



PROPOSED RULE MAKING

CR-102 (June 2012)

(Implements RCW 34.05.320)

Do NOT use for expedited rule making

Agency: Health Care Authority

- Preproposal Statement of Inquiry was filed as WSR 14-10-070 ; 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:

- 182-55-005, Authority and purpose
- 182-55-010, Definitions
- 182-55-015, Committee purpose
- 182-55-020, Committee selection
- 182-55-025, Committee member requirements and committee member terms
- 182-55-026, Committee governance
- 182-55-030, Committee coverage determination process
- 182-55-035, Committee coverage determination
- 182-55-040, Review and publication of coverage determinations
- 182-55-045, Advisory group
- 182-55-050, Health technology selection
- 182-55-055, Health technology assessment

Hearing location(s):

Health Care Authority
Cherry Street Plaza Building; Sue Crystal Conf Rm 106B
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: October 27, 2015 Time: 10:00 a.m.

Date of intended adoption: Not sooner than October 28, 2015
(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 October 23, 2015

Assistance for persons with disabilities:

Contact Amber Lougheed by 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 Health Care Authority (HCA) has not reviewed Chapter 182-55 WAC since its adoption in 2006. HCA is conducting this rule-making action to provide clarification and modernization of the rules, as well as the adoption of a rule(s) addressing administrative review processes of Health Technology Assessment (HTA) actions and decisions

Reasons supporting proposal: See purpose of the proposal above.

Statutory authority for adoption: RCW 41.05.021, 41.05.160

Statute being implemented: RCW 41.05.021, 41.05.160

Is rule necessary because of a:

- Federal Law? Yes No
 - Federal Court Decision? Yes No
 - State Court Decision? Yes No
 - If yes, CITATION: Yes No
- King County Superior Court, No. 13-2-03122-1 SEA

DATE September 22, 2015

NAME (type or print)
Wendy Barcus

SIGNATURE

TITLE HCA Rules Coordinator

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: September 22, 2015

TIME: 3:45 PM

WSR 15-19-151

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters: None

Name of proponent: Health Care Authority

- Private
- Public
- Governmental

Name of agency personnel responsible for:

Name	Office Location	Phone
Drafting..... Melinda Froud	P.O. Box 42716 Olympia, Washington	(360) 725-1408
Implementation.... David Iseminger	P.O. Box 45504 Olympia, Washington	(360) 725-9792
Enforcement..... David Iseminger	P.O. Box 45504 Olympia, Washington	(360) 725-9792

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 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 06-23-083, filed 11/13/06, effective 12/14/06)

WAC 182-55-005 Authority and purpose. Under RCW 70.14.080 through 70.14.140, the ~~((administrator))~~ director of the Washington state health care authority is required to ~~((establish and))~~ provide administrative support for, and is authorized to adopt rules to govern~~((,))~~ the health technology clinical committee and a health technology assessment program ~~((that uses evidence to make coverage determinations for participating state agencies that purchased health care))~~ within the health care authority. The health technology assessment program will:

- ~~(1) ((Selects health technologies for assessment;~~
- ~~(2))~~ Contract ~~((s))~~ with an evidence-based technology assessment center to produce health technology assessments;
- ~~((3) Establishes an))~~ (2) Administratively support the independent health technology clinical committee; and
- ~~((4))~~ (3) Maintain ~~((s))~~ a centralized, internet-based communication tool.

AMENDATORY SECTION (Amending WSR 06-23-083, filed 11/13/06, effective 12/14/06)

WAC 182-55-010 Definitions. When used in this chapter:

~~(1) ("Administrator" means the administrator of the Washington state health care authority under chapter 41.05 RCW, as set forth in RCW 70.14.080, as amended.~~

~~(2))~~ "Advisory group" as defined in RCW 70.14.080 means a group established under RCW 70.14.110 (2)(c).

(2) "Centralized, internet-based communication tool" means the health care authority's health technology assessment program internet web pages established pursuant to RCW 70.14.130(1).

(3) "Committee" as defined in RCW 70.14.080 means the health technology clinical committee (HTCC) established under RCW 70.14.090.

(4) "Coverage determination" as defined in RCW 70.14.080 means a determination of the circumstances, if any, under which a health technology will be included as a covered benefit in a state-purchased health care program ~~((, as set forth in RCW 70.14.080, as amended))~~.

