

May 13, 2022

Update 5/09/2022

PQAC Meeting Materials



CERTIFICATION OF ENROLLMENT

ENGROSSED SUBSTITUTE HOUSE BILL 1329

Chapter 115, Laws of 2022

67th Legislature
2022 Regular Session

OPEN PUBLIC MEETINGS—VARIOUS PROVISIONS

EFFECTIVE DATE: June 9, 2022—Except for sections 5 through 11, which take effect March 24, 2022.

Passed by the House March 7, 2022
Yeas 87 Nays 11

LAURIE JINKINS

**Speaker of the House of
Representatives**

Passed by the Senate March 3, 2022
Yeas 47 Nays 0

DENNY HECK

President of the Senate

Approved March 24, 2022 8:34 AM

JAY INSLEE

Governor of the State of Washington

CERTIFICATE

I, Bernard Dean, Chief Clerk of the House of Representatives of the State of Washington, do hereby certify that the attached is **ENGROSSED SUBSTITUTE HOUSE BILL 1329** as passed by the House of Representatives and the Senate on the dates hereon set forth.

BERNARD DEAN

Chief Clerk

FILED

March 24, 2022

**Secretary of State
State of Washington**

ENGROSSED SUBSTITUTE HOUSE BILL 1329

AS AMENDED BY THE SENATE

Passed Legislature - 2022 Regular Session

State of Washington 67th Legislature 2021 Regular Session

By House Local Government (originally sponsored by Representatives Wicks, Pollet, Taylor, Ryu, Wylie, Shewmake, Bateman, Lovick, Fey, Morgan, Lekanoff, Harris-Talley, and Peterson)

READ FIRST TIME 02/15/21.

1 AN ACT Relating to public meeting accessibility and
2 participation; amending RCW 42.30.010, 42.30.030, 42.30.040,
3 42.30.050, 42.30.070, 42.30.077, 42.30.080, 42.30.090, 42.30.110, and
4 42.30.900; adding new sections to chapter 42.30 RCW; creating a new
5 section; and declaring an emergency.

6 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

7 NEW SECTION. **Sec. 1.** The legislature finds and declares that,
8 due to technological advances since the 1971 adoption of the open
9 public meetings act, elected officials no longer conduct the public's
10 business solely at in-person meetings, but can and do utilize
11 telephonic and other electronic methods to efficiently conduct the
12 business of state and local government remotely. Further, limitations
13 on public gatherings required as the result of a disaster or
14 emergency, for example, to assist in preventing the spread of
15 infectious diseases, may affirmatively necessitate the use of
16 technology and the avoidance of in-person attendance at public
17 meetings for the conduct of governmental business. It is the policy
18 of the state that a governing body's actions, including
19 deliberations, shall be taken and conducted in the open. When the
20 public cannot observe and participate in person, it may limit
21 participation in democracy. Therefore, this act shall be construed in

1 favor of ensuring access by the public to observe elected officials
2 when they meet pursuant to this act. It is the intent of this act to
3 modernize and update the open public meetings act emergency
4 procedures to reflect technological advances, while maintaining the
5 act's public policy that governing body's actions and deliberations
6 be taken and conducted openly while balancing public safety in
7 emergency conditions. Governing bodies are encouraged to adopt
8 resolutions or ordinances establishing where and how meetings will be
9 held in the event of an emergency, in order to allow the public to
10 more easily learn about and observe public agency action in an
11 emergent situation.

12 The legislature further finds people participating in their
13 government, especially through public comment, is an essential part
14 of developing public policy. The legislature finds that there are
15 numerous developing technologies that can be used to facilitate
16 public comment, especially for those with disabilities, underserved
17 communities, and those who face time or distance challenges when
18 traveling to public meetings. Therefore, the legislature intends to
19 encourage public agencies to make use of remote access tools as fully
20 as practicable to encourage public engagement and better serve their
21 communities.

22 **Sec. 2.** RCW 42.30.010 and 1971 ex.s. c 250 s 1 are each amended
23 to read as follows:

24 The legislature finds and declares that all public commissions,
25 boards, councils, committees, subcommittees, departments, divisions,
26 offices, and all other public agencies of this state and subdivisions
27 thereof exist to aid in the conduct of the people's business. It is
28 the intent of this chapter that their actions be taken openly and
29 that their deliberations be conducted openly.

30 The people of this state do not yield their sovereignty to the
31 agencies which serve them. The people, in delegating authority, do
32 not give their public servants the right to decide what is good for
33 the people to know and what is not good for them to know. The people
34 insist on remaining informed and informing the people's public
35 servants of their views so that they may retain control over the
36 instruments they have created. For these reasons, even when not
37 required by law, public agencies are encouraged to incorporate and
38 accept public comment during their decision-making process.

1 **Sec. 3.** RCW 42.30.030 and 1971 ex.s. c 250 s 3 are each amended
2 to read as follows:

3 (1) All meetings of the governing body of a public agency shall
4 be open and public and all persons shall be permitted to attend any
5 meeting of the governing body of a public agency, except as otherwise
6 provided in this chapter.

7 (2) Public agencies are encouraged to provide for the increased
8 ability of the public to observe and participate in the meetings of
9 governing bodies through real-time telephonic, electronic, internet,
10 or other readily available means of remote access that do not require
11 an additional cost to access the meeting.

12 NEW SECTION. **Sec. 4.** A new section is added to chapter 42.30
13 RCW to read as follows:

14 (1) Public agencies are encouraged to make an audio or video
15 recording of, or to provide an online streaming option for, all
16 regular meetings of its governing body, and to make recordings of
17 these meetings available online for a minimum of six months.

18 (2) This section does not alter a local government's
19 recordkeeping requirements under chapter 42.56 RCW.

20 NEW SECTION. **Sec. 5.** A new section is added to chapter 42.30
21 RCW to read as follows:

22 (1) If, after the declaration of an emergency by a local or state
23 government or agency, or by the federal government, a public agency
24 determines that it cannot hold a meeting of the governing body with
25 members or public attendance in person with reasonable safety because
26 of the emergency, the public agency may:

27 (a) Hold a remote meeting of the governing body without a
28 physical location; or

29 (b) Hold a meeting of the governing body at which the physical
30 attendance by some or all members of the public is limited due to a
31 declared emergency.

32 (2) During a remote meeting, members of the governing body may
33 appear or attend by phone or by other electronic means that allows
34 real-time verbal communication without being in the same physical
35 location. For a remote meeting or a meeting at which the physical
36 attendance by some or all members of the public is limited due to a
37 declared emergency, the public agency must provide an option for the
38 public to listen to the proceedings telephonically or by using a

1 readily available alternative in real-time that does not require any
2 additional cost for participation. Free readily available options
3 include, but are not limited to, broadcast by the public agency on a
4 locally available cable television station that is available
5 throughout the jurisdiction or other electronic, internet, or other
6 means of remote access that does not require any additional cost for
7 access to the program. The public agency may also allow the other
8 electronic means of remote access.

9 (3) No action may be taken at a remote meeting or a meeting at
10 which the physical attendance by some or all members of the public is
11 limited due to a declared emergency if the public agency has not
12 provided an option for the public to listen to proceedings pursuant
13 to subsection (2) of this section, except for an executive session as
14 authorized in this chapter.

15 (4) Notice of a remote meeting without a physical location or a
16 meeting at which the physical attendance by some or all members of
17 the public is limited due to a declared emergency must be provided in
18 accordance with this chapter and must include instructions on how the
19 public may listen live to proceedings and on how the public may
20 access any other electronic means of remote access offered by the
21 public agency.

22 (5) A remote meeting or a meeting at which the physical
23 attendance by some or all members of the public is limited due to a
24 declared emergency that is held under the provisions of this section
25 shall be considered open and public in compliance with the
26 requirements of this chapter. Nothing in this section alters the
27 ability of public agencies to take action in response to an emergency
28 as provided for in RCW 42.30.070, or to have members of a governing
29 body participate in a meeting remotely with no declared emergency.

30 (6) Notwithstanding any other provision in this section, any
31 governing body of a public agency which held some of its regular
32 meetings remotely prior to March 1, 2020, may continue to hold some
33 of its regular meetings remotely with no declared emergency so long
34 as the public agency provides an option for the public to listen to
35 the proceedings pursuant to subsection (2) of this section.

36 **Sec. 6.** RCW 42.30.040 and 2012 c 117 s 124 are each amended to
37 read as follows:

38 A member of the public shall not be required, as a condition to
39 attendance at a meeting of a governing body, to register his or her

1 name and other information, to complete a questionnaire, or otherwise
2 to fulfill any condition precedent to his or her attendance. This
3 section does not prohibit any generally applicable conditions
4 determined by the governing body to be reasonably necessary to
5 protect the public health or safety, or to protect against
6 interruption of the meeting, including a meeting at which the
7 physical attendance by some or all members of the public is limited
8 due to a declared emergency.

