

Oregon Board of Pharmacy
BOARD MEETING AGENDA
Meeting Location:
Portland State Office Building
800 NE Oregon Street, Portland, OR 97232
June 6-7, 2018
Updated 6.4.18

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, June 6, 2018 @ 8:30AM – Conference Rm A
Thursday, June 7, 2018 @ 8:30AM – Conference Room A

≈ If special accommodations are needed for you to attend or participate in this Board Meeting, please contact
Loretta Glenn at: (971) 673-0001. ≈

WEDNESDAY, JUNE 6, 2018

I. 8:30AM OPEN SESSION, Penny Reher, R.Ph, Presiding

A. Roll Call

B. 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. Deficiency Notifications
4. Case Review

B. Employee Performance Review pursuant to ORS 192.660(2)(i).

IV. OPEN SESSION - PUBLIC MAY ATTEND - At the conclusion of Executive Session, the Board may convene Open Session to begin some of the following scheduled agenda items - **time permitting at approximately 3:30PM.**

V. 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 – none
2. MPJE Scores – none

3. License/Registration Ratification – March 23, 2018 – May 25, 2018
4. Pharmacy Technician Extensions – March 5, 2018 – May 31, 2018
5. Board Minutes – February 7-8, 2018, May 2, 2018

VI. ISSUES/ACTIVITIES

A. Board Meeting Dates

• August 8-10, 2018*	Portland	(*3 day meeting)
• October 3-4, 2018	Portland	
• November 7, 2018	Portland	(<i>Strategic Planning</i>) note changed to 1 day
• December 12-13, 2018	Portland	
• February 6-8, 2019*	Portland	(*3 day meeting)
• April 3-4, 2019	Portland	
• June 5-6, 2019	Portland	
• August 7-9, 2019*	Portland	(*3 day meeting)
• October 2-3, 2019	Portland	
• November 6-7, 2019	Portland	(<i>Strategic Planning</i>)
• December 11-12, 2019	Portland	

B. Rulemaking Hearing Dates

(The following dates are reserved for potential rulemaking hearings and identified only for planning purposes and approved by the Board. Actual Rulemaking Activities will be noticed as required by law and may deviate from this schedule as needed.)

- November 27, 2018
- May 22, 2019
- November 26, 2019

C. Committees/Meetings

1. OSHP Annual Meeting – 4/27-29/2018, Gleneden Beach – *Watt/Karbowicz*
2. NABP 114th Annual Meeting – 5/5-8/2018, Denver, CO – **#A & A1**
DeBarmore/Watt/Karbowicz
3. NABP District VI-VIII, Mtg Kansas City, MO 10/14-17/2018 **#A2** *MacLean*
Action Necessary

D. Board Member/Staff Presentations – *Reher*

- Linn Benton – 4/17/18 – *Baldwin/Gin*
- Pharmacy Coalition – 5/8/18 – *Efremoff/MacLean*
- Professional Practice Roundtable – 5/22/18 – *Watt/Karbowicz*

E. Financial/Budget Report – *Watt/MacLean* **#B**

F. Legislative update – *Watt*

G. Reports:

1. Board President/Members
2. Executive Director
3. Board Counsel
4. Compliance Director
5. Pharmacist Consultant
6. Administrative Director
7. Licensing Program Supervisor

8. Project Manager

Adjourn

THURSDAY, JUNE 7, 2018

8:30AM

VII. OPEN SESSION, Penny Reher, R.Ph, Presiding

A. Roll Call

B. Motions for Contested Cases & Disciplinary Action

Action Necessary

VIII. GENERAL ADMINISTRATION

A. Rules

*First Look ** Second Look *** Third Look **** Fourth Look

1. Review Rulemaking Hearing Report & Comments **#C**

2. Consider Adoption of Rules

• Div 019 – Naloxone Temp to Perm Rule**** **#C1 & C1a**

• Div 020 – Formulary Committee** **#C2**

• Div 045 – Compounding**** **#C3, C3a, C3b, C3c, C3d**

3. Consider Adoption of Temporary Rules - *none*

4. Rules Review –

5. Rules Advisory Committee – update

6. Consider Rules and send to Rulemaking Hearing - *none*

7. Policy Issues for Discussion - *Efremoff/Karbowicz*

• Prioritize Rulemaking Initiatives **#C4** (carry over from April 2018)

• Authority and Continuation of Therapy draft rules/policy

B. Discussion Items

1. Waiver Requests –

i. Partners in Care request **#D** *Efremoff*

Action Necessary

2. Expedited Partner Therapy – *Reher*

3. Technician Research Council update – Karbowicz **#D2, D2a**

APPEARANCE

Action Necessary

11:20 AM Emilio DeBess, DVM, MPH - Oregon Veterinary Board President and
State Public Health Veterinarian

Dr. Allison Lamb, DVM and Oregon Veterinary Board Member

Lori Makinen, Executive Director – Oregon Veterinary Board

Re: Veterinary Board proposal request - **#E, Ea** *Efremoff*

Certified Euthanasia Technicians & ORS 475.185 **#E1** CONFIDENTIAL - *Efremoff*

Noon – Lunch break (*Some or all of the items below may occur before or after lunch depending on the length of the Board's discussions.*)

C. Public Health and Pharmacy Formulary Advisory Committee – *Watt/Karbowicz*

1. Committee meeting update

Agenda – June 6-7, 2018

NOTE: The Board may rearrange its agenda to accommodate the Board or members of the public.

Page 3 of 4

2. Committee Recommendation update

D. Strategic Planning – Watt/MacLean

- Planning for 2018 session update

1:00PM

IX. ANNUAL BOARD BUSINESS MEETING (1.00 hr)

- A. Recognition of outgoing Board Member Kate James *Action Necessary*
- B. Election of New Officers *Action Necessary*
- C. Approval of ACPE accredited schools & colleges of pharmacy **#F** *Action Necessary*
- D. Approval of ACPE Continuing Education Process **#F** *Action Necessary*
- E. Update on Board appointments
 - a. Wassim Ayoub - Pharmacist Member – appointed, effective 7/1/18
- F. Review / Reports & Committee/Council appointments & Updates
 - a. *Rural Health Coordinating Council – reappointment consideration*
 - i. Leanne Yantis **#F1 & F2** *Action Necessary*
 - b. *Oregon Board of Naturopathic Medicine Formulary Council* **#F3**
 - c. *Oregon Patient Safety Commission* **#F4**
 - d. *Immunization Policy Advisory Team* **#F5**
 - e. *Council on Optometric Non-Topical Formulary - update*
 - f. *Oregon Board of Nursing Home Administrators - update*
- G. Schedule of Administrative Fees - Review & Update **#F6** *Action Necessary*
- H. Approve current version of Fed. List of Controlled Substances **#F8** *Action Necessary*
- I. Review the TOEFL NABP updates – none
- J. Affirm use of 7/2014 AG's Model Rules of Procedure **#F7** *Action Necessary*
- K. Review and revise? Board's A, B & C document (*Delegated Authority to Staff, Board Policies and Compliance Guidelines*) **#** *Action Necessary*
- L. Review & affirm Board Per Diem Policy **#F10** *Action Necessary*
- M. Five Year Rule Review Update *Action Necessary*
- N. Board Best Practices Performance Measure review **#F12** *Action Necessary*

X. OPEN FORUM – *At the completion of regular Board business, the Board provides an opportunity to make comments or present issues of general interest. The Board will not deliberate any issues or requests during Open Forum. Therefore, Open Forum should not be used to make formal requests to the Board, nor to address issues currently under investigation or requests pending before the Board. If you wish to be called upon, please sign up on the sheet at the podium in advance for inclusion.*

XI. EXECUTIVE SESSION – NOT OPEN TO THE PUBLIC pursuant to ORS 192.660(2)(i)

- A. Employee Performance Review

XII. Open Session

Adjourn

JUNE 2018 / A

Transitions in Pharmacy Regulation

Marc Watt, RPh & Fiona Karbowicz, RPh

114th NABP Annual Meeting
May 5-8, 2018
Denver, Colorado

TO CLIMB *UPWARD*,
WE MUST THINK *FORWARD* 



Specific Goals

- ❖ Share Oregon's insights and experiences addressing pharmacist prescribing scope
- ❖ Discuss considerations on the horizon for the evolution of pharmacy regulation



TO CLIMB *UPWARD*,
WE MUST THINK *FORWARD* 

Assessment Question

JUNE 2018 / A

True or False?

Current regulatory processes are sustainable for all new scopes of pharmacy advancements.



TO CLIMB *UPWARD*,
WE MUST THINK *FORWARD* 

Assessment Question

JUNE 2018 / A

Which of the following is TRUE regarding the expansion of pharmacist scope of practice?

- A. Distributing and dispensing of medications will no longer be a pharmacist responsibility.
- B. Developing and implementing a peer review process will assist in sustaining the enforcement and compliance of prescribing services.
- C. As prescriptive services continue to evolve, documentation will become less crucial as pharmacists will be viewed as prescribers.



TO CLIMB *UPWARD*,
WE MUST THINK *FORWARD* 

Assessment Question

JUNE 2018 / A

Which of the following recommendations for the Oregon Public Health and Pharmacy Formulary Advisory Committee to review are not included in the statutory language?

- A. Rapid strep tests
- B. Albuterol MDIs
- C. Diabetic testing supplies
- D. Discharge medications for transitions of care
- E. All of the above are suggested in ORS 689.649



TO CLIMB *UPWARD*,
WE MUST THINK *FORWARD* 

Current Regulatory Processes

JUNE 2018 / A

- Rules for the drug outlet
 - or PLACE where drugs are and where the practice of pharmacy occurs
- Rules for the licensees
 - or PEOPLE who work with the drugs



TO CLIMB *UPWARD*,
WE MUST THINK *FORWARD* 

Current Regulatory Processes

JUNE 2018 / A

- Complexities pose challenges for licensure & compliance
 - Practice Evolution
 - Specialization
 - Board Resource Allocation



TO CLIMB *UPWARD*,
WE MUST THINK *FORWARD* 

Rule Writing

JUNE 2018 / A

- Updating current rules or writing new rules
 - Early step: Determine level of rule detail necessary for patient safety outcome
 - Consider building in flexibility, when appropriate
 - Obtain public and stakeholder input
- Clearly articulated Board expectations are key, both rule and policy



TO CLIMB *UPWARD*,
WE MUST THINK *FORWARD* 

Process – Contraceptive Prescribing

- 2015 → Oregon HB 2879
 - Overall Directive: The Oregon Board of Pharmacy shall adopt rules to establish standard procedures for the prescribing of contraceptives by a pharmacist.
 - Statutory Details:
 - In consultation with Medical Board, Health Authority, and SMEs
 - RPH Training Program
 - Self-Screening Risk Assessment Tool for Patient
 - Prohibit appointments



Process – Contraceptive Prescribing

JUNE 2018 / A

- OBOP Rule Construction
 - Determine level of details needed to ensure safe patient outcomes
 - Decision? Detailed rules necessary



TO CLIMB *UPWARD*,
WE MUST THINK *FORWARD* 

Process – Contraceptive Prescribing

JUNE 2018 / A

- Statewide expectation to succeed
- Envisioned success and positive patient outcomes...
...would be based on pharmacist engagement
 - Empower and inspire the pharmacist to participate
- How?
 - Build awareness and comprehension



TO CLIMB *UPWARD*,
WE MUST THINK *FORWARD* 

Process – Contraceptive Prescribing

- Robust Training Program developed
 - Competency assurance
- Algorithm developed (*Consistent care* → *Safe care*)
 - Step-by-step patient “workup” outlined in detail
- Without this focused process, Oregon would not have seen the large-scale implementation



Take-Aways

- State association partnerships are critical
- Legislative relationships are essential
- Learning from other health care providers is advised
- Process not sustainable for ALL new scope advancements



TO CLIMB *UPWARD*,
WE MUST THINK *FORWARD* 

Considerations

- General, less prescriptive rules needed moving forward
- Consider incorporating existing foundational elements defining standard of care
 - APhA Pharmacist Patient Care Process
- Peer Review



Oregon Contraceptive Prescribing

JUNE 2018 / A

- Success!
- Certified pharmacists are available in over 60% of Oregon zip codes in the state
- Billing realities
- Ongoing OBOP efforts



TO CLIMB *UPWARD*,
WE MUST THINK *FORWARD* 

EVOLUTION of PRESCRIBING Beyond Contraceptives



TO CLIMB *UPWARD*,
WE MUST THINK *FORWARD* 

Lessons Learned

- Training was necessary
- Algorithm or Protocol was necessary
- Certificate or credential required for reimbursement
- Not all pharmacists knew or understood the limitations of their authority
- Ongoing training and clinical review required



Success leads to....

- Legislators asked, “What else can pharmacists do?”
- State-specific political realities
 - 2015 – Autonomous prescriptive authority for contraceptives
 - 2016 – Autonomous prescriptive authority for naloxone
- State pharmacy associations collaborated with OBOP to craft language for 2017 HB 2397



2017 HB 2397

JUNE 2018 / A

- Statutory directive: A pharmacist may prescribe from a formulary of post-diagnostic drugs and devices or protocols established by a committee convened by the Board.
- The Public Health and Pharmacy Formulary Advisory Committee shall consist of:
 - 2 MDs / 2 NPs / 3 Pharmacists
- Committee reviews concept submissions/requests and makes recommendations to the Board to adopt by rule
- Codified as [ORS 689.649](#)



TO CLIMB *UPWARD*,
WE MUST THINK *FORWARD* 

Committee Considerations

JUNE 2018 / A

- The PHPFAC membership was appointed and has met twice so far this year
- Addressed and recommended items:
 - Extension of Prescription Therapy
 - Devices
 - Certain Cough & Cold remedies (OTC and Rx)



TO CLIMB *UPWARD*,
WE MUST THINK *FORWARD* 

Addressing Pharmacist Prescriptive Authority

JUNE 2018 / A

- Next step: Write rules and policy
- Recall that:
 - Process of OBOP creating training, protocol, templates, etc., not sustainable for ALL new scope advancements
- Consider foundational elements articulating standard of practice



TO CLIMB *UPWARD*,
WE MUST THINK *FORWARD* 

Paradigm

JUNE 2018 / A

- Entering into the new arena of advanced pharmacy practice is like building an addition to an existing house
 - Addition: New authorities, such as prescribing
 - But we are not moving into a new house...
 - **Must continue to keep our current house in order *as well***



TO CLIMB *UPWARD*,
WE MUST THINK *FORWARD* ➤

Addressing Pharmacist Prescriptive Authority

- Determine specificity of rules necessary for positive outcomes
- What administrative rules are needed for safe, competent practice and for investigations/citations versus what can the Board put forth as policy directives?
- Are policy directives enforceable in an administrative law hearing?



Compliance and Enforcement

JUNE 2018 / A

- The Board must evolve its processes
 - Investigation of cases / Inspections of Pharmacy Outlets
 - Increased reliance on a peer review process to evaluate a pharmacist's decision-making
- The public expects us to regulate the practice in order to maintain patient safety



TO CLIMB *UPWARD*,
WE MUST THINK *FORWARD* 

Additional Considerations

- Only a pharmacist can practice pharmacy
- The Board has a peripheral role to play in the billing, credentialing and privileging processes
 - Assimilate into existing constructs
 - Implications for pharmacist malpractice
- Optimal patient care necessitates the pharmacist activities become part of the EHR



Past & Present → Future

JUNE 2018 / A

- Pharmacists role is evolving and expanding
- Distribution, drug delivery, and dispensing will continue to be foundational to the practice
- Boards must proactively determine their approach to pharmacy regulation in tandem with evolution/expansion



TO CLIMB *UPWARD*,
WE MUST THINK *FORWARD* 

Assessment Questions

JUNE 2018 / A

True or False?

Current regulatory processes are sustainable for all new scopes of pharmacy advancements.



TO CLIMB *UPWARD*,
WE MUST THINK *FORWARD* 

Assessment Questions

JUNE 2018 / A

True or **False**?

Current regulatory processes are sustainable for all new scopes of pharmacy advancements.



TO CLIMB *UPWARD*,
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Assessment Questions

JUNE 2018 / A

Which of the following is TRUE regarding the expansion of pharmacist scope of practice?

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Assessment Questions

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NABP May 9, 2018

Delegates Approve Six Resolutions at the NABP 114th Annual Meeting

<https://nabp.pharmacy/resolutions-nabp-annual-meeting-2018/>

Save the Date

NABP/AACP
Districts VI, VII & VIII
Annual Meeting

The Westin Kansas City at Crown Center
Kansas City, Missouri
October 14~17, 2018



BOARD OF PHARMACY
AY19 CASH FLOW - March 2018
OF Appn 30235

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							
0205 Other Business Licenses	4,431,667	4,431,667		4,431,667	1,746,653	2,685,015	39%
0210 Other NonBusiness Licenses and Fees	505,552	505,552		505,552	68,262	437,290	14%
0505 Fines and Forfeits	420,000	420,000		420,000	197,154	222,846	47%
0605 Interest and Investments	48,000	48,000		48,000	57,961	(9,961)	121%
0975 Other Revenue	39,700	39,700		39,700	38,933	767	98%
SubTotal Revenue	5,444,919	5,444,919	0	5,444,919	2,108,963	3,335,956	39%
TRANSFERS							
2443 Transfer out to OHA--Workforce Data	(409,357)	(409,357)		(409,357)	23,388	(432,745)	-6%
2443 Transfer out to OHA--PDMP program	-	0	0	0	-	0	0%
SubTotal Transfers	(409,357)	(409,357)	0	(409,357)	23,388	(432,745)	-6%
TOTAL REVENUE & TRANSFERS	5,035,562	5,035,562	0	5,035,562	2,085,575	3,768,701	41%
PERSONAL SERVICES							
3110 Regular Employees	3,191,268	3,191,268	104,724	3,295,992	1,182,158	2,113,833.64	36%
Board Member Stipends	-	-	-	0	-	-	-
3160 Temporary Appointments	25,222	25,222	-	25,222	-	25,222	0%
3170 Overtime Payments	-	-	-	0	283	(283)	0%
3190 All Other Differential O/Class Lead V	183,457	183,457	-	183,457	72,268	111,189	39%
3210 Employment Relations Board Assess	1,083	1,083	-	1,083	379	704	35%
3220 Public Employees Retirement Contrib	504,012	504,012	3,269	507,281	173,427	333,854	34%
3221 Pension Bond Contribution	195,224	195,224	(3,502)	191,722	73,208	118,514	38%
3230 Social Security Taxes	256,020	256,020	-	256,020	90,194	165,826	35%
3240 Unemployment Assessment	-	-	-	0	-	-	0%
3250 Workers' Compensation Assessment	1,380	1,380	-	1,380	371	1,009	27%
3260 Mass Transit Tax	20,334	20,334	-	20,334	7,495	12,839	37%
3270 Flexible Benefits	666,720	666,720	24,720	691,440	237,488	453,952	34%
3455 Vacancy Savings-ORBITS only	(169,448)	(169,448)	-	(169,448)	-	(169,448)	0%
3465 Reconciliation Adjustment-ORBITS only	-	-	-	0	-	-	0%
3470 Undistributed Personal Services-ORBITS	-	-	-	0	-	-	0%
3991 PERS Policy Adjustment-ORBITS	-	-	-	0	-	-	0%
SubTotal Personal Services	4,875,272	4,875,272	129,211	5,004,483	1,837,273	3,167,210	37%
SERVICES AND SUPPLIES							
4100 InState Travel	102,270	102,270	Proj all	102,270	32,475	69,795	32%
4125 Out of State Travel	15,724	15,724	-	15,724	1,526	14,198	10%
4150 Employee Training	52,335	52,335	-	52,335	6,060	46,275	12%
4175 Office Expenses	123,883	123,883	-	123,883	22,283	101,600	18%
4200 Telecommunications	43,879	43,879	-	43,879	14,158	29,721	32%
4225 State Govt. Service Chgs.	119,969	119,969	-	119,969	56,429	63,540	47%
4250 Data Processing	73,694	73,694	-	73,694	18,275	55,419	25%
4275 Publicity & Publications	37,712	37,712	-	37,712	4,349	33,363	12%
4300 Professional Services	402,408	402,408	-	402,408	102,248	300,160	25%
4315 IT Professional Services	353,340	353,340	-	353,340	10,500	342,840	3%
4325 Attorney General	326,595	326,595	-	326,595	205,834	120,761	63%
4375 Employee Recruitment & Develop	207	207	-	207	-	207	0%
4400 Dues & Subscriptions	4,583	4,583	-	4,583	1,435	3,148	31%
4425 Facilities Rent & Taxes	219,519	219,519	-	219,519	63,324	156,195	29%
4475 Facilities Maintenance	51	51	-	51	70	(19)	138%
4525 Medical Supplies and Services	1,110	1,110	-	1,110	1,910	(800)	172%
4575 Agency Program Related S&S	229,434	229,434	-	229,434	63,041	166,393	27%
4650 Other Services & Supplies	278,652	278,652	-	278,652	123,388	155,264	44%
4700 Expendable Property	10,499	10,499	-	10,499	689	9,810	7%
4715 IT Expendable Property	43,976	43,976	-	43,976	3,496	40,480	8%
5550 Data Processing Software	-	-	-	0	-	-	0%
5600 Data Processing Hardware	8,296	8,296	-	8,296	-	8,296	0%
SubTotal Services and Supplies	2,448,136	2,448,136	-	2,448,136	731,489	1,716,647	30%
SPECIAL PAYMENTS							
6085 Other Special Payments	11,991	11,991	-	11,991	-	11,991	0%
6443 Special Payments to OHA-HPSP	-	-	-	-	-	-	0%
SubTotal Transfers	11,991	11,991	0	11,991	0	11,991	0%
Total Expenditures Budget	7,335,399	7,335,399	129,211	7,464,610	2,568,762	4,895,848	34%
7,057,070							
LAB % PS	66%			67%		Target	100%
LAB % S&S	33%			33%			
LAB % SP	0%			0%			

AY17 Ending Cash Balance	Cash	4,794,930
Revenue less Expenditures	Actuals	2,085,575
Total Revenue & Transfers		(2,568,762)
Total Expenditures		(483,187)
Total Revenues & Transfers less Expenditures		4,311,743
AY19 Cash Balance after the Fiscal Month Closed		
Budgeted Revenues not yet received (zero) less Estimated Transfers to OHA-PMP & Workforce Data program to be mac		0
Budgeted Expenditures not yet spent		(4,895,848)
AY19 Estimated Cash Balance		(584,106)
Cash Balance Contingency (Months)		(1.91) months

Revenue received is more than budgeted so zero is not yet received



Oregon

Kate Brown, Governor

JUNE 2018 / C

Oregon Board of Pharmacy

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Date: May 25, 2018

To: Oregon Board of Pharmacy

From: Mo Klein

Subject: Hearings Officer's Report on Rulemaking Hearing

Hearing Date: May 23, 2018

Hearing Location: Portland State Office Building, Room 1A

Title of Proposed Rules: OAR 855-020-0105

**The composition and function of the Public Health and Pharmacy
Formulary Advisory Committee**

OAR 855-019-0460

**Amend naloxone prescribing rules related to possession, distribution
and counseling**

OAR 855-080-2200

Repeals outdated and adopts new drug compounding rules

Proposed: OAR 855-045-0200, 855-045-0210, 855-045-220, 855-045-230,
855-045-240, 855-045-250, 855-045-260, 855-045-270, 855-045-0500,
855-045-0510, 855-045-0520, 855-045-0530, 855-045-0540, 855-045-
0550, 855-045-0560, 855-045-0570, 855-045-0600, 855-045-0610, 855-
045-0620, 855-045-0630

Repeal: 855-045-0200 through 855-045-0630

The rulemaking hearing on the proposed rules was convened at 9:30 a.m. People were asked to sign the registration list if they wished to comment on the proposed rules and were informed of the procedures for making comments. They were also told that the hearing was being recorded.

Copies of the proposed rules were available for attendees.

Attendance included about 20 public, 8 OBOP Staff, 6 OBOP Board members

The following pages include a staff response to the comments collected during this rulemaking cycle, summaries of the oral and written comments, and copies of all written comments. An audio file is available of the hearing which includes all oral comments.

Summary of Oral Comments
Rulemaking Hearing May 23, 2018; 9:30 a.m.
Audio file available

Formulary Committee

None

Naloxone

Rob Nutt, Oregon Department of Corrections

Asked a question, can Naltrexone could be included in the Naloxone rule.

Compounding

Eric Lintner, Consonus Health

Extra licensing for Sterile Compounding.

Primarily a question from Eric regarding the proposed inspections. He wonders how they will work, what is the entity who will inspect, will there be an extra cost for the inspection, what type of inspection will be required. Depending on what this inspection will include, it may be onerous. (No written comments submitted.)

Dan Rackham, Samaritan Lebanon Community Hospital

Does not think these rules are ready for implementation. There are many questions on the rules as written. He submitted a written comment with details.

Also questions on a BUD for repackaged injectable opioids, during a current shortage, from 30 hours to 6 days. This is sterile compounding.

Adam Gustafson, Natalie Gustafson, Lloyd Center Pharmacy

Submitted a written comment that is a detailed look at the proposal, with many specific questions and suggestions for rewording. Their first proposal is to refer to the USP standards, if that is not possible, they suggest a detailed overhaul of the language to ensure a workable set of rule for compounding.

Jacob Thompson, Providence Health and Services

Submitted a written testimony. Looks at USP as the gold standard, would encourage 'meet the current USP standards'. Also, does not like the portion that allows compounding for items not commercially available. Would like OBOP to allow a better method to get proposed rules to stakeholders, and allow time for their review and discussion.

Kyle Mulder, Technical Safety Services

Sent a comment on the self-checklist being out of date

Marty Hiers, NW Compounding Pharmacy (Roseburg OR)

Intention is great, but pitfalls in wording. One fear is that the final wording of USP is not known. Also, the cost of compliance of USP is not known. The container closures are requested by patients, which may pose issues. The "difficult to compound" may cause issues. A committee may be warranted for review of the new rules. He does not see the benefit of many of the items being proposed.

Eric Lintner (2nd comment), Consonus Health

Certification - Past issues have been with companies not following the existing rules. Seems unfair and expensive to add additional regulation to the companies following the rules. Does not see improved safety for patients by the new rules. Supports USP as a better solution, for interpretation and compliance, vs each state having their own different rules.

Summary of Written Comments

Naloxone Rule

None

Formulary Committee Rules

None

Compounding Rules Summary of each response

AAD and ASDSA (Dermatologists) – does not want physician offices to be under the purview of OBOP, encourages OBOP to wait until the USPs are finalized, would like a longer time period for ‘immediate use’, and is concerned that the cost to comply with regulations in offices will be extremely high.

ASPS PSF (Plastic Surgeons) – would like to see office (non-sterile) compounding not included in rules. Suggests that physicians keep a log in patients’ medical record that covers medications that were compounded.

CVS (Paul) – Encourages OBOP to refer to USP instead of creating their own language. They do support the registration of compounders, and the inspection of the same. They have submitted several language changes if OBOP determines to move forward with their own compounding language.

Lloyd Center Pharmacy (Gustafson) – Listed many issues with the proposed text for compounding, on a section by section basis.

Lloyd Center Pharmacy (2)(Gustafson) – concern with outside agency inspections, and does not think inspecting only in-state, sterile, compounders provides a level playing field. Would like to see all compounders inspected, including out of state.

NW Compounding (Marty Hiers) – concern about inspection by non-OBOP personnel, also isn’t convinced USP 795 and 797 are going to be helpful to Oregon Compounders. Does not think the proposed Oregon rules are ready to adopt as more clarification is required.

Kaiser Permanente Foundation (Jaeger) – suggested word changes to several rules.

Laatsch (for ASPS) – question – Will changes regulate physician in-office compounding?

Legacy Health- supports compliance with USP 795, 797, and all applicable chapters of USP. They encourage simplifying and removing other proposed rules. They encourage the formation of an administrative rule advisory committee.

Mulder – Include compliance to USP 797 to keep OR regulations current. Also mentions that our “self-checklist” is out of date given requirements of 797.

Mulder(2) – Lists several items that are not clear in 797 including air pressure, temperature, HEPA

NCPA – Has provided several specific word changes to proposed rules.

OSHP – Does not support the current proposal for compounding rules. Suggests an advisory committee for future input on the rules, and is happy to assist.

Providence Health (Thompson)-Supports referring to USP 795 and 797. In the case OBOP moves forward with their own specific rules, new wording, and concerns are listed to be considered. Providence also suggest that a Rules Advisory Committee be formed to evaluate any additional rules beyond rules 855-045-0520.

Rackham – Provided a redlined copy of the proposed rules. The comments were based on an older revision of the proposed rules, but most comments were regarding the current version.

Rackham(2) – Representing 13 hospitals and health systems, a request is made to change the beyond use date to 6 days from the current 30 hours for injectable opioids being repackaged by and for hospital and health systems.

Attachment 1– Written Comments received by OBOP



AMERICAN ACADEMY of
DERMATOLOGY | ASSOCIATION



May 23, 2018

Oregon Board of Pharmacy
Portland State Office
Building, Conf. Rm 1A
800 NE Oregon Street, Suite 150
Portland, OR 97232

RE: Compounding proposal, OAR 855-045-0200; OAR 855-045-0500 through
855-045-0630

Dear Members of the Oregon Board of Pharmacy:

On behalf of the undersigned organizations, representing approximately 200 dermatologists in Oregon and approximately 14,000 dermatologists nationwide, we appreciate the opportunity to provide comments to the Oregon Board of Pharmacy ("Board") on proposed rules governing compounding set forth in OAR Chapter 855. We urge the Board to refrain from adopting any changes to the compounding rules due to this issue being unresolved at the national level and impact on patient access.

As dermatologists who diagnose and treat more than 3,000 skin diseases, including skin cancer, eczema, infections, psoriasis, immunologic diseases, and many genetic disorders, we rely heavily on compounded medications. Prescribing and/or directly administering compounded medications allows us to tailor treatments to the unique needs of our patients in a timely manner, resulting in better outcomes. The compounding in which dermatologists engage involves low-risk practices, such as compounding or administering mixing FDA-approved medications, diluting steroids for intralesional injections, and administering topical medications. A widely used local anesthetic in surgical dermatologic procedures is lidocaine with epinephrine mixed with a small amount of sodium bicarbonate in order to buffer the solution and make the injection much less painful.¹

While we believe that the regulation of compounding in physician offices for their patients should be under the purview of the state medical board, it is essential that state

¹ Kouba DJ, LoPiccolo MC, Alam M, Bordeaux JS, Cohen B, Hanke CW, et al. Guidelines for the Use of Local Anesthesia in Office-based Dermatologic Surgery. J Am Acad Dermatol. 2016 Feb 27.

boards of medicine work collaboratively with the state pharmacy boards and other federal and state policymakers concerning the development of in-office preparations.

National Context

Concurrently, multiple stakeholders, such as the U.S. Food and Drug Administration (FDA), U.S. Pharmacopeia (USP), and Federation of State Medical Boards are scrutinizing the safety of in-office preparations and developing policy in order to prevent tragedies like those that occurred at the New England Compounding Center. This scrutiny extends to common simple practices in dermatology, such as buffering lidocaine and reconstituting botulinum toxin. Ready availability of these preparations is important to avoid disruption of medical procedures, maintain clinic flow and to prevent medical waste.

Unfortunately, relevant policymakers, such as FDA or USP, have not provided our organizations data to support mandating physicians who prepare low-risk medications in their offices to obtain the same equipment and comply with the same process as large compounding facilities. We believe the FDA is considering infection control breaches in outpatient settings as reported by the U.S. Centers for Disease Control and Prevention (CDC); however, the CDC examples are not specific or unique to the preparation of in-office compounded medications.²

The Board has relied on USP policy as it develops its own compounding rules. USP is currently reviewing and potentially revising Chapter 797 governing Pharmaceutical Compounding—Sterile Preparations. We have communicated our concerns to USP that the Cundell data, which has been used to support its proposed revisions to Chapter 797 on *Pharmaceutical Compounding – Sterile Compounding*, is not representative of clinical settings nor is it relevant to the types of drugs compounded by dermatologists in the office setting.³ We have attached for your consideration a list of relevant studies that refute the Cundell data.⁴ After receiving more than 8,000 comments, some of which opposed the burdensome requirements on physicians, USP is expected to release a second revised draft for stakeholder input in July 2018. Moving forward with the proposal before USP finalizes its revisions of Chapter 797 is premature and has the potential to create inconsistency and confusion in the regulation of compounding drugs.

² U.S. Centers for Disease Control and Prevention. Outbreaks and Patient Notifications in Outpatient Settings, Selected Examples, 2010-2014. Available at: www.cdc.gov/HAI/settings/outpatient/outbreaks-patient-notifications.html

³ Cundell A. 2002. Review of the Media Selection and Incubation Conditions for the Compendial Sterility and Microbial Limit Tests. *Pharmacopeial Forum*. 28(6):2034-41.

Lastly, in its recently issued 2018 Compounding Policy Priorities, the FDA acknowledges a need to revise draft guidance documents, acknowledging the negligible patient risk in the contexts discussed in this letter:⁵

*These guidance documents will be followed by revised draft guidance describing examples of conditions that the FDA considers to be insanitary and in violation of the FD&C Act. **This guidance will address concerns raised by some providers who compound small quantities of drugs in their offices for patient use, and as part of their routine clinical practice. This came up in the setting of certain dermatological procedures, for example. The FDA plans to better define the circumstances under which we believe drugs are being mixed and applied in a manner that creates negligible patient risk, and therefore wouldn't be subject to the same compliance policy under the agency's risk-based approach to implementing these requirements.***

“Immediate Use”

Section 855-045-0620 would define “immediate-use provisions” in accordance with USP standards. It is our understanding that USP will be proposing a one-hour exemption from compliance with its *Chapter 797 Pharmaceutical Compounding – Sterile Preparations*. This timeframe would severely impact patient access. Many dermatologists compound drugs, such as buffered lidocaine, at the beginning of the day. This is particularly true for Mohs micrographic surgery (“Mohs surgery”), which may require a patient to spend several hours in the office. For the reasons set forth below, “immediate use” should exceed 24-hours.

Mohs surgery is a specialized surgery used exclusively to treat skin cancer. Mohs surgery is an outpatient procedure that entails staged excision of skin cancer while sparing normal skin. This procedure necessitates re-administration of lidocaine to the area until microscopic clearance of the tumor and closure are completed.

Two recent studies demonstrate extremely low levels of adverse events and no anesthesia toxicity. The Alam study, a 23-center study including nearly 21,000 Mohs procedures, found 149 adverse events and no deaths were reported.⁶ It demonstrates that lidocaine toxicity is not an issue, particularly in a Mohs procedure where a large volume of 1% lidocaine is used. The Alam study demonstrates that Mohs surgery is safe, with a very low rate of adverse events, an exceedingly low rate of serious adverse events, and an undetectable mortality rate.

⁵<https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm592795.htm>

⁶ Alam, M. et al. “Adverse Events Associated With Mohs Micrographic Surgery. *JAMA Dermatology*, 2013

In addition, a 2012 prospective multicenter cohort study further demonstrates the safety of Mohs surgery with the patient under local anesthesia. It included 1,550 patients with 1,792 tumors, resulting in no major complications during Mohs surgery or reconstruction. Minor complications were rare and occurred at a rate of 2.6%.⁷

Given the shortage of manufactured lidocaine with epinephrine, dermatology practices are adding epinephrine to lidocaine and other local anesthetics themselves for pain control and vasoconstriction. Pate et al. (2016) found that syringes filled with lidocaine; lidocaine and epinephrine; lidocaine with sodium bicarbonate; and lidocaine, epinephrine, and sodium bicarbonate and **stored for up to four weeks**, when prepared using aseptic technique and when stored in controlled room and controlled cold temperatures, are not prone to bacterial or fungal contamination.⁸ Zero of the 160 samples showed growth where streaked. This study had a larger sample size than a 1999 study, which found that 36 syringes of buffered lidocaine with epinephrine and sodium bicarbonate stored in room temperature were also not prone to bacterial or fungal contamination.⁹

In both studies, multi-dose vials are used. According to CDC, multi-dose vials typically contain an anti-microbial preservative to help prevent the growth of bacteria. In addition, lidocaine and other local anesthetics used in dermatology have antimicrobial properties.¹⁰

Economic Impact

The Board estimates that the fiscal and economic impact could cost less than \$100,000 or more than a \$1,000,000 depending on current readiness. While we support the Board's efforts to ensure the safety of sterile compounded products, it is not reasonable to expect dermatologists who prepare simple compounds or dilutions used for intradermal or subcutaneous injections to adhere to the same standards as large compounding facilities. Dermatologists would be forced to close their offices due to the inability to incur such costs. We are extremely concerned that moving forward at this juncture will disrupt patient access to medications that have been safely prepared by dermatologists in their offices for years. For these reasons, we urge the Board to reject the amendments to the compounding regulations until such stakeholders finalize the appropriate level of oversight based on scientific evidence in order to improve the safety of in-office preparations.

⁷ Merritt, B., et al. Bradley G. Merritt J Bradley G. Merritt Am Acad Dermatol, 2012, 1302-1309

⁸ Pate DA, Shimizu I, Akin R, Snodgrass K, Emrick A. Safety of Prefilled Buffered Lidocaine Syringes With and Without Epinephrine. Dermatol Surg. 2016 Mar;42(3):361-5.

⁹ Melman D, Siegel DM. Prefilled Syringes: Safe and Effective. Dermatol Surg 25(6):492-3.

¹⁰ Johnson SM, Saint John BE, Dine AP. Local Anesthetics as Antimicrobial Agents: A Review. Surg Infect. 2008;9:205-213.

ATTACHMENT:

1. Matsumoto AH1, Reifsnnyder AC, Hartwell GD, Angle JF, Selby JB Jr, Tegtmeyer CJ. *Reducing the discomfort of lidocaine administration through pH buffering*. J Vasc Interv Radiol. 1994 Jan-Feb;5(1):171-5.
2. Pascuet E1, Donnelly RF, Garceau D, Vaillancourt R. *Buffered lidocaine hydrochloride solution with and without epinephrine: stability in polypropylene syringes*. Can J Hosp Pharm. 2009 Sep;62(5):375-80.
3. Johnson SM1, Saint John BE, Dine AP. *Local anesthetics as antimicrobial agents: a review*. Surg Infect (Larchmt). 2008 Apr;9(2):205-13. doi: 10.1089/sur.2007.036. Review.
4. Colaric KB1, Overton DT, Moore K. *Pain reduction in lidocaine administration through buffering and warming*. Am J Emerg Med. 2000 Mar;18(2):235-6.
5. Osaki T1, Osaki MH1, Osaki TH1, Sant'Anna AE1, Yu MC1, Hofling-Lima AL1. *Absence of bacterial or fungal growth in vials of reconstituted botulinum toxin type A after storage*. Aesthet Surg J. 2015 Feb;35(2):189-93. doi: 10.1093/asj/sju072.
6. Alam M1, Bolotin D, Carruthers J, Hexsel D, Lawrence N, Minkis K, Ross EV. *Consensus statement regarding storage and reuse of previously reconstituted neuromodulators*. Dermatol Surg. 2015 Mar;41(3):321-6.
7. Hexsel D, Rutowitsch MS, de Castro LC, do Prado DZ, Lima MM. *Blind multicenter study of the efficacy and safety of injections of a commercial preparation of botulinum toxin type A reconstituted up to 15 days before injection*. Dermatol Surg. 2009 Jun;35(6):933-9; discussion 940.
8. Larson PO, Ragi G, Swandby M, Darcey B, Polzin G, Carey P. *Stability of buffered lidocaine and epinephrine used for local anesthesia*. J Dermatol Surg Oncol. 1991 May;17(5):411-4.
9. Liu A, Carruthers A, Cohen JL, Coleman WP 3rd, Dover JS, Hanke CW, Moy RL, Ozog DM. *Recommendations and current practices for the reconstitution and storage of botulinum toxin type A*. J Am Acad Dermatol. 2012 Sep;67(3):373-8.
10. Melman D, Siegel DM. *Prefilled syringes: safe and effective*. Dermatol Surg. 1999 Jun;25(6):492-3.
11. Pate DA, Shimizu I, Akin R, Snodgrass K, Emrick A. *Safety of Prefilled Buffered Lidocaine Syringes With and Without Epinephrine*. Dermatol Surg. 2016 Mar;42(3):361-5. doi: 10.1097/DSS.0000000000000624.