(5) "Director" means the director of the Washington state health care authority under chapter 41.05 RCW.

(6) "Health technology" as defined in RCW 70.14.080 means medical and surgical devices and procedures, medical equipment, and diagnostic tests. Health technologies do not include prescription drugs governed by RCW 70.14.050.

~~((6))~~ (7) "Participating agency" as defined in RCW 70.14.080 means the department of social and health services, the state health care authority, and the department of labor and industries ~~((, as set forth in RCW 70.14.080, as amended.~~

~~(7) "Reimbursement determination" means a determination to provide or deny reimbursement for a health technology included as a covered benefit in a specific circumstance for an individual patient who is eligible to receive health care services from the state purchased~~

health care program making the determination, as set forth in RCW 70.14.080, as amended)).

(8) "Health technology assessment" means a report produced by a contracted evidence-based technology assessment center as provided for in RCW 70.14.100(4) that is based on a systematic review of evidence of a technology's safety, efficacy, and cost-effectiveness.

AMENDATORY SECTION (Amending WSR 06-23-083, filed 11/13/06, effective 12/14/06)

WAC 182-55-015 Committee purpose. The purpose of the committee is to make coverage determinations for the participating agencies (~~((based on: A health technology assessment that reviews the scientific evidence of the relative safety, efficacy, and cost; information from any special advisory groups; and their professional knowledge and expertise))~~).

AMENDATORY SECTION (Amending WSR 06-23-083, filed 11/13/06, effective 12/14/06)

WAC 182-55-020 Committee selection. (1) The ~~((administrator))~~ director, in consultation with the participating state agencies, ~~((shall make appointments to))~~ appoints vacant committee positions ~~((, including the appointment of a chair,))~~ from a pool of interested applicants. Interested persons ~~((will be))~~ are provided an opportunity to submit applications to the ~~((administrator))~~ director for consideration.

(2) When appointing committee members, the ~~((administrator will))~~ director considers, in addition to the membership requirements imposed by RCW 70.14.090 ~~((and any))~~, other relevant information ~~((,))~~ including the following ~~((factors))~~: Practitioner specialty or type and use of health technologies, especially in relation to current committee member specialty or types; practice location and community knowledge; length of practice experience; knowledge of and experience with evidence-based medicine, including formal additional training in fields relevant to evidence-based medicine; medical quality assurance experience; and health technology assessment review experience.

AMENDATORY SECTION (Amending WSR 06-23-083, filed 11/13/06, effective 12/14/06)

WAC 182-55-025 Committee member requirements and committee member terms. (1) As a continuing condition of appointment, committee members:

(a) ~~((Shall))~~ Must not have a substantial financial conflict of interest, such as an interest in a health technology company, including the holding of stock options, or the receipt of honoraria, or consultant moneys;

(b) Must complete a conflict of interest disclosure form, update the form annually, and keep disclosure statements current;

(c) Must abide by confidentiality requirements and keep all personal medical information and proprietary information confidential; and

(d) ~~((Shall))~~ Must not utilize information gained as a result of committee membership outside of committee responsibilities, unless such information is publicly available. The ~~((administrator))~~ director, in his/her sole discretion, may disqualify committee members if ~~((he/she))~~ the director determines that the committee member has violated a condition of appointment.

~~(2) ((Committee members shall be appointed to a term of three years and shall serve until a successor is appointed. A member may be reappointed for additional three year terms for a total of nine years. One year after the end of a nine year term, a person is eligible for appointment to one additional three year term.))~~ Committee members serve staggered three-year terms. ~~((Of the initial members,))~~ In order to provide for staggered terms, ~~((some))~~ committee members may be appointed initially for less than three years. If ~~((an))~~ a committee member's initial appointment is for less than twenty-four months, that period of time ~~((shall))~~ is not ~~((be))~~ counted toward the limitation of years of appointment~~((. Vacancies on the committee will be filled for the balance of the unexpired term.))~~

~~(3) The appointed committee chair shall select a vice chair from among the committee membership; ratify committee bylaws approved by the administrator; and operate the committee according to the bylaws and committee member agreements))~~ described in subsection (3) of this section.

