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| **Agenda**<br>**Public Meeting** | **Oregon Board of Pharmacy – Workgroup**<br>**Collaborative Drug Therapy Management/**<br>**Clinical Pharmacy Agreements**<br>**May 4, 2023 1:00pm**<br><br>The workgroup will meet virtually.<br><br>**Public Attendance Options:**<br>**Virtually via Teams: Link**<br>**Audio Only: 503-446-4951 Phone Conference ID:824 009 989#**<br><br>*To sign up for Public Comment, email your request to pharmacy.rac@bop.oregon.gov by **12:00PM on 5/4/2023**.*<br><br>*If you need accommodations under the Americans with Disabilities Act (ADA), complete and submit the online OBOP Request for ADA Accommodations for Public Meetings form located on our website.* |

| Agenda Item | Content |
|---|---|
| Welcome | ❖ Roll Call and Introductions<br>❖ Workgroup Members<br>➢ Robert Davis – Public Member<br>➢ Tabitha Fridriksson, RPH, Director, Pharmacy Quality & Medication Safety – Kaiser Permanente<br>➢ Andrew Hibbard, RPH, Ambulatory Care Clinical Coordinator – CareOregon (Appointed by OSPA)<br>➢ Adriane Irwin, RPH, Associate Professor – OSU College of Pharmacy<br>➢ Michele Koder, RPH, Pharmacy Director – Multnomah County Health Department – Community Health Center<br>➢ Edward Saito, RPH, Clinical Pharmacist – Virginia Garcia Memorial Health Center<br>➢ Adam Saulles, RPH, Senior Clinical Manager– Providence/Credena Health<br>➢ Colleen Shipman, RPH, Inpatient Adult Clinical Director, Pharmacy Services –OHSU (Appointed by OSHP)<br>➢ Andrew Sowles, RPH, Manager Ambulatory Care Clinical Pharmacy Services – Salem Health Hospitals & Clinics<br>➢ Rachael DeBarmore, RPH, Board Member<br>➢ Shannon Beaman, RPH, Board Member |
| Committee Business | ❖ Workgroup - Purpose and Responsibilities<br>❖ Anticipated Rules Timeline<br>❖ Statutory Review<br>❖ Review of Proposed Rules<br>➢ Proposed Draft Rule Review Division 006/115 |

| | |
|---|---|
| | ❖ Committee Member Discussion |
| | ❖ Public Comment (if applicable) |
| Good of the Order | ❖ Closing Remarks |

Resources:

- Rulemaking Hearing Comments – December 14-16, 2022 Board Meeting mailing #A – (pg. 5-226)
- Board meeting minutes related to discussion of CDTM/CPA rules – Divisions 019/020/031/041/115 – Pharmacists
  - October 2022 Bd Mtg Minutes (pg. 15-16)
  - December 2022 Bd Mtg Minutes (pg. 16-17)
  - February 2023 Bd Mtg Minutes (pg.5)

*The Oregon Board of Pharmacy serves to promote and protect public health, safety, and welfare by ensuring high standards in the practice of pharmacy and through effective regulation of the manufacture and distribution of drugs.*

# Collaborative Drug Therapy Management / Clinical Pharmacy Agreements

OREGON BOARD OF PHARMACY

WORKGROUP– MAY 4, 2023

# OBOP MISSION

- *The Oregon Board of Pharmacy serves to promote and protect public health, safety and welfare by ensuring high standards in the practice of pharmacy and through effective regulation of the manufacture and distribution of drugs.*

# Roll Call

- Intern Workgroup Participants
  - Robert Davis
  - Tabitha Fridriksson, RPH
  - Andrew Hibbard, RPH
  - Adriane Irwin, RPH
  - Michele Koder, RPH
  - Edward Saito, RPH
  - Adam Saulles, RPH
  - Colleen Shipman, RPH
  - Andrew Sowles, RPH
- Board Members Present
  - Shannon Beaman, RPH
  - Rachael DeBarmore, RPH
- Staff Members Present
  - Jennifer Davis, Pharmacist Consultant
  - Rachel Melvin, Operations Policy Analyst
  - Joseph Schnabel, Executive Director
  - Joanna Tucker Davis, Assistant Attorney General

# Reminders

- Please be aware that any investigatory information is confidential and should not be discussed in a public meeting.

- When using examples, it is suggested that you phrase as the examples as hypothetical.