We appreciate the opportunity to provide these comments. Should you have any questions, please do not hesitate to contact Lisa Albany, director of state policy for the American Academy of Dermatology Association as staff representative for the undersigned organizations at (202) 842-3555 or lalbany@aad.org.

Sincerely,

A handwritten signature in cursive script that reads "Suzanne Olbricht, MD".

Suzanne Olbricht, MD, FAAD
President
American Academy of Dermatology Association

A handwritten signature in cursive script that reads "Lisa Donofrio".

Lisa M. Donofrio, MD
President
American Society for Dermatologic Surgery Association



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May 22, 2018

Oregon Board of Pharmacy
c/o Mo Klein
800 NE Oregon St., Suite 150
Portland, OR 97232

RE: Proposed Changes to OAR Chapter 855

Dear Members of the Oregon Board of Pharmacy:

I am writing on behalf of the American Society of Plastic Surgeons (ASPS) regarding the proposed changes to Oregon Administrative Rules (OAR) Chapter 855. ASPS is the largest association of plastic surgeons in the world, representing more than 94 percent of all board-certified plastic surgeons in the United States – including 83 board-certified plastic surgeons in Oregon. Our mission is to advance quality care for plastic surgery patients and promote public policy that protects patient safety.

We appreciate the Oregon Board of Pharmacy's (Board) effort to take a formal position on physician compounding. However, it is important to note that the legislative and regulatory backlash against in-office compounding began not as a result of physicians mishandling compounded medications, but rather as the result of the contamination of compounded products made by a compounding pharmacy. Therefore, we have outlined several sections of the proposed changes that we believe should either be amended or removed to better reflect the position of physicians on this issue.

855-045-055 would require all compounders to adhere to guidelines of the current edition of the United States Pharmacopeia (USP) Chapters 795 and 797, as well as all applicable chapters of USP and USP-NF related to the compounding practices at any location. Many pharmacy boards rely on United States Pharmacopeia (USP) policies to dictate physician compounding, but the Food and Drug Administration (FDA) has acknowledged the need to revise draft USP guidance documents related to compounding. Furthermore, in order to justify the adverse impact to physicians that onerous compounding rules may have, state pharmacy boards have cited a 2012 Centers for Disease Control and Prevention (CDC) study¹ that examines the use of single-use vials. This is misleading, as physician in-office compounding is typically performed by using multiple-dose vials, which are designed for multiple uses and include preservatives and manufacturer-specific expiration dates to ensure safety. ASPS recommends that the Board postpone the adoption of 855-045-055 until the updated guidance documents are written in order to reduce creating an undue burden on physicians who routinely compound drugs and medicine in a safe and sanitary manner that minimizes patient risk.

855-045-0530(5)(b) includes language that allows the compounding of a commercially-available drug product if it is not reasonably available in the market in time to meet the patient's needs. Further restricting physicians' ability to mix a drug such as lidocaine – which is listed as currently in shortage by the FDA – would limit treatment options for patients who are in need of these compounds. Therefore, we thank the Board for recognizing the difficulties that physicians face when dealing with drugs that are not commercially-available. Examples of mixtures that our physicians prepare – for which there are no commercially-available alternatives – on a frequent (often daily) basis are: sterile local anesthetics with sterile sodium bicarbonate to alleviate injection pain; sterile lidocaine with sterile bupivacaine for injection for longer-acting anesthesia; and lidocaine with triamcinolone when injecting hypertrophic/keloid scars to alleviate injection pain.

¹ <https://www.cdc.gov/injectionsafety/PDF/CDC-SDC-Position05022012.pdf>

855-045-0570 creates various recordkeeping requirements of compounders in Oregon. While ASPS appreciates the reasoning behind 855-045-0570, this rule places an unnecessary administrative burden on physician offices. Therefore, we respectfully request that the Board lessens this requirement by requiring physicians to keep a log of medications that were compounded in the patient's medical record. This would provide physicians with easily-accessible information if they would need to contact affected patients due to a recall.

Rules 855-045-0600 through 855-045-0630 cover the practice of sterile compounding. ASPS understands the Board's need to cover this practice for pharmacists and pharmacy personnel; however – as our physicians do not perform sterile compounding – we respectfully request that you exempt physicians from these requirements.

For the reasons outlined above, we urge you to amend the proposed changes to OAR Chapter 855. Thank you for your consideration of our position on this important issue. Please do not hesitate to contact Patrick Hermes, Director of Advocacy and Government Relations, at phermes@plasticsurgery.org or (847) 228-3331 with any questions.

Sincerely,

A handwritten signature in black ink, appearing to read 'Lynn Jeffers', with a stylized, cursive script.

Lynn Jeffers, MD
Board Vice President of Advocacy & Health Policy
American Society of Plastic Surgeons



Lauren Paul, PharmD | 200 Highland Corporate Drive | Woonsocket, RI 02895 | T: 540-604-3661

May 21, 2017

Marcus Watt, RPh
Executive Director
Oregon State Board of Pharmacy
800 NE Oregon Street; Suite 150
Portland, OR 97232

Re: Proposed Rule Amendments in Division 045 pertaining to Sterile and Non Sterile Compounding

Dear Executive Director Watt:

I am writing to you in my capacity as Sr Director of Pharmacy Regulatory Affairs for CVS Health and its family of pharmacies. CVS Health, the largest pharmacy health care provider in the United States, is uniquely positioned to provide diverse access points to care to patients in the state of Oregon through our integrated offerings across the spectrum of pharmacy care. CVS Health appreciates the opportunity to submit comments on the Oregon State Board of Pharmacy proposed rule amendments in Division 045 pertaining to sterile and non-sterile compounding. We would also like to thank the Board for their vigilance in continuously improving the laws and regulations that guide pharmacists, pharmacy interns and pharmacy technicians serving Oregon patients.

CVS Health appreciates the Board's proposed language requiring adherence to guidelines of current edition of United States Pharmacopeia Chapters 795 and 797, as well as all applicable Chapters of USP and USP-NF related to the compounding practices at any location. USP standards and guidelines are set by the Expert Compounding Committee which is comprised of 18 members, 10 of which are pharmacists. The committee is charged with developing new and to revise existing compounding related general chapters describing quality and practice standards for compounding of sterile and non-sterile preparations. As this is a committee of experts tasked to set the quality and practice standards for compounding, we feel that requiring adherence to these guidelines is sufficient for compounders to ensure proper and safe preparation. Also, with USP chapters 795, 797 and 800 currently under review and revision, significant changes in standards could occur before these are finalized and published. By requiring adherence to USP, this will be more efficient for the Board as changes to USP will cause additional amendments to this division be made. Therefore, we request the Board to consider removing the remaining sections, except registration outlined in OAR 855-045-0520 of the proposed amended division 045.

We would also request the Board amend language in OAR 55-045-0500(1) that requires an out of state compounder to follow their home state compounding rules or those of Oregon, whichever are more stringent. By nature of being a nonresident pharmacy, the pharmacy is required to follow the laws and regulations of the state in which they reside. Proposed OAR 855-045-0520 addresses registration requirements and requires an inspection and/or accreditation by a Board approved entity every 3 years to continue shipping sterile compounds and providing preparations to patients in Oregon. This inspection review will provide adequate assurances that compounding is being completed in a safe and quality manner.

Suggested Language:

855-045-0500

Compounding - Purpose

(1) These rules apply to any person, including any business entity, located in or outside Oregon that engages in the practice of compounding a drug for the use by a patient located in Oregon. Any person located outside Oregon must follow the compounding rules of their home state, ~~or these rules, whichever are more stringent~~



Lauren Paul, PharmD | 200 Highland Corporate Drive | Woonsocket, RI 02895 | T: 540-604-3661

Should the Board feel compelled to move forward with promulgating the remaining sections of Division 045, rather than requiring adherence to USP, we ask the Board to consider the following amendments:

855-045-0560 Compounding – Quality Controls

CVS Health understands the importance of a patient level recall, when needed, and has policies and procedures set in place for pharmacy staff to follow in the unlikely event this may occur. In lieu of reporting any patient level recall to the Board, we suggest that the recall information be retained for a period of 2 years at the pharmacy where it can be made available during inspection. We are unclear of the intent of the Board with the reporting of this information and do not find it to be necessary, if the patient is made aware of the recall and provided with the correct preparation. This would be similar to guidelines outlined in OAR 855-041-1036 regarding proper storage of drugs and the steps to take in the event of a temperature excursion.

Suggested Language:

855-045-0560

Compounding - Quality Controls

(3) The pharmacist-in-charge must establish a written adverse event reporting process and recall procedure. ~~The recall procedure must include notification to the Board in the event of a patient level recall.~~

Beyond Use Dating

Finally, we also request the Board consider amending language or removing "time" from the definition of Beyond Use Date and also the BUD labeling requirements for when a drug is added to a parenteral solution. California is the only state we are aware of that includes "date and time" as an optional element in their definition of beyond use date. Specifically, California Code of Regulations 1735.1 Beyond Use Date "means the date, or date and time, after which administration of a compounded drug preparation shall not begin, the preparation shall not be dispensed, and the preparation shall not be stored (other than for quarantine purposes)." CCR 1735.4 requires labeling in California to only include the "beyond use date" for the preparation. Therefore, we suggest amending the language to either remove time or something similar to California for BUD and labeling.

Suggested Language:

855-045-0510

Compounding - General Definitions

(2) "Beyond-Use Date" and "BUD" means the date ~~and time~~ after which a compounded product must not be used (or stored or transported). The date is determined from the date and time the preparation is compounded, according to risk level.

OR

(2) "Beyond-Use Date" and "BUD" means the date, or date and time, after which a compounded product must not be used (or stored or transported). The date is determined from the date and time the preparation is compounded, according to risk level.

855-045-0550

Compounding - Labeling

(2) In addition to the labeling requirements as specified in Division 41, whenever a drug is added to a parenteral solution under the direct supervision of a pharmacist, the label of the compounded drug dispensed or distributed must contain the following, at a minimum:

(b) The beyond use date, ~~to include date and time~~;



Lauren Paul, PharmD | 200 Highland Corporate Drive | Woonsocket, RI 02895 | T: 540-604-3661

CVS Health appreciates the opportunity to submit comments for the proposed amendment of these rules. If you have any questions, please contact me directly at 540-604-3661.

Sincerely,

A handwritten signature in black ink that reads "Lauren Paul, PharmD". The signature is written in a cursive, flowing style.

Lauren Paul, PharmD.
Sr Director, Pharmacy Regulatory Affairs
CVS Health

From:

Lloyd Center Pharmacy
438 E Burnside St
Portland, OR 97214
(503) 281-4161

May 23, 2018

RE: Comments on Division 045 Proposed Changes

To:

Oregon Board of Pharmacy
800 NE Oregon St, Suite 150
Portland, OR 97232-2162
(971) 673-0001

Dear Oregon Board of Pharmacy,

Enclosed, please find our comments on the proposed rule changes to Division 045.

We are happy to chat further about these comments or other issues relating to Division 045, so please don't hesitate to contact us if you have any questions.

Best regards,

Natalie Gustafson
Natalie@LCRX.com
Lloyd Center Pharmacy

1) General comment on the rules (not related to any specific section)**Comments:****1A) Timing of enforcement**

Upon passing of these rules, there is no specification about how long pharmacies will have before they must comply with the changes. Pharmacies will need time to interpret these new Board requirements, and time to come into compliance. Many of the changes are difficult, time intensive, expensive to implement, and will require third party consulting services which in current market conditions have long lead times. Providing a timeline for when enforcement will begin following the adoption of these rule changes will be needed, as it is unrealistic to say they will be enforceable from day 1.

These rules also do not provide the Board for any flexibility on when they will start to enforce either these rules, or future updates to USP chapters. As currently written, the Board must enforce whichever version of the specified USP chapters is currently active. There are currently major revisions in the pipeline for many USP chapters relating to compounding, and given the current wording the Board would have no option to delay enforcement if it deemed necessary based on community need. As an example, revisions to both USP <795> and <797> are being made right now, with an expected final publication date of June 1, 2019. USP has stated that these chapters will become "official" on December 1, 2019, just six months after publication. There are many changes being made in these chapters that will require expensive and time consuming renovations to buildings, and six months is likely not enough time for everyone to interpret the changes, come up with a plan for how to comply, and make the necessary infrastructure renovations in order to meet the new standards.

These rules do not allow the Board to selectively enforce certain parts of USP chapters if it deems relevant to do so. There are many significant upcoming changes to USP, and if the Board is going to enforce all relevant USP chapters for compounding, they may find that some of the changes may take our communities longer to implement or are infeasible to implement. With the current wording of the rules, the Board is required to enforce all of USP, even if it deems it to be in patient's best interest to selectively enforce parts.

1B) FDA guidance documents

Some of the rules are based on FDA guidance documents, which are not legally enforceable. The guidance documents are not based on USP, and have actually been found to be an overreach of the FDA's authority based on its interpretation of the Drug Quality and Security Act (DQSA).

1C) Reducing redundant wording

These rules seem to be requiring enforcement of USP. We suggest that when possible, the relevant USP chapter(s) are referenced, instead of rewriting parts of the chapters into the Board rules. Some of the wording of the Board rules differs from the wording of the USP chapters. Sometimes this is intentional, and sometimes this is because parts of USP are being summarized as Board rules. When summarizing USP, it would be preferable if the chapter is just referenced. This change will make Board rules easier to follow, and the Board rules will not become outdated as quickly when USP chapters are updated. For example, <795> and <797> are under revision and will have major changes in the next year, which will drastically change the language in the chapters.

2) Section 855-045-500 Compounding- Purpose

Quote: "(3) All drug compounding must adhere to guidelines of the current edition of the United States Pharmacopeia Chapters 795 (USP <795>) and 797 (USP <797>), as well as all applicable Chapters of USP and USP-NF related to the compounding practices at any location. This includes but is not limited to Chapters 7, 71, 85, 151, 659, 731, 823, 1072, 1116, 1160, 1163, 1211, and 1229.5."

Comments:**2A)**

We have concerns about the wording here. Specifically, the part that says "as well as all applicable chapters of USP and USP-NF related to the compounding practices at any location," and the reference to chapters above 1000. We believe the word "applicable" is too vague and may imply more chapters than the Board intends. Many chapters in the USP are for general notice only and contain no mandatory requirements. This is true of most chapters in the 1000 range.

For clarity, here is a quote directly from USP explaining that chapters beginning with 1000 are not mandatory except for in certain situations (from the USP Compounding Compendium, General Notices section):

"As stated in General Notices, general chapters numbered from 1000 to 1999 are considered interpretive and are intended to provide information on, give definition to, or describe a particular subject. They contain no mandatory requirements applicable to any official article unless specifically referenced in General Notices, a monograph, or a general chapter numbered below 1000."

By stating both "all applicable Chapters of USP and USP-NF" as well as specifically listing chapters in the 1000 range (1072, 1116, 1160, 1163, 1211 and 1229.5), the new rules could be interpreted as requiring compliance with all chapters above 1000, even those that USP itself does not necessarily require compliance with.

In addition, with big changes coming to USP in the next year, as well as unknown changes in the future, we suggest minimizing the inclusion of chapters above 1000 from the new rules in order to keep Oregon rules consistent with USP language.

Suggestion: Re-write as: "(3) All drug compounding must adhere to guidelines of the current edition of the United States Pharmacopeia Chapters 795 (USP <795>) and 797 (USP <797>)." Or include the chapter definition from USP so that you don't need to use the word "applicable" in the definition of which USP chapters must be followed.

2B)

There is no verbiage in the new rules regarding timing of enforcement. Specifically, providing the Board with the ability to delay enforcement of a current or future USP chapter in order to allow pharmacies time to get in compliance. Many of the changes in USP chapters relating to compounding have required huge changes in infrastructure, big additional expenses to daily operation, and significant process and training changes. With the current wording of the Order, the Board does not have an option to delay enforcement even if it wanted to. This would be true of the current USP chapters as written, or hypothetical changes years in the future.

Suggestion: Provide wording that allows the Board to delay enforcement of all or part of updates made to a current or future USP chapter if it deems relevant given circumstances in the community.

3) Section 855-045-0510 Compounding- General Definitions

3A)

Quote:

(1) "Batch" means any specific quantity greater than one of a drug or other material that is intended to have uniform character and quality, within specified limits, and is produced during a single preparation carried out during a single time period."

Comments:

This definition of Batch is ambiguous. Specifically, the part that says "greater than one of a drug." One capsule? One gram? One kilogram? One milliliter? One Liter? One syringe? One container? One vial? One quantity needed for patient dispensing?

Suggestion:

There are multiple ways to interpret this, and changing the wording to clarify what you mean here would be helpful.

3B)

Quote:

(2) "Beyond-Use Date" and "BUD" means the date and time after which a compounded product must not be used (or stored or transported). The date is determined from the date and time the preparation is compounded, according to risk level."

Comments

We have a wording concern here. Specifically relating to the part that says "(or stored or transported)."

The wording of this definition produces some challenging situations by saying that after the BUD has been reached a product may not be stored or transported.

Some examples:

(a) This definition is saying that the day a product reaches its BUD, it must be destroyed. This would preclude a pharmacy from having a quarantined bin for drug destruction where drugs are stored after BUD has been reached prior to being destroyed. Many compounds already have short expiration dates. This definition would mean that pharmacies would need to destroy drugs every day, instead of at regular intervals which are more conducive to workflows (once a week, twice a month, etc). This destruction is not practical as most pharmacies use reverse distributors or third parties to destroy their drugs. Pharmacies complying with USP <795> and <797> will have SOPs that address how drugs to be destroyed should be quarantined with clear labeling to prevent risk of using or dispensing.

(b) Some drugs are destroyed by third parties or reverse distributors. After BUD has been reached, as per this definition, we would not be allowed to "transport" these drugs to be safely destroyed by a third party.

The section in USP <795> on Stability Criteria and Beyond Use dating says: "The BUD is the date after which a compounded preparation shall not be used and is determined from the date when the preparation is compounded." USP's definition is safer, and does not include a mention of "or stored or transported."

Suggestion:

Use the USP definition of BUD, and remove the "or stored or transported" reference in the BUD definition.

3C)

Quote: "(3) "Hazardous Drug" means any drug identified as hazardous by the National Institute for Occupational Safety and Health (NIOSH) at the Centers for Disease Control or any drug that meets at least one of following six criteria. (a) Carcinogenicity. (b) Teratogenicity or developmental toxicity. (c) Reproductive toxicity in humans. (d) Organ toxicity at low doses in humans or animals. (e) Genotoxicity. (f) New drugs that mimic existing hazardous drugs in structure or toxicity.

Comments:

We are concerned with a hazardous drug being defined by an Oregon Board of Pharmacy Rule. Specifically, the concern is that there has been much debate about the definition of a "hazardous drug." Since USP is now using NIOSH to specify what drug is hazardous, there has been increased pressure for NIOSH to adjust its hazardous drug categories. If/when a change in the definition of a hazardous drug occurs, a new definition would be in conflict with the Oregon Board of Pharmacy rule.

We recognize that the wording used in the OBoP rule is taken from current USP text, but the definition is still rather vague. Specifically, NIOSH and USP (e.g. upcoming USP <800>) do not treat all hazardous drugs as equal, but the OBoP rule does not seem to differentiate.

Suggestion:

If OBoP would like to have USP followed, it may be simpler to just reference a USP or a NIOSH definition of hazardous drugs to reduce risk of conflicting definitions in the future.

4) Section 855-045-0520 Compounding- Registration**4A)**

Quote: "855-045-0520 (1) A pharmacy that compounds a drug and dispenses a patient specific drug must register with the Board as a retail drug outlet or an institutional drug outlet or both if dispensing to both and ambulatory and residential patient."

Comments:

The wording here is confusing. There is perhaps a typo in this part "if dispensing to both and ambulatory and residential patient."

Suggestion:

We believe the Board meant "an" not "and" in the quoted sentence, but clarification here is requested.

4B)

Quote: (2) In addition to obtaining an Oregon drug outlet registration, all compounding pharmacies must either pass an inspection by a Board approved entity or must receive accreditation by a Board approved entity, every 3 years at a minimum, in order to distribute or dispense sterile compounded preparations into and within Oregon."

Comments:

First, a question: What is considered a Board approved entity? Is a Board inspector a "Board approved entity?" What about JCAHO, PCAB or similar third party inspectors? Would this be required for infusion or satellite pharmacies?

Second, a concern: We believe it is inappropriate to only require an inspection or accreditation for pharmacies that dispense sterile compounded preparations. There are significant safety, quality and potency concerns related to non-sterile compounding pharmacies as well, and the Board should require inspection to protect Oregon patients. There are many non-sterile compounding pharmacies nationally, some that dispense very large volumes, and they should be held to the same standards of patient care and safety.

Given that the Board does not typically inspect pharmacies in other states, it seems even more important to require inspections at regular intervals.

Third, another concern: depending on the definition of what a "board approved entity" is, we feel that inspection every 3 years may be too infrequent. The Oregon Board inspects resident pharmacies every year. If the Oregon Board requires this for all resident Oregon pharmacies, why not require this of non-resident pharmacies as well? This new rule of requiring an inspection only every 3 years could lead to non-resident pharmacies being less regulated than resident pharmacies (which is likely true in our current laws as well).

We do not feel it is fair or appropriate for non-resident pharmacies to have less inspections and less oversight than resident pharmacies.

Suggestion:

For the safety of Oregon patients, require the regular inspections for both non-sterile and sterile compounding pharmacies.

And if an Oregon Board Pharmacy Inspection is a "Board Approved Entity," then consider reducing the time interval that inspections are required from 3 years to 1 year in order to place non-resident pharmacies on the same level as resident pharmacies.

5) Section 855-045-0530 Compounding- General Requirements

5A)

Quote: "(3) The equipment, components, devices, and utensils used for compounding of a drug preparation must be of appropriate design and capacity and must also be designed to protect the compounder from hazardous materials... A pharmacy must comply with all applicable USP standards commensurate with level of compounding being performed."

Comments:

How do you define "protect from hazardous material" for equipment or utensil? To our knowledge this is not language from USP. The concern is that by providing these kind of statements out of context from USP chapters that these become challenging to enforce or define.

This section also states that the “pharmacy must comply with all applicable USP standards.” If the Board would like for the rules to follow USP chapters, then perhaps it is simpler to just refer to the relevant USP chapter that the Board would like followed. We are not sure the added complexity and ambiguity of (3) is helpful.

Suggestion:

Remove (3), or refer to the relevant USP chapter on hazardous handling and safety.

5B)

Quote: (4) Any compounding activity that is not pursuant to a valid prescription or an order to prepare for administration and for a specific patient is considered to be manufacturing, and any person engaged in manufacturing must be registered in accordance with Division 060, with the following exceptions: (a) Compounding in anticipation of a prescription drug order or an order to prepare for administration, based on a history of receiving valid prescription drug orders for the compounded or sterile prepackaged drug product”

Comments:

We believe the wording which differentiates manufacturing versus compounding in anticipation is not appropriate. The Board’s definition of anticipatory compounding more closely resembles FDA wording, instead of what is in USP. Specifically, the USP defines compounding as “the preparation, mixing, assembling, altering, packaging, and labeling of a drug or device or other article, as the result of a practitioner’s order or in anticipation of such an order based on routine, regularly observed prescribing patterns.”

Part of our concern with this wording is in the logistics of how compounding works. Here is an example to illustrate our concern.

Situation 1: Imagine a doctor calls in a new compounded prescription for a new patient. The prescription is for a capsule, is a formula that has never been made before, has no refills, and has a quantity of 30. Most common compounding equipment for capsules requires you to make 100 capsules at a time. The remaining 70 capsules may never get used, but the encapsulation machine is designed to make 100 at a time, so we make 100, dispense 30 to the patient, and put 70 on our shelf in case we get another order for them before they reach BUD.

Situation 2: Imagine situation 1, but instead of a capsule it was an rapid dissolve tablet (RDT). RDT molds have a pre-defined number of “wells” in them, and they all must be filled in order to accurately make the RDTs. So we would need to make 96 RDTs in order to fill a prescription for 30.

In both these situations, we are concerned that the extra stock generated in the normal compounding process would have to be destroyed if following “strict” anticipatory compounding rules, since more stock was made than was needed for the prescription, and there is no history of orders for this formula. This is a huge waste, and we believe goes against the spirit of the

anticipatory compounding rules. Adjusting the wording in this rule to be less restrictive would help to allow for realistic compounding logistics in our pharmacies.

Suggestion:

Replace the following words:

"based on a history of receiving valid prescription"

with the USP wording: "based on routine, regularly observed prescribing patterns."

5C)

Quote: "(6) Compounding any drug product for human use that the FDA has identified as presenting demonstrable difficulties in compounding or has been withdrawn or removed from the market for safety or efficacy reasons is prohibited."

Comments:

We suggest removing terminology based on FDA guidance documents.

While we agree in restricting items that are withdrawn due to safety, efficacy is a more challenging situation. Utilizing off-label uses for drugs is a standard practice for prescribers. The wording in this rule which prevents compounding a drug that has been removed for efficacy reasons comes from an FDA guidance document, which is not enforceable, not part of federal law and is subject to change. We do not see a reason for including the "efficacy" portion of this rule, as it is challenging to define "efficacy." We believe that practitioners should be allowed to prescribe what they feel is best for the patient as long as it is safe for the patient. Additional restrictions should not be placed on practitioners or compounding pharmacies.

Suggestion:

Remove the prohibition on compounding drugs removed from the market for efficacy.

6) Section 855-045-0540 Compounding Personnel and Responsibilities

6A)

Quote: "(1) All personnel, who prepare and supervise the preparation of compounded pharmaceuticals must be provided with appropriate training and testing before they begin to prepare or supervise preparation of such products, including theoretical principles and practical skills of manipulations."

Comments:

The wording in this section is somewhat vague. For example, "such products" could be interpreted to mean that technicians must be trained in all tasks, even if their job responsibilities only include a subset of tasks. We are sure that the intention of the Board was to limit individuals from performing tasks they have not been trained to do, and not require everyone

know everything. A change in wording will help accomplish this. USP has relevant wording which is better: "Personnel are appropriately trained and are capable of performing and qualified to perform their assigned duties."

In addition, the part of the rule which states "including theoretical principles and practical skills of manipulations" is vague and potentially all encompassing. We suggest narrowing the training requirements to be more practical.

Suggestion:

Replace with USP wording: "Personnel are appropriately trained and are capable of performing and qualified to perform their assigned duties."

6B)

Quote: "(2) All personnel must possess the education, training and competency necessary to properly and safely perform compounding duties"

Comments:

We are concerned that this quote is too vague, for two reasons.

First, education could imply the need for a formal education (such as a degree or a formal certificate from an institution). We suspect that the Board is not requiring formal education, but is instead requiring proper training and knowledge, which can be obtained via on the job resources as opposed to institutions of higher learning or approved continuing education.

Second, it says "perform compounding duties" and not "assigned duties." As with our previous comment, this could be interpreted to mean that all personnel must know how to do all duties, which is unrealistic (and we believe not what the Board intends).

There are multiple references in <795> and <797> to ensure proper training and competency, so we do not believe the Board needs to include rules specifying training requirements. This is already accomplished by requiring USP <795> and <797> compliance, so these rules are redundant.

Suggestion:

Since training is already required and defined in USP <795> and <797>, and the Board requires <795> and <797> compliance, we suggest removing training from Board rules.

If you would like to keep training requirements in the Board rules, we suggest removing the word "education" and adding the words "assigned duties" to the quote in order to reduce ambiguity. So it would read: "All personnel must possess the training and competency necessary to properly and safely perform their assigned duties."

7) Section 855-045-550 Labeling**7A)**

Quote: "(1) In addition to the labeling requirements as specified in Division 41, the label of a compounded drug or medication order dispensed or distributed must contain the following, at a minimum (a) The generic or official name of each active ingredient"

Comments:

The common challenge with compounded medications is that many compounded formulas have so many ingredients that they will not fit on a label. Pharmacy dispensing software, even pharmacy dispensing software designed for compounding, is often inadequate at handling very long drug combinations.

Suggestions:

For names that will not fit on a label affixed to a container, allow an accompanying labeling or separate paperwork included with the prescription to contain the complete drug ingredient list if it is impractical to put on the label affixed to a vial.

Allow common acronyms. For instance, "dehydroepiandrosterone" is almost always referred to as "DHEA." Based on the current language it appears that acronyms are not allowed.

7B)

Quote: "(1) In addition to the labeling requirements as specified in Division 41, the label of a compounded drug or medication order dispensed or distributed must contain the following, at a minimum (c) The name of the base or diluent"

Comments:

Adding the name of all bases or diluents would be challenging. For instance, an oral suspension that contains both Ora-Sweet and Methylcellulose 1% gel would have to list out all those ingredients. No compounding software is set up to handle this type of labeling requirement. Currently, diluents and inactive ingredients only have to be listed on sterile compounded medications per USP. In order to accomplish this for sterile items, we have to manually type out on separate labeling software that is not linked to patient or prescription information which increases risk for error. There is currently no practical way to have this information listed on a prescription label.

Suggestion:

Do not require additional labeling requirements such as base or diluent to non-sterile compounded medications.

7C)

Quote: "(2) In addition to the labeling requirements as specified in Division 41, whenever a drug is added to a parenteral solution under the direct supervision of a pharmacist, the label of the

compounded drug dispensed or distributed must contain the following, at a minimum (a) The name, quantity and concentration of the drug added and the primary solution"

Comment:

We believe the wording here may be confusing. Should the label say the final concentration of the ingredients? Or the concentration of the ingredient that was added? If the latter, this could lead to some confusing labels, which we believe is not what the Board is hoping to accomplish with this rule.

7D)

Quote: "(2) In addition to the labeling requirements as specified in Division 41, whenever a drug is added to a parenteral solution under the direct supervision of a pharmacist, the label of the compounded drug dispensed or distributed must contain the following, at a minimum (b) The beyond use date, to include date and time"

Comment:

We do not believe that adding the time to a BUD is applicable in all situations. For example, the "time" of expiration for a compounded sterile item that has 45 day dating is not useful.

Also: how is "time" defined? From the moment a compound has begun to be prepared? From the time it has been sterilized? From the time it is completely finished and prepared for dispensing? Some compounds require hours to be completed from start to finish. It can be difficult to track down to this level.

Suggestion:

If you want time to be included on the label, we suggest adding wording to the rules such as "when appropriate, an in-use time should be included on the label." This wording is consistent with proposed updated USP <797> (not finalized yet, so this may change). Or you could simply reference the USP chapter.

7E)

Quote: (2) In addition to the labeling requirements as specified in Division 41, whenever a drug is added to a parenteral solution under the direct supervision of a pharmacist, the label of the compounded drug dispensed or distributed must contain the following, at a minimum (c) Recommended frequency/schedule for administration"

Comment:

Recommended frequency/schedule for administration is not a labeling requirement in USP. This type of information could vary or should be indicated by directions on the prescription. This wording also seems like it could be inappropriate in a hospital setting, such as if the bag or vial states one frequency but the physician order is for a different frequency. We think including this information on the label could lead to increased mistakes.

Suggestion:

Remove the requirement for "frequency/schedule for administration" from the label for safety and logistic reasons.

7F)

Quote: (2) In addition to the labeling requirements as specified in Division 41, whenever a drug is added to a parenteral solution under the direct supervision of a pharmacist, the label of the compounded drug dispensed or distributed must contain the following, at a minimum (e) The name or initials of person performing admixture"

Comments:

We do not believe that the name or initials of the person performing the admixture should be on the label, for several reasons.

First, from a safety standpoint, there is already a lot of information on the label. The name or initials of the person that performed the admixture serves no utility to either accurately describe the medication, or ensure that it is being used/administered correctly. Therefore, we believe it will be a distraction on the label. We believe it is important to only include relevant information on the label for safety reasons, and to prevent adding additional text that does not increase patient safety.

Second, this information is already required to be documented in the compounded preparation record. The goal of tracking who performed admixture is mostly for quality control and quality assurance purposes. This information should be retrievable for these purposes, but it does not belong on the label.

Third, what if multiple people were involved in compounding? Should all names be on the label, or just the "final" admixture technician?

Fourth, there is already a requirement to include the verifying pharmacist initials (which we also believe is likely not a beneficial piece of information to include on the label as this is more used for QC/QA purposes too, though we recognize is a current USP requirement). Also including the admixture name will cause more confusion.

Suggestion:

Do not require the name of the person performing the admixture to be on the label.

8) Section 855-045-570 Compounding- Records

8A)

Quote: "(4) Records for compounding must utilize a master formulation record. All master formula records must be developed and approved by the pharmacist for compounded preparations, and records for all preparations must contain, at a minimum..."

Comments:

Master formulation records can often be developed by or in collaboration with appropriately trained technicians or interns, with a final approval done by a pharmacist. This wording restricts development to pharmacists only.

As an example: imagine a formula being created that is a slight change in concentration of an existing formula. A trained technician or intern could create this new formula from the existing formula, and then give it to the pharmacist for final approval.

Allowing technicians to enter formulas initially is similar to how technicians are used in other parts of the pharmacy. Technicians routinely enter prescriptions into the computer, fill the prescription, and then a pharmacist does final verification. Math and calculations are a regular part of a technician's responsibilities in all pharmacy settings. It is normal pharmacy procedure to have a pharmacist verify technician work, instead of performing all tasks from start to end.

Suggestion:

Change the quote to remove the word "developed," and include the word "prior to dispensing." Such as:

"(4) Records for compounding must utilize a master formulation record. All master formula records must be approved by the pharmacist for compounded preparations prior to dispensing, and records for all preparations must contain, at a minimum..."

8B)

Quote: "(5) Any compounded product must be documented and the unique compounded preparation record, must include but not be limited to the following: (j) Physical evidence of the proper weight of each ingredient"

Comments:

We are concerned with the possible misinterpretation of the words "physical evidence." Specifically, three big problems:

First, analytical scales that are attached to a computer have their data recorded electronically when capturing tares and weights for an ingredient. In this situation, there is no "physical evidence" of the measurements because it is stored in a computer.

Second, liquid measurements, such as those measured in milliliters will prove a challenge. Analytical scales are of course not capable of measuring volumes, so there is no electronic weight that can be stored electronically or printed to paper. Liquids are measured using devices like graduated cylinders or syringes. Procedures can be used in these situations such as a second check to verify the quantity before writing down the weight on a worksheet, but it is unclear if this is considered "physical evidence."

Third, the rule specifies "weight," which implies mass. This excludes volume measurements.

Suggestion:

Remove the word "physical evidence" to reduce confusion, and replace with the word "documentation" and remove "weight" and replace with "amount." This would make the rule read: "...documentation of the proper amount of each ingredient."

Or perhaps since this is covered in USP chapters, the Board rules can simply refer to the relevant chapters.

8C)

Quote: "(5) Any compounded product must be documented and the unique compounded preparation record, must include but not be limited to the following: (k) Duplicate label as described in the Master Formulation Record"

Comment:

Question regarding this item. Certain softwares provide a barcode that allows this label to be pulled up electronically and reviewed or printed as needed. In this instance, would all labels need to physically be printed and attached to the compounding record, or would a barcode suffice?

8D)

Quote: "(5) Any compounded product must be documented and the unique compounded preparation record, must include but not be limited to the following: (m) Results of quality control procedures (e.g. weight range of filled capsules pH of aqueous liquids)"

Suggestion:

Minor grammatical error. Missing comma between "capsules" and "pH".

9) Section 855-045-0600 Sterile Compounding- Purpose

9A)

Quote: "The minimum standards of the current edition of the United States Pharmacopeia Chapter <797> and all other applicable USP Chapters regarding sterile compounded products must be met unless requirements listed are more stringent."

Comments:

We have the same concerns with this rule as we have expressed previously. Specifically:

These rules do not provide the Board for any flexibility on when they will start to enforce either these rules, or future updates to USP chapters. There are currently major revisions in the pipeline for many USP chapters relating to compounding, and given the current wording the Board would have no option to delay enforcement if it deemed necessary for the community.

These rules do not allow the Board to selectively enforce certain parts of USP chapters if it deems relevant to do so. There are many significant upcoming changes to USP, and if the Board is going to enforce all relevant USP chapters for compounding, they may find that some of the changes may take our communities longer to implement or are infeasible to implement. With the current wording of the rules, the Board is required to enforce all of USP, even if it deems it to be in patient's best interest to selectively enforce parts.

Suggestion:

To help allow for future unknown situations and to give pharmacies the time to prepare for changes, add wording that (a) specifies when enforcement begins on these new rule changes, (b) allows for the board to delay enforcement of current or future USP chapter changes if it deems necessary, and (c) allows the Board to selectively enforce all or part of current or future USP changes if it deems necessary.

10) Section 855-045-0610 Sterile Compounding- Personnel Compounding Sterile Preparations (CSPs)

10A)

Quote: "(3) Documented training for each person, including temporary personnel, must be performed and completed by the PIC or other supervising pharmacist prior to sterile compounding or supervising the preparation of sterile preparations, and must include, at a minimum:¶ (a) Fundamentals of sterile compounding manipulations;¶ (b) Responsibilities of compounding personnel;¶ (c) Purpose and utilization of policies and procedures;¶ (d) Use of all applicable equipment and supplies, to include automated compounding devices;¶ (e) Facility and personnel environmental sampling metrics, to include but not limited to:¶ (A) Garbing competency;¶ (B) Hand hygiene and proper work practices competency, via gloved fingertip sampling;¶ (C) Media-fill testing of aseptic manipulation competency, at least annually for low and medium-risk level compounding and semi-annually for high-risk level compounding; and¶ (D) Cleaning and disinfecting competency, to include surface sample testing;¶ (f) Understanding of primary and secondary engineering controls, such as function, use, testing, and certification;¶ (g) Assignment of BUDs;¶ (h) Quality assurance, quality releases and final checks of CSPs"

Comments:

The wording of this rule is too broad and confusing. Specifically:

- "Final checks of CSPs":

- The training requirement reads as if all personnel, including temporary personnel, must be trained in “final checks of CSPs.” Technicians should not need training in final checks of CSPs.
- “Use of all applicable equipment and supplies.”
 - “Applicable” is a vague term and could be interpreted to mean the use of all equipment in the sterile lab, even those that are not part of an employees responsibilities. A line such as “Personnel are appropriately trained and are capable of performing and qualified to perform their assigned duties” is more appropriate. “Assigned duties” is more specific and limits the scope of their training to those tasks which they are involved in.
- “(C) Media-fill testing... for low and medium-risk... and... high-risk...”
 - The terminology from current <797> of low, medium and high-risk compounding will be removed when <797> is updated. They are defining the types of sterile compounding differently. It may not be beneficial to include soon to be outdated terminology in rules.
- “(e) Facility and personnel environmental sampling metrics, to include but not limited to: (D) Cleaning and disinfecting competency, to include surface sample testing.”
 - The wording here is too all encompassing and again makes it sound like all sterile compounding personnel need to understand everything. Not all technicians will necessarily be involved in environmental monitoring. We think this is another great place to use of the word “assigned duties”, instead of requiring everyone to know everything. “Personnel are appropriately trained and are capable of performing and qualified to perform their assigned duties”
- “(i) For non-sterile-to-sterile batch compounding, written policies and procedures must include:¶ (A) Process validation for chosen sterilization methods; and¶ (B) End-product evaluation, quantitative, and qualitative testing”
 - The location of this part is confusing as it is referring to SOPs about batch compounding, and not personnel training. We do not think this rule belongs under the topic of “Documented training for each personnel... must include.” We are wondering if this was placed here in error and it belonged elsewhere in the rules?

