations Specialist, of the Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing, being sworn, state the following:

As required by AS 44.62.190, notice of the proposed adoption of changes to 12 AAC 52.105, 12 AAC 52.110, 12 AAC 52.300, and 12 AAC 52.993, dealing with temporary military courtesy licenses, emergency permit, license renewal, and duties of executive administrator, has been given by being

1. published in a newspaper or trade publication;
2. furnished to every person who has filed a request for notice of proposed action with the state agency;
3. furnished to appropriate state officials;
4. furnished to interested persons;
5. furnished to the Department of Law, along with a copy of the proposed regulation;
6. furnished electronically to incumbent State of Alaska legislators;
7. posted on the Alaska Online Public Notice System as required by AS 44.62.175(a)(1) and (b) and 44.62.190(a)(1).

As required by AS 44.62.190, additional regulation notice information regarding the proposed adoption of the regulation changes described above has been furnished to interested persons and those in (2), (4), and (6) of the list above. The additional regulation notice information also has been posted on the Alaska Online Public Notice System.

DATE: 3/31/22

Jun Maiquis, Regulations Specialist

SUBSCRIBED AND SWORN TO before me this 31 day of March, 2022.

Jolene Siirila
Notary Public in and for the
State of Alaska
My commission expires: w/office

Jolene Siirila
My Commission Expires
NOTARY PUBLIC
With Office
State of Alaska

AFFIDAVIT OF AGENCY RECORD OF PUBLIC COMMENT

I, Jun Maiquis, Regulations Specialist for the Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing, being duly sworn, state the following:

In compliance with AS 44.62.215, the Board of Pharmacy has kept a record of its use or rejection of factual or other substantive information that was submitted in writing as public comment and that was relevant to the accuracy, coverage, or other aspect of the Board of Pharmacy regulations on dealing with temporary military courtesy licenses, emergency permit, license renewal, and duties of executive administrator.

DATE: 3/31/22

Jun Maiquis, Regulations Specialist

SUBSCRIBED AND SWORN TO before me this 31 day of March, 2022.

Jolene Siirila
My Commission Expires
NOTARY PUBLIC
With Office
State of Alaska

Notary Public in and for the
State of Alaska
My commission expires: w/ office

ANCHORAGE DAILY NEWS
AFFIDAVIT OF PUBLICATION

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STATE OF ALASKA
THIRD JUDICIAL DISTRICT

Lisi Misa being first duly sworn on oath deposes and says that she is a representative of the Anchorage Daily News, a daily newspaper. That said newspaper has been approved by the Third Judicial Court, Anchorage, Alaska, and it now and has been published in the English language continually as a daily newspaper in Anchorage, Alaska, and it is now and during all said time was printed in an office maintained at the aforesaid place of publication of said newspaper. That the annexed is a copy of an advertisement as it was published in regular issues (and not in supplemental form) of said newspaper on

02/03/2022

and that such newspaper was regularly distributed to its subscribers during all of said period. That the full amount of the fee charged for the foregoing publication is not in excess of the rate charged private individuals.

Signed_____

Subscribed and sworn to before me
this 4th day of April 2022.

Notary Public in and for
The State of Alaska.
Third Division
Anchorage, Alaska

MY COMMISSION EXPIRES
7/14/2021

JADA L. NOWLING
Notary Public
State of Alaska
My Commission Expires Jul 14, 2024

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

The Board of Pharmacy (Board) proposes to adopt regulation changes in Title 12, Chapter 52 of the Alaska Administrative Code including the following:

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2. 12 AAC 52.110. Emergency permit to practice as a pharmacist, pharmacy intern, or pharmacy technician, is proposed to amend the emergency permit language as the intent was duplicative to the emergency courtesy license option.
3. 12 AAC 52.300. License renewal, is proposed to update language to be all inclusive of pharmacy license and registration types; clarifies renewal must be on department form; replaces copy of inspection report for pharmacies or facilities with an attestation; clarifies eligibility for renewal or new application required if there is a change; and adds administrative and executive administrator processing language.
4. 12 AAC 52.993. Executive administrator, is proposed to amend the executive administrator's duties by adding the ability to review and approve licenses or registrations as long as the applicant meets the requirements of the established checklist as codified in the regulations; clarifies role of executive administrator; creates efficiencies by allowing task delegation of the board to staff.

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A copy of the proposed regulation changes is available on the Alaska Online Public Notice System and by contacting Jun Maiquis at (907) 465-2537 or RegulationsAndPublicComment@alaska.gov, or go to https://www.commerce.alaska.gov/web/portals/5/pub/PHA-0222.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. Written comments and questions received are public records and are subject to public inspection.

Statutory Authority: AS 08.01.062; AS 08.01.063; AS 08.01.100; AS 08.80.005; AS 08.80.030; AS 08.80.147; AS 08.80.150; AS 08.80.155; AS 08.80.157; AS 08.80.165; AS 08.80.261; AS 08.80.270
Statutes Being Implemented, Interpreted, or Made Specific: AS 08.01.062; AS 08.01.063; AS 08.01.100; AS 08.80.005; AS 08.80.030; AS 08.80.147; AS 08.80.150; AS 08.80.155; AS 08.80.157; AS 08.80.165; AS 08.80.261; AS 08.80.270

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

DATE: 2/2/2022
/s/ Jun Maiquis,
Regulations Specialist
Division of Corporations, Business and
Professional Licensing

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.

Pub: February 3, 2022

AFFIDAVIT OF BOARD ACTION

I, Laura Carrillo, Executive Administrator for the Board of Pharmacy, being duly sworn, state the following:

The attached motion dealing with temporary military courtesy licenses, emergency permit, license renewal, and duties of executive administrator was passed by the Board of Pharmacy during its March 25, 2022 teleconference meeting.

Date: _____

Laura Carrillo Digitally signed by Laura Carrillo Date: 2022.03.31 00:52:53 -08'00'

Laura Carrillo, Executive Administrator

On a motion duly made by Justin Ruffridge to amend 12 AAC 52.110(a)(3) to read, "submits primary source verification that the applicant is currently licensed in another licensing jurisdiction and the applicant's license in the other jurisdiction is not suspended, revoked, or otherwise restricted except for failure to apply for renewal or failure to obtain the required continuing education requirements;" seconded by James Henderson and approved unanimously, it was:

RESOLVED to approve 12 AAC 52.110(a)(3) as amended and proposed.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Tammy Lindemuth				x
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Ramsey Bell	x			

The motion passed with no further discussion.

On a motion duly made by Ashley Schaber to amend 12 AAC 52.300(a) regarding renewal to include, "remote pharmacy", "pharmacist" and "pharmacy technician" and to add "unless extended due to an emergency or extenuating circumstance as determined by the board, seconded by James Henderson and approved unanimously, it was:

RESOLVED to approve 12 AAC 52.300(a) as amended and proposed.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Tammy Lindemuth				x
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Ramsey Bell	x			

The motion passed with further discussion. Ms. Carrillo stated the changes are not substantive per Department of Law and do not need to be re-released for public comment.

On a motion duly made by Ashley Schaber to approve 12 AAC 52.105 related to military licensing as proposed, 12 AAC 52.110 related to emergency permits as amended, 12 AAC 52.300 related to renewal as amended, and 12 AAC 52.993 related to executive administrator duties as proposed, seconded by James Henderson and approved unanimously, it was:

> **RESOLVED to approve 12 AAC 52.105, 12 AAC 52.110, 12 AAC 52.300, and 12 AAC 52.993 as amended and proposed.**

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Tammy Lindemuth				x
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Ramsey Bell	x			

The motion passed with no further discussion.

Unedited and Unapproved by the Department of Law For Use by the Publisher Only

Chapter 52. Board of Pharmacy.

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

12 AAC 52.105. Temporary military courtesy licenses. (a) The board shall issue a temporary military courtesy license to an active duty military member or spouse of an active duty military member of the armed forces of the United States to practice as a pharmacist, pharmacy intern, or pharmacy technician who meets the requirements of AS 08.01.063 and this section within 30 days after the board receives a completed application.

(b) An applicant for a temporary military courtesy license under this section must

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

(2) pay the temporary license application and license fees set out under 12 AAC 02.105;

(3) submit a copy of the applicant's military identification or military dependent identification card and a copy of current active duty military orders showing assignment to a duty station in this state;

(4) submit verification on a form provided by the department that the applicant is currently licensed in another licensing jurisdiction and the applicant's license in the other jurisdiction is not suspended, revoked, or otherwise restricted except for failure to apply for renewal or failure to obtain the required continuing education requirements; and

(5) not have been convicted of a felony or another crime that affects the applicant's ability to practice as a pharmacist, pharmacy intern, or pharmacy technician competently and safely.

(c) A temporary military courtesy license to active duty military personnel or spouse of military personnel under this section will be issued for a period of 180 days and may be renewed

for one additional period specified by the board, not to exceed 180 days.

(d) For an applicant applying for licensure under this section as a pharmacy technician, the board will accept as substantially equivalent any training completed while in the United States armed forces to work as a pharmacy technician or any technician license issued by another jurisdiction.

(e) While practicing under a temporary military courtesy license issued under this section, the holder of the temporary military courtesy license must comply with the standards of practice set out in AS 08.80 and this chapter.

(f) The board may refuse to issue a temporary military courtesy license for the same reasons that it may deny, suspend, or revoke a license under AS 08.80.261. (Eff. ____/____/_____, Register _____)

Authority:	AS 08.01.062	AS 08.80.005	AS 08.80.150
	AS 08.01.063	AS 08.80.030	AS 08.80.261

12 AAC 52.110 is amended to read:

12 AAC 52.110. Emergency <u>permit</u> [LICENSURE] to practice as a pharmacist, pharmacy intern, or pharmacy technician. (a) **<u>An emergency permit may be issued to practice as a pharmacist, pharmacy intern, or pharmacy technician in an urgent situation as determined by the board if the applicant</u>** [IF THE BOARD DETERMINES THAT AN EMERGENCY EXISTS REQUIRING THE PROVISION OF LICENSED COVERAGE IN A PHARMACY THAT IS TEMPORARILY WITHOUT THE SERVICES OF A PHARMACIST DUE TO DEATH, ILLNESS, OR OTHER EMERGENCY CIRCUMSTANCES, THE BOARD MAY ISSUE AN EMERGENCY PHARMACIST, PHARMACY INTERN, OR PHARMACY TECHNICIAN PERMIT TO AN APPLICANT WHO]

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

(2) pays the emergency permit fee required in 12 AAC 02.310;

(3) submits **primary source** verification [ON A FORM PROVIDED BY THE DEPARTMENT] that the applicant is currently licensed in another licensing jurisdiction and the applicant's license in the other jurisdiction is not suspended, revoked, or otherwise restricted except for failure to apply for renewal or failure to obtain the required continuing education requirements;

(4) repealed 10/31/2019; and

(5) has not been convicted of a felony or another crime that affects the applicant's ability to practice pharmacy competently and safely.

(b) An emergency permit [UNDER (a) OF THIS SECTION] is nonrenewable, and is valid for **120 consecutive** [90] days or until the **urgent situation is determined by the board to** [EMERGENCY CIRCUMSTANCES] no longer exist, whichever is **sooner** [SHORTER].

(c) Repealed 11/19/2020.

