



PROPOSED RULE MAKING

CR-102 (June 2012)

(Implements RCW 34.05.320)

Do NOT use for expedited rule making

Agency: Health Care Authority, Washington Apple Health

- Preproposal Statement of Inquiry was filed as WSR 16-09-011; or
- Expedited Rule Making--Proposed notice was filed as WSR _____; or
- Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1).

- Original Notice
- Supplemental Notice to WSR _____
- Continuance of WSR _____

Title of rule and other identifying information:

Chapter 182-50 WAC Prescription drug program

Hearing location:

Health Care Authority
Cherry Street Plaza Building; Sue Crystal Conf Rm 106A
626 - 8th Avenue, Olympia WA 98504

Metered public parking is available street side around building. A map is available at:
http://www.hca.wa.gov/documents/directions_to_csp.pdf
or directions can be obtained by calling: (360) 725-1000

Date: **July 26, 2016** Time: **10:00 a.m.**

Date of intended adoption: Not sooner than July 27, 2016
(Note: This is **NOT** the **effective** date)

Submit written comments to:

Name: HCA Rules Coordinator
Address: PO Box 45504, Olympia WA, 98504-5504
Delivery: 626 – 8th Avenue, Olympia WA 98504
e-mail arc@hca.wa.gov
fax (360) 586-9727

by **5:00 pm on July 26, 2016**

Assistance for persons with disabilities: Contact Amber Lougheed by July 22, 2016
e-mail: amber.lougheed@hca.wa.gov or (360) 725-1349
TTY (800) 848-5429 or 711

Purpose of the proposal and its anticipated effects, including any changes in existing rules:

The agency is amending chapter 182-50 WAC to clarify rules regarding therapeutic alternatives and therapeutic interchange.

Reasons supporting proposal: See purpose.

Statutory authority for adoption: RCW 41.05.021, 41.05.160

Statute being implemented: RCW 41.05.021, 41.05.160, 69.41.190

Is rule necessary because of a:

- Federal Law? Yes No
 - Federal Court Decision? Yes No
 - State Court Decision? Yes No
- If yes, CITATION:

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: June 06, 2016

TIME: 2:39 PM

WSR 16-13-030

DATE
June 6, 2016

NAME
Wendy Barcus

SIGNATURE

TITLE
HCA Rules Coordinator

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters: N/A

Name of proponent: Health Care Authority

- Private
 Public
 Governmental

Name of agency personnel responsible for:

Name	Office Location	Phone
Drafting..... Chantelle Diaz	PO Box 42716, Olympia WA, 98504-2716	(360) 725-1842
Implementation.... Ryan Pistoresi	PO Box 45502, Olympia WA, 98504-5502	(360) 725-0473
Enforcement..... Ryan Pistoresi	PO Box 45502, Olympia WA, 98504-5502	(360) 725-0473

Has a small business economic impact statement been prepared under chapter 19.85 RCW or has a school district fiscal impact statement been prepared under section 1, chapter 210, Laws of 2012?

Yes. Attach copy of small business economic impact statement or school district fiscal impact statement.

A copy of the statement may be obtained by contacting:

Name:

Address:

phone ()

fax ()

e-mail

No. Explain why no statement was prepared.

The agency has determined that the proposed filing does not impose a disproportionate cost impact on small businesses or nonprofits.

Is a cost-benefit analysis required under RCW 34.05.328?

Yes A preliminary cost-benefit analysis may be obtained by contacting:

Name:

Address:

phone ()

fax ()

e-mail

No: Please explain:

RCW 34.05.328 does not apply to Health Care Authority rules unless requested by the Joint Administrative Rules Review Committee or applied voluntarily.

AMENDATORY SECTION (Amending WSR 04-06-021, filed 2/23/04, effective 3/25/04)

WAC 182-50-001 Authority and purpose. RCW 41.05.021 (1)((+a)) (b)(iii) and 70.14.050 authorize the ((~~administrator~~)) director to establish an independent Washington state pharmacy and therapeutics committee within the health care authority to evaluate available evidence of the relative safety, efficacy and the effectiveness of prescription drugs within a class of prescription program drugs, in the development of an evidence-based prescription drug program for participating state purchased health care programs. This section requires the ((~~administrator~~)) director to adopt rules governing practitioner endorsement and use of ((~~any~~)) the Washington preferred drug list developed as part of the prescription drug program.

AMENDATORY SECTION (Amending WSR 07-19-031, filed 9/12/07, effective 10/13/07)

WAC 182-50-005 Definitions. When used in this chapter:

(1) "Appointing authority" ((~~shall~~)) means the following ((~~persons~~)) people acting jointly: The ((~~administrator~~)) director of the health care authority((~~, the secretary of the department of social and health services,~~)) and the director of the department of labor and industries.