Suggestion:

Many suggestions were included within the bulleted list above.

In general, much of this section was too vague and could be interpreted to mean that all staff must know every responsibility. If this section remains, we suggest using wording which includes “assigned duties” to make it more clear.

This section also covers topics that are explicitly described in USP chapters, so it seems simpler to refer to the USP chapter here and get rid of this section entirely from the Board rules. This will also make the Board rules simpler and consistent with USP when USP chapters are updated.

10B)

Quote: (5) The Pharmacist-In-Charge (PIC) must possess the education, training and proficiency necessary to properly and safely perform compounding duties undertaken or supervised."

Comments:

This rule is almost certainly illegal. Specifically, the rule states that the PIC must be able to perform every sterile compounding duty supervised. This precludes any person with a disability, injury, or other physical limitation from legally being a PIC of a compounding pharmacy.

From a practical standpoint, this rule is also overly broad. It is reasonable to expect the PIC to understand all of the sterile responsibilities and techniques in compounding. But it is impractical to expect a PIC to be able to perform every technique on their own. A PIC can safely and competently supervise sterile compounding if they understand how a technique should be done even if they are unable to perform the technique themselves. For an extreme example, imagine a one armed PIC.

In addition, as mentioned before the word "education" is overly broad in this context and should either be removed or clarified.

Suggestions:

Re-word this section to remove the requirement that a PIC be able to "perform" the duties, and remove the word "education" as it is overly broad. Specifically:

"(5) The Pharmacist-In-Charge (PIC) must possess the training and proficiency necessary to properly and safely supervise sterile compounding duties."

10C)

Quote: "(8) A pharmacy technician who compounds sterile preparations must: (a) Possess the education, training and proficiency as required to properly and safely perform compounding duties undertaken"

Comments:

We have the same concerns here about the word "education" as we have had elsewhere in the rules. It is too broad, not defined, and not necessary for the position.

Suggestion:

Remove the word "education" from this section.

11) Section 855-045-0620 Microbial Contamination Risk Levels and Beyond-Use-Dates

Comments:

We are not clear as to the purpose of this section being in the Board rules. These areas are already covered in <797>, and the proposed changes to <797> will remove the "low/med/high" risk level definitions. Referencing relevant USP chapters should be sufficient here.

Suggestion:

Remove this section, which will be outdated soon, and reference relevant USP sections instead.

From: Adam Gustafson
To: [PHARMACY RULEMAKING * BOP](#)
Subject: Additional comment for Division 045 changes
Date: Wednesday, May 23, 2018 2:50:13 PM

Hello!

Thank you for giving us the opportunity to speak at the rule hearing meeting this morning.

One of the items that was clarified for us at the meeting was what the board meant in 855-045-520 about a "board approved entity." Thanks for the clarification!

This email is an additional comment on the proposed rule changes to Division 045, specifically as it relates to 855-045-0520.

Here is the relevant quote from the rules:

Quote: (2) In addition to obtaining an Oregon drug outlet registration, all compounding pharmacies must either pass an inspection by a Board approved entity or must receive accreditation by a Board approved entity, every 3 years at a minimum, in order to distribute or dispense sterile compounded preparations into and within Oregon."

Comments:

At the meeting, the board clarified that the annual Board inspection is not considered a "Board approved entity" when the rules are referencing a required inspection or accreditation every 3 years for pharmacies that perform sterile compounding.

In our written comments previously submitted, we discussed this quote as part of our item "4B." This comment is an expansion on our previous written comments now that we understand the Board's intent better.

Specifically, we are concerned that only sterile pharmacies are required to have third party inspections every 3 years. We believe that this ruling should be extended to non-sterile pharmacies as well for patient safety and requirements consistency. We have several reasons for this:

1) Given that the Board does not inspect non-resident pharmacies, it seems important to require third party inspections/accreditation to all non-resident compounding pharmacies, and not just those shipping sterile prescriptions into Oregon. There are many non-sterile compounding pharmacies nationally, some that dispense very large volumes or that are in states with minimal Board oversight. Requiring inspection or accreditation would help address differences in state inspection and help protect Oregon patients.

2) Pharmacies that do both sterile and non-sterile compounding are unable to be inspected or accredited by third parties for just their sterile activities. Third party inspectors (correctly) require inspection/accreditation of non-sterile compounding activities if it is also being performed at the pharmacy. They also charge additional fees for everything they are inspecting, so inspecting a "sterile and non-sterile" pharmacy will be substantially more expensive and time consuming than inspecting just a "sterile" pharmacy.

In practice, this rule is requiring compounding pharmacies that are both "sterile and non-

sterile" to be inspected or accredited for non-sterile compounding activities, while "non-sterile only" pharmacies do not have any third party inspection or accreditation requirements. We believe that it makes sense to hold non-sterile compounding to consistent standards and oversight among pharmacies.

Thus, "sterile and non-sterile" compounding pharmacies will have an increased financial, logistical and time burden to not only to be inspected for their sterile operations, but also for their non-sterile operations. For this reason we believe the distinction between sterile and non-sterile compounding as it relates to inspection and accreditation is not appropriate.

We see several possible solutions to this, which are outlined in our Suggestions below.

Suggestion:

A) Non-resident pharmacies: Since the Board is not able to physically inspect non-resident pharmacies, we think that all compounding pharmacies (both sterile and non-sterile) should be required to have third party inspection or accreditation. This will help to account for differences in quality and quantity of inspections in other states.

B) Resident pharmacies: Since the Board is able to physically inspect resident pharmacies, we see two options available:

(1) If the Board feels third party inspection and accreditation is required, then all compounding pharmacies (both sterile and non-sterile) should be required to have it.

(2) If the Board feels that third party inspections or accreditation is too big of a burden for resident pharmacies that are inspected annually by the Board, then they can remove the requirement for resident compounding pharmacies to undergo third party inspection/accreditation.

Either way, we believe that both sterile and non-sterile pharmacies should be treated the same from a third party or accreditation requirements.

Thank you for your time! Please feel free to reach out to us with any questions.

Adam Gustafson
Lloyd Center Pharmacy
503-281-4161

KLEIN Mo * BOP

From: Marty Hiers <nwcompounding@yahoo.com>
Sent: Wednesday, May 23, 2018 2:52 PM
To: mo.klein@state.or.us
Subject: Proposed compounding rules

To whom it may concern,

When I was first made aware of the proposed changes to the Oregon State pharmacy rules in regards to compounding I was excited. We have needed clarification and unification for a long time and I welcomed the clarity and increase in patient safety that I hoped it would bring. Unfortunately, I hadn't reviewed the proposed rules much before it became apparent that the target I was hoping for had been missed.

The proposed rules by the board have me concerned in a few areas, specifically, the inspection by an outside entity, the adoption of the difficult to compound list and some other minor things. I don't see the need to have a separate outside entity carry out an inspection for sterile compounding if there is a clear set of rules for it and the board inspectors are already inspecting it. This seems like a way to force pharmacies to become accredited and pay an additional cost for no purpose and makes it appear as though the board inspectors are not qualified enough to carry out a full inspection. The difficult to compound list is still pending has been a source of contention and controversy since its first proposal and depending on how it is adopted could severely limit or all together end patients access to a vast majority of compounds, at least the ones we currently do. Other things like needing times on BUD and the names and concentrations of base solutions or creams is just tedious and unnecessary, even commercial products don't do that on their labels.

Using USP 795 and 797 as guidelines for rules for Oregon is a great place to start. However they are constantly changing and currently both have drafts that are pending approval. By adopting them in their entirety I feel it is going to hamstring pharmacies in Oregon and the board and make us subject to an ever increasingly difficult to understand and overbearing set of basically federal rules. There are many specifics I can site such as BUD for non sterile items and the testing needed to extend them beyond the very short ones set out in 795, or the ambiguity of what separates a sterile compounding area from a non-sterile compounding area. Overall, the basic backbone of them is solid but we should set them for us and not just follow whatever current guidelines are proposed for USP.

The adoption of USP 800 confuses and frustrates me greatly. My understanding is that the boards purpose is the safety of patients. USP 800 is basically a workplace and environmental rule set. I have not seen any justification for its existence other than theoretical issues that in my 15 years of compounding what we do have never happened. I am sure that in some cases like with chemo drugs it is totally warranted but some of the safety measures required for hormones and other items are way over the top. The only thing USP 800 would do in my practice is cost 10s or thousands of dollars to implement, restrict access to medications and greatly increase costs to patients.

While appreciate the effort that has gone into these proposed rules I don't feel they are at a point to be adopted. I think that with a little bit of work form a rules committee and some more time and input from the community a rule set that is specific for Oregon could be adopted without all the confusion and waste that is associated with the federal guidelines. As it stands now these rules depending on some of the clarification and interpretation would at best increase the cost of medications to patients and at worst put me completely out of business eliminating access to many patients medications for very little benefit.

George Hiers
Northwest Compounding Pharmacy
541-672-8399

KLEIN Mo * BOP

From: Katie E Jaeger <Kay.E.Jaeger@kp.org>
Sent: Monday, May 21, 2018 11:00 AM
To: PHARMACY RULEMAKING * BOP
Cc: Tabitha L Fridriksson
Subject: OBOP-Comments for Division 45 Rulemaking

Kaiser Permanente Foundation Healthplan of the Northwest
500 NE Multnomah St, Suite 100
Portland, OR 97232

Attn: Oregon Board of Pharmacy

Thank you for the opportunity to comment on the proposed rulemaking regarding Division 45 Compounding rules.

855-045-0550

Compounding - Labeling

(2) (a) The name, quantity and concentration of the drug added and the primary solution;

KP comment: Propose that we do not add all of this information to the label. The space on a label is limited. The source information of the compound is maintained on the compounding log. The additional information does not reflect the final product and can lead to patient confusion and a patient safety risk.

855-045-0610

Sterile Compounding - Personnel Compounding Sterile Preparations (CSPs)

(3) Documented training for each person, including temporary personnel, must be performed and completed by the PIC or other supervising pharmacist prior to sterile compounding or supervising the preparation of sterile preparations, and must include, at a minimum:

KP comment: Propose change in language to include: Documented training and competence for each person, including temporary personnel, must be verified by the PIC or other supervising pharmacist prior to sterile compounding or supervising the preparation of sterile preparations, and must include, at a minimum:

(n) Hazardous drug material handling.

KP comment: Propose change in language to include: Hazardous drug material handling and disposal.

(4) Personnel who fail any element of subsection (3) must be reinstructed and re-evaluated by trained sterile compounding personnel prior to performing compounding duties. Documentation to be kept on file.

KP comment: Suggest adding record retention period.

Thank you for your consideration,

Katie Jaeger, CPA

Pharmacy Regulatory-Northwest Region

(503)261-2138 (office) Cell phone: (503)-758-6887

(503)261-7567 (fax)

kponline.webex.com/meet/kay.e.jaeger

kp.org/thrive

This document has been created as part of the Quality Assurance/Peer Review Process at Kaiser Permanente under the protection of ORS 41.675 and RCW 4.24.250 and 70.41.200(3).

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From: Christian Laatsch
To: [PHARMACY RULEMAKING * BOP; PHARMACY BOARD * BOP](#)
Subject: Proposed amendments to Chapter 855
Date: Thursday, May 10, 2018 9:14:25 AM

To whom it may concern:

We received notice of the board's proposed amendments to rules related to compounding in Oregon. Are these changes restricted to pharmacies/pharmacists only, or would they also regulate physician in-office compounding?

Thank you in advance for any information you may be able to provide.

Christian Laatsch
Government Affairs Associate
American Society of Plastic Surgeons
claatsch@plasticsurgery.org
Work: (847) 228-3326
Cell: (262) 353-2715



Legacy Health
Pharmacy Services
1015 NW 22nd Avenue
Portland, OR 97210

To: Mo Klein
Project Manager
Oregon Board of Pharmacy

Re: Draft Rules for Compounding

Legacy Health Pharmacy Services has reviewed the Oregon Board of Pharmacy's proposed compounding rules and would like to provide further comment and encourage the formation of an administrative rule advisory committee (RAC) to further assist with safe compounding within the State of Oregon. We share similar concerns expressed at today's Rules Hearing around proposed / draft language that differs from current *and* draft USP < 795 >, < 797 > and < 800 > standards.

Legacy Health's hospital pharmacies are committed to compliance and patient safety with our nation's standards for sterile and non-sterile compounding. We would encourage the Oregon Board of Pharmacy to simplify the proposed compounding rules by adopting proposed language in **OAR 855-045-0500 (3)** "all drug compounding must adhere to guidelines of the current edition of the United States Pharmacopeia Chapters 795 (USP < 795 >) and 797 (USP < 797> as well as all applicable Chapters of USP and USP-NF related to the compounding practices at any location. By adoption of this language and removing other proposed rules, OBOP will be able to maintain current ruling based upon our national standards, (i.e. USP).

We support the Oregon Board of Pharmacy's mission "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." We believe that adoption of solo proposed **rule 855-045-0500** is in alignment with this mission. If the Oregon Board of Pharmacy deems it necessary to have additional rules for compounding, we hope that the pharmacy compounding community will be able to participate in the drafting of these rules through a rule advisory committee.

Thank you for your consideration.

Sincerely,
(electronic signatures)

Kathleen Stoner
Legacy Health
Vice President of Pharmacy

Michelle Murray
Legacy Health
Director, Clinical
and Quality Improvement

Carl Heisel
Legacy Health
Director, Legacy
Emanuel Medical
Center

From: Kyle Mulder
To: [PHARMACY RULEMAKING * BOP](#)
Subject: comment for proposed revision to compounding regulations
Date: Thursday, May 10, 2018 5:25:39 PM

The simple inclusion of compliance to USP 797 is the best way to keep OR regulations current.

I do suggest a significant review and expansion of the compounded sterile products section of the self checklist. Currently it still refers to the 24hr BUD rule, as well as not addressing many items that are required for a USP 797 compliant compounding suite or segregated compounding area.

Thank you,

Kyle Mulder
NSF, CETA CNBT, NEBB CPT CP
Controlled environment specialist
Technical Safety Services LLC Oregon
(503) 421-4634 Mobile
(800) 877-7742 Main office
kmulder@techsafety.com

For more information about TSS, please visit www.techsafety.com

KLEIN Mo * BOP

From: KARBOWICZ Fiona * BOP
Sent: Thursday, May 24, 2018 9:57 AM
To: KLEIN Mo * BOP; MACLEAN Karen S * BOP
Cc: EFREMOFF Brianne * BOP; FOX Cheryl * BOP; GIN Jane * BOP; BALL Joseph * BOP
Subject: FW: OR regulation clarification suggestions

FYI from Kyle Mulder.

I believe (based on his second sentence) that this is Rulemaking Commentary as well.

IEST is the Institute of Environmental Sciences and Technology. RP is Recommended Practices.

-----Original Message-----

From: Kyle Mulder <KMulder@techsafety.com>
Sent: Wednesday, May 23, 2018 3:09 PM
To: fiona.karbowicz@state.or.us
Subject: OR regulation clarification suggestions

Fiona,

Good to see and talk with you today. Sorry to send this to you and not the comment email, but I'm running very short on time. I'll send a PDF of that gap analysis over to you very soon.

A few of the hot topics that are not outlined well in current 797:

Ante room pressure requirement. Some people read the chapter and think the buffer room only has to be positive to the general area, but there shall be a differential between each ante room to general of minimum 0.020" water column. The non-hd shall be 0.020" to ante and HD rooms are -0.010" to -0.030" to ante or wherever they are accessed from. Airflow displacement should be discouraged (40 fpm or meat curtains).

Airflow visualization studies (often called smoke studies). Clearly required at no frequency in 797 and 800 in the hoods. Some people want to make those required every 6 months, I think that is bad and could write a book to you as to why. I suggest airflow visualization be required for hoods AND rooms every 4 years or when changes are made to layout, HVAC or process.

Turbulent flow ISO 5 areas are not allowed in 797, but people are still using turbulent flow isolators as well as poorly designed integrated iso 5 areas.

HEPA filter integrity for the clean rooms is suggested in current 797, I am told it will be required in new 797. It would be nice to just be able to do it and stop the back and forth arguing with clinical IQ, who believe it is required now.

Room temp. Currently 797 says should be below 20 C, 800 says shall, new 797 will likely be shall. Clarifying now might help a lot of poor, sweaty techs (and certifiers).

Dynamic vs static viables and non viable sampling. There is no question that dynamic/operational (should be called operational really) is the requirement, but it's not done at MANY locations.

That's it for certification stuff. There are tons of cleanroom construction issues, but an IEST RP is being created that would be very easy to reference once it is complete and it would address all those issues.

As always let me know if you have any questions,

Kyle Mulder
NSF, CETA CNBT, NEBB CPT CP
Controlled environment specialist
Technical Safety Services LLC.
(503) 421-4634 mobile
(800) 877-7742 main office
Kmulder@techsafety.com<mailto:Kmulder@techsafety.com> email

For more information about TSS, please visit: <https://www.techsafety.com><<https://www.techsafety.com/>>



May 23, 2018

Mo Klein
800 NE Oregon Street
Suite 150
Portland, OR 97232

RE: Notice of Proposed Rulemaking OAR 855-045-0500 through 855-045-0630

Dear Mr. Klein:

Thank you for the opportunity to provide comments to the Oregon Board of Pharmacy on proposed rulemaking for drug compounding, OAR 855-045-0500 through 855-045-0630.

The National Community Pharmacists Association represents the interests of America's community pharmacists, including the owners of more than 22,000 independent community pharmacies across the United States and 125 independent community pharmacies in Oregon. Together they represent an \$80 billion health care marketplace and employ 250,000 people.

According to a recent NCPA member survey, more than 88 percent of our members provide some form of compounding services. NCPA supports the principle that pharmacist-compounded medications are customized medications and that compounding is a necessary service to meet the needs of patient care. NCPA also supports safety and quality in compounding activities and encourages compounding pharmacists to become accredited by the Pharmacy Compounding Accreditation Board to promote these conditions. We believe it is critical to balance the standards and expectations of safety and quality with patient care needs and access to medications.

After reviewing the proposed rules, NCPA would like to present the following questions and comments for discussion.

1. Oregon Board of Pharmacy enforcement of USP General Chapter <800> upon finalization of proposed rules

Proposed OAR 855-045-0500 (3) (4) states: "All drug compounding must adhere to guidelines of the current edition of the United States Pharmacopeia Chapters 795 (USP <795>) and 797 (USP <797>), as well as any applicable Chapters of USP and USP-NF related to the compounding practices at any location. This includes but is not limited to Chapters 7, 71, 85, 151, 659, 731, 823, 1072, 1116, 1160, 1163, 1211, and 1229.5. (4) Compounding pharmacies and personnel must comply with federal and state regulations regarding compounding and handling hazardous drug products." Further, proposed OAR 855-045-0530 (3) states: "The equipment, components, devices, and utensils used for compounding of a drug preparation must be of appropriate design and capacity and must also be designed to protect the compounder from hazardous materials.

Mo Klein
May 23, 2018
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Minimum standards for pharmacies and equipment are dependent on the risk level of the products being prepared. A pharmacy must comply with all applicable USP standards commensurate with level of compounding being performed." USP General Chapter <800> is notably missing from the listing of applicable chapters but seems to be indirectly referenced in other proposed rules.

NCPA encourages the Oregon Board of Pharmacy to delay implementation and enforcement of USP <800> until December 1, 2019 to align with USP implementation of the chapter.

2. Clarification of the definition of "batch" and the connection to the requirements for non-sterile-to-sterile batch compounding

Proposed OAR 855-045-0510 (1) defines "batch" as "any specific quantity greater than one of a drug or other material that is intended to have uniform character and quality, within specified limits, and is produced during a single preparation carried out during a single time period." Proposed OAR 855-045-0610 (i) states "For non-sterile-to-sterile batch compounding, written policies and procedures must include: (A) process validation for chosen sterilization methods; and (B) End-product evaluation, quantitative, and qualitative testing." As it is currently written, the proposed rules seem to indicate that any non-sterile-to-sterile preparation of more than one vial or container would require sterility and end-product testing. NCPA is concerned that this requirement could have a substantial negative impact on patient care and access. For example, preservative-free dosage forms are individually packaged and would seem to require sterility and end-product testing under the proposed rules. The delayed access and increased cost associated with these requirements could prevent patients from receiving their much-needed medications. USP General Chapter <797> currently indicates sterility testing and bacterial endotoxin (pyrogen) testing should be done for high-risk level CSPs prepared in batches of more than 25 identical containers.

NCPA recommends the following change to proposed OAR 855-045-0610 (i): "For non-sterile-to-sterile batch compounding written policies and procedures must include: (A) process validation for chosen sterilization methods; and (B) End-product evaluation, quantitative, and qualitative testing **when appropriate**."

3. Clarification of the general requirements related to sterility of ingredients in compounded products

Proposed OAR 855-045-0530 (2) states: "The accuracy of identities, concentrations, amounts, purity, and sterility of ingredients in compounded products must be confirmed by reviewing labels on packages, observing and documenting correct measurements with approved and correctly standardized devices, and reviewing information in labeling and certificates of analysis provided by suppliers. (a) If the correct identity, concentration, amount, purity, and sterility of ingredients and components of compounded products cannot be confirmed, such ingredients and components must be discarded immediately." Many ingredients used in compounded products are not sterile. This proposed rule seems to prohibit the use of any non-sterile ingredient in a compounded product.

NCPA recommends the following change to proposed OAR 855-045-0530 (2): "The accuracy of identities, concentrations, amounts, purity, and sterility (**where applicable**) of ingredients in

Mo Klein
May 23, 2018
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compounded products must be confirmed by reviewing labels on packages, observing and documenting correct measurements with approved and correctly standardized devices, and reviewing information in labeling and certificates of analysis provided by suppliers. (a) If the correct identity, concentration, amount, purity, and sterility (**where applicable**) of ingredients and components of compounded products cannot be confirmed, such ingredients and components must be discarded immediately."

4. Clarification of the definition of the phrase "strength of significance"

Proposed OAR 855-045-0530 (5) states: "A drug product that is commercially available may only be compounded if: (a) It is medically warranted by the prescribing practitioner to provide an alternate ingredient, dosage form, or strength of significance, for an identified individual patient; or (b) The commercial product is not reasonably available in the market in time to meet the patient's needs." What does the Oregon Board of Pharmacy consider a "strength of significance"?

NCPA recommends the following change to proposed OAR 855-045-0530 (5): "A drug product that is commercially available may only be compounded if: (a) It is medically warranted by the prescribing practitioner to provide an alternate ingredient, dosage form, or strength ~~of significance~~, for an identified individual patient; or (b) The commercial product is not reasonably available in the market in time to meet the patient's needs."

5. Clarification of FDA identification of drug products prohibited in compounding for human use

Proposed OAR 855-045-0530 (6) states: "Compounding any drug product for human use that the FDA has identified as presenting demonstrable difficulties in compounding or has been withdrawn or removed from the market for safety or efficacy reasons is prohibited." NCPA is concerned that the intent behind the current wording of this proposed rule could be misconstrued, and drug products nominated for addition to the FDA Difficult to Compound List or to the Code of Federal Regulations under 21 C.F.R. §216.24 could be considered to meet this qualification and be prohibited prematurely.

NCPA recommends the following change to proposed OAR 855-045-0530 (6): "Compounding any drug product for human use that the FDA has ~~identified as presenting demonstrable difficulties in compounding included on the Difficult to Compound List or that~~ has been ~~included in 21 C.F.R. §216.24 withdrawn or removed from the market for safety or efficacy reasons~~ is prohibited."

6. Clarification of personnel compounding duties

Proposed OAR 855-045-0540 (2) states: "All personnel must possess the education, training and competency necessary to properly and safely perform compounding duties undertaken or supervised." NCPA supports appropriate authorization of personnel before compounding duties are undertaken.

Mo Klein

May 23, 2018

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NCPA recommends the following change to proposed OAR 855-045-0540 (2): "All personnel must possess the education, training and competency necessary to properly and safely perform compounding duties ~~undertaken or~~ supervised ~~or authorized to undertake.~~"

7. Clarification related to labeling of compounded drug products

Proposed OAR 855-045-0550 (1)(c) and (d) state: "The name of the base or diluent" and "The dosage form or route of administration" must be contained on the label of a compounded drug or medication order. While including the base or diluent makes sense when related to a cream, ointment, solution, or suspension, is this proposed rule intended to include all excipients used in capsules? NCPA is also concerned that the dosage form alone does not always imply one route of administration. For example, a gel could be applied topically, rectally, vaginally, or orally.

NCPA recommends the following change to OAR 855-045-0550 (1)(c): "The name of the base, ~~or~~ diluent, ~~or primary excipient.~~" NCPA recommends the following change to proposed OAR 855-045-0550 (1)(d): "The dosage form ~~or and~~ route of administration."

NCPA appreciates the opportunity to share our questions, comments, and recommendations with you. If you have any questions or would like to discuss our comments further, please contact me at 703-600-1179 or alliejo.shipman@ncpanet.org.

Sincerely,



Allie Jo Shipman
Associate Director, State Government Affairs



Together, we can make things happen...

Position Statement on Proposed Division 045 Compounding Rules Draft

The Oregon Society of Health-System Pharmacist does not support the rules as proposed by the Oregon Board of Pharmacy.

The Oregon Society of Health System Pharmacists (OSHP) has heard from licensees and OSHP members stating concerns with the proposed Division 045 Compounding Rules Draft set for rulemaking. Based on concerns about the impact to licensees and costs associated with adoption of these rules, OSHP opposes the current draft going into rule. We suggest further input from licensees be considered by OBOP, possibly through creation of a Rules Advisory Committee.

We appreciate the work of OBOP and would be happy to assist in identifying subject matter experts to participate in an advisory committee. Thank you for considering this input.

Sincerely,

A handwritten signature in black ink that reads "Dan R".

Dan Rackham

OSHP President 2017-18

Providence Health & Services
4400 NE Halsey St. Building 2
Portland, OR 97213



May 22, 2018

TO: Mo Klein
Project Manager
Oregon Board of Pharmacy

FROM: Jacob Thompson, PharmD, MS
Regional Director of Pharmacy Operations & Compliance
Providence Health & Services – Oregon

RE: Rule Making for Drug Compounding Rules

Thank you for the opportunity to comment on the proposed rules regarding the 4/26/2018 "Filing Caption: Repeals outdated and adopts new drug compounding rules" within Chapter 855-045. I am providing comments in my capacity as Regional Director of Pharmacy Operations & Compliance representing Providence Health & Services – OR. As the largest health system in the State of Oregon, it is important that we maintain our Values of Compassion, Dignity, Justice, Excellence and Integrity. Providence Health & Services prides our Value of Excellence as "We set the highest standards for ourselves and our ministries. Through transformation and innovation, we strive to improve the health and quality of life in our communities. We commit to compassionate, safe and reliable practices for the care of all." Aligning with Excellence, Providence Health & Services agrees with the Board that "all compounding must adhere to the guidelines of USP 795 and 797" as these guidelines are important to maintaining patient safety throughout the compounding process. Providence Health & Services consider the United States Pharmacopeia (USP) as the "Gold Standard" for sterile and non-sterile compounding. We believe it is important to follow the most up to date USP guidelines and specifically support the rule 855-045-0500 (3): "All drug compounding must adhere to guidelines of the current edition of the United States Pharmacopeia 795 (USP <795>) and 797 (USP <797>)."

We do have a few concerns with the proposed rules that we hope the Board will address:

- 1) While the rules do require adherence to the current edition of USP <795> and USP <797>, the proposed rules still have specifics called out separately throughout. USP chapters are currently under review in 2018 and thus could include updates that could counter the rules being proposed. **Our recommendation is to remove all proposed rules except 855-045-0500 and 855-045-0520.**

If the Board does not support our first concern and recommendation, we hope the Board will address these additional concerns:

- 2) Rule 855-045-0510 (2) and 855-045-0550 requires date and time for "Beyond-Use Date(s)". USP defines BUDs as "the date after which a compounded preparation shall not be used; determined from the date the preparation is compounded." USP chapters do not require time and it is not commonly used practice to include both date and time when applying beyond-use dates when using extended dating (e.g. 28 days, etc...). **Our recommendation is to remove "time" from this rule and apply the USP definition verbatim.**
- 3) Rule 855-045-0520 (2) refers to "a Board approved entity, every 3 years," but this list was not attached to the proposed rules, not made available in the February or April agenda, nor was as it easily accessible online. It is not possible to understand this impact without the list of "Board approved entities". **Our recommendation is to share this list for comment so outlets can assess the impact of this rule.**

Providence Health & Services
4400 NE Halsey St. Building 2
Portland, OR 97213



- 4) Rule 855-045-0530 (5) requires "a drug product that is commercially available may only be compounded if it is medically warranted or not commercially available in a reasonable time. Drug manufacturers continue to buy generic drugs to only create an oligopoly and raise drug prices. This is done for compounded products as well. For example, dexmedetomidine (Precedex®) makes a commercially available 100 ml (4 mcg/ml) and 50 ml (4 mcg/ml) for \$75.85 and \$41.71 (WAC pricing). However, the generic vial and base solution cost less than \$5. This product is used over 10,000 times for our institutions. It is common practice for pharmacies (institutional, 503A and 503B) to compound commercially available products. USP <797> does not require this rule or its intent. **Our recommendation is to eliminate 855-045-0530 (5).**
- 5) Rule 855-045-0540 (5)(a) states that "a pharmacist who engages in compounding must: Perform and document the review and verification of each step of the compounding process." It is common practice for a pharmacy technician to perform steps of a compounding process with pharmacist verification at the end of the process or at key points in the compounding process. It would be extremely burdensome for a pharmacist to perform each step of a compounding process. **Our recommendation is to eliminate 855-045-0540 (5)(a).**
- 6) Rule 855-045-0540 (5)(b) states that "a pharmacist who engages in compounding must: provide written information about the compounded preparation's active ingredient(s) to the patient at the time of dispensing." It is unclear if this rule was meant for institutional pharmacies who compound or just retail pharmacy outlets. It would be extremely burdensome for a pharmacist to notify every patient in the institutional outlet ("inpatient") or retail outlet ("ambulatory infusion centers") when their medication was compounded. **Our recommendation is to eliminate 855-045-0540 (5)(b).**
- 7) Rule 855-045-0560 (3) requires notification to the Board in the event of a patient-level recall. Providence Health & Services has policies and procedures in place when recalling medications. Some of these notifications are not due to a compounding error, but due to manufacturer recalls. There are many unmet questions on this notification. Does one patient recall require a notification to the Board? How quickly? What types of records are required? **Our recommendation is to eliminate "The recall procedure must include notification to the Board in the event of a patient-level recall."**
- 8) Rule 855-045-0570 (2)(b) requires a pharmacist to sign off on competency, training, and education for personnel. It is common practice across the State and US for pharmacy technicians to be the trainers of pharmacists and pharmacy technicians who compound. These technicians are often the ones actually compounding and are expected to be our subject matter experts when appropriately educated. **Our recommendation is to change the rule to include pharmacy technicians who are trained or educated by a PIC or pharmacist.**
- 9) Rule 855-045-0570 (5)(j) requires documentation of "physical evidence of proper weight of each ingredient." It is not practical for every ingredient to have documentation of proper weight, as often volume is sufficient. Requiring physical evidence would be extremely costly for outlets in Oregon. Additionally, it is not clear if a pharmacist signature would suffice this rule or if actual documentation of the physical weight or volume is necessary (i.e. picture or scale recordings). Again, requiring documentation of a picture or scale recordings would be extremely costly for outlets in Oregon. **Our recommendation is for the rule to be changed to "physical evidence of proper weight or volume of each ingredient" and that a pharmacist signature be acceptable.**
- 10) We are concerned that there may be other aspects of the proposed rules that could impact the practice of pharmacy across the state. While these rules have been discussed since the first of the year, it has been difficult to facilitate conversation on the

Providence Health & Services
4400 NE Halsey St. Building 2
Portland, OR 97213



rules since they were not published until 4/26/18. This has left very little time for necessary review with other professional colleagues within the state and with subject matter experts across the country. As stated in the Notice, these rules could have significant practice and fiscal impact across the state. If the rules are going to go beyond compliance with current USP chapters, **our recommendation is for a Rules Advisory Committee be formed to evaluate any additional rules beyond rules 855-045-0520.**

We appreciate the work of the Board and its mission. Thank you for the opportunity to provide comment on these proposed rules.

Sincerely,

A handwritten signature in black ink that reads "Jacob M. Thompson".

JACOB M. THOMPSON

To: Oregon Board of Pharmacy

From D. RACKHAM

Several pharmacists and pharmacy managers involved in sterile and non-sterile compounding reviewed the Division 045 Compounding Rules Draft. On their behalf, I respectfully submit the following comments, suggestions for edit and questions on the draft rules:

855-045-0520

(2) In addition to obtaining an Oregon pharmacy drug outlet registration, all compounding

77 pharmacies must either pass an inspection by a Board approved entity or must receive

78 accreditation by a Board approved entity, every 3 years at a minimum, in order to

79 distribute or dispense sterile compounded preparations into and within Oregon.

855-045-0530

99 (1) All active pharmaceutical ingredients must be obtained from an FDA and Board

100 registered manufacturer.

(2) (b) Ingredients that do not have expiration dates assigned by the manufacturer or

124 supplier, must be labeled on the container with the date of receipt and must be assigned an

125 expiration date not to exceed two years after receipt of the component.

(5) (b) The commercial product is not reasonably available in the market in time to meet the

167 patient's needs.

Commented [DR1]: How will pharmacies know who board approved entities are? Is DNV, Samaritans accreditation agency a board approved entity? Does this mean that any pharmacy that does compounding has to be accredited?

Commented [DR2]: Active pharmaceutical ingredients may need to be included in definitions, some have questions on whether bases, dyes, colors and flavors need obtained from FDA and Board registered manufacturer

Commented [DR3]: Can there be exceptions for shortages when importing non-US based products? I assume sodium chloride 0.9% would be considered an active pharmaceutical ingredient, not sure if the imported small volume parenterals were Board registered. Are all manufacturers currently registered with OBOP?

Commented [DR4]: Why 2 years? Why not follow USP 795 (3 years) and USP 797 (1 year). Is this evidence based?

Commented [DR5]: May cost be used as a justification for not reasonably available?

855-045-0550

(B) For a sterile compounded product, in the absence of stability and sterility testing, USP

247 797 limits the BUD of a compounded sterile product to the following, based on risk level:

Risk Level	Controlled Room Temperature	Cold Temperature	Frozen
Immediate Use	1 hour from start of compounding	NA	NA
Low – Segregated Compounding Area	12 hours or less from compounding	NA	NA
Low	48 hours	14 days	45 days
Medium	30 hours	9 days	45 days
High	24 hours	3 days	45 days

Commented [DR6]: This is being updated in new USP 797 draft and categories, definitions and BUDs are changing - suggest referencing 797 standards rather than using specifics to allow for changes over years.

(2) (d) The scheduled time for administration;

(2) (h) The name or initials of the verifying pharmacist.

Commented [DR7]: Why is this needed on the label? Home infusion setting describes difficulty doing this when sending out multiple doses at a time and patients will be confused. A patient will not be digging through to look for the Tuesday 8pm dose, they will just get one every 8 hours. Why is this necessary on an IV product and not oral tablets?

855-045-0580

(2) (b) Name and signature of the PIC or other pharmacist employed by the pharmacy who is

Commented [DR8]: Is an electronic link to who verified acceptable?

316 designated as responsible for validating the completion of all training.

Commented [DR9]: Can a technician conduct the training and RPh validate?

(4) (B) Mixing temperatures or other environmental controls;

(4) (C) Duration of mixing; and

Commented [DR10]: Are we expected to record the temperature of the mixing room on a master formulation record each time we mix?

(4) (A) Generic name and quantity ~~or~~ and concentration of each active ingredient;

Commented [DR11]: Why must this be recorded and to what level of detail is needed? Hours, minutes, seconds?

370 (a) Name, strength, and dosage form of the preparation;

Commented [DR12]: Not sure if form should be here, but line 325 is identical and includes "form"

380 (f) Name of the person who prepared the preparation, name of the person who performed

381 the quality control procedures, and name of the compounder who approved the
382 preparation;

Commented [DR13]: Does technician/pharmacist initials suffice here? Or do we need 3 initials now?

390 (j) Physical evidence of the proper weight of each ingredient;

Commented [DR14]: Is this for sterile and non-sterile or non-sterile only? What's an example of what OBOP would like to see for this?

855-045-6510

(3) Documented training for each person, including temporary personnel, must be
429 performed and completed by the PIC or other supervising pharmacist prior to
sterile

Commented [DR15]: Can a technician do this? Says must be performed and completed by a pharmacist, but technicians are often a better choice.

430 compounding or supervising the preparation of sterile preparations, and must
include, at a

(4) Personnel who fail any element of subsection (3) must be reinstructed and re-
evaluated

480 by trained sterile compounding personnel prior to performing compounding
duties.

481 Documentation to be kept on file.

Commented [DR16]: For how long?

(a) The PIC must not be in charge of more than one licensed compounding pharmacy
at a

492 time. The PIC must be on site at that pharmacy for a minimum of twenty hours
per week.

493

494 For DISCUSSION:

495 • Does the Board want to keep this requirement?

Commented [DR17]: Yes, we agree with this requirement and think it should be kept.

496

497 If so, does the Board want to include waiver language for a specific pharmacy to
request a

498 waiver, per specific circumstances (to be outlined by the Board, such as rural location)?

(7) (b) Successfully complete the required competency training appropriate for the type of

Commented [DR18]: Will the Board determine what's required or leave up to pharmacies?

557 compounding performed or supervised;

(f) Compound batch sizes that the pharmacist has determined are of an appropriate size to

569 maintain product integrity and safety.

570 • Does this need to be further defined?

571 • Does the Board want to require end product testing for certain batch sizes (for example,

572 If Batch Size > __, compounder must perform.....)

573 • Does the Board want to require an Annual Report for all compounding pharmacies to

574 notify OBOP about details such as batch sizes, % of compounding performed patient575

specific vs. non-patient specific, etc.?