9 **Sec. 7.** RCW 42.30.050 and 1971 ex.s. c 250 s 5 are each amended
10 to read as follows:

11 In the event that any meeting is interrupted by a group or groups
12 of persons so as to render the orderly conduct of such meeting
13 unfeasible and order cannot be restored by the removal of individuals
14 who are interrupting the meeting, the members of the governing body
15 conducting the meeting may order the meeting room cleared and
16 continue in session or may adjourn the meeting and reconvene at
17 another location selected by majority vote of the members. In such a
18 session, final disposition may be taken only on matters appearing on
19 the agenda. Representatives of the press or other news media, except
20 those participating in the disturbance, shall be allowed to attend
21 any session held pursuant to this section. Nothing in this section
22 shall prohibit the governing body from establishing a procedure for
23 readmitting an individual or individuals not responsible for
24 disturbing the orderly conduct of the meeting. Nothing in this
25 section prohibits the governing body from stopping people from
26 speaking to the governing body when not recognized by the governing
27 body to speak.

28 **Sec. 8.** RCW 42.30.070 and 1983 c 155 s 2 are each amended to
29 read as follows:

30 The governing body of a public agency shall provide the time for
31 holding regular meetings by ordinance, resolution, bylaws, or by
32 whatever other rule is required for the conduct of business by that
33 body. Unless otherwise provided for in the act under which the public
34 agency was formed, meetings of the governing body need not be held
35 within the boundaries of the territory over which the public agency
36 exercises jurisdiction. If at any time any regular meeting falls on a
37 holiday, such regular meeting shall be held on the next business day.
38 If, by reason of fire, flood, earthquake, or other emergency, there

1 is a need for expedited action by a governing body to meet the
2 emergency, the presiding officer of the governing body may provide
3 for a meeting site other than the regular meeting site, for a remote
4 meeting without a physical location, or for a meeting at which the
5 physical attendance by some or all members of the public is limited
6 due to a declared emergency, and the notice requirements of this
7 chapter shall be suspended during such emergency. It shall not be a
8 violation of the requirements of this chapter for a majority of the
9 members of a governing body to travel together or gather for purposes
10 other than a regular meeting or a special meeting as these terms are
11 used in this chapter: PROVIDED, That they take no action as defined
12 in this chapter.

13 **Sec. 9.** RCW 42.30.077 and 2014 c 61 s 2 are each amended to read
14 as follows:

15 (1) Public agencies with governing bodies must make the agenda of
16 each regular meeting of the governing body available online no later
17 than (~~twenty-four~~) 24 hours in advance of the published start time
18 of the meeting. An agency subject to provisions of this section (~~is~~
19 not required to post an agenda if it does not have a website or if it
20 employs fewer than ten full-time equivalent employees)) may share a
21 website with, or have its website hosted by, another public agency to
22 post meeting agendas, minutes, budgets, contact information, and
23 other records, including any resolution or ordinance adopted by the
24 agency establishing where and how the public agency will meet in the
25 event of an emergency. Nothing in this section prohibits subsequent
26 modifications to agendas nor invalidates any otherwise legal action
27 taken at a meeting where the agenda was not posted in accordance with
28 this section. Nothing in this section modifies notice requirements or
29 shall be construed as establishing that a public body or agency's
30 online posting of an agenda as required by this section is sufficient
31 notice to satisfy public notice requirements established under other
32 laws. Failure to post an agenda in accordance with this section shall
33 not provide a basis for awarding attorney fees under RCW 42.30.120 or
34 commencing an action for mandamus or injunction under RCW 42.30.130.

35 (2) A special purpose district, city, or town subject to the
36 provisions of this section is not required to post an agenda online
37 if the district, city, or town:

38 (a) Has an aggregate valuation of the property subject to
39 taxation by the district, city, or town of less than \$400,000,000, as

1 placed on the last completed and balanced tax rolls of the county
2 preceding the date of the most recent tax levy;

3 (b) Has a population within its jurisdiction of under 3,000
4 persons; and

5 (c) Provides confirmation to the state auditor at the time it
6 files its annual reports under RCW 43.09.230 that the cost of posting
7 notices on a website of its own, a shared website, or on the website
8 of the county in which the largest portion of the district's, city's,
9 or town's population resides, would exceed one-tenth of one percent
10 of the district's, city's, or town's budget.

11 **Sec. 10.** RCW 42.30.080 and 2012 c 188 s 1 are each amended to
12 read as follows:

13 (1) A special meeting may be called at any time by the presiding
14 officer of the governing body of a public agency or by a majority of
15 the members of the governing body by delivering written notice
16 personally, by mail, by fax, or by ~~((electronic mail))~~ email to each
17 member of the governing body. Written notice shall be deemed waived
18 in the following circumstances:

19 (a) A member submits a written waiver of notice with the clerk or
20 secretary of the governing body at or prior to the time the meeting
21 convenes. A written waiver may be given by telegram, fax, or
22 ~~((electronic mail))~~ email; or

23 (b) A member is actually present at the time the meeting
24 convenes.

25 (2) Notice of a special meeting called under subsection (1) of
26 this section shall be:

27 (a) Delivered to each local newspaper of general circulation and
28 local radio or television station that has on file with the governing
29 body a written request to be notified of such special meeting or of
30 all special meetings;

31 (b) Posted on the agency's website. An agency is not required to
32 post a special meeting notice on its website if it ~~((i))~~ does not
33 have a website ~~((i))~~ or share a website with another agency.
34 Except in the case of a remote meeting or a meeting at which the
35 physical attendance by some or all members of the public is limited
36 due to a declared emergency as provided for in this chapter, an
37 agency is not required to post a special meeting notice on its
38 website if it employs ~~((fewer than ten))~~ no full-time equivalent
39 employees ~~((i))~~, or ~~((iii))~~ does not employ personnel whose duty, as

1 defined by a job description or existing contract, is to maintain or
2 update the website; and

3 (c) Prominently displayed at the main entrance of the agency's
4 principal location and the meeting site if it is not held at the
5 agency's principal location and is not held as a remote meeting;
6 except that during a declared emergency which prevents a meeting from
7 being held in-person with reasonable safety an agency that hosts a
8 website or shares a website with another agency may instead post
9 notice of a remote meeting without a physical location on the website
10 hosted or shared by the agency.

11 Such notice must be delivered or posted, as applicable, at least
12 (~~twenty-four~~) 24 hours before the time of such meeting as specified
13 in the notice.

14 (3) The call and notices required under subsections (1) and (2)
15 of this section shall specify the time and place of the special
16 meeting and the business to be transacted. Final disposition shall
17 not be taken on any other matter at such meetings by the governing
18 body.

19 (4) The notices provided in this section may be dispensed with in
20 the event a special meeting is called to deal with an emergency
21 involving injury or damage to persons or property or the likelihood
22 of such injury or damage, when time requirements of such notice would
23 make notice impractical and increase the likelihood of such injury or
24 damage, or when the required notice cannot be posted or displayed
25 with reasonable safety, including but not limited to declared
26 emergencies in which travel to physically post notice is barred or
27 advised against.

28 **Sec. 11.** RCW 42.30.090 and 2012 c 117 s 125 are each amended to
29 read as follows:

30 The governing body of a public agency may adjourn any regular,
31 adjourned regular, special, or adjourned special meeting to a time
32 and place specified in the order of adjournment. Less than a quorum
33 may so adjourn from time to time. If all members are absent from any
34 regular or adjourned regular meeting the clerk or secretary of the
35 governing body may declare the meeting adjourned to a stated time and
36 place. He or she shall cause a written notice of the adjournment to
37 be given in the same manner as provided in RCW 42.30.080 for special
38 meetings, unless such notice is waived as provided for special
39 meetings. (~~Whenever~~) Except in the case of remote meetings without

1 a physical location as provided for in this chapter, whenever any
2 meeting is adjourned a copy of the order or notice of adjournment
3 shall be conspicuously posted immediately after the time of the
4 adjournment on or near the door of the place where the regular,
5 adjourned regular, special, or adjourned special meeting was held.
6 When a regular or adjourned regular meeting is adjourned as provided
7 in this section, the resulting adjourned regular meeting is a regular
8 meeting for all purposes. When an order of adjournment of any meeting
9 fails to state the hour at which the adjourned meeting is to be held,
10 it shall be held at the hour specified for regular meetings by
11 ordinance, resolution, bylaw, or other rule.

12 **Sec. 12.** RCW 42.30.110 and 2019 c 162 s 2 are each amended to
13 read as follows:

14 (1) Nothing contained in this chapter may be construed to prevent
15 a governing body from holding an executive session during a regular
16 or special meeting:

17 (a) (i) To consider matters affecting national security;

18 (ii) To consider, if in compliance with any required data
19 security breach disclosure under RCW 19.255.010 and 42.56.590, and
20 with legal counsel available, information regarding the
21 infrastructure and security of computer and telecommunications
22 networks, security and service recovery plans, security risk
23 assessments and security test results to the extent that they
24 identify specific system vulnerabilities, and other information that
25 if made public may increase the risk to the confidentiality,
26 integrity, or availability of agency security or to information
27 technology infrastructure or assets;

28 (b) To consider the selection of a site or the acquisition of
29 real estate by lease or purchase when public knowledge regarding such
30 consideration would cause a likelihood of increased price;

31 (c) To consider the minimum price at which real estate will be
32 offered for sale or lease when public knowledge regarding such
33 consideration would cause a likelihood of decreased price. However,
34 final action selling or leasing public property shall be taken in a
35 meeting open to the public;

36 (d) To review negotiations on the performance of publicly bid
37 contracts when public knowledge regarding such consideration would
38 cause a likelihood of increased costs;

1 (e) To consider, in the case of an export trading company,
2 financial and commercial information supplied by private persons to
3 the export trading company;

4 (f) To receive and evaluate complaints or charges brought against
5 a public officer or employee. However, upon the request of such
6 officer or employee, a public hearing or a meeting open to the public
7 shall be conducted upon such complaint or charge;

8 (g) To evaluate the qualifications of an applicant for public
9 employment or to review the performance of a public employee.
10 However, subject to RCW 42.30.140(4), discussion by a governing body
11 of salaries, wages, and other conditions of employment to be
12 generally applied within the agency shall occur in a meeting open to
13 the public, and when a governing body elects to take final action
14 hiring, setting the salary of an individual employee or class of
15 employees, or discharging or disciplining an employee, that action
16 shall be taken in a meeting open to the public;

17 (h) To evaluate the qualifications of a candidate for appointment
18 to elective office. However, any interview of such candidate and
19 final action appointing a candidate to elective office shall be in a
20 meeting open to the public;

21 (i) To discuss with legal counsel representing the agency matters
22 relating to agency enforcement actions, or to discuss with legal
23 counsel representing the agency litigation or potential litigation to
24 which the agency, the governing body, or a member acting in an
25 official capacity is, or is likely to become, a party, when public
26 knowledge regarding the discussion is likely to result in an adverse
27 legal or financial consequence to the agency.

