BOARD MEETING AGENDA

Oregon Board of Pharmacy
800 NE Oregon Street
Portland, OR 97232
August 10-12, 2016

1891- Celebrating 125 Years of Excellence - 2016

The mission of the Oregon State Board of Pharmacy is to promote, preserve and protect the public health, safety and welfare by ensuring high standards in the practice of pharmacy and by regulating the quality, manufacture, sale and distribution of drugs.

Wednesday, August 10, 2016 @ 8:30 AM, Conference Room 1A
Thursday, August 11, 2016 @ 8:30 AM, Conference Room 1A
Friday, August 12, 2016 @ 9:00 AM, Conference Room 1A (*note the later start time*)
≈ If special accommodations are needed for you to attend or participate in this Board Meeting, please contact Loretta Glenn at: (971) 673-0001. ≈

WEDNESDAY, AUGUST 10, 2016

I. 8:30 *AM* OPEN SESSION, Kate James, R.Ph, Presiding

A. Roll Call

B. Introduction & Installation of new Pharmacist Board Member Rachael DeBarmore

C. Agenda Review and Approval *Action Necessary*

II. Contested Case Deliberation pursuant to ORS 192.690(1) - **Not Open to the Public**

III. EXECUTIVE SESSION – NOT OPEN TO THE PUBLIC, pursuant to ORS 676.175, ORS 192.660 (1) (2) (f) (k).

A. Items for Consideration and Discussion:
   1. Deliberation on Disciplinary Cases and Investigations
   2. Personal Appearances
   3. Warning Notices
   4. Case Review

IV. OPEN SESSION - PUBLIC MAY ATTEND - At the conclusion of Executive Session, the Board may convene Open Session to begin the scheduled agenda for August 11, 2016. Items that may be covered are marked with an asterisk *.

Adjourn

THURSDAY, AUGUST 11, 2016

8:30AM
V. OPEN SESSION, Kate James, R.Ph. Presiding

A. Roll Call

B. Introduce New Pharmacist Board Member Rachael DeBarmore

C. Motions for Contested Cases & Disciplinary Action *Action Necessary*

9:00AM
VI. GENERAL ADMINISTRATION

A. Discussion Items
1. Waiver Requests - *Miner* *Action Necessary*
   - SIRUM waiver requests **#A**
   - Volunteers in Medicine waiver request **#A1**
2. Ashland Community Hospital TCVP request - Miner **#A2** *Action Necessary*
3. Delegation of Board Authority review & update **#A3** – *Miner/Efremoff* *Action Necessary*

APPEARANCES
11:00 AM Jackson Leong R.Ph., Director of Pharmacy/PIC, PayLess Drug Stores, Inc.
PayLess Drug/Talyst: Requesting Board approval of Automated Dispensing Machine in a Nursing Home (**#B-CONFIDENTIAL) and #B1-B3**

Noon - Lunch break

Resume outstanding Discussion items or move on to Issues and Activities

***VII. ISSUES/ACTIVITIES**

*A. Reports:
1. Board President/Members
2. Executive Director **#C**
3. Board Counsel
4. Compliance Director
5. Pharmacist Consultant
6. Administrative Director
7. Licensing Department Supervisor
8. Project Manager

*B. Board Member/Staff Presentations – *James*
- Pharmacy Coalition –
- Professional Practice Roundtable – 9/8/16
- Health System Outreach Meeting – 8/18/16

*C. Committees/Meetings
1. NABP District 6,7,8 Meeting 9/11-14/2016, Portland, OR – *Watt/MacLean*
2. OSPA Annual Mtg. 10/21-23,2016, Clackamas, OR – *Karbowicz*

3. OSHP Mtg. 11/5/2016, Portland, OR - *Karbowicz*
4. OSPA Lane Co. Mid-Winter Mtg. 2/18-19/2017, Eugene, OR – *Watt/Karbowicz*

*D. Board Meeting Dates

• September 11-14, 2016	Portland	NABP District VI-VII annual meeting
• October 5-6, 2016	Portland	
• November 2-3, 2016	Silverton	(*Strategic Planning*)
• December 7-8, 2016	Portland	
• February 16-17, 2017*	Eugene	
• April 5-6, 2017	Portland	
• June 7-8, 2017	Portland	
• August 9-11, 2017*	Portland	(*3 day meeting*)
• October 11-10, 2017	Portland	
• November 8-9, 2017	TBA	(*Strategic Planning*)
• December 13-14, 2017	Portland	

*E. Rulemaking Hearing Dates
- November 22, 2016
- May 25, 2017
- November 28, 2017

*F. Financial/Budget Report – *Watt/MacLean* **#D-D1**(10 min)

G. Legislative update – *Watt* (none)

H. Strategic Planning – *MacLean*
- 2016 planning update

I. Approve Consent Agenda* *Action Necessary*

*Items listed under the consent agenda are considered to be routine agency matters and will be approved by a single motion of the Board without separate discussion. If separate discussion is desired, that item will be removed from the consent agenda and placed on the regular business agenda.

1. NAPLEX Scores – Jan 1, 2016 – April 30, 2016 **#E - CONFIDENTIAL**
2. MPJE Scores – Jan 1, 2016 – April 30, 2016 **#E1 - CONFIDENTIAL**
3. License/Registration Ratification - June 8, 2016 – August 9, 2016
4. Extension Requests **#E2**
5. Approval of Board Meeting Minutes – June 9-10, 2016

VIII. OPEN FORUM At the completion of regular Board Business, any Board licensee or member of the public is invited to meet with the Board to discuss issues of interest (typically the last item of the meeting)

Note: If time allows, the Board may begin the scheduled rules agenda for August 12, 2016.

Adjourn

FRIDAY, AUGUST 12, 2016

(8:30 AM Board Member and Staff Photos)

9:00AM *approximate meeting start time*
IX. OPEN SESSION, Kate James, R.Ph. Presiding

A. Roll Call

X. GENERAL ADMINISTRATION continued...

A. Discussion Items
   1. Payless/Talyst presentation review - *Miner*

B. Rules
   1. Review Rulemaking Hearing Report & Comments – *MacLean* **#F**
   2. Consider Adoption of Temporary Rules - none
   3. Send Rules to Rulemaking Hearing – none
   4. Consider Adoption of Rules **#F1**
      a) Div 041 – Epinephrine

Phase II First look **

   5. Rules for Discussion
      a) Div 007 & 041 - Drug Room**#F2**
      b) Div 010 - Criminal Background Checks** **#F3**
      c) Div 019 - Volunteer Limited Liability** **#F4-F4a**
      d) Div 019 & 041 - Resident PIC** **#F5**
      e) Div 019 & 041 – Naloxone** **#F6**
      f) Div 041 & 080 - Drug Take Back** **#F7**
      g) Div 043 - Practitioner Dispensing Outlets** **#F8-F8b**
      h) Div 044 - Charitable Pharmacy and REMS Drugs** **#F9**
      i) Div 080 - Controlled Substance 1** **#F10**

XII. OPEN FORUM At the completion of regular Board Business, any Board licensee or member of the public is invited to meet with the Board to discuss issues of interest (typically the last item of the meeting)

Adjourn

July 1, 2016

Waiver request Sirum Charitable Pharmacy

Discussion:

Sirum is presenting two requests for waivers.
The first would give them the ability to receive donations of refrigerated items. It appears that they will have a plan to maintain proper storage temperatures from a donor that meets the criteria for proper storage drugs such as practitioners, pharmacies and other distributers. If the Board determines that they want to grant the waiver you may want to require a plan or procedure to be approved by the Board to accomplish this transfer of refrigerated medications.
The second requested waiver asks for the ability to dispense filled prescriptions to patients in other states. They will be properly licensed in the state that where the prescriptions are delivered. In the 2016 legislative session language was add to ORS 689.772 (2) which reads "The program may accept and distribute **within this state**" This was language we requested to restrict the functions of the charitable pharmacies to this state only. While this is a noble idea to expand our program to other states we have concerns about our charitable pharmacies dispensing out of state regarding the new DQSA regulations and guidelines. The FDA has not given us clear guidance on track and trace activities with regards to charitable pharmacies and they roll as a dispenser.

Recommendations
We recommend the granting of the waiver request with the submission of a Board approved procedure for proper storage of refrigerated drugs during the donation transfer period. The second request would need a change or reversal of statutory language which was just enacted in the 2016 legislative session. With time and a better understanding of the DQSA implications for dispensers the Board could revisit with a statutory language change.

855-044-0050

Drug Distribution

(1) A charitable pharmacy may not distribute a donated prescription drug that:

(a) Fails to meet the requirements of the program;

(b) Has not been stored in accordance with manufacturer's recommendations;

(c) Has been repackaged, except that a drug that has been repackaged for a long-term care pharmacy may be distributed;

(d) Bears an expiration date that is less than nine months from the date the drug is donated;

(e) Is adulterated or misbranded;

(f) Is a controlled substance;

(g) Is a drug that requires a special registration for dispensing;

(h) Is an over-the-counter drug;

(i) Requires specialty storage or handling;

(j) Requires refrigeration;

(k) Is a compounded drug; or

(L) In the pharmacist's professional judgment, may be unfit for dispensing.

(2) A charitable pharmacy may only dispense a drug to a person who:

(a) Has a valid prescription for the drug; and

(b) Is a resident of Oregon; and

(c) Is underinsured or does not have adequate health insurance coverage for the prescription drug requested; or

(d) Is enrolled in a program of public assistance as defined in ORS 411.010;

(3) A drug may only be dispensed by a pharmacist or by a practitioner who has been given dispensing privileges by their licensing board and is acting within their scope of practice, or by a registered nurse subject to the following:

(a) A registered nurse who is an employee of a charitable pharmacy may dispense a drug to a client of the charitable pharmacy; and

(b) Such dispensing by a registered nurse shall be pursuant to the order of a person authorized to prescribe the drug.

(4) The dispensing practitioner must provide the patient with appropriate counseling on the use of the drug and any potential side effects, and may provide written drug information;

(5) A recipient of a drug under this program must sign a Recipient Form, provided by the Board, that attests that the recipient has been notified that:

(a) The prescription drug was donated to the program;

(b) A visual inspection was conducted by a pharmacist to ensure that the drug has not expired, been adulterated or misbranded, and is in its original, sealed packaging;

(c) A pharmacist has determined that the drug is safe to distribute based on the accuracy of the Donor's Form and the visual inspection by the pharmacist;

(d) Participants in the program are immune from liability as provided in ORS 689.780; and

(e) That they are qualified to receive the drug as specified in section (2) of this rule.

(6) Upon written request the Board may waive any of the requirements of this rule if a waiver will further public health and safety. A waiver granted under this section shall only be effective when it is issued in writing.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.772 & 689.774
Hist.: BP 6-2010, f. & cert. ef. 6-29-10

855-031-0026

Ratio & Supervision

(1) A pharmacist may not supervise more than one intern at a time at a TPI site who performs the duties of an intern as listed in OAR 855-019-0200(3)(g). A pharmacist may supervise more than one intern if only one intern performs the duties of an intern as listed in OAR 855-019-0200(3)(g) and if other interns supervised by the pharmacist perform the duties listed in OAR 855-025-0040.

(2) A preceptor may not supervise more than two interns simultaneously during a shift at an SRI site where patient specific recommendations for care or medications are provided without prior written authorization of the Board.

(3) With the written approval of a school of pharmacy, and when in their professional judgment it is appropriate, a preceptor may supervise up to 10 interns at public-health outreach programs such as informational health fairs that provide general information but not direct patient care.

(4) For immunization clinics, an immunizing pharmacist may supervise up to two immunizing interns.

(5) A licensed preceptor may delegate the preceptor responsibilities to another licensed pharmacist or preceptor.

(6) The majority of an intern's overall experience must be with a licensed pharmacist preceptor.

Stat. Auth.: ORS 689.151, 689.205
Stats. Implemented: 689.255 & 2009 OL Ch. 536
Hist.: BP 9-2011, f. 12-30-11, cert. ef. 1-1-12

Enrolled
Senate Bill 1514

Printed pursuant to Senate Interim Rule 213.28 by order of the President of the Senate in conformance with presession filing rules, indicating neither advocacy nor opposition on the part of the President (at the request of Senate Interim Committee on Human Services and Early Childhood)
CHAPTER ..

.....

AN ACT

Relating to prescription drugs; amending ORS 689.772 and 689.774; and declaring an emergency.

Be It Enacted by the People of the State of Oregon:

SECTION 1. ORS 689.772 is amended to read:

689.772. (1) There is created in the State Board of Pharmacy the Charitable Prescription Drug Program. The purpose of the program is to distribute donated prescription drugs to needy or uninsured individuals. Participation in the program is voluntary.

(2) The program may accept and distribute **within this state**:

(a) Prescription drugs received **as donations** in original, sealed, tamper-evident packaging that displays the lot number and expiration date of the drug; [*and*]

(b) Sealed single unit dose packages received in opened packages containing multiple single unit doses[.]**; and**

(c) Prescription drugs

Mr. Gary Miner, R.Ph.
Compliance Director
Oregon Board of Pharmacy
800 NE Oregon #150
Portland, Oregon 97232

June 29, 2016

Request by SIRUM Charitable Pharmacy for Waivers within the Charitable Prescription Drug Program.

Dear Mr. Miner:

Per 855-044-0050 (6), we seek the following waiver from the Charitable Prescription Drug Program rules to reduce prescription drug waste and further public health by allowing patients in need to receive access to their prescription drugs:

We request a waiver of OARs Section **855-044-0050 (1)(j)** which prohibits the distribution of donated prescription drugs that require refridgeration. Eligible medicine donors like skilled nursing facilities have unused, unopened medications such as insulin that have been kept in proper cold chain: i.e. courrier from dispensing pharmacy and refridgeration at the facility. We request that prescription drugs that require refridgeration be eligible for donation if the cold chain of the drug is maintained at the donor facility and in transit to the SIRUM Charitable Pharmacy (e.g. commerical carrier with insulated shipping containers, coolant packs and a temperature logger).

Sincerely,

George Wang
Co-founder & Director, SIRUM

CP-0000014
SIRUM Charitable Pharmacy
334 SE 5th Ave
Hillsboro, OR 97123

Mr. Gary Miner, R.Ph.
Compliance Director
Oregon Board of Pharmacy
800 NE Oregon #150
Portland, Oregon 97232

June 29, 2016

Request by SIRUM Charitable Pharmacy for Waivers within the Charitable Prescription Drug Program.

Dear Mr. Miner:

Per 855-044-0050 (6), we seek the following waiver from the Charitable Prescription Drug Program rules to reduce prescription drug waste and further public health by allowing patients in need to receive access to their prescription drugs:

We request a waiver from dispensing donated medicine only to residents of Oregon, OARs Section **855-044-0050 (2)(b)**. Because many donors are only willing to donate medicine in an all or none manner, our Charitable Pharmacy receives some donated medicine which are not needed by Oregon residents. Instead of having this medicine expire on our shelves, we ask the Board to allow us the option to dispense these drugs to patients in need in other states with a valid prescription. Before dispensing into other states, we would obtain the proper out-of-state licensing. In addition, we will prioritize Oregon residents in need before residents of other states.

Sincerely,

George Wang
Co-founder & Director, SIRUM

CP-0000014
SIRUM Charitable Pharmacy
334 SE 5th Ave
Hillsboro, OR 97123

June 29, 2016

Volunteers in Medicine Charitable Pharmacy waiver request

Volunteers in Medicine Charitable Pharmacy (VMCP) are requesting two waivers. One for the required lot number on accepted and donated drugs and allow donations from other health care provides other than LTC facilities {OAR855-044-0030(2)(a) and 855-044-0070(1)(b)}. The second request is to use volunteer nurses as the dispensing Registered Nurse {855-044-0050(3)(a)

Discussion:
The waiver for the lot number exception has been granted to other Charitable Pharmacies with the provision that if a recall occurs then all of the recalled drugs would be destroyed. A clarification in the waiver can include the appropriate donation of drugs in a partial manufacturer original container. The second part of this request does not need a waiver but maybe a clarification. We have allowed the donation of unused drugs from Medication Assistance programs and samples. This would include full or partial packets of drugs and full and drugs in manufacture original containers.

The waiver request for volunteer registered nurses to perform final verification, dispensing and appropriate patient counseling is the first time the Board has been asked for this waiver. The rule requires these functions should be performed by a Registered Nurse who is an employee of the pharmacy. The discussion about this section of rule when adopted centered on accountability and consistency using only RNs who are employed. A concern was creating a situation where there are several RNs working limited hours which would place public at a greater risk regarding dispensing errors.

Recommendation-

Approve the waiver for the lot numbers and use of drugs contained in partial bulk manufacturer original container. The use of other practitioners as a source for mediation donations has been allow as long as all the donation criteria is met.
Deny the waiver for use of non-employee RNs as dispensers but the Board can encourage the use of volunteer RNs to aid in the process but an employed RN would be responsible for the final verification and supervision of the dispensing.

855-044-0030

Drug Donation

(1) A charitable pharmacy may not accept:

(a) Any controlled substance or any kit, package or blister pack that contains any controlled substance;

(b) A non-prescription drug;

(c) A drug in a container or package that does not contain a product identification label (PIL), except that a drug in a manufacturer's original container or a manufacturer's blister pack does not need to bear a PIL.

(2) A charitable pharmacy may accept:

(a) A prescription drug received in original, sealed, tamper-evident packaging that displays the lot number and expiration date of the drug; and

(b) Sealed single unit dose packages received in opened packages containing multiple single unit doses.

(3) The following are examples of acceptable packaging:

(a) Manufacturer's original container;

(b) Single-dose blister packs in sealed outer package;

(c) Single-dose blister packs in opened outer package;

(d) Tamper-evident hospice kit containing manufacturer's original containers.

(4) Donated drugs that do not meet the above criteria or are judged by the pharmacist to be unsafe for re-dispensing must be stored separately from the drug supply until they can be destroyed.

(5) A charitable pharmacy may accept a drug from:

(a) An individual;

(b) A long-term care facility;

(c) A pharmacy;

(d) A practitioner who has been given dispensing privileges by their licensing board and is acting within their scope of practice;

(e) Another registered charitable pharmacy;

(f) A medical clinic;

(g) A drug manufacturer or wholesaler;

(h) A Medication Assistance Program (MAP) such as those supported by drug manufacturers.

(6) The donor must certify on a Donor Form provided by the Board that the donated drug has been properly stored, in accordance with manufacturer's recommendations, and has never been opened, used, adulterated or misbranded.

(7) Upon written request, the Board may waive any of the requirements of this rule if a waiver will further public health and safety. A waiver granted under this section shall only be effective when it is issued in writing.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.772 & 689.774
Hist.: BP 6-2010, f. & cert. ef. 6-29-10

855-044-0070

Records

(1) A charitable pharmacy must maintain a donation record of all drugs received that includes:

(a) Donor's name and address;

(b) Drug manufacturer, lot number, name and strength;

(c) Drug quantity;

(d) Expiration date of the drug;

(e) Date donated; and

(f) The unique identifier.

(2) A charitable pharmacy must maintain a distribution and dispensing record that includes:

(a) Drug name and strength;

(b) Quantity distributed;

(c) Name of manufacturer;

(d) Lot number and expiration date;

(e) Date of distribution or dispensing;

(f) Name and address of recipient.

(3) A charitable pharmacy must maintain a record of all drugs that are destroyed.

(4) In addition to the above records, a charitable pharmacy must cross-reference the donation record and the distribution and dispensing record with the appropriate donor and recipient forms.

(5) A charitable pharmacy must make an annual report to the Board by completing a form provided by the Board and submitting it with their application for renewal of registration.

(6) All records required by these rules must be retained for three years and made available to the Board upon request.

(7) Upon written request the Board may waive any of the requirements of this rule if a waiver will further public health and safety. A waiver granted under this section shall only be effective when it is issued in writing.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.774
Hist.: BP 6-2010, f. & cert. ef. 6-29-10; BP 9-2014, f. & cert. ef. 12-4-14

855-044-0050

Drug Distribution

(1) A charitable pharmacy may not distribute a donated prescription drug that:

(a) Fails to meet the requirements of the program;

(b) Has not been stored in accordance with manufacturer's recommendations;

(c) Has been repackaged, except that a drug that has been repackaged for a long-term care pharmacy may be distributed;

(d) Bears an expiration date that is less than nine months from the date the drug is donated;

(e) Is adulterated or misbranded;

(f) Is a controlled substance;

(g) Is a drug that requires a special registration for dispensing;

(h) Is an over-the-counter drug;

(i) Requires specialty storage or handling;

(j) Requires refrigeration;

(k) Is a compounded drug; or

(L) In the pharmacist's professional judgment, may be unfit for dispensing.

(2) A charitable pharmacy may only dispense a drug to a person who:

(a) Has a valid prescription for the drug; and

(b) Is a resident of Oregon; and

(c) Is underinsured or does not have adequate health insurance coverage for the prescription drug requested; or

(d) Is enrolled in a program of public assistance as defined in ORS 411.010;

(3) A drug may only be dispensed by a pharmacist or by a practitioner who has been given dispensing privileges by their licensing board and is acting within their scope of practice, or by a registered nurse subject to the following:

(a) A registered nurse who is an employee of a charitable pharmacy may dispense a drug to a client of the charitable pharmacy; and

(b) Such dispensing by a registered nurse shall be pursuant to the order of a person authorized to prescribe the drug.

(4) The dispensing practitioner must provide the patient with appropriate counseling on the use of the drug and any potential side effects, and may provide written drug information;

(5) A recipient of a drug under this program must sign a Recipient Form, provided by the Board, that attests that the recipient has been notified that:

(a) The prescription drug was donated to the program;

(b) A visual inspection was conducted by a pharmacist to ensure that the drug has not expired, been adulterated or misbranded, and is in its original, sealed packaging;

(c) A pharmacist has determined that the drug is safe to distribute based on the accuracy of the Donor's Form and the visual inspection by the pharmacist;

(d) Participants in the program are immune from liability as provided in ORS 689.780; and

(e) That they are qualified to receive the drug as specified in section (2) of this rule.

(6) Upon written request the Board may waive any of the requirements of this rule if a waiver will further public health and safety. A waiver granted under this section shall only be effective when it is issued in writing.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.772 & 689.774
Hist.: BP 6-2010, f. & cert. ef. 6-29-10

Volunteers in Medicine Charitable Pharmacy

Good morning Gary,
I've included the new waiver request regarding using volunteer RN's and tacked on the waiver request I recently sent regarding using donated meds without lot numbers (thought it might be helpful to have both requests in one place).

Regarding OAR 855-044-0050 (3)-(3)(a) we seek a waiver to allow volunteer registered nurses as well as volunteer licensed pharmacists and practitioners with dispensing privileges to work in the lead role of the charitable pharmacy. This role includes the duties of final verify, dispensing and appropriate patient counseling as needed. The volunteer leads will always be working under either the staff pharmacist, the staff registered nurse, or both. Volunteers in Medicine relies on the use of volunteers to help keep costs low which allows the clinic to continue to give care to our patients who are unable to afford traditional medical care options. The largest pool of professional volunteer applicants are registered nurses, and the ability to use these volunteers as a lead in the pharmacy would greatly improve our ability to have the lead role filled by volunteers, which in turn allows the staff to be available to fill other needed roles in the pharmacy.
The volunteer leads will be trained by both the staff pharmacist and staff registered nurse, and will be closely supervised until training is complete. The lead will always have access to counseling cue cards and on-line clinical resources, and will be encouraged to pass problems on to a staff member.

Regarding ORS 689.772 (2)(a), OARs 855-044-0030 (2)(a) and 855-044-0070 (1)(b) we seek the following waiver from the Charitable Prescription Drug Program rules to increase access to donated prescription drugs and further public health: we request a waiver to allow the donation from other types of pharmacies, including, but not limited to long term care pharmacies, of repackaged medications that do not have a lot number, as long as the medicine has not left the control of a pharmacy or clinician. One example of this is a Medication Assistance Program (MAP) drug that is repackaged and sent from a mail order pharmacy to a safety-net pharmacy for a specific patient. When a patient does not pick-up this medicine, it is currently being destroyed even though the medicine has not left the control of the pharmacist. Drugs dispensed to patients are not required to have lot numbers on the medication label, which removes a large pool of medicine that would otherwise meet all the requirements of the Charitable Prescription Drug Program. We ask that this type of medicine be eligible for donation.

Thank you,
Laura Van Horn
Pharmacist and Point of Contact
Volunteers in Medicine Charitable Pharmacy

Technician Checking Validation Program (TCVP) Checklist

A hospital may not operate a TCVP without prior written approval from the Oregon Board of Pharmacy. To apply for approval, the hospital must submit the following to the Board:

- [x] Copies of written training material that will be used to train technicians as technician checkers
- [x] Copies of the policy and procedures for the proposed TCVP
- [x] A description of how the proposed TVCP will improve patient safety by focusing on assessing the accuracy and appropriateness of the medications ordered and on educating staff and patients
- [x] Other items as requested by the Board

From: White, Matthew [mailto:MATTHEW.WHITE@asante.org]
Sent: Sunday, July 10, 2016 2:34 PM
To: Gary Miner
Cc: Toner, Mike; Watson, Amy; White, Matthew
Subject: TCVP Ash;and Community Hospital Proposal / Application
Importance: High

Oregon Board of Pharmacy
800 NE Oregon St., Suite 150
Portland, OR 97232-2162
Phone: 971-673-0001
Fax: 971-673-0002

Dear Oregon Board of Pharmacy,

It is our pleasure to present to you Ashland Community Hospital (AACH) Pharmacy's proposal for initiation of the Technician Checking Validation Program (TCVP). Currently, AACH has a growing clinical program. We believe that this program will benefit patient safety by allowing pharmacists to be freed up from checking responsibilities and be redirected toward focusing on assessing the accuracy and appropriateness of the medications ordered and on educating staff and patients. TCVP will also allow us to focus additional time in the preparing medication lists for providers.

With this very exciting time in hospital pharmacy, your approval of the TCVP program as attached and proposed would greatly enhance patient safety by allowing, in a time of careful resource planning, the ability to redirect the pharmacist to our current and expanding clinical duties previously outlined.

Please find attached the documents, training, and policy that were part of the Rogue Regional Medical Center, and Three Rivers Medical Center application, approved in 2012 & 2015. The AACH program will utilize the same documents, training, and policy. Thank you for your consideration of this proposal.

Sincerely,

Matthew White, PharmD, MHA
Pharmacist
541-829-9936
matthew.white@asante.org

Mike Toner, RPh
Pharmacy Manager
541-201-4050
michael.toner@asante.org

Ashland Community Hospital
280 Maple Street
Ashland, OR 97520

ASANTE®

Document Title: Technician Checking Validation Program TCVP, Asante	**Document Number** 400-PHAR-XXXX	**Document Type** ☒ Policy ☒ Procedure
Date of Origin:	**Department of Origin:** Pharmacy	
Effective Date:	**Owner Position:** Pharmacist	
Review Due Date:	**Regulations:** ORS 689.205, ORS 689.155, Rules 855-041-5100 to 855-041-5170	
Key Words: 100-PHAR-0022, 400-PHAR-XXXX, Technician, Checker, Validation, Program, TCVP		
Approved: Signature: /s/ Amy Watson, PharmD Title: Pharmacy Service Line Director Date:		

PURPOSE

The TCVP is a tool to allow the re-direction of a pharmacist from a distributive task to a cognitive task. It is designed to allow a pharmacist to improve patient safety by focusing on assessing the accuracy and appropriateness of the medications ordered and on educating staff and patients.

DEFINITIONS

In addition to the definitions outlined in ORS 855-041-5100, ARRMC pharmacy will make the following definitions:

Unit of Use cart fill:

- Patient specific bins filled with unit doses as defined by ORS 855-041-5100 (6)
- Patient specific unit dose and OmniCell Load Labels

ADC or non-emergent trays and kits:

- Non-Patient-Specific orders for filling the OmniCells

POLICY

The hospital pharmacy will operate the Technician Checking Validation Program (TCVP) within the guidelines of Oregon rules ORS 855-041-5100 to ORS 855-041-5170.

The hospital pharmacy will not operate a TCVP without current written approval from the Oregon Board of Pharmacy.

The pharmacy and the PIC will comply with all requirements listed in ORS 855-041-5120 and with any additional procedures outlined below.

This program will comply with technician eligibility and training as outlined in ORS 855-041-5130 and with any additional eligibility and training requirements outlined below.

This program will follow the initial validation and quality control process as outlined in ORS 855-041-5140 and with any additional procedures outlined below.

Technicians will comply with the checking procedure outlined in ORS 855-041-5150 and with any additional procedures outlined below.

This program will operate ONLY within the eligible special functions as outlined in ORS 855-041-5160.

Records will be kept as outlined by ORS 855-041-5170 for the specified time frame therein and will be available for inspection at any time. Records will be kept as outlined in the procedure below.

PROCEDURES

Initial Validation & Quality Assurance

In addition to the complying with the initial validation and quality control process as outlined in ORS 855-041-5140, the following procedures will be followed:

- Prior to initial validation, the technician checker candidate will complete a online examination and pass with a score of 80% or higher.
- The training pharmacist will schedule practical sessions for individual training. The technician may request as many of these sessions as they feel they need before completing the checking portion of the validation process.
- The training pharmacist will schedule an observation time for the technician to observe pharmacist checking. The technician may request as many of these sessions as they feel they need before completing the checking portion of the validation process.
- The technician checker will be provided as long as they need to check doses accurately. There will not be a time limit on Initial Validation checks or Quality Assurance checks.

Checking Procedure

In addition to checking all doses in accordance to ORS 855-041-5150, the technician will do the following:

- If at ARRMC, Complete the OMNI & Near Miss Reporting Form 100-PH-1006 when any error is detected in checking made by any hospital personnel.
- Recruit a pharmacist to check any medications on the high risk list.
- Report to the pharmacists when checking is completed.