(3) A committee member may be appointed for a total of nine years of service on the committee, but an initial appointment that is less than twenty-four months will not be included in the nine-year limitation. One year after the end of nine consecutive years of service, a former committee member is eligible for appointment to one additional three-year term.

(4) A committee member may serve until a successor is appointed to his or her position notwithstanding the limits on service in subsection (3) of this section.

(5) Mid-term vacancies on the committee are filled for the remainder of the unexpired three-year term.

NEW SECTION

WAC 182-55-026 Committee governance. (1) The committee may establish bylaws, within the applicable statutory and regulatory requirements, to govern the orderly resolution of the committee's purposes. Committee bylaws shall be published on the centralized, internet-based communication tool.

(2) The director appoints a committee chair.

(3) The committee chair:

(a) Selects a vice-chair from among the committee membership;

(b) Presents bylaws, or amendments to the bylaws, to the committee for review and ratification; and

(c) Operates the committee according to the bylaws and committee member agreements.

AMENDATORY SECTION (Amending WSR 06-23-083, filed 11/13/06, effective 12/14/06)

WAC 182-55-030 Committee coverage determination process. (1) In making a coverage determination, committee members shall review and consider the health technology assessment. The committee may also consider other information it deems relevant, including other information provided by the ~~((administrator))~~ director, reports ~~((and/))~~ or testimony from an advisory group, and submissions or comments from the public.

(2) The committee shall give the greatest weight to the evidence determined, based on objective factors, to be the most valid and reliable, considering the nature and source of the evidence, the empirical characteristic of the studies or trials upon which the evidence is based, and the consistency of the outcome with comparable studies. The committee may also consider additional evidentiary valuation factors such as recency ~~((date of information)); relevance (the applicability of the information to the key questions presented or participating agency programs and clients); and bias (presence of conflict of interest or political considerations))~~, relevance, and bias.

AMENDATORY SECTION (Amending WSR 06-23-083, filed 11/13/06, effective 12/14/06)

WAC 182-55-035 Committee coverage determination. Based on the evidence regarding safety, efficacy, and cost-effectiveness of the health technology, the committee shall:

(1) Determine the conditions, if any, under which the health technology will be included as a covered benefit in health care programs of participating agencies by deciding that:

(a) Coverage is allowed without special conditions because the evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for all indicated conditions; or

(b) Coverage is allowed with special conditions because the evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective in only certain situations; or

(c) Coverage is not allowed because either the evidence is insufficient to conclude that the health technology is safe, efficacious, and cost-effective or the evidence is sufficient to conclude that the health technology is unsafe, ~~((ineffectual))~~ inefficacious, or not cost-effective.

(2) Identify whether the coverage determination is consistent with the identified medicare ~~((decisions))~~ national coverage determinations and expert treatment guidelines.

(3) For decisions that are inconsistent with either the identified medicare ~~((decisions))~~ national coverage determinations or expert treatment guidelines, specify the reason(s) for the decision and the evidentiary basis.

(4) For covered health technologies, specify criteria for participating agencies to use when deciding whether the health technology is medically necessary or proper and necessary treatment.

WAC 182-55-040 Review and publication of ((committee)) coverage determinations. (1) For each health technology reviewed by the committee, the director reviews the sufficiency and validity of the health technology review process for that health technology and certifies the coverage determination for that health technology before implementation by a participating agency. The review occurs after publication of the final committee coverage determination, as described in this section, and includes whether the:

(a) Notification of the review of the health technology was made on the centralized, internet-based communication tool as required by RCW 70.14.130 (1)(a);

(b) Health technology assessment provided to the committee met the requirements in RCW 70.14.100(4) and WAC 182-55-055;

(c) Health technology assessment was publicly available at least fourteen calendar days before the committee's consideration of the health technology assessment;

(d) Health technology assessment was considered by the committee in an open and transparent process, as required by RCW 70.14.110 (2)(a);

(e) Committee provided an opportunity for public comment prior to the committee's final coverage determination decision;

(f) Committee acknowledged public comment timely received after publication of the committee's draft coverage determination and before the committee's final coverage determination decision;

(g) Committee's final coverage determination specifies the reason(s) for a decision that is inconsistent with the identified medicare national coverage determinations and expert treatment guidelines for the reviewed health technology; and

(h) Committee meetings complied with the requirements of the Open Public Meetings Act as required by RCW 70.14.090(3).