28 This subsection (1)(i) does not permit a governing body to hold
29 an executive session solely because an attorney representing the
30 agency is present. For purposes of this subsection (1)(i), "potential
31 litigation" means matters protected by RPC 1.6 or RCW 5.60.060(2)(a)
32 concerning:

33 (i) Litigation that has been specifically threatened to which the
34 agency, the governing body, or a member acting in an official
35 capacity is, or is likely to become, a party;

36 (ii) Litigation that the agency reasonably believes may be
37 commenced by or against the agency, the governing body, or a member
38 acting in an official capacity; or

39 (iii) Litigation or legal risks of a proposed action or current
40 practice that the agency has identified when public discussion of the

1 litigation or legal risks is likely to result in an adverse legal or
2 financial consequence to the agency;

3 (j) To consider, in the case of the state library commission or
4 its advisory bodies, western library network prices, products,
5 equipment, and services, when such discussion would be likely to
6 adversely affect the network's ability to conduct business in a
7 competitive economic climate. However, final action on these matters
8 shall be taken in a meeting open to the public;

9 (k) To consider, in the case of the state investment board,
10 financial and commercial information when the information relates to
11 the investment of public trust or retirement funds and when public
12 knowledge regarding the discussion would result in loss to such funds
13 or in private loss to the providers of this information;

14 (l) To consider proprietary or confidential nonpublished
15 information related to the development, acquisition, or
16 implementation of state purchased health care services as provided in
17 RCW 41.05.026;

18 (m) To consider in the case of the life sciences discovery fund
19 authority, the substance of grant applications and grant awards when
20 public knowledge regarding the discussion would reasonably be
21 expected to result in private loss to the providers of this
22 information;

23 (n) To consider in the case of a health sciences and services
24 authority, the substance of grant applications and grant awards when
25 public knowledge regarding the discussion would reasonably be
26 expected to result in private loss to the providers of this
27 information;

28 (o) To consider information regarding staff privileges or quality
29 improvement committees under RCW 70.41.205.

30 (2) Before convening in executive session, the presiding officer
31 of a governing body shall publicly announce the purpose for excluding
32 the public from the meeting place, and the time when the executive
33 session will be concluded. The executive session may be extended to a
34 stated later time by announcement of the presiding officer. The
35 announced purpose of excluding the public must be entered into the
36 minutes of the meeting required by RCW 42.30.035.

37 NEW SECTION. **Sec. 13.** A new section is added to chapter 42.30
38 RCW to read as follows:

1 (1) Except in an emergency situation, the governing body of a
2 public agency shall provide an opportunity at or before every regular
3 meeting at which final action is taken for public comment. The public
4 comment required under this section may be taken orally at a public
5 meeting, or by providing an opportunity for written testimony to be
6 submitted before or at the meeting. If the governing body accepts
7 written testimony, this testimony must be distributed to the
8 governing body. The governing body may set a reasonable deadline for
9 the submission of written testimony before the meeting.

10 (2) Upon the request of any individual who will have difficulty
11 attending a meeting of the governing body of a public agency by
12 reason of disability, limited mobility, or for any other reason that
13 makes physical attendance at a meeting difficult, the governing body
14 shall, when feasible, provide an opportunity for that individual to
15 provide oral comment at the meeting remotely if oral comment from
16 other members of the public will be accepted at the meeting.

17 (3) Nothing in this section prevents a governing body from
18 allowing public comment on items not on the meeting agenda.

19 (4) Nothing in this section diminishes the authority of governing
20 bodies to deal with interruptions under RCW 42.30.050, limits the
21 ability of the governing body to put limitations on the time
22 available for public comment or on how public comment is accepted, or
23 requires a governing body to accept public comment that renders
24 orderly conduct of the meeting unfeasible.

25 **Sec. 14.** RCW 42.30.900 and 1971 ex.s. c 250 s 16 are each
26 amended to read as follows:

27 This chapter may be known and cited as the (~~"Open Public~~
28 ~~Meetings Act of 1971".~~) Washington state open public meetings act or
29 OPMA.

30 NEW SECTION. **Sec. 15.** Sections 5 through 11 of this act are
31 necessary for the immediate preservation of the public peace, health,
32 or safety, or support of the state government and its existing public
33 institutions, and take effect immediately.

Passed by the House March 7, 2022.
Passed by the Senate March 3, 2022.
Approved by the Governor March 24, 2022.
Filed in Office of Secretary of State March 24, 2022.

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Rules and Rulemaking

WA Pharmacy Quality Assurance Commission 2022

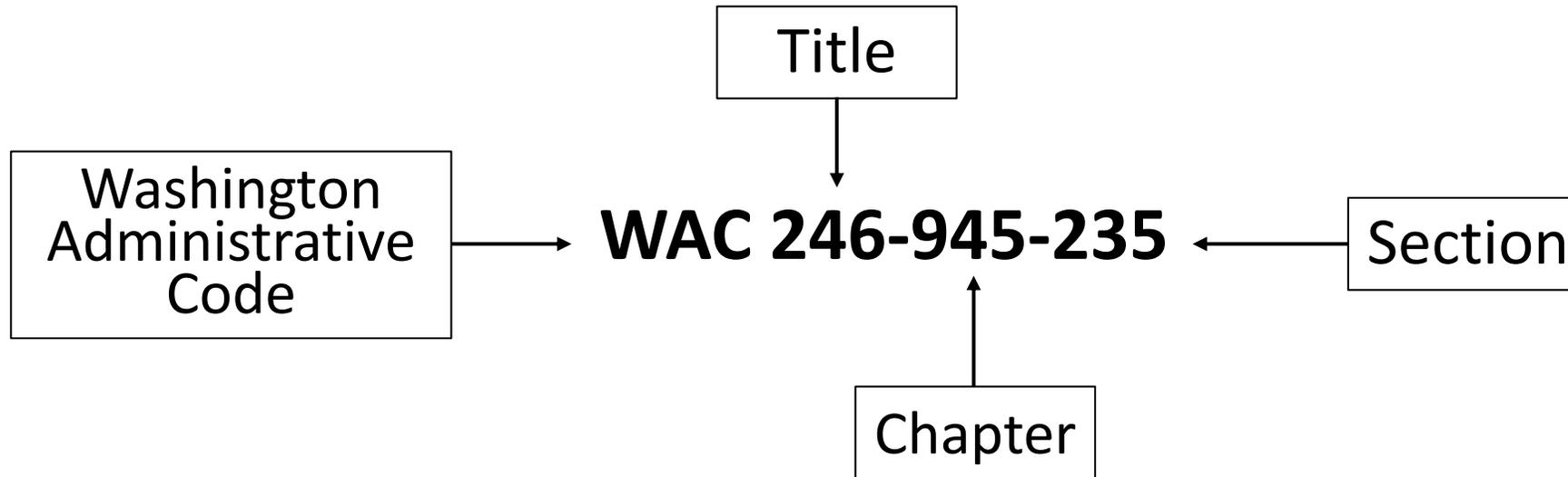
May 13, 2022

What is a Rule?

Washington Administrative Code (WAC)

- Rule = regulation
- A written requirement applying to a broad population (groups or entities) that enables, guides, or directs them to do something or prohibits some action/behavior
 - Penalties for violations
 - Requirements to receive benefits/privileges
 - Setting qualifications/standards for individual licenses or permits
 - Setting standards for the selling of materials

WAC Numbering System



- **Title:** Each agency gets their own title number from the code reviser
 - Department of Health and State Board of Health → Title 246 WAC
- **Chapter:** Identifies subject matters regulated under agency's statutes
 - Pharmacy Quality Assurance Commission → Chapter 246-945 WAC
- **Section:** Each section is considered an individual rule
 - "Nonresident pharmacy license" → WAC 246-945-235

Rules vs. Laws



- RCW: Revised Code of Washington
 - Enacted by the Legislature and signed by the Governor
 - Enacted via initiative process
- Rulemaking authority must be granted by the RCW
 - Rules must fit with the specific statutory authority
 - Most common for the pharmacy commission? RCW 18.64.005
- Policy/Interpretive Statements
 - Written expression of agency opinion, non-enforceable

Initiating Rulemaking

When to engage in rulemaking?