(d) **Repealed** ____/____/_____ [IN AN URGENT SITUATION, THE BOARD MAY ISSUE AN EMERGENCY COURTESY LICENSE TO PRACTICE AS A PHARMACIST, PHARMACY INTERN, OR PHARMACY TECHNICIAN TO AN APPLICANT WHO MEETS THE REQUIREMENTS OF THIS SECTION. THE BOARD MAY RESTRICT THE LICENSE TO ONLY THOSE SERVICES REQUIRED TO RESPOND TO THE URGENT SITUATION. THE LICENSEE MAY NOT PRACTICE AS A PHARMACIST, PHARMACY INTERN, OR PHARMACY TECHNICIAN OUTSIDE THE SCOPE OF THE LIMITED PURPOSE FOR WHICH THE EMERGENCY COURTESY LICENSE IS ISSUED].

(e) **Repealed** ____/____/_____ [AN APPLICANT FOR AN EMERGENCY COURTESY LICENSE UNDER THIS SECTION MUST SUBMIT TO THE DEPARTMENT A

COMPLETED APPLICATION ON A FORM PROVIDED BY THE DEPARTMENT. A COMPLETE APPLICATION INCLUDES THE APPLICABLE APPLICATION AND LICENSING FEES ESTABLISHED IN 12 AAC 02.105].

(f) **Repealed** ____/____/_____ [AN EMERGENCY COURTESY LICENSE ISSUED UNDER THIS SECTION IS VALID FOR THE PERIOD SPECIFIED BY THE BOARD AND MAY NOT EXCEED 120 CONSECUTIVE DAYS. AN EMERGENCY COURTESY LICENSE MAY BE RENEWED FOR ONE ADDITIONAL PERIOD SPECIFIED BY THE BOARD, NOT TO EXCEED 120 CONSECUTIVE DAYS].

(g) The board will not issue, and an emergency **permit** [COURTESY LICENSE] holder may not use, an emergency **permit** [COURTESY LICENSE] as a substitute for a temporary license or other license required under AS 08.80.

(h) While practicing under an emergency **permit** [COURTESY LICENSE ISSUED UNDER THIS SECTION], the holder of the emergency courtesy license must comply with the standards of practice set out in AS 08.80 and this chapter.

(i) The board may refuse to issue an emergency **permit** [COURTESY LICENSE] for the same reasons that it may deny, suspend, or revoke a license under AS 08.80.261.

(j) In this section, "urgent situation" means a health crisis requiring an increased availability of pharmacists, pharmacy interns, [.] or pharmacy technicians. (Eff. 1/16/98, Register 145; am 1/17/2007, Register 181; am 8/12/2007, Register 183; am 10/31/2019, Register 232; am 11/19/2020, Register 236; am ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.155

12 AAC 52.300 is amended to read:

12 AAC 52.300. License renewal. (a) Pharmacy, **remote pharmacy,** wholesale drug

distributor, **outsourcing facility, third-party logistics provider, pharmacist, pharmacy technician,** and drug room licenses expire on June 30 of even-numbered years**, unless extended due to an emergency or extenuating circumstance as determined by the board**.

(b) An applicant for renewal of a pharmacy, wholesale drug distributor, **outsourcing facility, third-party logistics provider,** or drug room license **must** [SHALL] submit **on or before the license expiration date**

(1) a completed renewal application **on a form provided by the department**;

(2) the license renewal fees required in 12 AAC 02.310; and

(3) **an attestation that** a [COMPLETED] self-inspection of the premises **using the** [QUESTIONNAIRE ON A] form provided by the department **was completed within the last two years or since the last time the license or registration was initially issued. The self-inspection must be retained, and available upon request, for the duration of the licensing period in which it was completed**.

(c) An applicant for renewal of a pharmacist or pharmacy technician license shall submit on or before the license expiration date

(1) a completed renewal application **on a form provided by the department**;

(2) the license renewal fees required in 12 AAC 02.310; and

(3) an attestation that the applicant has met all continuing education requirements of 12 AAC 52.320 – 12 AAC 52.350;

(4) repealed 4/3/2020.

(d) A pharmacy that has changed its name, physical address, or ownership since the date it was first issued or last renewed is not eligible for renewal.

(e) A wholesale drug distributor that has changed its name, physical address, ownership, or facility manager is not eligible for renewal if the change occurred 30 days

after the date a renewal application is submitted to the board.

(f) An outsourcing facility or third-party logistics provider that has changed its name, physical address, ownership, or facility manager is not eligible for renewal.

(g) All renewal applications will be administratively processed and will not require board review unless the executive administrator has reason to believe that renewing the license poses an immediate threat to public health or safety. (Eff. 1/16/98, Register 145; am 2/26/2000, Register 153; am 5/5/2000, Register 154; am 5/26/2006, Register 178; am 4/3/2020, Register 234; am 8/30/2020, Register 235; am ____/____/_____, Register _____)

Authority: AS 08.01.100 AS 08.80.030 AS 08.80.157
AS 08.80.005 AS 08.80.147 AS 08.80.165

12 AAC 52.993 is amended by adding a new paragraph to read:

(6) review and approve applications for licensure or registration as long as the applicant meets the requirements established for the license type for which they are applying.

(Eff. 10/31/2019, Register 232; am ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.270

THE STATE of ALASKA
GOVERNOR MIKE DUNLEAVY

Department of Commerce, Community, and Economic Development

DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING
Juneau Office

P.O. Box 110806
Juneau, AK 99811-0806
Main: 907.465.2550
Toll free fax: 907.465.2974

Notice of Proposed Changes in The Regulations of the Alaska Board of Pharmacy

Proposed Regulations - FAQ

May 2022

1. What is the purpose of the proposed regulations? What will this regulation do?

12 AAC 52.020. Pharmacy license

• Replaces copy of inspection report with an attestation
• Updates language from "facility" to "pharmacy"
• Clarifies that a pharmacy with a name change, ownership, or physical address change must apply for a new license (from 12 AAC 52.030 for change of facility location or name section and12 AAC 52.040 for change of facility ownership)
• New checklist language added for executive administrator and board review/approval
• Reduce administrative burden and onerous paperwork requirements

12 AAC 52.030. Change of pharmacy location or name

• Repeals change of pharmacy location of name as the language will be amended and incorporated in 12 AAC 52.020; simplifies regulations
• Standardizes requirements for wholesalers to apply for a new license if there is a change of location or name (this is to repeal and adopt into 12 AAC 52.020)
• Reduce administrative burden and onerous paperwork requirements

12 AAC 52.040. Change of pharmacy ownership

• Repeals this section as it will be cleaned up and incorporated in 12 AAC 52.020
• Standardizes requirements for facilities to apply for a new license if there is a change in ownership (this is to repeal and adopt into 12 AAC 52.020)
• Reduce administrative burden and onerous paperwork requirements

12 AAC 52.070. Application for pharmacist license by examination

• Removes the transcript and diploma requirements (NABP already requires these for scheduling exams)
• Clarifies diploma requirement for foreign graduates
• Allows verification of experience signed by employer/school to come from applicant instead of coming directly from verifier
• New checklist language added for executive administrator and board review/approval

• Replaces the requirement to have verification of 1,500 academic hours submitted by the pharmacy school on behalf of the applicant with an attestation from the applicant the hours were completed
• Clarifies applications can be administratively approved by the executive administrator under certain circumstances
• Supports the ease of qualified applicants to staff pharmacies and other institutions where pharmacists are needed to provide adequate patient care
• Reduces regulatory barriers to licensure and simplifies administrative processing of applications
• Removes redundancies for applicants

12 AAC 52.080. Internship requirements for a pharmacist license
• Repeals the section on internship requirements in 12 AAC 52.080 because changes proposed in 12 AAC 52.070(b)(6) already includes the requirement for the intern to attest they've completed all hours required for graduation from a pharmacy program; all pharmacy programs require at least 1,500 hours of instruction of practice
• Supports the ease of qualified applicants to staff pharmacies and other institutions where pharmacist interns are needed to provide adequate patient care
• Reduces regulatory barriers to licensure and simplifies administrative processing of applications

12 AAC 52.092. Eligibility to sit for examination
• Removes redundant language already in 12 AAC 52.070
• Updates language from "approval" to "eligibility" consistent with NABP terminology
• New checklist language added to clarify eligibility requirements
• Reduce administrative burden and onerous paperwork requirements
• Removes redundancies for applicants

12 AAC 52.095. Application for pharmacist license by reciprocity
• Removes the authorization for release of records requirement
• Removes the transcript and diploma requirement (NABP already requires these for scheduling exams)
• Clarifies diploma requirement for foreign graduates
• Allows verification of experience signed by employer/school to come from applicant instead of coming directly from verifier
• Clarifies applications can be administratively approved by the executive administrator under certain circumstances
• Removes the verification of licensure requirement and instead accepts the license transfer application
• Removes the requirement to document verification of experience and instead accepts an indication the applicant has graduated from a pharmacy curriculum
• Supports the ease of qualified applicants to staff pharmacies and other institutions where pharmacists are needed to provide adequate patient care
• Reduces regulatory barriers to licensure and simplifies administrative processing of applications

12 AAC 52.120. Review of pharmacist intern license application
• Removes checklist language.
• Clarifies applications can be administratively approved by the executive administrator under certain circumstances.
• Clarifies current pharmacy students and students who have graduated within a year of application may apply for an intern license.

• Removes the authorization of release of records requirement
• Extends the duration of the license from two years to five years
• Removes the affidavit of moral character requirement
• Clarifies that a pharmacist intern licensee cannot renew their license; they must reapply for licensure if the license is still needed after 5 years
• Supports the ease of qualified applicants to staff pharmacies and other institutions where pharmacist interns are needed to provide adequate patient care
• Reduces regulatory barriers to licensure and simplifies administrative processing of applications

12 AAC 52.130. Registration of pharmacies located outside of the state
• Simplifies fee language
• Accepts a copy of license in jurisdiction rather than requiring a certified copy
• Replaces copy of inspection report with an attestation
• Removes onerous requirements, reduces administrative burden.

