Chapter 182-55 WAC
HEALTH TECHNOLOGY ASSESSMENT PROGRAM

Last Update: 8/26/16

WAC

WAC 182-55-005 Authority and purpose. Under RCW 70.14.080 through 70.14.140, the director of the Washington state health care authority provides administrative support for, and adopts rules to govern the health technology clinical committee and a health technology assessment program within the health care authority. The health technology assessment program will:

(1) Contract with an evidence-based technology assessment center to produce health technology assessments;

(2) Administratively support the independent health technology clinical committee; and

(3) Maintain a centralized, internet-based communication tool.

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 16-18-023, § 182-55-005, filed 8/26/16, effective 9/26/16. Statutory Authority: RCW 41.05.013, 41.05.160, and 70.14.090. WSR 06-23-083 (Order 06-10), § 182-55-005, filed 11/13/06, effective 12/14/06.]

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

(1) "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 under RCW 70.14.130(1).

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

(5) "Decisions made under the federal medicare program" means national coverage determinations issued by the Centers for Medicare and Medicaid Services stating whether and to what extent medicare covers specific services, procedures, or technologies.

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

(7) "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.

(8) "Health technology assessment" means a report produced by a contracted, evidence-based, technology assessment center or other ap-

propriate entity, as provided for in RCW 70.14.100(4), based on a systematic review of evidence of a technology's safety, efficacy, and cost-effectiveness.

(9) "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.

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 16-18-023, § 182-55-010, filed 8/26/16, effective 9/26/16. Statutory Authority: RCW 41.05.013, 41.05.160, and 70.14.090. WSR 06-23-083 (Order 06-10), § 182-55-010, 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 as described under RCW 70.14.110.

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 16-18-023, § 182-55-015, filed 8/26/16, effective 9/26/16. Statutory Authority: RCW 41.05.013, 41.05.160, and 70.14.090. WSR 06-23-083 (Order 06-10), § 182-55-015, filed 11/13/06, effective 12/14/06.]

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

(2) When appointing committee members, the director considers, in addition to the membership requirements imposed by RCW 70.14.090, other relevant information, including:

(a) Practitioner specialty or type and use of health technologies, especially in relation to current committee member specialty or types;

(b) Practice location and community knowledge;

(c) Length of practice experience;

(d) Knowledge of and experience with evidence-based medicine, including formal additional training in fields relevant to evidence-based medicine;

(e) Medical quality assurance experience; and

(f) Health technology assessment review experience.

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 16-18-023, § 182-55-020, filed 8/26/16, effective 9/26/16. Statutory Authority: RCW 41.05.013, 41.05.160, and 70.14.090. WSR 06-23-083 (Order 06-10), § 182-55-020, 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 must:

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

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

(d) Not use information gained from committee membership outside of committee responsibilities, unless the information is publicly available.

(2) The director has the sole discretion to terminate a committee member's appointment if the director determines that the committee member has violated a condition of appointment.

(3) Committee members serve staggered three-year terms. To provide for staggered terms, committee members may be appointed initially for less than three years.

(4) A committee member may be appointed for a total of nine years of committee service, but an initial appointment of less than twenty-four months is not included in the nine-year limitation.

(5) A committee member may serve until that member's successor is appointed, notwithstanding the limits on service in subsection (3) of this section.

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

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 16-18-023, § 182-55-025, filed 8/26/16, effective 9/26/16. Statutory Authority: RCW 41.05.013, 41.05.160, and 70.14.090. WSR 06-23-083 (Order 06-10), § 182-55-025, filed 11/13/06, effective 12/14/06.]

WAC 182-55-026 Committee governance. (1) The committee may establish bylaws, within applicable statutory and regulatory requirements, to govern the orderly resolution of the committee's purposes. Proposed bylaw amendments are published on the centralized, internet-based communication tool at least fourteen calendar days before adoption by the committee. Before adoption, the committee gives an opportunity at an open public meeting for public comment on proposed bylaw amendments. 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.

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 16-18-023, § 182-55-026, filed 8/26/16, effective 9/26/16.]

WAC 182-55-030 Committee coverage determination process. (1) In making a coverage determination, committee members shall review and consider evidence regarding the safety, efficacy, and cost-effectiveness of the technology as set forth in the health technology assessment. The committee also considers other information it deems relevant, including other information provided by the director, reports 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 reli-

able, 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 also considers additional evidentiary valuation factors such as recency, relevance, and bias.

(3) The committee also considers any unique impacts the health technology has on specific populations based on factors like sex, age, ethnicity, race, or disability, as identified in the health technology assessment.

(4) The committee provides an opportunity for public comment after the health technology assessment is published on the centralized, internet-based communication tool and before the committee's final coverage determination decision.