Commented [DR19]: What will the Board do with this information? Is a quality system in place at OBOP to analyze the data submitted and correlate with outcomes? This will be a tremendous amount of work for pharmacies to submit so if we're required to do so, we will expect OBOP to be using the data in a meaningful way

855-045-0620

594

595 Microbial Contamination Risk Levels and Beyond-Use-Dates

596

597 Risk levels of CSPs recognized by USP <797> are based on the probability of

598 contamination by microbial, chemical or physical agents. Low-Risk and Medium-Risk

599 Level CSPs are determined by the potential for microbial contamination during

600 preparation, and High-Risk Level CSPs by the potential for not being properly sterilized

601 before administration to patients. These risk levels, including Immediate-use provisions,

602 are defined, and products must be prepared and managed per current USP standards.

Commented [DR20]: These definitions (low, medium, high risk) are changing in the new USP 797 draft so best not to use them or will need to be updated when 797 draft final.

DRAFT

May 22, 2018

Dear Oregon Board of Pharmacy,

There is currently a nationwide injectable opioid shortage being referred to as "the other opioid crisis." This shortage is expected to last into 2019. Hospitals are buying whatever dosage form that is available and this often results in purchasing of dosage sizes that are larger package size than needed for a single dose (e.g. hydromorphone 2mg vial when average dose is 0.5mg). As a result, many hospitals have started or are contemplating repackaging these larger doses into smaller doses to avoid waste of a drug that is in critically short supply.

On behalf of the health system pharmacists in Oregon we are requesting a temporary exception to USP 797 beyond use dating for repackaged injectable opioids. Our request is to temporarily allow hospitals to assign a 6 day beyond use date for repackaged injectable opioids when stored at room temperature.

Based on USP 797 standards, hospitals repackaging opioids are assigning a 30 hour beyond use date for room temperature storage under the medium risk compounded sterile product (CSP) classification. Extending this beyond use dating to 6 days would allow for significantly less waste of expiring product and less burdensome impact on staff repackaging injectable opioids.

The request for 6 day beyond use dating at room temperature comes from the latest draft USP 797 guidelines. These guidelines classify CSPs prepared in a cleanroom environment as category 2 CSPs and may be given a 6 day beyond use date if prepared from only sterile starting components.¹ For your reference, the second page of this letter includes the Table from the draft standards with inclusion of 6 day room temperature beyond use dating.

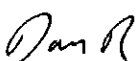
Oregon hospitals are struggling to continue to supply injectable opioids to patients needing intravenous pain management including surgical patients, oncology patients and hospice patients. This temporary measure would allow for hospitals to continue to provide essential pain management to some of our most vulnerable patients.

Thank you for considering this request.

Representatives from the following hospitals and health systems discussed this request and indicated their support on 5-22-18:

- Legacy, Providence, Samaritan, Peacehealth, Asante, Salem Health, St. Charles, Willamette Valley Medical Center, Adventist, Tuality, Oregon State Hospital, Kaiser Permanente.

Sincerely,



Dan Rackham, PharmD, BCPS
Pharmacy Manager, Samaritan Lebanon Community Hospital
President, Oregon Society of Health System Pharmacists 2017-18

Reference

1. USP-NF (Sept. 25, 2015). <797> Pharmaceutical Compounding – Sterile Preparations. Retrieved from http://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/usp-gc-797-proposed-revisions-sep-2015.pdf

Table 8. BUDs for Category 2 CSPs^a

Preparation Characteristics				Storage Conditions		
	Method of Achieving Sterility	Sterility Testing Performed	Preservative Added	Controlled Room Temperature (20°–25°)	Refrigerator (2°–8°)	Freezer (–25° to –10°) ^b
BUD	Aseptically prepared CSPs	No	No	Prepared from one or more nonsterile starting component 4 days	Prepared from one or more nonsterile starting component 7 days	Prepared from one or more nonsterile starting component 45 days
				Prepared from only sterile starting components 6 days	Prepared from only sterile starting components 9 days	Prepared from only sterile starting components 45 days
		Yes	Yes ^c	28 days	42 days	45 days
			No	28 days	42 days	45 days
			Yes ^d	42 days	42 days	45 days
	Terminally Sterilized CSPs	No	No	14 days	28 days	45 days
			Yes ^c	28 days	42 days	45 days
		Yes	No	28 days	42 days	45 days
			Yes ^d	42 days	42 days	45 days

^a The BUDs specified in the table indicate the days after the Category 2 CSP is prepared beyond which the CSP cannot be used. The BUD is determined from the time the CSP is compounded. One day is equivalent to 24 hours.

^b The integrity of the container–closure system with the particular CSP in it must have been demonstrated for 45 days at frozen storage. The container–closure integrity test needs to be conducted only once on each formulation in the particular container–closure system in which it will be stored or released/dispensed.

^c The particular CSP formulation must pass antimicrobial effectiveness testing in accordance with (51) at the time of preparation. The test must be completed and the results obtained on the specific formulation before any of the CSP is dispensed. The test needs to be conducted only once on each formulation in the

Staff Response:

Staff recommends that the proposed compounding rules not be adopted at this time, but be re-evaluated via Board discussion at the June 2018 meeting.

Expectation of full compliance with the USP Chapter standards is not negotiable, as exhibited by the Pew Charitable Trusts report, *State Oversight of Drug Compounding*, published in February 2018. Oregon is only one of a handful of states that has yet to require full compliance with the USP standards, and our patients deserve the care and drug safety they have come to rely on from the pharmacy profession.

Staff is not recommending a Rules Advisory Committee. The Board and staff identify and utilize the necessary tools for the rule writing process including workgroups, national meetings, conversing with local pharmacists at professional society meetings, roundtable meetings, coalition meetings, and annual pharmacy inspections. For the rewrite of Division 045 (compounding rules), rule drafts have been informed by a great deal of stakeholder input and subject matter expertise.

In the early part of the process, staff held two compounding work group meetings (April 2014 and July 2014). To gain insights from other states and the federal oversight of compounding policy and regulation, staff participated in all six of the FDA's 50 State Compounding Conferences, held in December 2012, March 2014, March 2015, November 2015, September 2016 and September 2017.

Additionally, staff have conversed regularly with licensees via phone and email and at association meetings, pharmacy roundtable meetings, coalition meetings and numerous pharmacy inspections, gaining insights to current compounding processes in Oregon, as well as the challenges licensees face when complying with USP Chapter standards.

The proposed rules are the compilation of all these efforts as well as input/policy directives from the Board at meetings since 2012.

The proposed Temporary rule in OAR 855-019-0460 is provided for the Board's review to consider for permanent rulemaking.

ORS 689.681(4) states "Notwithstanding any other provision of law, a pharmacy, a health care professional with prescription and dispensing privileges or *any other person designated by the State Board of Pharmacy by rule may distribute* unit-of-use packages of naloxone, and the necessary medical supplies to administer the naloxone.

The **bold** and ~~strike-through~~ edits below represent the current Temporary Rule that expires June 26, 2018.

Certain entities are in the position to provide naloxone distribution within their agency. In order to allow this to occur, sub (8) was added.

855-019-0460

Delivery of Care

(1) A pharmacist can prescribe naloxone and the necessary medical supplies for opiate overdose training.

(2) A pharmacist can prescribe naloxone and the necessary medical supplies to an individual or entity seeking naloxone.

(3) The pharmacist shall determine that the individual (or the individual on behalf of an entity) seeking naloxone demonstrates understanding of educational materials related to opioid overdose prevention, recognition, response, and the administration of naloxone.

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

(5) The pharmacist shall dispense the naloxone product in a properly labeled container.

~~(5)~~ **(6)** Naloxone may not be dispensed **prescribed** without **offering to provide** oral counseling to the authorized recipient, ~~to~~ **which may** include dose, effectiveness, adverse effects, storage conditions, and safety.

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

(8) Any person, having once lawfully obtained naloxone may possess, distribute or administer it for the purpose of reversing opiate overdose.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.305, 689.681, 689.682 and 689.684

Goodman, Diane M. *Should Everyone Carry Narcan®? Let's Think This Through*. Medscape ; April 6, 2018. (Accessed 24 May 2018).

The proposed rules implement the [2017 HB 2397](#) signed by Governor Kate Brown on May 18, 2017. The multi-disciplinary Public Health and Pharmacy Formulary Advisory Committee will make recommendations for the Board to adopt by rule, protocols, drugs/drug categories, and devices fitting for pharmacists to prescribe.

Per statute, the Board shall establish a formulary of drugs and devices, as recommended by the committee that a pharmacist may prescribe and dispense to a patient pursuant to a diagnosis by a health care practitioner, who has prescriptive authority and who is qualified to make the diagnosis.

The formulary may include post-diagnostic drugs and devices such as diabetic testing supplies, emergency refills of insulin, albuterol inhalers, epinephrine auto-injectors, smoking cessation aids, discharge medications for transitions of care, rapid strep tests and spacers.

WEBPAGE:

These proposed rules create a new Division 020 in Oregon Board of Pharmacy's Chapter 855 dedicated to these processes.

DIVISION 20

Pharmacist Prescriptive Authority

855-020-0105 - Public Health and Pharmacy Formulary Advisory Committee

(1) The Public Health and Pharmacy Formulary Advisory committee shall consist of:

(a) Two physicians licensed to practice medicine under ORS 677.100 to 677.228;

(b) Two advanced practice registered nurses who have prescriptive authority and who are licensed by the Oregon State Board of Nursing; and

(c) Three pharmacists licensed by the State Board of Pharmacy, at least one of whom is employed as a community pharmacist and one of whom is employed as a health system pharmacist.

(2) A pharmacist may submit a concept, on a form prescribed by the Board to the committee for consideration, for the development of a protocol or the addition of a drug or device to the formulary.

(3) The committee shall recommend to the Board, for adoption by rule, a protocol, formulary of drugs and devices from which a pharmacist may prescribe and dispense to a patient pursuant to a diagnosis by a qualified health care practitioner.

(4) The committee shall periodically review the formulary and protocol compendium and recommend the revisions to the board for adoption by rule.

Stat. Auth.: ORS 689.205

Stat. Implemented: 689.645, 689.649

DRAFT

DIVISION 045 COMPOUNDING

Rules 855-045-0200 through 855-045-0630 are proposed to be repealed.

855-045-0500

COMPOUNDING

Purpose

(1) These rules apply to any person, including any business entity, located in or outside Oregon that engages in the practice of compounding a drug for the use by a patient located in Oregon. Any person located outside Oregon must follow the compounding rules of their home state or these rules, whichever are more stringent.

(2) These rules apply to sterile and non-sterile compounding of medications.

(3) All drug compounding must adhere to guidelines of the current edition of the United States Pharmacopeia Chapters 795 (USP <795>) and 797 (USP <797>), as well as all applicable Chapters of USP and USP-NF related to the compounding practices at any location. This includes but is not limited to Chapters 7, 71, 85, 151, 659, 731, 823, 1072, 1116, 1160, 1163, 1211, and 1229.5.

(4) Compounding pharmacies and personnel must comply with federal and state regulations regarding compounding and handling hazardous drug products.

Stat. Auth.: ORS 689.205

Stats Implemented: ORS 689.155

855-045-0510

General Definitions

(1) “Batch” means any specific quantity greater than one of a drug or other material that is intended to have uniform character and quality, within specified limits, and is produced during a single preparation carried out during a single time period.

(2) “Beyond-Use Date” and “BUD” means the date and time after which a compounded product must not be used (or stored or transported). The date is determined from the date and time the preparation is compounded, according to risk level.

(3) “Hazardous Drug” means any drug identified as hazardous by the National Institute for Occupational Safety and Health (NIOSH) at the Centers for Disease Control or any drug that meets at least one of following six criteria.

40 (a) Carcinogenicity.

41 (b) Teratogenicity or developmental toxicity.

42 (c) Reproductive toxicity in humans.

43 (d) Organ toxicity at low doses in humans or animals.

44 (e) Genotoxicity.

45 (f) New drugs that mimic existing hazardous drugs in structure or toxicity.

47 Stat. Auth.: ORS 689.205

48 Stats Implemented: ORS 689.155

51 855-045-0520

53 Registration

55 (1) A pharmacy that compounds a drug and dispenses a patient specific drug must register
56 with the Board as a retail drug outlet or an institutional drug outlet or both if dispensing to
57 both and ambulatory and residential patient. This applies to resident and non-resident
58 pharmacies.

60 (2) In addition to obtaining an Oregon drug outlet registration, all compounding
61 pharmacies must either pass an inspection by a Board approved entity or must receive
62 accreditation by a Board approved entity, every 3 years at a minimum, in order to
63 distribute or dispense sterile compounded preparations into and within Oregon.

65 (3) A non-resident facility distributing non-patient specific drugs into Oregon must be
66 registered with the Federal Drug Administration as a 503B Outsourcing Facility and
67 register as an Oregon Manufacturer.

69 (4) A resident facility distributing non-patient specific drugs outside of Oregon must
70 register with the Federal Drug Administration as a 503B Outsourcing Facility and register
71 as an Oregon Manufacturer.

73 Stat. Auth.: ORS 689.205

74 Stats Implemented: ORS 689.155

77 855-045-0530

79 General Requirements for Compounding

81 (1) All active pharmaceutical ingredients must be obtained from an FDA and Board
82 registered manufacturer.

(2) The accuracy of identities, concentrations, amounts, purity, and sterility of ingredients in compounded products must be confirmed by reviewing labels on packages, observing and documenting correct measurements with approved and correctly standardized devices, and reviewing information in labeling and certificates of analysis provided by suppliers.

(a) If the correct identity, concentration, amount, purity and sterility of ingredients and components of compounded products cannot be confirmed, such ingredients and components must be discarded immediately.

(3) The equipment, components, devices, and utensils used for compounding of a drug preparation must be of appropriate design and capacity and must also be designed to protect the compounder from hazardous materials. Minimum standards for pharmacies and equipment are dependent on the risk level of the products being prepared. A pharmacy must comply with all applicable USP standards commensurate with level of compounding being performed.

(a) Equipment must be of suitable composition that a surface which contacts a component is neither reactive nor alters the purity of a compounded preparation.

(b) Equipment must be stored to protect it from contamination and must be located to facilitate its use, maintenance and cleaning.

(c) Automated, mechanical, electronic and other types of equipment must be routinely inspected, cleaned and calibrated per the stricter requirement of USP or the manufacturer's specification.

(4) Any compounding activity that is not pursuant to a valid prescription or an order to prepare for administration and for a specific patient is considered to be manufacturing, and any person engaged in manufacturing must be registered in accordance with Division 060, with the following exceptions:

(a) Compounding in anticipation of a prescription drug order or an order to prepare for administration, based on a history of receiving valid prescription drug orders for the compounded or sterile prepackaged drug product; or

(b) Preparing non-controlled compounded products by an Oregon pharmacy for a practitioner located in Oregon, documented by use of Board approved Shared Pharmacy Services agreement.

(5) A drug product that is commercially available may only be compounded if:

(a) It is medically warranted by the prescribing practitioner to provide an alternate ingredient, dosage form, or strength of significance, for an identified individual patient; or

(b) The commercial product is not reasonably available in the market in time to meet the patient's needs.

(c) Justification of compounding pursuant to OAR 855-045-0530(5) must be documented and retained by the pharmacy for a minimum of three years and be made available for inspection.

(6) Compounding any drug product for human use that the FDA has identified as presenting demonstrable difficulties in compounding or has been withdrawn or removed from the market for safety or efficacy reasons is prohibited.

Stat. Auth.: ORS 689.205

Stats Implemented: ORS 689.155

855-045-0540

Compounding Personnel and Responsibilities

(1) All personnel, who prepare and supervise the preparation of compounded pharmaceuticals must be provided with appropriate training and testing before they begin to prepare or supervise preparation of such products, including theoretical principles and practical skills of manipulations.

(2) All personnel must possess the education, training and competency necessary to properly and safely perform compounding duties undertaken or supervised.

(3) A person licensed to practice pharmacy by the Oregon Board of Pharmacy who is working in a compounding pharmacy, including a pharmacy that only prepares sterile parenteral products, has the duty to exercise that degree of care, skill, diligence and professional judgment that is used by ordinarily competent, careful pharmacists in the same or similar circumstances.

(4) The pharmacist in charge (PIC) and the drug outlet must establish pharmacy's standard operating procedures and processes in accordance with the guidelines of current USP Chapters, as applicable, for all compounding related activities of the pharmacy and is responsible for the overall ongoing validation of the compounding competency of pharmacists and technicians.

(5) A pharmacist who engages in compounding must:

(a) Perform and document the review and verification of each step of the compounding process;

(b) Provide written information about the compounded preparation's active ingredient(s) to the patient at the time of dispensing. If there is no written information available, the

patient must be advised that the drug had been compounded and how to contact a pharmacist, and if appropriate, the prescriber, concerning the medication; and

(c) Compound batch sizes that have been determined are of an appropriate size to maintain product integrity and safety.

(d) Maintain proper BUDs for all compounded preparations, including aliquots.

Stat. Auth.: ORS 689.205

Stats Implemented: ORS 689.155

OAR 855-045-0550

Labeling

(1) In addition to the labeling requirements as specified in Division 41, the label of a compounded drug or medication order dispensed or distributed must contain the following, at a minimum:

(a) The generic or official name of each active ingredient;

(b) The strength or concentration of each active ingredient;

(c) The name of the base or diluent;

(d) The dosage form or route of administration;

(e) The total quantity of the drug product;

(f) A beyond-use-date (BUD), compliant with current USP chapters;

(g) Handling, storage or drug specific instructions, cautionary information, and warnings as necessary or appropriate for proper use and patient safety; and

(h) A statement that the product has been compounded by the pharmacy (An auxiliary label may be used on the container to meet this requirement).

(2) In addition to the labeling requirements as specified in Division 41, whenever a drug is added to a parenteral solution under the direct supervision of a pharmacist, the label of the compounded drug dispensed or distributed must contain the following, at a minimum

(a) The name, quantity and concentration of the drug added and the primary solution;

(b) The beyond use date, to include date and time;

(c) Recommended frequency/schedule for administration

(d) The infusion rate, when applicable;

(e) The name or initials of person performing admixture;

(f) The identification of the pharmacy where the admixture was performed; and

(g) The name or initials of the verifying pharmacist.

Stat. Auth.: ORS 689.205

Stats Implemented: ORS 689.155

855-045-0560

Quality Controls for Compounding

(1) The pharmacist-in-charge and drug outlet must develop and the pharmacy must follow quality control procedures to monitor the compounding environment and quality of compounded drug preparations for conformity with the quality indicators established for the preparation.

(2) The pharmacist-in-charge must adhere to the provisions of all applicable USP chapters for development and ongoing adherence to quality control procedures. Such procedures must be documented and be available for inspection.

(3) The pharmacist-in-charge must establish a written adverse event reporting process and recall procedure. The recall procedure must include notification to the Board in the event of a patient-level recall.

Stat. Auth.: ORS 689.205

Stats Implemented: ORS 689.155

855-045-0570

Records

(1) All compounding records, including training documents, master formulation records, compounded preparation records, and individual prescription records, must be maintained electronically or manually, stored in an organized manner, retained for a minimum of three years and be made readily available for inspection by the Board.

(2) The pharmacy must maintain a training record for each person, including temporary personnel, who compound preparations. At a minimum, the record must contain:

(a) Documentation of initial and continuing competency, training, and education for personnel; and

(b) Name and signature of the PIC or other pharmacist employed by the pharmacy who is designated as responsible for validating the completion of all training.

(3) The pharmacy must maintain an organized index of master formulation records for all compounded products.

(4) Records for compounding must utilize a master formulation record. All master formula records must be developed and approved by the pharmacist for compounded preparations, and records for all preparations must contain, at a minimum:

(a) The name, strength and dosage form of the preparation;

(b) Calculations needed to determine and verify quantities of components and doses of ingredients;

(c) Description of all ingredients and their quantities;

(d) Compatibility and stability information, including references when available;

(e) Equipment needed to prepare the preparation when appropriate;

(f) Mixing instructions that must include:

(A) Order of mixing;

(B) Mixing temperatures or other environmental controls;

(C) Duration of mixing; and

(D) Other factors pertinent to the replication of the preparation as compounded.

(g) Sample labeling information, to contain, at a minimum:

(A) Generic name and quantity or concentration of each active ingredient;

(B) Assigned BUD;

(C) Storage conditions; and

(D) Prescription or control number, whichever is applicable.

(h) Containers and closures used in dispensing;

(i) Packaging and storage requirements;

(j) Descriptions of final preparation;

(k) Quality control procedures and expected results; and

(l) Appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate.

(5) Any compounded product must be documented and the unique compounded preparation record, must include but not be limited to the following:

(a) Name, strength, and dosage of the preparation;

(b) Master Formulation Record reference for the preparation;

(c) Names and quantities of all components;

(d) Sources, lot numbers and expiration dates of components;

(e) Total quantity compounded;

(f) Name of the person who prepared the preparation, name of the person who performed the quality control procedures, and name of the compounder who approved the preparation;

(g) Time and date of preparation;

(h) Assigned control or prescription number;

(i) Assigned BUD;

(j) Physical evidence of the proper weight of each ingredient;

(k) Duplicate label as described in the Master Formulation Record;

(l) Description of final preparation;

(m) Results of quality control procedures (e.g. weight range of filled capsules pH of aqueous liquids)

(n) Documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver.

STERILE COMPOUNDING

855-045-0600

Purpose – Sterile Compounding

The requirements of this chapter apply to any person or facility that compounds sterile drug preparations (CSPs). These rules represent minimum sterile compounding practices for the preparation of drug products to be dispensed or administered. The minimum standards of the current edition of the United States Pharmacopeia Chapter <797> and all other applicable USP Chapters regarding sterile compounded products must be met unless requirements listed are more stringent.

Stat. Auth.: ORS 689.205

Stats Implemented: ORS 689.155

OAR 855-045-0610

Personnel Compounding Sterile Preparations (CSPs)

(1) These rules apply to all persons who prepare compounded sterile preparations (CSPs) and all places where CSPs are prepared.

(2) Compounding personnel are responsible for ensuring that CSPs are accurately identified, measured, diluted, and mixed and are correctly purified, sterilized, packaged, sealed, labeled, stored, dispensed, and distributed.

(3) Documented training for each person, including temporary personnel, must be performed and completed by the PIC or other supervising pharmacist prior to sterile compounding or supervising the preparation of sterile preparations, and must include, at a minimum:

(a) Fundamentals of sterile compounding manipulations;

(b) Responsibilities of compounding personnel;

(c) Purpose and utilization of policies and procedures;

(d) Use of all applicable equipment and supplies, to include automated compounding devices;

(e) Facility and personnel environmental sampling metrics, to include but not limited to:

(A) Garbing competency;

(B) Hand hygiene and proper work practices competency, via gloved fingertip sampling;

(C) Media-fill testing of aseptic manipulation competency, at least annually for low and medium-risk level compounding and semi-annually for high-risk level compounding; and

(D) Cleaning and disinfecting competency, to include surface sample testing;

(f) Understanding of primary and secondary engineering controls, such as function, use, testing, and certification;

(g) Assignment of BUDs;

(h) Quality assurance, quality releases and final checks of CSPs;

(i) For non-sterile-to-sterile batch compounding, written policies and procedures must include:

(A) Process validation for chosen sterilization methods; and

(B) End-product evaluation, quantitative, and qualitative testing.

(j) Labeling and packaging controls;

(k) Batch documentation;

(l) Cleaning and disinfecting of controlled environments;

(m) Filtration and sterility processes, moist and dry-heat sterilization, bacterial endotoxin (pyrogen) testing, as applicable to risk level; and

(n) Hazardous drug material handling.

(4) Personnel who fail any element of subsection (3) must be reinstructed and re-evaluated by trained sterile compounding personnel prior to performing compounding duties. Documentation to be kept on file.

(5) The Pharmacist-In-Charge (PIC) must possess the education, training and proficiency necessary to properly and safely perform compounding duties undertaken or supervised.

(6) The PIC and drug outlet must establish and enforce written policies and procedures in compliance with standards set forth in the current Chapters of USP and USP-NF, and are designed to ensure accountability, accuracy, quality, safety and uniformity in the sterile compounding process. They must include but not be limited to:

(a) Education, training, and competency evaluation of all regular and temporary personnel;

(b) Proper hand hygiene and garbing for all CSP compounding;

(c) Proper maintenance and calibration of primary and secondary engineering controls as well as other areas and equipment used in the compounding process;

(d) Compounding procedures including but not limited to the use of automated compounding devices, and other specific procedures for CSPs;

(e) CSP compounding methodology and formula information, to include assignment of appropriate risk levels for all CSPs;

(f) Determination of beyond-use-dates;

(g) Appropriate sterilization and other preparation checks and release tests of CSPs;

(h) Verification of compounding accuracy and sterility for CSPs;

(i) Labeling, to include all names and amounts/concentrations of active ingredients;

(j) Proper maintenance of environmental quality and control, to include appropriate environmental sampling testing;

(k) Finished preparation release checks and tests;

(l) Cleaning and disinfecting the direct and contiguous compounding areas;

(m) Recall procedures for CSPs;

(n) Drug disposal, including hazardous waste if applicable. Hazardous waste disposal must comply with all federal and state regulations;

(o) Procurement, container selection, shipping, delivery and storage of pharmaceutical materials including compounded drug preparations and components used in the compounding of sterile preparations and drug delivery devices;

(p) Patient care and instructions;

(q) Quality assurance and control, to include adverse event and recall reporting per OAR 855-045-0570.

(7) A pharmacist who compounds or supervises sterile preparations must:

(a) Possess the education, training and proficiency required to properly and safely perform compounding duties undertaken or supervised;

(b) Successfully complete the required competency training appropriate for the type of compounding performed or supervised;

(c) Inspect and approve all ingredients, drug preparation containers, closures, labeling, and any other materials involved in the compounding process;

(d) Review all compounding records for accuracy and conduct in-process and final checks to ensure that safe compounding processes have occurred in the compounding process; and

(e) Ensure proper maintenance, cleanliness, calibration, and use of all equipment used in the compounding process.

(f) Compound batch sizes that the pharmacist has determined are of an appropriate size to maintain product integrity and safety.

(8) A pharmacy technician who compounds sterile preparations must:

(a) Possess the education, training and proficiency as required to properly and safely perform compounding duties undertaken;

(b) Successfully complete the required competency training appropriate for the type of compounding performed by the pharmacy technician;

(c) Respond to in-process and completion checks;

(d) Maintain appropriate records; and

(d) Ensure proper maintenance, cleanliness, and use of all equipment used in the compounding process.

Stat. Auth.: ORS 689.205

Stats Implemented: ORS 689.155

OAR 855-045-0620

Microbial Contamination Risk Levels and Beyond-Use-Dates

Risk levels of CSPs recognized by USP <797> are based on the probability of contamination by microbial, chemical or physical agents. Low-Risk and Medium-Risk Level CSPs are determined by the potential for microbial contamination during preparation, and High-Risk Level CSPs by the potential for not being properly sterilized before administration to patients. These risk levels, including Immediate-use provisions, are defined, and products must be prepared and managed per current USP standards.

Stat. Auth.: ORS 689.205

Stats Implemented: ORS 689.155

509
510 **855-045-0630**

511 **Records**

512 **(1) In addition to the requirements set forth in 855-045-0580, records for all compounded**
513 **sterile products (CSPs) must include:**

514
515 **(a) Primary solution;**

516
517 **(b) Container specification (e.g., syringe, pump cassette); and**

518
519 **(c) Infusion rate, when applicable;**

520
521 **(2) Sterile compounding training documentation must include:**

522
523 **(a) Printed name and signature of the person receiving the training;**

524
525 **(b) Name and signature of the person providing the training or evaluating competencies;**
526 **and**

527
528 **(c) Dates and results of all elements found in OAR 855-045-0610(3).**

529
530 **(3) Records of maintenance and certifications for all equipment, including environmental**
531 **sampling must be maintained electronically or manually, stored in an organized manner,**
532 **retained for a minimum of three years and be made readily available for inspection by the**
533 **Board.**

534
535 **(4) Records of cleaning and disinfecting of all compounding areas and equipment must be**
536 **maintained electronically or manually, stored in an organized manner, retained for a**
537 **minimum of three years and be made readily available for inspection by the Board.**

538
539 **(5) All records, procedures, training, and documentation must be maintained electronically**
540 **or manually, stored in an organized manner, retained for a minimum of three years and be**
541 **made readily available for inspection by the Board.**

542
543 **Stat. Auth.: ORS 689.205**

544 **Stats Implemented: ORS 689.155**

Compounding Law Five Years Later, FDA Implementation Slow, Industry Criticism Significant

By Stephen Barlas

P&T Community The Online Resource for P&T Decision Makers PT. 2018;43(5)

<https://www.ptcommunity.com/system/files/pdf/ptj4305271.pdf>

At the May 2018 NABP Annual meeting, USP gave an update.

Here is a timeline:

Below is the timeline associated for the proposed revisions to <795> and <797> and opportunities to engage with USP and provide input.



Note: The current version of General Chapters <795> and <797> published in USP-NF are official.

Here is a great link to this and a lot more background: <http://www.usp.org/compounding/updates-on-standards>

FDA CGMP Inspection of Outsourcing Facilities

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What are CGMPs?

- Under the Federal Food, Drug, and Cosmetic Act, a drug must be produced in accordance with current good manufacturing practice (CGMP).
 - FDA's CGMP regulations were first finalized in 1978, and are codified in Title 21 of the Code of Federal Regulations, parts 210 and 211.
- CGMPs provide for systems that assure proper design, monitoring, and control of manufacturing processes and facilities, including:
 - establishing strong quality management systems,
 - obtaining appropriate quality raw materials,
 - establishing robust operating procedures,
 - detecting and investigating product quality deviations, and
 - maintaining reliable testing laboratories.
- The basic tenet of CGMPs is that quality is not tested in, but built in.



CGMPs for Outsourcing facilities

- Unless a specific exemption applies, any drug that is not made in compliance with CGMP requirements is considered “adulterated” under the law (FD&C Act Section 501(a)(2)(B)).
- Outsourcing facilities are not exempt, and must comply with CGMP requirements.
 - See draft guidance, “Current Good Manufacturing Practice — Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act”
 - CGMP regulations specific to outsourcing facilities are under development.



CGMPs for Outsourcing facilities

- FDA recognizes the differences between compounding outsourcing facilities and conventional drug manufacturers, and the need, to some extent, to appropriately tailor CGMP requirements for outsourcing facilities.
- FDA evaluation of compliance with CGMP requirements by outsourcing facilities includes:
 - Assessing conformance with minimum standards
 - Identifying conditions that may represent a significant risk to patient safety



Insanitary Conditions

- FDA may also cite outsourcing facilities for insanitary conditions.
- FD&C Act 501(a)(2)(A) – “A drug is deemed to be adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.”
- The insanitary conditions prohibition applies to all facilities, regardless of type.



Overview of Outsourcing Facility Inspection Program

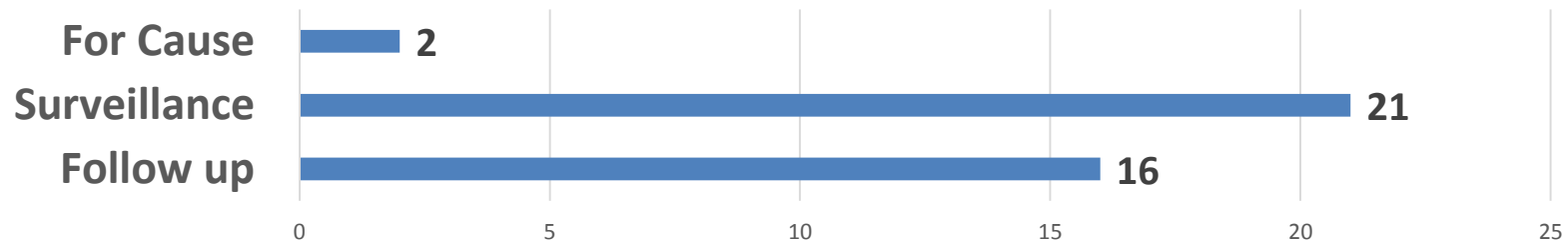
- To be eligible for the exemptions provided in section 503B, Outsourcing facilities must meet the conditions of section 503B(a) including:
 - Registration
 - Product reporting
 - Fees
- 77 entities registered as outsourcing facilities in FY 2017.
 - 6 small businesses
 - 6 facilities were initially registered as outsourcing facilities in FY 2017 but withdrew their registration before the end of the fiscal year.
 - On the last day of FY 2017, 71 facilities were registered.



Overview of Outsourcing Facility Inspection Program

- Inspection following initial registration (target 2 months)
- Risk based schedule; unannounced
- Duration: generally 8-10 business days
- Welcome & invite state participation
- Total: 39 inspections in FY 2017

Outsourcing Facility Inspections FY 2017





Goals for this Educational Session

- Describe key areas evaluated during FDA's CGMP inspection of an Outsourcing Facility, such as
 - Facility design
 - Equipment
 - HVAC
 - Aseptic operators and operations
- Discuss red flags that may indicate serious issues at a facility
- Respond to state requests for education on CGMPs to inform state oversight of outsourcing facilities
- Foster FDA-state communication and collaboration



CGMP Regulations and Guidance

The slides to follow describe practices related to:

- Regulatory requirements covered by CGMP regulations in Title 21 Code of Federal Regulations (CFR), parts 210 and 211, or
- Concepts described in published FDA guidance such as:
 - Sterile Drug Products Produced by Aseptic Processing —Current Good Manufacturing Practice (September 2004 – final guidance)
 - Current Good Manufacturing Practice — Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act (July 2014 – draft guidance)
 - Insanitary Conditions at Compounding Facilities (August 2016 – draft guidance)
- Unless stated as a requirement with a corresponding citation, slides describe FDA's current thinking as described in final guidance or statements in draft guidances, which, once finalized, will represent FDA's current thinking on the topic.



Types of content in this presentation

- **“In brief”** -- Outline of key topics or concepts in each section
- **Slides with photographs** – photographs of conditions that raise concerns taken during FDA inspections
- **“Form FDA 483 Observations”** -- examples of inspectional observations cited by FDA investigators
- **“Red flags”** – egregious conditions that raise serious quality concerns.



OUTLINE

PART ONE

Initial facility walk through

Aseptic operators and operations

Activity: Gowning worksheet

PART TWO

Process and facility design

Environmental and personnel monitoring

Activity: Case study 1

Product inspection and component control

BREAK

PART THREE

Packaging and labeling control

Records review

Activity: Case study 2

Special topics



PART ONE

Initial facility walk through

Aseptic operators and operations

Activity: Gowning worksheet



Initial Facility Walk-Through

WHY?

Opportunity to see conditions as they actually are, and identify obvious issues that may inform inspection approach



Initial Facility Walk-Through

In brief

- General facility design and equipment conditions
- Recordkeeping system
- Personnel, workflow



Initial Facility Walk-Through

Prior to walk-through, consider requesting documents such as:

- Complete drug product list (sterile and non-sterile drug products)
- Any out-of-specification sterility tests and all media fills results for the last year.
- Drug production log
- Organizational chart



Initial Facility Walk-Through

- Examination of facility design [work environment] and equipment for (examples below from FDA draft guidance on insanitary conditions):
 - Filth, dirt, dust, mold, mildew, insects, debris, trash
 - Peeling paint, chipped drywall, acoustic ceiling tiles with cut out holes
 - Cluttered equipment, unclean exhaust vent
 - Damaged/dirty/discolored HEPA
 - Water sources in the aseptic processing room
- Determination of whether the firm performs routine personnel monitoring and environmental monitoring of facilities and equipment



Initial Facility Walk-Through

- Identification of any significant issues with aseptic operators and operation, such as aseptic processing outside of ISO 5 classified air, lack of systems for air control.
- Identification of recordkeeping system, identification of any clear deficiencies such as apparent absence of such a system.

Egregious Conditions



Ongoing
construction

Egregious Conditions



Operations
ongoing

Egregious Conditions

Ceiling above the doorway to cleanroom with exposed insulation



Egregious Conditions



Visible
microbial
contamination

Egregious Conditions

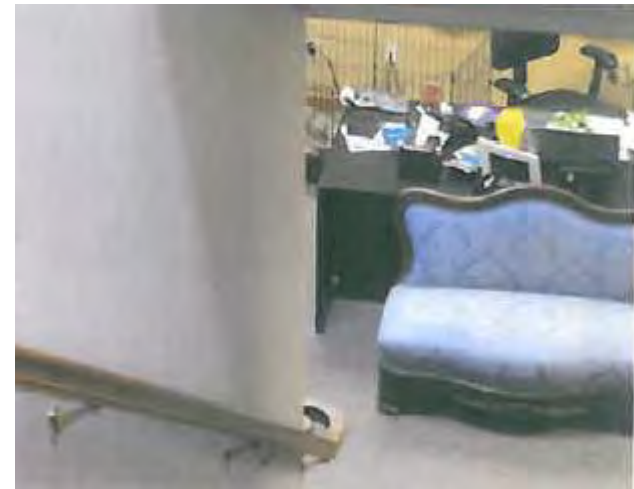
INITIAL FACILITY WALK THROUGH



Table for ISO-5 is laminated particle board

Egregious Conditions

- Left photo showing the ISO 7 & ISO 8
- Bottom photo showing the portable fence and pet bed.



Egregious Conditions



- Drinking water, obtained from an office-style top loaded 5-gallon bottled water dispenser in the kitchen area used without any processing to formulate injectable product.

Egregious Conditions



- Equipment, located in cleanroom, used to produce injectable drugs visibly dirty

Egregious Conditions



HEPA filters
visibly dirty



Initial Facility Walk-Through

Form FDA 483 Observations

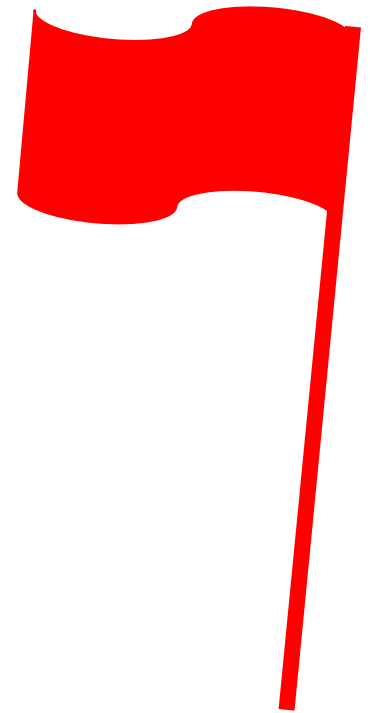
- Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.
 - A piece of apparent exposed particle board measuring approximately $\frac{3}{4}$ inches thick, 44 inches wide, and 6 inches deep was observed through the front edge guard vent of the ISO 5 LFH.



Initial Facility Walk-Through

Red flags

- Visible signs of filth, dirt, mold, insects, trash
- Aseptic manipulations outside of ISO-5 controlled air space
- Minimal or no recordkeeping system





Aseptic Operators and Operations

WHY?

Typically, the dirtiest items in the room are personnel.

Unqualified personnel and their actions can introduce contamination into the best designed and otherwise maintained facility



Aseptic Operators and Operations

In brief

- The highest risk of contamination occurs from or in connection with operators' aseptic technique practices.
- Observing gowning and aseptic operations is essential to a meaningful inspection.
- Importance of having sufficient time, based on the scale of operations, to observe a meaningful representation of aseptic operations.