(2) "Committee" means the independent Washington state pharmacy and therapeutics committee created by RCW 41.05.021 (1)((+a)) (b)(iii) and 70.14.050. At the election of the ((~~department of social and health services~~)) health care authority, the committee may serve as the drug use review board provided for in WAC ((~~388-530-1850~~)) 182-530-4000.

(3) "Drug" means the term as it is defined in RCW 69.41.010 ((~~+9~~) and (~~12~~)).

(4) "Endorsing practitioner" means a practitioner who ((~~has reviewed the preferred drug list and~~)) has notified the health care authority that he or she ((~~has agreed~~)) agrees to allow therapeutic interchange ((~~of a preferred drug for any nonpreferred drug in a given therapeutic class~~)).

(5) "Practitioner" means a health care provider, except a veterinarian, as defined at RCW 18.64.011((~~+9~~)).

(6) "Preferred drug" means a drug selected by the appointing authority for inclusion in the Washington preferred drug list used by applicable state agencies for state purchased health care programs.

(7) ((~~"Preferred drug list" or "PDL" means the list of drugs selected by the appointing authority to be used by applicable state agencies as the basis for the purchase of drugs in state purchased health care programs.~~

(~~8~~)) "Prescription" has the meaning set forth in RCW 18.64.011((~~+8~~)).

((~~+9~~)) (8) "Refill" means the continuation of therapy with the same drug, ((~~+~~)) including the renewal of a previous prescription or adjustments in dosage((~~-~~) when a prescription is for an antipsychotic, antidepressant, chemotherapy, antiretroviral, or immunosuppressive drug, or for the refill of a immunomodulator/antiviral treatment for

hepatitis C for which an established, fixed duration of therapy is prescribed for at least twenty four weeks but no more than forty eight weeks)).

((10)) (9) "State purchased health care" has the meaning set forth in RCW 41.05.011((2)).

((11) "Therapeutic alternatives" are drug products of different chemical structure within the same pharmacologic or therapeutic class and that are expected to have similar therapeutic effects and safety profiles when administered in therapeutically equivalent doses.

(12)) (10) "Therapeutic interchange" means to dispense((, with the endorsing practitioner's authorization, a therapeutic alternative to the)) a preferred drug in place of a prescribed nonpreferred drug within the same therapeutic class listed on the Washington preferred drug list.

(11) "Washington preferred drug list" or "WPDL" means the list of drugs selected by the appointing authority to be used by applicable state agencies as the basis for the purchase of drugs in state purchased health care programs.

AMENDATORY SECTION (Amending WSR 04-06-021, filed 2/23/04, effective 3/25/04)

WAC 182-50-010 Purpose of the pharmacy and therapeutics committee. The purpose of the committee is to evaluate the available evidence of the relative safety, efficacy, and effectiveness of prescription drugs within a class of prescription drugs and make recommendations to the appointing authority for its deliberation in the development of the Washington preferred drug list established in RCW 70.14.050.

AMENDATORY SECTION (Amending WSR 04-06-021, filed 2/23/04, effective 3/25/04)

WAC 182-50-015 Open Public Meetings Act and Administrative Procedure Act; exception as technical review committee. (1) Meetings of the pharmacy and therapeutics committee ((shall in all respects)) comply with the provisions of the Open Public Meetings Act, chapter 42.30 RCW, and ((shall be)) are subject to the provisions of the Administrative Procedure Act, chapter 34.05 RCW, as applicable.

(2) The pharmacy and therapeutics committee ((shall)) constitutes a technical review committee created to facilitate the development, acquisition, or implementation of ((a)) the Washington preferred drug list, for the purposes of state purchased health care under RCW 41.05.026, and ((as such)) may hold an executive session in accordance with chapter 42.30 RCW during any regular or special meeting to discuss information submitted in accordance with RCW 41.05.026 ((1) through (5)).

WAC 182-50-025 Membership and qualifications of pharmacy and therapeutics committee. (1) The committee ~~((shall))~~ consists of no fewer than ten members appointed by the appointing authority.

(2) The appointing authority has the sole right to appoint committee members and may terminate appointment of any member at any time during the term.

(3) The appointing authority ~~((will))~~ makes appointments to the committee from a pool of interested applicants. Interested ~~((persons will be))~~ people are provided an opportunity to submit applications to the appointing authority.

(4) Members ~~((shall))~~ enter into an agreement with the health care authority at the time of their appointment to the committee and ~~((shall))~~ act in accordance with all of its terms and conditions. Failure to do so may result in termination of the appointment.