Record Keeping

- A Technician Checking Validation Program (TCVP) binder will store all training and quality assurance documents.
- A tab will be established for each technician checker in the TCVP binder. Stored in each technicians tab will be the following forms, which contain all elements of record keeping as required by ORS 855-041-5170:
    - The training and examinations taken by the technician checker candidate
    - Initial validation, documented
    - Quality assurance checks
    - Artificially introduced errors
    - Technician errors

- All forms must have all applicable sections completely filled out to be considered valid record keeping
- A copy of this policy will be kept in the TCVP binder.
- A copy of all training materials will be kept in the TCVP binder.
- A copy of the TCVP high risk medication list (Appendix A) will be kept in the TCVP binder.

SCOPE

This policy and procedure applies to all pharmacy personnel licensed by the Oregon Board of Pharmacy working at Asante Rogue Regional Medical Center or Asante Three Rivers Medical Center and to the hospital pharmacies licensed therein.

RESPONSIBILITIES

It is the responsibility of the pharmacist-in-charge to ensure that all training is completed and documented prior to a technician performing as a technician checker.

SUBMITTED BY

Name / Position	Date

REVIEWED BY

Name / Position	Date
Oregon Board of Pharmacy	08/08/2012
Jeff Feyerharm, RPh / ARRMC Pharmacy Manager	11/21/2015
Jo Stuart, RPh / ATRMC Pharmacy Manager	11/23/2015
Matthew White, PharmD / Pharmacist	11/21/2015

REVISIONS

Revision date:	Revision Description:
8/15/2012	New Policy / Procedure
10/4/2012	Rebranded to new template
02/09/2015	Triennial Review: updated to reflect ALEC training, addition of form numbers
11/21/2015	Update to 400 level for inclusion of ATRMC

Technician Checking Validation Program (TCVP)
High Risk Medication List – Appendix A

- All unit doses labeled in the IV room for patient specific administration
- Injectable phytonadione (Vitamin K)
- Unfractionated heparin (therapeutic and flush concentrations)
- Insulin

Technician Checking Validation Program

Matthew White PharmD

Pharmacist

May 25, 2012

NOTE: Indicate whether e-learning has narration here

Prior to this review

- Read "History of Technician Checking Validation Program"
- Read the 4 Pharmacist Letter technician training modules
- Review 855-041-5100 to 855-041-5170
- Review 100-PHAR-0022 Technician Checking Validation Program (TCVP) Policy and Procedure
- Review TCVP forms
- Review TCVP High-Risk Medication List

Overview

- Generic vs Brand
- Handling & Storage
- Expiration Dates
- Dose forms
- Common Errors
- Why the technician checking validation program (TCVP) was created
- Definitions
- High Risk Medications
- Technician Eligibility & Training
- Initial Validation & Quality Assurance
- Pharmacist Responsibilities & Random Audits
- Checking Procedure
- Written Exam Preparation

Generic vs Brand Names

During the drug development process, a medication is given a generic and chemical name. Once the FDA approves the drug, the manufacturer proposes a brand name for their form of the drug. During the patent life of the drug, no generic forms are made; therefore, ordering the drug by brand name is the same as ordering it by generic name.

Generic and brand names can be found in common references. Common references

- Micromedex
- American Hospital Formulary Service
- Pediatric dosage handbook
- Drug facts and Comparisons
- http://www.fda.gov/cder/orange/obannual.pdf

Handling & Storage Conditions

- Some products may require special handling or storage conditions like:
- protect from light; bagged separately when in refrigerator; needs refrigeration etc.
- Identify products requiring special handling or storage conditions.

Expired / Contaminated

- Identify expired or contaminated products.
- Expiration dates must be checked on each dose of medication. If packaged (unit dose) from the manufacturer, this date must be on that packaging.
- Some products have special stability characteristics.

Dosing Forms

Some medications have unique dose forms. This affects how the drug can be given (e.g. whether or not it can be crushed or split). Examples include:

- Nifedipine (pro cardia XL) is a matrix tablet that slowly releases the medications from a "web-like" structure through a special hole in the tablet coating into the GI tract.
- Valproic acid (Depakote Sprinkles) are small beads that slowly release the drug in the small intestine; they must not be chewed but can be sprinkled on soft food and swallowed.

In caring for children and adults with special needs, we often must use/create dosage forms that are unique to our patient population. Examples include IV dilutions and oral liquid medications not available from the manufacturer.

Common Errors

Understand the potential impact of medication errors by reviewing past errors as reported in *Hospital Pharmacy as well as ISMP. Medication errors* should be preventable through effective system controls involving pharmacists, physicians, other prescribers, nurses and others. It is the responsibility of all staff to prevent medication errors through accurate job performance.

Look-a-like Sound-a-like medications

- Ampicillin / Amoxicillin
- Nifedipine / Nicardipine
- Timentin / Ticar
- Potassium Chloride / Potassium Gluconate
- Dopamine / Dobutamine

Route of Administration

Common Errors

Dilution Errors

- Many medications have more than one concentration available. This may result in an overdose or underdose of medication. Identify possible errors with multiple concentrations.

Abbreviations - Common acceptable medical abbreviations and symbols used in Pharmacy:

- Na = sodium, Ca= calcium, CI = chloride, S04 = improper use of sulfate, HC03 = bicarbonate, NS = normal saline, K = potassium, Mg = magnesium, P04 = phosphate, MS = improper use of morphine sulfate, D5W = 5% dextrose (in water), LR = lactated ringers

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Why the TCVP?

- TCVP is a tool to allow the re-direction of a pharmacist from a distributive task to a cognitive task
- TCVP is designed to allow a pharmacist to improve patient safety by focusing on assessing the accuracy and appropriateness of the medications ordered and on educating staff and patients
- Opens up new areas of specializing for technicians

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Definitions

- "Error" is any occurrence of a wrong drug, dose, quantity, or dosage form or the inclusion of any drug with an expired date in a line item. All errors in a line item counts as one error.
- "Line Item" is a checking unit for ADC restocking (example: one specific drug and dose, regardless of quantity).

Definitions

- "Technician Checking Validation Program (TCVP)" is a program that uses a technician checker to check functions completed by another technician.
- "Technician Checker" is an Oregon certified technician who has completed the TCVP validation process and is currently authorized to check another technician's work.

Definitions

- "Unit Dose" is the physical quantity of a drug product designed to be administered to a patient specifically labeled to identify the drug name, strength, dosage amount and volume, if applicable. The unit dosed drug can be obtained from the manufacturer or repackaged from an external re-packager. A drug may be repackaged on-site through a batch repackaging process that includes a pharmacist as a check. Unit dose examples include oral solids individually packaged by a manufacturer or re-packaged, oral liquids drawn up in a labeled oral syringe, all individually labeled injectable products, and pre-mixed IV products.

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What is involved?

- Only a hospital pharmacy may apply to participate in a TCVP.
  - policies and procedures
  - list of high-risk medications
  - written approval from the Oregon Board of Pharmacy
  - written training material
  - quality assurance and training documentation records and forms

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Drug Distribution System

- The hospital pharmacy must have a drug distribution system that is structured to allow for one additional check of the distributed medications by a licensed nurse or other licensed health care professional with authority to administer medications after the delivery of checked medications to participate in TCVP

High-Risk Medications

- The hospital pharmacy must develop policies and procedures for the TCVP to include a list of high-risk medications that are excluded from the TCVP.

Technician Eligibility

- Must be recommended for training by the technician supervisor
- Minimum of 1 year drug distribution experience

Technician Training

- Didactic lecture or equivalent training with a self-learning packet
- Practical sessions that consist of individual training in checking a cart fill or ADC that is provided by a pharmacist
  - observing a pharmacist performing checking
  - performing the initial check with a pharmacist verifying
- Written examination
- Initial Validation Process
  - Review Initial Validation Forms

Initial Validation / QA

- The introduction of artificial errors into a live or simulated environment, to monitor the ability of the technician to catch errors.
  - Review Artificial Errors Form
- The pharmacist must document and notify a technician checker of any errors found during training.
  - Review Technician Errors Form

Written Exam

- Prior to initial validation, the technician checker candidate will complete a written examination and pass with a score of 90% or higher. If the technician fails to pass the examination, they must submit in writing to the pharmacist trainer the correct answers and reasoning behind the question. The technician must pass an alternate written exam if they fail before initial validation.

Initial Validation Process

- The initial process to validate a trainee's ability to accurately check another technician's work must include:
  - Unit of Use validation
  - ADC, Non-emergent kits / trays validation
  - Each has a different set of rules

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Unit of Use Cart Fill Validation

- For initial validation of a trainee to check a unit of use cart fill, the trainee must obtain a 99.8% accuracy rate in 1500 total doses, divided among five separate training checks.
- A trainee who makes more than three errors in 1500 doses fails the validation and may not work as a technician checker until the checking process is repeated and until successfully completed.
- No Time Limit

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ADC, Non-Emergent Kits Validation

- For initial validation of a trainee to fill ADC or non-emergent trays and kits, the trainee must obtain a 99.8% accuracy rate in 500 total line items, divided among five separate training checks. A trainee who makes more than one error in 500 line items fails the validation and may not work as a technician checker until the checking process is repeated and until successfully completed.
- No Time Limit

Pharmacist Responsibilities

- In each initial validation check, a pharmacist must check the accuracy of all unit of use medications after the trainee has checked them. The pharmacist must document any errors in the unit of use cart and discuss them with the trainee.
  - Review Initial Validation Form

Pharmacist Responsibilities

- In each initial validation check, the pharmacist will introduce at least three errors. The pharmacist coordinating the training check will keep a record of the introduced errors and will ensure that all introduced errors are removed before medications are distributed.
  - Review Artificial Errors Form
- The pharmacist must document the results of each initial validation check and retain the results in the quality assurance file (TCVP Binder)

QA Checks

- Conducted in the same manner as the applicable initial validation process
- The quality check sample must consist of at least 300 doses for technicians checking unit of use carts and at least 100 line items for technicians checking ADC or non-emergent trays and kits.
- Random unannounced times

QA Checks Continued

- A technician checker who makes more than one error fails the quality check and may not work as a technician checker unless the technician first passes a second quality check within 30 days of the failed quality check. If the technician does not pass the second quality check within 30 days, the technician must be retrained and revalidated before working as a technician checker.
- Results are documented on QA forms
  - Review Quality Assurance Forms

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Timing of QA Checks

- A technician checker must undergo a quality check at least monthly. A technician checker who has successfully completed three consecutive monthly quality checks must be checked at least quarterly for at least one year. A technician checker who has successfully completed four consecutive quarterly quality checks must be checked at least every six months.
  - Review Quality Assurance Forms

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Random Error Report Audits

- Periodically, the technician supervisor will run a report of filling errors reported on each technician and evaluate each technician for continuing as a technician checker. The technician supervisor or pharmacy manager hav the discretion to revoke technician checker privileges at any time. If privileges are revoked, the technician is ineligible to undergo training until given permission by either the technician supervisor or the pharmacy manager in writing. The approval to retrain will be kept in the TCVP binder as described in the record keeping section.

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Retraining

- A technician checker who does not perform TCVP duties for more than six months must undergo initial validation as described in section one of this rule.

- Must be retrained if privileges are revoked by technician supervisor only after written permission is provided to the training pharmacist

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Checking Procedure

- A technician checker must use the following procedure when checking another technician's work:
  - A pharmacy technician fills the medication for the cart fill or ADC restocking batch or non-emergent trays and kits.
  - A technician checker must check the accuracy of cart fill batches or ADC or non-emergent trays and kits. The technician checker shall review the medications for the correct drug, dose, dosage form, and quantity and must review the expiration dates of medications.

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What to do if an error is discovered?

- Technician checker must record the error on the OMNI & Near Miss Reporting Form 100-PH-1006 and return the product to the technician who originally filled it, if available, or to another technician. The filling technician must correct the error and the technician checker must check the correction.
  - Review OMNI & Near Miss Reporting Form 100-PH-1006
- A pharmacist or another technician checker must check any cart fill batches, ADC or non-emergent tray or kit, or medication corrections filled by a technician checker

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Checking Procedure

- In addition to checking all doses in accordance to 855-041-5150, the technician will do the following:
  - Complete the OMNI & Near Miss Reporting Form 100-PH-1006 when any error is detected in checking made by any hospital personnel.
  - Recruit a pharmacist to check any medications on the high risk list.
  - Report to the charge pharmacist when checking is completed.

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Assistance

- Oregon Board of Pharmacy Law Website
- AsanteNet Policies & Procedures
- Pharmacist Trainer

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Written Exam

Please email Matthew White at mwhite@asante.org to schedule a time to take the written exam.

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Technician Checking Validation Program (TCVP) Initial Validation Record
Unit Of Use Certification

Technician Name: _____ **License #** _____

Requirement:	Date Verified:	Signature:
Technician has a minimum of 1 year drug distribution experience		
Didactic lecture or self-learning packet is completed		
Practical session consisting of individual training / observation of a pharmacist performing the checking process		
Written examination passed		

Initial Validation: 99.8% accuracy required defined as ≤ 3 errors in ≥ 1500 doses, divided over 5 initial validation checking sessions

	Date	# of Items Checked	# of Errors	% Accuracy	Signature
1					
2					
3					
4					
5					

Final Results:			

Error #	Date	Description	Error Discussed	
			Technician Initials	Pharmacist Initials
1				
2				
3				
4		STOP Validation and Restart Initial Validation Process		

_____ _____ _____

Certification Date **Pharmacist Signature** **Technician Signature**

Controlled Unless Printed

Technician Checking Validation Program (TCVP) Initial Validation Record
ADC or Non-Emergent Kits & Trays Certification

Technician Name: _____ **License #** _____

Requirement:	Date Verified:	Signature:
Technician has a minimum of 1 year drug distribution experience		
Didactic lecture or self-learning packet is completed		
Practical session consisting of individual training / observation of a pharmacist performing the checking process		
Written examination passed		

Initial Validation: 99.8% accuracy required defined as ≤ 1 error in ≥ 500 doses, divided over 5 initial validation checking sessions

	Date	# of Items Checked	# of Errors	% Accuracy	Signature
1					
2					
3					
4					
5					

Final Results:			

Error #	Date	Description	Error Discussed	
			Technician Initials	Pharmacist Initials
1				
2		STOP Validation and Restart Initial Validation Process		

_____ _____ _____

Certification Date **Pharmacist Signature** **Technician Signature**

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Technician Checking Validation Program (TCVP) Initial Validation Record
Artificial Error Introduction Log

Technician Name: _____ License # _____

Error #	Date	Description	Detected? (Y/N)	Pharmacist Initials
1				
2				
3				
1				
2				
3				
1				
2				
3				
1				
2				
3				
1				
2				
3				
1				
2				
3				
1				
2				
3				

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Technician Checking Validation Program (TCVP) Quality Assurance Record
ADC & Non-Emergent Kits & Trays

Technician Name: _____ **License #** _____

Initial Validation Date: _____

QA Checks: At least 3 artificial errors must be introduced and ≤ 1 errors in ≥ 100 line items by the technician is a pass. If >1 error this is a fail, must stop checking and restart with monthly checks and pass a QA check within 30 days to avoid repeating training and initial validation. If 2nd QA check is not passed all training and initial validation must be repeated before checking any further doses.

Monthly Checks:

	Date	# Items Checked	# Errors	% Accuracy	Signature	3 Artificial Errors?
1						
2						
3						

Quarterly Checks:

	Date	# Items Checked	# Errors	% Accuracy	Signature	3 Artificial Errors?
1						
2						
3						
4						

Biannual Checks:

	Date	# Items Checked	# Errors	% Accuracy	Signature	3 Artificial Errors?
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						

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Technician Checking Validation Program (TCVP) Quality Assurance Record
Unit of Use

Technician Name: _____ **License #** _____

Initial Validation Date: _____

QA Checks: At least 3 artificial errors must be introduced and ≤ 1 errors in ≥ 300 line items by the technician is a pass. If >1 error this is a fail, must stop checking and restart with monthly checks and pass a QA check within 30 days to avoid repeating training and initial validation. If 2nd QA check is not passed all training and initial validation must be repeated before checking any further doses.

Monthly Checks:

	Date	# Items Checked	# Errors	% Accuracy	Signature	3 Artificial Errors?
1						
2						
3						

Quarterly Checks:

	Date	# Items Checked	# Errors	% Accuracy	Signature	3 Artificial Errors?
1						
2						
3						
4						

Biannual Checks:

	Date	# Items Checked	# Errors	% Accuracy	Signature	3 Artificial Errors?
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						

Controlled Unless Printed

Technician Checking Validation Program (TCVP) Quality Assurance Record
Technician Errors Log

Technician Name: _____ License # _____

Date	Description	Error Discussed	
		Technician Initials	Pharmacist Initials

Dear Board Members,

In staff's efforts to provide transparency and clarity to the Board related to delegated authority and consistency for disciplinary actions, we have proposed to reorganize and split the existing Grid into 3 functional documents and reformat the content.

- Functional Documents:
  - 1. Staff Delegated Authority from the Board
  - 2. Certain Board Policies
  - 3. Guidelines for Staff and Compliance Board Packet location (key located below):
    - Administrative Discussion (AD): Case Presented by Compliance Director
      - independent vote
    - Case Review (CR): Case Presented by Investigator with Written Report
      - independent vote
    - Written Review (WR): Case Presented in like category with Written Report
      - independent vote
    - Consent Agenda (CA): Case Presented in single group (No Disciplinary Action) with Written Report
      - single vote

- Formatting: the documents have been reorganized and simplified for ease and transparency of review.

Staff greatly appreciates the Board's comments received and these topics have been highlighted in blue for Board discussion at the August Board Meeting.

Thank you again for all of your efforts and assistance in this process.

Best Regards,

Brianne Efremoff

Oregon Board of Pharmacy - Staff Delegated Authority

Revision date: 7/28/2016

Staff Delegated Authority

Subject	Description	# Comments
Intern Extensions	Authorize staff to extend pharmacy intern licenses one year to individuals that need additional time to complete their schooling and rotations.	
Technician extension requests	Authorize Executive and Administrative Directors and Licensing Department Supervisor to approve Pharmacy Technician extension requests as needed with the following parameter: • The licensee must have a clear Law Enforcement Data System (LEDS) background check; • No active disciplinary action; and • The extension is not to exceed one year from the original date of expiration	
Modified, negotiated, or default Orders	• Authorize Compliance Director and Executive Director to execute modified and negotiated consent orders as directed by the Board with pre-specified ranges. • Authorize Compliance Director and Executive Director to execute default orders approved by the Board. • Authorize Compliance Director and Executive Director to execute and accept Stipulated Orders of license surrender.	3
Probation Orders: modification of work restrictions	•Authorize Compliance Director and Executive Director together to issue letter granting time-sensitive modifications to probation work restrictions after 1 year from execution of Board Order. Will be presented at next Board meeting in Administrative Discussion. ~~• Authorize Compliance Director to issue letter granting time-sensitive temporary modications to probation work restrictions after 2 years from execution of Board Order to be presented at next Board meeting in Administrative Discussion.~~ ~~• Requests that do not fit the above parameters are to be presented for Board review.~~ ~~• Within the first two years of probation: No temporary modifications of work restrictions to be granted~~	
License for Consulting Pharmacies (Drugless Pharmacy, Remote Processing, Central Fill)	Authorize Compliance staff to review and approve outlet policies and procedures prior to granting a license	
Licensees on Board Screening Probation	Authorize Compliance staff to follow policy guidelines for non-compliance with probation sanctions	
Theft II or lower and greater than 5 years	Authorize staff to issue license and Email from Compliance Director	
One DUI/MIP (BAC < 0.20) or 2 over 10 years	Authorize staff to issue license and Email from Compliance Director	
Marijuana possession less than 1 oz prior to 7/1/2011	Authorize staff to issue license and Email from Compliance Director	4
Action taken by another state	Authorize Compliance staff to present cases based on original Board action by another state for revocations, suspensions, and probabtions.	

Oregon Board of Pharmacy - Board Policies

Revision date: 7/28/2016

Board Policies

Subject	Description	Approval Date
Foreign manufactures	Staff will not license foreign manufacturers but will license first possessor or manufacturer in the US or territory.	
Device wholesalers	Staff may waive surety bond or VAWD certification for device wholesalers with authorized state inspection.	
Release of information - federal subpoenas	Staff may disclose confidential investigative information to federal agencies in response to subpoenas or in a cooperative investigation.	
Release of information - health care boards/public	Staff may disclose confidential information to other relevant healthcare boards and other public entities consistent with ORS 676.177.	
Wholesalers - designated representative	Designated Representative of more than one facility within multiple states. Notification of need for corporation to appoint additional designated representative has been mailed by licensing. No response to Board's request. Staff may send second letter "certified return receipt" if response is not received within 15 days of original letter from licensing. Second letter to refer to failure to cooperate basis for disciplinary action.	
	Designated representative of more than one corporation within the same facility. Applicant must submit detailed description of managerial process and include the hours that he/she will be physically present at facility. Staff will review information on case-by-case basis.	
	Send to Compliance for Board Case Review	
Wholesaler Applications	Staff may review state wholesale inspection forms and include acceptable inspections on the state approved list.	
	Staff may make determination if the license requires a manufacturer or wholesaler license.	
	Staff may grant waivers if they determine that the license meets the state's small business requirements.	
	Staff may issue a license if the applicant has demonstrated registration with VAWD and submits confirmation of approval to the Board office when VAWD certified.	
	Send to Compliance for Board Case Review	

Oregon Board of Pharmacy - Guidelines for Presentation

Revision date: 7/28/2016

Guidelines for Presentation

Subject	Description	Notice of Proposed Disciplinary Action	Consent Order	Board Presentation	# Comments
CS annual inventory missing or not completed (or change in PIC) on time	Issue Non-Compliance Notification	$1,000 civil penalty per violation	$1,000 Civil Penalty stay $700 no further violations of PIC requirements for 3 years	Written Review	
Medication errors	Pharmacists, Interns and Technicians				3
	• 1st error	Issue Letter of Concern recommending that licensee complete an additional 3 hours of CE in medication error prevention		Case Review	
	• 2nd error or willfull harm/negligence	$1,000 civil penalty per violation	Reprimand and $1,000 civil penalty with $500 stayed and 3 hours of CE in medication error prevention	Case Review	
	• After a period of 3 years: Reset back to 1st error parameters				
Non-sufficient funds	Misrepresentation of proper payment of fees via non-sufficient funds	Revoke and $1,000 civil penalty	Reprimand and stay $0 - $1,000	Written Review	
PIC gap: resident pharmacy (* review at June 2017 Annual Business meeting)	• Gap for 1-5 days	Issue Letter of Concern		Consent Agenda	2
	• Gap starting with day 6	$1,000 civil penalty per violation	$1,000 civil penalty per week	Written Reivew	
	• Gap for 2 months or more			Case Review	
PIC gap: non-resident pharmacy (*review at June 2017 Annual Business meeting)	No PIC after 90 days			Case Review	2
PIC report missing or not completed on time	Issue Non-Compliance Notification	$1,000 civil penalty per violation	$1,000 stay $700 no further violations of PIC requirements for 3 years	Written Review	1
Preceptor	Registration not current: Issue Letter of Concern			Consent Agenda	
RPH renewals: CE Audits	CE not completed or completed outside of required timeframe				2
	• Non-responder	Revoke and $1,000 civil penalty per violation	Revoke	Case Review	
	• Discipline	$1,000 civil penalty per violation	$1,000 stay $0 - $1,000 and provide documentation of CE licensee was short	Case Review	
	OR				
	• In Lieu of Discipline Take and pass MPJE and complete and submit documentation of CE licensee was short within 120 days			Consent Agenda	
Technician renewals: CE Audits *review at June 2017 Annual Business meeting	CE not completed or completed outside of required timeframe				4
	• Non-responder	Revoke and $1,000 civil penalty	Revoke	Case Review	

This Footer only applies to the GUIDELINES doc only

KEY: Administrative Discussion (AD): Case Presented by Compliance Director, independent vote

Case Review (CR): Case Presented by Investigator with Written Report, independent vote Written Review (WR): Case Presented in like category with Written Report, independent vote

	• Non Discipline	Issue Letter of Concern	Consent Agenda	

~~Short counts~~	~~Complaints involving allegations of 'short counts' where pharmacist admits to violation~~	~~Issue Letter of Concern~~		~~Consent Agenda~~	1
~~Product ID Label (PIL)~~	~~If approximately 5% of a sampling of the labels is missing the PIL~~	~~$5,000 civil penatly~~			
Unregistered outlets	Unregistered wholesalers, manufacturers and out-of-state pharmacies	$10,000 civil penalty per violation	$10,000 civil penalty stay $0 - $10,000	Written Review	
Wholesalers - designated reps	If corrective action is not received from designated rep within 30 days	$10,000 civil penalty per violation	$10,000 civil penalty stay $0 - $10,000	Written Review	
Applications and renewals	**FELONY (THEFT, DRUGS (MARIJUANA), FRAUD, ACTIVE PROBATION)**				
	Convictions	Deny/Revoke	Deny/Revoke	Case Review	1
	Arrest or citation with no conviction (diversion; dismissed, case has not gone to trial yet)			Case Review	
	SEX OFFENDERS				
	Convicted Sex Offenders			Case Review	6
	THEFT				
	Theft II or lower - greater than 5 years	Refer to Staff Delegated Authority			
	Aggravated, Theft I			Case Review	
	CONTROLLED SUBSTANCE VIOLATIONS				
		Deny/Revoke	Deny/Revoke	Case Review	
	ALCOHOL/MARIJUANA (DUII/POSSESSION)				
	One DUI/MIP (BAC < 0.20) or 2 over 10 years	Refer to Staff Delegated Authority			2
	•One in the last 5 years (BAC >=0.20) •Two or more (less than 10 years) •BAC refused			Case Review	
	Marijuana possession less than 1 oz prior to 7/01/2011	Refer to Staff Delegated Authority			4
	Marijuana possesion less than 1 oz (between 7/01/2011-7/01/2015)	Deny	Grant license with no further violations for 3 years, 3 hours of CE (law or patient safety)	Written Review	
	Illegal marijuana possession (after 7/01/2015) or habitual/excessive use	Deny/Revoke	Deny/Revoke	Case Review	

	UNSWORN FALSIFICATION (RELATED TO FRAUD, THEFT, DRUGS, AND ALCOHOL CHARGES)				
	Felony conviction	Deny/Revoke and $1,000 civil penalty per violation	Deny/ Revoke	Case Review	
	Single LEDS incident	Deny/Revoke and $1,000 civil penalty per violation	$1,000 civil penalty stay $850 no further violations for 3 years, 3 hours of CE	Written Review	
	Multiple LEDS incidents	Deny/Revoke and $1,000 civil penalty per violation	Deny	Written Review	
Action taken by another state	~~Match~~ Original state order in which the violation is an OBOP violation			Case Review	4

Administrative Discussion (AD): Case Presented by Compliance Director, independent vote
Case Review (CR): Case Presented by Investigator with Written Report, independent vote
Written Review (WR): Case Presented in like category with Written Report, independent vote
Consent Agenda (CA): Case Presented in single group (No Disciplinary Action) with Written Report, single vote

Talyst / PayLess Drug discussion – OR Board of Pharmacy Questions

August 11, 2016 Presentation

1. What other states are using Talyst? **[slide 2]**
   - What laws/rules do other states have regulating/*restricting* the use of Talyst?
   - Talyst InSite Systems Implemented
     - California
     - Indiana
     - Pennsylvania
     - Florida
     - Maryland
     - Missouri
     - South Carolina
     - South Dakota
     - Ohio
     - Texas
   - Key rules in many states *permitting* use of In-Facility Automated Dispensing Units (Talyst' s InSite System) **[slide 11]**
     - Over two thirds of states have approved regulations for the use of In-Facility Automated Dispensing Units
     - New states BOP passed ADU regulations
       - Washington – May 26, 2016 – WA Commission approved draft language
         - WAC 246-874 - ADDDs
       - Kansas Board of Pharmacy – July 14, 2016 – KS BOP approved regulations
         - K.A.R. 68-9-3
     - Key rules:
       - Allow ADU placed in healthcare nursing facilities to package, label and dispense routine, PRN and emergency kit medications
       - Pharmacy to fill bulk non-patient specific medications in containers to be placed in ADU for dispensing to patient specific per prescriber order
       - Pharmacist in-charge to ensure there are compliance to written policy and procedures for use of ADU
       - Authorized license healthcare professionals from pharmacy and nursing facility to access medications from ADU
       - Bar code or electronic verification process utilized to ensure correct selection of medications placed into ADU

2. What types of error(s) occur and what is the error rate or each? QA on errors? **[slide 14]**
   - Main Type of Error: Packaging Error
     - Incorrect drug, Incorrect QTY
     - Results: favorable with greater than Six-Sigma accuracy (8,800 times more accurate/precise than human handling

3. What location(s) would have a Talyst? **[slide 12]**
   - Talyst InSite System target locations
     i. Skilled Nursing Facilities
     ii. Assisted Living Facilities (if appropriately staffed & regulated)
     iii. Correctional Facilities
     iv. Other: Healthcare Facilities with high acuity patient mix, short length of stay and in remote locations

   - Is use limited to a SNF with a RN/does RN administer medication? **[slide 12]**

- Most states allow this technology in Assisted Living
    i. Primarily implemented in Skilled Nursing Facilities
- Medication administration will be performed by the same licensed facility staff performing the job function today with outdated traditional punch cards (blister packs)/vials model

4. Who will access drug in machine (RN, LPN, MA, other)? **[slide 19]**
    - Access to the drug in the locked and secured InSite System
    - Approved licensed nursing facility staff and pharmacy staff will place bar coded canisters into the system
    - Request and dispensing of patient specific medication packets for administration can only be done after authorized users are granted access by secure password
    - All system transactions are logged with user information for the pharmacy and facility to track/monitor activities

5. Are meds prepared 1 pass at a time or all meds for the day prepared at one time or...? **[slide 19]**
    - InSite System is configurable to dispense medications prior to each med-pass or once a day
        i. More efficient and standard of practice is for the facility nursing staff to dispense a day's medication supply then stage and stock into secure medication carts to administer to patients during each med pass

6. How are controlled substances discrepancies identified and reconciled? Proof of use? **[slide 13]**
    - InSite has fully-enforced workflows with complete audit trail
        - who acted, what time, what actions and impact on inventory
    - All medications dispensed from the InSite System are logged/tracked to include specific pharmacy and facility nursing staff information.
    - InSite System Reports available to show dispensing of all medications including controlled substance medications.
        i. routines, PRN, re-dispense and emergency kit dispense.
    - eMAR integration
        i. final disposition of the item (consumed, refused/spit, dropped/lost, return bin, etc.)
    - Trending dispense reports are available will show trends by medication and by nurse to help reduce/prevent potential of diversion.