(2) After the committee makes its final coverage determination for a health technology, the director certifies in writing the coverage determination for implementation by a participating agency, unless the director identifies a failure to meet the requirements outlined in subsection (1) of this section in the committee's decision-making process.

(a) The director's certification occurs within thirty calendar days of the committee's final coverage determination.

(b) When the director denies the certification, the director must send the final coverage determination back to the committee for further consideration and indicate the certification requirements that were not met.

(c) When the director approves a certification, a copy of the written certification is published on the centralized, internet-based communication tool and in the Washington State Register.

(d) The director's final written certification decision can be appealed as other agency action, as described in RCW 34.05.570(4), by an aggrieved individual who is eligible to receive a participating agency's state-purchased health care program. An appeal must be filed in superior court and comply with all statutory requirements for judicial review of other agency action required in chapter 34.05 RCW.

(3) The ((administrator shall)) director will publish the final ((committee)) coverage determinations ((by posting on a)) on the cen-

tralized, internet-based communication tool within ten business days of the director's certification described in subsection (2) of this section.

~~((2))~~ (4) Upon publication, participating agencies will implement the committee coverage determination according to their statutory, regulatory, or contractual process unless(~~+~~

(a) ~~The determination conflicts with an applicable federal statute or regulation, or applicable state statute; or~~

(b) ~~Reimbursement is provided under an agency policy regarding experimental or investigational treatment, services under a clinical investigation approved by an institutional review board, or health technologies that have a humanitarian device exemption from the federal food and drug administration)~~ the provisions of RCW 70.14.120(1) apply.

AMENDATORY SECTION (Amending WSR 06-23-083, filed 11/13/06, effective 12/14/06)

WAC 182-55-045 Advisory group. (1) The committee chair, upon an affirmative vote of the committee members, may establish ad hoc temporary advisory ~~((group(s) if specialized expertise or input from enrollees or clients is needed to review a particular health technology or group of health technologies. The purpose or scope of the advisory group and time period shall be stated. The advisory group shall provide a report and/or testimony to the committee on the key questions identified by the committee as requiring the input of the advisory group.~~

~~(2) Advisory group membership~~)) groups pursuant to RCW 70.14.110 (2)(c). At the time an ad hoc temporary advisory group is formed, the committee must state the ad hoc temporary advisory group's objective and questions to address.

(2) The committee chair shall make recommendations to the director for appointments to the ad hoc temporary advisory group. An ad hoc temporary advisory group ((shall)) must include at least three members. ((Membership should reflect the diverse perspectives and/or technical expertise that drive the need for the specialized advisory group.)) The advisory group ((will generally)) must include at least one enrollee, client, or patient(~~+~~and)). The advisory group must have two or more experts or specialists within the field relevant to the health technology, preferably with demonstrated experience in the use, evaluation, or research of the health technology((. If substantial controversy over the health technology is present,)); at least one expert ~~((that is))~~ must be a proponent or advocate of the health technology and at least one expert ~~((that is))~~ must be an opponent or critic of the health technology ~~((should be appointed. A majority of each advisory group shall have no substantial financial interest in the health technology under review)).~~

(3) ~~((As a continuing condition of appointment, advisory group members~~

~~(a))~~ The committee chair, or designee, may disqualify or remove an advisory group member. Each advisory group member:

(a) Must not have a substantial financial conflict of interest, such as an interest in a health technology company, including the

holding of stock options, or the receipt of honoraria, or consultant moneys;

(b) Must complete an advisory group member agreement, including a conflict of interest disclosure form, and keep disclosure statements current;

~~((b))~~ (c) Must abide by confidentiality requirements and keep all personal medical information and proprietary information confidential; and

~~((e) Shall)~~ (d) Must not utilize information gained as a result of advisory group membership outside of advisory group responsibilities, unless such information is publicly available.

AMENDATORY SECTION (Amending WSR 06-23-083, filed 11/13/06, effective 12/14/06)

WAC 182-55-050 Health technology selection. (1) ~~((Prior to selection of a health technology for review or rereview, the administrator shall consider nominations from participating agencies and recommendations from the committee.))~~ The director, in consultation with participating agencies and the committee, selects health technologies to be reviewed or rereviewed by the committee.