(5) The membership composition at all times ~~((shall be))~~ is consistent with applicable federal requirements ~~((under the federal Social Security Act, Title 19 § 1927 and the requirements of the department of social and health services medical assistance administration))~~ for its drug utilization review board ~~((Therefore,))~~ under the federal Social Security Act, Title 19 Sec. 1927 and the requirements of the health care authority. Pharmacists and physicians each ~~((shall))~~ represent at least thirty-one percent, but no more than fifty-one percent of committee membership respectively.

(6) Members must be actively practicing in their clinical area of expertise throughout the entire term of their appointments.

(7) Members must have knowledge and expertise in one or more of the following:

(a) Clinically appropriate prescribing of covered outpatient drugs;

(b) Clinically appropriate dispensing and monitoring of covered outpatient drugs;

(c) Drug use review;

(d) Medical quality assurance;

(e) Disease state management; or

(f) Evidence-based medicine.

(8) Members of the committee ~~((shall))~~ must not be employed by a pharmaceutical manufacturer, a pharmacy benefits management company, or by any state agency administering state purchased health care programs during their terms ~~((shall))~~ and must not have been so employed ~~((and))~~ for eighteen months prior to their appointment.

(9) A member ~~((shall))~~ must not have a substantial financial conflict of interest including any interest in any pharmaceutical company, including the holding of stock options or the receipt of honoraria or consultant moneys. The appointing authority in its sole discretion may disqualify any potential member if it determines that a substantial conflict of interest exists.

(10) As part of the application process, prospective committee members ~~((shall))~~ must complete a conflict of interest disclosure form, provided by the appointing authority, and after appointment, annually by July 1st of each year. Members must keep their disclosure statements current and provide updated information whenever circumstances change.

(11) Committee members must agree to keep all proprietary information confidential.

AMENDATORY SECTION (Amending WSR 04-06-021, filed 2/23/04, effective 3/25/04)

WAC 182-50-030 Period of appointment. (1) Members (~~shall be~~) are appointed to a term of three years and (~~shall~~) serve until a successor is (~~duly~~) appointed. A member may be reappointed to one additional three-year term for a total of six years. One year after the end of a six-year term, a person is eligible for appointment to one additional three-year term.

(2) Committee members serve staggered three-year terms. Of the initial appointees, in order to provide for staggered terms, some members may be appointed initially for less than three years. If the initial appointment is for less than twenty-four months, that period of time (~~shall not be~~) is not counted toward the limitation of years of appointment described in subsection (1) of this section.

(3) Vacancies on the committee will be filled for the balance of the unexpired term from nominee lists for the appropriate committee category as provided under WAC 182-50-025.

(4) Members of the committee (~~will be~~) are compensated for participation in the work of the committee in accordance with a personal services contract executed after appointment and prior to commencement of activities related to the work of the committee.

AMENDATORY SECTION (Amending WSR 04-06-021, filed 2/23/04, effective 3/25/04)

WAC 182-50-035 Duties. Committee members (~~shall~~):

(1) Select a chair and a vice-chair from among the committee membership.

(2) Meet at least quarterly and may meet at other times at the discretion of the chair.

(3) Adopt a plan of operation that sets forth the policies and procedures established by the committee to develop an evidence-based prescription drug program as authorized by state law for approval by the appointing authority.

(4) Operate according to the plan of operation as approved by the appointing authority.

AMENDATORY SECTION (Amending WSR 07-19-031, filed 9/12/07, effective 10/13/07)

WAC 182-50-200 Endorsing practitioner therapeutic interchange program; effect of practitioner's endorsing status; dispense as written instructions. (1) When filling prescriptions for participating state purchased health care programs, pharmacists (~~shall dispense a~~

~~preferred drug in place of a drug not included in the preferred drug list in a given therapeutic class whenever pharmacists receive a prescription from)) must make a therapeutic interchange if the prescription is prescribed by an endorsing practitioner except:~~

~~(a) If the endorsing practitioner ((determines the nonpreferred drug is medically necessary by indicating)) indicates "dispense as written" on the nonpreferred prescription; ((or))~~

~~(b) If the prescription is a refill of an antipsychotic, antidepressant, antiepileptic, chemotherapy, antiretroviral, ((or)) immunosuppressive drug, or ((for the refill of a)) an immunomodulator/antiviral treatment for hepatitis C ((for which an established, fixed duration of therapy is prescribed for at least twenty four weeks but no more than forty eight weeks)); or~~

~~(c) If the pharmacy and therapeutics committee has determined that therapeutic interchange is not clinically appropriate for a specific drug or drug class on the Washington preferred drug list.~~

~~(2) When a therapeutic interchange is made, the pharmacist ((shall)) must notify the endorsing practitioner of the specific drug and dose dispensed.~~

~~((3) When a nonendorsing practitioner issues a prescription for a drug not included in the preferred drug list, the pharmacist shall dispense the prescribed drug in accordance with the requirements of RCW 69.41.100 through 69.41.180.))~~