- New/revised legislative requirements
- Changes in federal code or funding
- Court rulings
- Changes in national professional standards or consensus codes
- Technological changes
- Agency policy changes
- Executive orders
- Requests by interested/regulated parties such as professional associations
- Formal petitions by interested parties under RCW 34.05.330
- Changes in standards of practice or conduct
- Judicial orders

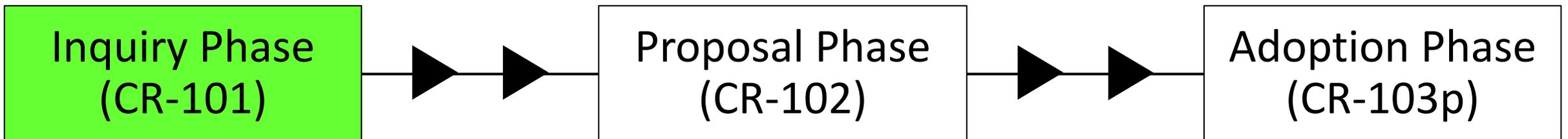
Standard Rulemaking

- **Inquiry Phase** (RCW 34.05.310)
 - CR-101
- **Proposal Phase** (RCW 34.05.320)
 - CR-102
- **Adoption Phase** (RCW 34.05.360)
 - CR-103p



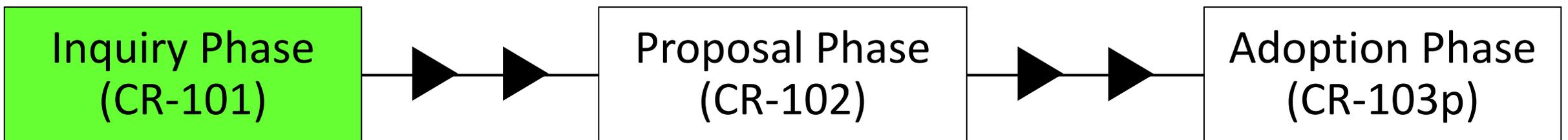
The Rulemaking Process

- EXAMPLE: Removing Epidiolex from Schedule V (WAC 246-945-056)
- Rulemaking is initiated
 - EXAMPLE: Petition for rulemaking received in April 2020
- Pre-proposal meeting (situational)



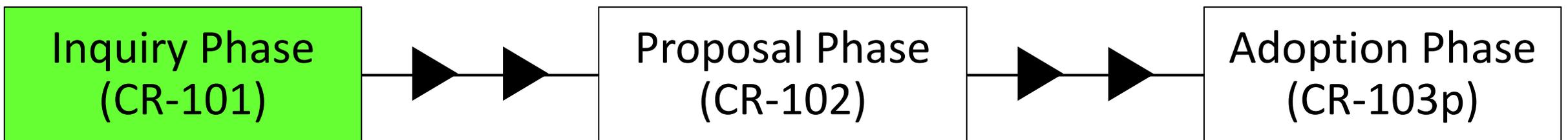
The Rulemaking Process (cont.)

- Finalize and file the CR-101 form
 - Cover memo (purpose/intent)
 - Estimated cost of rulemaking
 - Dear Tribal Leader letter
 - Statutory authority/bill description



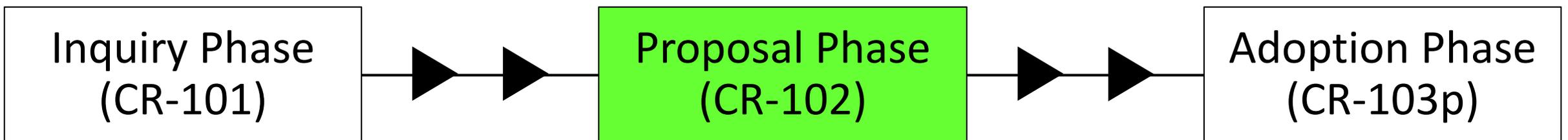
The Rulemaking Process (cont.)

- Division/agency review
 - Filed with Code Reviser once finalized
- Rules packages filed with the Washington State Register (WSR) in the Code Reviser's office
 - EXAMPLE: WSR 20-23-027
- Notify stakeholders/interested parties



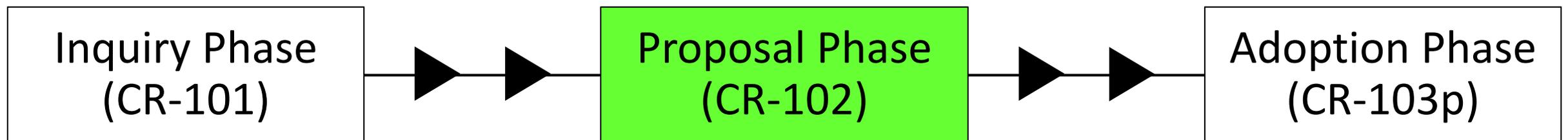
The Rulemaking Process (cont.)

- Begin drafting rule language
 - Public meetings
 - Rule language drafts
- Determine costs
 - Significant Analysis (CBA)
 - Is an SBEIS needed?
- SBEIS = Small Business Economic Impact Statement



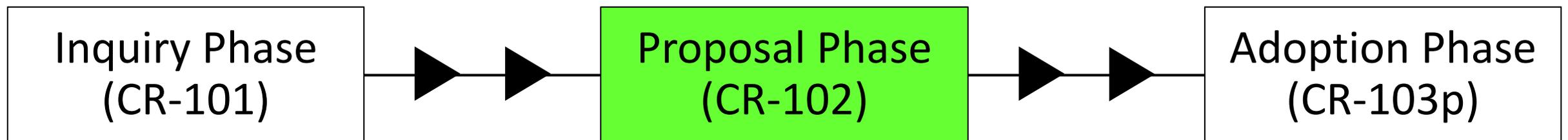
The Rulemaking Process (cont.)

- Internal review of CR-102 materials
- Preliminary CR-102 meetings (situational)
 - Program staff (address controversies)
 - Rules workshop (commission approval)
- The CR-102 form
 - Cover memo (purpose/intent/impact/implementation/controversies)
 - Preliminary cost of rulemaking form
 - OTS form (rule language)
 - Significant analysis (and SBEIS if necessary)
 - Statutory authority



The Rulemaking Process (cont.)

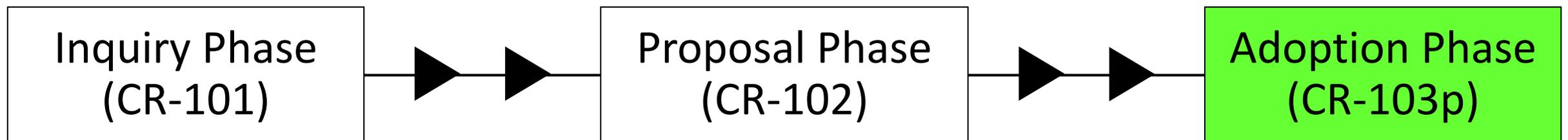
- Division/agency review
 - Filed with Code Reviser once finalized
 - Effective for 180 days from publication with the Washington State Register
 - EXAMPLE: WSR 22-05-089
- Notify stakeholders/interested parties (3 days)
- Public comment period
- The Public Hearing
 - Held at least 33 days after the CR-102 filing
 - Conducted in conformance with the Administrative Procedures Act (chapter 34.05 RCW)



The Rulemaking Process (cont.)



- Agency adopts rule
- Prepare the CR-103p form
 - Concise Explanatory Statement/cover memo
 - Rule Implementation Plan (significant rules only)
 - Final cost of rulemaking form
 - OTS language print-out
 - Statutory authority



The Rulemaking Process (cont.)

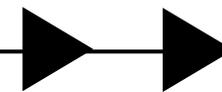


- Division/agency review
 - Filed with Code Reviser once finalized
 - Rule is effective 31 days after filing
- Notify stakeholders/interested parties
- Congratulations, it's a rule!

Inquiry Phase
(CR-101)



Proposal Phase
(CR-102)



Adoption Phase
(CR-103p)