(2) The ~~((administrator))~~ director or committee may also consider petitions requesting initial review of a health technology from interested parties. ~~((The administrator shall make available, including publication to the centralized internet based communication tool required at RCW 70.14.130, a petition for interested parties to request a health technology be selected for a review or rereview. Interested parties shall complete the petition and submit it to the administrator. The administrator, or designee, will provide copies of the petition to participating agencies and the committee for comment, and provide the completed petition, with any comments, to the administrator for consideration.~~

~~(2) Interested parties that have submitted a petition for the review or rereview of a health technology that was not selected by the administrator may submit the petition to the committee for review or rereview.~~

~~(3) The committee may consider petitions submitted by interested parties for review or rereview of a health technology. The committee shall apply the priority criteria set forth in RCW 70.14.100.~~

~~(4))~~ To suggest a topic for initial review, interested parties must use the petition form made available on the centralized, internet-based communication tool. The health technology assessment program will provide copies of the petition to the director, committee members, and participating agencies.

(a) Petitions are considered by the director, in consultation with participating agencies and the committee.

(b) Only after the director has declined to grant the petition can a petition be reviewed by the committee, pursuant to RCW 70.14.100(3).

(c) If a health technology is selected by the committee ~~((shall be)),~~ the health technology is referred to the ~~((administrator))~~ director for assignment to the next available contract for a health technology assessment review as described in RCW 70.14.100(4).

(3) Interested parties may submit a petition for the rereview of a health technology. Petitions for rereview are accepted only after a notice is published on the centralized, internet-based communication that the health technology is eligible for rereview. Interested parties must use the petition form made available on the centralized, internet-based communication tool and may submit to the health technology assessment program any new evidence that could change the previous coverage determination. The health technology assessment program will provide copies of the petition to the director, committee members, and participating agencies.

(a) Petitions are considered by the director, in consultation with participating agencies and the committee.

(b) Only after the director has declined to grant the petition can a petition be reviewed by the committee, pursuant to RCW 70.14.100(3).

AMENDATORY SECTION (Amending WSR 06-23-083, filed 11/13/06, effective 12/14/06)

WAC 182-55-055 Health technology assessment. (1) Upon providing notice of the selection of the health technology for review on the centralized, internet-based communication tool required by RCW 70.14.100 (1)(b), the ((administrator)) director shall post an invitation for interested parties to submit information relevant to the health technology for consideration by the evidence-based technology assessment center. ((Such)) The relevant information ((shall be required to)) must be submitted to the ((administrator,)) director or designee ((,no earlier than)) within thirty calendar days from the date of the notice.

(2) Upon notice of the selection of the health technology for review, the ((administrator)) director or designee shall request participating agencies to provide information relevant to the health technology, including data on safety, health outcome, and cost. ((Such)) The relevant information ((shall be required to)) must be submitted to the ((administrator,)) director or designee ((,no earlier than)) within thirty calendar days from the date of the notice.

(3) Upon notice of the selection of the health technology for review, the ((administrator)) director or designee shall ((require staff to)) identify ((and organize)) relevant federal medicare national coverage determinations and expert treatment guidelines, and any referenced information used as the basis for such determinations ((and/)or guidelines.

(4) The ((administrator)) director shall provide all information ((relevant to the selected health technology)) gathered pursuant to subsections (1), (2), and (3) of this section to the evidence-based technology assessment center((+)) and shall post such information, along with the key questions for review, on ((a)) the centralized, internet-based communication tool.

(5) Upon completion of the health technology assessment by the evidence-based technology assessment center, the ((administrator)) director shall provide the committee with:

(a) ((Final)) A copy of the health technology assessment;

(b) Information as to whether the federal medicare program has made a national coverage determination;

(c) A copy of identified medicare national coverage ((decisions)) determinations and accompanying information describing the basis for the decision; and

(d) Information as to whether expert treatment guidelines exist, including those from specialty physician organizations and patient advocacy organizations(~~;~~ and

~~(e) A copy of identified guidelines and accompanying information~~), and describing the basis for the guidelines.