Gowning

Potential areas to evaluate

- All outer gowning components used for aseptic operations should be sterile
- Gowning should be conducted such that sterile gowning apparel do not become contaminated (e.g. allowing sterile gown to touch floor, wall, or other nonsterile surface)
- No operator skin should be exposed after gowning is completed.
- Operators that leave and re-enter the cleanroom must re-gown properly (such that contaminants are not introduced)

Gowning



Gowning



Gowned employee working in the cleanroom, exposing legs

Gowning



ASEPTIC OPERATORS AND OPERATIONS



Gowning

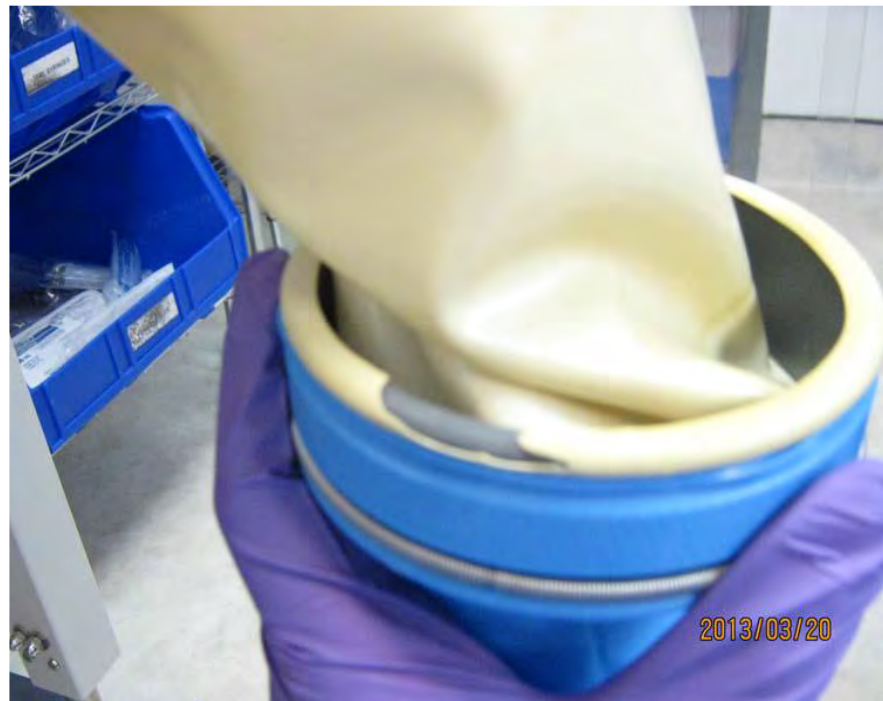


Gowning



Gowning

Sleeve used in the glove box used for aseptic manipulations is damaged.





Gowning

Form FDA 483 Observations

Clothing of personnel engaged in the manufacturing and processing of drug products is not appropriate for the duties they perform.

The following attire worn by the operator on 2/8/17 during sterile production was not adequate as follows:

- Non-sterile boot covers, non-sterile coveralls, non-sterile hair cover, non-sterile surgical mask, and protective eyewear were worn during sterile production.
- The hood of the non-sterile coverall and non-sterile surgical mask worn did not provide adequate coverage of the forehead, cheeks, and chin of the operator during sterile drug production.



Aseptic Technique

FDA guidance addresses the following aspects of aseptic technique:

- Personnel movement in classified air space
- Movement of materials into classified air space
- Handling nonsterile materials / disinfecting
- Process steps or manipulations that may create contamination concerns



Aseptic Technique

Potential areas to evaluate

- Unidirectional airflow should be protected
 - Personnel should not place their bodies or equipment in the path of unidirectional airflow in the ISO 5 area.
- Personnel should maintain the sterility of sterile items and surfaces
 - Sterile instruments should always be used in the handling of sterilized materials
 - Sterile gloves should be regularly sanitized or changed
 - Personnel should not directly contact sterile products, containers, closures, or critical surfaces with any part of their gown or gloves.

Aseptic Technique



Poor personnel practices – leaning into ISO-5

Aseptic Technique



Disruption of unidirectional airflow by aseptic operator.



Aseptic Technique

Potential areas to evaluate - Process flow and operations

- Movement of supplies, materials, and personnel into the clean room and into the critical ISO 5 zone should not create contamination risks.
- Materials should be disinfected according to appropriate procedures or, when used in critical areas, rendered sterile by a suitable method.
- Aseptic processing steps should not expose sterile product to conditions less than ISO 5.

Aseptic Technique



Stain due to product which had exploded due to excessive pressure applied when forcing product through a sterilizing filter. The device used to force through filter was a non-sterilized caulking gun





Aseptic Technique

Sterilizing filters

- “The “sterilizing filter” is not adequate to accomplish sterilization...” (FDA draft guidance on insanitary conditions)
 - How is adequacy of filter determined?
 - Filter manufacturer “Certificate of Suitability”
 - Post-filtration integrity test (in accordance with filter manufacturer instruction)
 - Baxter Healthcare Corp – August 26, 2016 – Letter to Pharmacies
 - Issuing a voluntary recall of 50 mm 0.2 micron “sterilizing” filter
 - Missing membrane layer
 - » No longer capable of filtering any microbial contaminants
 - Releases particles

Aseptic Technique



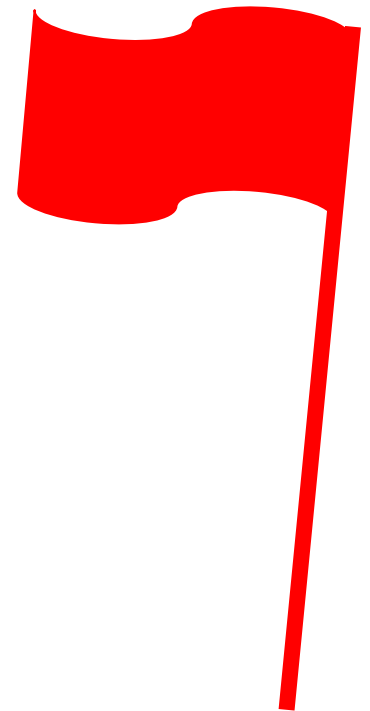
Coffee filters used to filter particulates in suspensions prior to filling and autoclaving



Aseptic Operators and Operations

Red flags

- Significant exposed skin
- Items in cleanroom that have not been cleaned and disinfected
- Filters used not pharmaceutical grade





Interactive Activity Gowning Worksheet



PART TWO

Process and facility design

Environmental and personnel monitoring

Activity: Case study 1

Product inspection and component control



Process and Facility Design

WHY?

Normal environmental conditions are not suitable for aseptic processing.



Process and Facility Design

21 CFR 211.42(b) states, in part, that “The flow of components, drug product containers, closures, labeling, in-process materials, and drug products through the building or buildings shall be designed to prevent contamination.”



Process and Facility Design

In brief:

- Air control / air flow and facility design - sterile drugs should be produced only in ISO 5 or better air quality.
- Facility layout and process flow - should be designed to prevent contamination and disruption of unidirectional flow.
- Cross contamination prevention.
- Cleaning and disinfecting.



Air particle control

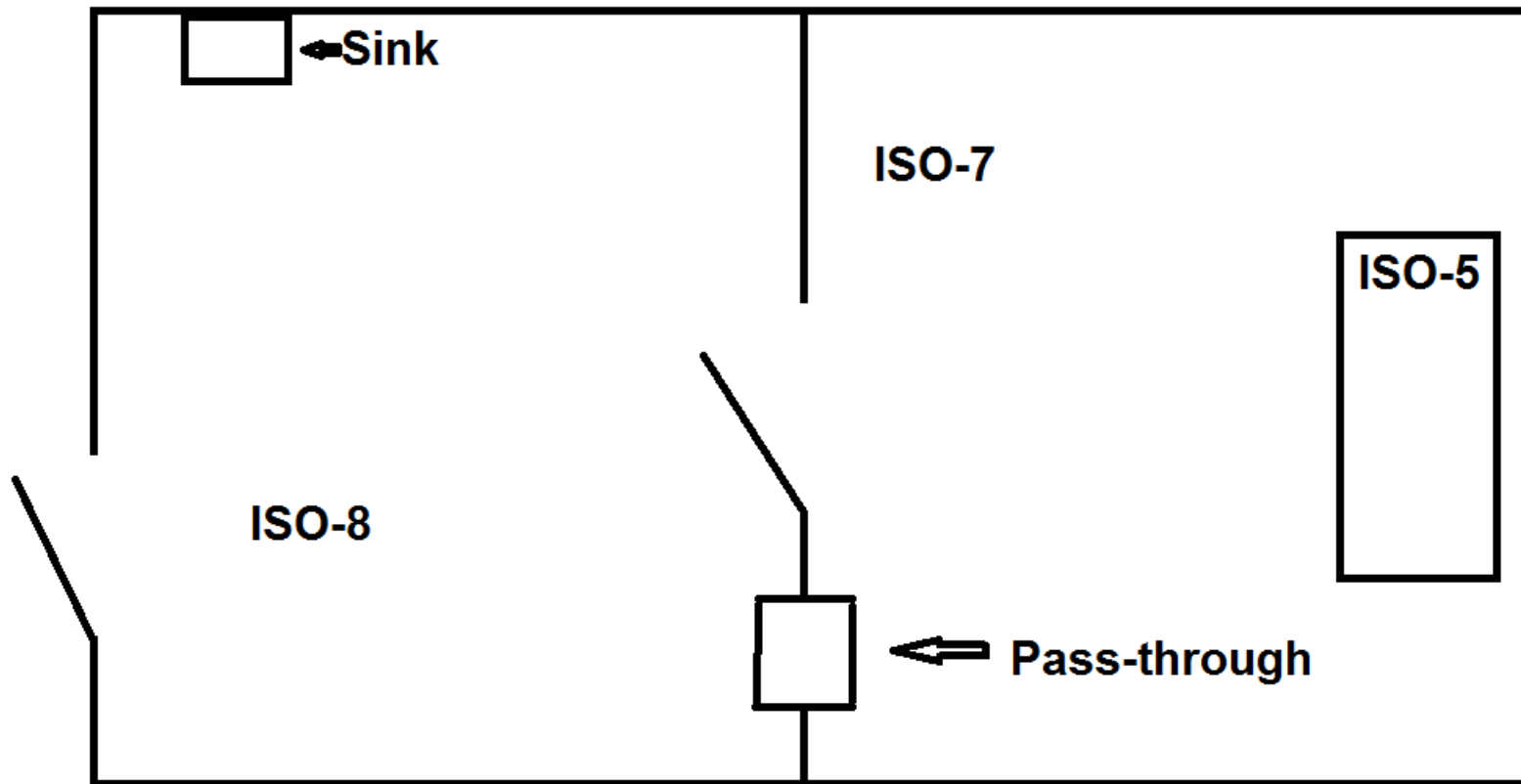
- “Normal” air contains numerous suspended particles.
- Suspended particles contain unknown numbers of microbes adhering to particle surfaces.
- Design of firm should include built-in features that remove and control number of air particles in aseptic processing areas.



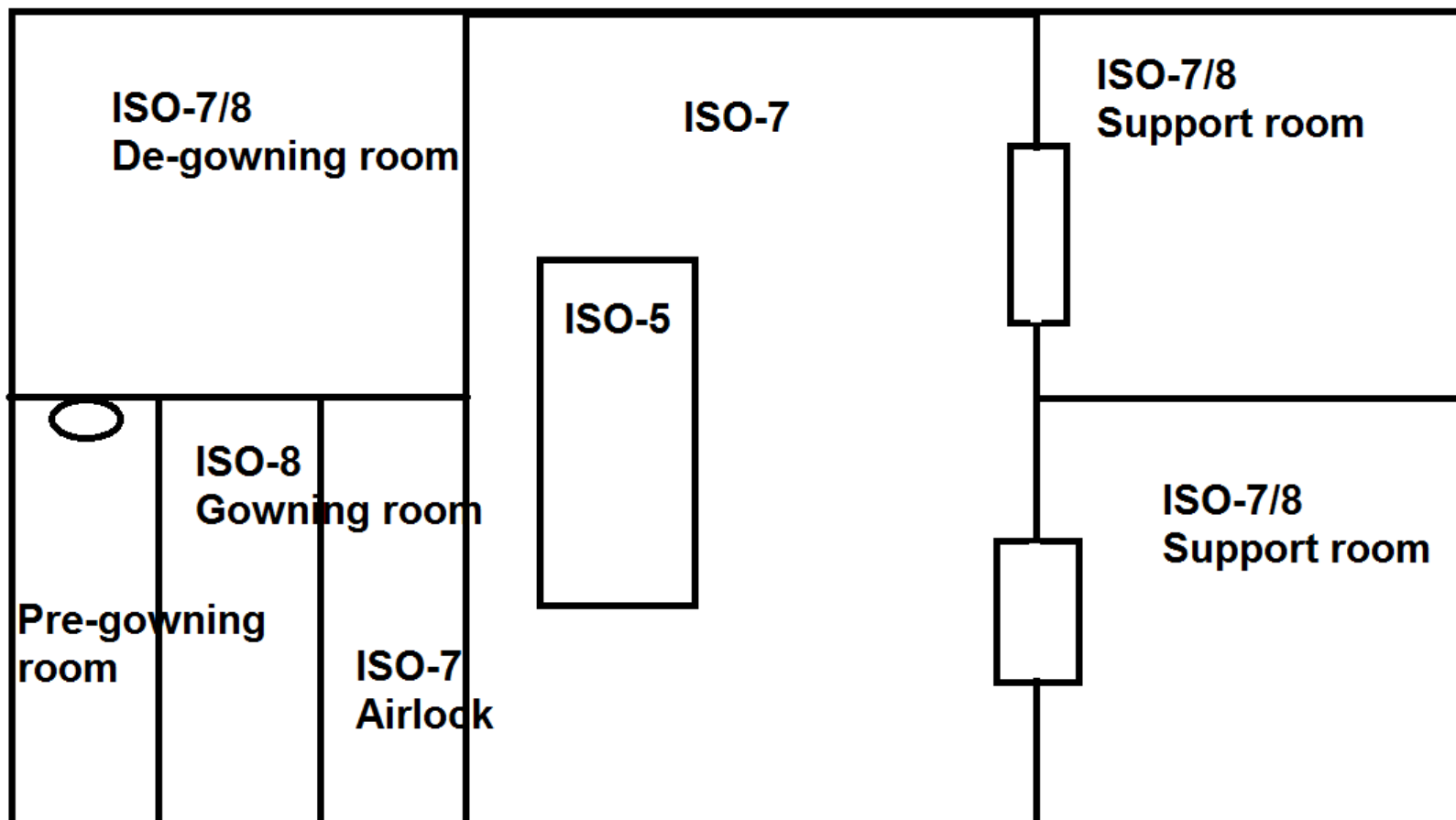
Standards for Air Cleanliness

- International Organization for Standardization (ISO) air cleanliness standards:
 - ISO-5: 3,520 particles of $0.5 \mu\text{m}/\text{m}^3$
 - ISO-7: 352,000 particles of $0.5 \mu\text{m}/\text{m}^3$
 - ISO-8: 3,520,000 particles of $0.5 \mu\text{m}/\text{m}^3$
- Air cleanliness within a defined space is brought about by “high-efficiency particulate arrestance” (HEPA) filters incorporated at key location within a firm’s central “heating, ventilation, and air-conditioning” (HVAC) system.

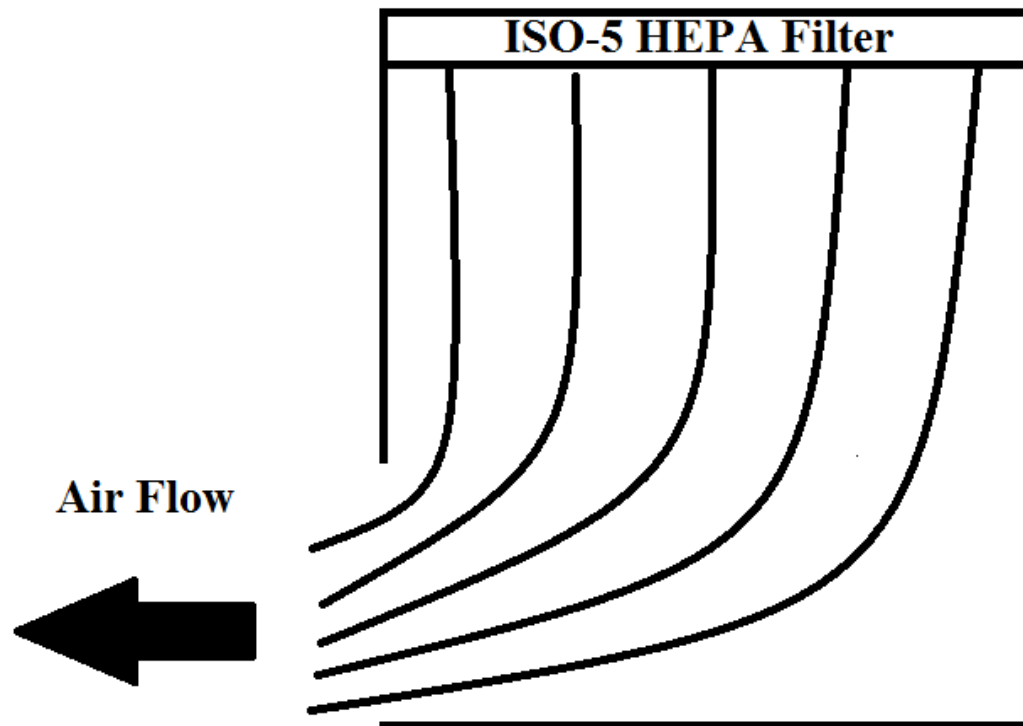
Basic Facility Design – “797” Pharmacy



Design – conventional CGMP manufacturer



Smoke Studies of the ISO-5





Cleanroom and Critical Area Design

Potential areas to evaluate

- The design of the ISO 5 should be appropriate for the aseptic operation.
- There should not be design flaws or disrepair that compromise the HEPA unidirectional airflow.
- If the firm uses an “isolator”, there should not be construction flaws or signs of disrepair that could compromise the aseptic process.
 - Differences in FDA and USP 797 definition of “isolator”
- Area over the work space in which sterile drug is exposed should have adequate HEPA coverage and air flow.



Cleanroom and Critical Area Design

Potential areas to evaluate

- Facilities should be designed with cascading air quality to protect the ISO 5 zone and prevent influx of contamination from adjacent areas or rooms of lower air quality.
- The area surrounding the ISO 5 zone should have an air cleanliness classification of ISO 7 or higher.
- The ISO 5 area should not have surfaces that are not smooth, hard and impervious or that are otherwise not easily cleanable.
- Air returns or air flow should not be obstructed by large equipment; air returns should be located by the floor (as stated in FDA draft guidance).

Cleanroom and Critical Area Design



ISO 5 glovebox (RABS) was located in an unclassified carpeted room where the room air was not HEPA filtered



Cleanroom and Critical Area Design

Cleanroom
separated from
unclassified
area by a plastic
curtain



Cleanroom and Critical Area Design



ISO-7 and ISO-8
cleanrooms
separated by
plastic held in
place by Velcro

Cleanroom and Critical Area Design



No pressure differential between ISO-7 and ISO-8



Cross Contamination

“If powder drugs are handled, procedures should be established and followed to appropriately manage cross-contamination risk, particularly if the powder is cytotoxic or highly sensitizing. FDA recommends the physical segregation of areas in which powder drugs are exposed to the environment. For penicillin/beta-lactam products, a separate facility (or physically separate space) is required (see § 211.42(d))”

-- Current Good Manufacturing Practice — Draft
Interim Guidance for Human Drug Compounding
Outsourcing Facilities Under Section 503B of the FD&C
Act



Process Flow and Operations

Potential areas to evaluate

- Processes flow that poses contamination risks, such as frequent personnel entry or exit, or introduction of materials into cleanroom without appropriate disinfection.
- Conditions under which in-process materials are held, such as partially-sealed or stoppered vials

Process Flow and Operations



Process Flow and Operations





Cleaning and Disinfecting

- Disinfectants and cleaning agents used in ISO 5 should be sterile.
- Wipe downs / disinfecting steps at every process transition (FDA draft guidance on insanitary conditions).
 - One disinfecting step does not lead to 100% kill of microorganisms. Successive wipes are necessary to effectively reduce the microbial bioburden.



Cleaning and Disinfecting

Potential areas to evaluate

- Frequency of cleaning and disinfection adequate
- Sporicidal disinfectants use
- Non-sterile disinfectants, non-sterile wipes used to disinfect aseptic processing areas
- Non-shedding wipes
- Disinfection of equipment, components, and supplies prior to transfer into the ISO 5 aseptic processing zone



Cleaning and Disinfecting

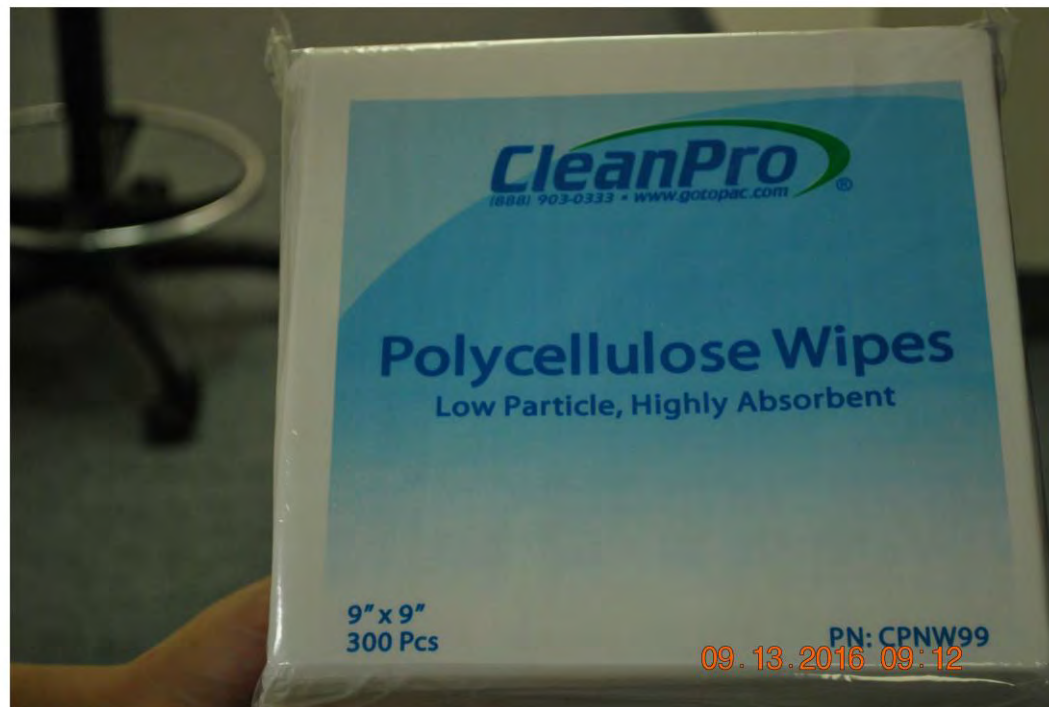
Concerning conditions discovered during inspection:

- Non-sterile wipes used to clean “aseptic” surfaces
- FDA analysis of these wipes – presence of:
 - ***Bacillus* sp. and other spore-formers**
 - Gram negative bacteria

Cleaning and Disinfecting



Cleaning and Disinfecting



Cleaning and Disinfecting

Form FDA 483 Observations

- Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.
 - Your firm uses non-sterile, low shedding wipes sprayed with 70% IPA to clean and wipe the metal HEPA filter grate and metal workbench of the ISO 5 LFH prior to sterile drug production.

Cleaning and Disinfecting



- Failure to routinely use a sporicidal agent, *correctly*
- Failure to review disinfectant label claim



Commonly Used Sporicidal Agents and Required Contact Time

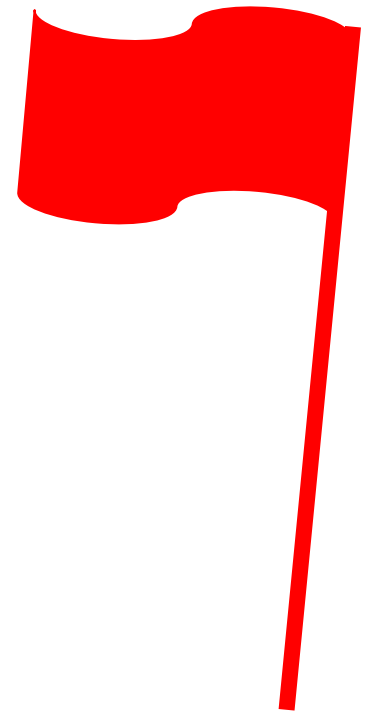
	<i>Clostridium</i> spores	<i>Bacillus</i> spores
Bleach 0.1%	25 min	25 min
Bleach 0.5%	5 min	10 min
Decon Spore 200 plus	3 min	6 hr
Peridox RTU	3 min	25 min
SporKlenz		30 min
SteriPlex	5 min	
TX690-TexCide	2 min	

Based on manufactures' labeling and published literature, subject to changes

Process and Facility Design

Red flags

- Lack of air control system
- Standalone dehumidifier or air conditioner
- Loose cleanroom ceiling tiles
- Disinfectants and cleaning agents used in ISO 5 not sterile
- Surfaces not cleanable surfaces





Environmental & Personnel Monitoring

WHY?

Sterility tests **alone** do not provide
an adequate assurance of sterility.
Quality is built in, not tested in.



Environmental & Personnel Monitoring

Control systems to prevent contamination during aseptic processing include “a system for monitoring environmental conditions.”

— 21 CFR 211.42(c)(10)(iv)

“Evaluating the quality of air and surfaces in the cleanroom environment should start with a well defined written program and scientifically sound methods. The monitoring program should cover all production shifts and include air, floors, walls, and equipment surfaces, including the critical surfaces that come in contact with the product, container, and closures.”

“A vigilant and responsive personnel monitoring program should be established.”

— *Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice Guidance for Industry*



Environmental & Personnel Monitoring

In brief:

- Environmental monitoring
 - Air
 - Surfaces
 - Pressure differentials between rooms
- Personnel monitoring
 - Sampling gloved fingertip as well as other areas of the gown



Pressure Differential Limits

“Pressure differential limits should be established, and control systems should include built-in alarms to detect excursions. Monitoring for pressure differentials, humidity, and temperatures should occur during production, and prompt action should be taken to correct inappropriate conditions.”

-- Current Good Manufacturing Practice — Draft Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act



Microbiological Monitoring

Potential areas to evaluate

- Monitoring the ISO 5 zone for microbiological contamination (viable monitoring) at least daily* during operation
 - Air
 - Surface
 - Personnel
- Locations for viable air and surface monitoring sampling capture areas of operations most prone to contamination
- Monitoring critical work surfaces at the end of operations
- Direct evidence of contamination (excessive microbiological counts, adverse trend of persistent contamination) in the ISO 5 area

*as recommended in FDA draft guidance on GCMO for outsourcing facilities

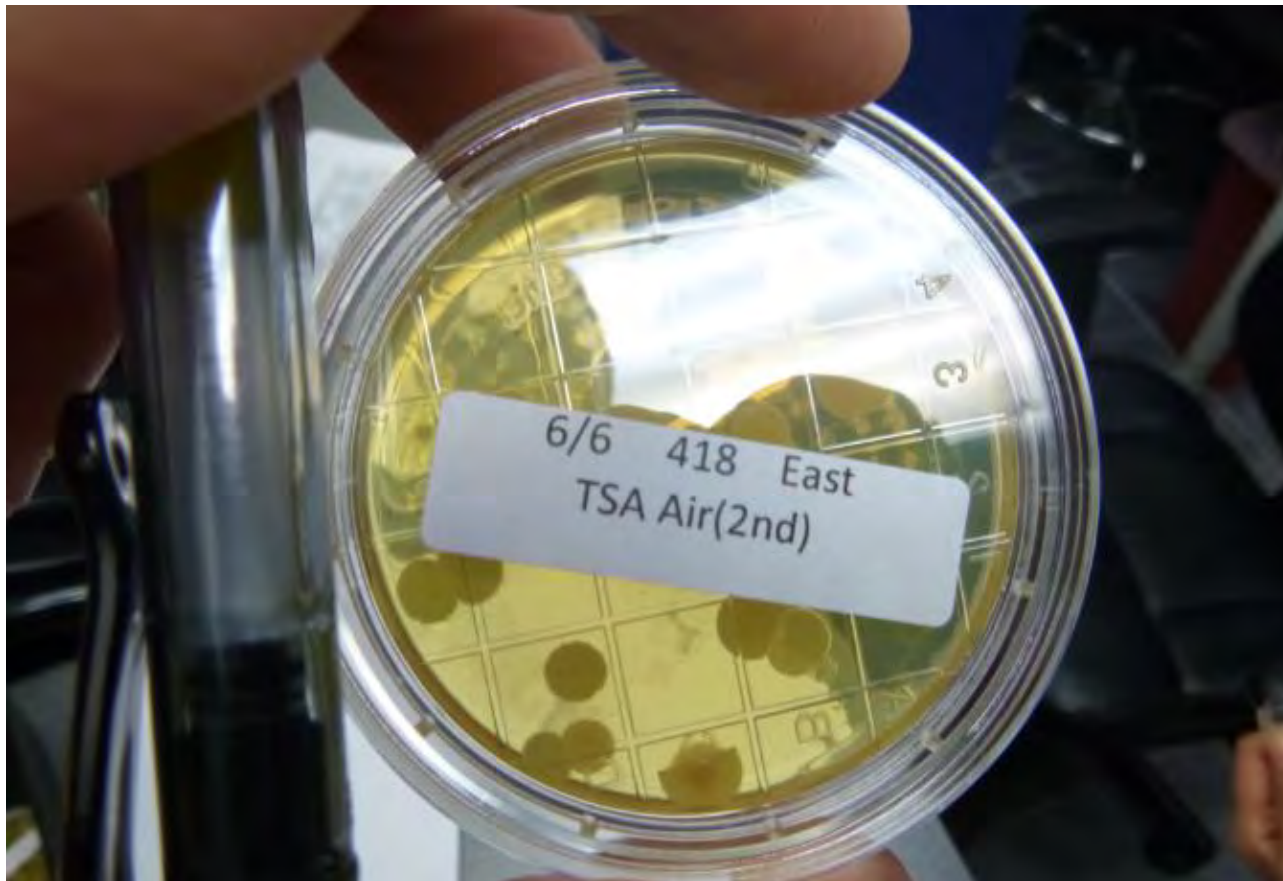


Environmental & Personnel Monitoring

Potential areas to evaluate

- Effectiveness of cleaning and sanitization procedures by taking surface samples associated with daily operations
- Established action limits for microbial contamination counts
- Appropriate actions when counts for microbial contamination in the ISO 5 zone exceed their established action limits

Microbiological Monitoring





Environmental & Personnel Monitoring

Potential areas to evaluate

- Environmental monitoring under dynamic and representative conditions (E.g. surface samples taken before, not after disinfection)



Environmental & Personnel Monitoring

Potential areas to evaluate

- Firm's monitoring data provide a meaningful evaluation of the conditions of the aseptic area and operations
- Potential negative trends in the critical ISO 5 zone that are not appropriately investigated and corrected
- Use of sporicidal disinfectants in response to any environmental monitoring findings of spore-forming organisms



Standards for Air Cleanliness

- International Organization for Standardization (ISO) air cleanliness standards:
 - ISO-5: 3,520 particles of $0.5 \mu\text{m}/\text{m}^3$
 - ISO-7: 352,000 particles of $0.5 \mu\text{m}/\text{m}^3$
 - ISO-8: 3,520,000 particles of $0.5 \mu\text{m}/\text{m}^3$
- Operational upper limits



Environmental Monitoring Action Levels

- Actionable EM results (from *USP <797>*):

Table 2. Recommended Action Levels for Microbial Contamination

Classification	Air Sample
ISO Class 5	> 1
ISO Class 7	> 10
ISO Class 8 or worse	> 100

Table 4. Recommended Action Levels for Microbial Contamination

Classification	Fingertip Sample	Surface Sample (Contact Plate) (cfu per plate)
ISO Class 5	> 3	> 3
ISO Class 7	N/A	> 5
ISO Class 8 or worse	N/A	> 100



Possible Areas For Sample Collection

- Gowning area.
 - Gown where employees gown to simulate regular facility conditions.
 - Check your partner.
- Passing in materials for collection.
 - Pass material in and out of the cleanroom as the firm does to simulate regular facility conditions.



Possible Areas For Sample Collection

- Touch plates.
 - Work/bench surfaces
 - Porous surfaces.
- Sponge stick/Q-tip swabs.
 - D/E use on solid surfaces.
 - Lethen use on porous surfaces.



Possible Areas For Sample Collection

- Laminar flow hood.
- Balance(s).
- Computer(s).
- Peristaltic pump(s).
- Work seat(s).
- Spray bottles.
- Trash can.
- Working bins.



Environmental & Personnel Monitoring

Form FDA 483 Observations

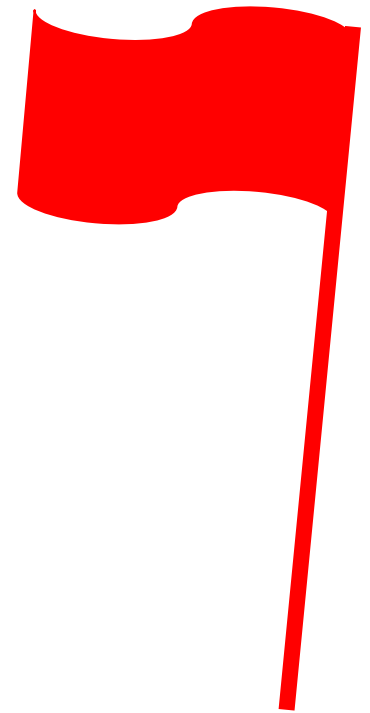
- Aseptic Processing Areas are deficient regarding the system for monitoring environmental conditions.
- Personnel monitoring of production operators is not conducted at least daily when sterile drug products are produced.
- Non-viable air sampling is not performed in the ISO 5 LFH and adjacent ISO classified areas when sterile drug products are produced.



Environmental & Personnel Monitoring

Red flags

- Infrequent environmental monitoring
- Environmental monitoring not representative of operational conditions
- Adverse trends in environmental monitoring





Interactive Activity Case Study 1



Product Inspection & Component Control

WHY?

- Contaminants and impurities in ingredients can end up in a finished drug
- Contaminants can form during processing
 - Breaches in the container/closure system can lead to product contamination or degradation



Product Inspection & Component Control

In brief

- Quality of starting materials
- Quality of container/closures
- Inspecting finished products for visible problems such as particulates



Component Control

“Controls over the source and quality of components are required, particularly when using non-sterile materials or ingredients, when producing compounded drug products, especially sterile drug products (21 CFR 211.82, 211.84, 211.87, 211.113).”

-- Current Good Manufacturing Practice — Draft Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act



Component Control

- In General - Reputable suppliers / supply chain control (risks)
- For bulk drug substances, review and periodic confirmation of COA
- FDA-approved sterile v. nonsterile starting materials
- Identity testing
- Bioburden / endotoxin testing

*Areas of interest identified in FDA draft interim guidance on CGMP for outsourcing facilities



Component Control

Statutory requirements

Bulk drug substances that can be used by outsourcing facilities in compounding products eligible for the 503B exemptions must:

- comply with USP or NF monographs (if an applicable monograph exists); and
- come from facilities registered with FDA; and
- be accompanied by a valid certificate of analysis



Container/Closures and Equipment

“If a facility does not use pre-sterilized and depyrogenated single-use equipment (e.g., filters, transfer tubing, temporary storage containers) and containers and closures (e.g., vials, syringes), the equipment, containers, and closures must be sterilized and depyrogenated before first use through sterilization and depyrogenation processes that have been validated, that is, demonstrated and documented to consistently achieve the desired result when performed under defined conditions (see §§ 211.67(a), (b) and 211.94(c)).”