# Workgroups

- *What is a Workgroup?*
  - A Workgroup may be established and used for to collect information on a specific topic and provide advice on rules in which there are issues that may substantially impact the interests of persons or entities (“stakeholders”), who will likely be affected by the proposed rulemaking.
- *What is the purpose of a Workgroup?*
  - Involve the public in the development of public policy
  - Estimate financial and racial equity impact on interested persons/entities
  - Members must represent the communities of persons likely to be affected by the rule

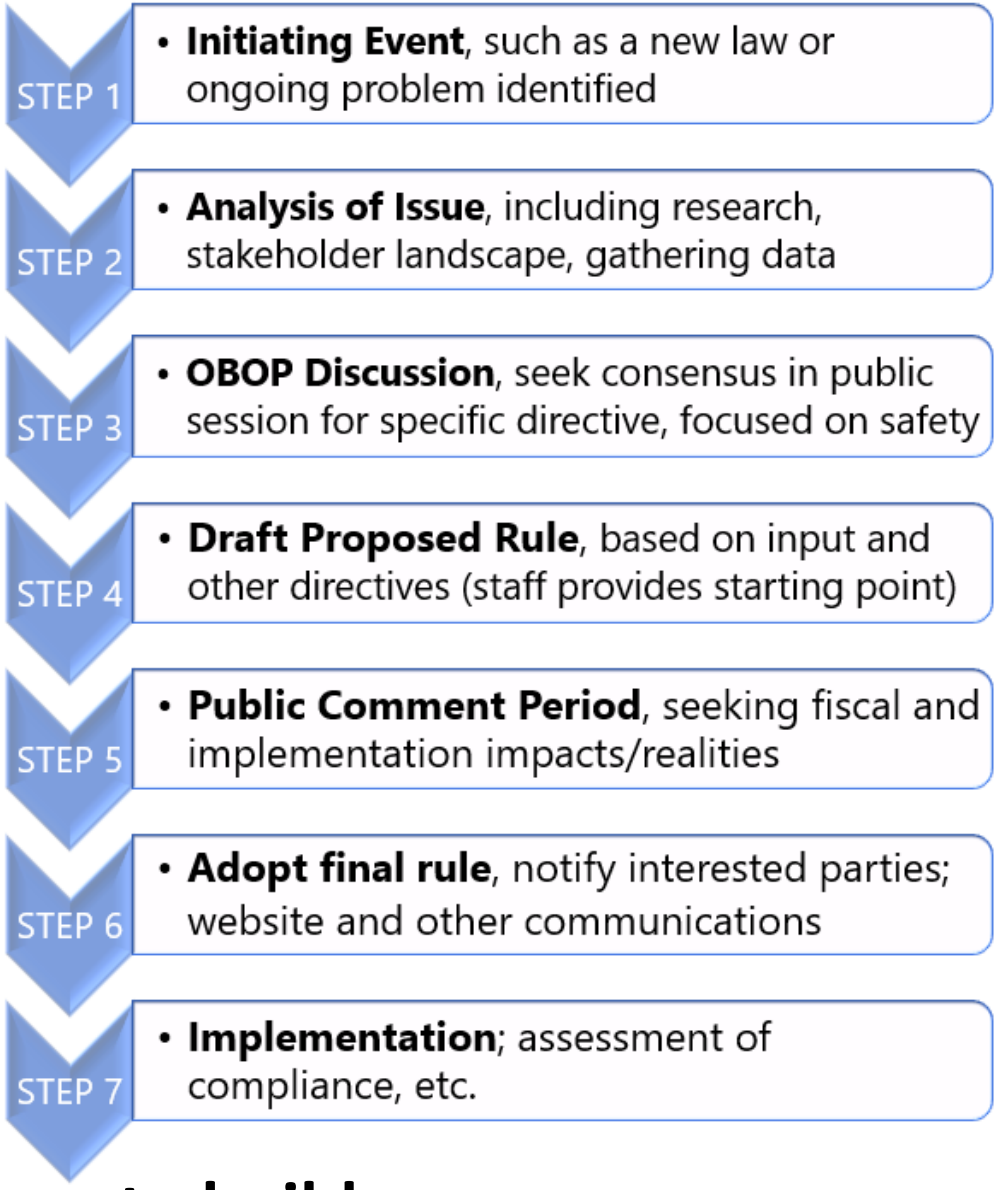
*A Workgroup’s role is advisory only.*

# Rules

- What is a rule?
  - Any agency directive, standard, regulation or statement
  - Of general applicability
  - That implements, interprets or prescribes law or policy, or
  - That describes the procedure or practice requirements of any agency.
- When is a rule required?
  - When required by / written into statute
  - Agency interpretation of broad statutory authority
  - To amend, suspend, or repeal existing rule
- Where are rules found?
  - Oregon Administrative Rules (OAR)-official compilation of rules & regulations having the force of law in Oregon