12 AAC 52.140. Pharmacy technician license
• Removes redundant renewal language
• Adds administrative/executive checklist language
• Creates processing efficiencies

12 AAC 52.200. Pharmacist-in-charge
• Removes redundant language in (a) since this is already addressed in 12 AAC 52.020
• Replaces "ensuring" with "establishing"
• Removes requirement to furnish names of all pharmacists employed by pharmacy upon request as the intent behind this is unclear; if it is for investigative purposes, this is already part of the process
• Clarifies a change form must be submitted for licensed (in-state) and registered (out-of-state) pharmacies
• Adds language to limit the number of locations a pharmacist may be the pharmacist-in-charge for/creates a mechanism to request permission to be responsible for more than one pharmacy
• Clarifies pharmacist-in-charge duties and limits the number of pharmacies a pharmacist can be responsible for to ensure adequate oversight of pharmacy personnel and patient care

12 AAC 52.230. Pharmacy technicians
• Clarifies duties requiring a pharmacy technician license
• Clarifies who may qualify to be a pharmacy technician

12 AAC 52.240. Pharmacist cooperative practice authority
• Conforms title to State Medical Board regulation, 12 AAC 40.983 by replacing "collaborative" with "cooperative"
• Removes redundant language that is already in 12 AAC 40.983
• Removes requirement for board to approve the agreement and instead endorses it if approved by the medical board
• Adds requirement for applicant to provide documentation the medical board or its delegate approved the agreement
• Reduces regulatory barriers, streamlines the approval process, and supports access to certain types of care

12 AAC 52.470. Refills
• Removes unnecessary language; simplifies regulation

12 AAC 52.585. Patient counseling
• Obligates a pharmacist or pharmacist intern to offer but not provide patient counseling
• Removes examples of the topics that may be included in counseling
• Clarifies the methods in which counseling can take place, e.g.: verbal, written, electronic
• Adds requirements for patient counseling when an opioid is being dispensed for the first time
• Simplifies regulations and adds mandatory counseling for opioids to educate the public on risks of use

12 AAC 52.610. Wholesale drug distributor license
• Clarifies applications can be administratively approved by the executive administrator under certain circumstances
• Removes notary requirement
• Removes requirement to provide names and resumes for facility managers, officers, directors, or primary stockholders
• Removes the requirement to provide an inspection report and instead accepts an attestation that either a self-inspection or VAWD inspection was completed
• Removes the requirement to submit fingerprints
• Clarifies that within 30 days of a change in location, ownership, or name, the wholesaler must apply for a new and separate license
• Removes requirement for the new facility manager to submit a new application as a result in a change
• Simplifies regulations and reduces barriers to providing medications to pharmacies

12 AAC 52.620. Wholesale drug facilities
• Include devices to the wholesale drug facilities regulations

12 AAC 52.635. Facility manager
• Creates a new section for facility manager
• Creates standardization amongst facilities to submit a change in facility manager form within 10 days (is currently in 12 AAC 52.610 for wholesalers with a 30-day timeframe, 12 AAC 52.696 with a 10-day requirement for outsourcing facilities, and in 12 AAC 52.697 with a 10-day requirement for 3PLs)
• Allows a facility manager to be in charge of more than one location
• Standardizes regulations

12 AAC 52.696. Outsourcing facilities
• Clarifies applications can be administratively approved by the executive administrator under certain circumstances
• Removes notary requirement
• Removes requirement to provide names and resumes for facility managers, officers, directors, or primary stockholders
• Removes the requirement to provide an inspection report and instead accepts an attestation that a self-inspection was completed
• Removes the requirement to submit fingerprints
• Clarifies that within 30 days of a change in location, ownership, or name, the wholesaler must apply for a new and separate license

• Removes requirement for the new facility manager to submit a new application as a result in a change
• Corrects the FDA citation
• Simplifies regulations and reduces barriers to providing medications to pharmacies

12 AAC 52.697. Third-party logistics providers
• Removes notary requirement
• Removes requirement to provide list of officers, directors, or stockholders
• Removes fingerprint requirement
• Removes resume requirement
• Replaces copy of inspection report with an attestation.
• Removes language regarding DEA registration (already a DEA requirement, board does not require documentation
• Adds language addressing new license when change occurs
• Reduces onerous paperwork requirements, alleviates time constraints by expanding change deadline from 10 days to 30 days
• Removes onerous paperwork requirements, improves administrative efficiencies, removes redundant language

12 AAC 52.860. Access to and conditions for use of the prescription drug monitoring program database
• Add a definition for "state medical examiner"

12 AAC 52.865. Reporting and reviewing PDMP information
• Update the reporting and reviewing of PDMP information

12 AAC 52.990. Display of license certificate
• Remove outdated language and regulations

2. What are the costs to comply with the proposed regulations?

None known.

3. When will the regulations be effective?

After the public comment deadline, comments received are compiled and given to the Board for consideration. The Board may adopt the regulation as written/publicly noticed, may amend and adopt them, choose to take no action, or may withdraw the proposed regulations in part or in its whole. After Board action, the adopted regulations goes to Department of Law (DOL) for final review/approval. DOL either approves or disapproves regulations. Once approved by DOL, it goes to the Lt. Governor for filing. Regulation takes effect on the 30th day after they have been filed by the Lt. Governor.

Chapter 52. Board of Pharmacy.

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

12 AAC 52.020 is repealed and readopted to read:

12 AAC 52.020. Pharmacy license. (a) An applicant for a pharmacy license shall submit the items required in (b) of this section for review and approval by the executive administrator. An application that does not clearly demonstrate qualifications for licensure must be reviewed and approved by the board.

(b) An applicant for a pharmacy license shall submit

(1) a complete, notarized application on a form provided by the department;

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

(3) an attestation that within 14 days after commencement of business, a self-inspection on a form provided by the department will be completed. The self-inspection must be retained, and available upon request, for the duration of the licensing period in which it was completed; and

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

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

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

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

(f) A pharmacy that has changed its name, ownership, or physical address shall apply for a new and separate license in accordance with this section. (Eff. 1/16/98, Register 145; am 2/26/2000, Register 153; am 2/11/2004, Register 169; am 2/15/2006, Register 177; am 1/17/2007, Register 181; am ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.330
AS 08.80.030

12 AAC 52.030 is repealed:

12 AAC 52.030. Change of pharmacy location or name. Repealed ____/____/_____. (Eff. 1/16/98, Register 145; am 2/26/2000, Register 153; am 2/11/2004, Register 169; am 1/17/2007, Register 181; repealed ____/____/_____, Register _____)

12 AAC 52.040 is repealed:

12 AAC 52.040. Change of pharmacy ownership. Repealed ____/____/_____. (Eff. 1/16/98, Register 145; am 2/26/2000, Register 153; am 2/11/2004, Register 169; am 1/17/2007, Register 181; repealed ____/____/_____, Register _____)

12 AAC 52.070 is repealed and readopted to read:

12 AAC 52.070. Application for pharmacist license by examination. (a) An applicant for a pharmacist license by examination shall submit the items required in this section for review and approval by the executive administrator. An application that does not clearly demonstrate qualification for licensure must be reviewed and approved by the board.

(b) An applicant for licensure under this section must submit to the department

(1) a complete, notarized application on a form provided by the department; the

application must include a statement from the applicant attesting to the applicant's fluency in reading, writing, and speaking the English language;

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

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

(4) a signed attestation that the applicant has completed the internship hours required to graduate from an accredited pharmacy;

(5) verification that the applicant has passed the examinations required in 12 AAC 52.090, sent directly to the department by the National Association of Boards of Pharmacy;

(6) verification that a foreign pharmacy graduate received the Foreign Pharmacy Graduate Examination Committee certificate, sent directly to the department by the National Association of Boards of Pharmacy, if applicable. (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 ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.110 AS 08.80.116
AS 08.80.030

Editor's note: Information about accredited colleges of pharmacy may be obtained from the Accreditation Council for Pharmacy Education, 20 North Clark Street, Suite 2500, Chicago, IL 60602-5109. Information about Foreign Pharmacy Graduate Examination Committee certification and colleges recognized by that committee may be obtained from the National Association of Boards of Pharmacy, Foreign Pharmacy Graduate Examination Committee, 1600 Feehanville Drive, Mount Prospect, IL 60056.

12 AAC 52.080 is repealed:

12 AAC 52.080. Internship requirements for a pharmacist license. Repealed ____/____/_____. (Eff. 1/16/98, Register 145; am 11/10/2001, Register 160; am 2/15/2006, Register 177; am 4/16/2016, Register 218; repealed ____/____/_____, Register _____)

12 AAC 52.092 is repealed and readopted 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 in 12 AAC 52.070 will be referred 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 ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.110

12 AAC 52.095 is repealed and readopted to read:

12 AAC 52.095. Application for pharmacist license by reciprocity. (a) An applicant for a pharmacist license by reciprocity shall submit the items required in this section for review and approval by the executive administrator. An application that does not clearly demonstrate qualifications for licensure must be reviewed and approved by the board. An applicant for a pharmacy license shall submit

(1) a complete, notarized application on a form provided by the department;

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

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

(4) an application for license transfer through the National Association of Boards of Pharmacy; the license by which the applicant is seeking reciprocity from must be current, unencumbered, and in good standing.

(b) An applicant for licensure under this section who has not taken the 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.

(c) Experience gained during rotation requirements at an accredited institution will be accepted by the board to satisfy AS 08.80.145(5). (Eff. 7/1/2007, Register 182; am 10/31/2019, Register 232; am ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.145

12 AAC 52.120 is repealed and readopted to read:

12 AAC 52.120. Review of pharmacist intern license application. (a) An applicant shall submit the requirements in (b) of this section for review and approval by the executive administrator. An application that does not clearly demonstrate qualifications for licensure must be reviewed and approved by the board.

(b) A pharmacist intern license will be issued to an applicant who

(1) submits a complete, notarized application on a form provided by the department;

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

(3) is

(A) presently enrolled in a college of pharmacy accredited by the ACPE and is satisfactorily progressing toward meeting the requirements for licensure as a

pharmacist; or

(B) a graduate of an accredited professional degree program from a school or college of pharmacy within one year preceding the date of application; or

(C) graduated from a college of pharmacy recognized by and earned certification from the Foreign Pharmacy Graduate Examination Committee of the National Association of Boards of Pharmacy; and

(4) certifies that the applicant has not been convicted of a felony or another crime that affects the applicant's ability to practice as a pharmacy intern competently and safely.

(c) A pharmacist intern license is valid for five years.

(d) An individual must be licensed as a pharmacist intern before beginning an internship in the state.

(e) A pharmacist intern license supersedes a pharmacy technician license and the pharmacy technician license shall be returned to the board.

(f) A pharmacist intern license may not be renewed. An applicant wishing to continue an internship in this state after the license has expired must reapply for a new license in accordance with this section. (Eff. 1/16/98, Register 145; am 2/11/2004, Register 169; am 2/15/2006, Register 177; am 1/17/2007, Register 181; am 11/16/2012, Register 204; am 7/9/2017, Register 223; am 6/29/2018, Register 226; am 10/31/2019, Register 232; am ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.110 AS 08.80.116
AS 08.80.030

12 AAC 52.130 is repealed and readopted to read:

12 AAC 52.130. Registration of pharmacies located outside of the state. (a) An

applicant for a pharmacy registration located outside of the state shall submit the requirements in (b) of this section for review and approval by the executive administrator. An application that does not clearly demonstrate qualifications for licensure must be reviewed and approved by the board.

(b) An out-of-state pharmacy registration will be issued to an applicant who

(1) submits a complete, notarized application on a form provided by the department that includes

(A) the ownership name;

(B) the pharmacy "doing business as" name, if applicable;

(C) the physical location of the facility;

(D) a mailing address and telephone number;

(E) the names of all partners or corporate officers involved in the dispensing of prescription drugs to residents of the state, if applicable;

(F) the name, license number, and contact information for the pharmacist-in-charge;

(G) the names of all pharmacists involved in the dispensing of prescription drugs to residents of the state, if applicable;

(H) completion of the professional fitness section of the application; and

(I) the name of the appointed registered agent;

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

(3) submits a copy of a current, valid facility license or registration from the jurisdiction where the pharmacy is located; and

(4) submits an attestation that was completed within the last two years. The self-

inspection must be made available upon request, for the duration of the licensing period in which it was completed.

(c) A pharmacy located outside of the state that ships, mails, or delivers prescription drugs into the state more than twice during a 12-month period shall register with the board.