Other Types of Rulemaking

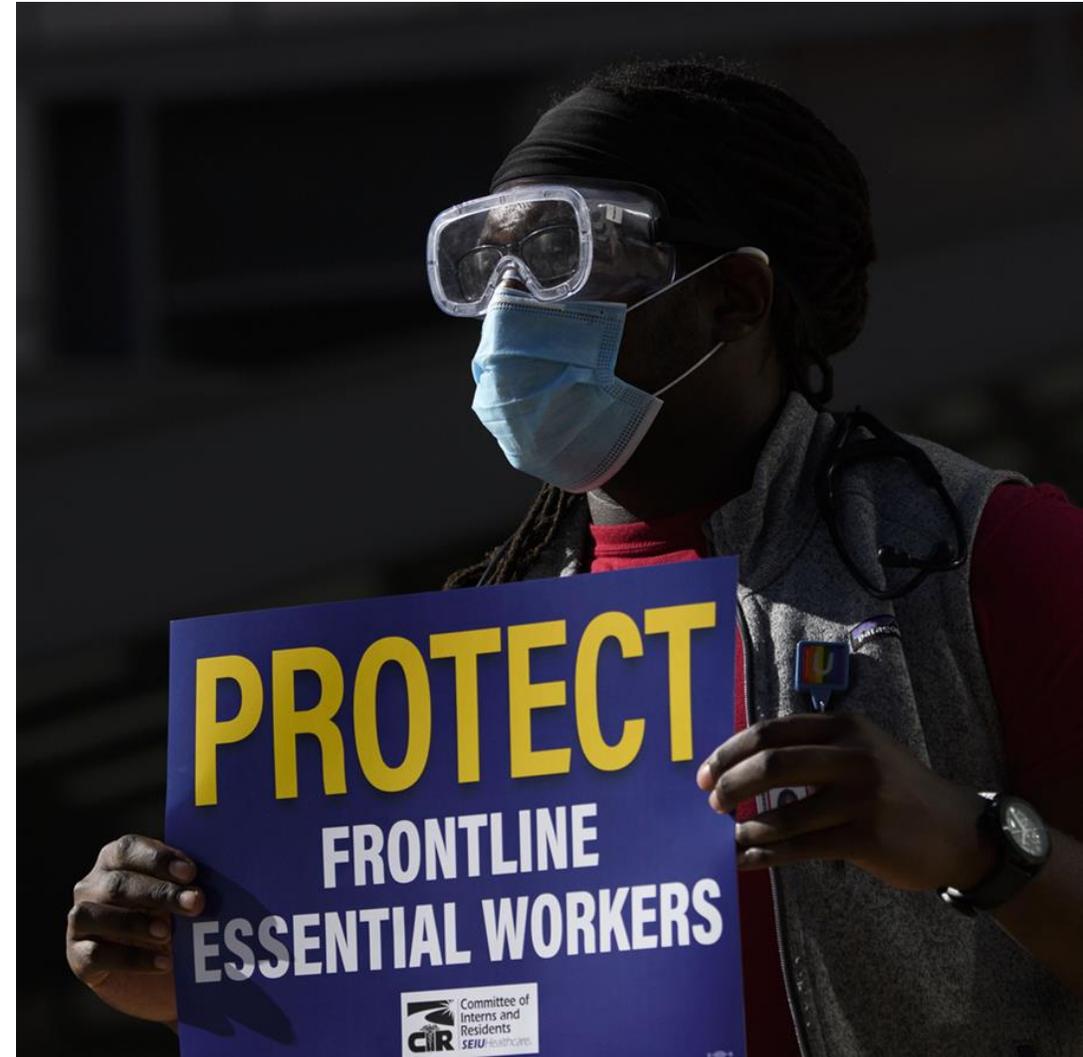
- **Exception rules** (per RCW 34.05.310)
 - Starts at CR-102
 - Circumstances:
 - Internal governmental operations
 - Incorporation by reference (e.g. federal statutes/regulations)
 - Correcting typos
 - Set/adjust fees pursuant to legislative standards
 - Agency hearing practices/procedures/requirements
 - Filing/process requirements for license or permit application
 - Public hearing is required
 - Public comment period: 20 days
 - Respond to objections in Concise Explanatory Statement

Other Types of Rulemaking (cont.)

- **Expedited rules** (per RCW 34.05.353)
 - Starts at CR-105
 - Circumstances:
 - Internal governmental operations
 - Incorporation by reference (e.g. federal statutes/regulations)
 - Correcting typos
 - Content of proposed rules dictated by statute
 - Proposed rules subject to prior comprehensive participation/input by interested parties
 - Amendment following legislative significant analysis under RCW 34.05.325
 - No public hearing
 - Public comment period: 45 days
 - Any objection re-starts the process as a CR-101

Other Types of Rulemaking (cont.)

- **Emergency rules** (per RCW 34.05.350 and 34.05.380)
 - Only use the CR-103e
 - Circumstances:
 - Immediate adoption, amendment, or repeal of a rule necessary to preserve public health, safety, or general welfare
 - State/federal law, federal rule, or federal deadline requiring immediate rule adoption to secure federal funds for the state
 - Rule duration: 120 days



PQAC Rules Priority List

Priority Ranking	Status	Title	Short Description	Most Recent WSR #
1	Refile	COVID - CII Prescribing (emergency)	Emergency rules for prescribing Schedule II drugs during COVID-19 pandemic	WSR 22-06-017 (Filed February 22, 2022)
1	Refile	Medication assistance (emergency - filed jointly with DOH)	Medication assistance emergency rules in accordance with chapter 69.41 RCW	WSR 22-07-063 (Filed March 17, 2022)
1	Refiling	Retired pharmacist (emergency)	Emergency rules for retired active pharmacist license status	WSR 22-04-062 (Filed January 28, 2022)
2	CR-101 filed	Accessible labeling (visual/print access and translated labels)	Standard/significant rules for setting/improving standards for prescription drug information access/comprehension	WSR 22-09-065 (Filed April 19, 2022)
2	Drafting CR-102	Retired pharmacist (standard)	Permanent rules for retired active pharmacist license status	WSR 21-09-063 (Filed April 19, 2021)
2	Drafting rule language	Medication assistance (standard - will file jointly with DOH)	Medication assistance rules in accordance with chapter 69.41 RCW	WSR 22-02-015 (Filed December 27, 2021)
2	CR-102 in review	Remote dispensing OUD medications - SSB 6086 (standard)	SSB 6086 - Implementing remote dispensing of OUD medications	WSR 20-17-123 (Filed August 18, 2020)
2	Pre-review of CR-102	Donation of unexpired drugs - SSB 6526 (standard)	SSB 6526 - Implementing the donation and reuse of unexpired drugs	WSR 20-17-143 (Filed August 19, 2020)

PQAC Rules Priority List (cont.)

Priority Ranking	Status	Title	Short Description	Most Recent WSR #
3	Drafting CR-105	Uniform Controlled Substances Act – Title 21 CFR (expedited)	Amend language in WAC 246-945-040 to incorporate by reference any changes in Title 21 CFR made after the rule’s effective date	Not yet filed
3	New	Dialysate and dialysis device manufacturer licensing	Determine sections in chapter 246-945 WAC (subsection -090 through -093 at least) to amend to comply with SSB 1675	Not yet filed
4	CR-101 in review	Access to drugs stored outside pharmacy (standard)	Allowing access to drugs stored outside the pharmacy by unlicensed employees of a health care facility	Not yet filed
4	New	Mobile OTP unit licensing	Amend WAC 246-945-060 to clarify licensing standards for mobile OTP units	Not yet filed
5	New	Zero Order Reports and Suspicious Orders (standard)	Amending WAC 246-945-001 and WAC 246-945-585 to adjust suspicious order and zero reporting requirement	Not yet filed
6	On hold	Technical fixes to chapter 246-945 WAC (expedited)	Typos and small edits to multiple sections in chapter 246-945 WAC	Not yet filed
7	On hold	AIDS education repeal - ESHB 1551 (expedited)	ESHB 1551 - Repealing AIDS education and training requirements	Not yet filed
8	On hold	Authorizing NABP FDA MOU	Sign MOU written by the NABP on human compounded drugs	Awaiting federal action/updated MOU
9	Filed; awaiting effective date	Removing Epidiolex from Schedule V (standard)	Permanent rules to delete Epidiolex from Schedule V	WSR 22-10-044 (Filed April 28, 2022)

Rules Overview

- Primary focus: Public welfare
- The necessity of taking time
 - Multiple levels of review catch mistakes
 - Community/stakeholder input is crucial

Questions?

CERTIFICATION OF ENROLLMENT

SUBSTITUTE HOUSE BILL 1675

67th Legislature
2022 Regular Session

Passed by the House January 26, 2022
Yeas 97 Nays 0

**Speaker of the House of
Representatives**

Passed by the Senate March 1, 2022
Yeas 48 Nays 0

President of the Senate

Approved

Governor of the State of Washington

CERTIFICATE

I, Bernard Dean, Chief Clerk of the House of Representatives of the State of Washington, do hereby certify that the attached is **SUBSTITUTE HOUSE BILL 1675** as passed by the House of Representatives and the Senate on the dates hereon set forth.

Chief Clerk

FILED

**Secretary of State
State of Washington**

SUBSTITUTE HOUSE BILL 1675

Passed Legislature - 2022 Regular Session

State of Washington 67th Legislature 2022 Regular Session

By House Health Care & Wellness (originally sponsored by Representatives Bateman, Maycumber, Leavitt, Graham, Dolan, Cody, Griffey, and Riccelli)

READ FIRST TIME 01/20/22.

1 AN ACT Relating to exempting a manufacturer of certain dialysate
2 and dialysis devices used by home dialysis patients or a
3 manufacturer's agent from the pharmacy practices act and legend drug
4 act; and amending RCW 18.64.257 and 69.41.032.

5 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

6 **Sec. 1.** RCW 18.64.257 and 2013 c 19 s 20 are each amended to
7 read as follows:

8 (1) This chapter shall not prevent a medicare-approved dialysis
9 center ((~~or~~)), a facility operating a medicare-approved home dialysis
10 program, a manufacturer, or a wholesaler, from selling, delivering,
11 possessing, or dispensing directly to its dialysis patients, ((~~in~~
12 ease or full shelf lots,)) if prescribed by a ((~~physician-licensed~~
13 under chapter 18.57 or 18.71 RCW)) practitioner acting within the
14 scope of the practitioner's practice, those dialysis devices and
15 legend drugs, including commercially available dialysate, used by
16 home dialysis patients, in case or full shelf lots, as determined by
17 the commission ((~~pursuant to rule~~)).