# Rulemaking Process

- Workgroup provides advice to agency
- Agency drafts rules
- Draft rules are filed with Secretary of State and notice given to interested parties
- Public may comment on rules before rules are enacted
- Agency considers public comment, discusses and determines final rules
- Rules are filed with Secretary of State




**Steps 3 & 4 are repeated as necessary to build consensus**

# Division Vision- DRAFT

| | |
|---|---|
| 100 | Definitions |
| **102** | **Procedural** |
| **104** | **Board Policies** |
| *110* | *Fees* |
| 112 | Public Health Emergency |
| **115** | **Pharmacist** |
| **120** | **Intern** |
| **125** | **COPT/PT** |
| 130 | HPSP |
| *135* | *CE *Eff. 7/1/2023* |

| | |
|---|---|
| **136** | **DO Pharmacy (RP)** |
| *139* | *DO Remote Dispensing Site Pharmacy (RP)* |
| *141* | *DO Kiosk (RP) *Eff. 2/15/2023* |
| *143* | *DO Locker (RP)* |
| 144 | DO Charitable Pharmacy (RP) |
| **156** | **DO Pharmacy (IP)** |
| 159 | DO Drug Room (IP) |
| 161 | DO RDF/RDM (IP) |
| 164 | DO Nuclear (IP) |
| 167 | DO LTC/Residential (IP) |
| 170 | DO Home Infusion (IP) |
| 173 | DO Home Dialysis (IP) |
| 176 | DO Home Health Care (IP) |
| 177 | DO Correctional Facility (IP) |
| 180 | Controlled Substances |
| **183** | **Compounding** |

| | |
|---|---|
| 186 | DO Nonprescription |
| 189 | DO Prophylactic |
| 191 | DO Devices |
| 194 | DO Practitioner Dispensing (RP) |
| 197 | DO CHC's |
| 199 | DO Animal Euthanasia |
| **200** | **Facility- Manufacturer** |
| **203** | **Facility- Wholesaler** |
| **206** | **Facility- DDA** |

# Proposed Timeline- DRAFT

- June 2022-April 2023: Board staff draft proposed rules
- May 2023: Workgroup meeting
- May 2023- June 2023: Board staff ongoing revision of proposed rules
  - June 2023: Board review proposed rules
  - July 2023: Rulemaking
  - August 2023: Board adoption of proposed rules with effective date TBD

**Typical rules process can take 2-3 years**
**This timeline will be adjusted based on board priorities**

# Introductions

- Name
- License type
- Current practice setting
- Previous experience with CDTM/CPAs
- Why you wanted to serve on this workgroup

# Workgroup Training

May 4, 2023

Assistant Attorney General Joanna Tucker Davis

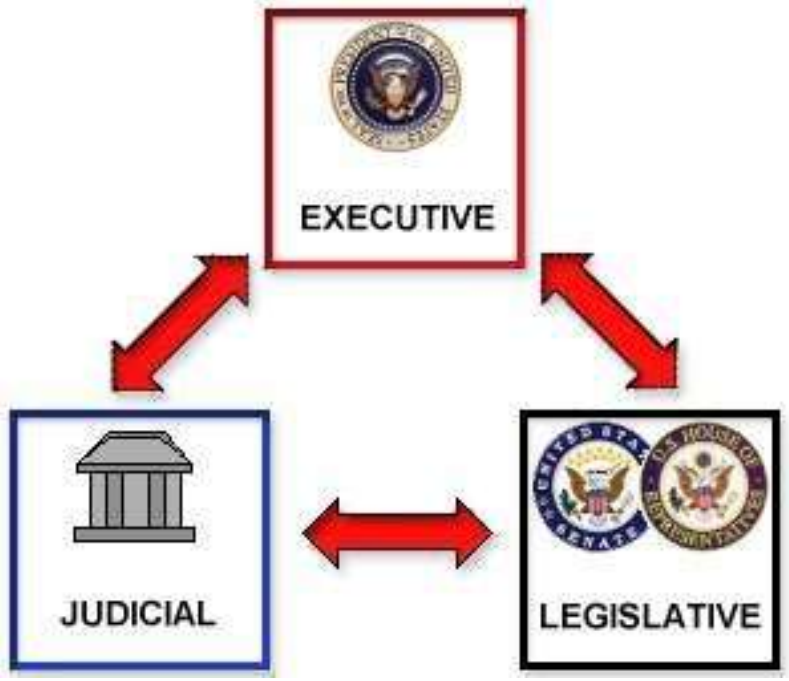
Board of Pharmacy

# Three Branches of Government

Legislature:
Makes the Laws

Executive Branch:
Carries out the
Laws

Judicial Branch:
Interprets the
Laws



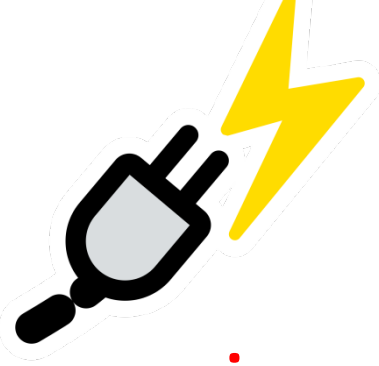
# What are statutes?