(d) In AS 08.80.158(b)(4), "proof satisfactory" means a sworn statement that the pharmacy maintains its records of prescription drugs dispensed to persons in the state so that the records are readily retrievable from the records of other prescription drugs dispensed by the pharmacy, with either a written description or a copy of the pharmacy's policies and procedures. (Eff. 1/16/98, Register 145; am 6/2/2004, Register 170; am 2/15/2006, Register 177; am 6/29/2018, Register 226; am ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.158

12 AAC 52.140 is amended to read:

12 AAC 52.140. Pharmacy technician license. (a) An applicant **shall submit the requirements in (b) of this section for review and approval by the executive administrator. An application that does not clearly demonstrate qualifications for licensure must be reviewed and approved by the board** [WHO MEETS THE REQUIREMENTS ON THE CHECKLIST SET OUT IN (b) OF THIS SECTION HAS DEMONSTRATED THE NECESSARY QUALIFICATIONS FOR A PHARMACY TECHNICIAN LICENSE. AN APPLICANT WHO DOES NOT MEET THE REQUIREMENTS ON THE CHECKLIST OR WHOSE RESPONSES ON THE FORM FOR APPLICATION DO NOT CLEARLY SHOW THAT THE APPLICANT IS QUALIFIED TO RECEIVE A PHARMACY TECHNICIAN LICENSE WILL NOT BE ISSUED A LICENSE UNLESS THE BOARD REVIEWS THE APPLICATION AND DETERMINES THAT THE APPLICANT MEETS THE

QUALIFICATIONS IN THIS SECTION FOR A PHARMACY TECHNICIAN LICENSE].

(b) **A** [THE FOLLOWING CHECKLIST IS ESTABLISHED BY THE BOARD FOR REVIEW OF AN APPLICATION FOR A PHARMACY TECHNICIAN LICENSE; A] pharmacy technician license will be issued to an applicant who

(1) submits a completed form for application, including

(A) the applicant's name, mailing address, and telephone number; and

(B) the applicant's date of birth that shows the applicant is at least 18 years old;

(2) certifies that the applicant has not been convicted of a felony or another crime that affects the applicant's ability to perform the duties of a pharmacy technician safely and competently;

(3) certifies that the applicant has earned a high school diploma or its equivalent and provides the name of the issuing institution and the date the diploma or its equivalent was issued;

(4) certifies that the applicant is fluent in the reading, writing, and speaking of the English language; and

(5) pays the **applicable fees** [APPLICATION FEE AND THE PHARMACY TECHNICIAN LICENSE FEE] established in 12 AAC 02.310.

(c) **Repealed ____/____/_____** [A PHARMACY TECHNICIAN LICENSE EXPIRES ON JUNE 30 OF EVEN-NUMBERED YEARS AND MAY BE RENEWED]. (Eff. 1/16/98, Register 145; am 2/15/2006, Register 177; am 1/17/2007, Register 181; am ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.200 is repealed and readopted to read:

12 AAC 52.200. Pharmacist-in-charge. (a) The responsibilities of the pharmacist-in-charge include

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

(2) training of all pharmacy personnel;

(3) ensuring adequate policies and procedures are in place for pharmacy operations;

(4) maintaining required records;

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

(6) ensuring effective controls against theft or diversion of prescription drugs.

(b) A pharmacist designated to replace the pharmacist-in-charge of a licensed or registered pharmacy shall notify the board within 10 days of that designation, by submitting a completed change of pharmacist-in-charge form provided by the department.

(c) Notwithstanding 12 AAC 52.425(a), a pharmacist may not serve as pharmacist-in-charge unless he or she is physically present in the pharmacy for a sufficient amount of time to provide supervision and control. A pharmacist may not serve as pharmacist-in-charge for more than one pharmacy at any one time except upon obtaining written permission from the board. (Eff. 1/16/98, Register 145; am 2/26/2000, Register 153; am 2/15/2006, Register 177; am 6/29/2018, Register 226; am ____/____/_____, Register _____)

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

12 AAC 52.230 is repealed and readopted to read:

12 AAC 52.230. Pharmacy technicians. (a) An individual who assists in performing functions included in the definition of the practice of pharmacy must be licensed as a pharmacy technician.

(b) Before an individual may perform the tasks of a pharmacy technician, or functions in accordance with 12 AAC 52.235, the individual shall complete training required by the pharmacist-in-charge. Duties performed must be consistent with the training received.

(c) Persons whose responsibilities are purely administrative, including bookkeepers, accountants, administrative staff and persons who transport or deliver completed prescriptions to a patient or patient's agent are not required to obtain a pharmacy technician license. (Eff. 1/16/98, Register 145; am 4/4/2002, Register 162; am 1/23/2003, Register 165; am 4/3/2020, Register 234; am 8/30/2020, Register 235; am ____/____/_____, Register _____)

Authority: AS 08.80.030 AS 08.80.480

12 AAC 52.240 is repealed and readopted to read:

12 AAC 52.240. Pharmacist cooperative practice authority. (a) To initiate or modify drug therapy in accordance with a written protocol, an authorizing pharmacist may file a joint application with a practitioner authorized to prescribe drugs under AS 08 to engage in a cooperative practice agreement in the pharmacist's practice. To engage in a cooperative practice agreement, the written protocol must first be approved by the State Medical Board under 12 AAC 40.983 and endorsed by the Board of Pharmacy before implementation of the agreement.

(b) The Board of Pharmacy will endorse a cooperative practice agreement if the applicant provides

(1) a joint application to engage in a cooperative practice agreement signed by the

authorizing practitioner and authorizing pharmacist;

(2) a copy of the written protocol containing the requirements in 12 AAC 40.983(c);

(3) a statement that the authorizing pharmacist and other participating personnel licensed under this chapter have met the training requirements in 12 AAC 52.992; and

(4) documentation of approval by the State Medical Board or its delegate.

(c) Unless the board is satisfied that the pharmacist has been adequately trained in the procedures outlined in the written protocol, the board will specify and require completion of additional training that covers those procedures before endorsing the cooperative practice agreement.

(d) Documentation related to the written protocol and a signed copy of the approved cooperative practice application must be maintained at the pharmacist's practice for the duration of the agreement.

(e) The agreement may be terminated upon written notice by the authorizing practitioners or pharmacist. The pharmacist shall notify the board on a form provided by the department within 30 days after an agreement is terminated.

(f) This section does not apply to participation, by a pharmacist practicing in an institutional facility, in drug therapy protocols and guidelines approved by the institutional facility's pharmacy and therapeutics committee or by another medical staff governing body of that institutional facility, if records related to the drug therapy protocols and guidelines are maintained and made available to the board upon request.

(g) An approved cooperative practice agreement is valid at the authorizing pharmacist's practice and permits all qualified personnel licensed under this chapter to engage in the agreement. (Eff. 11/10/2001, Register 160; am 2/11/2004, Register 169; am 11/16/2012, Register

204; am 10/31/2019, Register 232; am ____/____/_____, Register _____)

Authority: AS 08.80.030 AS 08.80.480

12 AAC 52.470(d) is amended to read:

12 AAC 52.470. Refills.

• • •

(d) A pharmacist or pharmacist intern may dispense any quantity of a prescription drug order so long as the

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

(2) DRUG IS NOT A FEDERAL OR STATE SCHEDULED CONTROLLED SUBSTANCE].

• • •

(Eff. 1/16/98, Register 145; am 6/29/2018, Register 226; 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 52.585 is repealed and readopted to read:

12 AAC 52.585. Patient counseling. (a) Following the review of a patient's records, if deemed necessary by the pharmacist, a pharmacist or pharmacist intern shall personally offer counseling to each patient or the patient's agent

(b) If a pharmacist or pharmacist intern provides counseling, they may provide the counseling by any verbal, written, or electronic means.

(c) This section does not apply to a pharmacist who dispenses drugs for inpatient use in a hospital or other institution if the drug is to be administered by a nurse or other appropriate health care provider.

(d) Before dispensing an opioid prescription for the first time to a patient or patient's agent, or upon a dose increase, a pharmacist or pharmacist intern shall advise the patient about the potential dangers of opioid dependency, overdose, and interactions. (Eff. 1/16/98, Register 145; am 5/15/2004, Register 170; am 7/9/2017, Register 223; am ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.480

12 AAC 52.610 is repealed and readopted to read:

12 AAC 52.610. Wholesale drug distributor license. (a) An applicant for a wholesale drug distributor license shall submit the requirements in (b) of this section for review and approval by the executive administrator. An application that does not clearly demonstrate qualifications for licensure must be reviewed and approved by the board.

(b) The board will issue a wholesale drug distributor license to an applicant who

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

(2) pays the applicable fees required in 12 AAC 02.310;

(3) provides the name of the facility manager who will manage the wholesale distribution of drugs or devices for the wholesale drug facility;

(4) submits an attestation that

(A) a self-inspection of the premises using the form provided by the department was completed within the last two years; or

(B) a Verification Accredited Wholesale Distributors (VAWD) inspection

has been completed; and

(5) submits a copy of a current valid license, permit, or registration to conduct operations in the jurisdiction in which it is located, if the applicant is a wholesale drug distributor located outside of this state.

(c) Within 30 days after a change in physical address, ownership, or name, the wholesale drug distributor must apply for a new and separate wholesale drug distributor license in accordance with this section.

(d) When a wholesale drug distributor ceases operations, the facility manager of the wholesale drug distributor shall notify the board on a form provided by the department of the cessation of operations; the form must be submitted within 10 days after the cessation of operations. (Eff. 1/16/98, Register 145; am 8/21/2002, Register 163; am 1/17/2007, Register 181; am 6/29/2018, Register 226; am 10/31/2019, Register 232; am ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.159

The introductory language of 12 AAC 52.620(a) is amended to read:

12 AAC 52.620. Wholesale drug facilities. (a) A wholesale drug facility in which drugs **<u>or devices</u>** are stored, repacked, or sold to persons, businesses, or government agencies that may legally purchase drugs **<u>or devices</u>** must

• • •

12 AAC 52.620(a)(6) and (7) are amended to read:

(6) restrict entry into areas inside the facility where drugs **<u>or devices</u>** are stored;

entry must be open to authorized personnel only;

(7) have a quarantine area for storage of drugs **or devices** that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in a secondary container that has been opened or the seal of which has been broken;

12 AAC 52.620(d) is amended to read:

(d) A wholesale drug distributor facility seeking to ship into or distribute prescription drugs **or devices** in this state must first verify that the purchaser of the prescription drugs holds a valid license under **AS 08** [AS 08.80]. (Eff. 1/16/98, Register 145; am 10/31/2019, Register 232; am ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.159

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

12 AAC 52.635. Facility manager. (a) A facility manager of a wholesale drug distributor, outsourcing facility, or third-party logistics provider designated to replace the facility manager of a facility shall notify the board within 10 days of that designation, by submitting a completed change of facility manager notice on a form provided by the department. The outgoing facility manager shall also notify the board within 10 days on a form provided by the department.

(b) A facility manager may be in charge of more than one location and may be designated as the facility manager for multiple facilities simultaneously. (Eff. ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.159

12 AAC 52.696 is repealed and readopted to read:

12 AAC 52.696. Outsourcing facilities. (a) An applicant for an outsourcing facility license shall submit the requirements in (b) of this section for review and approval by the executive administrator. An application that does not clearly demonstrate qualifications for licensure must be reviewed and approved by the board.

(b) The board will issue an outsourcing facility license to an applicant who

(1) submits a complete application on a form provided by the department;

(2) pays the applicable fees required in 12 AAC 02.310;

(3) provides the name of the designated facility manager;

(4) submits an attestation that a self-inspection of the premises using the form provided by the department was completed within the last two years; and

(5) submits the results of the most recent Good Manufacturing Practice (GMP) inspection by the United States Food and Drug Administration.