-- Current Good Manufacturing Practice — Draft Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act



Container/Closures and Equipment

Potential areas to evaluate

- Equipment, containers and closures that come into contact with the drug product should be evaluated to ensure adequacy for intended use, including for holding or storing sterilized equipment, containers or closures to ensure sterility and cleanliness at time of use.
- Validation of the sterilization and depyrogenation of non-sterile filters, transfer tubing and temporary container cycles should be done before first use to ensure that they have been demonstrated and documented to consistently achieve the desired result when performed under defined conditions

*Recommendations described in FDA draft interim guidance on CGMP for outsourcing facilities

Container/Closures and Equipment



Observed Issues

Toaster oven used to sterilize & depyrogenate glassware; oven was not capable of reaching high enough temperature to be effective



Container/Closures and Equipment

Potential areas to evaluate

- Controls to ensure equipment, containers, or closures maintain their sterility
- Storage and conditions of re-use of sterilized equipment, containers, or closures that pose a risk of contamination

*Recommendations described in FDA draft interim guidance on CGMP for outsourcing facilities

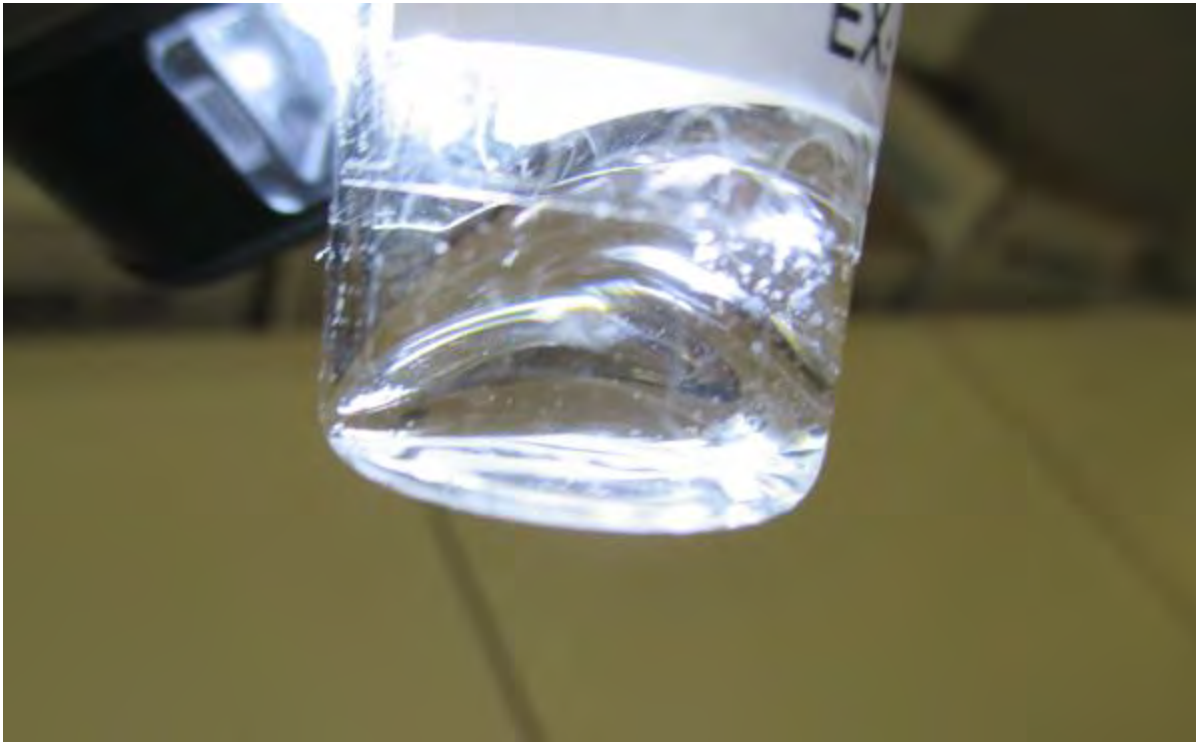


Product Inspection

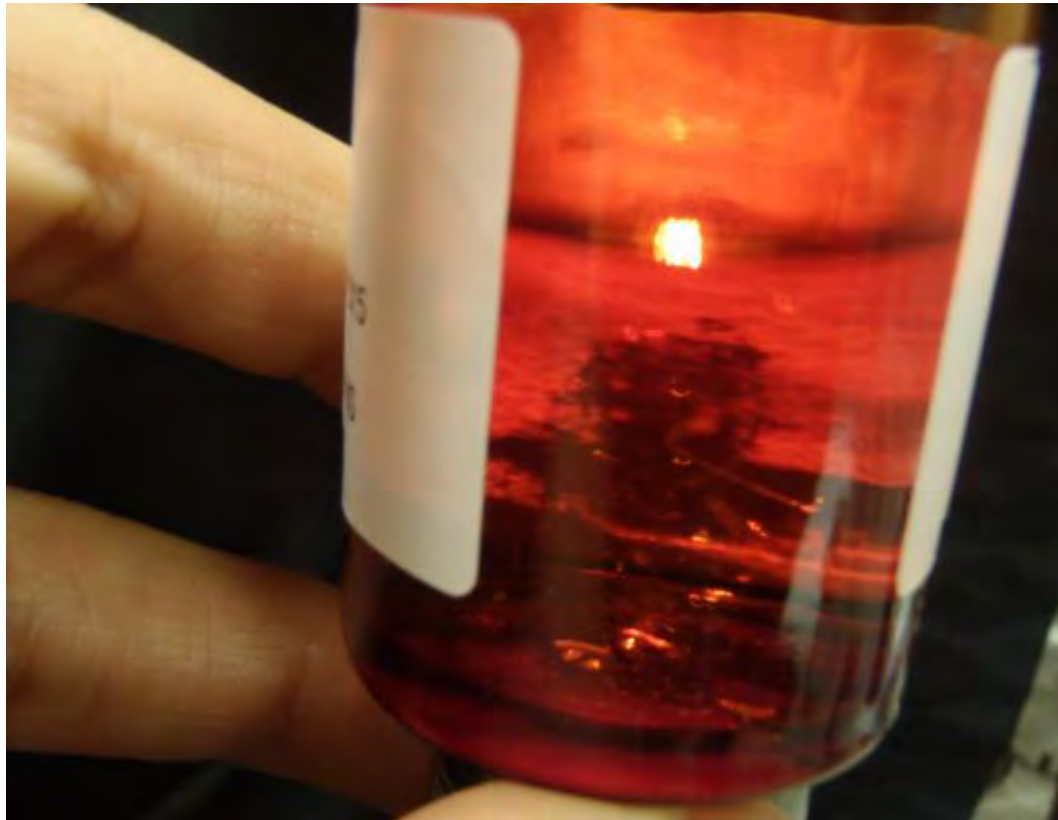
Possible approach for investigators

- Visually inspect the available bulk solutions, commercial product that has been used and is intended to be used in compounding operations, and the finished compounded product, for visible contamination
- Do not shake the vial(s) or container(s) before examination. Shaking of the container may disperse fungal growth into a suspension product and minimize detection.
- Use a flashlight for better visual examination of possible filamentous fungi growth in the bulk solution containers.

Product Inspection



Product Inspection



Product Inspection





Product Inspection & Component Control

Red flags

- Visible contamination “floaters”, particles, discoloration, leaking in finished product
- Condition of container and closure
- Container not suitable for intended use
- Bulk drug substances not suitable for drug manufacturing (e.g. chemical grade, lack of COA)





15 MINUTE BREAK



PART THREE

Packaging and labeling control

Records review

Activity: Case study 2

Special topics



Packaging and Labeling Control

WHY?

To ensure that mislabeling of product
does not occur.

Potential for serious patient harm
with incorrect labeling.



Packaging and Labeling Control

In brief

- Assessing labeling controls, including who has access control over the labeling
- Assessing the potential for labeling mix-ups



Packaging and Labeling Control

“There shall be written procedures describing in sufficient detail the receipt, identification, storage, handling, sampling, examination, and/or testing of labeling and packaging materials; such written procedures shall be followed. Labeling and packaging materials shall be representatively sampled, and examined or tested upon receipt and before use in packaging or labeling of a drug product.”

– 21 CFR 211.122(a)



Packaging and Labeling Control

Potential areas to evaluate

- Controls for issuing labels, examining issued labels, and reconciliation of used labels to prevent mix-ups
- Potential mix-ups - Physical/spatial separation between different labeling and packaging operations
- Adequate controls established to ensure proper identification of any filled containers of sterile products that will be stored unlabeled for any period of time
- Examination of labeled finished products for accuracy and thoroughness before release

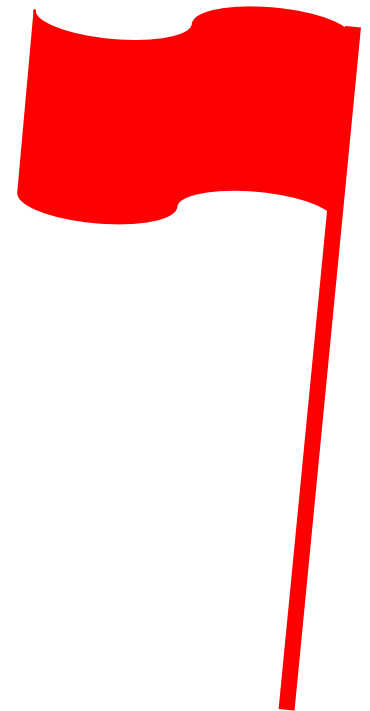
*Recommendations described in FDA draft interim guidance on CGMP for outsourcing facilities



Packaging and Labeling Control

Red flags

- Product containers that are not immediately labeled
- Multiple types of products being compounded in a single cleanroom with inadequate segregation of product and associated labels





Records Review

WHY?

Documentation of key quality controls such as release testing and environmental monitoring.

Shows how facility identifies and addresses problems.



Facility Record Review and Product Specific Review – Potential records to review

In brief

- Assess out-of-specification (OOS) results, sterility and other product test results, media fills, complaint files.
- Look for potential negative trends, potency concerns, and risks to sterility assurance.
- Review production log to understand production frequency and volume.



Facility Record Review

Outline of content in this section

- Master Formulation and Batch Records
- Sterility, Endotoxin Test
- Potency and Preservative Testing
- Pressure Differential Limits
- Media Fills/Process Simulations
- Qualification of the ISO 5 Area



Master Formulation and Batch Records

Potential records to evaluate

- Master production records (or their equivalent) prepared and used for all products
- Batch production records (or their equivalent) prepared and used for all products



Sterility, Endotoxin Test Records

Potential records to evaluate

- Records of analytical tests for sterility and endotoxin testing of the finished product before release
- Records of intrathecal products tested for endotoxin
- Out-of-specification (OOS) results, and documented investigations into OOS results

Sterility, Endotoxin Test Records

Form FDA 483 Observations

- Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements.
- Sterility testing was not performed on each finished batch for 20 of 23 drug products produced since 7/26/16 that are purported to be sterile.
- Endotoxin testing was not performed on each finished batch for the 23 drug products produced since 7/26/16.



A blue banner with a ribbon-like border containing the text "FDA 483" in white.

Potency and Preservative Testing

Form FDA 483 Observations

- Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications and identity and strength of each active ingredient prior to release.
- Potency testing is not performed for each batch of finished sterile and non-sterile drug products produced prior to release.



Pressure Differential Limits

Potential records to evaluate

- Calibration of pressure gauges
- Pressure differentials monitored during production
- Loss of positive pressure response include reporting, documenting, and investigating



Media Fills/Process Simulations

Media fill studies should closely simulate aseptic manufacturing operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.



Media Fills/Process Simulations

Potential records to evaluate

- Records of media fills or process simulations conducted under the most stressful/challenging conditions
- Records of media fill qualifications of aseptic operators

*Recommendations described in FDA draft interim guidance on CGMP for outsourcing facilities



Media Fills/Process Simulations

Potential records to evaluate

- Actions following a failed media fill, including investigations and new media fills to confirm that deficiencies have been corrected.
- Records on yield and reconciliation of containers filled and incubated
- Discarded units reasons documented
- Records on preparation of media, testing including pH, and growth promotion testing
- Media used within expiry



Qualification of the ISO 5 Area

The ISO 5 zone or critical area must be qualified (i.e., shown to meet the specifications; see §§211.42 and 211.113(b))

Potential records to evaluate

- HEPA integrity failures
 - Investigate the product impact
 - Appropriate corrective actions
- Smoke studies performed under dynamic conditions*
- Indications of poor air control (not unidirectional, turbulent) over the critical ISO 5 zone
- Portable ISO 5 units requalified after moving locations

*Recommendations described in FDA draft interim guidance on CGMP for outsourcing facilities



Product Specific Review

- 1. Product Stability***
- 2. Sterilization Control Strategy***
- 3. Hold Times***
- 4. Equipment, Containers, and Closures***



Product Specific Review – **Potential records to review**

- Selective review of sterile drug products for more detailed record review
- Select products for which there is the greatest combination of risk to public health:
 - processing risks, complaints, volume, and products with excessive beyond use dates/expiry dates



Product Stability

- A stability program must be established to assess the stability characteristics of finished drug products, and the results of stability testing must be used to determine appropriate storage conditions and expiration dates (21 CFR 211.166).
- Stability testing is used to ensure that a sterile drug product will retain its quality (for example, strength) and remain sterile through the labeled expiration date.

*Recommendations described in FDA draft interim guidance on CGMP for outsourcing facilities



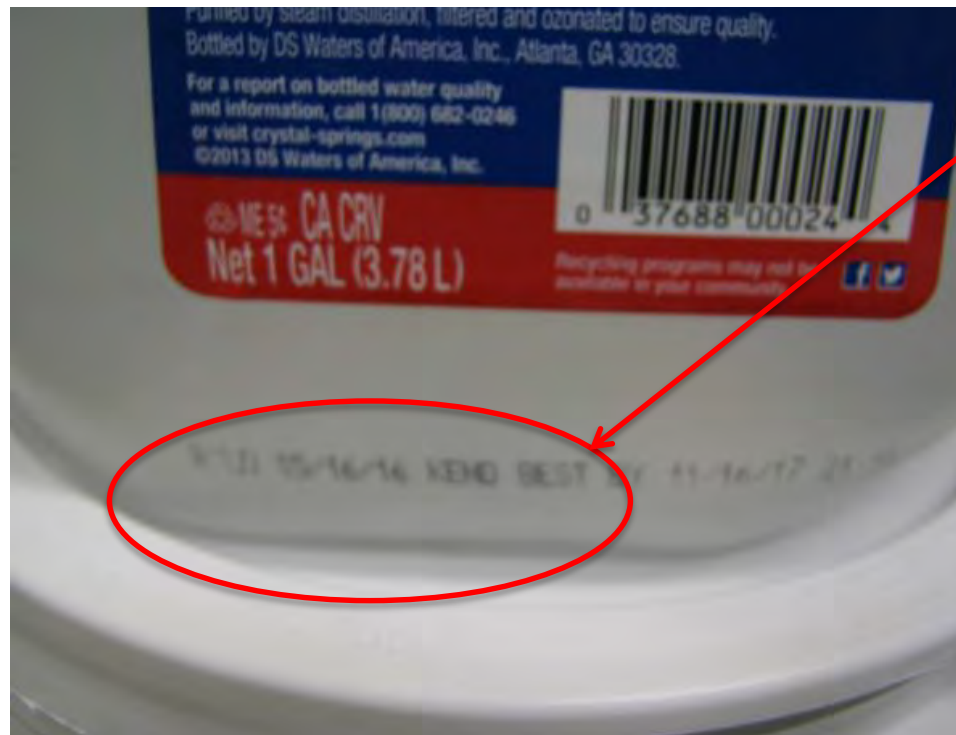
Product Stability

Potential records to evaluate

- Records showing product containers and closures are suitable for the product with which they will be used
- Stability studies exist to support extended beyond-use-dates

*Recommendations described in FDA draft interim guidance on CGMP for outsourcing facilities

Product Stability



The water was found to be expired with an expiration date of 5/16/2016.

Product Stability

Form FDA 483 Observations

There is no written testing program designed to assess the stability characteristics of drug products. For example, stability testing has not been performed for the following sterile drugs:

- Sterile drugs repackaged in the LFH
- Phenylephrine Hydrochloride Ophthalmic Solution



Sterilization Control Strategy

- “Acceptance of incoming lots of nonsterile components (including water) must include microbial and endotoxin testing (see § 211.84(d)(6)).”
- “The validation of sterilization operations (e.g., holding vessels, filling equipment, lyophilizer) and periodic verification activities and results must be documented (see § 211.113(b)).”
 - Current Good Manufacturing Practice — Draft Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act



Sterilization Control Strategy

Potential records to evaluate

If any of the identified products are produced using non-sterile components:

- Procedures for qualifying vendors and accepting incoming lots of the non-sterile components (including water)

*Recommendations described in FDA draft interim guidance on CGMP for outsourcing facilities

Sterilization Control Strategy





Sterilization Control Strategy

Potential areas to evaluate

- For products rendered sterile by filter sterilization:
 - Use of non-pharmaceutical sterilizing grade filters for product filtration*
 - Routine filter integrity testing

*described as an insanitary condition in FDA draft guidance



Sterilization Control Strategy

Potential areas to evaluate

- For products rendered sterile by terminal sterilization:
 - Validation of the sterilization process

*Recommendations described in FDA draft interim guidance on CGMP for outsourcing facilities



Sterilization Control Strategy

Form FDA 483 Observations

- Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.
 - The autoclave has not been validated to confirm effective sterilization through the designated sterilization time and temperature cycle of 7 minutes at 273°F for the syringe capper/de-capper device used in sterile drug production. Also Biological indicators are not used during the sterilization process.



Hold Times

- Storing or holding materials during processing (e.g., prior to sterilization; post-sterilization prior to container fill), also called hold times, must be assessed (see §§ 211.110(c), 211.111).
- Hold time(s) for production phases for a drug product should be limited. Limits should be supported by data and based on an understanding of the associated risk of increased bioburden and increased level of endotoxin.

--Current Good Manufacturing Practice — Draft Interim Guidance for Human Drug Compounding Outsourcing Facilities



Hold Times

Potential areas to evaluate

- Existence of data to support hold time



Equipment, Containers, and Closures

Potential areas to evaluate

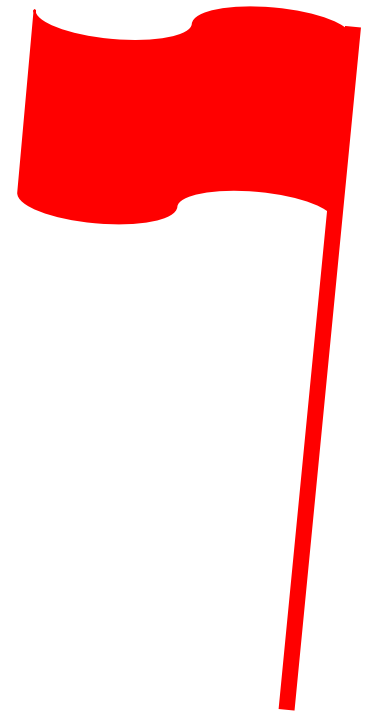
- Validation of on-site sterilization – validation of moist or dry heat method



Records Review

Red flags

- Depyrogenation in inappropriate equipment (e.g., toaster oven or autoclave)
- Lack of records, lack of investigation into OOS results, lack of COA's
- Multiple complaints regarding adverse events or product quality issues.





Interactive Activity Case Study 2



Special Topics

- Lyophilization
- Nonsterile versus sterile starting materials
- Hold times
- Autoclave qualification



Lyophilization

- Complex process, chances of failure are high.
- Moisture retained in product
- Stoppering of vials / partially stoppered vials



Lyophilization

Potential Questions

For any lyophilized products:

- Are the partially stoppered vials transported to the lyophilizer without ISO 5 protection?
- If product is aseptically processed and then lyophilized, what is the employee's aseptic technique between the ISO 5 area and transfer/loading of the lyophilizer with partially stoppered vials?

Lyophilization

Observed Issues

Lyophilizer located in the cleanroom. Oil leaked from the pump and a paper towel is used to absorb the oil





Nonsterile versus sterile starting materials

- How is sterilization done for the finished product?
- What are the cycle parameters?
- Is the autoclave certified?
- Temperature mapping
- If sterile filtration - is it qualified?
- Extended hold times



Hold Times - Possible considerations

- Hold times for water used in production
- Extended hold times when using nonsterile ingredients. Risk of proliferation of gram negative bacteria and endotoxins.



Autoclave Qualification - Issues to consider

- Gravity feed or density feed?
- Loading / unloading?
- Unloading directly into clean environment?
- Where is it located?
- Are items wrapped?



THANK YOU!

Contacts

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ian.deveau@fda.hhs.gov

FDA office of Intergovernmental Affairs:

iga@fda.hhs.gov

Date: 5/15/18

Waiver Request: Partners in Care Hospice House Inpatient unit is requesting a waiver to OAR 855-041-6800(2) to enhance patient safety and improve patient care by permitting 2 RNs to access the drug room, for license # DR-0000015.

- **Background:**

- **Requesting Waiver**

- **OAR 855-041-6800(2) One** registered nurse supervisor and **only one** in any given shift may have access to the drug room and may remove drugs therefrom, except in an emergency situation. In that case, such nurse may designate another licensed nurse to obtain the required drug(s). **Any access to the drug room deviating from the requirements of this section must be approved by the Board prior to implementation.** The registered nurse supervisor shall be designated in writing by the appropriate committee of the hospital and shall, prior to being permitted to obtain access to the drug room, receive thorough education and training in the proper methods of access, removal of drugs, and records and procedures required. Such education and training shall be given by the director of pharmacy, who shall require, at a minimum, the following records and procedures:

- **Detailed Process Proposed:**

- Patient acuity at this location requires 2 RNs to actively provide direct patient care on a daily basis.
 - Day shift routinely staffs 2 RNs except for low census.
 - Hospice patients often experience multiple symptoms that need intervention STAT and at times more than one nurse and one supervisor would need to access the med room in order to promptly meet the patient's acute needs.
 - This staffing model is necessary to provide safe and quality care for hospice inpatients requiring acute level of care

- **Discussion:**

Requester's Contact Info:

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Clinical Operations Director

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Oregon Board of Pharmacy - Technician Research Council Meeting Recap - March 22, 2018

Overview – Representatives from several facets of pharmacy including community, hospital, ambulatory care and long-term care gathered to discuss the possible expansion of Oregon technician duties.

The discussion encompassed the ability for pharmacists to delegate various tasks to technicians that do not require a pharmacist's professional judgement to allow more opportunities to provide clinical-based services and improve patient care. Many states are looking at technician duties, seems to be driven by the continued development and advancement in pharmacist's scope of practice as well as other pressures on the profession. The capacity for technicians to participate in expanded roles in states is at the discretion of the supervising pharmacist, while also accounting for the competencies and comfort of the technician in performing the delegated tasks. Additionally, it is reported that many technicians are eager to do more.

- Desire for more flexibility in rules around technician duties, particularly supervision and med rec, and must be evidence-based.
- Some participants desire to align pharmacy practice rules with medical practice (be more analogous to nurse practitioner and physicians)
- Suggested a prohibited task list would be more beneficial rather than a long, evolving "can do" list for expanded technician duties
 - Idaho adopted new rules for pharmacist delegation of non-judgmental tasks, which become effective in July 2018 – see <https://nabp.pharmacy/wp-content/uploads/2016/06/ID032017.pdf>
 - These tasks MAY be delegated, but are not required
- Additional research and discussion is needed. Details regarding education, training and certification to be discussed as these tasks are considered for expansion. It was proposed that these expanded duties will remain optional for participation at employer, pharmacist and technician levels.

Of particular interest were the following topics:

Technician Immunizations – Recent rule changes in Idaho permits technicians that have undergone appropriate training (ACPE Accredited Education course on appropriate technique, and holds current BLS) to administer vaccinations. It is reported that since the rule changes in Idaho last year, Albertsons representative stated that more than 10,000 vaccinations have been given by technicians. Pharmacists are still involved in determining the appropriateness of the vaccine, review of allergies and final check prior to administration. It is the supervising pharmacist's discretion to delegate this task and technicians have the ability to opt out of participating.

New Rxs, transfers and other medication authorizations – Currently, certain states allow technicians to accept new verbal orders, consult with prescriber for prescription clarification, and communicate prescription transfers if directed by the supervising pharmacist. Group discussed that taking new prescriptions and transfers are considered 'transitions of care' processes.

Information gathering – Representatives from Legacy and OHSU inpatient pharmacy addressed the need for a standardized process in performing medication reconciliation. This includes the use of a "high level script" for gathering medication information. Current policy allows technicians to utilize closed-ended questions for medication history gathering, however, the use of open-ended questions may

provide more meaningful and accurate depiction of what patient is taking. Desire for Board to allow for trust and leave it to training and ongoing competencies

- Desire for the Board to clarify the roles of techs in med rec processes: what they can/can't say, open vs. closed ended questions

Remote data entry by Technicians

- Would the Board consider allowing technicians to work (and be supervised) remotely for processes such as prescription data entry and billing? This would allow for uninterrupted data entry and make it possible for a person with a physical disability to function as a technician, who is otherwise not able to physically work in a traditional pharmacy.
- Would the Board consider allowing a technician work in a closed-door pharmacy prior to a pharmacist arriving, as all work is ultimately verified by a pharmacist?

Tech-check-tech – Would the Board consider expanding current TCVP processes and/or allow tech-check-tech processes in retail settings? Will Board consider technicians checking patient-specific products utilizing bar-code scanning?

Other items discussed:

- Increased roles for technicians in MTM and other Transitions of Care processes, i.e. technicians calling patients for follow-ups, making appointments, etc.
- Challenges if the rules are written differently for various settings- inpatient, outpatient, etc.
- Identify issues related to defining supervision (“direct eyes on” vs. overall/spot-checking)
- Increased liability for techs with increasing roles?
- Will technicians be permitted to perform physical assessments (vitals), point-of-care testing?
- How do techs get compensated for additional responsibilities? Will participating in new tasks be a requirement for all techs?
- If techs can demonstrate they can be beneficial in the delegated tasks, may support need for this
- Concerns about how business perspective enters in to this conversation – companies will look at financials. Will they replace pharmacists with technicians?
- ASHP revised standards re: technician roles – Changes in responsibilities for techs (entry vs. advanced)
- With the expansion of pharmacist’s role, the increased responsibilities and constant shift in pharmacist’s activity can place patient safety at risk. How does the Board address ongoing competencies for any new duties for technicians, for safety and accountability?

Materials provided by council member, Lauren Paul:

1. Adams, AJ. *Advancing Technician Practice: Deliberations of a Regulatory Board*. Research in Social and Administrative Pharmacy (2017). <http://dx.doi.org/10.1016/j.sapharm.2017.02.008>
2. Frost, TP and Adams, AJ. *Expanded Pharmacy Technician Roles: Accepting Verbal Prescriptions and Communicating Prescription Transfers*. Research in Social and Administrative Pharmacy (2016). <http://dx.doi.org/10.1016/j.sapharm.2016.11.010>
3. Frost, TP and Adams, AJ. *Tech-Check-Tech in Community Pharmacy Practice Settings*. Journal of Pharmacy Technology (2017).

4. Andreski M, Myers M, Gainer K, and Pudlo A. *The Iowa new practice model: Advancing technician roles to increase pharmacists' time to provide patient care services*. Journal of the American Pharmacists Association (2018)
5. Atkinson D, Adams A, and Bright D. *Should Pharmacy Technicians Administer Immunizations?* Innovations in Pharmacy. (2017)
6. Adams AJ. *Pharmacist Delegation; An approach to pharmacy technician regulation*. Research in Social and Administrative Pharmacy. (2018)
7. McKeirnan K, Frazier K, Nguyen M, Maclean L. *Training Pharmacy Technicians to Administer Immunizations*. Journal of the American Pharmacists Association (2018)
8. Adams AJ, Martin S, Stolpe S. *"Tech-check-tech": A review of the evidence on its safety and benefits*. American Journal of Health System Pharmacists. (2011)

Technician Research Council Members:

Laura Churns, Pharmacist (Albertsons)
Christine Kostechka, Technician (OHSU Inpatient)
Jackson Leong, Pharmacist (Propac Payless Long Term Care)
Doug Meyer, Pharmacist (Legacy Meridian Park Inpatient)
Lauren Paul, Pharmacist (CVS Health)
Patti Thrall, Technician (Samaritan Pharmacy Outpatient)
Amy Valdez, Pharmacist (Kaiser Permanente Ambulatory Care/Anticoag Clinic)

Oregon Board of Pharmacy attendees:

Cyndi Vipperman, Technician Member
Karen MacLean, Administrative Director
Fiona Karbowicz, Pharmacist Consultant

Drug Topics

May 7, 2018, Volume: 164 Issue 5

It's Time to Rethink Pharmacy Tech Staffing by Peter A. Kreckel, RPh

http://drugtopics.com/viewpoints/its-time-rethink-pharmacy-tech-staffing?cfcache=true&rememberme=1&elq_mid=1397&elq_cid=853242&GUID



Oregon

Kate Brown, Governor

JUNE 2018 / E

Veterinary Medical Examining Board

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May 21, 2018

Oregon Board of Pharmacy
Penny Reher, R.Ph., President
Rachael DeBarmore, R.Ph., Vice-President

Re: Waiver Request under OAR 855-043-0510(2)

Dear President Reher, Vice-President DeBarmore, and members of the Board:

The Veterinary Medical Examining Board is requesting that Oregon veterinary medical facilities be granted a waiver of registration as a Drug Practitioner Dispensing Outlet (DPDO). Under ORS 686.600, which allows the Board to inspect veterinary facilities, and OAR 875-015-0030(7), which sets standards for drug ordering, storage and dispensing, as well as requiring compliance with all pertinent state laws, the Board mandates standards that we believe to be substantially consonant with the requirements of DPDO. Copies of referenced statutes and rules are attached.

Elements of current drug rules that do not align precisely with DPDO, or require clarification, are:

- Extra dispensing log—veterinary practices currently maintain a separate log only for controlled drugs. Practices that use electronic recordkeeping software may be able to maintain a separate log for all prescribed drugs, but many practices still rely on paper records, where all prescriptions are kept in individual patient records. All DEA registrants are required to keep separate logs for controlled drugs.
- Annual inspections—inspection occurs continuously, but not every facility is inspected annually. The Board allows self-certification for facilities that are certified by the American Animal Hospital Association, which requires higher standards than those of OAR 875. We would propose to exempt AAHA facilities (currently 68) from physical inspection under the DPDO waiver, and to incorporate the OBP self-inspection form as an annual requirement for all facility license renewals.

If necessary for purposes of meeting DPDO standards, the Board will promulgate rules to incorporate requirements that may not be explicit in the Veterinary Practice Act. Current rules are attached.

Thank you for your consideration of this request.

Sincerely,

Emilio E. DeBess, DVM, MPH
Board Chair
State Public Health Veterinarian



875-015-0030**Minimum Veterinary Practice Standards**

Each veterinary medical facility shall comply with the following:

- (7) Biologicals and drugs: The minimum standards for drug procedures shall be:
 - (a) All biological substances shall be stored, maintained, administered, dispensed and prescribed in compliance with federal and state laws and manufacturers' recommendations;
 - (b) Controlled substances and legend drugs shall be dispensed, ordered or prescribed based on a VCPR and shall be labeled with the following:
 - (A) Name of client and identification of animal(s);
 - (B) Date dispensed;
 - (C) Complete directions for use;
 - (D) Name, strength, dosage and the amount of the drug dispensed;
 - (E) Manufacturer's expiration date;
 - (F) Name of prescribing veterinarian and veterinary medical facility.
 - (c) No biological or drug shall be administered or dispensed after the expiration date, for a fee.

875-015-0020**Minimum Requirements for Veterinary Medical Facilities and Veterinary Licensees**

Each veterinary medical facility and veterinary licensee shall comply with the following:

- (5) Storage: All supplies, including food and bedding, shall be stored in a manner that adequately protects such supplies against infestation, contamination or deterioration. Adequate refrigeration shall be provided for all supplies that are of a perishable nature, including foods, drugs and biologicals.

875-011-0010**Unprofessional or Dishonorable Conduct**

The Board interprets "unprofessional or dishonorable conduct" to include, but is not limited to the following:

- (14) Failure to mark or label a container of prescription or legend drugs with the date, name of drug, dosage frequency, identification of animal (if appropriate), and withdrawal time (if appropriate). Excludes legend drugs dispensed or ordered in original, unopened manufacturer's packaging for herd use.
- (15) Failure to comply with federal law concerning packaging and labeling of prescription or legend drugs.
- (16) Violation of any state or federal law relating to controlled substances, as defined in ORS 475.005(6), which the veterinarian obtained under the authority of the veterinary license.
- (17) Non-veterinary prescribing, use, theft or diversion of legend or controlled drugs.

875-010-0031**Registration of Veterinary Facilities; Managing Veterinarian; Registration Denial, Suspension, Revocation; Inspection**

(10) Inspection of Facilities: The purpose of inspection is to ensure that public health and safety is maintained by meeting the minimum facility standards listed in OAR 875-015-0020 and 875-015-0030. The Board may designate or employ qualified persons to do the inspections and may delegate inspections to other state or federal agency regulators. Prior to January 2017 the Board may accept self-certification of compliance by the Managing Veterinarian in-lieu-of inspection. This self-certification shall be submitted using a form provided by the Board.

- (a) The Board may inspect each veterinary facility:
 - (A) Before a new facility receives an initial facility registration
 - (B) Periodically, at least once every three years
- (b) The board may inspect any veterinary facility:
 - (A) At any time upon receipt of a complaint or if it has cause to believe the facility is noncompliant with OAR 875-015-0020 or 875-015-0030.

Date: 5/21/2018

Request/Inquiry Type: Waiver for veterinary Dispensing Practitioner Drug Outlets

- **Question(s):**

The Oregon Veterinary Medical Examining Board (OVMEB) requests a waiver to OAR 855-043-0510(12) to exempt their licensees from the requirement of registering with the Oregon Board of Pharmacy as a Dispensing Practitioner Drug Outlet (DPDO).

- **Background:**

Per ORS 686.600, the OVMEB has the authority to inspect veterinary facilities.

In 2017 and 2018, the OVMEB developed rules related to facility oversight, which set standards for drug ordering, storage and dispensing.

Two elements of the Oregon Board of Pharmacy rules for DPDOs are not aligned with the OVMEB rules.

- o Veterinarians are not required to maintain a separate dispensing log – many facilities retain the record of drugs dispensed in individual patient charts
- o Inspections are not performed annually, but rather continuously. Additionally the OVMEB allows certain facilities who are certified by the American Animal Hospital Association to self-certify.

- **Related ORS/OARs:**

Pharmacy

OAR 855-043-0510(12) The Board may grant a time-limited waiver exempting DPDO 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.

Veterinary

OAR 875-010-0031(10)

(10) Inspection of Facilities: The purpose of inspection is to ensure that public health and safety is maintained by meeting the minimum facility standards listed in OAR 875-015-0020 and 875-015-0030. The Board may designate or employ qualified persons to do the inspections and may delegate inspections to other state or federal agency regulators. Prior to January 2017 the Board may accept self-certification of compliance by the Managing Veterinarian in-lieu-of inspection. This self-certification shall be submitted using a form provided by the Board.

- (a) The Board may inspect each veterinary facility:
 - (A) Before a new facility receives an initial facility registration
 - (B) Periodically, at least once every three years
- (b) The board may inspect any veterinary facility:

- (A) At any time upon receipt of a complaint or if it has cause to believe the facility is noncompliant with OAR 875-015-0020 or 875-015-0030.
- (B) Upon a change in ownership or a change in the Managing Veterinarian
- (C) As follow-up at any time after an inspection has found non-compliant conditions.
- (c) Initial and periodic facility inspections may be waived for facilities holding a current American Animal Hospital Association (AHAA) certification.
- (d) Inspections may be documented in writing and by audio, video and still picture recording.
- (e) Upon an inspection finding of non-compliance with OAR 875-015-0020 or 875-015-0030, the Board or its representative may do any or all of the following:
 - (A) Establish a reasonable time line for bringing the facility into compliance
 - (B) Issue a civil penalty or citation
 - (C) Restrict facility operations when the failure to meet minimum facility standards poses an unresolved risk to public health and safety or other conditions noncompliant with OAR 875-015-0020 or 875-015-0030.

OAR 875-015-0030(7) Each veterinary medical facility shall comply with the following:

Biologicals and drugs: The minimum standards for drug procedures shall be:

- (a) All biological substances shall be stored, maintained, administered, dispensed and prescribed in compliance with federal and state laws and manufacturers' recommendations;
- (b) Controlled substances and legend drugs shall be dispensed, ordered or prescribed based on a VCPR and shall be labeled with the following:
 - (A) Name of client and identification of animal(s);
 - (B) Date dispensed;
 - (C) Complete directions for use;
 - (D) Name, strength, dosage and the amount of the drug dispensed;
 - (E) Manufacturer's expiration date;
 - (F) Name of prescribing veterinarian and veterinary medical facility.
- (c) No biological or drug shall be administered or dispensed after the expiration date, for a fee.

OAR 875-015-0020(5) Each veterinary medical facility and veterinary licensee shall comply with the following:

- (5) Storage: All supplies, including food and bedding, shall be stored in a manner that adequately protects such supplies against infestation, contamination or deterioration. Adequate refrigeration shall be provided for all supplies that are of a perishable nature, including foods, drugs and biologicals.

OAR 875-011-0010 The Board interprets "unprofessional or dishonorable conduct" to include, but is not limited to the following:

- (14) Failure to mark or label a container of prescription or legend drugs with the date, name of drug, dosage frequency, identification of animal (if appropriate), and withdrawal time (if appropriate). Excludes legend drugs dispensed or ordered in original, unopened manufacturer's packaging for herd use.
- (15) Failure to comply with federal law concerning packaging and labeling of prescription or legend drugs.

- (16) Violation of any state or federal law relating to controlled substances, as defined in ORS 475.005(6), which the veterinarian obtained under the authority of the veterinary license.
- (17) Non-veterinary prescribing, use, theft or diversion of legend or controlled drugs.

Source: <https://secure.sos.state.or.us/oard/displayDivisionRules.action?selectedDivision=4113>

Staff Recommendations:

Staff recommends Board discussion.

Requester's Contact Info:

*Lori Makinen, Executive Director
Oregon Veterinary Board
800 NE Oregon St., Ste. 407
Portland, OR 97232
971-673-0223
ovmeb.info@state.or.us*

2018 Accreditation Council for Pharmacy Education (ACPE) & Continuing Pharmacy Education (CPE or CE) Review

During the Board's Annual Business Meeting, the Board reviews and approves a list of the ACPE Accredited Professional Programs of Colleges and Schools of Pharmacy as well as the ACPE Continuing Education Process guidelines, policies and procedures.

The following are links from the ACPE website and the most efficient way to provide it for your review.

For **ACPE Accredited Professional Programs of Colleges and Schools of Pharmacy**, please click here:

<https://www.acpe-accredit.org/pharmd-program-accreditation/>. Towards the bottom of this web page is a link to *Programs by Status* and *Programs by State* and then you can click from there to review the Accredited / Candidate status or Pre-candidate status categories.

Main Continuing Education Provider Accreditation page: <https://www.acpe-accredit.org/continuing-education-provider-accreditation/>

Here are the things the Board usually reviews annually related to Continuing Education:

- 1) For ACPE **Guidelines associated with the ACPE Definition of CE for the Profession of Pharmacy**, effective January 2018, click here: https://www.acpe-accredit.org/pdf/CPE_Standards_Final.pdf
- 2) For ACPE: **Definition of Continuing Education for the Profession of Pharmacy**
<https://www.acpe-accredit.org/pdf/DefinitionofCE.pdf>
- 3) For **ACPE Continuing Pharmacy Education Provider Accreditation Program Policies and Procedures Manual: A Guide for ACPE accredited Providers**, effective January 1, 2009, updated July 2017 click here:
https://www.acpe-accredit.org/pdf/CPE_Policies_Procedures.pdf



RECEIVED

MAY 10 2018

OREGON BOARD OF PHARMACY

**ANNUAL BOARD & OTHER PHARMACIST APPOINTMENT
REPORT**

Please provide the Board with a description of your involvement related to the Board, Commission or Committee to which to serve as a Pharmacist appointee.

Submit your response by: **May 11, 2018** to Karen.S.MacLean@oregon.gov

Last Name: Yantis

First Name: Leanne

Date: 05/06/2018

Email: laldin218@aol.com

Work Phone: 949.697.4578

List the board, committee or commission to which you are appointed:

Rural Health Coordinating Council

Please provide a brief summary of your activities from the last year within your appointment. Be sure to include your term and meeting frequency.

Term - May 2017 to May 2018

The Rural Health Coordinating Council (RHCC), comprised of 13 organizational and 5 consumer members, met on a quarterly basis. Three meetings were in person and one meeting was available via teleconference. Each meeting commenced with a brief summary of projects supported by the Office of Rural Health (ORH). The purpose of the RHCC was to gain an understanding of the types of obstacles residents of rural and frontier counties faced while trying to access health care and emergency services, but also develop an appreciation for the support given to these communities by the ORH. Our discussions focused on highlights from the Annual Oregon Rural Health Conference, the ORH's 2017 Listening Tour and Annual Forum on Aging in Rural Oregon as well as various incentive programs, grants and legislative priorities supported by the ORH. Members of RHCC were given an opportunity at each meeting to discuss issues related to their respective organization or health-related concerns specific to their region.

May 9, 2018

Karen MacLean

Administrative Director

Oregon Board of Pharmacy

800 NE Oregon St, Suite # 150

Portland, Oregon 97232

Dear Ms. MacLean,

I am writing this letter to be considered by the Oregon Board of Pharmacy for an additional two-year appointment to OHSU's Rural Health Coordinating Council (RHCC), so I may continue to broaden my perspective of rural health issues in Oregon while supporting the efforts of the RHCC.

The Office of Rural Health (ORH) serves as a very valuable resource for rural and frontier communities. Through my participation in the RHCC, I have learned about the extensive support devoted to these communities in efforts to alleviate barriers to necessary health care and emergency services. I am very familiar with rural patient populations and have taken a personal interest in understanding the complexities of rural health disparities based on my experience as a practicing pharmacist in Curry County. Curry County, among others, has been identified by the ORH as an area where essential health care is lacking, thus, negatively impacting the health of community members. As an appointee by the Oregon Board of Pharmacy, I was able to bring a unique skillset, impart my pharmacy knowledge, and experience, and add value to the RHCC deliberation process in discussions of Curry County and similar areas.