7. Who will load the machine (RN, LPN, MA, other)? **[slide 20]**
    - Authorized licensed healthcare professionals from pharmacy and facility staff
        i. Same licensed nursing staff with current access to the medications at the facility
    - What happens to medication if patient refuses a dose or order is cancelled before administration?
    - Packet with refused/cancelled medication dose will be returned to a secured, locked container and retrieved by approved pharmacy staff defined by policy and procedure
    - Controlled substances will be secured and destroyed according to state regulations and facility policy

8. Re-Dispense (page 8)? Emergency Dispense? **[slide 20]**
    - Each option for specific type of dispense are subject to workflow rules
    - Re-dispense Option: allows for a nurse to acquire another dose in the case of a patient spitting a dose.
    - Emergency dispense Option: allow the nurse to gain access to a medication if the pharmacy is not available or for after hours. Similar to a manual emergency kit but with greater security and monitoring safeguards.

9. Who can override system? **[slide 16]**
    - Authorized Talyst support and pharmacy team member.
        i. System override are logged/tracked

10. How does Talyst software integrate with pharmacy software (real time, separate stand-alone systems)? **[slide 16]**
    - Talyst and pharmacy software are integrated through a secured real time HL7 interface
    - All authority comes from pharmacy information system (PMS/PhIS)

11. Who defines an emergency? (Is this following OAR 855-007?) **[slide 16]**
    - Emergency define the same as today

12. How does pharmacy bill insurance for dispensing/loading machine? **[slide 10]**
    - Billing occurs either same as now (per patient RX) with reconciliation to actual consumption, or post consumption, after counts are known
    - Pharmacy only bills for medication doses dispensed by the ADU
    - 3rd party payers are in support of this type of Short Cycle dispensing

13. Procedures vague in certain references -refer to designee, authorized user, unauthorized personnel, licensed nurse, healthcare professional **[slide 19]**
    - Authorized users are licensed healthcare professionals from the pharmacy and facility nursing staff
    - Written procedures are made specific to each facility at time of implementation

14. Does the DEA require the machine to be registered? **[slide 13]**
    - DEA registration is required for pharmacy to stock ADUs with controlled substances
        i. Best practice for pharmacy to obtain DEA license for each location.
    - DEA endorses In-facility Automated Dispensing Systems
        i. increased security
        ii. reduce diversion risks
        iii. reduce amount of controlled substances in circulation at the facility

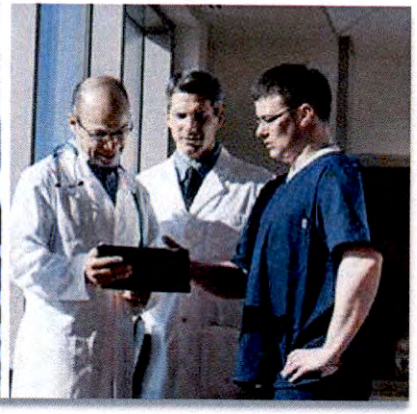
15. How many drugs will machine hold? **[slide 15]**
    - Up to 240 canisters in the InSite system

16. Training kit, super user **[slide 21]**
    - TCIP (Talyst Certified InSite Pharmacy) University
    - User guides, Policy and Procedures and Job Aids
    - Video Training
    - Pharmacy Training
        i. Train pharmacy team 4 weeks prior to 'go-live' implementation
        ii. Detailed training on system features/functions, process and reports
        iii. Train users, super-users and trainers or pharmacy implementation team
    - Facility Training
        i. Train facility staff 2-4 weeks prior to each facility implementation 'go-live'
        ii. 3 days facility onsite 'go-live' training during implementation week
        iii. Detailed training on system, process, reports and trouble shooting

PayLess Drug - Talyst
Requesting Board Approval of
Automated Dispensing System in Nursing Facilities

Oregon Board of Pharmacy
August 11, 2016

TALYST: Engineering the Safer Pharmacy



Founded:	2002
Employees:	100+
Support Partners:	86+
Customers:	600+

Locations Implemented Talyst InSite:

California	Missouri
Indiana	South Carolina
Florida	South Dakota
Pennsylvania	Ohio
Maryland	Texas

Long-Term Care Nursing Facility Challenges

- Patients are discharged from hospitals 24/7 and LTC Facilities demand for medications within short amount of time to continue patient care
- New admits to LTC Facilities are medically fragile therefore require immediate access to medications
- Pharmacies are trying to meet immediate patient care needs in facilities with rising acuity by providing STAT deliveries. However, resources will be stretched as acuity continues to rise.
- Facilities nursing staff are challenged with availability of time to provide good level of care during med pass
- Pharmacy-Facility continue to strive to find better alternative solution to provide in-facility access to medications, reduce medication waste and cost

The Current System

- Takes 2-4 hours or longer delivery times for new orders
- Slow and inefficient nurse medication prep and pass
- Time consuming facility required narcotic counts at every shift change
- Unused medications create waste, inefficiency and potential for diversion

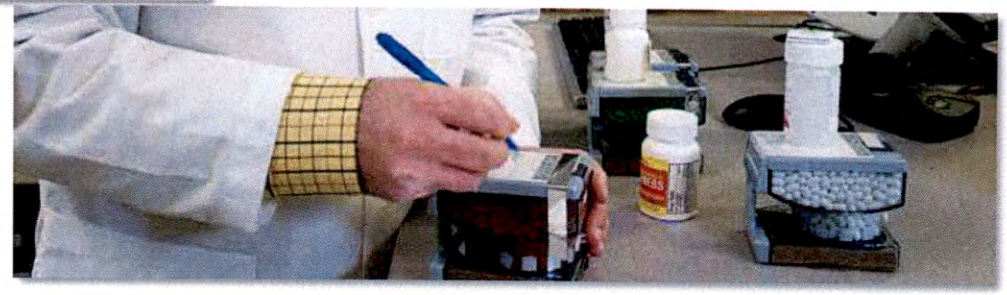
TALYST

In-Facility Dispensing System Advantages

- Increases accuracy of medication dispensing compared to manual punch cards process
- In-Facility Dispensing provides immediate access to medications
  - Access of most frequently prescribed oral solids medications
  - Reduce wait time for medication orders to improve patient care
- Pharmacists, Nurses and Prescribers collaborate to medication formulary to best service patients in each facility
- Significantly reduces medication waste with single daily dose or just-in-time dispensing
- Reduce nursing time in managing patient medications
  - Time savings in ordering, receiving, administer and return or dispose of medications
  - Time savings with controlled substance counts
- Reduces drug diversion

TALYST

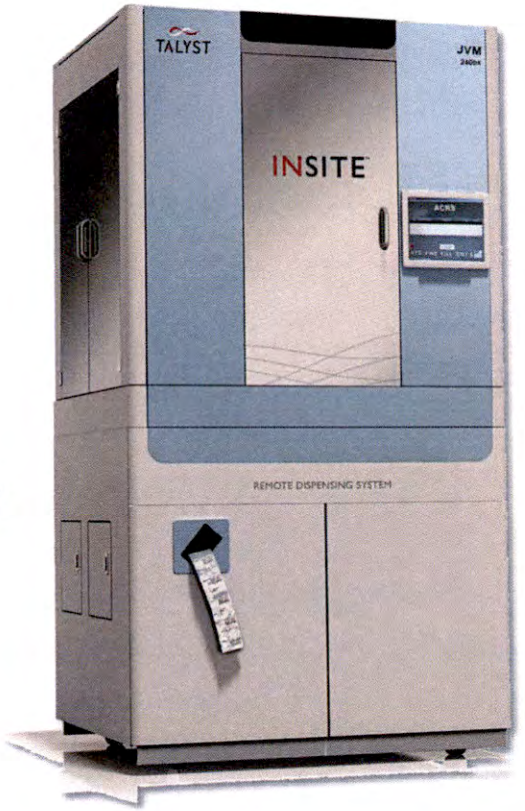
Benefits at the Facility and Pharmacy



- 10-30% savings on Part A pharmacy bill
- 24x7 access up to 240 oral solid medications
- 30% reduction in med prep/pass time
- 75% reduction in destruction and return process
- 90% reduction in time spent for controlled substance counts
- 50% reduction in delivery costs

InSite System In-Facility Packaging and Dispensing

- One or more ***automated dispensing systems are located in a secured location*** *at the LTC facility*
- The remote dispensing systems are considered an ***extension of the pharmacy***
- Nurses have ***access to pharmacist-approved medications 24x7***
- Patient-specific medications are dispensed ***on-demand and only when needed***.
- The system and inventory is ***controlled by pharmacy***



TALYST

In-Facility Packaging and Dispensing Process

Practitioner Writes Order

RX

Nurse Submits Order to Pharmacy

Pharmacist Approves

Inventory is Monitored and Replenished

Pharmacist Performs Final Check of Canister

Medications are Dispensed and Available to Package

Medications are Packaged On-Demand

Medication Dispensing

- Orders are submitted to the pharmacy via phone, fax, or electronically
- Pharmacist reviews and approves the order
- Licensed nursing staff retrieves medications daily, by shift, by med pass, or on-demand
- Medications are packaged in patient-specific, time-specific multi-dose medication packets
- Dispensing Options
  - Re-dispense Option: allows for a nurse to acquire another dose in the case of a patient spitting a dose.
  - Emergency dispense Option: allow the nurse to gain access to a medication if the pharmacy is not available or for after hours.
    - Similar to a manual emergency kit but with greater security and monitoring safeguards.
    - Emergency is define the same as today (OAR 855-007)
- Authorized Users
  - Authorized users are licensed healthcare professionals from the pharmacy and facility nursing staff
  - Written procedures are made specific to each facility at time of implementation

Pharmacy Billing and Short Cycle Dispensing

- Pharmacy bills insurance for dispensing from InSite
  - Billing occurs either same as now (per patient RX) with reconciliation to actual consumption, or post consumption, after counts are known
  - Pharmacy only bills for medication doses dispensed by the ADU
  - 3rd party payers are in support of this type of Short Cycle dispensing
- Short Cycle Dispensing

	MANUAL 7-DAY	IN-FACILITY DISPENSING
PHARMACY		
Meets 7-Day or less dispensing requirements	●	●
Reduces medication fill time		●
Reduces pharmacist check time		●
Reduces delivery costs		●
Preferred by long-term care facilities		●
Recognized by CMS as "most effective" at reducing waste		●
LONG-TERM CARE FACILITIES		
Increased availability of medications		●
Reduces time spent administering medication		●
Reduces narcotic count time		●
Increases nurse satisfaction		●

Key Rules - InSite

- Over two thirds of states have approved regulations for the use of In-Facility Automated Dispensing Units
- New states BOP passed ADU regulations
  - Washington – May 26, 2016 – WA Commission approved draft language
    - WAC 246-874 - ADDDs
  - Kansas Board of Pharmacy – July 14, 2016 – KS BOP approved regulations
    - K.A.R. 68-9-3
- Key rules:
  - Allow ADU placed in healthcare nursing facilities to package, label and dispense routine, PRN and emergency kit medications
  - Pharmacy to fill bulk non-patient specific medications in containers to be placed in ADU for dispensing to patient specific per prescriber order
  - Pharmacist in-charge to ensure there are compliance to written policy and procedures for use of ADU
  - Authorized license healthcare professionals from pharmacy and nursing facility to access medications from ADU
  - Bar code or electronic verification process utilized to ensure correct selection of medications placed into ADU

Locations

- Talyst InSite System target locations
  - Skilled Nursing Facilities
  - Assisted Living Facilities (if appropriately staffed & regulated)
  - Correctional Facilities
  - Other: Healthcare Facilities with high acuity patient mix, short length of stay and in remote locations
- Medication administration in ALF and SNF
  - Most states allow this technology in assisted living facilities
    - primarily implemented in skilled nursing facilities
  - Medication administration in skilled nursing facility will be performed by the same licensed facility staff performing the job function today with outdated traditional punch cards (blister packs)/vials model.

Controlled Substance

- InSite has fully-enforced workflows with complete audit trail (discrepancy/reconciliation)
  - Who acted, what time, what actions and impact on inventory
  - All medications dispensed from the InSite System are logged/tracked to include specific pharmacy and facility nursing staff information.
  - InSite System Reports available to show dispensing of all medications including controlled substance medications.
    - routines, PRN, re-dispense and emergency kit dispense.
  - eMAR integration
    - final disposition of the item (consumed, refused/spit, dropped/lost, return bin, etc.)
  - Trending dispense reports are available will show trends by medication and by nurse to help reduce/prevent diversion.

DEA registration

- DEA registration
  - DEA registration is required for pharmacy to stock ADUs with controlled substances
    - Best practice for pharmacy to obtain DEA license for each location.
  - DEA endorses In-facility Automated Dispensing Systems
    - increased security
    - reduce diversion risks
    - reduce amount of controlled substances in circulation at the facility

Accuracy and Security

- Main Type of Error: Packaging Error
  - Incorrect drug, Incorrect QTY
  - Results: favorable with greater than Six-Sigma accuracy (8,800 times more accurate/precise than human handling
- Canisters are validated for accuracy before leaving pharmacy
- Unique Chip ID to track medication information
- InSite System is lockable and installed in a secure med room with video monitoring capability
- Controlled substance medications are locked in a separate compartment
- Medication expiration dates and lot number are tracked

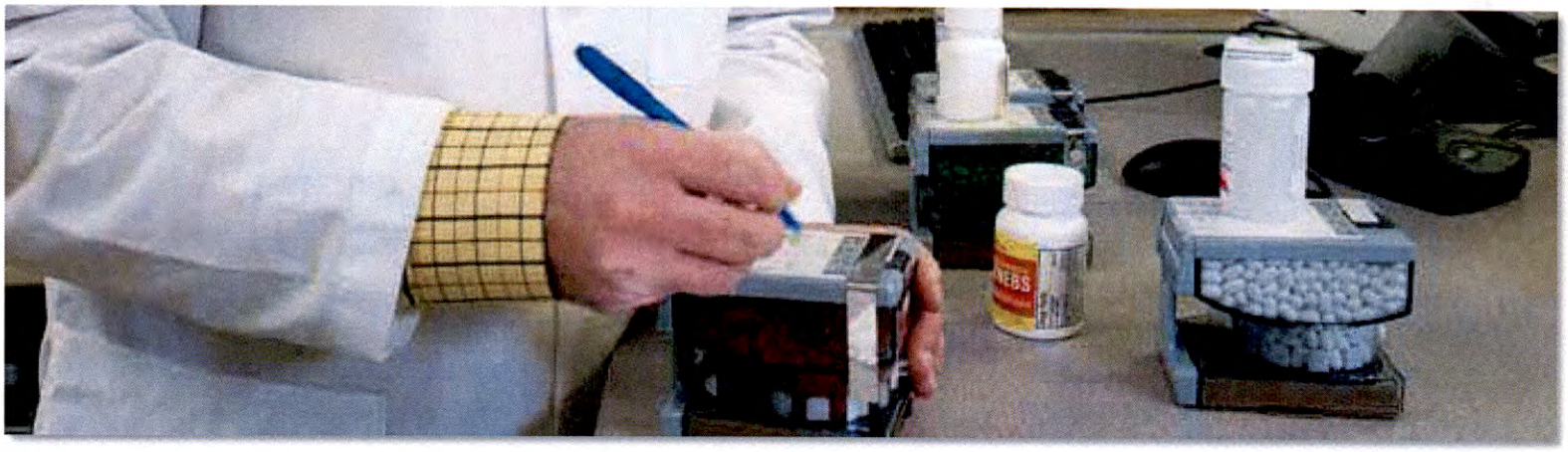
Hardware and Software

- Simple gravity based design
  - Medications are stored in the unit inside individual sealed canisters
- 240 active medication canisters available
  - Electronic Programmable Read-Only Memory Chip (EPROM)
    - Unique canister chip to track: medication, quantity, expiration date, lot number, fill date, technician and pharmacist
- Canister
  - Safe with tamper evident seal
  - Canister specifications
    - Unique canister build for each medication NDC to prevent loading and dispensing of incorrect medications
    - Bar-code scan technology to ensure accuracy of filling, verification and stocking
- Canister label and bar code
  - Medication Name, Strength and NDC
  - Color, size, shape and medication unique marking
  - Lot #, Expiration date, Quantity and Technician/Pharmacist information

Hardware and Software

- Nursing staff User Interface at Kiosk
  - Touch screen technology
  - Dispense options: New Order, Routine and PRN orders, Leave of Absence, Re-Dispense, Emergency Kit Dispense
- Bi-directional interface between pharmacy system and automated dispensing system
  - Talyst and pharmacy software are integrated through a secured real time HL7 interface
  - All authority comes from the pharmacy information system (PMS/PhIS)
- Emergency Disaster Recovery
  - Ability to dispense longer day supply and option to divert orders
- System Override
  - Authorized Talyst Support and pharmacy team member
    - All system override are logged/tracked

Canister Filling and Logistics



- Pharmacy monitors inventory levels and utilization to determine when to replenish medications
- Canisters are tested each time they are filled
- Label is printed and data is written to the microchip
- Pharmacist checks for correct meds, signs label, and seals canister
- Canisters delivered to facility 1-2 times per week
- System provides complete canister tracking

[Canister Calibration]

[Barcode Label Printer]

[ICRS Chip]

Canister Tracking

Event	Status	Description
Scan canister to ship	In Transit	The canister is in transit to the facility or is already at the facility but has not yet been scanned. The status of the canister will remain In Transit until the facility scans the canister to receive it.
Scan canister at facility	On Shelf	The facility has received the canister. The status of the canister will remain as On Shelf until facility loads the canister in the unit.
Load canister in the unit	Packager - Location #	The received canister has been placed in the unit. The canister location number appears in the Inventory Report (for example: "Packager-64")
Unload canister from the unit	On Shelf	The canister has been removed from the unit. The status of the canister will remain as On Shelf until it is loaded back in the unit or scanned to return it to the pharmacy.
Scan canister to return	Returned	The canister is in transit back to the pharmacy or is already at the pharmacy but not yet received. The status of the canister will remain as Returned until the pharmacy scans the canister to receive it.
Scan canister at pharmacy	Empty	The canister has been returned to the pharmacy.

** The Inventory Report shows the status of all canisters for one or more facilities*

Nursing Facility Process

- Authorized User
  - Authorized users are licensed healthcare professionals from pharmacy and facility nursing staff
  - Written procedures are made specific to each facility at time of implementation
- Facility nursing staff access to InSite (RN, LPN, other licensed healthcare professional)
  - Access to medication in a locked and secured system
  - Approved licensed nursing facility staff and pharmacy staff will place bar coded medication canisters into the system
  - Request and dispensing of patient specific medication packets for administration can only be done after authorized users are granted access by secure password
  - All system transactions are logged with user information for the pharmacy and facility to track/monitor activities
- InSite Med-Pass Dispense
  - System is configurable to dispense medications prior to each med-pass or once a day
    - Efficient and standard of practice is for the facility nursing staff to dispense a day's medication supply then stage and stock into secure medication carts to administer to patients during each med pass

Nursing Facility Process

- Loading the InSite (RN, LPN, MA, other)
  - Authorized licensed healthcare professionals from pharmacy and facility staff
    - Same staff with current access to the medications at the facility
- Refused dose or order is cancelled process prior to administration
  - Packet with refused/cancelled medication dose will be returned to a secured, locked container and retrieved by approved pharmacy staff defined by policy and procedure
  - Controlled substances will be secured and destroyed according to state regulations and facility policy

Training

- TCIP (Talyst Certified InSite Pharmacy) University
- Policy and Procedures, InSite User Guides, and Job Aids
- Video Training
- Pharmacy Training
  - Train pharmacy team 4 weeks prior to implementation 'go-live'
  - Detail training on system features/functions, process and reports
  - Train super-users, trainers and end users
- Facility Training
  - Train facility staff for 3 days during each facility implementation 'go-live'
  - Detail training on system, process, reports and trouble-shooting
- Train super-users, trainers and end users

System Reports

- Customize Report Tools
- Dispense Reports
  - Controlled substance and non-controlled substance reports
  - Leave of absence report
  - PRN dispense reports
  - Transaction log
- Medication Inventory Report
  - Expiring canister report
- Diversion Risk Report
  - Dash-Board

TALYST®

Thank You!

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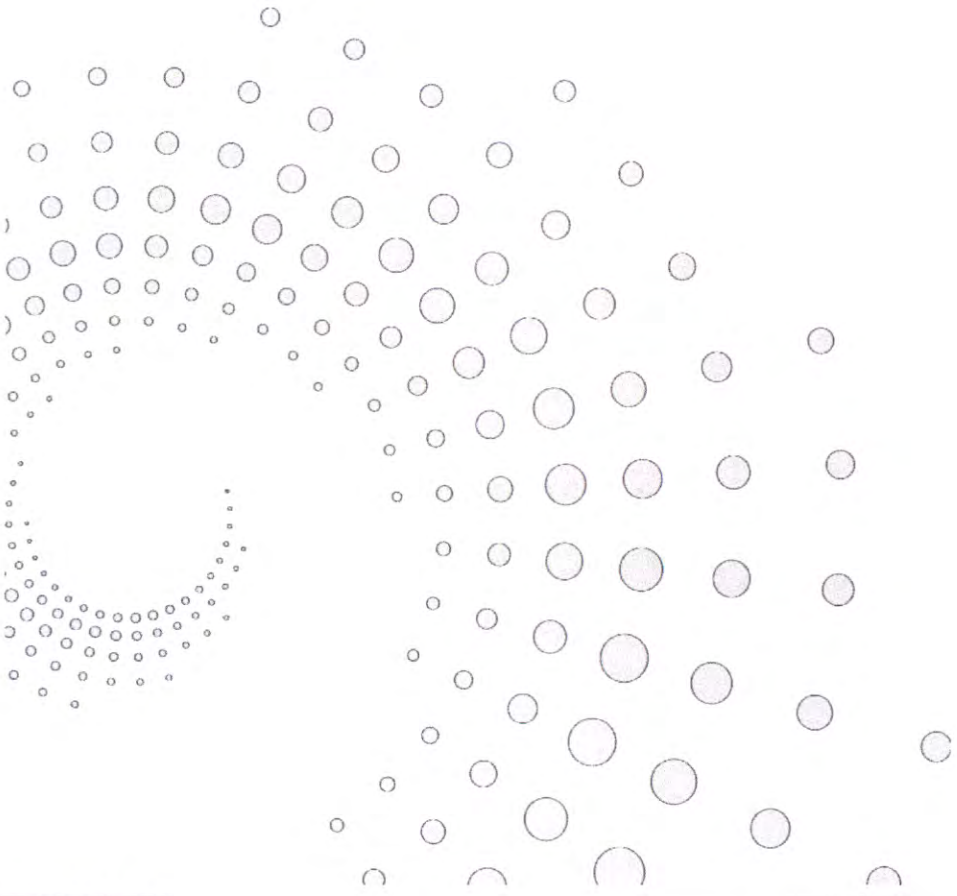
INSITE

Quick Reference Guide

InSite Remote Dispensing System

Long Term Care



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To contact Talyst Technical Support

Call:

Talyst Tech Support
1 (800) 541-4102

or email to: support@talyst.com

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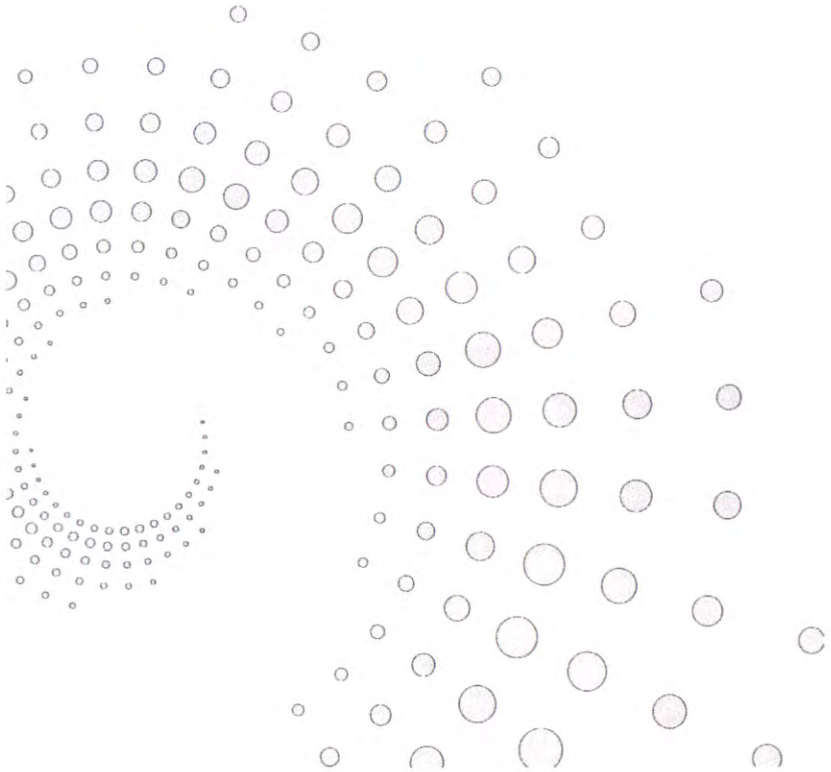
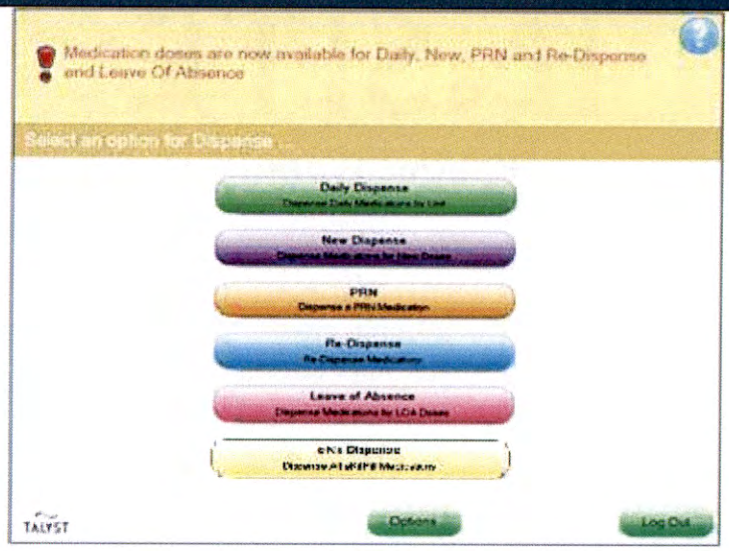
INSITE

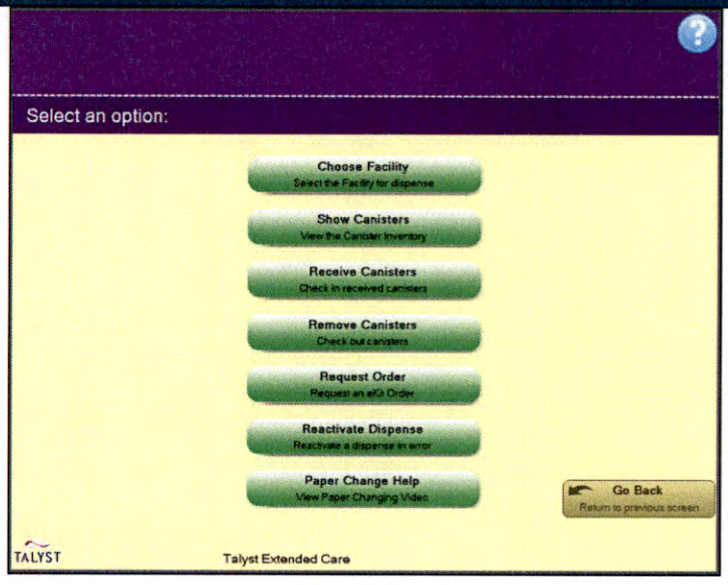
Routine Workflows



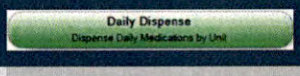
Main Menu (with eKit Dispense)



Options Menu

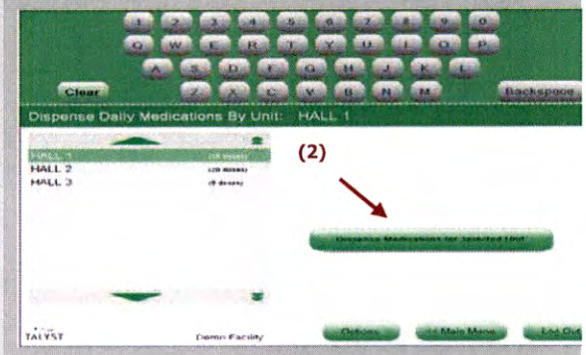


Daily Dispense



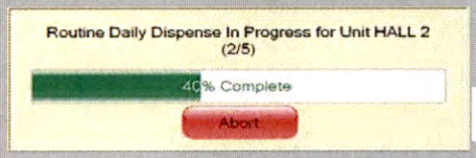
(1)

1. From **Main Menu** touch **Daily Dispense**.



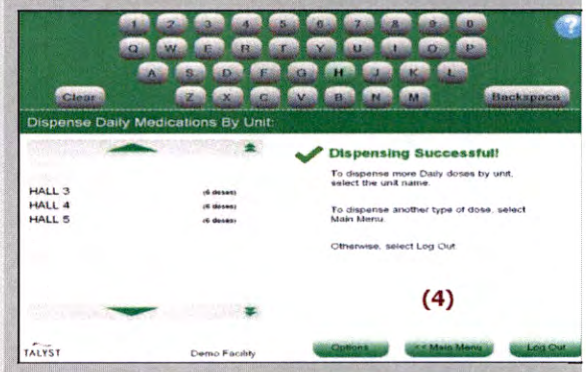
2. Select the Hall/Unit and touch **Dispense Medications for selected Unit**.