18 (2) The commission shall adopt rules to implement this section.

19 **Sec. 2.** RCW 69.41.032 and 2016 c 148 s 12 are each amended to
20 read as follows:

1 (1) This chapter shall not prevent a medicare-approved dialysis
2 center ((or)), a facility operating a medicare-approved home dialysis
3 program, a manufacturer, or a wholesaler, from selling, delivering,
4 possessing, or dispensing directly to ((its)) dialysis patients, ((in
5 case or full shelf lots,)) if prescribed by a ((physician licensed
6 under chapter 18.57 or 18.71 RCW)) practitioner acting within the

7 scope of the practitioner's practice, those legend drugs, including
8 commercially available dialysate, used by home dialysis patients, in
9 case or full shelf lots, as determined by the commission ((pursuant
10 to rule)).

11 (2) The commission shall adopt rules to implement this section.

--- END ---



PREPROPOSAL STATEMENT OF INQUIRY

**CR-101 (October 2017)
(Implements RCW 34.05.310)**

Do **NOT** use for expedited rule making

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: April 19, 2022

TIME: 10:27 AM

WSR 22-09-065

Agency: Department of Health- Pharmacy Quality Assurance Commission

Subject of possible rule making: Chapter 246-945 WAC, Prescription drug label accessibility standards. The Pharmacy Quality Assurance Commission (commission) is opening WACs 246-945-016 and 246-945-417 to consider including prescription label accessibility standards, and is also considering new sections to chapter 246-945 WAC on the subject of prescription drug label accessibility.

Statutes authorizing the agency to adopt rules on this subject: RCW 18.64.005; and RCW 69.41.240

Reasons why rules on this subject may be needed and what they might accomplish: On September 8, 2021, the commission received a petition requesting pharmacies provide accessible medication label options for patients. On October 22, 2021, the commission voted to approve the petition and consider rulemaking. Minimum requirements for outpatient prescription labeling are described in WAC 246-945-016, but does not reference accommodations for patients who are visually impaired, blind, or have other disabilities requiring additional prescription label options provided by their pharmacy. Clear comprehension of prescription drug label information is a matter of public health and safety for all persons, regardless of ability, and opening chapter 246-945 WAC would help align state regulatory standards with patient needs.

The commission also received a petition on January 13, 2022 requesting that translations of prescription directions on prescription labels be made available in multiple languages for ambulatory (community based) patients. The petition included an additional request to amend WAC 246-945-417 in order to establish a deadline by which pharmacy outpatient dispensing systems must comply with a requirement to translate prescription medication directions. The commission voted to approve the petition and consider rulemaking pertaining to the provision of translated prescription information by pharmacies on January 28, 2022. Improving prescription information comprehension for individuals for whom English is not their primary language is also a matter of public health.

Identify other federal and state agencies that regulate this subject and the process coordinating the rule with these agencies: The Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA) expanded the FDA's authorities and strengthened the agency's ability to advance public health. Section 904 of the FDASIA established a working group to develop best practices regarding prescription drug label standards to better accommodate visually impaired or blind individuals. This led to a 2016 United States Government Accountability Office report recommending the provision of accessible prescription drug labels, including the use of large print, braille, and audible labels. The commission does not require coordination with the federal agencies responsible for the implementation or enforcement of prescription drug label accessibility guidelines.

Process for developing new rule (check all that apply):

- Negotiated rule making
- Pilot rule making
- Agency study
- Other (describe) Collaborative

Interested parties can participate in the decision to adopt the new rule and formulation of the proposed rule before publication by contacting:

Name: Joshua Munroe
Address: PO Box 47852 Olympia, WA 98504-7852
Phone: 360-236-2987
Fax:

(If necessary)

Name:
Address:
Phone:
Fax:

TTY: 711
Email: PharmacyRules@doh.wa.gov
Web site:
Other:

TTY:
Email:
Web site:
Other:

Additional comments: Rule development takes place in open public meetings prior to a formal rule proposal and comment period. All rulemaking notices are sent via GovDelivery. To receive notices, interested persons may sign up by going to: <https://public.govdelivery.com/accounts/WADOH/subscriber/new>. After signing up, please click open the box labeled "Health Systems Quality Assurance." Next, click open the box labeled "Health Professions," then check the boxes next to either "Pharmacy Commission Meeting and Agenda" and/or "Pharmacy Commission Newsletter."

Date: 04/18/2022	Signature: 
Name: Teri Ferreira, RPh	
Title: Pharmacy Quality Assurance Chair	

Accessible Label Rule References

Translated Labels

California

- [CA Law 4076.6](#) - California
 - 4076.6(a) – Dispenser shall provide translated directions for use on patient request
 - Printed on container label
 - 4076.6(b) – Dispensers may use translations provided by the board of pharmacy
 - 4076.6(c) – Dispenser don't need to use languages beyond those that the board provides
 - 4076.6(d) – Dispensers may use their own translation services to comply with the section
 - 4076.6(e) – Dispensers are responsible for the accuracy of English-language directions for use provided to the patient
 - 4076.6(f) – Veterinarians are not considered dispensers for this section

New York

- [NY Law 6829](#) – New York
 - 6829(1) – Definitions provided for:
 - 6829(1)(a): “Covered pharmacy”
 - 6829(1)(b): “Limited English proficient individual”
 - 6829(1)(c): “Translation”
 - 6829(1)(d): “Competent oral interpretation”
 - 6829(1)(e): “Pharmacy primary languages”
 - 6829(1)(f): “Mail order pharmacy”
 - 6829(2)(a) – Pharmacies must provide free, competent oral interpretation services on patient request
 - 6829(2)(b) – Pharmacies must printed translated medication labels, warning labels, and other written material on patient request
 - 6829(2)(c) – Pharmacies may use staff or third-party contractors to provide translations
 - 6829(3) – Signage advertising translation services must be conspicuously posted
 - 6829(4) – The pharmacy commission is responsible for rulemaking in order to establish translation services
 - 6829(4)(a): Rules must state how to determine if patient is LEP
 - 6829(4)(b): Determine which languages are considered
 - 6829(4)(c): Manner and circumstances by which oral interpretation services are provided
 - 6829(4)(d): Which information is eligible for oral interpretation
 - 6829(4)(e): Anticipate how service is utilized, which resources used and what costs are incurred
 - 6829(4)(f): Establish compliance/monitoring standards
 - 6829(5) – Covered pharmacies are not liable for injuries resulting from third-party contractor translations

- 6829(6) – Must establish a process by which pharmacies may apply to receive a waiver from compliance
- 6829 (7) – Commissioner must coordinate with the commissioner of health to “effectuate” requirements of the section
- [NY Rule Section 63.11](#) – Interpretation and translation requirements for prescription drugs
 - 63.11(a) – Definitions for:
 - 63.11(a)(1): “Covered pharmacy”
 - 63.11(a)(2): “Corporate entity”
 - 63.11(a)(3): “Limited English proficiency individual”
 - 63.11(a)(4): “Translation”
 - 63.11(a)(5): “Competent oral interpretation”
 - 63.11(a)(6): “Pharmacy primary languages”
 - 63.11(a)(7): “Mail order pharmacy”
 - 63.11(b) – How competent oral interpretations are provided
 - 63.11(b)(1) – Covered pharmacies must provide oral translation services for patient counseling for free on request
 - 63.11(b)(2) – Covered pharmacies must provide oral translation services of medication/warning labels or other written materials for free on patient request
 - 63.11(b)(3) – Translations must be provided on site unless list of languages exceed seven
 - 63.11(b)(4) – Staff or third-party contractors are allowed to provide translated information
 - 63.11(c) – Notification requirements
 - 63.11(c)(1) – Conspicuous signage for advertising translation services
 - 63.11(c)(2) – Font size and type, design element requirements
 - 63.11(c)(3) – Placement of signage
 - 63.11(d) – Waivers for translation services
 - 63.11(d)(1) – One application per pharmacy
 - 63.11(d)(2) – Waiver applications must describe financial/physical constraints and impact on other services
 - 63.11(d)(3) – Reasons to deny waiver application
 - 63.11(d)(4) – Applicants must identify nearby services that can provide translation services
 - 63.11(d)(5) – Post notice of alternative services if waiver granted
 - 63.11(d)(6) – Waiver duration and renewal conditions
 - 63.11(e) – This section preempts local laws/ordinances, though cities of 100,000 or more may impose stricter regulations

Oregon

- [OR Law 689.564](#) – Prescription drug labels
 - 689.564(1) – Board of pharmacy responsible for rules establishing pharmacy printing of prescription drug labels in English and language requested by LEP individual. Rules must also:
 - 689.564(1)(a) – Define “limited English proficiency”

- 689.564(1)(b) – Determine which sections with which pharmacies must comply
 - 689.564(1)(c) – Determine list of drugs eligible for translation
 - 689.564(1)(d)(A) – Minimum list length of 14 languages other than English
 - 689.564(1)(d)(B) – Board must reassess/update list every 10 years
- 689.564(2)(a) – Third-party contractors may be used
 - 689.564(2)(b) – Liability exemptions for injury resulting from errors in third-party translations
- 689.564(3) – Not applicable to institutional drug outlets
- 689.564(4) – Grants board of pharmacy rulemaking authority
- 689.564(5) – Signage posting requirements

Texas

- [TX Rule 291.3](#) – Required notifications
 - 291.3(h)(2)(B)(viii) – Pharmacies must provide in their profile the type of language translation services, including translating services for persons with impairment of hearing
 - No requirements for services themselves, but that they need to announce any services pharmacies choose to use

Visual/print Accessibility

Arkansas

- [Arkansas Rule 054.00.75-6](#)
 - November 1, 2019
 - Font size for data elements in prescription drug card: 8 points or greater (no font type listed in this section of rule)

California

- [California Rule 1707.5](#) – Patient-centered labels for prescription drug containers
 - The following elements, clustered together, must comprise at least 50 percent of the label:
 - Name of patient
 - Name of drug/strength of drug
 - Directions for use
 - The condition/purpose for which the drug was prescribed
 - Font: At least 12-point font in sans serif typeface
 - Provides suggested phrasing to accommodate compliance

Massachusetts

- [MA Law MGLA 94C-21](#)
 - November 1, 2019
 - On request, prescription label must be printed in a size “allowing no more than ten characters per inch.”