- Laws that are enacted (created) by the legislature.

# Agencies only have the powers given to them by statutes.

- A state agency "has no inherent power, but only such power and authority as has been conferred upon it by its organic legislation."
- *Ochoco Const., Inc. v. Department of Land Conservation and Development, 295 Or 422, 426, 667 P2d 499 (1983).*

# What are rules?



- Laws that are promulgated (created) by agencies.
- Agency's power to create rules is grounded in its governing statutes.

- An agency is a creature of statute. It has no inherent power, but only such power and authority as has been conferred upon it by its organic legislation. This power includes that expressly conferred by statute as well as such implied power as is necessary to carry out the power expressly granted. Stated somewhat differently, a statute which creates an administrative agency and invests it with its power is likewise the measure of its power.
- *Ochoco Construction, Inc. v. Department of Land Conservation and Development, 56 Or App 32, 40 (1982).*

# What is a rule?

- ORS 183.005(9): "Rule" means any agency directive, standard, regulation or statement of general applicability that implements, interprets or prescribes law or policy, or describes the procedure or practice requirements of any agency. ***

- Rules can:
  - Create prohibitions: tell person affected what the person should not do.
  - Create mandates: tell person affected what the person must do.
  - Interpret laws: tell person affected how agency views a statute so that person affected has clarity.
  - Create entitlements: give person legal right to something (like a license if application requirements are fulfilled).
  - Describe procedure or policy of agency: give person knowledge about how agency will act.
- RULES SHOULD GIVE PUBLIC AND LICENSEE CLEAR NOTICE OF WHAT IS MUST BE DONE (OR NOT DONE) UNDER THE RULE.

# A Vocabulary Detour

- ORS = Oregon Revised Statute

  “ORS 689.005”

- OAR = Oregon Administrative Rule

  “OAR 855-001-0000”

# Statute vs. Rule

- Oregon Revised Statutes (ORS)
  - Adopted by Oregon legislature and  signed by the Governor
  - ORS 689 and ORS 475
- Oregon Administrative Rules (OAR)
  - Adopted by Board of Pharmacy
  - OAR 855

*Statutes and Rules are both “laws”*

Photo by Jens Johnsson from Pexels

# AG Opinion
# 40 OR Op Atty Gen 474 (1980)

- Inasmuch as a ‘prescription’ need not, under the statute, take any particular form, the written or oral direction might be embodied in one or more written or oral statements. There is nothing, as we see it, to preclude two statements separated in time from being deemed to constitute a prescription. Thus, a ‘prescription’ might, for example, take the form of (1) a practitioner's advance written authorization to substitute one specific brand-name or generic drug for another which is later designated in a written order, plus (2) the later order itself. The two statements would effectively constitute the ‘prescription’ for the substituted drug. The statute would also allow contemporaneous authorizations, written or oral, for such substitutions, that is authorizations given on a case-by-case basis,. Assuming that the advance general authorization described above were provided, the later order could instead specifically disallow the substitution in the given case by the prescriber's specific direction to that effect.”

# Timeline

- 1980: AG opinion allowing for drug substitution if practitioner had issued advanced written directive allowing for the substitution.
- 1998: CDTM rule enacted.
- 2015, HB 2028 (2015) was passed, which added clinical pharmacy services to ORS chapter 689, and added “clinical pharmacy agreements” to the statutes.

# CPA and Practice of Clinical Pharmacy

ORS 689.005:

- (4)“Clinical pharmacy agreement” means an agreement between a pharmacist or pharmacy and a health care organization or a physician as defined in ORS 677.010 or a naturopathic physician as defined in ORS 685.010 that permits the pharmacist to engage in the practice of clinical pharmacy for the benefit of the patients of the health care organization, physician or naturopathic physician.

- (30) “Practice of clinical pharmacy” means:
  (a) The health science discipline in which, in conjunction with the patient’s other practitioners, a pharmacist provides patient care to optimize medication therapy and to promote disease prevention and the patient’s health and wellness;
  (b) The provision of patient care services, including but not limited to post-diagnostic disease state management services; and
  (c) The practice of pharmacy by a pharmacist pursuant to a clinical pharmacy agreement.