3. A status bar displays. The packets



(3)

4. "*Dispensing Successful!*" screen displays.

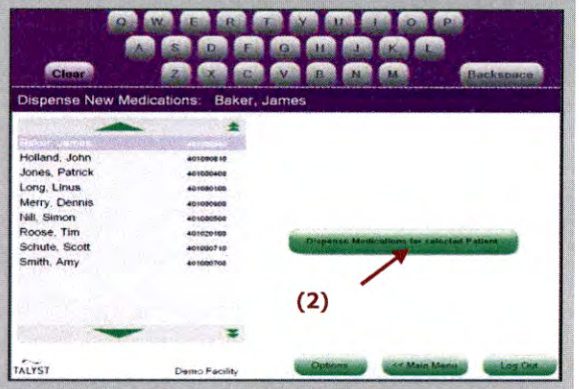


5. Prepare the packets for administration: 2 options
   - Separate the packets by tearing along the perforation, then place them in medication totes,
   - Roll the packets up and place them in totes or on the med

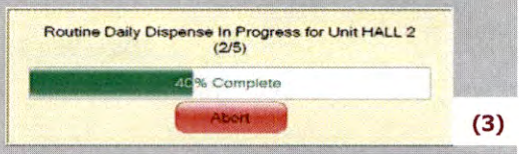
New Dispense

(1)

1. From **Main Menu** touch **New Dispense**.



2. Select the resident's name. Touch **Dispense Medication for selected Patient**.



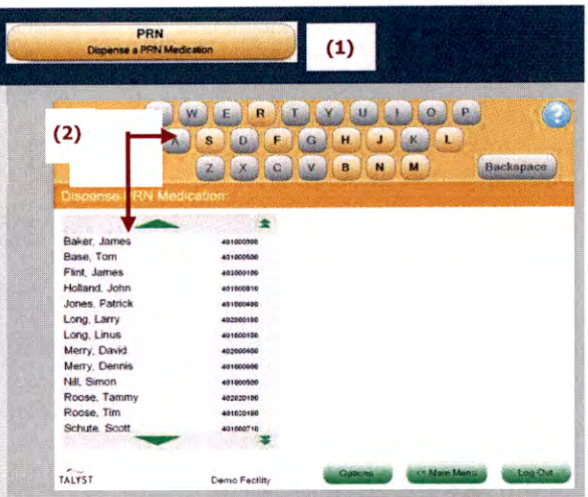
(3)

3. Status bar displays. Packets dispense.

4. *Dispensing Successful!* displays.

5. Prepare the packets for administration.

PRN



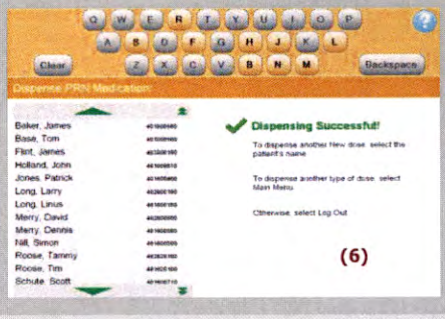
1. From **Main Menu** touch **PRN**.

2. List of residents display. Select the patient name.

3. List of PRN meds appears. Touch the med to be dispensed.

4. Touch **Dispense Medications Selected Above**.

5. Status bar displays.



6. Packets dispense. *Dispensing Successful!* displays.

7. Prepare the packets for administration.

Leave of Absence: Step 1

1. Double-click the **LOA Request** icon on your computer desktop (not within InSite Main Menu). A Logon window appears.

2. Enter your username and password. Click **OK**. The LOA Request window opens.

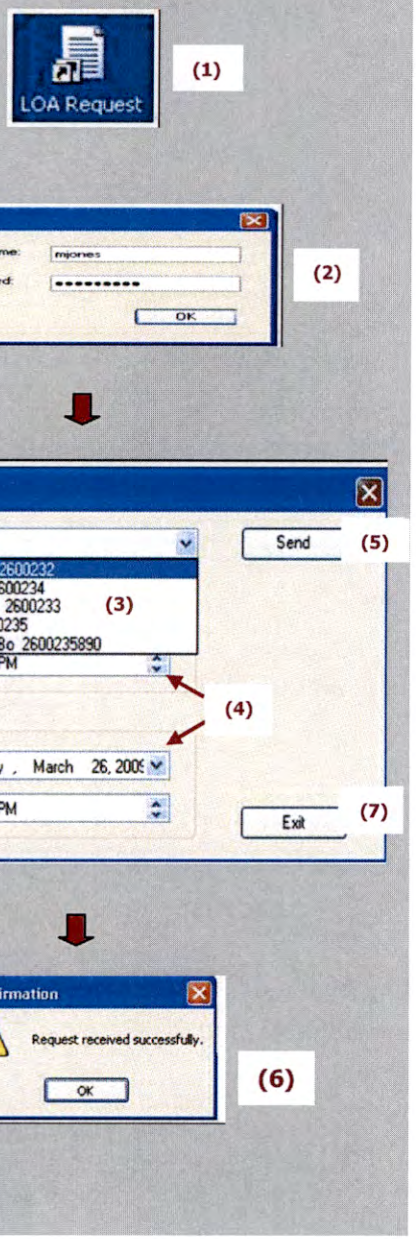
3. Click the **Patient** dropdown arrow, click the patient name.

4. Select the LOA's start and return date & time

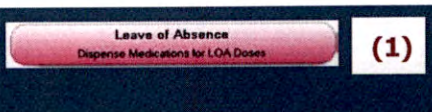
5. Click **Send**.

6. The confirmation window displays. Click **OK**.

7. Click **Exit**.



Leave of Absence: Step 2

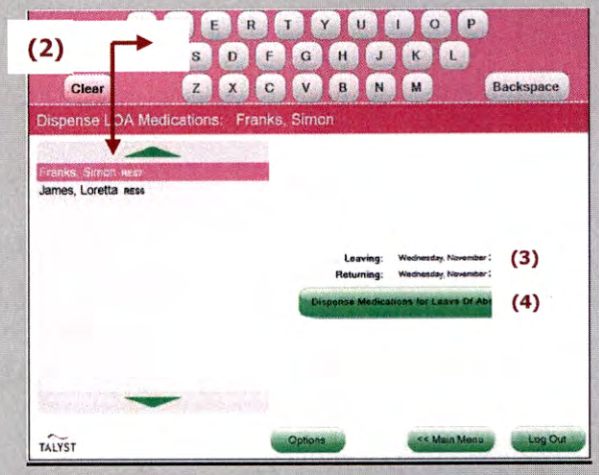


1. From **Main Menu** touch **Leave of Absence**.

2. Touch the letter of the patient's last name. A list with names appears.

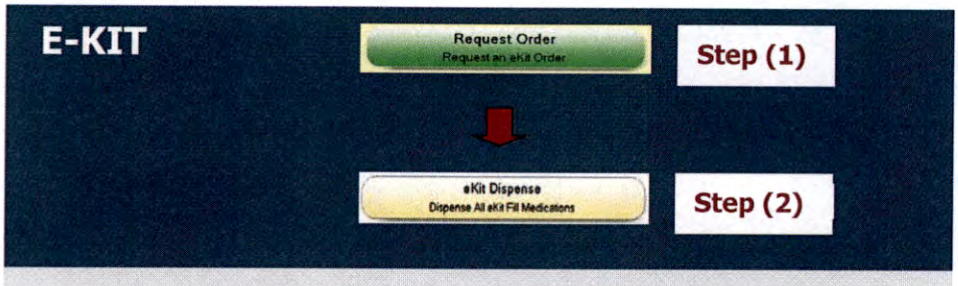
3. Select the patient name. The leave of absence dates display.

4. Touch **Dispense Medications for Leave of**



5. Packets dispense. *Dispensing Successful!* displays.

6. Prepare the packets for administration.



Only the authorized user can process an **e-Kit** request. The process requires a witness to logon during the request. The request and dispense process comprises of 2 steps:

Step 1: Requesting an e-Kit Order

1. From the **Options Menu**, touch **Request Order**.
2. Enter the patient first and last name, the patient identifier, date of birth and the requested medication. Enter the quantity.
3. Touch **Submit**.
4. A **Witness Required** information window pops up for a few seconds and is replaced by the **Login** screen.
5. Have the witness select his/her name and enter his/her password.
6. After a successful witness login a pop up screen indicates that the order was sent.

Once the order was sent successfully the **e-Kit Dispense** button in the **Main Menu** becomes enabled. You can now go ahead and dispense the e-Kit order you just placed.

Step 2: Dispensing an e-Kit Order

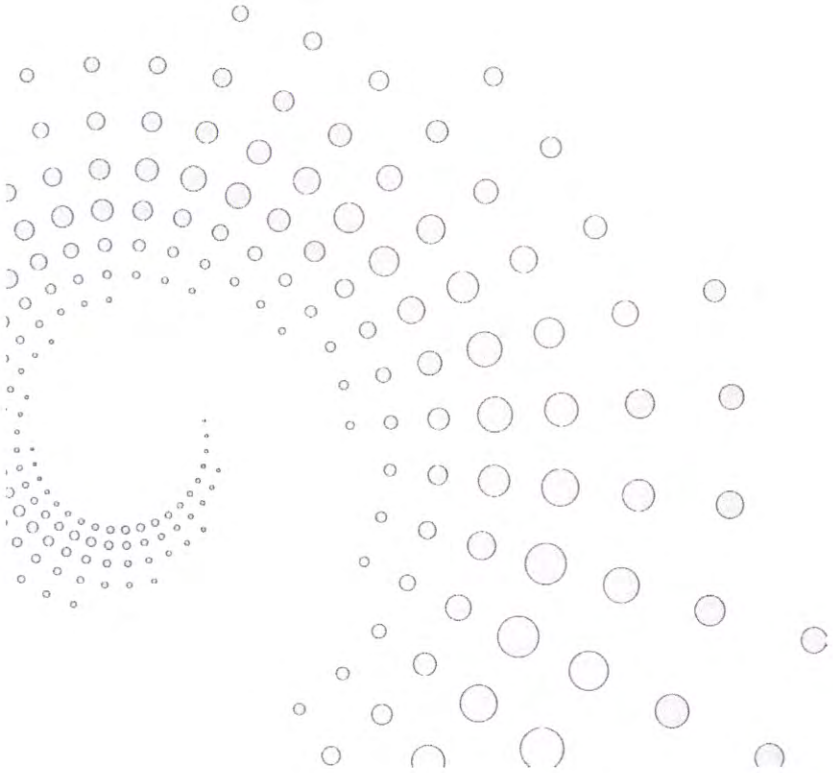
1. In the **Main Menu** touch **e-Kit Dispense**.
2. Touch **Dispense All**. The status bar appears.

"*Dispense Successful!*" displays and the packets exit the unit.

INSITE

Troubleshooting Dispense Errors

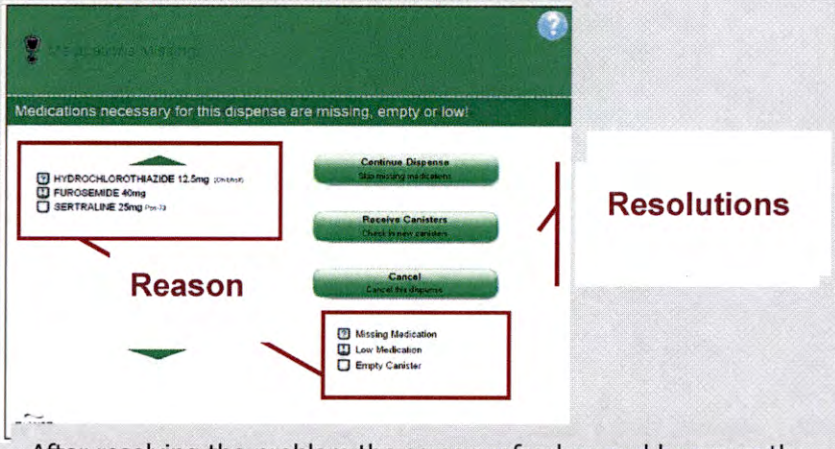
before and after dispense



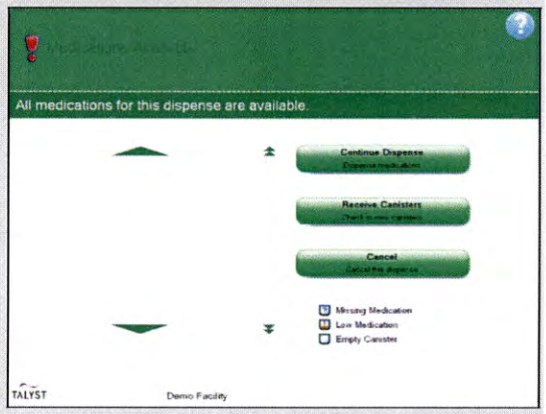
Dispense Errors before Dispense

Before dispensing an order, the system checks if the required amount of meds is in the canisters.
If the inventory in the unit is insufficient the **Missing Medication** screen appears stating the reasons and options to resolve the issue **before** the dispense starts (see Table 1).

Medications Missing/Medications Available screens



After resolving the problem the screen refreshes and becomes the **Medication Available** screen.



Status	Description
Missing	Medication is not in the inventory
Missing (on Shelf)	Medication is not in the dispensing unit, but in inventory – stored and waiting on the shelf
Low Medication	Canister will likely run out of medication during dispense
Empty	Canister in the dispensing unit is out of medication

Table 1: Insufficient Canister Inventory Reasons

To resolve the issue see next page.

Otherwise

Call:

Talyst Tech Support
1 (800) 541-4102

or email to: support@talyst.com

Dispense Errors before Dispense

- cont. -

Resolving Dispense Errors before Dispense

1. After you touched **Dispense All** to start the dispensing process, the **Medications Missing** screen displays.
2. Next to each unavailable drug an icon displays, indicating the reason.
3. You have 3 **Options (I – III)** to resolve the issues:

Option I: First resolve the problem, then continue the dispense (Talyst recommended)

1. Resolve the problem:

   Missing (on Shelf), Low Medication, Empty: Touch **Receive Canisters** and follow the replace empty canisters workflow (see pg. 20) to load new canisters in the unit.

   Jammed (Empty): To unjam a jammed canisters take the canister out of the unit and follow the steps in the User's Guide Appendix, pg. 10 to resolve the issue.

   Missing: Call the pharmacy and order the missing inventory.

2. Once you resolved the problem and close the unit door, the system checks the inventory status: the screen refreshes with updated information.

3. Touch **Continue Dispense**. All orders will dispense except for the Missing meds.

Talyst Tech Support
1 (800) 541-4102

Option II: First continue the dispense, then resolve the problem (mainly to use for Missing **medication)**

1. Touch **Continue Dispense.**

   Missing/ Missing (on Shelf), Empty: the unavailable meds will be skipped from the order and wait for dispense in the order screen until it's window of dispense expires.

   Low Medication: the medications in the canister will be dispensed unit the canister is depleted.
   You may have a missing medication information pack printed for packs that have meds missing.
   Once the packager knows that the canister is empty, it will stop trying to dispense from that canister. Orders for that med will still be available for first time dispense in the applicable order screen.

2. Resolve the problem:

   Missing (on Shelf), Low Medication, Empty: Go to **Options Menu**, touch **Receive Canisters**. Follow the **Replace Empty Canisters** workflow (see pg. 20) to load new canisters in the unit.

   Jammed (Empty): Take the canister out of the unit and follow the steps in the User's Guide Appendix,pg. 10 to resolve the issue.

   Missing: Call the pharmacy and order the missing inventory.

3. Go back to the applicable order button in the **Main Menu** to dispense the medications.

Option III: Cancel the dispense

1. Touch **Cancel**.
   The order will wait for dispense in the order screen until its window of dispense expires.

Dispense Errors during Dispense

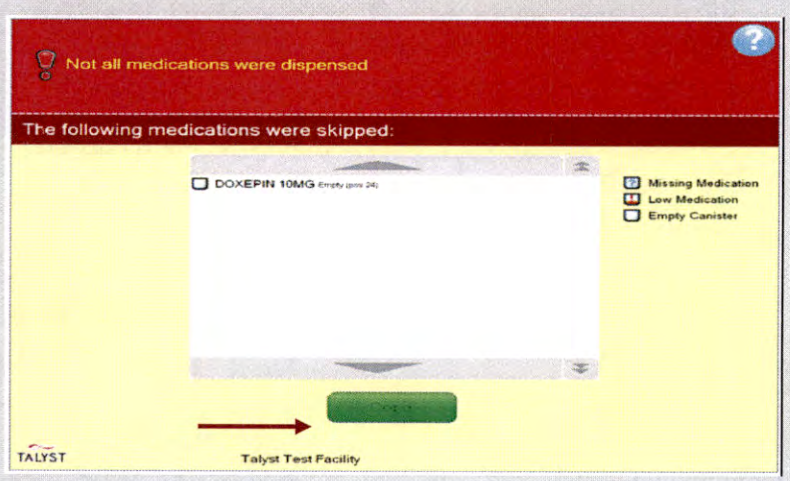
Missing Medication

If a canister runs out of meds or jams during a running dispense, a packet might not get filled. It will be empty and display incorrect information. A message displays and a "**Missed Medication**" information-packet prints.

1. A pop up screen asks you if you want to keep dispensing or load a new canister.

> **Note:** Talyst strongly suggests refraining from adding or removing any canister during the dispensing process, but to be performed before or after the dispensing orders.
>
> **⚠POTENTIAL INACCURATELY DISPENSED DRUGS!**
>
> If you need to change canisters during dispense, Talyst recommends close monitoring of the results of dispense and further suggests to be prepared to perform the appropriate Re-Dispense procedure for that order just dispensed.

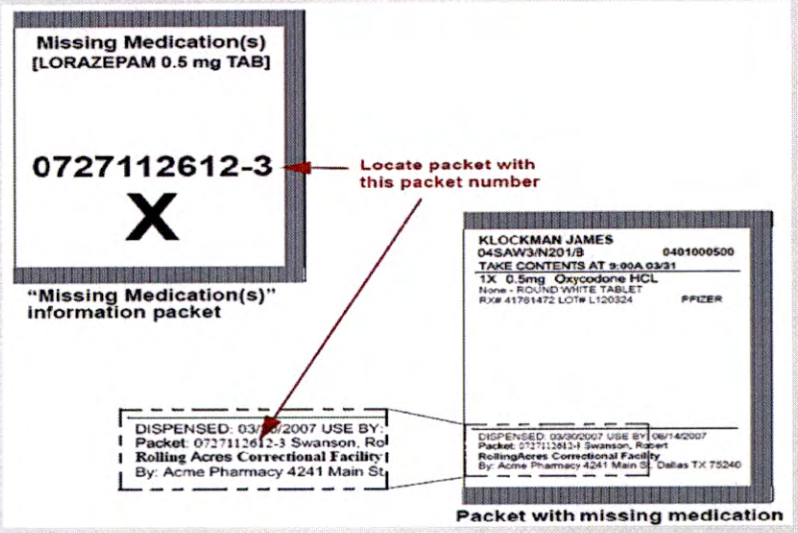
2. Proceed dispensing. The **Missing/Skipped Medication** screen displays at the end of dispense, showing all missing meds within the order. (Resolving Missing Meds, see next page)



Dispense Errors during Dispense

Resolving Missing Medication

Talyst Tech Support
1 (800) 541-4102

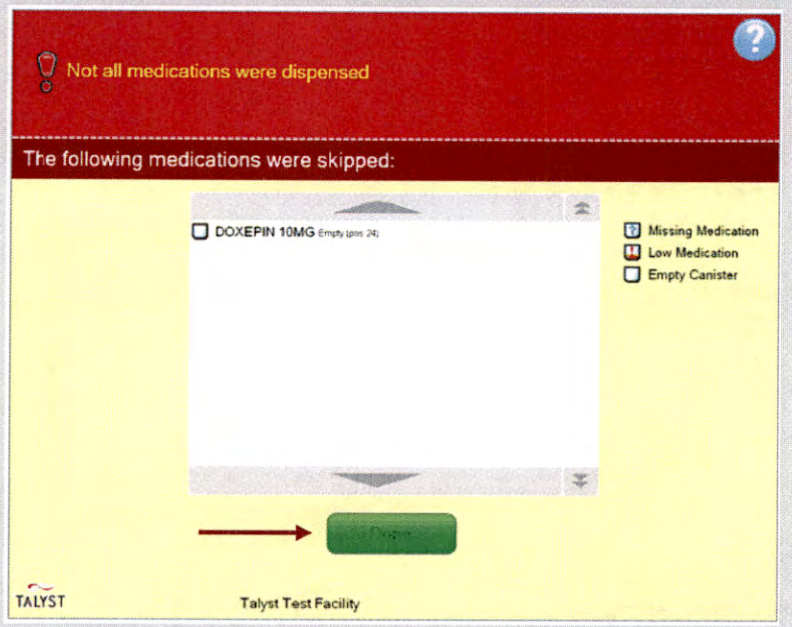


1. Each packet has a packet number. The Missing Medication(s) packet will show the number of the original packet that has meds missing.
2. Locate and identify the incorrect original packet.
3. Locate the empty canister listed in the screen.
4. Remove and replace the canister with a full canister. [see **Replace Empty Canister**, pg. 20]
5. After the canister is been loaded, touch **Done** on the **Missing/Skipped Medication** screen.
6. Go to **Main Menu** and dispense the order once again using the appropriate workflow button.

Dispense Errors during Dispense

Resolving Skipped Medication

When a dispense gets interrupted, some packets might be filled improperly. Once the (re-started) dispense ends the **Missing/Skipped Medication** screen displays all skipped meds within the order.



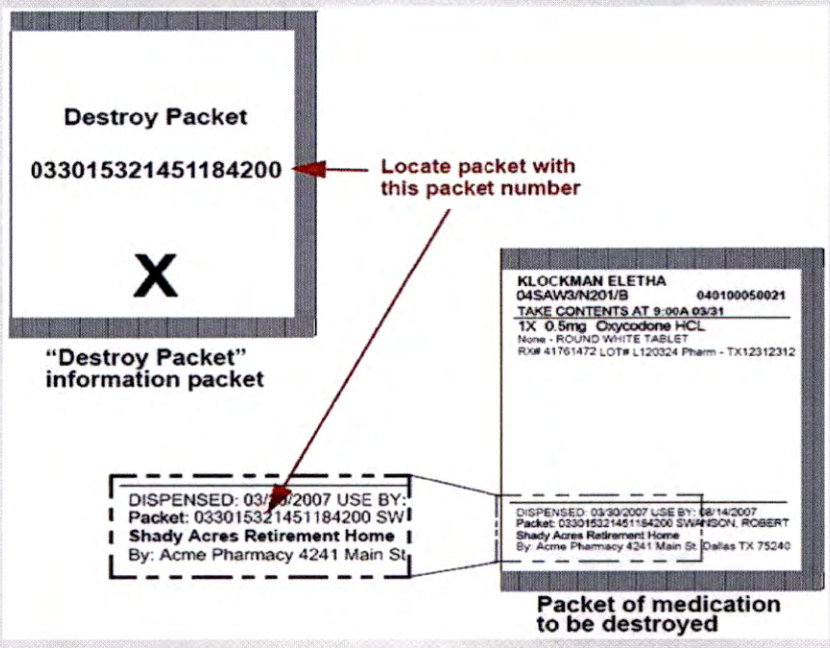
1. Locate the empty canister listed in the **Missing/Skipped Medications** screen.
2. Remove and replace the canister.
3. After the canister is loaded, touch **Done**.
4. Go to **Main Menu** and complete a **Re-Dispense**

Resolution for incorrectly packed meds:
see Destroy Packet (next page)

Dispense Errors during Dispense

Resolving "Destroy Packet

If an incorrect amount of meds was dispensed the packet has to be destroyed. The packet to be destroyed indicated by a **Destroy Packet** information-packet prints.

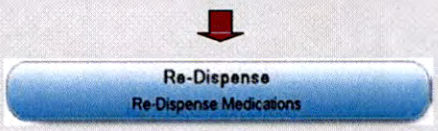


1. Once dispense is completed, check the string of packets for a **Destroy Packet**. It indicates the original packet number to be destroyed.

2. Staple the Destroy Packet info-packet together with the original packet and place them in a designated Destroy Bin.

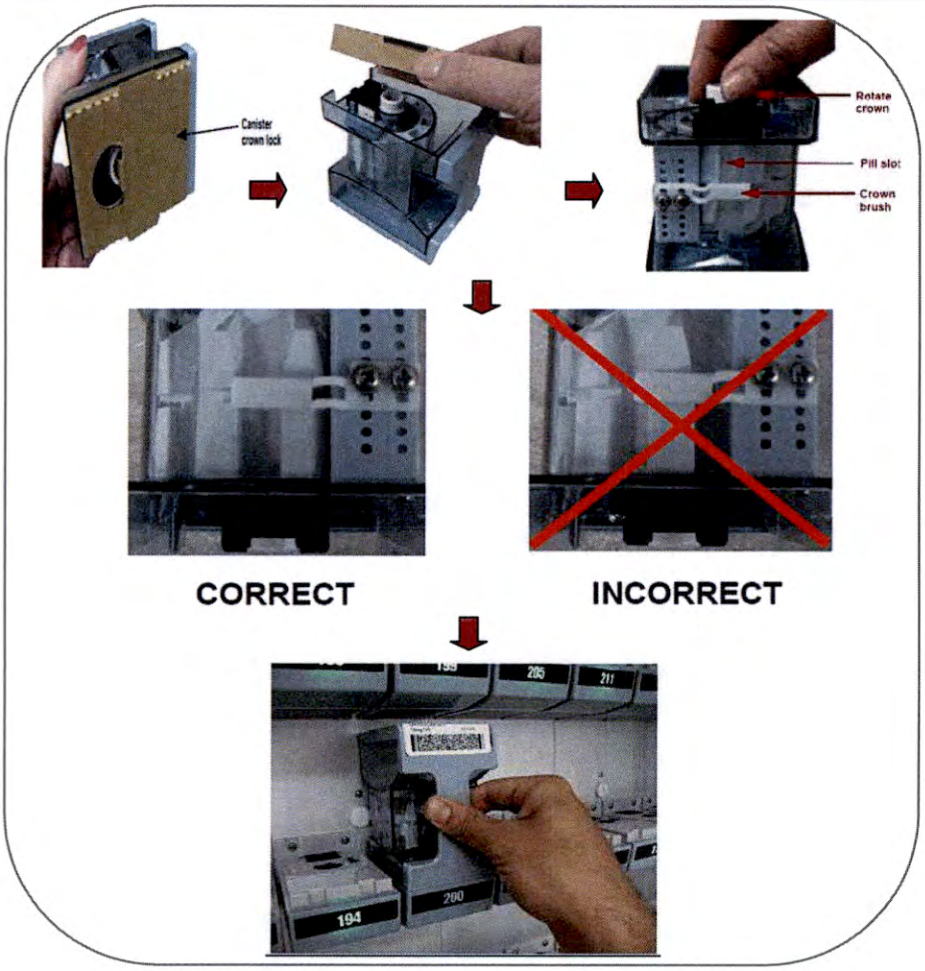
3. If necessary load new inventory in the unit.

4. Go to the **Main Menu** and complete a **Re-Dispense** with the entire contents of the packet (along with previously missing medication) [see **Re-Dispense**, pg. 21].

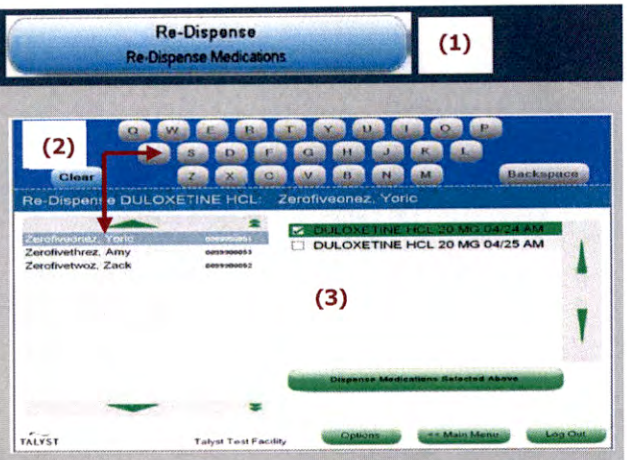


Replace Empty Canister

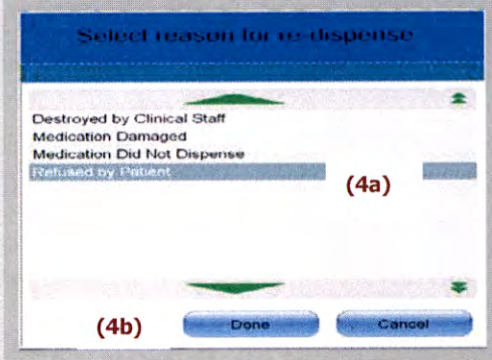
1. Take the new canister, turn it over and remove the canister crown lock.
2. Turn the crown until the crown brush is lined up over a pill slot, to make sure there are no pills in the slot.
3. Turn the canister over, ensuring that no pills fall into the pill slot that is lined up with the crown brush.
4. Load the new canister in any available position in the dispensing unit.