Nevada

- [NV Law 639.28015 – Notice of prescription readers](#)
 - Pharmacies must let patients know about availability of prescription readers and provide them on request
 - Definitions provided for “prescription reader” and what applies as a “retail community pharmacy”

New Jersey

- [New Jersey Rule 13-39-7.12 – Labeling](#)
 - March 30, 2022
 - Font size directions for warning label/sticker only
 - Must be at least 10-point font (not cursive) that is “clear and readable” per subsection (2)(iii)

New York

- [New York Rule Section 63.12](#) – Standardized patient-centered data elements to be used on all drug labels
 - Levels of information importance
 - Critical: Patient name, directions of use, drug name/strength
 - Important: Name/address/phone of pharmacy, patient’s address, name of prescriber, filling date, prescription/identifying number
 - Critical elements must be at least 12-point font, with highlighting/bolding used for emphasis
 - No highlighting/bolding of “Important” info

Oregon

- [Oregon Revised Statute \(ORS\) 689.561](#)
 - November 1, 2019
 - Definitions for “blind” and “prescription reader”
 - Notification of prescription readers to patients except for drugs dispensed by “an institutional drug outlet”
 - Readers must last duration of prescription and meet needs of identified impairment
 - Labels must be compatible with prescription readers
- [OR Rule 855-041-1131](#) – Prescription reader accessibility
 - Pharmacies must notify each person receiving a prescription that a prescription reader is available, and provide that reader if requested

Texas

- [Texas Rule 291.33 – Operational Standards](#)
 - December 14, 2020
 - Subsection TAC 291.33(a)(7)(A) includes language for “easily readable font size,” though later subsections describe this as at least ten-point Times New Roman.
 - Subsections with font size references:
 - TAC 291.33(a)(7)(A) – Dispensing container label
 - **NOTE:** There is also language in [TAC 562.006\(f\)](#) for the board to adopt rules requiring dispensing container labels be printed in an “easily readable font size”
 - TAC 291.33(7)(A)(ii) – Prescription drug ID number
 - TAC 291.33(7)(A)(vii) – Name of patient (or animal name/species if prescribed for animal)
 - TAC 291.33(7)(A)(viii) – Instructions for use



RULE-MAKING ORDER EMERGENCY RULE ONLY

CR-103E (December 2017) (Implements RCW 34.05.350 and 34.05.360)

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: February 22, 2022

TIME: 9:37 AM

WSR 22-06-017

Agency: Department of Health- Pharmacy Quality Assurance Commission

Effective date of rule:

Emergency Rules

- Immediately upon filing.
- Later (specify)

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

- Yes
 - No
- If Yes, explain:

Purpose: WAC 246-945-010 Prescription labeling, records, and advertising - Minimum requirements. The Pharmacy Quality Assurance Commission (commission) is adopting emergency rules to reduce burdens on practitioners prescribing Schedule II substances during the coronavirus disease (COVID-19) outbreak. This adopted emergency rule will extend WSR 21-22-029 filed on October 25, 2021. This emergency rule was originally filed on April 21, 2020 under WSR 20-09-133. It was refiled on July 10, 2020 after the commission's new chapter went into effect under WSR 20-15-058. This emergency rule will continue the existing emergency rule amending WAC 246-945-010 to increase the duration of time a practitioner has to deliver a signed prescription of a Schedule II substance to the pharmacy from seven days to fifteen days when a prescription is dispensed in an emergency. It also defines what a "signed prescription" means and allows for a practitioner to accomplish this requirement through paper, electronic transmission, facsimile, photograph, or scanned copy. These alternative methodologies support patients, practitioners, and pharmacists' efforts to practice social distancing and to help mitigate communal spread.

Citation of rules affected by this order:

- New: None
- Repealed: None
- Amended: WAC 246-945-010
- Suspended: None

Statutory authority for adoption: RCW 18.64.005; chapter 69.50 RCW

Other authority:

EMERGENCY RULE

Under RCW 34.05.350 the agency for good cause finds:

- That immediate adoption, amendment, or repeal of a rule is necessary for the preservation of the public health, safety, or general welfare, and that observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest.
- That state or federal law or federal rule or a federal deadline for state receipt of federal funds requires immediate adoption of a rule.

Reasons for this finding: The immediate amendment of this existing rule is necessary for the preservation of public health, safety, and general welfare. Interested parties and leaders from the pain community have highlighted this is an immediate need for Washingtonians. This emergency rule has been in effect since April 21, 2020. This emergency rule allows more time and more avenues for complying with the requirements during the ongoing COVID-19 pandemic, reducing burdens on practitioners and pharmacists, and sustaining patient access during this difficult time. The emergency rules follow guidance from the US drug enforcement agency and will help address this problem and reduce barriers for providers and patient populations in need of Schedule II prescriptions throughout this public health emergency. Observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to public interest.

**Note: If any category is left blank, it will be calculated as zero.
No descriptive text.**

**Count by whole WAC sections only, from the WAC number through the history note.
A section may be counted in more than one category.**

The number of sections adopted in order to comply with:

Federal statute:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Federal rules or standards:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Recently enacted state statutes:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>

The number of sections adopted at the request of a nongovernmental entity:

New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
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The number of sections adopted on the agency's own initiative:

New	<u>0</u>	Amended	<u>1</u>	Repealed	<u>0</u>
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The number of sections adopted in order to clarify, streamline, or reform agency procedures:

New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
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The number of sections adopted using:

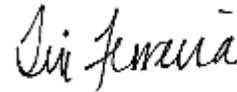
Negotiated rule making:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Pilot rule making:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Other alternative rule making:	New	<u>0</u>	Amended	<u>1</u>	Repealed	<u>0</u>

Date Adopted: 02/22/2022

Name: Teri Ferreira, RPh

Title: Pharmacy Quality Assurance Chair

Signature:



WAC 246-945-010 Prescription and chart order—Minimum requirements. (1) For the purposes of this section, prescription does not include chart orders as defined in RCW 18.64.011(3).

(2) For the purposes of WAC 246-945-010 through 246-945-013, prescription includes written and electronic prescriptions.

(3) A prescription for a noncontrolled legend drug must include, but is not limited to, the following:

(a) Prescriber's name;

(b) Name of patient, authorized entity, or animal name and species;

(c) Date of issuance;

(d) Drug name, strength, and quantity;

(e) Directions for use;

(f) Number of refills (if any);

(g) Instruction on whether or not a therapeutically equivalent generic drug or interchangeable biological product may be substituted, unless substitution is permitted under a prior-consent authorization;

(h) Prescriber's manual or electronic signature, or prescriber's authorized agent signature if allowed by law; and

(i) If the prescription is written, it must be written on tamper-resistant prescription pad or paper approved by the commission pursuant to RCW 18.64.500;

(4) A prescription for a controlled substance must include all the information listed in subsection (1) of this section and the following:

(a) Patient's address;

(b) Dosage form;

(c) Prescriber's address;

(d) Prescriber's DEA registration number; and

(e) Any other requirements listed in 21 C.F.R., Chapter II.

(5) A chart order must meet the requirements of RCW 18.64.550 and any other applicable requirements listed in 21 C.F.R., Chapter II.

(6) A controlled substance listed in Schedule II can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011 unless there is an "emergency."

(a) For the purposes of this subsection, an "emergency" exists when the immediate administration of the drug is necessary for proper treatment and no alternative treatment is available, and further, it is not possible for the practitioner to provide a written or electronic prescription for the drug at that time.

(b) If a Schedule II drug is dispensed in an emergency, the practitioner must deliver a signed prescription to the dispenser within (~~seven~~) fifteen days after authorizing an emergency oral prescription or if delivered by mail it must be postmarked within the (~~seven~~) fifteen day period, and further the pharmacist must note on the prescription that it was filled on an emergency basis.

(c) For the purposes of this subsection, a "signed prescription" shall be either:

(i) A paper prescription;

(ii) An electronic prescription;

(iii) A copy of the paper prescription sent via facsimile to the pharmacy; or

(iv) A photograph or scanned copy of the paper prescription sent to the pharmacy.

(7) A controlled substance listed in Schedule III, IV, or V, can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011, or an oral prescription. An oral prescription for a controlled substance listed in Schedule III, IV, or V must be promptly reduced to a written or electronic prescription that complies with WAC 246-945-011.

(8) A noncontrolled legend drug can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011, or an oral prescription. An oral prescription for a noncontrolled legend drug must be promptly reduced to a written or electronic prescription that complies with WAC 246-945-011.