# Clinical Pharmacy Agreements

ORS 689.005(4):

- “Clinical pharmacy agreement”
  - means an agreement
    - between a pharmacist or pharmacy and
    - a health care organization or
    - a physician as defined in ORS 677.010 or
    - a naturopathic physician as defined in ORS 685.010
  - that permits the pharmacist to engage in the practice of clinical pharmacy
  - for the benefit of the patients of the health care organization, physician or naturopathic physician.
  - Current CDTM agreements would be a type of clinical pharmacy agreement when they fit within this definition.

# ORS 414.764

**Payment for services provided by pharmacy or pharmacist.** (1) The Oregon Health Authority may reimburse a pharmacist or pharmacy for any health service:

(a) Provided to a medical assistance recipient who is not enrolled in a coordinated care organization or a prepaid managed care health services organization;

(b) That is within the lawful scope of practice of a pharmacist; and

(c) If the authority determines the service is within the types and extent of health care and services to be provided to medical assistance recipients under ORS 414.065.

(2) A coordinated care organization may reimburse a pharmacist or pharmacy for any health service:

(a) Provided to a medical assistance recipient who is enrolled in the coordinated care organization or a prepaid managed care health services organization that enters into a clinical pharmacy agreement with the pharmacist or pharmacy; and

(b) That is within the lawful scope of practice of a pharmacist. [2015 c.362 §6]

# OAR 855-019-0260
# Collaborative Drug Therapy Management

(1) As used in this rule "Collaborative Drug Therapy Management" (CDTM) means the participation by a practitioner and a pharmacist in the management of drug therapy pursuant to a written agreement that includes information on the dosage, frequency, duration and route of administration of the drug, authorized by a practitioner and initiated upon a prescription order for an individual patient and:

(a) Is agreed to by one practitioner and one pharmacist; or

(b) Is agreed to by one or more practitioners in a single organized medical group, such as a hospital medical staff, clinic or group practice, including but not limited to organized medical groups using a pharmacy and therapeutics committee, and one or more pharmacists.

# OAR 855-019-0260
# Collaborative Drug Therapy Management

(2) A pharmacist shall engage in collaborative drug therapy management with a practitioner only under a written arrangement that includes:

(a) The identification, either by name or by description, of each of the participating pharmacists;

(b) The identification, by name or description, of each of the participating practitioners or group of practitioners;

(c) The name of the principal pharmacist and practitioner who are responsible for development, training, administration, and quality assurance of the arrangement;

# OAR 855-019-0260

# Collaborative Drug Therapy Management

(2)(d) The types of decisions that the pharmacist is allowed to make, which may include:

(A) A detailed description of the types of diseases, drugs, or drug categories involved, and the activities allowed in each case;

(B) A detailed description of the methods, procedures, decision criteria, and plan the pharmacist is to follow when conducting allowed activities;

(C) A detailed description of the activities the pharmacist is to follow including documentation of decisions made and a plan or appropriate mechanism for communication, feedback, and reporting to the practitioner concerning specific decisions made. In addition to the agreement, documentation shall occur on the prescription record, patient profile, a separate log book, or in some other appropriate system;

# OAR 855-019-0260
# Collaborative Drug Therapy Management

(2)(e) Training requirement for pharmacist participation and ongoing assessment of competency, if necessary;

(f) Quality assurance and periodic review by a panel of the participating pharmacists and practitioners;

(g) Authorization by the practitioner for the pharmacist to participate in collaborative drug therapy; and

(h) A requirement for the collaborative drug therapy arrangement to be reviewed and updated, or discontinued at least every two years;

# OAR 855-019-0260
# Collaborative Drug Therapy Management

(3) The collaborative drug therapy arrangement and associated records must be kept on file in the pharmacy and made available to any appropriate health licensing board upon request.

(4) Nothing in this rule shall be construed to allow therapeutic substitution outside of the CDTM agreement.

# OAR 847-015-0040

# Collaborative Drug Therapy Management

**847-015-0040**
**Collaborative Drug Therapy Management**

(1) "Collaborative Drug Therapy Management" as used in this section means the participation by a physician and a pharmacist in the management of drug therapy pursuant to a written protocol that includes information specific to the dosage, frequency, duration and route of administration of the drug, authorized by a physician and initiated upon a prescription order for an individual patient and:

(a) Is agreed to by one physician and one pharmacist; or

(b) Is agreed to by one or more physicians in a single organized medical group, such as a hospital medical staff, clinic or group practice, including but not limited to organized medical groups using a pharmacy and therapeutics committee, and one or more pharmacists.