Re-Dispense

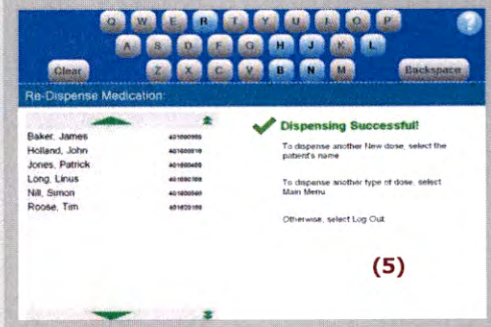


1. From **Main Menu** touch **Re-Dispense**.
2. List of patient names appear. Select the patient name.
3. List of patient specific meds appears. Touch the drug to be re-dispensed.



4. Screen pops up

   (a) Touch a reason for re-dispense.
   (b) Touch **Done**.



5. Packets dispense. *Dispensing Successful!* displays.

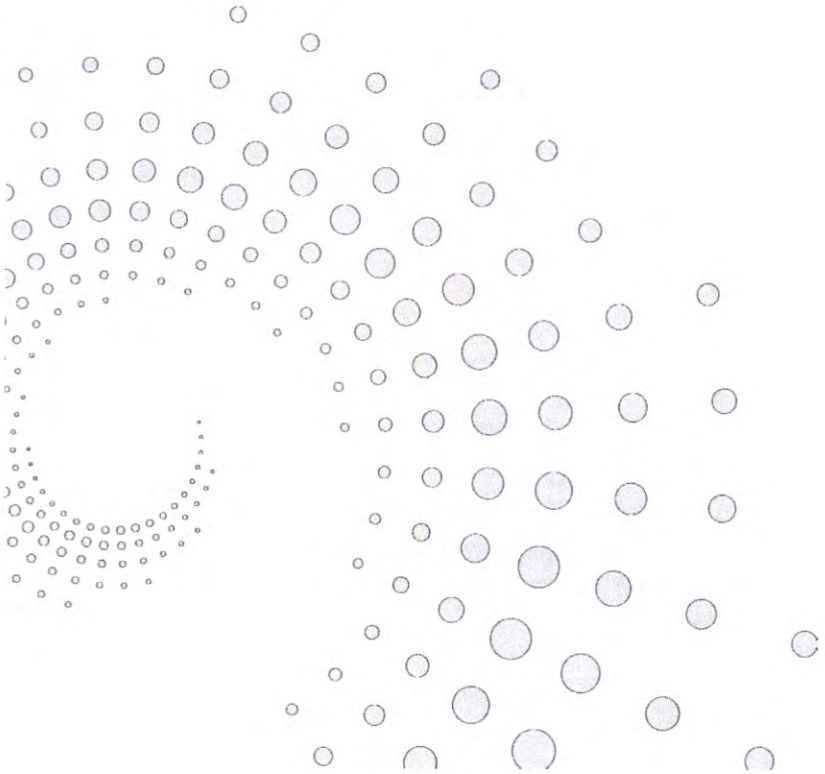
6. Prepare the packets for administration.

To contact Talyst Technical Support

Call:

Talyst Tech Support
1 (800) 541-4102

or email to: support@talyst.com



National Transportation Safety Board
Washington, DC 20594

Office of the Chairman

May 25, 2016

The Honorable Kate Brown
Governor of Oregon
State Capitol Building
900 Court Street NE, Ste. 160
Salem, OR 97301

Dear Governor Brown:

Thank you for the April 12, 2016, letter from Ms. Kathleen Haley, Executive Director, Oregon Medical Board, regarding Safety Recommendations I-14-1 and -2. We issued these recommendations to all 50 states on September 23, 2014, as a result of our safety study *Drug Use Trends in Aviation: Assessing the Risk of Pilot Impairment*, SS 14/01.

I-14-1

> Include in all state guidelines regarding prescribing controlled substances for pain a recommendation that health care providers discuss with patients the effect their medical condition and medication use may have on their ability to safely operate a vehicle in any mode of transportation.

We note that, on November 19, 2015, the Oregon State Board of Nursing voted to add the recommended guidance to its revised "Prescriptive and Dispensing Authority in Oregon," and that on April 8, 2016, the Oregon Medical Board amended its Statement of Philosophy on Pain Management to contain the same guidance. These actions satisfy Safety Recommendation I-14-1, which is classified "Closed—Acceptable Action."

I-14-2

> Use existing newsletters or other routine forms of communication with licensed health care providers and pharmacists to highlight the importance of routinely discussing with patients the effect their diagnosed medical conditions or recommended drugs may have on their ability to safely operate a vehicle in any mode of transportation.

We note that the Oregon Board of Pharmacy and the Oregon Board of Nursing each published an article in the February 2016 editions of their respective newsletters satisfying their part of this recommendation, and that a similar article was published in the Winter 2016 *Oregon*

Medical Board Report newsletter. In addition, on its webpage dedicated to pain management information, the Oregon Medical Board stresses the importance of routinely discussing with patients the effects of their medical conditions and medications. These actions satisfy Safety Recommendation I-14-2, which is classified "Closed—Acceptable Action."

We appreciate the prompt and effective actions taken by the Oregon boards to implement these important safety recommendations to improve safety in all modes of transportation.

Sincerely,

Christopher A. Hart
Chairman
Approved for Electronic Transmittal
No Hard Copy Will Follow

cc: Ms. Stacey O'Neil
Executive Assistant to
Karmen Fore, Senior Director for
Federal/Regional Affairs and
Transportation
Office of Governor Kate Brown
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BOARD OF PHARMACY
AY17 CASH FLOW
OF Appn 30235

May 2016 Financial Report

Budget Objects	REVENUE & EXPENDITURES	LAB ORBITS BUDGET	Rstars Financial Plan	EBoard or Adj Budget or Salary Pot	Adjusted Financial Plan	ACTUALS To Date	Unobligated Balance	% Expended	
REVENUE			REV Proj as of 1/31/16						
0205	Other Business Licenses	4,924,832	5,012,583		5,012,583	2,003,826	3,008,758	40%	
0210	Other NonBusiness Licenses and Fees	65,855	127,584		127,584	125,438	2,145	98%	
0505	Fines and Forfeits	270,000	360,573		360,573	297,915	62,657	83%	
0605	Interest and Investments	35,000	43,095		43,095	30,900	12,195	72%	
0975	Other Revenue	29,700	37,811		37,811	26,542	11,270	70%	
	SubTotal Revenue	5,325,387	5,581,646	0	5,581,646	2,484,621	3,097,025	45%	
TRANSFERS									
2443	Transfer out to OHA--Workforce Data	65,855	65,855		65,855	47,053	18,803	71%	
2443	Transfer out to OHA--PDMP program	283,590	283,590	0	283,590	-	283,590	0%	
	SubTotal Transfers	349,445	**349,445**	**0**	**349,445**	**47,053**	**302,393**	13%	
TOTAL REVENUE & TRANSFERS		**5,674,832**	**5,931,091**	**0**	**5,931,091**	**2,437,568**	**2,794,632**	**41%**	
PERSONAL SERVICES			PS Proj from OSPS Detail						
3110	Regular Employees	2,872,872	2,803,994	142,105	2,946,099	1,218,185	1,757,073.65	41%	
	Board Member Stipends		29,160		29,160				
3160	Temporary Appointments	24,322	-		0	-	-	0%	
3170	Overtime Payments		-		0	120	(120)	0%	
3190	All Other Differential O/Class Lead Work	176,911	174,819		174,819	79,890	94,929	46%	
3210	Employment Relations Board Assessment	880	897		897	397	499	44%	
3220	Public Employees Retirement Contrib	478,038	439,339	22,438	461,777	185,838	275,938	40%	
3221	Pension Bond Contribution	176,574	177,625	2,878	180,503	77,112	103,391	43%	
3230	Social Security Taxes	235,168	225,505	10,871	236,376	94,696	141,680	40%	
3240	Unemployment Assessment				0	3,298	(3,298)	0%	
3250	Workers' Compensation Assessments	1,380	1,318		1,318	537	781	41%	
3260	Mass Transit Tax	18,445	17,873	853	18,726	7,780	10,946	42%	
3270	Flexible Benefits	610,560	561,103	21,680	582,783	244,539	338,243	42%	
3455	Vacancy Savings-ORBITS only				0		-	0%	
3465	Reconciliation Adjustment-ORBITS only				0		-	0%	
3470	Undistributed Personal Services-ORBITS		204,746		204,746		204,746	0%	
3991	PERS Policy Adjustment-ORBITS				0		-	0%	
	SubTotal Personal Services	**4,595,150**	4,636,378	200,825	4,837,203	1,912,392	2,924,810	40%	$ 2,924,810
SERVICES AND SUPPLIES			Proj all						
4100	InState Travel	**106,639**	106,639		106,639	38,293	68,346	36%	
4125	Out of State Travel	**19,985**	19,985		19,985	5,132	14,853	26%	
4150	Employee Training	**48,559**	48,559		48,559	7,921	40,638	16%	
4175	Office Expenses	**119,463**	119,463		119,463	65,816	53,647	55%	
4200	Telecommunications	**36,349**	36,349		36,349	13,352	22,997	37%	
4225	State Govt. Service Chgs.	**72,769**	72,769		72,769	36,462	36,307	50%	
4250	Data Processing	**56,060**	56,060		56,060	25,108	30,952	45%	
4275	Publicity & Publications	**37,593**	37,593		37,593	8,902	28,691	24%	
4300	Professional Services	**116,711**	116,711		116,711	63,434	53,277	54%	
4315	IT Professional Services	**78,096**	78,096		78,096	18,900	59,196	24%	
4325	Attorney General	**314,038**	314,038		314,038	151,624	162,414	48%	
4375	Employee Recruitment & Develop	**200**	200		200	-	200	0%	
4400	Dues & Subscriptions	**4,419**	4,419		4,419	1,486	2,933	34%	
4425	Facilities Rent & Taxes	**217,606**	217,606		217,606	79,516	138,091	37%	
4475	Facilities Maintenance	**49**	49		49	-	49	0%	
4525	Medical Supplies and Services	**1,070**	1,070		1,070	231	839	22%	
4575	Agency Program Related S&S	**221,248**	221,248		221,248	76,104	145,144	34%	
4650	Other Services & Supplies	**292,293**	292,293		292,293	113,002	179,291	39%	
4700	Expendable Property	**10,124**	10,124		10,124	1,660	8,464	16%	
4715	IT Expendable Property	**40,285**	40,285		40,285	9,823	30,462	24%	
5550	Data Processing Software	**271,077**	271,077		271,077	-	271,077	0%	
5600	Data Processing Hardware	**8,000**	8,000		8,000	-	8,000	0%	
					0				
	SubTotal Services and Supplies	**2,072,633**	2,072,633	-	2,072,633	716,766	1,355,867	35%	$ 1,355,867
SPECIAL PAYMENTS									
6085	Other Special Payments	11,563	11,563		11,563	-	11,563	0%	
6443	Special Payments to OHA-HPSP	176,899	176,899		176,899	113,092	63,807	64%	
	SubTotal Transfers	**188,462**	188,462	0	188,462	113,092	75,370	64%	$ 75,370
Total Expenditures Budget		**6,856,245**	**6,897,473**	**200,825**	**7,098,298**	**2,742,250**	**4,356,048**	**39%**	**$ 4,356,048**
					7,057,070				
	LAB % PS	67%			68%		Target	100%	
	LAB % S&S	30%			29%				
	LAB % SP	3%			3%				

			Cash
AY15 Ending Cash Balance			5,094,726
Revenue less Expenditures		Actuals	
Total Revenue & Transfers		2,437,568	
Total Expenditures		(2,742,250)	
Total Revenues & Transfers less Expenditures		**(304,682)**	(304,682)
AY17 Cash Balance after the Fiscal Month Closed			**4,790,044**
Budgeted Revenues not yet received less Estimated Transfers to OHA-PMP & Workforce Data program to be made			2,794,632
Budgeted Expenditures not yet spent			(4,356,048)
AY17 Estimated Cash Balance			**3,228,628**
Cash Balance Contingency (Months)			11.30 months

BOARD OF PHARMACY
AY17 CASH FLOW
OF Appn 30235

June 2016 Financial Report

Budget Objects	REVENUE & EXPENDITURES	LAB ORBITS BUDGET	Rstars Financial Plan	EBoard or Adj Budget or Salary Pot	Adjusted Financial Plan	ACTUALS To Date	Unobligated Balance	% Expended	
REVENUE			REV Proj as of 1/31/16						
0205	Other Business Licenses	4,924,832	5,012,583		5,012,583	2,054,386	2,958,198	41%	
0210	Other NonBusiness Licenses and Fees	65,855	127,584		127,584	144,265	(16,682)	113%	
0505	Fines and Forfeits	270,000	360,573		360,573	306,995	53,577	85%	
0605	Interest and Investments	35,000	43,095		43,095	34,351	8,744	80%	
0975	Other Revenue	29,700	37,811		37,811	28,803	9,009	76%	
	SubTotal Revenue	5,325,387	5,581,646	0	5,581,646	2,568,800	3,012,846	46%	
TRANSFERS									
2443	Transfer out to OHA--Workforce Data	65,855	65,855		65,855	47,053	18,803	71%	
2443	Transfer out to OHA--PDMP program	283,590	283,590	0	283,590	-	283,590	0%	
	SubTotal Transfers	349,445	**349,445**	**0**	**349,445**	**47,053**	**302,393**	13%	
TOTAL REVENUE & TRANSFERS		**5,674,832**	**5,931,091**	**0**	**5,931,091**	**2,521,747**	**2,710,453**	**43%**	
PERSONAL SERVICES			PS Proj from OSPS Detail						
3110	Regular Employees	2,872,872	2,774,620	142,105	2,916,725	1,333,504	1,612,380.26	46%	
	Board Member Stipends		29,160		29,160				
3160	Temporary Appointments	24,322	-		0	-	-	0%	
3170	Overtime Payments		-		0	120	(120)	0%	
3190	All Other Differential O/Class Lead Work	176,911	174,819		174,819	87,102	87,717	50%	
3210	Employment Relations Board Assessment	880	895		895	434	461	48%	
3220	Public Employees Retirement Contrib	478,038	434,842	22,438	457,280	202,773	254,507	44%	
3221	Pension Bond Contribution	176,574	175,863	2,878	178,741	83,923	94,818	47%	
3230	Social Security Taxes	235,168	223,075	10,871	233,946	103,887	130,059	44%	
3240	Unemployment Assessment				0	3,298	(3,298)	0%	
3250	Workers' Compensation Assessments	1,380	1,308		1,308	587	721	45%	
3260	Mass Transit Tax	18,445	17,697	853	18,550	8,511	10,039	46%	
3270	Flexible Benefits	610,560	559,693	21,680	581,373	267,481	313,892	46%	
3455	Vacancy Savings-ORBITS only				0		-	0%	
3465	Reconciliation Adjustment-ORBITS only				0		-	0%	
3470	Undistributed Personal Services-ORBITS		204,746		204,746		204,746	0%	
3991	PERS Policy Adjustment-ORBITS				0		-	0%	
	SubTotal Personal Services	**4,595,150**	4,596,718	200,825	4,797,543	2,091,620	2,705,923	44%	$ 2,705,923
SERVICES AND SUPPLIES			Proj all						
4100	InState Travel	**106,639**	106,639		106,639	47,425	59,214	44%	
4125	Out of State Travel	**19,985**	19,985		19,985	7,136	12,849	36%	
4150	Employee Training	**48,559**	48,559		48,559	10,203	38,356	21%	
4175	Office Expenses	**119,463**	119,463		119,463	59,177	60,286	50%	
4200	Telecommunications	**36,349**	36,349		36,349	16,995	19,354	47%	
4225	State Govt. Service Chgs.	**72,769**	72,769	4,638	77,407	36,477	40,930	47%	
4250	Data Processing	**56,060**	56,060		56,060	25,241	30,819	45%	
4275	Publicity & Publications	**37,593**	37,593		37,593	11,672	25,921	31%	
4300	Professional Services	**116,711**	116,711		116,711	90,115	26,596	77%	
4315	IT Professional Services	**78,096**	78,096		78,096	18,900	59,196	24%	
4325	Attorney General	**314,038**	314,038		314,038	151,677	162,361	48%	
4375	Employee Recruitment & Develop	**200**	200		200	-	200	0%	
4400	Dues & Subscriptions	**4,419**	4,419		4,419	3,005	1,414	68%	
4425	Facilities Rent & Taxes	**217,606**	217,606		217,606	88,431	129,175	41%	
4475	Facilities Maintenance	**49**	49		49	-	49	0%	
4525	Medical Supplies and Services	**1,070**	1,070		1,070	231	839	22%	
4575	Agency Program Related S&S	**221,248**	221,248		221,248	88,105	133,143	40%	
4650	Other Services & Supplies	**292,293**	292,293		292,293	113,122	179,171	39%	
4700	Expendable Property	**10,124**	10,124		10,124	7,559	2,565	75%	
4715	IT Expendable Property	**40,285**	40,285		40,285	10,248	30,037	25%	
5550	Data Processing Software	**271,077**	271,077		271,077	-	271,077	0%	
5600	Data Processing Hardware	**8,000**	8,000		8,000	-	8,000	0%	
					0				
	SubTotal Services and Supplies	**2,072,633**	2,072,633	4,638	2,077,271	785,718	1,291,553	38%	$ 1,291,553
SPECIAL PAYMENTS									
6085	Other Special Payments	11,563	11,563		11,563	-	11,563	0%	
6443	Special Payments to OHA-HPSP	176,899	176,899		176,899	113,092	63,807	64%	
	SubTotal Transfers	**188,462**	188,462	0	188,462	113,092	75,370	64%	$ 75,370
Total Expenditures Budget		**6,856,245**	**6,857,813**	**205,463**	**7,063,276**	**2,990,430**	**4,072,846**	**42%**	**$ 4,072,846**
					7,057,070				
	LAB % PS	67%			68%		Target	100%	
	LAB % S&S	30%			29%				
	LAB % SP	3%			3%				

		Cash
AY15 Ending Cash Balance		5,094,726
Revenue less Expenditures	Actuals	
Total Revenue & Transfers	2,521,747	
Total Expenditures	(2,990,430)	
Total Revenues & Transfers less Expenditures	**(468,683)**	(468,683)
AY17 Cash Balance after the Fiscal Month Closed		**4,626,043**
Budgeted Revenues not yet received less Estimated Transfers to OHA-PMP & Workforce Data program to be made		2,710,453
Budgeted Expenditures not yet spent		(4,072,846)
AY17 Estimated Cash Balance		**3,263,651**
Cash Balance Contingency (Months)		11.42 months

Pharmacy Technician Extensions 5/13/16-7/11/16

Date Requested:	Name:	Lic #	Date Granted:	New Expiration Date:	Reinstatement	Extension	How Long?	Notes
3/29/2016	AMANDA SALINAS	T-0020428	5/16/2016	11/18/2016	X	X		
5/26/2016	MICHAEL WARREN	T-0020455	5/26/2016	9/2/2016		X		3 Months
5/26/2016	THA THACH	T-0020447	5/31/2016	7/29/2016	X	X		2 Months
6/3/2016	SAVANNAH CLENDENIN	T-0020467	6/3/2016	9/4/2016		X		3 Months
6/3/2016	LARISSA ADA	T-0020470	6/3/2016	9/8/2016		X		3 Months
6/13/2016	IANA SULTANTI	T-0020505	6/13/2016	9/19/2016		X		3 Months
6/30/2016	SOLOME MEKBIB	T-0020477	7/13/2016	9/30/2016	X	X		90 Days
7/11/2016	MELISSA ARNOLD	T-0017292	N/A	N/A	N/A	N/A	N/A	Denied - Hasn't been Lapsed for more than 5 years.

Oregon
Kate Brown, Governor

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To: Board Members

From: Karen MacLean

Date: July 26, 2016

Subject: Hearing Officer's Report for Proposed Rules in Division 041

General Background:
A public hearing was held at the Portland State Office Building, located at 800 NE Oregon St. Conference Room 1A Portland, OR 97232 on May 24, 2016 at 9:30am that included this rule among other rules.

The Board received comments at that time that revised the rule enough, that the Board decided to notice for public comment again. The deadline for public comment was July 25, 2016 at 4:30.

- Div 041 Amends rules for acquisition of epinephrine by an entity, pursuant to a prescription.

No requests for an additional rulemaking hearing were made regarding these rules after second notice.

Summary of Written Comments:
The Board received one written comment on proposed rules in Division 041. (855-041-2320)

A pharmacist emailed to request that the Board consider clarifying the quantity allowed to dispense. Based on his comments, epinephrine auto-injector products are manufactured in dual-packs only ("As I understand it, the rule states that the amount to be dispensed is sufficient to treat one patient.") This causes concerns about having ½ packages left in inventory and the inability to bill for partial packages of drugs.

Staff response: In 2013, the OHA revised their Certificate of Completion to clarify that dispensing a dual-pack is considered a "single" dispense. Additionally, new language in this rule attempts to clarify this concern using the language "dose package", highlighted here:

> (2)(b)(B)(ii) The prescription shall be limited to one adult and one child dose package per trained employee per location.

Staff recommends utilizing similar language in (2)(a)(A) and does not consider this a substantial edit.

A copy of the written comment is included as part of the permanent rulemaking record.

From: Karen S MacLean
To: Marcus Watt; Gary Miner; Fiona Karbowicz
Subject: FW: Proposed Rulemaking regarding Epinephrine
Date: Friday, July 01, 2016 9:41:30 AM

FYI

-----Original Message-----
From: Gold Hill Pharmacy [mailto:store@goldhillpharmacy.com]
Sent: Thursday, June 30, 2016 12:55 PM
To: Karen S MacLean
Subject: Proposed Rulemaking regarding Epinephrine

Karen,

The part of the proposed rule regarding Epinephrine emergency dispensing about which I would like to comment is the quantity allowed. As I understand it, the rule states that the amount to be dispensed is sufficient to treat one patient. Currently all available products on the market come in packs of two, and at a high price. I would recommend changing the quantity to two devices so that pharmacies are not left with 1/2 package. Also, our software will not let us fill for a partial package for drugs of this type.

Alex Frum, R.Ph.

Gold Hill Pharmacy

855-041-2320

Epinephrine

(1) A pharmacist may fill an order for epinephrine to be used by trainees to treat an anaphylactic reaction. Trainees must be 18 years of age or older and must have responsibility for or contact with at least one (1) other person as a result of the trainee's occupation or volunteer status, such as, but not limited to, a camp counselor, scout leader, forest ranger, school employee, tour guide or chaperone.

(2) Individuals must successfully complete a training program approved by the Oregon Health Authority, Public Health Division. Upon successful completion, the trainee will receive the following certificates:

(a) Statement of Completion; and

(b) Authorization to Obtain Epinephrine.

(3) ~~(a) Distribution~~ **Acquisition** of epinephrine from a pharmacy to be used for the treatment of allergic emergencies may occur in the following manner**s**:

~~(b)~~ **(a)** A ~~trainee may obtain~~ **pharmacist may dispense** epinephrine **to a trainee** upon presentation of the Statement of Completion and Authorization to Obtain Epinephrine certificate to a pharmacy which:

(A) A pharmacist may generate a prescription for, and dispense an emergency supply of epinephrine for not more than one ~~(1) child and one (1) adult in an automatic injection device~~ **adult and one child dose package**, as specified by the supervising professional whose name, signature, and license number appear on the Authorization to Obtain Epinephrine certificate.

(B) The pharmacist who generates the hardcopy prescription for epinephrine in this manner shall reduce the prescription to writing, and file the prescription in a manner appropriate for a non-controlled substance.

(C) Once the pharmacist generates the epinephrine prescription, the pharmacist shall write in the appropriate space provided on the Authorization to Obtain Epinephrine certificate, the date and the number of doses dispensed, and return the certificate to the trainee.

~~(4)~~ **(D)** The Statement of Completion and the Authorization to Obtain Epinephrine certificate may be used to obtain epinephrine up to four (4) times within three (3) years from the date of the initial training.

~~(a)~~ **(E)** Both the Statement of Completion and the Authorization to Obtain Epinephrine certificate expire three (3) years from the date of the trainee's last Oregon Health Authority approved allergy response training.

~~(b)~~ **(F)** Upon completion of the training, the trainee will receive a new Statement of Completion and Authorization to Obtain Epinephrine certificate, with a valid duration of three (3) years.

(b) A pharmacist may dispense epinephrine to an entity when:

(A) The epinephrine is acquired by a valid prescription presented to the pharmacy;

(B) The prescription identifies the entity as the patient for the purpose of prescribing;

(i) The pharmacist shall use the name of the entity as the patient for the purpose of labeling the prescription.

(ii) The prescription shall be limited to one adult and one child dose package per trained employee per location.

(C) For the purpose of this rule, an entity conducts business at a single physical location.

Stat. Auth: ORS 689.205
Stats. Implemented: ORS 689.155**, 433.825**

Proposed

The proposed rule amendments to *Div 007 Public Health Emergency* and *041 Operation of Pharmacies* update rules related to the registration and regulation of Drug Rooms.

The rule (1) describes oversight of long-term storage of state and federal emergency medications in a Drug Room (2) clarifies that secondary storage areas related to Retail Pharmacies can register as a Drug Room; and (3) allows a Drug Room to be affiliated with an Institutional Pharmacy.

Proposed edits to Sections 855-041-4100 and -4120 are set forth FYI related to the Talyst conversation being discussed at the August 2016 Board meeting.

855-007-0060

SNS and State Stockpile Emergency Drugs

(1) General: When drugs from the Strategic National Stockpile (SNS) are delivered to the state, the drugs may be delivered to a state Receipt, Staging and Storage center (RSS) for further distribution to Points of Dispensing (PODs) selected by OSPHD. State drugs (state stockpile) may also be delivered to the RSS.

(2) **Temporary** ~~S~~**s**torage of drugs from SNS or state stockpile:

(a) The RSS, PODs and local health departments (LHD) are authorized to store any drugs from the SNS or state stockpile prior to and during an emergency without any registration from the Board.

(b) All such drugs must be stored in accordance with manufacturers' guidelines.

(c) This authority to possess drugs shall extend beyond the declared emergency until procedures issued by OSPHD for the return or destruction of unused drugs have been completed.

(3) A long-term drug storage area for state and federal emergency medications not otherwise registered as a drug outlet must be approved by the Board, comply with storage and security requirements, and register as a Drug Room.

Stat. Auth.: ORS 401.065, 433.441 ~~&~~**, 689.305,** 689.205
Stats. Implemented: ORS 689.155

855-041-1001

Definitions

(1) "Biological product" means, with respect to the prevention, treatment or cure of a disease or condition of human beings, a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component, blood derivative, allergenic product, protein other than a chemically synthesized polypeptide, analogous products or arsphenamine or any other trivalent organic arsenic compound.

(2) "Biosimilar product" means a biological product licensed by the United States Food and Drug Administration pursuant to 42 U.S.C. 262(k)(3)(A)(i).

(3) "Drug room" is a drug storage area registered with the Board which is secure and lockable.

~~(3)~~ **(4)** "Interchangeable" means, in reference to a biological product, that the United States Food and Drug Administration has determined that a biosimilar product meets the safety standards set forth in 42 U.S.C. 262(k)(4).

~~(4)~~ **(5)** "Reference biological product" means the biological product licensed pursuant to 42 U.S.C. 262(a) against which a biological product is evaluated in an application submitted to the United States Food and Drug Administration for licensure of a biological product as a biosimilar product or for determination that a biosimilar product is interchangeable.

Stat. Auth.: ORS 689.205 ~~& 2013 OL Ch 342~~ **,ORS 689.522**
Stats. Implemented: ORS 689.155 ~~& 2013 OL Ch~~ 342 **,ORS 689.522**

855-041-1036

Proper Storage of Drugs

(1) A pharmacy 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.

(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 pharmacy must quarantine drugs which are outdated, adulterated, misbranded or suspect.
Cold Storage and Monitoring.

(2) A pharmacy 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; and

(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 pharmacy 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 that it is safe for continued use. This documentation must include details of the information source;

(F) A written emergency action plan; and

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

(3) Vaccine Drug Storage:

(a) A pharmacy that stores vaccines must comply with section two of this rule and the following:

(A) Vaccines must be stored in the temperature stable sections of the refrigerator;

(B) A centrally placed and accurate buffered probe thermometer, such as glycol or glass beads, calibrated within a plus or minus 0.5 °C variance must be utilized;

(C) Each freezer and refrigerator compartment must have its own exterior door and independent thermostat control;

(D) A system of continuous temperature monitoring with automated data logging and physical confirmation must be utilized. Documentation of the temperature of each active storage unit must be logged at least twice daily, data must be downloaded weekly, and system validations must be conducted quarterly; and

(E) Must adhere to a written quality assurance process to avoid temperature excursions.

(4) A retail drug outlet may store drugs in another location that is registered as a Drug Room and meets all Pharmacy drug storage and security requirements.

Stat. Auth.: ORS 689.205, 689.325
Stats. Implemented: ORS 689.155

855-041-5005

Definitions

For purposes of these rules, OAR 855-041-5000 through 855-041-9999 the following definitions apply:

(1) "Institutional Facility" means a hospital or other health care facility which is an inpatient care facility referred to in ORS 442.015, which includes long-term care facilities and special inpatient care facilities, and such facility is licensed by the appropriate state agency. For the purpose of this rule, an Institutional Facility is a Residential Drug Outlet.

(2) "Institutional Pharmacy" means a pharmacy where medications are dispensed to other health care professionals for administration to institutionalized patients served by an institutional facility, and which is:

(a) Located within the institutional facility;

(b) Located outside the facility but provides pharmaceutical services to institutionalized patients; and

(c) For the purpose of this rule, an Institutional Pharmacy is a Residential Pharmacy.