(c) Within 30 days after a change in physical address, ownership, or name, the outsourcing facility must apply for a new and separate outsourcing facility license in accordance with this section.

(d) When an outsourcing facility ceases operations, the facility manager must submit to the board a written notice of the cessation of operations. The written notice must be submitted within 10 days after the cessation of operations and include

(1) the date the outsourcing facility ceased operations; and

(2) arrangement for the records of the outsourcing facility to be retained for two years.

(e) The outsourcing facility must be registered as an outsourcing facility and compliant with the United States Food and Drug Administration (FDA) under sec. 503b, P.L. 113-54 (Food

Drug and Cosmetic Act). (Eff. 10/31/2019, Register 232; am ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.159 AS 08.80.480

AS 08.80.030

12 AAC 52.697 is repealed and readopted to read:

12 AAC 52.697. Third-party logistics providers. (a) An applicant for a third-party logistics provider license shall submit the requirements in (b) of this section for review and approval by the executive administrator. An application that does not clearly demonstrate qualifications for licensure must be reviewed and approved by the board.

(b) The board will issue a third-party logistics provider license to an applicant who

(1) submits a complete application on a form provided by the department;

(2) pays the fees required in 12 AAC 02.310;

(3) provides the name of the designated facility manager; and

(4) submits an attestation that a self-inspection of the premises using the form provided by the department was completed within the last two years.

(c) Within 30 days after a change in physical address, ownership, or name, the third-party logistics provider must apply for a new and separate third-party logistics provider license in accordance with this section.

(d) When a third-party logistics provider ceases operations, the facility manager must submit to the board a written notice of the cessation of operations. The written notice must be submitted within 10 days after the cessation of operations and include

(1) the date the third-party logistics provider ceased operations; and

(2) arrangement for the records of the third-party logistics provider to be retained for two years. (Eff. 10/31/2019, Register 232; am ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.159 AS 08.80.480

AS 08.80.030

12 AAC 52.860 is amended by adding a new subsection to read:

12 AAC 52.860. Access to and conditions for use of the prescription drug monitoring program database.

. . .

(f) For the purposes of AS 17.30.200(d)(9), "state medical examiner" means an employee of the State Medical Examiner's Office who has requested access in writing to the board before the release of information. (Eff. 12/29/2011, Register 200; am 6/7/2018, Register 226; am ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.865 is repealed and readopted to read:

12 AAC 52.865. Reporting and reviewing PDMP information. (a) Unless excused from reporting under AS 17.30.200(t), a pharmacist-in-charge must submit information on behalf of the employing pharmacy required under AS 17.30.200(b) and other details required by the American Society of Automation in Pharmacy (ASAP), if the pharmacist-in-charge is not present, a pharmacist or third-party vendor may report on behalf of the pharmacy. A practitioner, practitioner's delegate, or third-party vendor may also report on behalf of the practitioner.

(b) Unless excused from reporting under AS 17.30.200(t), a pharmacist or practitioner required to submit information under AS 17.30.200(b) must submit the information to the PDMP daily.

(c) If the pharmacist or practitioner did not dispense any Schedule II, III, or IV controlled

substances on the previous day, the pharmacist or practitioner must submit a zero report.

(d) The time computation under 12 AAC 02.920(b) applies to a submission of information under AS 17.30.200(b) and this section.

(e) For the purposes of AS 17.30.200(b)(1), "other appropriate identifier" and for the purposes of 17.30.200(b)(8), "other appropriate identifying information" mean the state-issued license number of the prescribing practitioner and state-issued license number of the dispensing pharmacist or practitioner.

(f) Not later than 72 hours after discovering an error in information submitted under AS 17.30.200(b), a pharmacist or practitioner required to submit the information under AS 17.30.200(b) must notify the PDMP administrator. The time computation under 12 AAC 02.920(b) applies to a submission of information correcting an error in information submitted under AS 17.30.200(b).

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

(h) Unless excused from reviewing the PDMP under AS 17.30.200(k)(4)(A) – (B), a practitioner, but not a pharmacist, must review the information in the PDMP to check a patient's prescription records before dispensing, prescribing, or administering a schedule II or III controlled substance under federal law. (Eff. 12/29/2011, Register 200; am 6/7/2018, Register 226; am ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.990 is amended to read:

12 AAC 52.990. Display of license certificate. A licensee shall conspicuously display, in the practice site, the licensee's current license certificate. [PENDING RECEIPT OF THE CURRENT LICENSE CERTIFICATE FROM THE DEPARTMENT, THE LICENSEE SHALL DISPLAY THE DEPARTMENT'S INTERNET WEB SITE POSTING CONFIRMING LICENSURE. THE CURRENT LICENSE CERTIFICATE, OR WEB SITE POSTING CONFIRMING LICENSURE, OF A LICENSEE PRACTICING IN AN INSTITUTIONAL FACILITY MAY BE DISPLAYED IN A CENTRAL LOCATION.] (Eff. 1/16/98, Register 145; am 6/2/2004, Register 170; am ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.855. Registration With the Prescription Drug Monitoring Program [CONTROLLED SUBSTANCE PRESCRIPTION DATABASE.]

…..

[(f) A PHARMACIST OR PRACTITIONER REQUIRED TO REGISTER WITH THE PDMP MAY ACCESS INFORMATION IN THE PDMP USING ANOTHER REGISTRANT'S CREDENTIALS ONLY AS AUTHORIZED BY A CONTRACT EXECUTED BY THE DEPARTMENT FOR THE PURPOSES OF AS 47.05.270.]

12 AAC 52.860. Access to and Conditions for Use of the Prescription Drug Monitoring Program [DATABASE]**.**

…..

12 AAC 52.865. Reporting and Reviewing PDMP information.

…..

(a) Unless excused from reporting under AS 17.30.200(t), a **pharmacist-in-charge** [PHARMACIST] must submit information **on behalf of the employing pharmacy** required under AS 17.30.200(b) **and other details required by the American Society of Automation in Pharmacy (ASAP)**, if the pharmacist-in-charge is not present**, a pharmacist or third-party vendor may report on behalf of the pharmacy. A practitioner, practitioner's delegate, or third-party vendor may also report on behalf of the practitioner**.

(b) Unless excused from reporting under AS 17.30.200(t), a pharmacist or practitioner required to submit information under AS 17.30.200(b) must submit the information to the PDMP daily [AS OF THE PREVIOUS SUBMISSION DATE].

(c) **If the pharmacist or practitioner did not dispense any Schedule II, III, or IV controlled substances on the previous day, the pharmacist or practitioner must submit a zero report.**

(d) The time computation under 12 AAC 02.920(b) applies to a submission of information under AS 17.30.200(b) and this section.

Commented [CLN(1]: Modernize title.

Commented [CLN(2]: This conflicts with our current MOU with the HIE. The HIE is unable to provide us with an audit report for when providers review patients via their medical director's credentials. We signed off on the MOU on the assurance that an audit trail would be available upon request so we can meaningfully track mandatory use and ensure security.

Commented [CLN(3]: Modernize

(e) [(d)] For the purposes of AS 17.30.200(b)(1), "other appropriate identifier" and for the purposes of 17.30.200(b)(8), "other appropriate identifying information" mean the state-issued license number of the prescribing practitioner and state-issued license number of the dispensing pharmacist or practitioner.

(f) [(e)] Not later than 72 hours after discovering an error in information submitted under AS 17.30.200(b), a pharmacist or practitioner required to submit the information under AS 17.30.200(b) must [SUBMIT INFORMATION CORRECTING THE ERROR TO] **notify** the PDMP administrator. The time computation under 12 AAC 02.920(b) applies to a submission of information correcting an error in information submitted under AS 17.30.200(b).

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

(h) To submit data for an animal prescription, a pharmacist or veterinarian must report

(1) the first name of the animal;

(2) last name of the owner;

(3) date of birth of the owner;

(4) species of the animal;

(5) address of the owner;

(6) name, quantity, and dose of the drug; and

(7) other details required by ASAP standards, including the correct species code, PAT 02.

Commented [4]:
What is this?

Commented [5]:
Patient = 02 "PAT 02" means it is a prescription for an animal as opposed to a human, which is coded as "PAT 01"

Commented [6R5]:
Consider removing this and stopping at correct species code. What happens if this changes?

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

(j) A veterinarian required to review the PDMP under AS 17.30.200(k) satisfies this requirement by reviewing data pertaining to the animal's owner. For the purpose of this section, "owner" means the client identified in 12 AAC 68.100 and defined in 12 AAC 68.990.

Commented [7]:
Is this correct?

Commented [8]:
Maybe should be "as described in 12 AAC 68.990(1)"? This is the definition for "client"

12 AAC 52.423. Remote Pharmacy License.

….

(a) A central pharmacy that wishes to provide pharmacy services through a remote pharmacy in the state using a telepharmacy system as provided in 12 AAC 52.425 must apply to the board for a license. The central pharmacy applying under this section must submit to the department

(1) a complete, notarized application on a form provided by the department;

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

(3) comply with the requirements of 12 AAC 52.020.

(b) The board will approve an application to provide pharmacy services through a remote pharmacy if the central pharmacy establishes that [(1)] it is able to comply with the requirements of 12 AAC 52.425[; AND (2) THERE IS NO ACCESS TO A NON-REMOTE PHARMACY WITHIN TEN ROAD MILES OF THE PROPOSED REMOTE PHARMACY SITE UNLESS THE NON-REMOTE PHARMACY IS PREVENTED BY FEDERAL LAW FROM PROVIDING PHARMACY SERVICES TO ALL THE INDIVIDUALS WITHIN THE TEN ROAD MILES].

(c) An applicant for renewal of a remote pharmacy license must comply with the requirements of 12 AAC 52.300.

12 AAC 52.NEW. Automated Distribution Kiosks.

….

(a) A licensed pharmacy in this state may install and use automated drug distribution kiosks which are accessible to the patient or the patient's agent, while the pharmacy is open or closed, for the purpose of purchasing their completed prescription drug orders if

(1) the kiosk is securely installed within 10-feet of the licensed pharmacy and is properly secured to prevent easy removal. The kiosk may be

(A) bolted to the floor;

(B) framed into the wall; or

(C) secured in any other physical means which prevents easy removal;

(2) prior to the completed prescription drug order being loaded into the kiosk, the pharmacist has counseled the patient in accordance with 12 AAC 52.230; and

(3) no drugs that are a controlled substance as defined by state or federal law are placed in the kiosk and there is a conspicuously posted sign on the machine which states "this machine does not contain controlled substances".

(4) the sign must use a minimum of size 72 font and red color;

(b) The pharmacist on duty is responsible for

(1) assigning, discontinuing, or modifying access to the system by pharmacy technicians or pharmacist interns; and

(2) ensuring proper maintenance of the kiosk.

(c) This section does not apply to

(1) prescription drug dispensing or distribution machines used in institutional facilities; or

(2) other professional practices in accordance with AS 08.80.400.

(d) In AS 08.80, "automated distribution kiosks" means a vending machine that stores and distributes prescription drugs or devices, and maintains a record of transactions initiated or completed.

12 AAC 52.420. Security.

…..

(c) Excluding prescription drugs or devices held within an automated distribution

kiosk, all drugs, devices, and other items or products that are restricted to sale by or under the direct supervision of a pharmacist shall be kept in the prescription department.