(2) A physician shall engage in collaborative drug therapy management with a pharmacist only under a written arrangement that includes:

(a) The identification, either by name or by description, of the participating pharmacist(s);

(b) The identification, by name, of the participating physician(s);

(c) The name of the physician and principal pharmacist who are responsible for development, training, administration, and quality assurance of the arrangement;

(d) A detailed description of the collaborative role the pharmacist(s) shall play, including but not limited to:

(A) Written protocol for specific drugs pursuant to which the pharmacist will base drug therapy management decisions for an individual patient;

(B) Circumstances which will cause the pharmacist to initiate communication with the physician, including but not limited to the need for new prescription orders and reports of patients' therapeutic responses or adverse effects;

(C) Training requirement for pharmacist participation and ongoing assessment of competency, if necessary;

(D) Quality assurance and periodic review by a panel of the participating physicians(s) and pharmacist(s).

(e) Authorization by the physician(s) for the pharmacist(s) to participate in the collaborative drug therapy;

(f) A provision for the collaborative drug therapy arrangement to be reviewed and updated, or discontinued at least every two years; and

(g) A description of the mechanism for the pharmacist(s) to communicate to the physician(s) and for documentation of the implementation of the collaborative drug therapy.

(3) Nothing in this rule shall be construed to allow therapeutic substitution.

(4) The collaborative drug therapy protocol must be kept on file in the pharmacy and made available to the Board of Pharmacy and the Oregon Medical Board upon request

# CDTM vs. CPA

- CDTM is based on the concept that it is a pre-agreed upon prescription order (aka “protocol”) that is activated by the prescriber by an order for an individual patient.
  - “Heparin per pharmacy protocol for DVT”
  - “Vancomycin per pharmacy protocol for sepsis”
  - “Tylenol per pharmacy protocol for fever”

- CPA is based on statutory authority. It is broader than a CDTM and can be activated by prescribers as listed in the law by an order for an individual patient.
  - “Diabetes management per order for diabetes”
  - “Heart failure management per order for CHF”

# Collaborative Drug Therapy Management (CDTM)

Pat Wilson, M.D.
4156 Main Street Corvallis, OR 97332
(541) 737-9384

1 Patient Name_____Date_____
Address_____

2 Drug: Quantity:

Directions:

Refill X_____

3 Signed:_____,MD
DEA #:_____

# Collaborative Drug Therapy Management (CDTM)

1 = Patient information

2 = Drug therapy instructions/protocol

3 = Prescriber's authorization (signature)

1 + 2 + 3 = complete prescription

CDTM is based on the principle that when all 3 elements above are present, it is a complete prescription.

# Discussion Items – CDTM/CPA

- OAR 855-006-0005 Definitions
- OAR 855-115-0315 Services: Clinical Pharmacy Agreement

# FINAL THOUGHTS

# THANK YOU FOR YOUR PARTICIPATION!

----------1st DRAFT (October 2022/December 2022/February 2023)----------

History of Board review:

- October 2022- Board did not discuss this rule due to meeting time constraints but sent to November 2022 rulemaking hearing for the purpose of requesting public comment on proposed rules.
- December 2022- Board did not discuss the entire rule due to meeting time constraints. See mailing #A (pg. 5-226) for rulemaking hearing comments.
- February 2023- Board discussed the rule and requested workgroup.

**855-006-0005**

**Definitions**

As used in OAR Chapter 855:

(~~9~~**10**) "Clinical Pharmacy Agreement" means an agreement between a Pharmacist or pharmacy and a health care organization or a physician **as defined in ORS 677.010 or a naturopathic physician as defined in ORS 685.010** that permits the Pharmacist to engage in the practice of clinical pharmacy for the benefit of the patients of the health care organization**,** or physician **or naturopathic physician**.
NOTE: Board adopted this amended definition at the December 2022 board meeting.

(1~~0~~**1**) "Collaborative Drug Therapy Management" means the participation by a Pharmacist in the management of drug therapy pursuant to a written protocol that includes information specific to the dosage, frequency, duration, and route of administration of the drug, authorized by a practitioner and initiated upon a prescription order for an individual patient and:

(a) Is agreed to by one Pharmacist and one practitioner; or

(b) Is agreed to by one or more Pharmacists at a single pharmacy registered by the board and one or more practitioners in a single organized medical group, such as a hospital medical staff, clinic, or group practice, including but not limited to organized medical groups using a pharmacy and therapeutics committee.