(3) "Drug Room" means a secure and lockable location within ~~an inpatient~~ **a** care facility that does not have a pharmacy **or a Board approved location associated with a licensed institutional pharmacy.**

855-041-4100 [Talyst]

Definitions

(1) "Automated Pharmacy System" (APS) means a mechanical system that performs operations or activities, including but not limited to, those related to the storage, packaging, dispensing, or distribution of medications, but not including compounding or administration, and that collects, controls, and maintains all transaction information.

(2) "Remote Dispensing Facility" (RDF) means a facility where drugs are prepared for administration and where requisite pharmacist supervision is provided remotely as approved by the Board.

(3) "Remote Dispensing Machine" (RDM) means a component of an Automated Pharmacy System that contains ~~prepackaged~~ drugs for dispensing.

(4) "Responsible Pharmacy" means the licensed pharmacy that is responsible for the APS, and RDM.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155

855-041-4120

Drug Delivery and Control

(1) Each RDM must be registered with the Board, under the control of and connected via computer with a Responsible Pharmacy, but not located in a pharmacy. RDMs must be used only in settings with an established program of pharmaceutical care that ensures prescription orders are reviewed by a pharmacist before release to the patient. The Responsible Pharmacy must establish the policies and procedures necessary to fulfill the requirements of all applicable state and federal laws and regulations.

(2) The following must be conspicuously displayed at the site of the RDM:

(a) RDM license;

(b) DEA registration if required;

(c) A certified copy of the Responsible Pharmacy license; and

(d) A certified copy of the Pharmacist-In-Charge license.

(3) Documentation as to type of equipment, serial numbers, content, policies and procedures, and location shall be maintained in the pharmacy for review by the board. Such documentation must include, but is not limited to:

(a) Location of RDM(s);

(b) Manufacturer's name and model for each RDM;

(c) Description of how the RDM is used;

(d) Quality assurance procedures to determine continued appropriate use of the automated device; and

(e) Policies and procedures for training of appropriate personnel, system operation, safety, security, accuracy, patient confidentiality, oral counseling by a pharmacist or pharmacist-intern, access, and malfunction.

(4) Policies and procedures addressing the operation of the RDM must be maintained in the pharmacy responsible for the APS and at the location at which the RDM has been installed.

(5) All events involving the contents of the RDM must be recorded electronically. Records must be maintained by the pharmacy for a minimum of three years and must be readily available to the Board. Such records shall include:

(a) Identity of RDM accessed;

(b) Identification of the individual accessing the RDM;

(c) Type of transaction;

(d) Date and time of transaction;

(e) Name, strength, dosage form, and quantity of the drug accessed;

(f) Name of the patient for whom the drug was ordered;

(g) Name of the prescribing practitioner

(h) Such additional information as the pharmacist-in-charge may deem necessary; and

(6) Only ~~an Oregon registered technician or an Oregon licensed pharmacist~~ **Board licensee** may have access to the RDM.

(7) Only ~~an Oregon registered technician or an Oregon licensed pharmacist~~ **Board licensee** may stock medications in the RDM.

(8) All containers of medications stored in the RDM shall be packaged and labeled in accordance with state and federal laws and regulations, including OAR 855-041-1130.

(9) All aspects of handling controlled substances shall meet the requirements of all state and federal laws and regulations.

(10) Oral counseling, as required by OAR 855-019-0230, shall be provided by the pharmacist at the time of dispensing by a two-way audio and video hookup with the Responsible Pharmacy.

(11) The Automated Pharmacy Systems shall provide a mechanism for securing and accounting for wasted, discarded or unused medications in accordance with existing state and federal laws and regulations.

(12) The RDM must be clearly marked with the name, address, and phone number of the Responsible Pharmacy and Pharmacist-In-Charge.

(13) A Responsible Pharmacy located outside of Oregon that operates a RDM in Oregon must be currently licensed and in good standing in Oregon. The Pharmacist-In-Charge must also be currently licensed and in good-standing both in Oregon and in the state in which the Responsible Pharmacy is located.

(14) The Board may allow an RDM located in a licensed residential facility, that provides 24 hour nursing care, to be exempt from certain requirements, if written policies and procedures permit a registered nurse to perform sections (6), (7), and (10) of this rule.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.205

The proposed rule amendments reference new statewide rules on criminal records checks recently adopted by the Department of Administrative Services (DAS), and incorporate language specific to the Oregon Board of Pharmacy that is consistent with ORS chapter 181A and the DAS rules.

This rulemaking is required by House Bill 3168 (2013) and House Bill 2250 (2015), which gave the Department of Administrative Services the authority to adopt statewide administrative rules for criminal records checks and required other agencies to repeal or amend existing rules as needed in order to be consistent with the statewide rules.

The rule (1) gives the purpose, (2) specifies the individuals subject to the criminal records check under this rule includes all applicants and licensees as well as Board employees, volunteers and applicants, (3) incorporates the statewide rules on how a criminal records check is conducted, (4) provides the factors the Board will consider when making a fitness determination, (5) provides the potential fitness determination outcomes and their consequences, (6) maintains that criminal records information is confidential, (7) requires the Board to provide criminal records information to the individual subject to the check, (8) provides the appeals process, and (9) maintains the fee charged to the individual for criminal records checks.

The proposed rulemaking also repeals the Oregon Board of Pharmacy's conflicting procedural rules related to criminal background checks.

855-010-0045

State and Nationwide Criminal Background Checks for Licensure

(1) The purpose of this rule is to provide for the reasonable screening of: applicants for licensure; directors, officers and designated representatives of drug outlets applying for registration; and individuals subject to investigation by the Board, in order to determine if they have a history of criminal behavior such that they are not fit to be granted or retain a license or registration issued by the Board.

(2) "Subject individual" means a person from whom the Board may require **legible** fingerprints for the purpose of ~~enabling the Board to request a state or nationwide~~ **a** criminal records check **and fitness determination of all applicants and licensees.** In this rule, subject individual means: applicants for licensure or renewal of a license; directors, officers and designated representatives of drug outlets applying for registration or renewal of a registration; and individuals subject to an investigation by the Board. **[181A.170, 181A.195(1)(b), 676.303, 689.207]**

~~(3) This rule is to be applied when evaluating the criminal history of a subject individual and conducting fitness determinations based upon such history. The fact that a subject individual~~

~~does not have an adverse criminal history does not guarantee the granting or renewal of a license, or registration.~~

~~(4)~~**(3) Criminal records checks and fitness determinations are conducted according to ORS 181A.170 to 181A.215, ORS 670.280, and OAR 125-007-0200 to 127-007-0310.**

(a) The Board ~~may~~ **will** request that the **Oregon** Department of State Police conduct a state ~~criminal history check~~ and ~~a national~~ **nationwide** criminal ~~history~~ **records** check, using fingerprint identification of subject individuals. The Board may conduct state criminal records checks on subject individuals and any licensee through the Law Enforcement Data System maintained by the Department of State Police in accordance with rules adopted, and procedures established, by the Department of State Police. Criminal history information obtained from the Law Enforcement Data System must be handled in accordance with ORS Chapter 181, OAR 257-010 to 257-015 and applicable Oregon State Police procedures. [181A.195(2), (4)-(6)]

(b) All background checks must include available state and national data, unless obtaining one or the other is an acceptable alternative. [existing language from old (6)]

(c) The applicant or licensee must disclose all arrests, charges, and convictions regardless of the outcome or date of occurrence. Disclosure includes any military, juvenile, expunged or set aside criminal records. [DHS's 407-007-0030(2)(a)(A)]

(d) The Board may require additional information from the applicant or licensee, such as, but not limited to, proof of identity, previous names, residential history or additional criminal, judicial or other background information. [125-004-0220(4), previous (7)]

~~(5) Additional Information Required. In order to conduct a state and national criminal history check and fitness determination, the Board may require additional information from the subject individual as necessary. Additional information may include but is not limited to, proof of identity; residential history; names used while living at each residence; or additional criminal, judicial, or other background information.~~ [moved to various parts,]

~~(6)~~**(4)** ~~In making the fitness determination,~~ **If the applicant or licensee has potentially disqualifying criminal offender information**, the Board ~~may~~ **will** consider **the following factors in making the fitness determination**: [181A.195(10)(d)]

(a) The nature of any record that may include but is not limited to any record of arrest or conviction for:

(A) Any drug or alcohol offence;

(B) Any felony;

(C) Any offence involving fraud, theft, identity theft or other instance of dishonesty;

(D) Any offence involving violation of federal importation or customs laws or rules;

(E) Any offence requiring registration as a sex offender.

(b) The facts that support the conviction or indictment or that indicate the making of the false statement;

(c) The relevancy, if any, of the crime or the false statement to the specific requirements of the subject individual's license or registration; and

(d) Intervening circumstances relevant to the responsibilities and circumstances of the license or registration. Intervening circumstances include but are not limited to:

(A) The passage of time since the commission of the crime;

(B) The age of the subject individual at the time of the crime;

(C) The likelihood of a repetition of offenses or of the commission of another crime;

(D) The subsequent commission of another relevant crime;

(E) Whether the conviction was set aside and the legal effect of setting aside the conviction; and

(F) A recommendation of an employer.

(e) Any false statement or **omission** made by the individual regarding the criminal history of the individual;

(f) Any refusal to submit or consent to a criminal record check including a refusal to provide fingerprint identification;

(g) Any other pertinent information obtained as part of an investigation.

~~(7) If a subject individual is determined to be unfit, then the individual may not be granted a license or registration or a renewal of a license or registration. The Board may make a fitness determination conditional upon applicant's acceptance of probation, conditions, limitations, or other restrictions upon licensure or registration.~~

~~(8) All background checks shall be requested to include available state and national data, unless obtaining one or the other is an acceptable alternative~~. [moved to (3)(b)]

(5) The Board will make a fitness determination consistent with the outcomes provided in OAR 125-007-0260.

(a) An approval does not guarantee the granting or renewal of a license. [previous(3)]

(b) A restricted or conditional approval may necessitate probation, conditions, limitations, or other restrictions on licensure.

(c) A denial prohibits the applicant from being granted a license or prohibits the licensee from holding a license.

(d) An incomplete fitness determination results if the applicant or licensee refuses to consent to the criminal history check, refuses to be fingerprinted or respond to written correspondence, or discontinues the criminal records process for any reason. Incomplete fitness determinations may not be appealed.

~~(9)~~**(6)** Criminal offender information is confidential. Dissemination of information received under this rule may only be made to people with a demonstrated and legitimate need to know the information. When the information is part of the investigation of an applicant or licensee, it is confidential pursuant to ORS 676.175. Any fingerprint cards used to conduct a check shall be destroyed by either the Federal Bureau of Investigation or the Department of State Police as specified in ORS 181.534.

~~(10)~~**(7)** The Board will permit the subject individual for whom a fingerprint-based criminal records check was conducted to inspect the individual's own state and national criminal offender records and, if requested by the subject individual, provide the individual with a copy of the individual's own state and national criminal offender records.

~~(11)~~ **(8)** ~~If an~~ **An** applicant, licensee or certificate holder **may appeal a final fitness determination pursuant to OAR 125-007-0300.** ~~is determined not to be fit for a license or registration, they are entitled to a contested case hearing pursuant to ORS 183.413 to 470~~ and in accordance with OAR 855-001-0005 to 0017.

~~(12)~~**(9)** A challenge to the accuracy or completeness of **criminal history information must be made in accordance with OAR 125-007-0300(7)** ~~information provided by the Department of State Police, Federal Bureau of Investigation and agencies reporting information must be made through the Department of State Police, Federal Bureau of Investigation or reporting agency and not through the contested case process.~~

~~(13)~~**(10)** Request for re-evaluation following correction. If the subject individual successfully contests the accuracy or completeness of information provided by the Oregon State Police, the Federal Bureau of Investigation or other agency reporting information to the Board, the Board will conduct a new criminal history check and re-evaluate the criminal history upon submission of a new criminal history request form.

~~(14) If the subject individual discontinues the application or fails to cooperate with the criminal history check process then the application is considered incomplete.~~ [moved to (5)(d)]

~~(15)~~ **(11)** ~~Subject individuals will be required to pay the actual costs charged by the Department of State Police for the state and national criminal background check.~~ **The applicant or licensee must pay a criminal records check fee for the actual cost of acquiring and furnishing the criminal offender information**. [181A.195(9)(e), 125-007-0330]

Stat. Auth.: ORS ~~181.534,~~ 676.303, 689.205 **181A.195**
Stats. Implemented: ~~ORS 181.534~~ **181A.170, 181A.195, 181A.215, 676.175, 676.303**

~~**Criminal Background Checks**~~
~~**Employees, Applicants for Employment and Volunteers**~~

~~**855-010-0050**~~

~~**Purpose**~~

~~The purpose of these rules is to provide for the reasonable screening of subject individuals to determine if they have a history of criminal behavior such that they are not fit to work or volunteer for the Board. The fact that the Board determines that a subject individual is fit does not guarantee the individual a position as a Board employee, volunteer, or that the individual will be hired by the Board.~~

~~Stat. Auth.: ORS 181.534, 676.303, 689.205~~
~~Stats. Implemented: ORS 181.534~~

~~**855-010-0055**~~

~~**Definitions**~~

~~As used in OAR 855-010-0050 through 855-010-0086, unless the context of the rule requires otherwise, the following definitions apply:~~

~~(1) Conviction: A final judgment on a verdict or finding of guilty, a plea of guilty, or a plea of nolo contendere (no contest) or any determination of guilt entered by a court of law against a subject individual in a criminal case, unless that judgment has been reversed or set aside by a subsequent court decision.~~

~~(2) Fitness determination: A determination made by the Board, pursuant to the process established under OAR 855-010-0060, that a subject individual is fit or not fit to be a Board employee or volunteer.~~

~~(3) Criminal offender information: Records and related data concerning physical description and vital statistics, fingerprints received and compiled by the Oregon State Police (OSP) to identify~~

~~criminal offenders and alleged offenders, records of arrests and the nature and disposition of criminal charges, including sentencing, confinement, parole and release records.~~

~~(4) Criminal records check: One or more of the following three processes undertaken by the Board to check the criminal history of a subject individual:~~

~~(a) A name-based check of criminal offender information conducted through the Law enforcement Data System (LEDS) maintained by the OSP, in accordance with the rules adopted and procedures established by the OSP;~~

~~(b) A check of Oregon criminal offender information, through fingerprint identification and other means, conducted by the OSP at the Board's request (Oregon Criminal Records Check); or~~

~~(c) A nationwide check of federal criminal offender information, through fingerprint identification and other means, conducted by the OSP through the FBI or otherwise at the Board's request (Nationwide Criminal Records Check).~~

~~(5) Criminal Records Request form: A Board-approved form, completed by a subject individual, requesting the Board to conduct a criminal records check.~~

~~(6) False statement: In association with an activity governed by these rules, a subject individual either:~~

~~(a) Provided the Board with false information about the subject individual's criminal history, including but not limited to false information about the individual's identity or conviction record; or~~

~~(b) Failed to provide the Board information material to determining the individual's criminal history.~~

~~(7) Subject Individual: An individual identified in OAR 855-010-0057 as someone from whom the Board may require a criminal records check.~~

~~Stat. Auth.: ORS 181.534, 676.303, 689.205~~
~~Stats. Implemented: ORS 181.534~~

~~855-010-0057~~

~~Subject Individual~~

~~The Board may require a subject individual to complete a criminal records check pursuant to these rules because the person is:~~

~~(1) A Board employee~~

~~(2) A Board volunteer; or~~

~~(3) An applicant for employment with the Board.~~

~~Stat. Auth.: ORS 181.534, 676.303, 689.205~~
~~Stats. Implemented: ORS 181.534~~

~~**855-010-0060**~~

~~**Criminal Records Check Process**~~

~~(1) Disclosure of Information by Subject Individual.~~

~~(a) Preliminary to a criminal records check, a subject individual must complete and sign the Board Criminal Records Request form and a fingerprint card. Both forms ask for identifying information (e.g., name, birth date, social security number, physical characteristics, driver's license or identification card number and current address of the subject individual). The Board Criminal Records Request form also requires information about the subject individual's prior residences in other states and any other identifying information deemed necessary by the Board.~~

~~(b) A subject individual must complete and submit to the Board the Criminal Records Request form and, if requested, a fingerprint card within five business days of receiving the forms. The Board may extend the deadline for good cause.~~

~~(c) The Board may require additional information from the subject individual as necessary to complete the criminal records check and fitness determination, such as, but not limited to, proof of identity, or additional criminal, judicial, or other background information.~~

~~(d) The Board shall not request a fingerprint card from a subject individual under the age of 18 years unless the subject individual is emancipated pursuant to ORS 419B.550 et seq, or unless the Board also requests the written consent of a parent or guardian. In such case, such parent or guardian and youth must be informed that they are not required to consent. Notwithstanding, failure to consent may be construed as a refusal to consent under OAR 855-010-0065(3).~~

~~(2) When a Criminal Records Check is required. The Board may conduct, or request the OSP to conduct, a criminal record check when:~~

~~(a) An individual meets the definition of a subject individual; or~~

~~(b) Required by federal law or regulation, by state statute or administrative rule, or by contract or written agreement with the Board.~~

~~(3) Which Criminal Records Check is conducted. When the Board determines under section (2) of this rule that a criminal records check is needed, the Board may request or conduct a LEDS~~

~~Criminal Records Check, an Oregon Criminal Records Check, a Nationwide Criminal Records Check, or any combination thereof.~~

~~Stat. Auth.: ORS 181.534, 676.303, 689.205~~
~~Stats. Implemented: ORS 181.534~~

~~855-010-0065~~

~~Final Fitness Determination~~

~~(1) If the Board elects to conduct a criminal records check, the Board shall make a fitness determination about a subject individual based on information provided by the subject individual under OAR 855-010-0060(1), any criminal records check conducted, and any false statement made by the subject individual.~~

~~(2) In making a fitness determination about a subject individual, the Board will also consider the factors in subsections (a) through (f) below in relation to information provided by the subject individual under OAR 855-010-0060(1), any LEDS report or criminal offender information obtained through a criminal records check, and other information known by the Board. To assist in considering these factors, the Board may obtain any other information deemed relevant from the subject individual or any other source, including law enforcement and criminal justice agencies or courts within or outside of Oregon. To acquire other criminal offender information from the subject individual, the Board may request to meet with the subject individual, and may request to receive written materials or authorization to obtain other relevant information, from the subject individual. The subject individual shall meet with the Board if requested and provide additional information or authorization within a reasonable period of time, as established by the Board. The Board will use all collected information in considering:~~

~~(a) Whether the subject individual has been convicted, found guilty except for insanity (or a comparable disposition), or has a pending indictment for a crime listed in OAR 855-010-0067;~~

~~(b) The nature of any crime identified under section (2)(a) of this rule;~~

~~(c) The facts that support the conviction, finding of guilty except for insanity, or pending indictment;~~

~~(d) Any facts that indicate the subject individual made a false statement;~~

~~(e) The relevance, if any, of a crime identified under section (2)(a) of this rule or of a false statement made by the subject individual to the specific requirements of the subject individual's present or proposed position, services or employment; and~~

~~(f) The following intervening circumstances, to the extent that they are relevant to the responsibilities and circumstances of the services or employment for which the fitness determination is being made:~~

~~(A) The passage of time since the commission or alleged commission of a crime identified under section (2)(a) of this rule;~~

~~(B) The age of the subject individual at the time of the commission or alleged commission of a crime identified under section (2)(a) of this rule;~~

~~(C) The likelihood of a repetition of offenses or of the commission of another crime;~~

~~(D) The subsequent commission of another crime listed in OAR 855-010-0067;~~

~~(E) Whether a conviction identified under section (2)(a) of this rule has been set aside, and the legal effect of setting aside the conviction;~~

~~(F) A recommendation of an employer;~~

~~(G) The disposition of a pending indictment identified under section (2)(a) of this rule;~~

~~(H) Whether the subject individual has been arrested for or charged with a crime listed under OAR 855-010-0067;~~

~~(I) Whether the subject individual is being investigated, or has an outstanding warrant, for a crime listed under OAR 855-010-0067;~~

~~(J) Whether the subject individual is currently on probation, parole or another form of post-prison supervision for a crime listed under 855-010-0067;~~

~~(K) Whether the subject individual has a deferred sentence or conditional discharge in connection with a crime listed under OAR 855-010-0067;~~

~~(L) Whether the subject individual has been adjudicated in a juvenile court and found to be within the court's jurisdiction for an offense that would have constituted a crime listed in OAR 855-010-0067if committed by an adult;~~

~~(M) Periods of incarceration of the subject individual;~~

~~(N) The education and work history (paid or volunteer) of the subject individual since the commission or alleged commission of a crime.~~

~~(3) Refusal to Consent. If a subject individual refuses to submit or consent to a criminal records check including fingerprint identification, the Board will deny the employment of the subject individual or deny any applicable position or authority to provide services. A person may not appeal any determination made based on a refusal to consent.~~

~~(4) If a subject individual is determined to be not fit, the subject individual may not be employed by or provide services as a volunteer to the Board.~~

~~(5) Final Order. A completed final fitness determination is a final order of the Board unless the affected subject individual appeals the determination by requesting a contested case hearing as provided by OAR 855-010-0080(2) or an alternative appeals process as provided by OAR 855-010-0080(6).~~

~~Stat. Auth.: ORS 181.534, 676.303, 689.205~~
~~Stats. Implemented: ORS 181.534~~

~~855-010-0067~~

~~Potentially Disqualifying Crimes~~

~~(1) Crimes Relevant to a Fitness Determination:~~

~~(a) All felonies;~~

~~(b) All misdemeanors;~~

~~(c) Any United States Military crime or international crime;~~

~~(2) Evaluation of Crimes. The Board shall evaluate a crime on the basis of the law of the jurisdiction in which the crime or offense occurred, as those laws are in effect at the time of the fitness determination.~~

~~(3) Expunged Juvenile Record. Under no circumstances shall a subject individual be determined to be not fit under these rules on the basis of the existence or contents of a juvenile record that has been expunged pursuant to ORS 419A.260 and ORS 419A.262.~~

~~Stat. Auth.: ORS 181.534, 676.303, 689.205~~
~~Stats. Implemented: ORS 181.534~~

~~855-010-0070~~

~~Incomplete Fitness Determination~~

~~(1) The Board will close a preliminary or final fitness determination as incomplete when:~~

~~(a) Circumstances change so that a person no longer meets the definition of a "subject individual" under OAR 855-010-0057;~~

~~(b) The subject individual does not submit materials or information within the time required under OAR 855-010-0060;~~

~~(c) The Board cannot locate or contact the subject individual;~~

~~(d) The subject individual fails or refuses to cooperate with the Board's attempts to acquire other criminal records information under OAR 855-010-0065; or~~

~~(e) The Board determines that the subject individual is not eligible or not qualified for the position of employee or volunteer, for a reason unrelated to the fitness determination process.~~

~~(f) The position is no longer open.~~

~~(2) A subject individual does not have a right to a contested case hearing under OAR 855-010-0080(2) or a right to an alternative appeals process under OAR 855-010-0080(6) to challenge the closing of a fitness determination as incomplete.~~

~~Stat. Auth.: ORS 181.534, 676.303, 689.205~~
~~Stats. Implemented: ORS 181.534~~

~~855-010-0075~~

~~Notice to Subject Individual of Fitness Determination~~

~~The Board shall inform the subject individual who has been determined not to be fit on the basis of a criminal records check, via personal service, or registered or certified mail to the most current address provided by the subject individual, of such disqualification.~~

~~Stat. Auth.: ORS 181.534, 676.303, 689.205~~
~~Stats. Implemented: ORS 181.534~~

~~855-010-0080~~

~~Appealing a Fitness Determination~~

~~(1) Purpose: Sections (2) to (5) of this rule set forth the contested case hearing process a subject individual must use to appeal a completed final fitness determination made under OAR 855-010-0065 that the individual is not fit to hold a position with, or provide services to the Board as an employee or volunteer. Section (6) of this rule identifies an alternative appeal process available only to current Board employees.~~

~~(2) Appeal process.~~

~~(a) To request a contested case hearing, the subject individual or the subject individual's legal representative must submit a written request for a contested case hearing to the address specified in the notice provided under OAR 855-010-0075. To be timely, the request must be received by the Board at the specified address within 14 calendar days of the date stated on the notice. The Board shall address a request received after expiration of the deadline as provided under OAR 137-003-0528.~~

~~(b) When a timely request is received by the Board under subsection (a), a contested case hearing shall be conducted by an administrative law judge assigned by the Office of Administrative Hearings, pursuant to the Attorney General's Uniform and Model Rules, "Procedural Rules, Office of Administrative Hearings" OAR 137-003-0501 to 137-003-0700, as supplemented by the provisions of this rule.~~

~~(3) Discovery. The Board or the administrative law judge may protect information made confidential by ORS 181.534(15) or other applicable law as provided under OAR 137-003-0570(7) or (8).~~

~~(4) No Public Attendance. Contested case hearings on fitness determinations are closed to non-participants.~~

~~(5) Proposed and Final Order:~~

~~(a) Proposed Order. After a hearing, the administrative law judge will issue a proposed order.~~

~~(b) Exceptions. Exceptions, if any, shall be filed within 14 calendar days after service of the proposed order. The proposed order shall provide an address to which exceptions must be sent.~~

~~(c) Default. A completed final fitness determination made under OAR 855-010-0065 becomes final:~~

~~(A) Unless the subject individual makes a timely request for a hearing; or~~

~~(B) When a party withdraws a hearing request, notifies the Board or the ALJ that the party will not appear, or fails to appear at the hearing.~~

~~(6) Alternative Process. A subject individual currently employed by the Board may choose to appeal a fitness determination either under the process made available by this rule or through a process made available by applicable personnel rules, policies and collective bargaining provisions. A subject individual's decision to appeal a fitness determination through applicable personnel rules, policies, and collective bargaining provisions is an election of remedies as to the rights of the individual with respect to the fitness determination and is a waiver of the contested case process made available by this rule.~~

~~(7) Remedy. The only remedy that may be awarded is a determination that the subject individual is fit or not fit. Under no circumstances shall the Board be required to place a subject individual~~

~~in any position, nor shall the Board be required to accept services or enter into a contractual agreement with a subject individual.~~

~~(8) Challenging Criminal Offender Information. A subject individual may not use the appeals process established by this rule to challenge the accuracy or completeness of information provided by the OSP, the FBI, or agencies reporting information to the OSP or the FBI.~~

~~(a) To challenge information identified in this section of the rule, a subject individual may use any process made available by the agency that provided the information.~~

~~(b) If the subject individual successfully challenges the accuracy or completeness of information provided by the OSP, the FBI, or an agency reporting information to the OSP or the FBI, the subject individual may request that the Board conduct a new criminal records check and re-evaluate the original fitness determination made under OAR 855-010-0065 by submitting a new Board Criminal Records Request form. This provision only applies if the position for which the original criminal history check was conducted is vacant and available.~~

~~(9) Appealing a fitness determination under section (2) or section (6) of this rule, challenging criminal offender information with the agency that provided the information, or requesting a new criminal records check and re-evaluation of the original fitness determination under section (8)(b) of this rule, will not delay or postpone the Board's hiring process or employment decisions.~~

~~Stat. Auth.: ORS 181.534, 676.303, 689.205~~
~~Stats. Implemented: ORS 181.534~~

~~855-010-0085~~

~~Recordkeeping and Confidentiality~~

~~Any information obtained in the criminal records check is confidential. The Board must restrict the dissemination of information obtained in the criminal records check. Only those persons, as identified by the Board, with a demonstrated and legitimate need to know the information, may have access to criminal records check records.~~

~~Stat. Auth.: ORS 181.534, 676.303, 689.205~~
~~Stats. Implemented: ORS 181.534~~

855-010-0086

State and Nationwide Criminal Background Checks for Employees, Volunteers and Employment Applicants

(1) The Board requires a criminal records check and fitness determination for Board employees, volunteers or applicants for employment with the Board.

(2) Criminal records checks and fitness determinations are conducted pursuant to ORS 181A.170 to 181A.215 and OAR 125-007-0200 to 125-007-0310.

(a) To complete the criminal records check and fitness determination, the Board may require additional information from the employee, volunteer or applicant, such as, but not limited to, proof of identity or additional criminal, judicial or other background information.

(b) If the employee, volunteer or applicant has potentially disqualifying criminal offender information, the Board will consider factors listed in ORS 181A.195 before making a fitness determination.

(c) An approved fitness determination does not guarantee employment.

(d) An incomplete fitness determination does not entitle the employee, volunteer or applicant the right to appeal under OAR 125-007-0300.

(3) Pursuant to ORS 181A.195, ORS 676.175, and OAR 125-007-0310, information obtained in the criminal records check is confidential and will not be disseminated by the Board except to persons with a demonstrated and legitimate need to know the information.

(4) The Board may charge a fee to the employee, volunteer or applicant for the criminal records check . The fee will not exceed the fee charged the Board by the OSP and the FBI to obtain such information.

Stat. Auth.: ORS ~~181.534,~~ 676.303, 689.205 **181A.195**
Stats. Implemented: ~~ORS 181.534~~ **181A.170, 181A.195, 181A.215, 676.175, 676.303**

855-010-0087

Fees

~~(1) The Board may charge a fee for acquiring criminal offender information for use in making a fitness determination that will not exceed the fee charged the Board by the OSP and the FBI to obtain such information.~~

~~(2) The Board may charge the fee to the subject individual on whom criminal offender information is sought.~~

(1) The applicant or licensee must pay a criminal records check fee for the actual cost of acquiring and furnishing the criminal offender information. The fee will not exceed the fee charged the Board by the OSP and the FBI to obtain such information.