(d) Excluding prescription drugs or devices held within an automated distribution kiosk, the prescription department shall be secured to prevent unauthorized access when a pharmacist is not available to provide direct supervision.

(f) Excluding prescription drugs or devices held within an automated distribution kiosk, prescriptions shall be stored in the prescription department and may be removed only under the direct supervision of a pharmacist and for immediate delivery to the patient, the patient's agent, or the person delivering the prescription to the patient or the patient's agent.

12 AAC 52.010. Classification of licensure.

….

(b) The board will issue the following categories of licenses or registrations to a qualified facility:

….

(7) third-party logistics provider license **located outside of the state**;

(8) outsourcing facility license **located outside of the state**;

(10) manufacturer located outside of the state.

Commented [CLN(9]: Aligns with (5) and (9) since the board only has authority to regulate these facilities if outside of Alaska.

12 AAC 52.300. License and registration renewal

Commented [CLN(10]: To include out-of-state pharmacies

….

12 AAC 52.300. License and registration renewal. (a) Pharmacy, remote pharmacy, wholesale drug distributor, outsourcing facility, third-party logistics provider, **manufacturer**, pharmacist, pharmacy technician, and drug room licenses must be renewed biennially on or before a date set by the department.

12 AAC 52.995. Definitions.

Commented [CLN(11]: From NABP model act and legal guidance from Megyn.

….

(a) In this chapter, unless the context requires otherwise,

…. **(39) "manufacturer" means a person or entity, including a virtual manufacturer, engaged in the manufacturing of drugs or devices. A manufacturer which distributes its own manufactured drugs or devices does not constitute wholesale drug**

distribution. To manufacture also does not include the distribution of minimal quantities of a drug by a licensed retail pharmacy to a licensed practitioner for office use.

(40) "virtual manufacturer" means a manufacturer that sells a prescription drug or device but never physically possesses the product.

….

(e) In 12 AAC 52.610 – 12 AAC 52.697, "[FACILITY MANAGER] **designated representative**" means the responsible manager who serves as the supervisor or manager and is responsible for ensuring the third-party logistics provider, wholesale drug distributor, [OR] outsourcing facility, **or manufacturer** is in compliance with all state and federal laws and regulations pertaining to the operations.

Commented [CLN(12]: Will need to be adjusted to include the regulation for manufacturer licensing.

12 AAC 52.635. [FACILITY MANAGER] **Designated representative.**

Commented [CLN(13]: Aligns with recognized industry term; see NABP model act

….

(a) a [FACILITY MANAGER] **designated representative** of a wholesale drug distributor, outsourcing facility, [OR] third-party logistics provider, **or manufacturer** designated to replace the [FACILITY MANAGER] **designated representative** of a facility shall notify the board within 10 days of that designation, by submitting a completed change of [FACILITY MANAGER] **designated representative** notice on a form provided by the department. The outgoing [FACILITY MANAGER] **designated representative** shall also notify the board within 10 days on a form provided by the department.

(b) a [FACILITY MANAGER] **designated representative** may be in charge of more than one location and may be designated as the [FACILITY MANAGER] **designated representative** for multiple facilities simultaneously.

12 AAC 52.NEW. Manufacturer license.

Commented [CLN(14]: Required license type per AS 08.80.480(17); board must create regulations.

12 AAC 52.610. Manufacturer. (a) An out-of-state applicant for a manufacturer license shall submit the requirements in (b) of this section for review and approval by the executive administrator. An application that does not clearly demonstrate qualifications for licensure must

be reviewed and approved by the board.

(b) The board will issue a manufacturer license to an applicant who

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

(2) pays the applicable fees required in 12 AAC 02.310;

(3) provides the name of the designated representative who will manage the manufacture of drugs or devices for the wholesale drug facility;

(4) submits an attestation that

(A) a self-inspection of the premises using the form provided by the department was completed within the last two years; or

(B) an inspection of the premise by a third-party was completed within the last two years;

(5) <u>submits an attestation that it holds a license as a manufacturer in another jurisdiction and that the license is in good standing;</u>

(c) A manufacturer operating as a virtual manufacturer must indicate on the application that it operates as a virtual manufacturer that meets the definition of 12 AAC 52.995.

(d) Within 30 days after a change in physical address, ownership, or name, the manufacturer must apply for a new and separate manufacturer license in accordance with this section.

(e) When a manufacturer ceases operations, the designated representative of the wholesale drug distributor shall notify the board on a form provided by the department of the cessation of operations; the form must be submitted within 10 days after the cessation of operations.

(f) a manufacturer that distributes drugs and devices it does not directly manufacturer must hold a separate wholesale drug distributor license.

(g) a manufacturer that provides logistics services must hold a separate third-party

logistics provider license.

12 AAC 52.610. Wholesale drug distributor license.

….

(b) The board will issue a wholesale drug distributor license to an applicant who

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

(2) pays the applicable fees required in 12 AAC 02.310;

(3) provides the name of the [FACILITY MANAGER] **designated representative** who will manage the wholesale distribution of drugs or devices for the wholesale drug facility;

…

(d) When a wholesale drug distributor ceases operations, the [FACILITY MANAGER] **designated representative** of the wholesale drug distributor shall notify the board on a form provided by the department of the cessation of operations; the form must be submitted within 10 days after the cessation of operations.

12 AAC 52.696. Outsourcing facilities

….

12 AAC 52.696. Outsourcing facilities. (a) An **out-of-state** applicant for an outsourcing facility license shall submit the requirements in (b) of this section for review and approval by the executive administrator. An application that does not clearly demonstrate qualifications for licensure must be reviewed and approved by the board.

(b) The board will issue an outsourcing facility license to an applicant who

(1) submits a complete application on a form provided by the department;

(2) pays the applicable fees required in 12 AAC 02.310;

Commented [CLN(15]: Conforming changes to update terminology/introduction of manufacturer section.

Commented [CLN(16]: Aligns with recognized industry term; see NABP model act

Commented [CLN(17]: Because the board can only regulate outsourcing facilities located outside of Alaska per AS 08.80.157(k) and AS 08.80.159.

(3) provides the name of the designated [FACILITY MANAGER] **representative**;

(4) submits an attestation that it holds a license as an outsourcing facility in another jurisdiction and that the license is in good standing;

~~(4)~~ **(5)** submits an attestation that a self-inspection of the premises using the form provided by the department was completed within the last two years; and

~~(5)~~ **(6)** submits the results of the most recent Good Manufacturing Practice (GMP) inspection by the United States Food and Drug Administration.

…

(d) When an outsourcing facility ceases operations, the [FACILITY MANAGER] **designated representative** must submit to the board a written notice of the cessation of operations. The written notice must be submitted within 10 days after the cessation of operations and include

12 AAC 52.697. Third-party logistics providers

….

12 AAC 52.697. Third-party logistics providers. (a) An **out-of-state** applicant for a third-party logistics provider license shall submit the requirements in (b) of this section for review and approval by the executive administrator. An application that does not clearly demonstrate qualifications for licensure must be reviewed and approved by the board.

Commented [CLN(18]: Because the board can only regulate 3PLs located outside of Alaska per AS 08.80.157(k) and AS 08.80.159.

(b) The board will issue a third-party logistics provider license to an applicant who

(1) submits a complete application on a form provided by the department;

(2) pays the fees required in 12 AAC 02.310;

(3) provides the name of the designated [FACILITY MANAGER] **representative**;

(4) submits an attestation that it holds a license as an outsourcing facility in another jurisdiction and that the license is in good standing; and

~~(4)~~ **(5)** submits an attestation that a self-inspection of the premises using the form provided by the department was completed within the last two years.

…

(d) When a third-party logistics provider ceases operations, the [FACILITY MANAGER] **designated representative** must submit to the board a written notice of the cessation of operations. The written notice must be submitted within 10 days after the cessation of operations and include

12 AAC 52.020. Pharmacy license

Commented [CLN(19]: Per Megyn/proposed rules

….

(g) If a retail pharmacy sells prescription drugs to licensed practitioners for office use exceeds 5 percent of the total dollar volume of the pharmacy's annual prescription drug sales, the retail pharmacy must hold a separate wholesale drug distributor license.

(h) a pharmacy located outside of the state is not required to submit an annual information update required in AS 08.80.158 to the board if the registration has been issued for less than 3 months.

12 AAC 52.250. Job shadowing in pharmacy

Commented [CLN(20]: Repeal in its entirety; the board does not regulate any aspect of job shadowing.

[(a) A PHARMACIST-IN-CHARGE OR JOB SHADOWING PRECEPTOR OF A PHARMACY MAY ALLOW JOB SHADOWING BY A STUDENT IN THE PHARMACY ONLY AS SPECIFIED IN THIS SECTION.

(b) BEFORE A STUDENT BEGINS A JOB SHADOWING PROGRAM UNDER THIS

SECTION, THE PHARMACIST-IN-CHARGE OR JOB SHADOWING PRECEPTOR SHALL COMPLETE THAT PORTION OF THE JOB SHADOWING DOCUMENTATION FORM PRESCRIBED BY THE BOARD, WHICH INCLUDES THE NAMES OF THE PHARMACY, THE PARTICIPATING STUDENT, AND THE PHARMACIST-IN-CHARGE OR JOB SHADOWING PRECEPTOR. THE STUDENT AND THE PHARMACIST-IN-CHARGE OR PRECEPTOR, SHALL SIGN THE FORM. THE PARENT OR GUARDIAN OF THE STUDENT SHALL ALSO SIGN THE FORM IF THE STUDENT IS LESS THAN 18 YEARS OF AGE.

(c) THE PHARMACIST-IN-CHARGE OR, IF APPLICABLE, THE JOB SHADOWING PRECEPTOR SHALL FAMILIARIZE THE STUDENT WITH THE CONFIDENTIALITY REQUIREMENTS OF 45 C.F.R., PARTS 160 AND 164 (HIPAA) AND ENSURE COMPLIANCE WITH THIS SECTION AND THE RELEVANT SECTIONS OF AS 08.80 AND THIS CHAPTER.

(d) A PHARMACIST-IN-CHARGE OR JOB SHADOWING PRECEPTOR MAY NOT ALLOW

(1) A STUDENT IN A JOB SHADOWING PROGRAM TO

(A) RECEIVE ANY REMUNERATION OR OTHER COMPENSATION;

(B) PERFORM JOB SHADOWING FOR MORE THAN 50 HOURS;

(C) PERFORM ANY FUNCTIONS RESERVED FOR LICENSED, CERTIFIED, OR REGISTERED PHARMACY PERSONNEL;

(2) A RATIO OF JOB SHADOWING STUDENT TO PHARMACIST-IN-CHARGE OR JOB SHADOWING PRECEPTOR OTHER THAN ONE TO ONE.

(e) AFTER COMPLETION OF THE JOB SHADOWING PROGRAM BY A STUDENT, THE PHARMACIST-IN-CHARGE OR JOB SHADOWING PRECEPTOR SHALL COMPLETE THAT PORTION OF THE JOB SHADOWING DOCUMENTATION FORM PRESCRIBED BY THE BOARD WHERE THE PHARMACIST-IN-CHARGE OR JOB SHADOWING PRECEPTOR PROVIDES THE DATE AND TIME IN HOURS STUDENT WAS PRESENT AND JOB SHADOWING IN THE PHARMACY, ANY PATIENT COUNSELING OBSERVATIONS, PROBLEMS THAT MAY HAVE OCCURRED DURING JOB SHADOWING. THE JOB SHADOWING DOCUMENTATION FORM MUST BE KEPT IN THE PHARMACY RECORD FOR AT LEAST TWO YEARS AFTER THE JOB SHADOWING PROGRAM HAS BEEN COMPLETED BY THAT STUDENT.