~~855-019-0260~~ **855-115-0120**

**Services:** ~~Collaborative Drug Therapy Management~~ **Clinical Pharmacy Agreement**

~~(1) As used in this rule "Collaborative Drug Therapy Management" (CDTM) means the participation by a practitioner and a pharmacist in the management of drug therapy pursuant to a written agreement that includes information on the dosage, frequency, duration and route of administration of the drug, authorized by a practitioner and initiated upon a prescription order for an individual patient and:~~

~~(a) Is agreed to by one practitioner and one pharmacist; or~~

~~(b) Is agreed to by one or more practitioners in a single organized medical group, such as a hospital medical staff, clinic or group practice, including but not limited to organized medical groups using a pharmacy and therapeutics committee, and one or more pharmacists.~~

(~~1~~2) A **P**~~p~~harmacist **or pharmacy** ~~shall~~ **may** engage in ~~collaborative drug therapy management~~ **a Clinical Pharmacy Agreement** with a ~~practitioner~~ **health care organization, physician or naturopathic physician** only under a written ~~arrangement~~ **agreement** that includes:

(a) The identification, either by name or by description, of each ~~of the~~ participating **P**~~p~~harmacist~~s~~;

(b) The identification, **either** by name or description, of each ~~practitioner~~ **participating physician, naturopathic physician, or providers of a healthcare organization** ~~of the participating practitioners or group of practitioners~~;

(c) The name of the principal **P**~~p~~harmacist and ~~practitioner~~ **physician, naturopathic physician or provider on behalf of the healthcare organization** who are responsible for development, training, administration, and quality assurance of the ~~arrangement~~ **agreement**;

(d) The types of decisions that the **P**~~p~~harmacist is allowed to make, which ~~may~~ **must include a detailed description of the:**

**(A) Methods by which a physician or naturopathic physician or a provider on behalf of a healthcare organization enters a patient into the agreement;**

(B) ~~A detailed description of the types of d~~**D**iagnoses, drugs, or drug categories involved, and the activities allowed ~~in each case;~~**. The drug information must include the dosage, frequency, duration and route of administration of the drug.**

(C) ~~A detailed description of the m~~**M**ethods, procedures, decision criteria, and plan the ~~p~~**P**harmacist is to follow when conducting allowed activities;

(D) ~~A detailed description of the~~ **Documentation the Pharmacist is to complete** ~~activities the pharmacist is to follow including documentation of~~ **concerning** decisions made and a plan or appropriate mechanism for communication, feedback, and reporting to the practitioner concerning specific decisions made. In addition to the agreement, documentation ~~shall~~ **must** occur on the prescription record, patient profile, a separate log book, or in some other appropriate system;

(E) Circumstances which will cause the **P**~~p~~harmacist to initiate communication with the practitioner, including but not limited to the need for a new prescription order and a report of a patient's therapeutic response or any adverse effect.

(e) Training requirement for **P**~~p~~harmacist participation and ongoing assessment of competency, if necessary;

(f) Quality ~~assurance~~ **improvement** and periodic review by a panel of the participating **P**~~p~~harmacists and practitioners;

(g) Authorization by the practitioner for the **P**~~p~~harmacist to participate in collaborative drug therapy; and

(h) A requirement for the ~~collaborative drug therapy arrangement~~ **Clinical Pharmacy Agreement** to be reviewed and updated, or discontinued at least every two years;

(3) **The Pharmacist must document and keep a record of each patient encounter where the clinical pharmacy agreement is utilized.** ~~The collaborative drug therapy arrangement and associated records must be kept on file in the pharmacy and made available to any appropriate health licensing board upon request.~~

(4) **Records and documents must be retained according to OAR 855-102-0050.**~~Nothing in this rule shall be construed to allow therapeutic substitution outside of the CDTM agreement.~~

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

----------2nd DRAFT (April 2023)----------
History of Board review:

- April 2023- Board did not discuss due to time constraints.

Highlights:

- Blue= Change since 1st draft
- Green= Moved language within rule.

855-006-0005
Definitions

(9) "Clinical Pharmacy Agreement" means an agreement between a Pharmacist or pharmacy and a health care organization or a physician as defined in ORS 677.010 or a naturopathic physician as defined in ORS 685.010 that permits the Pharmacist to engage in the practice of clinical pharmacy for the benefit of the patients of the health care organization, or physician or naturopathic physician.
Note: Adopted effective 12/21/2022

(10) "Collaborative Drug Therapy Management" means the ~~participation by~~ **process in which a** Pharmacist **or pharmacy and providers on behalf of a health care organization, a physician as defined in ORS 677.010 or a naturopathic physician as defined in ORS 685.010 agree to a pre-specified** ~~in the management of~~ drug therapy **management** ~~pursuant to a written~~ protocol that ~~includes information specific to the dosage, frequency, duration, and route of administration of the drug, authorized by a practitioner and initiated upon a~~ **is initiated for an individual patient on the** prescription order **of a participating provider.** ~~for an individual patient and:~~

~~(a) Is agreed to by one Pharmacist and one practitioner; or~~
~~(b) Is agreed to by one or more Pharmacists at a single pharmacy registered by the board and one or more practitioners in a single organized medical group, such as a hospital medical staff, clinic, or group practice, including but not limited to organized medical groups using a pharmacy and therapeutics committee.~~