(2) The Board may charge a fee to the employee, volunteer or applicant for the criminal records check . The fee will not exceed the fee charged the Board by the OSP and the FBI to obtain such information.

Stat. Auth.: ORS ~~181.534~~, 676.303, 689.205
Stats. Implemented: ORS ~~181.534~~ **689.205**

DRAFT

The proposed rule amendment references new statewide laws related to limited liability for pharmacist volunteers, put forth by ORS 676.340 and ORS 676.345. A pharmacist who has registered and who provides health care services without compensation is not liable for any injury, death or other loss arising out of the provision of those services, unless the injury, death or other loss results from the gross negligence of the health practitioner.

The rule states that pharmacists may claim the state liability limitation upon registration with the Oregon Board of Pharmacy.

Board staff has begun development the required registration process – see Limited Liability Form

855-019-0123

Liability Limitations for Volunteers

(1) A pharmacist may register with the Board for the limitation on liability provided by ORS 676.340, which provides a licensee with specific exemptions from liability for the provision of pharmacy services to defined charitable organizations without compensation under the terms of the law.

(2) A no cost registration may be issued by the Board upon receipt of a completed application. Registration requires submission of a signed form provided by the Board in accordance with ORS 676.345(2).

(3) Registration will expire at the licensee's next license renewal date and may be renewed biennially. It is the licensee's responsibility to ensure his or her active registration in this program.

(4) Nothing in this section relieves licensee from the responsibility to comply with Board regulations and still may be subject to disciplinary actions.

(5) Patients treated under the provisions of ORS 676.340 and 676.345 retain their rights to file complaints against a licensed pharmacist with the Board.

Stat. Auth.: ORS 676.340, 689.205
Stats. Implemented: ORS 676.340, 676.345

Limited Liability Registration

OREGON BOARD OF PHARMACY

Registry for Limited Liability for Pharmacists

Name: _____ License Number: _____

Primary Practice Location Address: _____

City: _____ State: _____ Zip: _____

I certify that:

1. Before providing pharmacy services to the patient, I will obtain the signature of the patient, or the signature of a person who has authority under law to make health care decisions for the patient, acknowledging receipt of a written statement that notifies the patient that services are provided without compensation and that my liability is limited and that I may not be held liable for any injury, death or other loss arising out of the provision of those services that is caused by my negligence unless the injury, death or other loss results from gross negligence.
2. I will provide pharmacy services to patients without compensation, except for reimbursement for laboratory fees, testing services, and other out-of-pocket expenses, which must be authorized by the patient prior to incurring the expense.
3. I will provide without compensation only those services that are within the scope of my active Oregon Pharmacist license.
4. I understand that this registration is effective until the due date of my next renewal, and I must renew biennially for this limited liability to remain in effect.
5. I wish the Board to acknowledge receipt of this form by:

   ☐ A telephone call to: _____

   ☐ An email to: _____

Signature _____ Date: _____

Keep a copy for your files

Mail to: Oregon Board of Pharmacy, 800 NE Oregon St, Ste 150, Portland, OR 97232

676.340 Limitations on liability of health practitioners providing health care services without compensation; requirements; exceptions; attorney fees; applicability. (1) Notwithstanding any other provision of law, a health practitioner described in subsection (7) of this section who has registered under ORS 676.345 and who provides health care services without compensation is not liable for any injury, death or other loss arising out of the provision of those services, unless the injury, death or other loss results from the gross negligence of the health practitioner.

(2) A health practitioner may claim the limitation on liability provided by this section only if the patient receiving health care services, or a person who has authority under law to make health care decisions for the patient, signs a statement that notifies the patient that the health care services are provided without compensation and that the health practitioner may be held liable for death, injury or other loss only to the extent provided by this section. The statement required under this subsection must be signed before the health care services are provided.

(3) A health practitioner may claim the limitation on liability provided by this section only if the health practitioner obtains the patient's informed consent for the health care services before providing the services, or receives the informed consent of a person who has authority under law to make health care decisions for the patient.

(4) A health practitioner provides health care services without compensation for the purposes of subsection (1) of this section even though the practitioner requires payment of laboratory fees, testing services and other out-of-pocket expenses.

(5) A health practitioner provides health care services without compensation for the purposes of subsection (1) of this section even though the practitioner provides services at a health clinic that receives compensation from the patient, as long as the health practitioner does not personally receive compensation for the services.

(6) In any civil action in which a health practitioner prevails based on the limitation on liability provided by this section, the court shall award all reasonable attorney fees incurred by the health practitioner in defending the action.

(7) This section applies only to:

(a) A physician licensed under ORS 677.100 to 677.228;

(b) A nurse licensed under ORS 678.040 to 678.101;

(c) A nurse practitioner licensed under ORS 678.375 to 678.390;

(d) A clinical nurse specialist certified under ORS 678.370 and 678.372;

(e) A physician assistant licensed under ORS 677.505 to 677.525;

(f) A dental hygienist licensed under ORS 680.010 to 680.205;

(g) A dentist licensed under ORS 679.060 to 679.180;

(h) A pharmacist licensed under ORS chapter 689; and

(i) An optometrist licensed under ORS chapter 683. [1999 c.771 §1; 1999 c.771 §3; 2005 c.462 §2; 2012 c.41 §3]

676.345 Registration program for health care professionals claiming liability limitation; program requirements. (1) A health practitioner described in ORS 676.340 (7) may claim the liability limitation provided by ORS 676.340 only if the health practitioner has registered with a health professional regulatory board in the manner provided by this section. Registration under this section must be made:

(a) By a physician or physician assistant, with the Oregon Medical Board;

(b) By a nurse, nurse practitioner or clinical nurse specialist, with the Oregon State Board of Nursing;

(c) By a dentist or dental hygienist, with the Oregon Board of Dentistry;

(d) By a pharmacist, with the State Board of Pharmacy; and

(e) By an optometrist, with the Oregon Board of Optometry.

(2) The health professional regulatory boards listed in subsection (1) of this section shall establish a registration program for the health practitioners who provide health care services without compensation and who wish to be subject to the liability limitation provided by ORS 676.340. All health practitioners registering under the program must provide the health professional regulatory board with:

(a) A statement that the health practitioner will provide health care services to patients without compensation, except for reimbursement for laboratory fees, testing services and other out-of-pocket expenses;

(b) A statement that the health practitioner will provide the notice required by ORS 676.340 (2) in the manner provided by ORS 676.340 (2) before providing the services; and

(c) A statement that the health practitioner will only provide health care services without compensation that are within the scope of the health practitioner's license.

(3) Registration under this section must be made annually. The health professional regulatory boards listed in subsection (1) of this section shall charge no fee for registration under this section. [1999 c.771 §2; 1999 c.771 §4; 2005 c.462 §3; 2012 c.41 §4]

855-019-0123

Liability Limitations for Volunteers

(1) A pharmacist may register with the Board for the limitation on liability provided by ORS 676.340, which provides a licensee with specific exemptions from liability for the provision of pharmacy services to defined charitable organizations without compensation under the terms of the law.

(2) A no cost registration may be issued by the Board upon receipt of a completed application. Registration requires submission of a signed form provided by the Board in accordance with ORS 676.345(2).

(3) Registration will expire at the licensee's next license renewal date and may be renewed biennially. It is the licensee's responsibility to ensure his or her active registration in this program.

(4) Nothing in this section relieves licensee from the responsibility to comply with Board regulations and still may be subject to disciplinary actions.

(5) Patients treated under the provisions of ORS 676.340 and 676.345 retain their rights to file complaints against a licensed pharmacist with the Board.

The proposed rule amendments to *Div 019 Pharmacists* and *Div 041Operation of Pharmacies* update regulations related to PIC expectations in Oregon Pharmacies. The Board adopted rules, effective July 2015, related to the PIC expectations in Non-Resident Pharmacies. Proposed edits will allow consistency in these related rules.

The rule (1) states that a pharmacy must employ a Pharmacist-in-Charge who shall be practicing onsite an average of 20 hours or fifty percent of the pharmacy operating hours if less than 40 hours per week; (2) allows the Board to authorize a temporary timeframe for the minimal hours requirement; (3) permits a pharmacist to be PIC of up to two Oregon Pharmacies; and (4) clarifies reporting requirements of an Oregon Pharmacy.

855-019-0300

Duties of a Pharmacist-in-Charge

(1) In accordance with Division 41 of this chapter of rules, a pharmacy must, at all times have one Pharmacist-in-Charge (PIC) **practicing onsite an average of 20 hours or fifty percent of the pharmacy operating hours if less than 40 hours per week except as authorized by 855-041-1010(2)**~~employed on a regular basis~~.

(2) In order to be a PIC, a pharmacist must have:

(a) Completed at least one year of pharmacy practice; or

(b) Completed a Board approved PIC training course either before the appointment or within 30 days after the appointment. ~~With the approval of the Board, this course may be employer provided and may qualify for continuing education credit.~~

(3) ~~A pharmacist may not be designated PIC of more than two pharmacies without prior written approval by the Board. If such approval is given, the pharmacist must comply with the requirements in sub-section (4)(e) of this rule~~. **A pharmacist may be designated as a PIC of up to two Oregon licensed pharmacies only upon notification of the second site to the Board in writing within 15 days.**

(4) The PIC must perform the following the duties and responsibilities:

(a) When a change of PIC occurs, both outgoing and incoming PICs must report the change to the Board within 15 days of the occurrence, on a form provided by the Board;

(b) The new PIC must complete an inspection on the PIC Annual Self-Inspection Form, within 15 days of becoming PIC;

(c) The PIC may not authorize non-pharmacist employees to have unsupervised access to the pharmacy, except in the case of hospitals that do not have a 24-hour pharmacy where access may be granted as specified in OAR 855-041-~~0120~~ -**6310**;

(d) In a hospital only, the PIC is responsible for providing education and training to the nurse supervisor who has been designated to have access to the pharmacy department in the absence of a pharmacist;

~~(e) A pharmacist designated as PIC for more than one pharmacy shall personally conduct and document a quarterly compliance audit at each location. This audit shall be on the Quarterly PIC Compliance Audit Form provided by the Board;~~

~~(f)~~ **(e)** If a discrepancy is noted on a Board inspection, the PIC must submit a plan of correction within **15 days for a Non-Compliance Notification and** 30 days of receiving a **Deficiency Notification.** ~~notice.~~

~~(g)~~ **(f)** The records and forms required by this section must be filed in the pharmacy, made available to the Board for inspection upon request, and must be retained for three years.

(5) The PIC is responsible for ensuring that the following activities are correctly completed:

(a) An inventory of all controlled substances must be taken within 15 days before or after the effective date of change of PIC, and must be dated and signed by the new PIC. This inventory must be maintained in the pharmacy for three years and in accordance with all federal laws and regulations;

(b) Verifying, on employment and as appropriate, but not less than annually, the licensure of all pharmacy personnel who are required to be licensed by the Board;

(c) Conducting an annual inspection of the pharmacy using the PIC Annual Self-Inspection Form provided by the Board, by February 1 each year. The completed self-inspection forms must be signed and dated by the PIC and maintained for three years from the date of completion;

(d) Conducting an annual inventory of all controlled drugs as required by OAR 855-080;

(e) Performing a quarterly inventory reconciliation of all Schedule II controlled drugs.

(f) Ensuring that all pharmacy staff have been trained appropriately for the practice site. Such training should include an annual review of the PIC Self-Inspection Report;

(g) ~~Implementing a~~ **Overseeing the Continuous** ~~q~~**Q**uality ~~a~~**A**ssurance ~~p~~**P**lan for the pharmacy.

(h) The records and forms required by this section must be filed in the pharmacy, made available to the Board for inspection upon request, and must be retained for three years.

(6) The PIC, along with other licensed pharmacy personnel, must ensure that the pharmacy is in compliance with all state and federal laws and rules governing the practice of pharmacy ~~and that all controlled substance records and inventories are maintained in accordance with all state and federal laws and rules~~.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151, 689.155

DRAFT

855-041-1010

Personnel (Both Retail and Institutional Drug Outlets)

(1) Each **resident** pharmacy must ~~have~~ **employ** one pharmacist-in-charge **(PIC)** ~~employed on a regular basis at that location~~ who shall be responsible for the daily operation of the pharmacy. **The PIC must be practicing onsite a minimum of 20 hours or fifty percent of the pharmacy operating hours if less than 40 hours per week.** The pharmacist-in-charge shall be indicated on the application for a new or relocated pharmacy and for pharmacy renewal registration.

(2) Upon written request the Board may grant a temporary minimal absentee time for the PIC. The request must include the period of time the absentee would be in effect and the reason for the request. An authorization granted under this section will only be effective when issued by the Board in writing.

(3) In the absence of the PIC during an Board approved period, the outlet will be responsible for completion of PIC requirements, such as the annual inventory and PIC Self-Inspection Report.

(4) A resident pharmacy that terminates or allows a Board licensee to resign in lieu of termination must report the termination or resignation to the Board within 10 working days.

(5) ~~(2) The~~ **A** pharmacy must ensure that it is in compliance with all state and federal laws and rules governing the practice of pharmacy~~ and that all controlled substance records and inventories are maintained in conformance with the keeping and inventory requirements of federal law and board rules~~.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151, 689.155, 689.305

The proposed rule amendments to *Div 019 Pharmacists* and *Div 041Operation of Pharmacies* incorporate new statutory language put forth by House Bill 4124 (2016), available at this link: https://olis.leg.state.or.us/liz/2016R1/Downloads/MeasureDocument/HB4124/Enrolled

2016 HB 4124 permits pharmacists to prescribe and distribute unit-of-use packages of naloxone to individuals who conduct or complete OHA approved training. It allows a trainer to possess and distribute naloxone to trainees, and allows trainees to possess and administer naloxone to an individual experiencing an opiate overdose.

The rule (1) gives the purpose; (2) specifies the qualifications of participating pharmacists and individuals; and (3) outlines the delivery of care expectations for the pharmacist and pharmacy, including documentation and recordkeeping.

855-019-0450

Pharmacist Prescribing of Naloxone

Purpose

The purpose of OAR 855-019-0450 through 855-019-0460 is to develop standard procedures for the prescribing of naloxone by a pharmacist in Oregon.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305, 689.681 & 2016 OL Ch. 100

855-019-0455

Qualifications

(1) A pharmacist educated in opiate overdose and naloxone rescue may prescribe unit-of-use naloxone and the necessary medical supplies to administer the naloxone for an individual who:

(a) Conducts training that meets that criteria established by the Oregon Health Authority (OHA) so that the person may possess and distribute naloxone and the necessary medicals supplies to persons who successfully complete the training; or

(b) Has successfully completed training that meets criteria established by the OHA allowing the person to possess and administer naloxone to any individual who appears to be experiencing an opiate overdose.

(2) A pharmacist who prescribes naloxone is required to maintain professional competency.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305, 689.681 & 2016 OL Ch. 100

855-019-0460

Delivery of Care

(1) A pharmacist can distribute naloxone and the necessary medical supplies for administration to a person, organization, or other entity that conducts training. The pharmacist shall document products distributed to a qualified trainer via invoice. Documentation shall be kept on file in the dispensing pharmacy for 3 years and made available to the Board upon request.

(2) A pharmacist can prescribe and dispense naloxone and the necessary medical supplies to an individual who has completed an Oregon Health Authority approved training.

(a) The pharmacist shall determine that the individual seeking naloxone demonstrates understanding of educational materials related to opioid overdose prevention, recognition, response, and the administration of naloxone.

(b) The pharmacist may prescribe naloxone in any FDA approved dosage form. A pharmacist may prescribe the necessary medical supplies needed to administer naloxone.

(c) The pharmacist shall dispense the naloxone product in a container labeled with the following information:

(i) Directions for use;

(ii) Individual's name; and

(iii) Pharmacist's name as the prescriber.

(d) The pharmacist shall provide the trained individual with appropriate counseling and information on the naloxone product dispensed, to include dose, effectiveness, adverse effects, storage conditions, and safety. The individual cannot waive the consultation.

(e) The pharmacist must document the encounter and the prescription, and maintain records for three years.

(3) The pharmacy providing naloxone services must establish, maintain, and enforce written procedures including, but not limited to:

(a) Providing a workflow process and physical location that maintains confidentiality and is not susceptible to distraction; and

(b) Documentation and recordkeeping.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305, 689.681 & 2016 OL Ch. 100

855-041-2340

Pharmacist Prescribing of Naloxone

(1) A pharmacist educated in opiate overdose and naloxone rescue may prescribe unit-of-use naloxone and the necessary medical supplies to administer the naloxone to an individual who:

(a) Conducts training that meets that criteria established by the Oregon Health Authority (OHA) so that the person may possess and distribute naloxone and the necessary medicals supplies to persons who successfully complete the training; or

(b) Has successfully completed training that meets criteria established by the OHA allowing the person to possess and administer naloxone to any individual who appears to be experiencing an opiate overdose.

(2) The pharmacy providing naloxone services must establish, maintain and enforce written procedures including, but not limited to:

(a) Providing a workflow process and physical location that maintains confidentiality and is not susceptible to distraction; and

(b) Documentation and recordkeeping.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305, 689.681 & 2016 OL Ch. 100

The proposed rule amendments to *Div 041Operation of Pharmacies* and *Div 080 Schedule of Controlled Substances* put forth the requirements for a pharmacy to lawfully participate in Drug Take Back initiatives. Congress adopted the Secure & Responsible Drug Disposal act in 2010 and DEA published its Final Rule on Disposal of Controlled Substances in 2014. Additional information is available: http://www.deadiversion.usdoj.gov/drug_disposal/

The rule (1) states that a pharmacy must comply with all DEA regulations for secure and responsible drug disposal (2) directs a pharmacy to notify the Board of its Take Back program (3) outlines the minimum policies and procedures to be established by the pharmacy, including recordkeeping; and (4) prohibits pharmacy staff from handling collected drugs and using the receptacles to dispose of pharmacy stock.

855-041-1045

Returned Drugs and Devices

(1) Pharmacists, pharmacies, pharmacy technicians, and certified pharmacy technicians may only accept the return of controlled substances upon receiving a waiver from the Board of Pharmacy.

(2) Pharmacists, pharmacies, pharmacy technicians, and certified pharmacy technicians may accept the return of drugs or devices as defined by ORS 689.005 once the drugs or devices have been removed from the pharmacy only if;

(a) The drugs or devices are accepted for destruction or disposal and;

(b) The drugs or devices were dispensed in error, were defective, adulterated, misbranded, dispensed beyond their expiration date, were unable to be delivered to the patient, or are subject of a drug or device recall; or

(c) After consultation, a pharmacist determines that, in the pharmacist's professional judgment, harm could result to the public or a patient if the drugs or devices were not accepted for return.

(3) Not withstanding section 2 of this rule, drugs or devices previously dispensed or distributed may be returned and redispensed or redistributed provided all the following conditions are met:

(a) The drug is in an unopened, tamper-evident unit;

(b) The drugs or devices have remained at all times in control of a person trained and knowledgeable in the storage and administration of drugs in long term care facilities or supervised living groups using the services of a consultant pharmacist;

(c) The drug or device has not been adulterated or misbranded and has been stored under conditions meeting United States Pharmacopeia standards.

(4) Upon written request, the Board may waive any of the requirements of this rule if a waiver will further public health or safety or the health and safety of a patient. A waiver granted under this section shall only be effective when it is issued by the Board in writing.

Stat. Auth.: ORS ~~475 & 689~~ **689.205**
Stats. Implemented: **ORS 689.305**

855-041-1046

Secure and Responsible Drug Disposal

(1) A pharmacy registered with the DEA as an authorized collector may collect controlled and non-controlled drugs for destruction in accordance with all applicable federal laws.

(2) A pharmacy that operates a drug take-back collection program shall notify the Board in writing prior initiating the program and shall establish and enforce policies and procedures, including but not limited to:

(a) Provision of secure location of the collection receptacle, which must be accessible to the public and cannot be placed behind the pharmacy counter; and

(b) Provision of adequate security measures, including proper installation and maintenance of collection receptacle, tracking of liners, and key accountability; and

(c) Personnel training and accountability.

(3) Pharmacy personnel shall not count, sort, inventory, or otherwise handle drugs collected.

(4) A pharmacy shall not dispose of quarantined, recalled or outdated drugs from pharmacy stock in a collection receptacle.

(5) A pharmacy shall maintain disposal records for a minimum of 3 years.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305

855-080-0105

Disposal of Drugs

(1) Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other drugs until they are destroyed or returned to their supplier.

(2) Controlled substances which are expired, deteriorated or unwanted shall be disposed of in conformance with ~~**21 CFR 1307.21.**~~ **21 CFR 1317.**

(3) Expired, deteriorated, discontinued, or unwanted controlled substances in a long-term care facility shall be destroyed and the destruction jointly witnessed on the premises by any two of the following:

(a) The consultant pharmacist or registered nurse designee.

(b) The Director of Nursing Services or supervising nurse designee

(c) The administrator of the facility or an administrative designee

(d) A Registered Nurse employed by the facility

(4) The destruction shall be documented and signed by the witnesses and the document retained at the facility for a period of at least three years. Copies of the document shall be sent to the consultant pharmacist. Any destruction of controlled substances deviating from this procedure must be approved by the Board prior to implementation.

(5) Upon written request, the Board may waive any of the requirements of this rule if a waiver will further public health or safety or the health and safety of a patient. A waiver granted under this section shall only be effective when it is issued by the Board in writing.

Stat. Auth.: ORS ~~475.035 &~~ 689.205
Stats. Implemented: ORS 689.305

For proposed language additions to *Div 043 Practitioner Dispensing*, please see related documents: DOJ Final Opinion Dispensing Practitioner Drug Outlet Registration 2.6.2013 and Non-Pharmacy Dispensing Concept Final Version 12.4.2014

Practitioner Dispensing Outlets

855-043-0505

Purpose and Scope

These rules are intended to distinguish between traditional and non-traditional dispensing of drugs by a practitioner who has been granted dispensing privileges from their licensing board and dispenses from their practice location. A practitioner who participates in non-traditional dispensing must register the dispensing outlet with the Board as a Practitioner Dispensing Outlet (PDO).

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305

855-043-0510

Definitions

(1) Traditional dispensing means the dispensing of a drug to a patient by a practitioner, and is:

(a) An FDA manufacturer's sample human drug or medication assistance program (MAP) drug;

(b) A small amount of drugs to start therapy or incidental to a procedure or office visit, up to a 72 hour supply; or

(c) An amount greater than a 72 hour supply if the drug is:

(A) A drug in the manufacturer's original unit-of-use packaging, such as a metered-dose-inhaler; or

(B) A full course of therapy, if in the professional judgment of the practitioner would be in the patient's best interest, such as a course of antibiotic therapy.

(2) Non-traditional dispensing means the dispensing of drugs to a patient and is:

(a) A drug therapy greater than a 72 hour supply, not contemplated within section (1)(c); or

(b) Any refill.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305

855-043-0515

Registration

(1) A practitioner who dispenses a drug must register their dispensing site with the Board as a PDO in the category of Retail Drug Outlet on a form provided by the Board, and must renew its registration annually on a renewal form provided by the Board.

(2) A practitioner is exempt from this registration requirement if practitioner only engages in traditional dispensing.

(3) The initial application must state the location of the PDO and the name of the person applying for registration. When the person applying for registration is not the owner of the dispensing site, the application must disclose the name and address of the owner and the applicant's affiliation with the owner.

(a) If more than one individual owns the dispensing site, the names and addresses of the partners or persons holding the three largest ownership interests in the dispensing site must be disclosed on the application.

(b)If the owner is a corporation, the application must state the name of the corporation as filed with the Corporation Division of the Oregon Secretary of State, including the names of the corporation's officers.

(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.

(5) An initial application must be accompanied by the fee established in division 110 of this chapter. The fee is not to exceed $100.

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

(7) All registration renewal applications must be accompanied by the annual renewal fee (not to exceed $100) established in Division 110 of this chapter and must contain the information required in sections (2) and (3) of this rule.

(8) The PDO registration expires December 31, annually. If the annual renewal fee referred to in section (5) of this rule is not paid by November 30 of the current year, the applicant for renewal must submit the delinquent fee established in division 110 of this chapter with the renewal application.

(9) The registration is not transferable and the registration fee cannot be prorated.

(10) The registrant must notify the Board, within 15 days, of any substantial change to the information provided on the registration application. Substantial change shall include but not be limited to: change of ownership; change of business address; change of normal business hours; any disciplinary action taken or pending by any state or federal authority against the registrant, or any of its principals, owners, directors, officers, consultant pharmacist or supervising physician.

(11) A new registration form is required for a change of ownership or location and must be submitted to the Board with the fees as specified in division 110 of this chapter within 15 days of the change.

(12) The Board may grant a time-limited waiver exempting PDO registration when a practitioner licensing board submits a request to the Board with a plan to annually inspect the dispensing facility to the standards of the Board.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305

Policies and Procedures

855-043-0520

The registered PDO must maintain written policies and procedures for the management of drugs intended for dispensing, to include security, acquisition, storage, dispensing and drug delivery, disposal and recordkeeping . ***BOP will craft a sample set***

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305

855-043-0525

Security

(1) All drugs must be kept in a locked drug cabinet or designated drug storage area that is sufficiently secure to deny access to unauthorized persons. The drug cabinet or designated drug storage area must remain locked and secured when not in use.

(2) No drug dispensing machine may be placed in a waiting room or an area that is accessible by the public.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305,

855-043-0530

Drug Acquisition

The registered PDO must verify that all drugs are acquired from a registrant of the Board.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305,

855-043-0535

Drug Storage

All drugs must be stored according to manufacturer's published guidelines and be stored in appropriate conditions of temperature, light, humidity, sanitation, ventilation, and space.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305

855-043-0540

Labeling

(1) A prescription must be labeled with the following information:

(a) Unique identifier (i.e prescription number);

(b) Name of patient;

(c) Name of prescriber;

(d) Name, address, and phone number of the clinic;

(e) Date of dispensing;

(f) Name and strength of the drug. If the drug does not have a brand name, then the generic name of the drug and the drug manufacturer must be stated;

(g) Quantity dispensed;

(h) Directions for use;

(i) Initials of the dispensing practitioner;

(j) Cautionary statements, if any, as required by law; and

(k) Manufacturer's expiration date, or an earlier date if preferable, after which the patient should not use the drug; and

(l) Any dispensed prescription medication, other than those in unit dose or unit of use packaging, shall be labeled with its physical description, including any identification code that may appear on tablets and capsules.

(2) Not withstanding any other requirements in this rule, when a drug is dispensed in the practice of an Expedited Partner Therapy treatment protocol, as described in OAR 855-041-4000 through 4005, the name of the patient may be omitted.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305

855-043-0545

Dispensing and Drug Delivery

(1) Drugs dispensed from PDO by a practitioner must be personally dispensed by the practitioner.

(2) Prior to dispensing a medication a drug utilization review must be performed by the practitioner which includes but is not limited to drug interactions, drug allergies and duplicate drug therapy.

(3) The practitioner must orally counsel the patient concerning all new drugs, unless circumstances would render oral counseling ineffective.

(4) A PDO must comply with all requirements of State or federal law.

(5) A PDO must dispense a drug in a new container that complies with the current provisions of the Federal Consumer Packaging Act (Public Law 91-601, 91st Congress, S. 2162) and rules or regulations and with the current United States Pharmacopoeia/National Formulary monographs for preservation, packaging, storage and labeling.

(6) Drugs must be prepackaged by the practitioner, a pharmacy, or a manufacturer registered with the Board.

(7) A PDO may not accept the return of drugs from a previously dispensed prescription and must maintain a list of sites in Oregon where drugs may be disposed.

(8) Must have access to the most current issue of at least one pharmaceutical reference with current, properly filed supplements and updates appropriate to and based on the standards of practice for the setting.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305

855-043-0550

Disposal of Drugs

Drugs that are outdated, damaged, deteriorated, misbranded, adulterated, or identified as suspect or illegitimate must be documented, quarantined and physically separated from other drugs until they are destroyed or returned to the supplier.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305

855-043-0555

Record Keeping

(1) A dispensing record must be maintained separately from the patient chart and kept for a minimum of three years. The record must show, at a minimum, the following:

(a) Name of patient;

(b) Unique identifier (i.e. prescription number);

(c) Dose, dosage form, quantity dispensed and either the brand name of drug, or generic name and name of manufacturer or distributor;

(d) Directions for use;

(e) Date of dispensing; and

(f) Initials of person dispensing the prescription.

(2) All records of receipt and disposal of drugs must be kept for a minimum of three years.

(3) All records required by these rules or by other State and federal law must be readily retrievable and available for inspection by the Board.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305

855-043-0560

Inspections

(1) The PDO must complete the Board Self Inspection Form by January 1, annually.

(2) Each PDO will be inspected on a routine basis and shall be scheduled in advance with the practitioner, to occur during normal business hours.

(3) The inspection shall focus on the acquisition, storage, labeling and recordkeeping of drugs intended for dispensing and any violation will apply to the PDO registration and not to the practitioner.

(4) The Board of Pharmacy shall refer any disciplinary action taken against a PDO to the practitioner's licensing Board.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305

ELLEN F. ROSENBLUM
Attorney General

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FEB 7 2013
OREGON BOARD OF PHARMACY

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February 6, 2013

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Re: Opinion Request OP-2013-1

Dear Executive Directors:

Among other things, the State Board of Pharmacy (board) is responsible for regulating the practice of pharmacy in Oregon, which includes issuing licenses to persons to engage in the practice of pharmacy. ORS 689.151. The board is also responsible for issuing "certificates of registration" to "drug outlets." ORS 689.305. Pursuant to ORS 689.225(1), physicians, dentists, veterinarians, osteopaths and "other practitioners of the healing arts" do not need to obtain a license to engage in the practice of pharmacy to administer and dispense drugs to their patients if their own licensing laws authorize them to do so.