(f) IN THIS SECTION,

(1) "JOB SHADOWING" MEANS FOR EDUCATIONAL PURPOSES AND THROUGH OBSERVATION ONLY, THE OBSERVATION BY A STUDENT OF THE FUNCTIONS AND DUTIES OF A PHARMACY AND PHARMACY STAFF WITH THE INTENDED PURPOSE OF GIVING THE STUDENT AN OPPORTUNITY TO OBSERVE CAREER POSSIBILITIES AVAILABLE IN THE FIELD OF PHARMACY;

(2) "JOB SHADOWING PRECEPTOR" MEANS A LICENSED PHARMACIST, OTHER THAN THE PHARMACIST-IN-CHARGE, DESIGNATED BY THE PHARMACIST-IN-CHARGE TO SUPERVISE A STUDENT WHILE THAT STUDENT IS JOB SHADOWING;

(3) "STUDENT" MEANS A PERSON CURRENTLY ENROLLED IN A HIGH SCHOOL OR POST-SECONDARY EDUCATION PROGRAM.]

12 AAC 52.670. Drug recalls

Commented [CLN(21]: Recommend repeal; drug recalls are regulated by the FDA

[12 AAC 52.670. DRUG RECALLS. A WHOLESALE DRUG DISTRIBUTOR SHALL PREPARE AND FOLLOW

WRITTEN POLICY FOR HANDLING THE RECALL OF A DRUG DUE TO

(1) A VOLUNTARY ACTION ON THE PART OF THE MANUFACTURER;

(2) AN ORDER OF THE FOOD AND DRUG ADMINISTRATION, OR OF ANY OTHER FEDERAL, STATE, OR LOCAL GOVERNMENT AGENCY; OR

(3) THE REPLACEMENT OF AN EXISTING DRUG WITH AN IMPROVED DRUG OR NEW PACKAGE DESIGN.]

12 AAC 52.220. Pharmacist interns

Commented [CLN(22]: Recommend repeal; pharmacist interns applying for a permanent pharmacist license must provide verification of internship or work experience anyway.

….

[(d) A PHARMACIST INTERN SHALL FILE WITH THE BOARD A REPORT OF WORK EXPERIENCE ON A FORM PROVIDED BY THE DEPARTMENT WITHIN 30 DAYS OF COMPLETION OR TERMINATION OF AN INTERNSHIP IN THE PRACTICE OF PHARMACY REQUIRED UNDER 12 AAC 52.080.]

Note to board: Regulations **NOT** included here but mentioned in the FY22 Annual Report:

- Inventory loss/notifications by wholesale drug distributors
- HB 145 regulations that must be implemented by July 2023 (I've included a summary in the annual report of areas the board needs to write regulations for)

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 16	FY 17	Biennium	FY 18	FY 19	Biennium	FY 20	FY 21	Biennium	FY 22 1st - 3rd QTR
Revenue										
Revenue from License Fees	$ 802,230	$ 208,755	$ 1,010,985	$ 801,317	$ 213,770	$ 1,015,087	$ 631,105	$ 1,121,447	$ 1,752,552	$ 320,870
General Fund Received								$ -	-	$ -
Allowable Third Party Reimbursements	-	3,256	3,256	210	962	1,172	$ -	$ -	-	$ -
TOTAL REVENUE	$ 802,230	$ 212,011	$ 1,014,241	$ 801,527	$ 214,732	$ 1,016,259	$ 631,105	$ 1,121,447	$ 1,752,552	$ 320,870
Expenditures										
Non Investigation Expenditures										
1000 - Personal Services	156,115	151,947	308,062	204,727	194,745	399,472	199,334	278,612	477,946	188,666
2000 - Travel	16,676	11,119	27,795	13,704	8,299	22,003	2,641	-	2,641	1,758
3000 - Services	13,361	14,293	27,654	21,960	27,781	49,741	45,283	46,180	91,463	12,844
4000 - Commodities	111	519	630	-	26	26	521	-	521	82
5000 - Capital Outlay	-		-	-		-	-	-	-	-
Total Non-Investigation Expenditures	186,263	177,878	364,141	240,391	230,851	471,242	247,779	324,792	572,571	203,350
Investigation Expenditures										
1000-Personal Services	68,935	63,727	132,662	68,679	69,997	138,676	57,738	106,494	164,232	64,732
2000 - Travel					-	-	1,260	-	1,260	198
3023 - Expert Witness	-	2,800	2,800	-	-	-	-	-	-	-
3088 - Inter-Agency Legal	1,451	23,355	24,806	-	3,062	3,062	2,537	1,269	3,806	-
3094 - Inter-Agency Hearing/Mediation	-	883	883	-	-	-	694	152	846	1,758
3000 - Services other					400	400	269	216	485	4,232
4000 - Commodities					-	-	-	-	-	-
Total Investigation Expenditures	70,386	90,765	161,151	68,679	73,459	142,138	62,498	108,131	170,629	70,920
Total Direct Expenditures	256,649	268,643	525,292	309,070	304,310	613,380	310,277	432,923	743,200	274,270
Indirect Expenditures										
Internal Administrative Costs	128,025	123,008	251,033	150,986	155,128	306,114	164,443	191,897	356,340	143,923
Departmental Costs	48,707	73,682	122,389	78,139	81,374	159,513	58,131	75,431	133,562	56,573
Statewide Costs	15,564	26,226	41,790	30,555	27,069	57,624	33,868	52,856	86,724	39,642
Total Indirect Expenditures	192,296	222,916	415,212	259,680	263,571	523,251	256,442	320,184	576,626	240,138
						-			-	
TOTAL EXPENDITURES	**$ 448,945**	**$ 491,559**	**$ 940,504**	**$ 568,750**	**$ 567,881**	**$ 1,136,631**	**$ 566,719**	**$ 753,107**	**$ 1,319,826**	**$ 514,408**
Cumulative Surplus (Deficit)										
Beginning Cumulative Surplus (Deficit)	$ 201,479	$ 554,764		$ 275,216	$ 507,993		$ 154,844	$ 219,230		$ 587,570
Annual Increase/(Decrease)	353,285	(279,548)		232,777	(353,149)		64,386	368,340		(193,538)
Ending Cumulative Surplus (Deficit)	$ 554,764	$ 275,216		$ 507,993	154,844		$ 219,230	$ 587,570		$ 394,032
Statistical Information										
Number of Licenses for Indirect calculation	4,649	5,068		5,680	6,203		5,934	6,917		

Additional information:

- *Fee analysis required if the cumulative is less than zero; fee analysis recommended when the cumulative is less than current year expenditures; no fee increases needed if cumulative is over the current year expenses **
- *Most recent fee change: Fee change FY20*
- *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 progr*

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	126,774.80				126,774.80
1014 - Overtime	1,048.89				1,048.89
1023 - Leave Taken	24,624.02				24,624.02
1028 - Alaska Supplemental Benefit	9,356.60				9,356.60
1029 - Public Employee's Retirement System Defined Benefits	3,682.84				3,682.84
1030 - Public Employee's Retirement System Defined Contribution	7,443.37				7,443.37
1034 - Public Employee's Retirement System Defined Cont Health Reim	4,304.80				4,304.80
1035 - Public Employee's Retiremnt Sys Defined Cont Retiree Medical	1,499.49				1,499.49
1037 - Public Employee's Retiremnt Sys Defined Benefit Unfnd Liab	28,965.86				28,965.86
1039 - Unemployment Insurance	340.92				340.92
1040 - Group Health Insurance	35,320.99				35,320.99
1041 - Basic Life and Travel	46.24				46.24
1042 - Worker's Compensation Insurance	1,340.61				1,340.61
1047 - Leave Cash In Employer Charge	2,587.64				2,587.64
1048 - Terminal Leave Employer Charge	2,306.18				2,306.18
1053 - Medicare Tax	2,122.60				2,122.60
1077 - ASEA Legal Trust	131.69				131.69
1079 - ASEA Injury Leave Usage	25.12				25.12
1080 - SU Legal Trst	14.85				14.85
1970 - Personal Services Transfer	1,167.92				1,167.92
2007 - In-State Non-Employee Lodging		807.48			807.48
3001 - Test Monitor/Proctor			-		-
3044 - Courier			3.55		3.55
3045 - Postage			88.49		88.49
3046 - Advertising			1,157.78		1,157.78
3094 - Inter-Agency Hearing/Mediation			1,757.70		1,757.70
4002 - Business Supplies				81.87	81.87
1016 - Other Premium Pay	23.88				23.88
2000 - In-State Employee Airfare		4.21			4.21
2002 - In-State Employee Lodging		447.00			447.00
2005 - In-State Non-Employee Airfare		697.23			697.23
1062 - GGU Business Leave Bank Contributions	250.89				250.89
3088 - Inter-Agency Legal			8,458.00		8,458.00
3100 - Inter-Agency Safety			5,390.00		5,390.00
1069 - SU Business Leave Bank Contributions	18.36				18.36
3085 - Inter-Agency Mail			1,977.64		1,977.64
Grand Total	**253,398.56**	**1,955.92**	**18,833.16**	**81.87**	**274,269.51**

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

Summary of All Professional Licensing
Schedule of Revenues and Expenditures

Prescription Drug Monitoring Program	FY 16	FY 17	Biennium	FY 18	FY 19	Biennium	FY 20	FY 21	Biennium	FY 22 1st - 3rd QTR
Revenue										
Revenue from License Fees			$ -	$ -	$ 90,765	$ 90,765	$ 26,150	$ 191,320	$ 217,470	$ 30,715
General Fund Received								$ -	-	$ -
Allowable Third Party Reimbursements	-	-	-	-	-	-	$ -	$ -	-	$ -
TOTAL REVENUE	$ -	$ -	$ -	$ -	$ 90,765	$ 90,765	$ 26,150	$ 191,320	$ 217,470	$ 30,715
Expenditures										
Non Investigation Expenditures										
1000 - Personal Services			-	-	6,043	6,043	41,343	(238)	41,105	(6,317)
2000 - Travel			-	-	-	-	796	-	796	-
3000 - Services			-	-	11	11	6,155	1,966	8,121	5,426
4000 - Commodities			-	-	-	-	-	-	-	-
5000 - Capital Outlay	-		-	-		-	-	-	-	-
Total Non-Investigation Expenditures	-	-	-	-	6,054	6,054	48,294	1,728	50,022	(891)
Investigation Expenditures										
1000-Personal Services			-		-	-	-	-	-	-
2000 - Travel					-	-	-	-	-	-
3023 - Expert Witness			-	-	-	-	-	-	-	-
3088 - Inter-Agency Legal			-	-	-	-	-	-	-	-
3094 - Inter-Agency Hearing/Mediation			-	-	-	-	-	-	-	-
3000 - Services other					-	-	-	-	-	-
4000 - Commodities					-	-	-	-	-	-
Total Investigation Expenditures	-	-	-	-	-	-	-	-	-	-
Total Direct Expenditures	-	-	-	-	6,054	6,054	48,294	1,728	50,022	(891)
Indirect Expenditures										
Internal Administrative Costs			-		-	-	-	-	-	-
Departmental Costs			-		-	-	-	-	-	-
Statewide Costs			-		-	-	-	-	-	-
Total Indirect Expenditures	-	-	-	-	-	-	-	-	-	-
						-			-	
TOTAL EXPENDITURES	**$ -**	**$ -**	**$ -**	**$ -**	**$ 6,054**	**$ 6,054**	**$ 48,294**	**$ 1,728**	**$ 50,022**	**$ (891)**
Cumulative Surplus (Deficit)										
Beginning Cumulative Surplus (Deficit)	$ -	$ -		$ -	$ -		$ 84,711	$ 62,567		$ 252,159
Annual Increase/(Decrease)	-	-		-	84,711		(22,144)	189,592		31,606
Ending Cumulative Surplus (Deficit)	$ -	$ -		$ -	84,711		$ 62,567	$ 252,159		$ 283,765
Statistical Information										
Number of Licenses for Indirect calculation					-	-	-	-		