As I conclude my two-year appointment, one valuable impression left upon me is that a multi-disciplinarian approach, with pharmacists as collaborative members, would be an ideal strategy to address the unmet health care needs of rural and frontier communities within the state of Oregon. The profession of pharmacy continues to evolve by expanding the level at which pharmacists can practice commensurate to their level of education and training. Thus, pharmacists could be an additional resource needed to help alleviate these gaps in needed services, subsequently allowing pharmacists to be added to Oregon's Rural Provider Tax Credit.

It has been an honor to serve on the RHCC and personally worthwhile to learn about the issues impacting rural and frontier communities. Thank you for taking the time to consider extending my two-year appointment.

Sincerely,

Leanne Yantis

Leanne Elizabeth Yantis
 3982 Wheeler Lane
 West Linn, Oregon 97068
 949.697.4578
Laldin218@aol.com

Education:

Aug 03 - May 07	University of New Mexico Doctor of Pharmacy	Albuquerque, NM
Oct 98 - Mar 01	Antioch University Master of Arts Psychology	Los Angeles, CA
Oct 96 - Jul 97	Exeter University Student Exchange program with University of New Mexico	Exeter, England
Aug 93 - May 98	University of New Mexico Bachelor of Science Psychology/ minor Mathematics	Albuquerque, NM

Professional Experience:

Apr 17- present	Advanced Health Clinical Pharmacist - Remote Conducted clinical reviews of prior authorizations for coverage determination. Utilized the Oregon Health Authority's Prioritized List of Health Services to ensure medical conditions were funded and guideline notes supported non-formulary agents. Evaluated drug literature, corresponding treatment guidelines, and drug utilization reviews to assess medical appropriateness of requested medications. Applied drug use criteria to make benefit decisions and provided evidence-based recommendations for least costly alternatives when appropriate in order to support quality, cost-effective treatment.	Coos Bay, OR
Feb 09 – Oct 17	Corner Drug Store Co-Owner/Pharmacist Provided quality customer service to patients by prioritizing the tasks at hand, managed pharmacy workflow and delegated duties in medium-volume pharmacy. Supervised pharmacy technicians filling and dispensing prescription orders and verified correctness of medication packs delivered to nursing facilities. Reviewed patient profiles for drug-drug interactions, drug allergies, provided medication counseling to patients to promote optimal therapy management and assisted medical providers through medication consultation. Devised all pharmacy policies and procedures while maintaining all pharmacy practices where in accordance with Oregon Board of Pharmacy and HIPAA. Established protocols for off-site flu shot clinics, naloxone prescribing and medication disposal program. Implemented a free home delivery service to underserved rural communities 30 miles north and 30 miles south of the pharmacy. Managed pharmacy personnel. Interviewed candidates, hired staff and determined employee performance goals. Managed inventory and pharmacy/store purchases. Researched vendors and negotiated wholesale contracts. Increased pharmacy reimbursement rates for targeted patient populations by improving quality metrics through the implementation of a	Gold Beach, OR

medication synchronization program, Time My Meds. Provided medication therapy management (MTM) to patients with multiple disease-states, identified by EQuIPP, aimed at increasing adherence to statins, anti-hypertensive and oral diabetic agents. Ensured eligible Medicare patients received optimal disease-state management through delivery of in-person/telephonic comprehensive medication reviews (CMR).

May 07- Feb 09	Rite Aid Pharmacy Pharmacy Manager Managed and supervised staff while performing daily operations of filling prescription orders. Reviewed individual orders for drug-drug interactions and allergies and provided medication consultations and recommendations to patients and physicians. Ensured pharmacy practices were in accordance with Oregon Board of Pharmacy and HIPAA.	Brookings, OR
May 05 - May 07	Sav-On Pharmacy Pharmacy Intern Processed and dispensed medications ordered by physicians. Consulted with patients on the proper use and potential side effects of medications.	Albuquerque, NM Lake Forest, CA
Aug 04 - May 06	Express Scripts, Inc. Pharmacy Intern Entered and filled mailed-in prescriptions, notified doctors of possible drug-drug interactions and continued cost containment strategies by informing doctors and patients of possible drug conversions.	Albuquerque, NM

Clinical Clerkships:

Apr 07	Walgreens Corporate Internship Accompanied and shadowed the District Manager during store visits where pharmacist performances were reviewed and strategies were discussed to improve overall pharmacy workflow.	Cook County, IL
Mar 07	Taos/Picuris Indian Health Center Rural Health Interdisciplinary Program (RHIP) Nephrology Assisted clinical pharmacist in medication reviews for patients receiving dialysis, monitored treatment of anemia, assisted with drug utilization review of Aranesp, and provided patient education regarding proper use of medication to acute and chronic kidney disease patients.	Taos, NM
Feb 07	University of New Mexico Hospital Pediatric Oncology Reviewed daily chemotherapy regimens for individual patients, re-calculated doses, and assessed drug regimens for optimal nausea prevention and pain treatment. Provided and conducted surveys to family members and patients with the goal of assessing and refining supportive care.	Albuquerque, NM

Jan 07	New Mexico Behavioral Health Institute Psychiatry Served as a drug information source to acute multi-disciplinary team. Reviewed daily medication profiles and laboratory values in order to assess and monitor psychiatric drug therapy.	Las Vegas, NM
Nov 06	Health Centers for Northern New Mexico Rural Health Interdisciplinary Program (RHIP) Primary Care Worked with clinical pharmacist to monitor and adjust drug therapy based on interpretation of INR values for anti-coagulation patients. Provided medication/nutrition counseling to patients to prevent drug-drug/drug-food interactions. Maintained inventory and conducted chart reviews for medication appropriateness for outlying clinics in rural New Mexico. Organized and presented weekly OTC/prescription medication information sessions to seniors at local senior citizen center during "Brown Bag Days."	Espanola, NM
Sept 06 - Oct 06	GE Healthcare Nuclear Pharmacy Learned basic practice standards of radio nucleotide safety in a nuclear pharmacy and how to prepare and calibrate radio-labeled products for administration to patients.	Anaheim, CA
Aug 06	Frasier Medical Pharmacy Compounding Pharmacy Aseptically prepared and dispensed custom-tailored hormone replacement compounds to patients. Counseled patients on potential side effects and monitoring parameters of treatment.	Santa Fe, NM
Volunteer Experience:		
Sept 16 – present	Oregon Office of Rural Health Rural Health Coordinating Council (RHCC) Member Appointed by the Oregon Board of Pharmacy to serve a 2-year term as a member of RHCC. Collaborated with a team of 18 members, comprised of health care professionals and consumers, in order help rural counterparts receive needed services through allocation of resources.	Portland, OR
Oct 15 – Aug 17	State Emergency Registry of Volunteers in Oregon (SERV-OR) Curry County Medical Reserve Corps (CCMRC) Registered volunteer of SERV-OR. Joined local team of health care and public health professionals to establish an organized medical response to health-related public emergencies. Completed Tactical Emergency Casualty Care course.	Brookings, OR
Apr 16 – Aug 17	Curry Community Health Board of Directors Secretary/Treasurer Supported fellow board members and CEO of Curry Community Health, a nonprofit private corporation, in the pursuit of expanding primary care, mental	Gold Beach, OR

Luke 9:2 Ministries Medical Team

Medical Team Member

Additional Training:

Contraception Education and Certification for the Pharmacist

APhA Training Certificate: Delivering Medication Therapy Management

APhA Training Certificate: Pharmacy-Based Cardiovascular Disease Risk Management

APhA Training Certificate: The Pharmacist and Patient-Centered Diabetes Care

Aug 03 - May 07

University of New Mexico College of Pharmacy
Dean's List

Member, Rho Chi Honor Society

Jan 14 - present

Member, Oregon Society of Health-System Pharmacists

Member, Oregon State Pharmacy Association

Aug 07- present

Oregon State Registered Pharmacist RPH – 0011104

ANNUAL BOARD & OTHER PHARMACIST APPOINTMENT REPORT

Please provide the Board with a description of your involvement related to the Board, Commission or Committee to which to serve as a Pharmacist appointee.

Submit your response by: **May 11, 2018** to Karen.S.MacLean@oregon.gov

Last Name: Bednar

First Name: Justin

Date: 5/2/2018

Email: bednarj@gmail.com

Work Phone: 503-988-5827

List the board, committee or commission to which you are appointed:

Naturopathic Formulary Council

Please provide a brief summary of your activities from the last year within your appointment. Be sure to include your term and meeting frequency.

-Meeting Frequency: 2 times per year

-My 2nd 2 year term

-Majority of pharmacist input for this council is providing perspective into the appropriateness of Naturopathic Providers prescribing new medications to the market. I think Natalie and I bring complementary perspective to this council, with my background in psychiatric and ambulatory pharmacy along with Natalie's expertise in community and compounding pharmacy. From a public safety perspective, I believe the role of the pharmacist on this council continues to be integral to making this a robust Formulary Council.

ANNUAL BOARD & OTHER PHARMACIST APPOINTMENT REPORT

Please provide the Board with a description of your involvement related to the Board, Commission or Committee to which to serve as a Pharmacist appointee.

Submit your response by: **May 11, 2018** to Karen.S.MacLean@oregon.gov

Last Name: Gustafson

First Name: Natalie

Date: 5/4/18

Email: natalie@lcrx.com

Work Phone: 503-281-4161

List the board, committee or commission to which you are appointed:

Oregon Board of Naturopathic Medicine Formulary Council

Please provide a brief summary of your activities from the last year within your appointment. Be sure to include your term and meeting frequency.

I have been on the OBNM Formulary Council since August 2011, with my current term ending Jun 2019. We meet every six months, typically in March and September or early October.

In the last two years the main project we have worked on has been simplifying the formularies to reduce confusion and clarifying prescribing for naturopathic physicians. Through our work and analysis, we helped determine that the two old formularies, an itemized list 850-060-225 and a more updated list by drug class 850-060-226 were no longer necessary. Based on our suggestions, this work helped create the new rule 850-60-223, which is much more streamlined and clear.

Another issue that came up in the last year was ketamine prescribing and if there were restrictions for naturopathic physicians. This discussion led to research on classifications and if route, such as intravenous use, would be a factor.

We continued to discuss physician dispensing and the change in rules 855-043-0505. Also, we discussed the change in CE requirements for naturopathic physicians and met with a representative from Oregon Prescription Drug Monitoring Program.

ANNUAL BOARD & OTHER PHARMACIST APPOINTMENT REPORT

Please provide the Board with a description of your involvement related to the Board, Commission or Committee to which to serve as a Pharmacist appointee.

Submit your response by: **May 11, 2018** to Karen.S.MacLean@oregon.gov

Last Name: Gustafson

First Name: Natalie

Date: 5/4/18

Email: natalie@lcrx.com

Work Phone: 503-281-4161

List the board, committee or commission to which you are appointed:

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Please provide a brief summary of your activities from the last year within your appointment. Be sure to include your term and meeting frequency.

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Another issue that came up in the last year was ketamine prescribing and if there were restrictions for naturopathic physicians. This discussion led to research on classifications and if route, such as intravenous use, would be a factor.

We continued to discuss physician dispensing and the change in rules 855-043-0505. Also, we discussed the change in CE requirements for naturopathic physicians and met with a representative from Oregon Prescription Drug Monitoring Program.

ANNUAL BOARD & OTHER PHARMACIST APPOINTMENT REPORT

Please provide the Board with a description of your involvement related to the Board, Commission or Committee to which to serve as a Pharmacist appointee.

Submit your response by: **May 11, 2018** to Karen.S.MacLean@oregon.gov

Last Name: Howrey

First Name: Linda

Date: 5/2/2018

Email: Linda.H58@ons.com

Work Phone: 503-778-0800

List the board, committee or commission to which you are appointed:

IPAT- Immunization Practice Advisory Team
Oregon Board of Naturopathic Medicine Formulary Council

Please provide a brief summary of your activities from the last year within your appointment. Be sure to include your term and meeting frequency.

IPAT usually meets 6 times a year. Most recently August 2017, March 2017, June 4 2017 was canceled, Sept 7, 2017, Dec 7 2017, March 1, 2018. We meet every 6 months, typically in March and September or early October.

We are scheduled to meet June 7 2018, Sept 6 2018, Dec 6 2018. In the last two years the main project we have worked on has been simplifying the formularies to reduce confusion and clarifying prescribing for naturopathic physicians. Through our work and analysis, we helped determine that the two old formularies, an itemized list 850-060-225 and a more updated list by drug class 850-060-226 were no longer necessary. Based on our suggestions, this work helped create the new rule 850-060-223, which is much more streamlined and clear. Regarding immunizations, ACIP recommendations, VFC and potential issues, ALERT, and any immunization policy issues that may affect public health.

Another issue that came up in the last year was ketamine prescribing and if there were restrictions for naturopathic physicians. This discussion led to research on classifications and if route, such as intravenous use, would be a factor. The last several meetings have focused on the makeup of the team and assessing if all groups are represented. We have also addressed the priority of the topics IPAT should focus on.

In the March 1, 2018 meeting, it was proposed I be removed from the BOP representation and Fiona be added. We continued to discuss physician dispensing and the change in rules 855-043-0505. Also, we discussed the change in CE requirements for naturopathic physicians and met with a representative from Oregon Prescription Drug Monitoring Program. I would be representing Community Pharmacy instead.

My understanding is that BOP has already been approached and agreed. Fiona should be the BOP representative going forward.

Schedule of Administrative Fees

In accordance with OAR 107-001-030 and 855-110-0015(4), the Board of Pharmacy established the following fees: Upon request fees may be waived as specified in OAR 855-110-0015(7).

1. General:

Provide an estimate of costs for the services requested:	No charge
The first 30 minutes of staff time to provide the information requested:	No charge
After 30 minutes, staff time will be charged at:	
(i) Administrative staff time:	\$25 per hour in increments of 15 minutes;
(ii) Management or pharmacist time:	\$40 per hour in increments of 15 minutes;
(iii) IT Consultant time	\$75 per hour or part thereof;
(iv) Department of Justice (DOJ) attorney fees:	Actual costs as billed to the agency by DOJ.

2. Duplication and delivery of records:

Each page printed or copied after the first 10:	\$0.07 B/W, \$0.40 color per page.
Records provided on digital media such as CD, or any other media:	\$5 / CD Other media at actual cost.
Electronic mail message including attachments:	No charge, however staff time may apply.
Mail or other delivery service:	Actual cost.
Electronic lists of licensees and registrants:	\$80 per category
Electronic lists of <u>individual</u> licensees BASIC list (name, mailing address, public email address)	\$25 per category, this does not apply to outlets
Manual license verification:	\$10 per license number (including lapsed and inactive numbers).
Certified copies (two per page)	No charge for first page \$5 per additional page
Duplicate wall certificates:	\$20 each

4. Publications:

Copies of Laws and Rules (available free through the Board web site):	\$25 per CD or paper set for delivery within the USA; \$25 plus actual delivery costs for delivery outside the USA;

JUNE 2018 / F7

OREGON

ATTORNEY GENERAL'S

ADMINISTRATIVE LAW MANUAL

AND

UNIFORM AND MODEL RULES OF

PROCEDURE

UNDER THE

ADMINISTRATIVE PROCEDURES ACT



ELLEN F. ROSENBLUM
Attorney General

July 2014

CONTROLLED SUBSTANCES

- ALPHABETICAL ORDER -

SUBSTANCE	DEA NUMBER	CSA SCH	NARC	OTHER NAMES
6-bromo-androsta-1,4-diene-3,17-dione	4000	III	N	
[3,2-c]-furazan-5 α -androstan-17 β -ol	4000	III	N	
[3,2-c]pyrazole-androst-4-en-17 β -ol	4000	III	N	
1-(1-Phenylcyclohexyl)pyrrolidine	7458	I	N	PCPy, PHP, rolicyclidine
1-(2-Phenylethyl)-4-phenyl-4-acetoxypiperidine	9663	I	Y	PEPAP, synthetic heroin
1-[1-(2-Thienyl)cyclohexyl]piperidine	7470	I	N	TCP, tenocyclidine
1-[1-(2-Thienyl)cyclohexyl]pyrrolidine	7473	I	N	TCPy
13Beta-ethyl-17beta-hydroxygon-4-en-3-one	4000	III	N	
17Alpha-methyl-3alpha,17beta-dihydroxy-5alpha-androstane	4000	III	N	
17Alpha-methyl-3beta,17beta-dihydroxy-5alpha-androstane	4000	III	N	
17Alpha-methyl-3beta,17beta-dihydroxyandrost-4-ene	4000	III	N	
17Alpha-methyl-4-hydroxynandrolone (17alpha-methyl-4-hydroxy-17beta-hydroxyestr-4-en-3-one)	4000	III	N	
17Alpha-methyl-delta1-dihydrotestosterone (17beta-hydroxy-17alpha-methyl-5alpha-androst-1-en-3-one)	4000	III	N	17-Alpha-methyl-1-testosterone
17 α -Methyl-5 α -androstan-17 β -ol	4000	III	N	
17 α -methyl-androst-2-ene-3,17 β -diol	4000	III	N	
17 α -methyl-androsta-1,4-diene-3,17 β -diol	4000	III	N	
17 α -Methyl-androstan-3-hydroxyimine-17 β -ol	4000	III	N	
17 β -Hydroxy-androstano[2,3-d]isoxazole	4000	III	N	
17 β -Hydroxy-androstano[3,2-c]isoxazole	4000	III	N	
18a-Homo-3-hydroxy-estra-2,5(10)-dien-17-one	4000	III	N	
19-Nor-4,9(10)-androstadienedione	4000	III	N	
19-Nor-4-androstenediol (3beta,17beta-dihydroxyestr-4-ene; 3alpha,17beta-dihydroxyestr-4-ene)	4000	III	N	
19-Nor-4-androstenedione (estr-4-en-3,17-dione)	4000	III	N	
19-Nor-5-androstenediol (3beta,17beta-dihydroxyestr-5-ene; 3alpha,17beta-dihydroxyestr-5-ene)	4000	III	N	
19-Nor-5-androstenedione (estr-5-en-3,17-dione)	4000	III	N	
1-Androstenediol (3beta,17beta-dihydroxy-5alpha-androst-1-ene; 3alpha,17beta-dihydroxy-5alpha-androst-1-ene)	4000	III	N	

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SUBSTANCE	DEA NUMBER	CSA SCH	NARC	OTHER NAMES
1-Androstenedione (5alpha-androst-1-en-3,17-dione)	4000	III	N	
1-Methyl-4-phenyl-4-propionoxypiperidine	9661	I	Y	MPPP, synthetic heroin
1-Phenylcyclohexylamine	7460	II	N	PCP precursor
1-Piperidinocyclohexanecarbonitrile	8603	II	N	PCC, PCP precursor
2-(1-(4-fluorobenzyl)-1Hindazole-3-carboxamido)-3-methylbutanoate	7021	I	N	FUB-AMB, MMB- FUBINACA, AMB-FUBINACA
2-(2,5-Dimethoxy-4-(n)-propylphenyl) ethanamine (2C-P)	7524	I	N	2C-P
2-(2,5-Dimethoxy-4-ethylphenyl) ethanamine (2C-E)	7509	I	N	2C-E (Positional Isomer: 2,5-Dimethoxy-3,4-dimethylphenethylamine (2C-G))
2-(2,5-Dimethoxy-4-methylphenyl) ethanamine (2C-D)	7508	I	N	2C-D
2-(2,5-Dimethoxy-4-nitro-phenyl) ethanamine (2C-N)	7521	I	N	2C-N
2-(2,5-Dimethoxyphenyl) ethanamine (2C-H)	7517	I	N	2C-H
2-(4-bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl) ethanamine (25B-NBOMe)	7536	I	N	25B-NBOMe, 2C-B-NBOMe, 25B, Cimbi-36
2-(4-Chloro-2,5-dimethoxyphenyl) ethanamine (2C-C)	7519	I	N	2C-C
2-(4-chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl) ethanamine (25C-NBOMe)	7537	I	N	25C-NBOMe, 2C-C-NBOMe, 25C, Cimbi-82
2-(4-Ethylthio-2,5-dimethoxyphenyl) ethanamine (2C-T-2)	7385	I	N	2C-T-2
2-(4-iodo-2,5-dimethoxyphenyl) ethanamine (2C-I)	7518	I	N	2C-I
2-(4-iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl) ethanamine (25I-NBOMe)	7538	I	N	25I-NBOMe, 2C-I-NBOMe, 25I, Cimbi-5
2-(4-Isopropylthio)-2,5-dimethoxyphenyl) ethanamine (2C-T-4)	7532	I	N	2C-T-4 (Positional Isomer: 2,5-Dimethoxy-4-ethylthioamphetamine (Aleph-2))
2,5-Dimethoxy-4-(n)-propylthiophenethylamine (2C-T-7)	7348	I	N	2C-T-7 (Positional Isomer: 2,5-Dimethoxy-4-ethylthioamphetamine (Aleph-2))
2,5-Dimethoxy-4-ethylamphetamine	7399	I	N	DOET
2,5-Dimethoxyamphetamine	7396	I	N	DMA, 2,5-DMA
2-methoxy-N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide	9825	I	Y	Methoxyacetyl fentanyl
2α,17α-dimethyl-17β-hydroxy-5β-androstan-3-one	4000	III	N	
2α,3α-epithio-17α-methyl-5α-androstan-17β-ol	4000	III	N	
3,4,5-Trimethoxyamphetamine	7390	I	N	TMA (Positional Isomers: 2,4,5-Trimethoxy-amphetamine (TMA-5), 2,4,6-Trimethoxy-amphetamine (TMA-6), Escaline)
3,4-Methylenedioxyamphetamine	7400	I	N	MDA, Love Drug
3,4-Methylenedioxymethamphetamine	7405	I	N	MDMA, Ecstasy, XTC
3,4-Methylenedioxy-N-ethylamphetamine	7404	I	N	N-ethyl MDA, MDE, MDEA
3Alpha,17beta-dihydroxy-5alpha-androstane	4000	III	N	
3Beta,17beta-dihydroxy-5alpha-androstane	4000	III	N	
3-Fluoro-N-methylcathinone (3-FMC)	1233	I	N	1-(3-fluorophenyl)-2-(methylamino)propan-1-one (Positional isomer: 2-FMC)

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3-Methylfentanyl	9813	I	Y	China White, fentanyl
3-Methylthiofentanyl	9833	I	Y	China White, fentanyl
3β-hydroxy-estra-4,9,11-trien-17-one	4000	III	N	
4-Androstenediol (3beta,17beta-dihydroxy-androst-4-ene)	4000	III	N	4-AD
4-Androstenedione (androst-4-en-3,17-dione)	4000	III	N	
4-Anilino-N-phenethyl-4-piperidine (ANPP)	8333	II	N	ANPP, Despropionyl fentanyl
4-Bromo-2,5-dimethoxyamphetamine	7391	I	N	DOB, 4-bromo-DMA
4-Bromo-2,5-dimethoxyphenethylamine	7392	I	N	2C-B, Nexus, has been sold as Ecstasy, i.e. MDMA
4-chloro-17α-methyl-17β-hydroxy-androst-4-en-3-one	4000	III	N	
4-chloro-17α-methyl-17β-hydroxy-androst-4-ene-3,11-dione	4000	III	N	
4-chloro-17α-methyl-androst-4-ene-3β,17β-diol	4000	III	N	
4-chloro-17α-methyl-androsta-1,4-diene-3,17β-diol	4000	III	N	
4-Dihydrotestosterone (17beta-hydroxyandrost-3-one)	4000	III	N	Anabolex, Andractim, Pesomax, Stanolone
4-Fluoroisobutyryl fentanyl (N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide)	9824	I	Y	Para-fluoroisobutyryl fentanyl
4-Fluoro-N-methylcathinone (4-FMC)	1238	I	N	flephedrone; 1-(4-fluorophenyl)-2-(methylamino)propan-1-one) (Positional isomer: 2-FMC)
4-Hydroxy-19-nortestosterone (4,17beta-dihydroxyestr-4-en-3-one)	4000	III	N	
4-Hydroxy-androst-4-ene-3,17-dione	4000	III	N	Listed as 4-Hydroxy-androst-4-ene-3,17-dione[3,2-c]pyrazole-5α-androstan-17β-ol
4-Hydroxytestosterone (4,17beta-dihydroxyandrost-4-en-3-one)	4000	III	N	
4-Methoxyamphetamine	7411	I	N	PMA
4-Methyl-2,5-dimethoxyamphetamine	7395	I	N	DOM, STP (Positional Isomer: 2,5-Dimethoxy-3,4-dimethylphenethylamine (2C-G))
4-Methyl-alpha-pyrrolidinopropiophenone (4-MePPP)	7498	I	N	MePPP, 4-methyl-α-pyrrolidinopropiophenone, 1-(4-methylphenyl)-2-(pyrrolidin-1-yl)-propan-1-one)
4-Methylaminorex (cis isomer)	1590	I	N	U4Euh, McN-422
4-Methyl-N-ethylcathinone (4-MEC)	1249	I	N	2-(ethylamino)-1-(4-methylphenyl)propan-1-one)(Positional Isomers:3-methylethcathinone (3-MEC), 4-ethylmethcathinone (4-EMC), 4-methylbuphedrone (4-MeMABP;4-MeBP), 3,4-dimethylmethcathinone(3,4-DMMC),N-ethylbuphedrone (NEB),N-ethyl-N-methylcathinone(EMC))
5-Androstenediol (3beta,17beta-dihydroxy-androst-5-ene)	4000	III	N	
5-Androstenedione (androst-5-en-3,17-dione)	4000	III	N	

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5F-ADB; 5F-MDMB-PINACA (Methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate)	7034	I	N	5F-ADB, 5F-MDMB-PINACA
5F-AMB (Methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methylbutanoate)	7033	I	N	5F-AMB
5F-APINACA, 5F-AKB48 (N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide)	7049	I	N	5F-APINACA, 5F-AKB48
5-Fluoro-UR-144 and XLR11 [1-(5-Fluoro-pentyl)1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone	7011	I	N	5-Fluoro-UR-144, XLR-11 and XLR11
5F-PB-22 (Quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate)	7225	I	N	5-Fluoro-PB-22; 5F-PB-22
5-Methoxy-3,4-methylenedioxyamphetamine	7401	I	N	MMDA
5-Methoxy-N,N-diisopropyltryptamine	7439	I	N	5-MeO-DIPT (Positional Isomer: 5-Methoxy-N,N-dipropyltryptamine (5-MeO-DPT))
5-Methoxy-N,N-dimethyltryptamine	7431	I	N	5-MeO-DMT (Positional Isomer: 4-Methoxy-N,N-dimethyltryptamine (4-MeO-DMT))
5α-Androstan-3,6,17-trione	4000	III	N	
6-bromo-androstan-3,17-dione	4000	III	N	
6α-Methyl-androst-4-ene-3,17-dione	4000	III	N	
AB-CHMINACA (N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide)	7031	I	N	AB-CHMINACA
AB-FUBINACA (N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide)	7012	I	N	AB-FUBINACA
AB-PINACA (N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide)	7023	I	N	AB-PINACA
Acetorphine	9319	I	Y	
Acetyl Fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide)	9821	I	Y	
Acetyl-alpha-methylfentanyl	9815	I	Y	
Acetyldihydrocodeine	9051	I	Y	Acetylcodone
Acetylmethadol	9601	I	Y	Methadyl acetate
Acryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylacrylamide)	9811	I	Y	Acryloylfentanyl
ADB-FUBINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide)	7010	I	N	ADB-FUBINACA
ADB-PINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide)	7035	I	N	ADB-PINACA
AH-7921 (3,4-dichloro-N-[(1-dimethylamino)cyclohexylmethyl]benzamide))	9551	I	Y	AH-7921
Alfaxalone	2731	IV	N	Alfaxan, 5α-pregnan-3α-ol-11,20-dione
Alfentanil	9737	II	Y	Alfenta
Allylprodine	9602	I	Y	
Alphacetylmethadol except levo-alphacetylmethadol	9603	I	Y	

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Alpha-ethyltryptamine	7249	I	N	ET, Trip
Alphameprodine	9604	I	Y	
Alphamethadol	9605	I	Y	
Alpha-methylfentanyl	9814	I	Y	China White, fentanyl
Alpha-methylthiofentanyl	9832	I	Y	China White, fentanyl
Alpha-methyltryptamine	7432	I	N	AMT (Positional Isomer: N-Methyltryptamine)
Alphaprodine	9010	II	Y	Nisentil
alpha-pyrrolidinobutiophenone (α-PBP)	7546	I	N	1-phenyl-2-(pyrrolidin-1-yl)butan-1-one
alpha-pyrrolidinopentiophenone (α-PVP)	7545	I	N	α-pyrrolidinovalerophenone, 1-phenyl-2- (pyrrolidin-1-yl)pentan-1-one)(Positional isomers: 4-methyl-α-pyrrolidinobutiophenone (4-MePBP), 1-phenyl-2-(piperidin-1-yl)butan-1-one)
Alprazolam	2882	IV	N	Xanax
AM2201 (1-(5-Fluoropentyl)-3-(1-naphthoyl) indole)	7201	I	N	AM2201
AM-694 (1-(5-Fluoropentyl)-3-(2-iodobenzoyl) indole)	7694	I	N	AM-694
Aminorex	1585	I	N	has been sold as methamphetamine
Amobarbital	2125	II	N	Amytal, Tuinal
Amobarbital & noncontrolled active ingred.	2126	III	N	
Amobarbital suppository dosage form	2126	III	N	
Amphetamine	1100	II	N	Dexedrine, Adderall, Obetrol
Anabolic steroids	4000	III	N	"Body Building" drugs
Androstenedione (5α-androstan-3,17-dione)	4000	III	N	
Anileridine	9020	II	Y	Leritine
APINACA and AKB48 N-(1-Adamantyl)-1-pentyl-1H-indazole-3-carboxamide	7048	I	N	APINACA and AKB48
Aprobarbital	2100	III	N	Alurate
Barbital	2145	IV	N	Veronal, Plexonal, barbitone
Barbituric acid derivative	2100	III	N	Barbiturates not specifically listed
Benzethidine	9606	I	Y	
Benzphetamine	1228	III	N	Didrex, Inapetyl
Benzylmorphine	9052	I	Y	
Betacetylmethadol	9607	I	Y	
Beta-hydroxy-3-methylfentanyl	9831	I	Y	China White, fentanyl
Beta-hydroxyfentanyl	9830	I	Y	China White, fentanyl
Beta-hydroxythiofentanyl	9836	I	Y	N-[1-[2-hydroxy-2-(thiophen-2-yl)ethyl]piperidin-4-yl]-N-phenylpropionamide, N-[1-[2-hydroxy-2-(2-thienyl)ethyl]-4-piperidinyl]-N-phenylpropanamide
Betameprodine	9608	I	Y	
Betamethadol	9609	I	Y	

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Betaprodine	9611	I	Y	
Bezitramide	9800	II	Y	Burgodin
Bolasterone (7alpha,17alpha-dimethyl-17beta-hydroxyandrost-4-en-3-one)	4000	III	N	
Boldenone (17beta-hydroxyandrost-1,4-diene-3-one)	4000	III	N	Equipoise, Parenabol, Vebonol, dehydrotestosterone
Boldione	4000	III	N	
Brivaracetam	2710	V	N	BRV, UCB-34714, Briviact, ((2S)-2-[(4R)-2-oxo-4-propylpyrrolidin-1-yl] butanamide)
Bromazepam	2748	IV	N	Lexotan, Lexatin, Lexotanol
Bufotenine	7433	I	N	Mappine, N,N-dimethylserotonin
Buprenorphine	9064	III	Y	Buprenex, Temgesic, Subutex, Suboxone
Butabarbital (secbutabarbital)	2100	III	N	Butisol, Butibel
Butalbital	2100	III	N	Fiorinal, Butalbital with aspirin
Butobarbital (butethal)	2100	III	N	Soneryl (UK)
Butorphanol	9720	IV	N	Stadol, Stadol NS, Torbugesic, Torbutrol
Butylone	7541	I	N	bk-MBDB; 1-(1,3-benzodioxol-5-yl)-2-(methylamino)butan-1-one (Positional Isomers: ethylone (bk-MDEA; MDEC), dimethylone (bk-MDDMA; MDDMC))
Butyryl Fentanyl	9822	I	Y	N-(1-phenethylpiperidin-4-yl)-N-phenylbutyramide, N-(1-phenethylpiperidin-4-yl)-N-phenylbutanamide
Calusterone (7beta,17alpha-dimethyl-17beta-hydroxyandrost-4-en-3-one)	4000	III	N	Methosarb
Camazepam	2749	IV	N	Albego, Limpidon, Paxor
Carfentanil	9743	II	Y	Wildnil
Carisoprodol	8192	IV	N	Soma
Cathine	1230	IV	N	Constituent of "Khat" plant, (+)-norpseudoephedrine
Cathinone	1235	I	N	Constituent of "Khat" plant
Chloral betaine	2460	IV	N	Beta Chlor
Chloral hydrate	2465	IV	N	Noctec
Chlordiazepoxide	2744	IV	N	Librium, Libritabs, Limbitrol, SK-Lygen
Chlorhexadol	2510	III	N	Mechloral, Mecoral, Medodorm, Chloralodol
Chlorphentermine	1645	III	N	Pre-Sate, Lucofen, Apседon, Desopimon
Clobazam	2751	IV	N	Urbadan, Urbanyl
Clonazepam	2737	IV	N	Klonopin, Clonopin
Clonitazene	9612	I	Y	
Clorazepate	2768	IV	N	Tranxene
Clortermine	1647	III	N	Voranyl
Clostebol (4-chloro-17beta-hydroxyandrost-4-en-3-one)	4000	III	N	Alfa-Trofodermin, Clostene, 4-chlorotestosterone
Clotiazepam	2752	IV	N	Trecalmo, Rize, Clozan, Veratran

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Clozapolam	2753	IV	N	Akton, Lubalix, Olcadil, Sepazon
Coca Leaves	9040	II	Y	
Cocaine	9041	II	Y	Methyl benzoyllecgonine, Crack
Codeine	9050	II	Y	Morphine methyl ester, methyl morphine
Codeine & isoquinoline alkaloid 90 mg/du	9803	III	Y	Codeine with papaverine or noscapine
Codeine combination product 90 mg/du	9804	III	Y	Empirin, Fiorinal, Tylenol, ASA or APAP w/codeine
Codeine methylbromide	9070	I	Y	
Codeine preparations - 200 mg/(100 ml or 100 gm)		V	Y	Cosanyl, Robitussin A-C, Cheracol, Cerase, Pediacof
Codeine-N-oxide	9053	I	Y	
CP-47,497 (5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl-phenol])	7297	I	N	CP-47,497
CP-47,497 C8 Homologue (5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl-phenol])	7298	I	N	CP-47,497 C8 Homologue
Cyclopentyl fentanyl	9847	I	Y	N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopentanecarboxamide
Cyclopropyl Fentanyl	9845	I	Y	N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopropanecarboxamide
Cyprenorphine	9054	I	Y	
Dehydrochloromethyltestosterone (4-chloro-17beta-hydroxy-17alpha-methylandro-1,4-dien-3-one)	4000	III	N	Oral-Turinabol
Delorazepam	2754	IV	N	
Delta1-dihydrotestosterone (17beta-hydroxy-5alpha-androst-1-en-3-one)	4000	III	N	1-Testosterone
Desomorphine	9055	I	Y	
Desoxymethyltestosterone	4000	III	N	
Dexfenfluramine	1670	IV	N	Redux
Dextromoramide	9613	I	Y	Palfium, Jetrium, Narcolo
Dextropropoxyphene dosage forms	9278	IV	Y	Darvon, propoxyphene, Darvocet, Propacet
Dextropropoxyphene, bulk (non-dosage forms)	9273	II	Y	Propoxyphene
Diampromide	9615	I	Y	
Diazepam	2765	IV	N	Valium, Diastat
Dichloralphenazone	2467	IV	N	Midrin, dichloralantipyrene
Diethylpropion	1610	IV	N	Tenuate, Tepanil
Diethylthiambutene	9616	I	Y	
Diethyltryptamine	7434	I	N	DET, N,N-Diethyltryptamine (Positional Isomer: N-Methyl-N-isopropyltryptamine (MiPT))
Difenoxin	9168	I	Y	Lyspafen
Difenoxin 1 mg/25 ug AtSO4/du	9167	IV	Y	Motofen
Difenoxin preparations - 0.5 mg/25 ug AtSO4/du		V	Y	Motofen
Dihydrocodeine	9120	II	Y	Didrate, Parzone

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Dihydrocodeine combination product 90 mg/du	9807	III	Y	Synalgos-DC, Compal
Dihydrocodeine preparations 100mg/(100 ml or 100 gm)		V	Y	Cophene-S, various others
Dihydroetorphine	9334	II	Y	DHE
Dihydromorphine	9145	I	Y	
Dimenoxadol	9617	I	Y	
Dimepheptanol	9618	I	Y	
Dimethylthiambutene	9619	I	Y	
Dimethyltryptamine	7435	I	N	DMT
Dioxaphetyl butyrate	9621	I	Y	
Diphenoxylate	9170	II	Y	
Diphenoxylate preparations 2.5 mg/25 ug AtSO4		V	Y	Lomotil, Logen
Dipipanone	9622	I	Y	Dipipan, phenylpiperone HCl, Diconal, Wellconal
Dronabinol (synthetic) in sesame oil in soft gelatin capsule as approved by FDA	7369	III	N	Marinol, synthetic THC in sesame oil/soft gelatin as approved by FDA
Dronabinol in an oral solution in a drug product approved for marketing by the U.S. Food and Drug Administration	7365	II	N	Syndros
Drostanolone (17beta-hydroxy-2alpha-methyl-5alpha-androstan-3-one)	4000	III	N	Drolban, Masterid, Permastril
Drotebanol	9335	I	Y	Metebanyl, oxymethebanol
Ecgonine	9180	II	Y	Cocaine precursor, in Coca leaves
Eluxadolone	9725	IV	N	VIBERZI
Embutramide	2020	III	N	Tributane
Estazolam	2756	IV	N	ProSom, Domnamid, Eurodin, Nuctalon
Estra-4,9,11-triene-3,17-dione	4000	III	N	
Ethchlorvynol	2540	IV	N	Placidyl
Ethinamate	2545	IV	N	Valmid, Valamin
Ethyl loflazepate	2758	IV	N	
Ethylestrenol (17alpha-ethyl-17beta-hydroxyestr-4-ene)	4000	III	N	Maxibolin, Orabolin, Durabolin-O, Duraboral
Ethylmethylthiambutene	9623	I	Y	
Ethylmorphine	9190	II	Y	Dionin
Ethylmorphine combination product 15 mg/du	9808	III	Y	
Ethylmorphine preparations 100 mg/(100 ml or 100 gm)		V	Y	
Etonitazene	9624	I	Y	
Etorphine (except HCl)	9056	I	Y	
Etorphine HCl	9059	II	Y	M 99
Etoperidine	9625	I	Y	
Ezogabine	2779	V	N	Potiga