The pharmacy, nursing, dentistry, medical, naturopathic, and veterinary boards ask the following question concerning whether the exemption in ORS 689.225(1) affects the drug outlet registration requirement in ORS 689.305.

QUESTION

Are the practice sites of dispensing practitioners who are exempt from the requirement to obtain a license to practice pharmacy under ORS 689.225(1) subject to the "drug outlet" registration requirement imposed by ORS 689.305?

SHORT ANSWER

We conclude that ORS 689.225(1) does not exempt those practice sites from the drug outlet registration requirement. We also conclude, although the answer is not free from all doubt, that those sites are "drug outlets" subject to the registration requirement if drugs are dispensed for consideration from them.

DISCUSSION

A. Methodology

To answer the question, we must interpret several statutes in ORS chapter 689. The Oregon Supreme Court has established the following methodology for interpreting statutes: The goal is to determine the intent of the legislature by first examining the statute's text, in context, and, where appropriate, we also may also consult legislative history to the extent that it is helpful. *PGE v. Bureau of Labor and Industries,* 317 Or 606, 610, 859 P2d 1143 (1993); *State v. Gaines,* 346 Or 160, 171-73, 206 P3d 1042 (2009).

B. Scope of exception in ORS 689.225(1)

ORS 689.225(1) provides that:

> A person may not engage in the practice of pharmacy unless the person is licensed under this chapter. Nothing in this section prevents physicians, dentists, veterinarians, osteopaths or other practitioners of the healing arts who are licensed under the laws of this state from dispensing and administering prescription drugs to their patients in the practice of their respective professions where specifically authorized to do so by law of this state.

ORS 689.151 gives the board authority to regulate and control the practice of pharmacy, including issuing licenses. A qualified applicant may obtain a license to practice pharmacy either by taking an examination or through reciprocity. ORS 689.151(1).

ORS 689.005 contains the definitions as used in chapter 689. Subsection (28)(b) of that statute defines the "practice of pharmacy" to include "[t]he compounding, dispensing and labeling of drugs and devices, except labeling by a manufacturer, packer or distributor of nonprescription drugs and commercially packaged legend drugs or devices." ORS 689.005(28)(b). "Dispense" or

"dispensing" means "the preparation and delivery of a prescription drug pursuant to the lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription drug." ORS 689.005(8).

Read in that context, ORS 689.225(1), generally prevents a person from dispensing drugs unless the person has obtained, through examination or reciprocity, a license to engage in the practice of pharmacy under ORS 689.151(1). But ORS 689.225(1) specifies "[n]othing in this section prevents" Oregon-licensed practitioners of the healing arts who are authorized by their own licensing laws to dispense drugs from dispensing drugs in accordance with their own licensing laws. "Nothing in this section prevents" means nothing in ORS 689.225(1). ORS 689.225(1) prevents only engaging in the practice of pharmacy without having obtained a license and that license is obtained through examination or reciprocity under ORS 689.151(1). Stated another way, this language merely clarifies that ORS 689.225(1) does not require practitioners whose own licensing laws authorize them to dispense and administer prescription drugs to obtain a license under ORS 689.151(1).

ORS 689.225(1) does *not* say that the practice sites of those practitioners are exempt from registration. ORS 689.225(1) is concerned solely with the professional licensing of pharmacists. Other provisions in ORS 689 govern the registration of drug outlets. Specifically, ORS 689.305(1) provides that "[*a*]*ll* drug outlets shall annually register with the State Board of Pharmacy." (Emphasis added). ORS 689.335(1) states that "[n]o drug outlet designated in ORS 689.305 shall be operated until a certificate of registration has been issued to said facility."

We conclude that the legislature did not intend the exemption in ORS 689.225(1) to exempt the practice sites of dispensing practitioners from the drug outlet registration requirement.

The drug outlet registration requirement applies to "all" drug outlets and "no" outlet may operate without a certificate of registration. There are no exceptions. We turn to whether the practice sites of dispensing practitioners are "drug outlets" for purposes of the registration requirement.

C. Definition of drug outlet

ORS 689.005(12) defines a "drug outlet" as:

> [A]ny pharmacy, nursing home, shelter home, convalescent home, extended care facility, drug abuse treatment center, penal institution, hospital, family planning clinic, student health center, retail store, wholesaler, manufacturer, mail-order vendor or other establishment with facilities located within or out of this state that is engaged in dispensing, delivery or distribution of drugs within this state.

There is no question that nursing homes, shelter homes, convalescent homes, extended care facilities, drug abuse treatment centers, penal institutions, hospitals, family planning clinics and student health centers are "drug outlets" subject to the registration requirement regardless of whether practitioners who are exempt from the licensing requirement under ORS 689.225(1) dispense drugs at those places. "Dispensing practitioner's offices" or "dispensing practitioner's clinics," however, are not specifically listed and, therefore, must fit within one of the more general types of listed "drug outlet."

The most general of those is "[a]ny * * * other establishment with facilities located within or out of this state that is engaged in dispensing, delivery or distribution of drugs within this state." The practice sites of dispensing practitioners are engaged in dispensing drugs in Oregon. The question is whether they are "establishments" for purposes of the statute. "Establishment" is not defined for purposes of ORS chapter 689 so we give it its plain meaning. *See PGE v. BOLI;* 316 Or at 610 (providing that, in interpreting the text, we give words that are not statutorily defined, their plain, natural and ordinary meanings).

There are three potentially pertinent plain meanings of "establishment": (1) "something that has been established"; (2) "a more or less fixed and usually sizable place of business or residence together with all the things that are an essential part of it (as grounds, furniture, fixtures, retinue, employees)"; and, (3) "a public or private institution (as a school or hospital)." WEBSTER'S THIRD NEW INT'L DICTIONARY at 778 (2d ed 2002). "Establish," as pertinent, means "to place, install, or set up in a permanent or relatively enduring position especially as regards living quarters, business, social life, or possession." *Id.*

Under those definitions, an "establishment" potentially could mean either a place or an established entity. ORS 689.005(12) refers to "an establishment *with* facilities [whether within or without Oregon]* * * that *is* engaged in dispensing[.]" (Emphasis added). The "establishment" is the drug outlet, rather than the "facilities" because an establishment is singular and the statute uses the singular "is" whereas "facilities" is plural and the statute does not use the plural "are engaged." But an "establishment" could still be a "facility" that has facilities in or outside Oregon. The pertinent definitions of "facility" are "**5a :** something that promotes the ease of any action, operation, transaction, or code of conduct – usually used in the plural < excellent *facilities* for graduate study> **b:** something (as a hospital, machinery, plumbing) that is built, constructed, installed or established to serve some particular function or to serve or facilitate some particular end." WEBSTER'S at 812.

ORS 689.005(12) refers to "other establishment" at the end of a long list, suggesting that the things that preceded "other establishment" on the list are "establishments" too. The list includes both places (such as pharmacies, hospitals and retail stores) and entities, such as a "manufacturer" (defined as "a person" by ORS 689.005(21)), a "wholesaler" (which is not defined, but a "wholesale drug outlet" is defined as "any person" ORS 689.006(36)) and mail order vendors (which is not defined but appears to refer to a type of business entity). The common thread between listed outlets that are not physical places (manufacturer [the definition of which excludes the preparation of drugs by an individual for their own use, ORS 689.005(20)]

wholesaler, and mail order vendor) is that they are entities involved in disseminating drugs in Oregon. Therefore "establishment" does not appear to mean a personal residence no matter how sizeable it is. Nor are those places limited to "institutions."

Turning to other context, the statutes appear to use "drug outlet" somewhat inconsistently. As discussed, some "drug outlets" are defined as persons, rather than facilities. But ORS 689.335(1) prohibits a "drug outlet designated in ORS 689.305" from being operated "until a certificate of registration has been issued *to said facility*." (Emphasis added). "Said facility" necessarily means "drug outlet" for purposes of that statute. On the other hand, while "manufacturer" and "wholesale drug outlets" are defined as "persons," ORS 689.315(4)(a) provides that manufacturers and wholesalers shall acquire a separate registration for each place at which they carry on their business. In those instances, the "manufacturer" or "wholesaler" "person" may have the obligation to apply for a certificate, but the certificate applies to the specific places where they do business.

Another piece of relevant context is the use of the word "establishment" in a related statute in ORS chapter 689. Generally, when the legislature uses the same word in a related statute, we presume that it intends the same meaning. *Tharp v. PSRB,* 338 Or 413, 110 P3d 103 (2005). The legislature uses the term "establishment" in ORS 689.005(34), which defines "shopkeeper" (which is subject to the registration requirement as a "nonprescription drug outlet" under ORS 689.005(22)). A shopkeeper is defined as "a business *or other establishment,* open to the general public, for the sale or nonprofit distribution of drugs." (Emphasis added). That use of "establishment" is particularly pertinent not only because it is used in a related statute, but because the legislature added "other establishment" in that provision at the same time that it added "other establishment" to the definition in ORS 689.005(12). Or Laws 2005, ch 313, section 11. As used in ORS 689.005(34), "other" refers to an "establishment" other than a "business" suggesting both that the legislature considered a "business" to be one type of establishment and that it considered things that were not businesses to be establishments as well. A "business" can be either "a commercial or industrial enterprise" or "a place where such an enterprise is carried on." WEBSTER'S at 302. Other language in the definition of "shopkeeper" specifies that the "business or other establishment" must be "open to the public for the sale or nonprofit distribution of drugs." This provision is helpful context insofar as it shows that the legislature considered both businesses and nonprofits to be types of "establishments."

In short, it is not possible to tell precisely what the legislature intended by "other establishment" as used in ORS 689.005(12), except that it appears to have been intended to encompass both businesses and nonprofit organizations. Although not free from doubt, we conclude that the legislature most likely used the term consistently with ORS 689.335(1), the provision imposing the prohibition on operating a drug outlet without a certificate, in the sense of a facility. Accordingly, "other establishment" most likely includes the facility from which a business or nonprofit organization dispenses, delivers or distributes drugs to Oregonians. The practice sites of dispensing practitioners fit within that definition and, therefore, are "drug outlets," and must annually register with the board pursuant to ORS 689.305(1).

D. Outlet Classification

ORS 689.305(2)(a) requires "[e]ach drug outlet" to apply for a certificate of registration in one or more of five listed classifications: (1) retail drug outlet; (2) institutional drug outlet; (3) manufacturing drug outlet; (4) wholesale drug outlet; or, (5) nonprescription drug outlet. Drug outlets must meet criteria established by the board to qualify for registration in a particular classification. ORS 689.305(3). The board may issue various types of certificates to drug outlets with "varying restrictions" when the board deems it "necessary by reason of the type of drug outlet requesting the certificate." *Id.*

Although the board establishes the criteria to qualify for registration in a particular classification, the classifications themselves are defined by statute (with the exception of manufacturing drug outlet, but "manufacturer" is defined). The definitions of institutional drug outlet, wholesale drug outlet and nonprescription drug outlet do not need to be discussed, because they clearly do not include the places from which practitioners dispense drugs to their patients. The only applicable classification is "retail drug outlet," which is defined as:

> [A] place used for the conduct of the retail sale, administering or dispensing or compounding of drugs or chemicals or for the administering or dispensing of prescriptions and licensed by the board as a place wherein the practice of pharmacy may lawfully occur.

We first note that "retail drug outlet" is defined as "a place," therefore, the certificate of registration in this classification – consistent with ORS 689.335(1) – applies to the facility. A dispensing practitioner's office or clinic fits within a place "used for the conduct of * * * dispensing * * * drugs" and also "for * * * dispensing prescriptions." In fact, those phrases mean exactly the same thing according to the applicable definitions provided in ORS 689.005:

> (8) "Dispensing" or "dispensing" means the preparation and delivery of a prescription drug pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription drug.
>
> (10) "Drug" means:
>
> (a) Articles recognized as drugs in the official United States Pharmacopoeia, official National Formulary, official Homeopathic Pharmacopoeia, other drug compendium or any supplement to any of them;
>
> (b) Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in human or other animal;
>
> (c) Articles, other than food, intended to affect the structure or function of the body of humans or other animals; and
>
> (d) Articles intended for use as a component of any articles specified in paragraph (a), (b) or (c) of this subsection.

> (32) "Prescription * * * means a written, oral or electronically transmitted direction, given by a practitioner authorized to prescribe drugs, for the preparation and use of a drug. When the context requires, "prescription" also means the drug prepared under such written, oral or electronically transmitted direction.

According to those definitions, while any kind of drug may be "administered" only prescription drugs are "dispensed."

That raises the question why the legislature would include both the places used to "dispense drugs" and the places used to "dispense prescriptions" in the definition. We assume that the legislature does not engage in meaningless repetition, but intends all language used to have some independent effect. In other words, we assume that the legislature used "dispense" twice for a reason.

One possible reason is that the definition is intended to be separated into two clauses, the first of which applies to all places that are used to conduct the retail sale, administering or dispensing or compounding of drugs or chemicals" and the second to apply to places used "for the administering or dispensing of prescriptions and licensed by the board as a place wherein the practice of pharmacy may lawfully occur." As to the latter, a "pharmacy" is the only place defined under ORS 689.005 as "a place that * * * is licensed and approved by the board where the practice of pharmacy may lawfully occur[.]" ORS 689.005(26). If the legislature intended "retail drug outlets" to encompass only "pharmacies" (*i.e.,* be subject to the requirement that the place be a licensed pharmacy) it could simply have defined a "retail drug outlet" as a "pharmacy" particularly since "pharmacy" is defined to exclude manufacturers and wholesalers. *Id.* If the only intended distinction was between places that disseminate nonprescription drugs and places that disseminate prescription drugs, "dispensing" would not have been included in the first clause. We conclude that the legislature intended two separate clauses and that the requirement that the place be licensed by the board as a place wherein the practice of pharmacy may lawfully occur apply only to the second

The next question is whether the adjective "retail" as used in the first clause applies to each listed activity (administering, dispensing and compounding) or only to the "sale. "Retail" is not defined, but its plain meaning used as an adjective is "of, relating to, or engaged in the sale of commodities at retail." WEBSTER'S at 1938. The pertinent plain meaning of the verb "retail" is "to sell in small quantities * * * [and] to sell directly to the ultimate consumer." *Id.* "Sale" means "the act of selling: a contract transferring absolute or general ownership of property from one person or corporate body to another for a price (as a sum of money or any other consideration) * * * distinguished from *gift.*" *Id.* at 2003. Although it is reasonable to conclude that "retail" was intended only to modify "sale," there also are reasons to conclude that it may have been intended to modify all the activities for the purpose of imposing two requirements: (1) transfer for consideration; (2) and transfer directly to the ultimate consumer. That interpretation is consistent with the purpose of the provision, which is intended to distinguish a "retail drug outlet" from other types of drug outlets, such as "manufacturing" and "wholesale" drug outlets. "Compounding" is an included activity both in the retail drug outlet definition and in the definition of a manufacturer. Applying "retail" to its use in the retail drug outlet definition

supports the distinction between the two that the classifications are attempting to draw. We also note that practitioner compounding is explicitly excluded from the definition of "manufacturer." *See* ORS 689.005(20) (defining "manufacture" to include the preparation, compounding, packaging or labeling of a drug, but excluding those activities when done "[b]y a practitioner as an incident to administering or dispensing of a drug in the course of professional practice."). No similar exclusion is provided in the definition of "retail drug outlet" suggesting that no exclusion was intended.

The interpretation that "retail" applies to all of the activities in the first clause is also consistent with how the legislature applied a similar modifying term in another definition. ORS 689.005(36) defines "wholesale drug outlet" as "any person who imports, stores, distributes or sells for resale any drugs including legend drugs or nonprescription drugs." Unless the "for resale" language modifies activities other than "sells" in that definition, any "person" who stores drugs would qualify as a "wholesale drug outlet." We doubt that the wholesale drug outlet classification was intended to encompass anyone who stores drugs. We also doubt that the retail drug outlet classification was intended to include compounding by a manufacturer.

We conclude that the text and context suggest that "retail drug outlet" as defined in ORS 689.005(33) most likely includes all places used for dispensing drugs to an ultimate consumer for consideration, including the places where dispensing practitioners dispense medications to their patients for consideration.

E. Legislative History

Finally, we have examined the legislative history, but the history does not change our conclusions based on the text and context. The drug outlet registration requirement was enacted in 1979 as part Senate Bill 866 (1979), which was an overhaul and recodification of the pharmacy code. The issue whether the practice sites of dispensing practitioners were subject to the drug outlet registration requirement was not discussed.

The language "other establishment with facilities within or out of this state that is engaged in dispensing, delivery or distribution of drugs within this state" was not part of the original definition of "drug outlet", but was added to the definition in 2005 as a –A4 amendment to Senate Bill 512. One non-legislator witness testified before a House Committee that the amendment was a "technical amendment" needed to ensure that the Oregon Food Bank could be registered as a drug outlet. The Food Bank wished to provide donated nonprescription drugs to Oregonians. Testimony of Tom Holt, House Health and Human Services Committee (SB 512), May 18, 2005, http://landru.leg.state.or.us.audio at 1:10:00. At the time, no wording in the definition of "drug outlet" fit the Food Bank. As discussed, the definition of "shopkeeper" also was amended at that time to include establishments other than businesses and the nonprofit distribution of drugs.

Although according to the testimony of one non-legislator witness, the reason for requesting the amendment was to ensure that the Oregon Food Bank qualified as a drug outlet, the language that was enacted into law is much broader. The Oregon Supreme Court recently reiterated that:

> [T]here is no more persuasive evidence of the intent of the legislature than the words by which the legislature undertook to give expression to its wishes. Only the text of a statute receives the consideration and approval of a majority of the members of the legislature, as required to have the effect of the law. The formal requirements of lawmaking produce the best source from which to discern the legislature's intent, for it is not the intent of the individual legislators that governs, but the intent of the legislature as formally enacted into law[.]
>
> *Halperin v. Pitts,* 352 Or 482, 486, 287 P3d 1069 (2012).

Finally, we note that, in 2012, the legislature enacted Senate Bill 1565, concerning physician assistant dispensing. Section 2(2)(b) (D) of that bill requires the board to adopt rules that require "[t]he supervising physician or supervising physician organization that applies for dispensing authority for a physician assistant to * * * * * [s]ubmit to the board documentation showing that the supervising physician or supervising physician organization has registered the facility from which the physician assistant will dispense drugs as a drug outlet with the State Board of Pharmacy under ORS 689.305." Although that is a later-enacted statute and does not illuminate the intent of earlier enactments, we point it out merely to demonstrate that our conclusion that ORS 689.305 requires such facilities to be registered is consistent with the legislature's understanding of what ORS 689.305 requires.

F. Conclusion

We conclude that the practice sites of practitioners who dispense drugs for consideration to their patients in accordance with their own professional licensing laws, but who are not required under ORS 689.225(1) to obtain a license to engage in the practice of pharmacy from the board to do so, are "drug outlets" under ORS 689.005(12) and subject to the drug outlet registration requirement in ORS 689.305.

Sincerely,

Steven A. Wolf
Chief Counsel
General Counsel Division

SAW:nog/JUSTICE-#3968819
c: Kyle Martin, DOJ
Tom Cowan, DOJ

Non Pharmacy Dispensing Concept

Objective Obtain cooperation to implement oversight of dispensaries in accordance with current Oregon law via collaborative discussions with all stakeholders to build consensus, eliminate barriers, and develop solutions that work. Reflect on the shared desired outcomes and agree on smart implementation solution, focused on Patient Safety as the priority.

Background The Oregon Board of Pharmacy regulates the commerce of all drugs from the source (manufacturer) to the end user (patient). The Board intends to focus solely on drug acquisition, storage, labeling, and record keeping of non-pharmacy dispensing outlets. The Board does not intend to regulate 'traditional dispensing' of drugs by practitioners.

Concept Summary

- To define the limits of 'traditional dispensing' we may use OAR 855-041-6410 as a potential guide.
  - A selection of drugs to be included, such as:
    - samples
    - small amounts of drugs to start therapy (up to 72 hour supply)
    - short duration therapies incidental to procedure/office visit (up to 72 hour supply)
    - For the intention of this concept, "drug" shall specifically be defined *as FDA-approved human prescription (legend) drugs*
  - Exceptions to > 72 hour supply:
    - Drugs in the manufacturer's original unit-of-use packaging such as inhalers or topical drugs (excludes oral solids)
    - A full course of therapy, such as an antibiotic or steroid taper, may be dispensed if, in the professional judgment of the practitioner, this would be in the patient's best interest.

- To define the threshold of registration of non-pharmacy dispensing outlets, the following are considered outside 'traditional dispensing' and would require registration as a non-pharmacy dispensing outlet:
  - If you utilize automation, such as a vending machine, for drug dispensing
  - If you dispense drugs for therapies > 72 hour supply
  - If you dispense refills (intent to include "continuation of drug therapy")

- Proposed outlet registration fee:
  - Up to $100.00 per year for non-pharmacy dispensing license

- Inspections processes:
  - Inspections will be scheduled in advance with practitioner. Practitioner may choose to invite own licensing Board.
  - BOP staff estimates it will take 30 minutes to inspect a facility
  - Inspection focus will be only on the acquisition, storage, labeling, and record keeping practices of the outlet/facility. Focus will only be on drugs intended for *dispensing* (not administration).

- Compliance process:
  - Compliance via education philosophy
  - Use of Self Inspection form ("open book test")
  - Any violation is on the OUTLET, not the practitioner
  - Practitioner board will be made aware of pharmacy board actions

The proposed rule amendments to *Div 044 Charitable Pharmacies* incorporate new statutory language put forth by Senate Bill 1514 (2016), available at this link: https://olis.leg.state.or.us/liz/2016R1/Downloads/MeasureDocument/SB1514/Enrolled

The rule (1) clarifies that this is an Oregon specific program that allows donations and distribution of donated drugs within Oregon; and (2) prohibits a Charitable Pharmacy from accepting an FDA REMS drug.

DIVISION 44

CHARITABLE PHARMACIES

855-044-0001

Purpose

The purpose of the program is to provide a process to make donated prescription drugs available to needy or uninsured individuals and those with limited access to pharmaceuticals. Under the rules in this Division, a Charitable Pharmacy that is registered with the Oregon Board of Pharmacy (Board) may accept ~~donated~~ drugs for **donation and** distribution **within this state** when the pharmacist can reasonably be assured of the purity and integrity of the drug. The program may not include categories of drugs specified by the Board as excluded from the program.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.772 & 689.774

855-044-0030

Drug Donation

(1) A charitable pharmacy may not accept:

(a) Any controlled substance or any kit, package or blister pack that contains any controlled substance;

(b) A non-prescription drug;

(c) A drug in a container or package that does not contain a product identification label (PIL), except that a drug in a manufacturer's original container or a manufacturer's blister pack does not need to bear a PIL~~;~~.

(d) An FDA REMS (Risk Evaluation and Mitigation Strategy) drug;

(e) A drug donated from another state.

(2) A charitable pharmacy may accept:

(a) A prescription drug received in original, sealed, tamper-evident packaging that displays the lot number and expiration date of the drug; and

(b) Sealed single unit dose packages received in opened packages containing multiple single unit doses.

(3) The following are examples of acceptable packaging:

(a) Manufacturer's original container;

(b) Single-dose blister packs in sealed outer package;

(c) Single-dose blister packs in opened outer package;

(d) Tamper-evident hospice kit containing manufacturer's original containers.

(4) Donated drugs that do not meet the above criteria or are judged by the pharmacist to be unsafe for re-dispensing must be stored separately from the drug supply until they can be destroyed.

(5) A charitable pharmacy may accept a drug from:

(a) An individual;

(b) A long-term care facility;

(c) A pharmacy;

(d) A practitioner who has been given dispensing privileges by their licensing board and is acting within their scope of practice;

(e) Another registered charitable pharmacy;

(f) A medical clinic;

(g) A drug manufacturer or wholesaler;

(h) A Medication Assistance Program (MAP) such as those supported by drug manufacturers.

(6) The donor must certify on a Donor Form provided by the Board that the donated drug has been properly stored, in accordance with manufacturer's recommendations, and has never been opened, used, adulterated or misbranded.

(7) Upon written request, the Board may waive any of the requirements of this rule if a waiver will further public health and safety. A waiver granted under this section shall only be effective when it is issued in writing.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.772 & 689.774

DRAFT

The proposed rule amendment to *Div 080 Schedule of Controlled Substances* adds synthetic opioids/fentanyl derivatives (known as U-47700 and W-18) to Oregon Schedule CI drugs. Schedule I also includes any substituted derivatives of fentanyl that are not specifically listed, or are not FDA approved.

These rules were written with input from the Oregon State Police and subject matter experts.

855-080-0021

Schedule I

(1) Schedule I consists of the drugs and other substances, by whatever official, common, usual, chemical, or brand name designated, listed in 21CFR part 1308.11, and unless specifically excepted or unless listed in another schedule, any quantity of the following substances, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(a) 1,4-butanediol;

(b) gamma-butyrolactone

(c) Methamphetamine, except as listed in OAR 855-080-0022;

(d) dichloro-N-(2-(dimethylamino)cyclohexyl)-N-methylbenzamide (U-47700)

(e) 4-chloro-N-[1-[2-(4-nitrophenyl)ethyl]piperidin-2-ylidene]benzenesulfonamide (W-18)

~~(d)~~ **(f)** Substituted derivatives of cathinone and methcathinone that are not listed in OARs 855-080-0022 through 0026 (Schedules II through V) or are not FDA approved drugs, including but not limited to,

(A) Methylmethcathinone (Mephedrone);

(B) Methylenedioxypyrovalerone (MDPV);

(C) Methylenedioxymethylcathinone (Methylone);

(D) 2-Methylamino-3',4'-(methylenedioxy)-butyrophenone (Butylone);

(E) Fluoromethcathinone (Flephedrone);

(F) 4-Methoxymethcathinone (Methedrone).

(2) Schedule I also includes any compounds in the following structural classes (2a–2k) and their salts, that are not FDA approved drugs, unless specifically excepted or when in the possession of

an FDA registered manufacturer or a registered research facility, or a person for the purpose of sale to an FDA registered manufacturer or a registered research facility:

(a) Naphthoylindoles: Any compound containing a 3-(1-naphthoyl)indole structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent. Examples of this structural class include but are not limited to: JWH-015, JWH-018, JWH-019, JWH-073, JWH-081, JWH-122, JWH-200, JWH-210, AM-1220, MAM-2201 and AM-2201;

(b) Phenylacetylindoles: Any compound containing a 3-phenylacetylindole structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent, whether or not substituted in the phenyl ring to any extent. Examples of this structural class include but are not limited to: JWH-167, JWH -201, JWH-203, JWH-250, JWH-251, JWH-302 and RCS-8;

(c) Benzoylindoles: Any compound containing a 3-(benzoyl)indole structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent. Examples of this structural class include but are not limited to: RCS-4, AM-694, AM-1241, and AM-2233;

(d) Cyclohexylphenols: Any compound containing a 2-(3-hydroxycyclohexyl)phenol structure with substitution at the 5-position of the phenolic ring whether or not substituted in the cyclohexyl ring to any extent. Examples of this structural class include but are not limited to: CP 47,497 and its C8 homologue (cannabicyclohexanol);

(e) Naphthylmethylindoles: Any compound containing a 1H-indol-3-yl-(1-naphthyl)methane structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent;

(f) Naphthoylpyrroles: Any compound containing a 3-(1-naphthoyl)pyrrole structure with substitution at the nitrogen atom of the pyrrole ring whether or not further substituted in the pyrrole ring to any extent and whether or not substituted in the naphthyl ring to any extent;

(g) Naphthylmethylindenes: Any compound containing a 1-(1-naphthylmethyl)indene structure with substitution at the 3-position of the indene ring whether or not further substituted in the indene ring to any extent and whether or not substituted in the naphthyl ring to any extent;

(h) Cyclopropanoylindoles: Any compound containing an 3-(cyclopropylmethanoyl)indole structure with substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent and whether or not substituted in the cyclopropyl ring to any extent. Examples of this structural class include but are not limited to: UR-144, XLR-11 and A-796,260;

(i) Adamantoylindoles: Any compound containing a 3-(1-adamantoyl)indole structure with substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent and whether or not substituted in the adamantyl ring to any extent. Examples of this structural class include but are not limited to: AM-1248 and

AB-001;

(j) Adamantylindolecarboxamides: Any compound containing an N-adamantyl-1-indole-3-carboxamide with substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent and whether or not substituted in the adamantyl ring to any extent. Examples of this structural class include but are not limited to: STS-135 and 2NE1; and

(k) Adamantylindazolecarboxamides: Any compound containing an N-adamantyl-1-indazole-3-carboxamide with substitution at the nitrogen atom of the indazole ring, whether or not further substituted in the indazole ring to any extent and whether or not substituted in the adamantyl ring to any extent. Examples of this structural class include but are not limited to: AKB48.

(3) Schedule I also includes any other cannabinoid receptor agonist that is not listed in OARs 855-080-0022 through 0026 (Schedules II through V) or is not an FDA approved drug.

(4) Schedule I also includes any substituted derivatives of fentanyl that are not listed in OARs 855-080-0022 through 0026 (Schedules II through V) or are not FDA approved drugs, and are derived from fentanyl by any substitution on or replacement of the phenethyl group, any substitution on the piperidine ring, any substitution on or replacement of the propanamide group, any substitution on the phenyl group, or any combination of the above.

~~(4)~~ **(5)** Exceptions. The following are exceptions to subsection (1) of this rule:

(a) 1, 4-butanediol and gamma-butyrolactone when in the possession of a person for the purpose of its sale to a legitimate manufacturer of industrial products and the person is in compliance with the Drug Enforcement Administration requirements for List I Chemicals;

(b) 1,4-butanediol and gamma-butyrolactone when in the possession of a person for the purpose of the legitimate manufacture of industrial products;

(c) Marijuana and delta-9-tetrahydrocannabinol (THC).

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 475.035, 475.059 & 475.065