~~855-019-0260~~ **855-115-0315**
**Services:** ~~Collaborative Drug Therapy Management~~ **Clinical Pharmacy Agreement**

~~(1) As used in this rule "Collaborative Drug Therapy Management" (CDTM) means the participation by a practitioner and a pharmacist in the management of drug therapy pursuant to a written agreement that includes information on the dosage, frequency, duration and route of administration of the drug, authorized by a practitioner and initiated upon a prescription order for an individual patient and:~~

~~(a) Is agreed to by one practitioner and one pharmacist; or~~

~~(b) Is agreed to by one or more practitioners in a single organized medical group, such as a hospital medical staff, clinic or group practice, including but not limited to organized medical groups using a pharmacy and therapeutics committee, and one or more pharmacists.~~

(**1**~~2~~) A **P**~~p~~harmacist **or pharmacy** ~~shall~~ **may** engage in ~~collaborative drug therapy management~~ **the practice of clinical pharmacy under a Clinical Pharmacy Agreement** with a ~~practitioner~~ **health care organization, physician or naturopathic physician** only under a written ~~arrangement~~ **agreement** that includes:

(~~c~~**a**) The name of the principal **P**~~p~~harmacist and ~~practitioner~~ **physician, naturopathic physician or provider on behalf of the healthcare organization** who are responsible for development, training, administration, and quality assurance of the ~~arrangement~~ **agreement**;

(~~a~~**b**) The identification, either by name or by description, of each ~~of the~~ participating **P**~~p~~harmacist~~s~~;

(~~b~~**c**) The identification, **either** by name or description, of each ~~practitioner~~ **participating physician, naturopathic physician, or providers of a healthcare organization** ~~of the participating practitioners or group of practitioners~~;

**(d) Methods by which a participating physician or naturopathic physician or a provider on behalf of a healthcare organization enters a patient into the agreement;**

(~~d~~**e**) The types of ~~decisions~~ **clinical pharmacy activities** that the **P**~~p~~harmacist is allowed to **perform** ~~make, which may include:~~

~~(A) A detailed description of the types of diseases, drugs, or drug categories involved, and the activities allowed in each case;~~**~~. The drug information must include the dosage, frequency, duration and route of administration of the drug.~~**

~~(B) A detailed description of the methods, procedures, decision criteria, and plan the pharmacist is to follow when conducting allowed activities~~

(~~C~~**(f)**) ~~A detailed description of the~~ **Documentation the Pharmacist is to complete** ~~activities the pharmacist is to follow including documentation of~~ **concerning** decisions made and a plan or appropriate mechanism for communication, feedback, and reporting to the practitioner concerning specific decisions made. ~~In addition to the agreement, documentation shall occur on the prescription record, patient profile, a separate log book, or in some other appropriate system;~~

(~~D~~**g**) Circumstances which will cause the **P**~~p~~harmacist to initiate communication with the practitioner~~,~~ ~~including but not limited to the need for a new prescription order and a report of a patient's therapeutic response or any adverse effect~~.

(~~e~~**h**) Training requirement for **P**~~p~~harmacist participation and ongoing assessment of competency, if necessary;

(~~f~~**i**) Quality ~~assurance~~ **improvement** and periodic review by a panel of the participating **P**~~p~~harmacists and practitioners;

(~~g~~**j**) Authorization by the practitioner for the **P**~~p~~harmacist to participate in collaborative drug therapy; and

(~~h~~**k**) A requirement for the ~~collaborative drug therapy arrangement~~ **Clinical Pharmacy Agreement** to be reviewed and updated, or discontinued at least every two years

(2) A **P**~~p~~harmacist ~~shall~~ **may** engage in ~~c~~**C**ollaborative ~~d~~**D**rug ~~t~~**T**herapy ~~m~~**M**anagement**, a type of Clinical Pharmacy Agreement,** with a ~~practitioner~~ **health care organization, physician or naturopathic physician** only under a written ~~arrangement~~ **agreement** that includes **all of the elements in (1)(a)-(k) and must include the dosage, frequency, duration and route of administration of the drug.**

(3) **The Pharmacist must document and keep a record of each patient encounter where an agreement in (1) or (2) is utilized.** ~~The collaborative drug therapy arrangement and associated records must be kept on file in the pharmacy and made available to any appropriate health licensing board upon request.~~ **In addition to the agreement, documentation must occur on the prescription record, patient profile, electronic medical record, or in some other appropriate system.**

(4) **Records and documents must be retained according to OAR 855-102-0050.**~~Nothing in this rule shall be construed to allow therapeutic substitution outside of the CDTM agreement.~~

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