Additional information:

- *Fee analysis required if the cumulative is less than zero; fee analysis recommended when the cumulative is less than current year expenditures; no fee increases needed if cumulative is over the current year expenses **
- *Most recent fee change: No fee change since FY18*
- *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 progr*

Appropriation Name (Ex)	(All)
Sub Unit	(All)
PL Task Code	PDMP

Sum of Budgetary Expenditures	**Object Type Name (Ex)**		
Object Name (Ex)	**1000 - Personal Services**	**3000 - Services**	**Grand Total**
1011 - Regular Compensation	1,721.53		1,721.53
1014 - Overtime	180.26		180.26
1023 - Leave Taken	223.62		223.62
1028 - Alaska Supplemental Benefit	130.54		130.54
1029 - Public Employee's Retirement System Defined Benefits	178.87		178.87
1030 - Public Employee's Retirement System Defined Contribution	80.30		80.30
1034 - Public Employee's Retirement System Defined Cont Health Reim	59.74		59.74
1035 - Public Employee's Retiremnt Sys Defined Cont Retiree Medical	15.99		15.99
1037 - Public Employee's Retiremnt Sys Defined Benefit Unfnd Liab	298.27		298.27
1039 - Unemployment Insurance	5.52		5.52
1040 - Group Health Insurance	538.34		538.34
1041 - Basic Life and Travel	0.38		0.38
1042 - Worker's Compensation Insurance	18.85		18.85
1047 - Leave Cash In Employer Charge	33.19		33.19
1048 - Terminal Leave Employer Charge	29.17		29.17
1053 - Medicare Tax	29.88		29.88
1077 - ASEA Legal Trust	2.28		2.28
1970 - Personal Services Transfer	(9,864.18)		(9,864.18)
3002 - Memberships		300.00	300.00
3088 - Inter-Agency Legal		4,110.62	4,110.62
3085 - Inter-Agency Mail		1,015.71	1,015.71
Grand Total	**(6,317.45)**	**5,426.33**	**(891.12)**

Julie Sande
Commissioner
www.Commerce.Alaska.Gov
Department of Commerce, Community, and Economic Development
Anchorage, Alaska
STATE OF ALASKA
PRESS RELEASE

For Immediate Release **22-011**

Governor Dunleavy Issues Administrative Order 335 to Reduce Licensing Delays

May 20, 2022 (ANCHORAGE, AK) – To reduce administrative burdens on applicants for professional licenses and address the immediate need for expedited licensure, Governor Mike Dunleavy has issued Administrative Order 335 directing the Department of Commerce, Community, and Economic Development (DCCED), Division of Corporations, Business and Professional Licensing (CBPL), to cease certain secondary functions and issue licenses to qualified persons using an accelerated process.

"The purpose of this Administrative Order is immediately address the backlog of Alaskans who are waiting for licensure in order to legally enter the workforce in their chosen field," stated **Governor Dunleavy**.

"I took swift action to relieve licensing staff of various duties that detract from their ability to review and issue licenses, We must do everything we can to address delays in licensure, and Alaska's professional licensing boards and staff need both the tools and leeway to modernize processes and remove unnecessary requirements that do not further public protection. State processes should not be a barrier to entering the workforce, and yet over the years an incredibly complex web of State Statutes and regulations has done just that."

Administrative Order 335, available at gov.alaska.gov/admin-orders, urges state professional licensing boards to implement expedited temporary licensure measures and to identify outdated or ineffective regulations by the end of the summer.

DCCED Commissioner Julie Sande stated, "I am so grateful for Governor Dunleavy's support on this critical issue. The success of businesses throughout Alaska depends on our ability to quickly get folks out into the workplace. This issue is at the heart of our ability to grow our economy, strengthen communities, and protect consumers in Alaska. Empowering CBPL staff to focus on mission critical tasks will have an immediate impact on the backlog while staff work to continue to fill vacancies in key positions within the CBPL team. I also appreciate the understanding and cooperative approach that the licensing board members and staff have demonstrated as we work towards making right-touch regulatory changes."

The mission of the Division of Corporations, Business, and Professional Licensing (CBPL) is to inspire public confidence through balanced regulation of competent professional and business services. CBPL is a division of the Department of Commerce, Community, and Economic Development (DCCED). For more information on DCCED, visit ***www.commerce.alaska.gov****. Come work with us! Current job postings for CBPL can be found at :* https://www.governmentjobs.com/careers/alaska?keywords=Corporations.

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Media Contact: Victoria Caltagirone, DCCED PIO, (907) 269-7396, victoria.caltagirone@alaska.gov

Analysis and Recommendations to improve the Physician/Pharmacy Cooperative Agreement Process

Prepared by Laura Carrillo and Natalie Norberg

Background:

Physician/Pharmacist cooperative practice agreements currently exist as an optional patient care management tool under AS 08.80 and 12 AAC 40.983 (Medical Board Regulation) and 12 AAC52.240 (Pharmacy Board Regulations). Such agreements allow pharmacists to prescribe, administer, and treat a very limited set of conditions with pharmaceutical interventions. Examples include treatment for immunizations, emergency contraception, travel medication, and hypertension.

HB 145 allows physicians/pharmacists to continue engaging in cooperative practice agreements but clarifies services pharmacists can independently provide for general wellness, disease prevention, and drug utilization services. This bill empowers the Board of Pharmacy to adopt regulations to ensure these services remain within their existing practice authority and provides for the ability for pharmacists to bill for these services.

Analysis/Recommendations:

The existing process for reviewing, approving, and file maintenance of these agreements is duplicative and administratively burdensome. Currently the Medical Board and Board of Pharmacy have separate forms and separate, highly detailed review processes which entail each board to independently review and endorse each plan.

The following are recommendations to address these inefficiencies and streamline the Physician/Pharmacist cooperative practice agreement process:

1. Create one practice agreement form that both boards endorse
2. Adopt a reviewing protocol and procedure endorsed by both boards that ensures the Medical Board is primarily responsible for conducting the qualitative review of all practice agreement applications (based on a checklist comprised of the criteria outlined in 12 AAC 40.983) and decides whether the practice agreement may be approved or denied. Next the form is forwarded to the Board of Pharmacy administrative staff to be filed in the pharmacist's licensing file.
    - Note: to eliminate the Board of Pharmacy from having the responsibility to dually approve practice agreements the Medical Board will need to revise regulation 12 AAC 40.983 (k).

Next Steps:	Person(s) Responsible	Date Due:
1. The Medical Board and Board of Pharmacy EA's create new form and draft policy procedure for processing applications including how denied requests may appeal or be offered an opportunity for a remediation plan.	Laura & Natalie	4/30/2021
2. Introduce draft regulation change language at the May 13-14 Medical Board Meeting for review	Natalie	5/13/2021
3. Identify, draft and introduce any regulatory clean-up language needed by the Board of Pharmacy for example, the Medical Board would request the name of the plans be changed to "Physician/Pharmacist Cooperative Practice Agreement" instead of "Pharmacist Collaborative Practice Agreement"/	Laura	
4. Submit a work order to changes to be made to the Portal for how Cooperative Agreements are tracked.	Laura	

Policy & Procedure for Reviewing/Approving Cooperative Practice Agreements

Prepared by Laura Carrillo and Natalie Norberg

Initial Review/Approval:

1. Cooperative Practice Agreement on Form 08-4410 is submitted to the State Medical Board.
2. Assigned OLE will create a record in Portal using program = Medical and License Type = Cooperative Practice Agreement.
3. State Medical Board or its designee reviews/approves the agreement and copy of protocol per checklist #OL-720.
4. If approved, Medical Board EA updates the checklist and keeps the Portal record as 'In-Process'
5. Pharmacy Board EA reviews in-process cooperative agreement records monthly for MED approval. If approved, Board of Pharmacy EA endorses, completes the checklist, and saves the record as 'Active'
6. Assigned OLE will mail a copy of approved agreement and approval letter to the address on record.

Timelines:

1. Agreements should be reviewed monthly via
2. The Board of Pharmacy or its EA will review/approve endorsement within 2 - 4 weeks of approval by the State Medical Board/EA.

Denied Requests/Appeals:

If the board is not satisfied that the pharmacist has been adequately trained to engage in the protocol(s), the board will specify additional trainings that must be completed prior to endorsement of/engaging in the protocol.

Historical Note Only:

Before the below effective date of this policy and procedure, old collaborative practice agreements will be found by navigating to Search → Licenses → Statuses = Check All; Programs = Collaborative Practice; Types = Collaborative Practice Agreement. If searching for specific providers/pharmacists, navigate to Relationships → Program = Collaborative Practice; Type = Collaborative Practice Agreement.

Date approved:

Date effective:

DRAFT

Board of Pharmacy Task List
(Tasks from previous meetings: November 28, 2021 - March 25, 2022)

Number of tasks assigned	Completed	Pending
5	5	0

No.	Task	Assigned	Status
1	Ms. Carrillo will work on the regulation FAQs for the board's large regulation project approved at the board's March 2022 meeting and will submit the documents to the regulation's specialist.	Laura Carrillo	Completed (Public comment ends 06/13/2022)
2	Ms. Carrillo will add remote pharmacies and kiosks to the June 2022 meeting agenda	Laura Carrillo	Completed 05/09/2022
3	Ms. Carrillo will update the board of pharmacy's roster to reflect current seat nominations.	Laura Carrillo	Completed 06/03/2022
4	Ashley Schaber will participate in the MPJE item review workshop	Ashley Schaber	Completed 05/31/2022
5	Ms. Carrillo will work on the board's annual report and 2023 strategic plan	Laura Carrillo	Completed 05/31/2022

Ongoing previous tasks:

From November 2021 meeting	Ms. Carrillo will share the draft documents with the Medical Board's EA, Natalie Norberg, to finalize the cooperative practice application, checklist, and policy/procedure. Ms. Carrillo will then provide an update to the board on this at its February 17-18, 2022 meeting.	Laura Carrillo	Pending (met on 12/14/2021 and 02/09/2022); public comment on regulations end 06/13/2022
From February 2022 meeting	Ms. Carrillo will provide an update to the board on the number of pharmacies with outstanding annual reports	Laura Carrillo	Ongoing
From March 2022 meeting	Ms. Carrillo will track the number of pharmacies providing internet services at the time of the next renewal.	Laura Carrillo	Pending renewal season 04/01/2022 – 06/30/2022