RULE-MAKING ORDER EMERGENCY RULE ONLY

CR-103E (December 2017) (Implements RCW 34.05.350 and 34.05.360)

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: March 17, 2022

TIME: 7:51 AM

WSR 22-07-063

Agency: Department of Health- Pharmacy Quality Assurance Commission

Effective date of rule:

Emergency Rules

- Immediately upon filing.
- Later (specify)

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

- Yes
 - No
- If Yes, explain:

Purpose: WACs 246-945-710, 246-945-712, 246-945-714, 246-945-716, 246-945-718, 246-945-720, 246-945-722, 246-945-724, 246-945-726, and 246-945-728 - Medication assistance. The Pharmacy Quality Assurance Commission (commission) and Department of Health (department) are filing jointly to reinstate medication assistance rules as permitted under chapter 69.41 RCW. This adopted emergency rule will extend WSR 21-23-098 filed on November 17, 2021. This rule establishes criteria for medication assistance in community-based and in-home care settings in accordance with chapter 69.41 RCW. The definition for medication assistance provided in RCW 69.41.010(15) states:

"Medication assistance" means assistance rendered by a nonpractitioner to an individual residing in a community-based care setting or in-home care setting to facilitate the individual's self-administration of a legend drug or controlled substance. It includes reminding or coaching the individual, handing the medication container to the individual, opening the individual's medication container, using an enabler, or placing the medication in the individual's hand, and such other means of medication assistance as defined by rule adopted by the department...

These emergency rules provide further definitions for terms used within this definition such as "enabler" and establish those "other means of medication assistance as defined by rule adopted by the department." These rules help impacted individuals retain their independence and live in the least restrictive setting, such as their own home, longer by providing means and guidance for medication assistance. Also, with the direction provided in RCW 69.41.010(15), the rules are being filed under the joint authority of the commission and the department.

Citation of rules affected by this order:

- New: WAC 246-945-710, 246-945-712, 246-945-714, 246-945-716, 246-945-718, 246-945-720, 246-945-722, 246-945-724, 246-945-726, 246-945-728
- Repealed: None
- Amended: None
- Suspended: None

Statutory authority for adoption: RCW 18.64.005; RCW 69.41.010(15); RCW 69.41.075

Other authority:

EMERGENCY RULE

Under RCW 34.05.350 the agency for good cause finds:

- That immediate adoption, amendment, or repeal of a rule is necessary for the preservation of the public health, safety, or general welfare, and that observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest.
- That state or federal law or federal rule or a federal deadline for state receipt of federal funds requires immediate adoption of a rule.

Reasons for this finding: The commission's new chapter, chapter 246-945 WAC, became effective in July 2020. The old rules, including the former rules on medication assistance (chapter 246-888 WAC), were repealed in March 2021. The commission's repeal of chapter 246-888 WAC has resulted in unintended disruptions for medication assistance in the community-based and in-home care settings permitted under chapter 69.41 RCW. Emergency rulemaking is necessary to immediately restore medication assistance regulations to preserve patient safety and welfare while the commission and the department work on permanent rulemaking. Permanent rulemaking has been authorized but delayed due to the ongoing coronavirus disease 2019 pandemic.

**Note: If any category is left blank, it will be calculated as zero.
No descriptive text.**

**Count by whole WAC sections only, from the WAC number through the history note.
A section may be counted in more than one category.**

The number of sections adopted in order to comply with:

Federal statute:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Federal rules or standards:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Recently enacted state statutes:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>

The number of sections adopted at the request of a nongovernmental entity:

New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
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The number of sections adopted on the agency's own initiative:

New	<u>10</u>	Amended	<u>0</u>	Repealed	<u>0</u>
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The number of sections adopted in order to clarify, streamline, or reform agency procedures:

New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
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The number of sections adopted using:

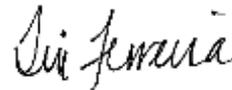
Negotiated rule making:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Pilot rule making:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Other alternative rule making:	New	<u>10</u>	Amended	<u>0</u>	Repealed	<u>0</u>

Date Adopted: 03/17/2022

Name: Teri Ferreira, RPh and Kristin Peterson, JD

Title: Pharmacy Quality Assurance Chair and Deputy Secretary, Policy and Planning

Signature:



PART 5 - MEDICATION ASSISTANCE

NEW SECTION

WAC 246-945-710 Scope and applicability. (1) This section through WAC 246-945-728 only apply to medication assistance provided in community-based care settings and in-home care settings.

(2) The following definitions apply to this section through WAC 246-945-728 unless the context requires otherwise:

- (a) "Medication" means legend drugs and controlled substances; and
- (b) "Practitioner" has the same meaning as in RCW 69.41.010(17).

NEW SECTION

WAC 246-945-712 Self-administration with assistance, independent self-administration, and medication administration. (1) Self-administration with assistance means assistance with legend drugs and controlled substances rendered by a nonpractitioner to an individual residing in a community-based care setting or an in-home care setting. It includes reminding or coaching the individual to take their medication, handing the medication container to the individual, opening the medication container, using an enabler, or placing the medication in the hand of the individual/resident. The individual/resident must be able to put the medication into their mouth or apply or instill the medication. The individual/resident does not necessarily need to state the name of the medication, intended effects, side effects, or other details, but must be aware that they are receiving medication. Assistance may be provided by a nonpractitioner with prefilled insulin syringes. Assistance is limited to handing the prefilled insulin syringe to an individual/resident. Assistance with the administration of any other intravenous or injectable medication is specifically excluded. The individual/resident retains the right to refuse medication. Self-administration with assistance shall occur immediately prior to the ingestion or application of a medication.

(2) Independent self-administration occurs when an individual/resident is independently able to directly apply a legend drug or controlled substance by ingestion, inhalation, injection or other means. In licensed assisted living facilities, self-administration may include situations in which an individual cannot physically self-administer medications but can accurately direct others. These regulations do not limit the rights of people with functional disabilities to self-direct care according to chapter 74.39 RCW.

(3) If an individual/resident is not able to physically ingest or apply a medication independently or with assistance, then the medication must be administered to the individual/resident by a person legally authorized to do so (e.g., physician, nurse, pharmacist). All

laws and regulations applicable to medication administration apply. If an individual/resident cannot safely self-administer medication or self-administer with assistance or cannot indicate an awareness that they are taking a medication, then the medication must be administered to the individual/resident by a person legally authorized to do so.

NEW SECTION

WAC 246-945-714 Self-administration with assistance in a community-based care setting or an in-home setting. (1) An individual/resident, or their representative, in a community-based care setting or an in-home setting may request self-administration with assistance.

(2) No additional separate assessment or documentation of the needs of the individual/resident are required in order to initiate self-administration with assistance. It is recommended that providers document their decision-making process in the health record of the individual or resident health record.

(3) A nonpractitioner may help in the preparation of legend drugs and controlled substances for self-administration where a practitioner has determined and communicated orally or by written direction that such medication preparation assistance is necessary and appropriate.

NEW SECTION

WAC 246-945-716 Enabler. (1) Enablers are physical devices used to facilitate an individual's/resident's self-administration of a medication. Physical devices include, but are not limited to, a medicine cup, glass, cup, spoon, bowl, prefilled syringes, syringes used to measure liquids, specially adapted table surface, straw, piece of cloth, or fabric.

(2) An individual's hand may also be an enabler. The practice of "hand-over-hand" administration is not allowed. Medication administration with assistance includes steadying or guiding an individual's hand while he or she applies or instills medications such as ointments, eye, ear, and nasal preparations.

NEW SECTION

WAC 246-945-718 Alteration of medication for self-administration with assistance. Alteration of a medication for self-administration with assistance includes, but is not limited to, crushing tablets, cutting tablets in half, opening capsules, mixing powdered medications with foods or liquids, or mixing tablets or capsules with foods or liquids. Individuals/residents must be aware that the medication is being altered or added to their food.

NEW SECTION

WAC 246-945-720 Medication alteration. A practitioner practicing within their scope of practice must determine that it is safe to alter a legend drug or controlled substance. If the medication is altered, and a practitioner has determined that such medication alteration is necessary and appropriate, the determination shall be communicated orally or by written direction. Documentation of the appropriateness of the alteration must be on the prescription container, or in the individual's/resident's record.

NEW SECTION

WAC 246-945-722 Types of assistance provided by nonpractitioner. A nonpractitioner can transfer a medication from one container to another for the purpose of an individual dose. Examples include: Pouring a liquid medication from the medication container to a calibrated spoon or medication cup.

NEW SECTION

WAC 246-945-724 Oxygen order/prescription requirements. Under state law, oxygen is not a medication and is not covered under this rule. While oxygen is not considered a medication under state law, oxygen does require an order/prescription from a practitioner.

NEW SECTION

WAC 246-945-726 Self-administration with assistance of medication through a gastrostomy or "g-tube." If a prescription is written as an oral medication via "g-tube," and if a practitioner has determined that the medication can be altered, if necessary, for use via "g-tube," the rules as outlined for self-administration with assistance would also apply.

NEW SECTION

WAC 246-945-728 Other medication assistance requirements. A practitioner, nonpractitioner, and an individual/resident or their representative should be familiar with the rules specifically regulating the residential setting. The department of social and health services has adopted rules relating to medication services in assisted living facilities and adult family homes.