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Fencamfamin	1760	IV	N	Reactivan
Fenethylamine	1503	I	N	Captagon, amfetamine, ethylphenylamine
Fenfluramine	1670	IV	N	Pondimin, Ponderal
Fenproporex	1575	IV	N	Gacilin, Solvolip
Fentanyl	9801	II	Y	Duragesic, Oralet, Actiq, Sublimaze, Innovar
Fentanyl related-compounds as defined in 21 CFR 1308.11(h)	9850	I	Y	
Fludiazepam	2759	IV	N	
Flunitrazepam	2763	IV	N	Rohypnol, Narcozep, Darkene, Roipnol
Fluoxymesterone (9-fluoro-17alpha-methyl-11beta,17beta-dihydroxyandrost-4-en-3-one)	4000	III	N	Anadroid-F, Halotestin, Ora-Testryl
Flurazepam	2767	IV	N	Dalmane
Formebolone (2-formyl-17alpha-methyl-11alpha,17beta-dihydroxyandrost-1,4-dien-3-one)	4000	III	N	Esiclone, Hubernol
Fospropofol	2138	IV	N	Lusedra
Furanyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylfuran-2-carboxamide)	9834	I	Y	
Furazabol (17alpha-methyl-17beta-hydroxyandrostano[2,3-c]-furan)	4000	III	N	Frazalon, Miotolon, Qu Zhi Shu
Furethidine	9626	I	Y	
Gamma Hydroxybutyric Acid	2010	I	N	GHB, gamma hydroxybutyrate, sodium oxybate
Gamma Hydroxybutyric Acid preparations	2012	III	N	Xyrem
Glutethimide	2550	II	N	Doriden, Dorimide
Halazepam	2762	IV	N	Paxipam
Haloxazolam	2771	IV	N	
Heroin	9200	I	Y	Diacetylmorphine, diamorphine
Hydrocodone	9193	II	Y	dihydrocodeinone
Hydromorphanol	9301	I	Y	
Hydromorphone	9150	II	Y	Dilaudid, dihydromorphine
Hydroxypethidine	9627	I	Y	
Ibogaine	7260	I	N	Constituent of "Tabernanthe iboga" plant
Isobutyl fentanyl	9827	I	Y	N-(1-phenethylpiperidin-4-yl)-N-phenylisobutyramide
Isomethadone	9226	II	Y	Isoamidone
JWH-018 (also known as AM678) (1-Pentyl-3-(1-naphthyl)indole)	7118	I	N	JWH-018 and AM-678
JWH-019 (1-Hexyl-3-(1-naphthyl)indole)	7019	I	N	JWH-019
JWH-073 (1-Butyl-3-(1-naphthyl)indole)	7173	I	N	JWH-073
JWH-081 (1-Pentyl-3-(1-(4-methoxynaphthyl) indole)	7081	I	N	JWH-081
JWH-122 (1-Pentyl-3-(4-methyl-1-naphthyl) indole)	7122	I	N	JWH-122

Abbreviations: "NARC"= Narcotic, "CSA SCH"= CSA Schedule

SUBSTANCE	DEA NUMBER	CSA SCH	NARC	OTHER NAMES
JWH-200 (1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole)	7200	I	N	JWH-200
JWH-203 (1-Pentyl-3-(2-chlorophenylacetyl) indole)	7203	I	N	JWH-203
JWH-250 (1-Pentyl-3-(2-methoxyphenylacetyl) indole)	6250	I	N	JWH-250
JWH-398 (1-Pentyl-3-(4-chloro-1-naphthoyl) indole)	7398	I	N	JWH-398
Ketamine	7285	III	N	Ketaset, Ketalar, Special K, K
Ketazolam	2772	IV	N	Anxon, Loftran, Solatran, Contamex
Ketobemidone	9628	I	Y	Cliradon
Lacosamide	2746	V	N	Vimpat
Levo-alphaacetylmethadol	9648	II	Y	LAAM, long acting methadone, levomethadyl acetate
Levomethorphan	9210	II	Y	
Levomoramide	9629	I	Y	
Levophenacymorphan	9631	I	Y	
Levorphanol	9220	II	Y	Levo-Dromoran
Lisdexamfetamine	1205	II	N	Vyvanse
Loprazolam	2773	IV	N	
Lorazepam	2885	IV	N	Ativan
Lorcaserin	1625	IV	N	Belviq
Lormetazepam	2774	IV	N	Noctamid
Lysergic acid	7300	III	N	LSD precursor
Lysergic acid amide	7310	III	N	LSD precursor
Lysergic acid diethylamide	7315	I	N	LSD, lysergide
MAB-CHMINACA (N-(1-amino-3,3dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide)	7032	I	N	MAB-CHMINACA and ADB-CHMINACA
Marihuana	7360	I	N	Cannabis, marijuana
Marihuana Extract	7350	I	N	
Mazindol	1605	IV	N	Sanorex, Mazanor
MDMB-CHMICA, MMB-CHMINACA (Methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate)	7042	I	N	MDMB-CHMICA, MMB-CHMINACA
MDMB-FUBINACA (Methyl 2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate)	7020	I	N	MDMB-FUBINACA
MDPV (3,4-Methylenedioxypyrovalerone)	7535	I	N	MDPV
Mebutamate	2800	IV	N	Capla
Mecloqualone	2572	I	N	Nubarene
Medazepam	2836	IV	N	Nobrium
Mefenorex	1580	IV	N	Anorexic, Amexate, Doracil, Pondinil
Meperidine	9230	II	Y	Demerol, Mepergan, pethidine

Abbreviations: "NARC"= Narcotic, "CSA SCH"= CSA Schedule

SUBSTANCE	DEA NUMBER	CSA SCH	NARC	OTHER NAMES
Meperidine intermediate-A	9232	II	Y	Meperidine precursor
Meperidine intermediate-B	9233	II	Y	Meperidine precursor, normeperidine
Meperidine intermediate-C	9234	II	Y	Meperidine precursor
Mephedrone (4-Methyl-N-methylcathinone)	1248	I	N	(Positional Isomers: 3-Methyl-methcathinone, Buphedrone, Ethcathinone, N,N-Dimethyl-cathinone)
Meprobamate	2820	IV	N	Miltown, Equanil, Micrainin, Equagesic, Meprospan
Mescaline	7381	I	N	Constituent of "Peyote" cacti
Mestanolone (17alpha-methyl-17beta-hydroxy-5alpha-androstan-3-one)	4000	III	N	Assimil, Ermalone, Methybol, Tantarone
Mesterolone (1alpha-methyl-17beta-hydroxy-5alpha-androstan-3-one)	4000	III	N	Androviron, Proviron, Testiwop
Metazocine	9240	II	Y	
Methadone	9250	II	Y	Dolophine, Methadose, Amidone
Methadone intermediate	9254	II	Y	Methadone precursor
Methamphetamine	1105	II	N	Desoxyn, D-desoxyephedrine, ICE, Crank, Speed
Methandienone (17alpha-methyl-17beta-hydroxyandrost-1,4-dien-3-one)	4000	III	N	Dianabol, Metabolina, Nerobol, Perbolin
Methandriol (17alpha-methyl-3beta,17beta-dihydroxyandrost-5-ene)	4000	III	N	Sinesex, Stenediol, Troformone
Methaqualone	2565	I	N	Quaalude, Parest, Somnafac, Opitmil, Mandrax
Methasterone (2alpha,17alpha-dimethyl-5alpha-androstan-17beta-ol-3-one)	4000	III	N	Methasterone; 2α,17α-dimethyl-17β-hydroxy-5α-androstan-3-one
Methcathinone	1237	I	N	N-Methylcathinone, "cat"
Methenolone (1-methyl-17beta-hydroxy-5alpha-androst-1-en-3-one)	4000	III	N	Primobolan, Primobolan Depot, Primobolan S
Methohexital	2264	IV	N	Brevital
Methylidesorphine	9302	I	Y	
Methyldienolone (17alpha-methyl-17beta-hydroxyestra-4,9(10)-dien-3-one)	4000	III	N	
Methyldihydromorphine	9304	I	Y	
Methylone (3,4-Methylenedioxy-N-methylcathinone)	7540	I	N	(Positional Isomer: 2,3-methylenedioxymethcathinone (2,3-MDMC, 1-(benzo[d][1,3]dioxol-4-yl)-2-(methylamino)propan-1-one))
Methylphenidate	1724	II	N	Concerta, Ritalin, Methylin
Methylphenobarbital (mephobarbital)	2250	IV	N	Mebaral, mephobarbital
Methyltestosterone (17alpha-methyl-17beta-hydroxyandrost-4-en-3-one)	4000	III	N	Android, Oreton, Testred, Virilon
Methyltrienolone (17alpha-methyl-17beta-hydroxyestra-4,9,11-trien-3-one)	4000	III	N	Metribolone
Methypylon	2575	III	N	Noludar
Metopon	9260	II	Y	

Abbreviations: "NARC"= Narcotic, "CSA SCH"= CSA Schedule

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SUBSTANCE	DEA NUMBER	CSA SCH	NARC	OTHER NAMES
Mibolerone (7alpha,17alpha-dimethyl-17beta-hydroxyestr-4-en-3-one)	4000	III	N	Cheque, Matenon
Midazolam	2884	IV	N	Versed
Modafinil	1680	IV	N	Provigil
Moramide-intermediate	9802	II	Y	
Morpheridine	9632	I	Y	
Morphine	9300	II	Y	MS Contin, Roxanol, Oramorph, RMS, MSIR
Morphine combination product/50 mg/(100 ml or 100 gm)	9810	III	Y	
Morphine methylbromide	9305	I	Y	
Morphine methylsulfonate	9306	I	Y	
Morphine-N-oxide	9307	I	Y	
MT-45 (1-cyclohexyl-4-(1,2-diphenylethyl)piperazine))	9560	I	Y	MT-45
Myrophine	9308	I	Y	
N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran-2-carboxamide	9843	I	Y	Tetrahydrofuranfentanyl
N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)propionamide	9816	I	Y	Ortho-fluorofentanyl or 2-fluorofentanyl
N,N-Dimethylamphetamine	1480	I	N	
Nabilone	7379	II	N	Cesamet
Nalorphine	9400	III	Y	Nalline
Nandrolone (17beta-hydroxyestr-4-en-3-one)	4000	III	N	Deca-Durabolin, Durabolin, Durabolin-50
Naphyrone	1258	I	N	naphthylpyrovalerone; 1-(naphthalen-2-yl)-2-(pyrrolidin-1-yl)pentan-1-one) (Positional Isomer: α-naphyrone)
N-Benzylpiperazine	7493	I	N	BZP, 1-benzylpiperazine
N-Ethyl-1-phenylcyclohexylamine	7455	I	N	PCE
N-Ethyl-3-piperidyl benzilate	7482	I	N	JB 323
N-Ethylamphetamine	1475	I	N	NEA
N-Hydroxy-3,4-methylenedioxyamphetamine	7402	I	N	N-hydroxy MDA
Nicocodeine	9309	I	Y	
Nicomorphine	9312	I	Y	Vilan
Nimetazepam	2837	IV	N	Erimin
Nitrazepam	2834	IV	N	Mogadon
N-Methyl-3-piperidyl benzilate	7484	I	N	JB 336
Noracymethadol	9633	I	Y	
Norbolethone (13beta,17alpha-diethyl-17beta-hydroxygon-4-en-3-one)	4000	III	N	Genabol
Norclostebol (4-chloro-17beta-hydroxyestr-4-en-3-one)	4000	III	N	Anabol-4-19, Lentabol
Nordiazepam	2838	IV	N	Nordazepam, Demadar, Madar

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SUBSTANCE	DEA NUMBER	CSA SCH	NARC	OTHER NAMES
Norethandrolone (17alpha-ethyl-17beta-hydroxyestr-4-en-3-one)	4000	III	N	Nilevar, Pronabol, Solevar
Norlevorphanol	9634	I	Y	
Normethadone	9635	I	Y	Phenyldimazone
Normethandrolone (17alpha-methyl-17beta-hydroxyestr-4-en-3-one)	4000	III	N	Lutenin, Matronal, Orgasteron
Normorphine	9313	I	Y	
Norpipanone	9636	I	Y	
Ocfentanil	9838	I	Y	N-(2-fluorophenyl)-2-methoxy-N-(1-phenethylpiperidin-4-yl)acetamide
Opium combination product 25 mg/du	9809	III	Y	Paregoric, other combination products
Opium extracts	9610	II	Y	
Opium fluid extract	9620	II	Y	
Opium poppy	9650	II	Y	Papaver somniferum
Opium preparations - 100 mg/(100 ml or 100 gm)		V	Y	Parepectolin, Kapectolin PG, Kaolin Pectin P.G.
Opium tincture	9630	II	Y	Laudanum
Opium, granulated	9640	II	Y	Granulated opium
Opium, powdered	9639	II	Y	Powdered opium
Opium, raw	9600	II	Y	Raw opium, gum opium
Oripavine	9330	II	Y	
Oxandrolone (17alpha-methyl-17beta-hydroxy-2-oxa-5alpha-androstan-3-one)	4000	III	N	Anavar, Lonavar, Oxandrin, Provitar, Vasorome
Oxazepam	2835	IV	N	Serax, Serenid-D
Oxazolam	2839	IV	N	Serenal, Converal
Oxycodone	9143	II	Y	OxyContin, Percocet, Endocet, Roxicodone, Roxicet,
Oxymesterone (17alpha-methyl-4,17beta-dihydroxyandrost-4-en-3-one)	4000	III	N	Anamidol, Balnimax, Oranabol, Oranabol 10
Oxymetholone (17alpha-methyl-2-hydroxymethylene-17beta-hydroxy-5alpha-androstan-3-one)	4000	III	N	Anadrol-50, Adroyd, Anapolon, Anasteron, Pardroyd
Oxymorphone	9652	II	Y	Numorphan
Para-chloroisobutyl fentanyl	9826	I	Y	N-(4-chlorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide
Para-fluorobutyl fentanyl	9823	I	Y	N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)butyramide
Para-Fluorofentanyl	9812	I	Y	China White, fentanyl
Parahexyl	7374	I	N	Synhexyl,
Paraldehyde	2585	IV	N	Paral
Para-methoxybutyl fentanyl	9837	I	Y	N-(4-methoxyphenyl)-N-(1-phenethylpiperidin-4-yl)butyramide
PB-22 (Quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate)	7222	I	N	QUPIC; PB-22
Pemoline	1530	IV	N	Cylert

Abbreviations: "NARC"= Narcotic, "CSA SCH"= CSA Schedule

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SUBSTANCE	DEA NUMBER	CSA SCH	NARC	OTHER NAMES
Pentazocine	9709	IV	N	Talwin, Talwin NX, Talacen, Talwin Compound
Pentedrone (α-methylaminovalerophenone)	1246	I	N	2-(methylamino)-1-phenylpentan-1-one)(Positional Isomers:3-methylethcathinone (3-MEC), 4-ethylmethcathinone (4-EMC), 4-methylbuphedrone (4-MeMABP;4-MeBP), 3,4-dimethylmethcathinone (3,4-DMMC),N-ethylbuphedrone (NEB),N-ethyl-N-methylcathinone(EMC))
Pentobarbital	2270	II	N	Nembutal
Pentobarbital & noncontrolled active ingred.	2271	III	N	FP-3
Pentobarbital suppository dosage form	2271	III	N	WANS
Pentylone	7542	I	N	bk-MBDP; 1-(1,3-benzodioxol-5-yl)-2-(methylamino)pentan-1-one) (Positional Isomers: dibutylone (bk-DMBDB) and propylone (3',4'-methylenedioxy-N-propylaminocathinone, 1-(benzo[d][1,3]dioxol-5-yl)-2-(propylamino)propan-1-one))
Perampanel	2261	III	N	Fycompa, [2-(2-oxo-1-phenyl-5-pyridin-2-yl-1,2-dihydropyridin-3-yl) benzonitrile]
Petrichloral	2591	IV	N	Pentaerythritol chloral, Periclor
Peyote	7415	I	N	Cactus which contains mescaline
Phenadoxone	9637	I	Y	
Phenampromide	9638	I	Y	
Phenazocine	9715	II	Y	Narphen, Prinadol
Phencyclidine	7471	II	N	PCP, Sernylan
Phendimetrazine	1615	III	N	Plegine, Prelu-2, Bontril, Melfiat, Statobex
Phenmetrazine	1631	II	N	Preludin
Phenobarbital	2285	IV	N	Luminal, Bellergal-S
Phenomorphan	9647	I	Y	
Phenoperidine	9641	I	Y	Operidine, Lealgin
Phentermine	1640	IV	N	Ionamin, Fastin, Adipex-P, Obe-Nix, Zantryl
Phenylacetone	8501	II	N	P2P, phenyl-2-propanone, benzyl methyl ketone
Pholcodine	9314	I	Y	Copholco, Adaphol, Codisol, Lantuss, Pholcolin
Piminodine	9730	II	Y	
Pinazepam	2883	IV	N	Domar
Pipradrol	1750	IV	N	Detaril, Stimolag Fortis
Piritramide	9642	I	Y	Piridolan
Poppy Straw	9650	II	Y	Opium poppy capsules, poppy heads
Poppy Straw Concentrate	9670	II	Y	Concentrate of Poppy Straw, CPS
Prazepam	2764	IV	N	Centrax
Pregabalin	2782	V	N	Lyrica
Proheptazine	9643	I	Y	

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SUBSTANCE	DEA NUMBER	CSA SCH	NARC	OTHER NAMES
Propiridine	9644	I	Y	
Propiram	9649	I	Y	Algeril
Prostanazol (17beta-hydroxy-5alpha-androstano[3,2-c]pyrazole)	4000	III	N	Prostanazol; [3,2-c]pyrazole-5α-androstan-17β-ol
Psilocybin	7437	I	N	Constituent of "Magic mushrooms"
Psilocyn	7438	I	N	Psilocin, constituent of "Magic mushrooms"
Pyrovalerone	1485	V	N	Centroton, Thymergix
Quazepam	2881	IV	N	Doral
Racemethorphan	9732	II	Y	
Racemoramide	9645	I	Y	
Racemorphan	9733	II	Y	Dromoran
Remifentanil	9739	II	Y	Ultiva
Secobarbital	2315	II	N	Seconal, Tuinal
Secobarbital & noncontrolled active ingred	2316	III	N	
Secobarbital suppository dosage form	2316	III	N	
Sibutramine	1675	IV	N	Meridia
SPA	1635	IV	N	1-dimethylamino-1,2-diphenylethane, Lefetamine
SR-18 (Also known as RCS-8) (1-Cyclohexylethyl-3-(2-methoxyphenylacetyl) indole)	7008	I	N	SR-18 and RCS-8
SR-19 (Also known as RCS-4) (1-Pentyl-3-[(4-methoxy)-benzoyl] indole)	7104	I	N	SR-19 and RCS-4
Stanozolol (17alpha-methyl-17beta-hydroxy-5alpha-androst-2-eno[3,2-c]-pyrazole)	4000	III	N	Winstrol, Winstrol-V
Stenbolone (17beta-hydroxy-2-methyl--5alpha-androst-1-en-3-one)	4000	III	N	
Stimulant compounds previously excepted	1405	III	N	Mediatric
Sufentanil	9740	II	Y	Sufenta
Sulfondiethylmethane	2600	III	N	
Sulfonethylmethane	2605	III	N	
Sulfonmethane	2610	III	N	
Suvorexant	2223	IV	N	MK-4305, [(7R)-4-(5-chloro-1,3-benzoxazol-2-yl)-7-methyl-1,4-diazepan-1-yl][5-methyl-2-(2H-1,2,3-triazol-2-yl)phenyl]methanone
Talbutal	2100	III	N	Lotusate
Tapentadol	9780	II	Y	
Temazepam	2925	IV	N	Restoril
Testolactone (13-hydroxy-3-oxo-13,17-secoandrost-1,4-dien-17-oic acid lactone)	4000	III	N	Teolit, Teslac
Testosterone (17beta-hydroxyandrost-4-en-3-one)	4000	III	N	Android-T, Androlan, Depotest, Delatestryl
Tetrahydrocannabinols	7370	I	N	THC, Delta-8 THC, Delta-9 THC, dronabinol and others

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SUBSTANCE	DEA NUMBER	CSA SCH	NARC	OTHER NAMES
Tetrahydrogestrinone (13beta,17alpha-diethyl-17beta-hydroxygon-4,9,11-trien-3-one)	4000	III	N	THG
Tetrazepam	2886	IV	N	Myolastan, Musaril
Thebacon	9315	I	Y	Acetylhydrocodone, Acedicon, Thebacetyl
Thebaine	9333	II	Y	Precursor of many narcotics
Thiafentanil	9729	II	Y	Thianil
Thiamylal	2100	III	N	Surital
Thiofentanyl	9835	I	Y	Chine white, fentanyl
Thiopental	2100	III	N	Pentothal
THJ-2201 [1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone	7024	I	N	THJ-2201
Tiletamine & Zolazepam Combination Product	7295	III	N	Telazol
Tilidine	9750	I	Y	Tilidate, Valoron, Kitadol, Lak, Tilsa
Tramadol (2-[(dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexanol)	9752	IV	Y	Tramadol
Trenbolone (17beta-hydroxyestr-4,9,11-trien-3-one)	4000	III	N	Finaplix-S, Finajet, Parabolan
Triazolam	2887	IV	N	Halcion
Trimeperidine	9646	I	Y	Promedolum
U-47700 (3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methylbenzamide)	9547	I	Y	U-47700
UR-144 (1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone	7144	I	N	UR-144
Valeryl fentanyl	9840	I	Y	N-(1-phenethylpiperidin-4-yl)-N-phenylpentanamide
Vinbarbital	2100	III	N	Delvinal, vinbarbitone
Zaleplon	2781	IV	N	Sonata
Zolpidem	2783	IV	N	Ambien, Ivadal, Stilnoct, Stilnox
Zopiclone	2784	IV	N	Lunesta

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**OREGON BOARD OF PHARMACY
PER DIEM & EXPENSE REIMBURSEMENT POLICY**

PER DIEM AND EXPENSES

The following Oregon Statutes (ORS) guide the Board's policy for Per Diem compensation and reimbursement for expenses - ORS 292.210 - 292.250, 292.495, 689.115(4), 689.175(1), ORS, 689.645, 2017 OL Ch. 106:

292.495 Compensation and expenses of members of state boards and commissions. (1) Subject to the availability of funds therefor in the budget of the state board or commission, and except as otherwise provided by law, *any member of a state board or commission, other than a member who is employed in full-time public service*, who is authorized by law to receive compensation for time spent in performance of official duties, *shall receive a payment of \$30 for each day or portion thereof during which the member is actually engaged in the performance of official duties.*

(2) Except as otherwise provided by law, *all members of state boards and commissions, including those employed in full-time public service, may receive actual and necessary travel or other expenses actually incurred in the performance of their official duties within the limits provided by law or by the Oregon Department of Administrative Services under ORS 292.210 to 292.250.*

(3) As used in subsection (2) of this section, "other expenses" includes expenses incurred by a member of a state board or commission in employing a substitute to perform duties, including personal, normally performed by the member which the member is unable to perform because of the performance of official duties and which by the nature of such duties cannot be delayed without risk to health or safety. No member shall be reimbursed for expenses incurred in employing a substitute in excess of \$25 per day. [1969 c.314 §1; 1973 c.224 §2; 1975 c.441 §1; 1979 c.616 §1]

689.115(4) OBOP Compensation

(4) Members of the board are entitled to compensation and expenses as provided in ORS 292.495. *The board may provide by rule for compensation to board members for the performance of official duties at a rate that is greater than the rate provided in ORS 292.495.* [1979 c.777 §§7,8,9,11; 1987 c.108 §2; 2009 c.535 §29]

689.175 Compensation of board members (1) Each member of the State Board of Pharmacy shall receive compensation for each day on which the member is engaged in performance of the official duties of the board, and reimbursement for all expenses incurred in connection with the discharge of such official duties as provided in ORS 292.495.

2017 OL Ch. 106 – Public Health and Pharmacy Formulary Advisory Committee

(5) Members of the committee are entitled to compensation and expenses as provided in ORS 292.495, to be paid by the State Board of Pharmacy.

COMPENSATION

Board members and Public Health and Pharmacy Formulary Advisory Committee appointees authorized by ORS 292.495(1) may choose if eligible, to receive up to \$100 daily allowable per diem adopted under OAR 855-010-0020 when attending a Board of Pharmacy Board or Public Health and Pharmacy Formulary Advisory Committee meeting that lasts a minimum of three hours. Travel time and preparation time for meetings will not be compensated other than when there is an allowable expense reimbursement.

For the purpose of compensation, a board member or Public Health and Pharmacy Formulary Advisory Committee appointee is considered engaged in the performance of official duties when:

- ❖ The activity furthers the Board's mission; and
- ❖ Attending a board meeting; or
- ❖ Attending a Public Health & Pharmacy Formulary Advisory Committee meeting; or
- ❖ Engaged in an activity which is either at the request of the board chair or authorized by a vote of the board in advance of the activity.
- ❖ All per diem shall be calculated as whichever amount is the greater of :
 - a) \$50 after a minimum of three hours of service daily; or
 - b) \$100 after a minimum of six hours of service.

Note -1 : 292.495(1) does not allow a member who is employed in full-time public service to receive compensation.

*Note -2 : The Board **has** elected to adopt a rule as 689.115(4) allows to be compensated at a rate that is greater than the \$30 listed in ORS 292.495.*

Board/Committee members will report meetings and activities to staff and they will process per diem assignments monthly. In the interest of efficiency and cost savings, all members have been asked to set up *direct deposit* for per diem.

EXPENSE REIMBURSEMENT

Expenses incurred in the course of a Board/Committee Member's official duties will be reimbursed pursuant to ORS 292.210-292.250 and the Department of Administrative Services Fiscal Policies and Procedures identified in the Oregon Accounting Manual (OAM).

Reimbursements typically include mileage and hotel/meal reimbursement for individuals that have to travel to the Board office for Board/Committee meetings and require an overnight stay or anytime a member is required to travel to an out of state meeting to represent the Board.

Reimbursements are calculated based on the OAM allowable or actual and necessary if receipts are submitted.

Board/Committee Members are asked to submit reimbursement requests in a timely manner. Staff prepares the paperwork for signature and sends it to member's following each meeting or official activity. All members have been asked to set up direct deposit for reimbursements to reduce the overall cost to the agency.

Appendix A

Best Practices Self-Assessment Guidance

Annually, board members are to self-evaluate their adherence to a set of best practices and report the percent of total best practices met by the board (percent of yes responses in the table below) in the *Annual Performance Progress Report* as specified in the agency Budget Instructions.

Recommended Assessment Process

1. Select a neutral party to facilitate the self-evaluation (recommended, not required).
2. Individual board members complete the score card shown below.
3. Tabulate the results for all board members (can be done by neutral party in advance).
4. Discuss the results—particularly the results for those areas where there are disparate responses or where the group agrees that they are not adhering to a best practice.
5. Record the group's joint response to each best practice on a new score card. If consensus is not achieved, the board or commission should record the response as "no."

Best Practices Assessment Score Card

Best Practices Criteria	Yes	No
1. Executive Director's performance expectations are current.		
2. Executive Director's receives annual performance feedback.		
3. The agency's mission and high-level goals are current and applicable.		
4. The board reviews the <i>Annual Performance Progress Report</i> .		
5. The board is appropriately involved in review of agency's key communications.		
6. The board is appropriately involved in policy-making activities.		
7. The agency's policy option packages are aligned with their mission and goals.		
8. The board reviews all proposed budgets.		
9. The board periodically reviews key financial information and audit findings.		
10. The board is appropriately accounting for resources.		
11. The agency adheres to accounting rules and other relevant financial controls.		
12. Board members act in accordance with their roles as public representatives.		
13. The board coordinates with others where responsibilities and interests overlap.		
14. The board members identify and attend appropriate training sessions.		
15. The board reviews its management practices to ensure best practices are utilized.		
16. Others [The board may add additional best practices; however, they are not to be counted when calculating the percentage adherence to best practices.]		
Total Number		
Percentage of Total		

Analyzing Assessment Results and Defining Next Steps

Once the above table has been completed, the board will want to prepare responses to the following questions. Responses should be integrated into the *Annual Performance Progress Report*, which is due from agencies on September 30th of each year.

- How are we doing?
- How do we compare to others and/or to our target? (Once this data is available.)
- What factors are affecting our results?
- What needs to be done to improve future performance?

Oregon Board of Pharmacy Rules Prioritization Plan

RULE	DESCRIPTION	BOARD MEMBER PRIORITIZATION
HB 2397 Public Health and Pharmacist Formulary Advisory Committee	CURRENTLY IN DEVELOPMENT-Describes the formulary advisory committee, pharmacist prescribing requirements, and the formulary of drugs and devices ☐ Rx Extension ☐ Devices ☐ Cough/Cold	1
Compounding	CURRENTLY IN DEVELOPMENT - Updates the compounding rules to reflect the federal requirements	2
OR licensed supervisor/PIC Empowerment	CURRENTLY IN DEVELOPMENT - Clarifies the boards expectations for PIC responsibilities and the licensure of supervisors directing PICs	3
Use of Technology for Drug Distribution, Drug Dispensing and Drug Delivery	Defines the licensure, minimum security requirements, minimum standards of practice, and minimum delivery requirements for technology assisted practice of pharmacy / Counseling and other professional expectations in all pharmacies	5
Pharmacy Technician	Define the duties a supervising pharmacist may delegate to a pharmacy technician to perform	4
Long Term Care	Describes the boards expectations for long term care facilities	7

Based on averaged numbers –Board Priorities for discussion @ 6/2018 meeting.

2019 Budget Fee Update	Karen/Marc; Must be effective 7/1/2019	9
Controlled Substance Inventory and Reconciliation Expectations	Re-define and clarify the expectations; perpetual inventory, etc.	6
Drug Donation	Specifies when an Oregon charitable pharmacy may accept certain (non-previously dispensed) out-of-state prescription donations	15
Drug Room	Re-categorization for this “catch-all” category	13
Biosimilar Definitions	Update definitions from new statute change	12
Immediate Inspections	Allows for the board to charge a fee for accommodating the need for an immediate inspection	9
Consulting Pharmacist Records	Consultant pharmacist must own his/her own records	11
Non-resident drug outlet reporting of discipline within 30 days	Compliance need	10
Medical Devices/Class C	Federal law updates	14
Paperless Renewals	Remove post-card notifications	16
OTHERS??		

Based on averaged numbers –Board Priorities for discussion @ 6/2018 meeting.

ANNUAL BOARD & OTHER PHARMACIST APPOINTMENT REPORT

Please provide the Board with a description of your involvement related to the Board, Commission or Committee to which to serve as a Pharmacist appointee.

Submit your response by: **May 11, 2018** to Karen.S.MacLean@oregon.gov

Last Name: Gustafson

First Name: Natalie

Date: 5/4/18

Email: natalie@lcrx.com

Work Phone: 503-281-4161

List the board, committee or commission to which you are appointed:

Oregon Board of Naturopathic Medicine Formulary Council

Please provide a brief summary of your activities from the last year within your appointment. Be sure to include your term and meeting frequency.

I have been on the OBNM Formulary Council since August 2011, with my current term ending Jun 2019. We meet every six months, typically in March and September or early October.

In the last two years the main project we have worked on has been simplifying the formularies to reduce confusion and clarifying prescribing for naturopathic physicians. Through our work and analysis, we helped determine that the two old formularies, an itemized list 850-060-225 and a more updated list by drug class 850-060-226 were no longer necessary. Based on our suggestions, this work helped create the new rule 850-60-223, which is much more streamlined and clear.

Another issue that came up in the last year was ketamine prescribing and if there were restrictions for naturopathic physicians. This discussion led to research on classifications and if route, such as intravenous use, would be a factor.

We continued to discuss physician dispensing and the change in rules 855-043-0505. Also, we discussed the change in CE requirements for naturopathic physicians and met with a representative from Oregon Prescription Drug Monitoring Program.

These draft rules implement the [2017 HB 2397](#) signed by Governor Kate Brown on May 18, 2017. The multi-disciplinary Public Health and Pharmacy Formulary Advisory Committee will make recommendations for the Board to adopt by rule of protocols, drugs, and devices fitting for pharmacists to prescribe.

These rules establish a pharmacist’s authority to prescribe drugs and devices, and via protocols recommended by the committee adopted by the Board’s formulary. These rules create the formulary and protocol compendia, per recommendations of the committee.

These rules describe the Board’s compliance expectations for prescribing from the formulary. Standards defined include (1) education and competency, (2) patient assessment, and determination of inclusion, exclusion and referral criteria (3) collaboration with other healthcare providers, including mandated notification (4) treatment and follow-up care planning, (5) record-keeping, and (6) prohibited practices.

Sources include: [The Joint Commission of Pharmacy Practitioner Pharmacists’ Patient Care Process](#)

DIVISION 20

Pharmacist Prescriptive Authority

855-020-0110 Prescribing Scope of Practice

(1) A pharmacist located and licensed in Oregon acting in good faith and exercising reasonable care may prescribe and dispense FDA-approved drugs and devices included on the formulary and protocol compendia, set forth in this Division.

Note: Using “FDA-approved” here means that some items will be excluded, including compounded drugs, vitamins and supplements

(2) A pharmacist shall only prescribe a drug or device within the pharmacist’s scope of practice, and in accordance with federal and state regulations.

(3) At a minimum for each drug or device the pharmacist prescribes, the pharmacist must create, approve, and maintain a procedure / protocol to include related rule requirements and based on current clinical guidelines that must include:

(a) Patient inclusion and exclusion criteria; and

(b) Explicit medical referral criteria.

(4) At the time of prescribing, the pharmacist shall collect subjective and objective information about the patient’s health history and clinical status, including diagnosis, when applicable. The patient assessment shall be performed in a face-to-face in-person interaction and not through electronic means.

(5) The pharmacist shall assess, develop and implement appropriate treatment goals, monitoring parameters, and follow-up care plan, in accordance with clinical guidelines. This visit summary shall be provided to the patient.

(6) The pharmacist shall provide notification of prescriptive activity, preferably via an interoperable information technology system, to the patient’s identified primary care provider or other care providers when applicable, within five business days following the prescribing of a formulary drug or device.

(7) The pharmacist is responsible for recognizing limits of knowledge and experience and for resolving situations beyond his or her pharmacist expertise by consulting with or referring patients to another health care provider.

(8) The pharmacist shall maintain all records associated with prescribing for a minimum of X years, including but not limited to the patient assessment protocol, documentation of the prescription record, consultation, and visit summary and a copy must be made available to the patient, provider, and Board upon request.

For Board considerations:

How long will these records need to be kept?

- *Shall they attempt to match other health care providers?*
- *Traditional prescription records is 3 years, contraceptive prescribing records is 5 years (due to the 3 year limitation for prescribing without practitioner follow-up), and other medical/billing records may be up to and beyond 10 years*
- *Records associated with these regulations contemplate the acts of both prescribing and dispensing occurring in a single interaction and location*
- *Does there need to be a secondary rule in Div 041 for outlet records responsibilities?*

Is there a need to address, in rule, the “shared responsibilities” between a pharmacist and the outlet in which they practice pharmacy?

-For example, meaning that for investigatory work, the Board needs a pharmacist to have explicit access to each of their prescribing record/notes (aka they have to be able to “own” their records) but the records shall be stored at the outlet.

Stat. Auth.: ORS 689.205

Stat. Implemented: 689.645, 689.649

855-020-0120 Prohibited Prescribing Practices

The responsibility and authority to prescribe pursuant to the Formulary Compendia is upon the pharmacist. Only a pharmacist practices pharmacy as defined in ORS 689.005.

(1) A pharmacist shall not prescribe a drug or device contrary to the standard of care.

(2) A pharmacist shall not prescribe a drug or device to self or immediate family members.

(3) A pharmacist shall not prescribe a drug or device solely via electronic means, which includes but is not limited to online survey, conference call, or forms of real-time audio-video conferencing.

Considerations to add, related to conflict of interest:

- *A pharmacist may not prescribe a drug or device solely for personal financial gain*
- *Circumstances where there is a conflict of financial (or other type of interest)*

Stat. Auth.: ORS 689.205

Stat. Implemented: 689.645, 689.649

OAR 855-020-0200 Formulary Compendium

A pharmacist may prescribe, according to regulations outlined in this Division, an FDA-approved drug and device listed in this compendium, pursuant to a documented diagnosis by a health care practitioner who has prescriptive authority and who is qualified to make the diagnosis.

(1) Devices

(a) Diabetic blood sugar testing supplies;

(b) Pen needles;

(c) Syringes;

(d) Nebulizers and associated supplies;

(e) Inhalation spacers;

(f) Peak flow meters;

(g) International Normalized Ratio (INR) testing supplies;

(h) Enteral nutrition supplies; and

(i) Ostomy products and supplies.

(2) Medications *(placeholder for adding drugs that may come as the committee continues to meet)*

Stat. Auth.: ORS 689.205, 689.649

Stat. Implemented: 689.645, 689.649

OAR 855-020-0300 Protocol Compendium

A pharmacist may prescribe, via protocol and according to regulations outlined in this Division, an FDA-approved drug and device listed in this compendium,

(1) Continuation of therapy

(a) A pharmacist may prescribe any non-controlled medication to extend a patient's prescription therapy to avoid the interruption of the treatment; and

(b) In such cases, a pharmacist shall only prescribe a drug quantity sufficient for the circumstances, not to exceed a sixty (60) day supply, and no more than two extensions in a twelve (12) month period per medication.

(2) Conditions

(a) Cough and cold symptom management

(A) Pseudoephedrine products for patients 18 years of age and older, verified by positive identification, not to exceed 3.6 grams or a sixty (60) count quantity per prescription, whichever is less, or a total of three prescriptions in a twelve (12) month period. Pharmacist must review PDMP prior to issuing prescription and retain documentation of PDMP review;

(B) Benzonatate, for the treatment of cough, not to exceed a seven (7) day supply;

(C) Short-acting beta agonists, not to exceed one metered-dose inhaler or one box of nebulizer ampules, per year;

(D) Intranasal corticosteroids.

Stat. Auth.: ORS 689.205, 689.649

Stat. Implemented: 689.645, 689.649

Visit Summary

Collect Patients Name: _____ DOB: _____

Chief Complaint	Subjective Data ☐ On Back	Objective Data ☐ On Back	History of Present Illness ☐ On Back
	☐ Allergies ☐ Past Medical History ☐ Social History		
	Medications	Post-diagnostic? ☐ No ☐ Yes	
	<u>Adherence</u> ☐ Past 90 day use <u>Safety</u> ☐ Relevant Medications	Diagnosis: _____ ☐ Therapy Initiation ☐ Extension of Therapy ☐ Device ☐ Other	

Assessment

<u>Per Protocol</u> ☐ Attached ☐ Inclusion Criteria Met ☐ Exclusion Criteria Met ☐ Referral Criteria Met	

Resource(s) Used

(e.g. Protocol, Guideline(s), Other Evidence Based Source, etc.)

Treatment Care Plan

☐ Treatment Goals ☐ Monitoring Parameters	For _____ Address _____ Date _____ Rx # _____ Refills _____ RPh Signature _____ NPI/DEA # _____ Address _____
OR ☐ Referral Reason	

Follow-up:

☐ Office/Pharmacy Visit **OR** ☐ Phone Call With: _____ Date: _____
☐ Provider Referral: _____
☐ Notification Sent

Prescribing RPh Printed Name RPh Signature Date

Subjective Data

Objective Data

History of Present Illness

Assessment

Care Plan