(5) After the committee makes a final coverage determination, the health technology assessment program publishes it on the centralized, internet-based communication tool and submits a notice in the *Washington State Register*.

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 16-18-023, § 182-55-030, filed 8/26/16, effective 9/26/16. Statutory Authority: RCW 41.05.013, 41.05.160, and 70.14.090. WSR 06-23-083 (Order 06-10), § 182-55-030, filed 11/13/06, effective 12/14/06.]

WAC 182-55-035 Committee coverage determination. 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, inefficacious, or not cost-effective.

(2) Identify whether the coverage determination is consistent with decisions made under the federal medicare program and expert treatment guidelines.

(3) For decisions that are inconsistent with either decisions made under the federal medicare program or expert treatment guidelines, including those from specialty physician and patient advocacy organizations, specify the substantial evidence regarding the safety, efficacy, and cost-effectiveness of the technology that supports the contrary determination.

(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.

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 16-18-023, § 182-55-035, filed 8/26/16, effective 9/26/16. Statutory Authority: RCW 41.05.013, 41.05.160, and 70.14.090. WSR 06-23-083 (Order 06-10), § 182-55-035, filed 11/13/06, effective 12/14/06.]

WAC 182-55-040 Health care authority's implementation of final coverage determinations. This section applies to all final coverage determinations made after August 1, 2016.

(1) The health care authority reviews the final coverage determination for conflicts identified in RCW 70.14.120 (1)(a) and (b).

(2) The health care authority reviews whether the health technology review process meets the requirements in this subsection before compliance by the health care authority's state-purchased health care programs. The review includes whether the:

(a) Notification of the health technology selected for review 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 published on the centralized, internet-based communication tool 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 or reasons for a decision that is inconsistent with the identified decisions made under the federal medicare program and expert treatment guidelines, including those from specialty physician and patient advocacy organizations, 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).

(3) After the health care authority completes its reviews under subsections (1) and (2) of this section, it establishes an implementation date for each of the health care authority's state-purchased health care programs and publishes the implementation dates on the health care authority's website.

(4) The health care authority's implementation of a final coverage determination can be reviewed as other agency action under RCW 34.05.570(4). A petition for review 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.

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 16-18-023, § 182-55-040, filed 8/26/16, effective 9/26/16. Statutory Authority: RCW 41.05.013, 41.05.160, and 70.14.090. WSR 06-23-083 (Order 06-10), § 182-55-040, filed 11/13/06, effective 12/14/06.]

WAC 182-55-041 Judicial review of final coverage determination. Nothing in this chapter limits the superior court's inherent authority to review health technology clinical committee determinations to the extent of assuring the decisions are not arbitrary, capricious, or contrary to law.

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 16-18-023, § 182-55-041, filed 8/26/16, effective 9/26/16.]

WAC 182-55-045 Advisory group. (1) The committee chair, upon an affirmative vote of the committee members, may establish ad hoc temporary advisory groups under 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. Notice of the formation of an ad hoc temporary advisory group, and information about how to participate, shall be posted on the centralized, internet-based communication tool.

(2) The committee chair, or designee, may appoint or remove an advisory group member. An ad hoc temporary advisory group must include at least three members. The advisory group will generally include at least one enrollee, client, or patient. The advisory group must have:

(a) 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;

(b) At least one expert who is a proponent or advocate of the health technology; and

(c) At least one expert who is an opponent or critic of the health technology.

(3) Each advisory group member must:

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

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

(d) Not utilize information gained as a result of advisory group membership outside of advisory group responsibilities, unless such information is publicly available.

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 16-18-023, § 182-55-045, filed 8/26/16, effective 9/26/16. Statutory Authority: RCW 41.05.013, 41.05.160, and 70.14.090. WSR 06-23-083 (Order 06-10), § 182-55-045, filed 11/13/06, effective 12/14/06.]

WAC 182-55-050 Health technology selection. (1) The director, in consultation with participating agencies and the committee, selects health technologies to be reviewed or rereviewed by the committee.

(2) The director or committee may also consider petitions requesting initial review of a health technology from interested parties. 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 considered for selection by the committee, as described in RCW 70.14.100(3).

(c) If a health technology is selected by the committee, the health technology is referred to the 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. Interested parties must use the petition form available on the centralized, internet-based communication tool and may submit to the health technology assessment program evidence that has since become available 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, as described in RCW 70.14.100(3).

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 16-18-023, § 182-55-050, filed 8/26/16, effective 9/26/16. Statutory Authority: RCW 41.05.013, 41.05.160, and 70.14.090. WSR 06-23-083 (Order 06-10), § 182-55-050, filed 11/13/06, effective 12/14/06.]

WAC 182-55-055 Health technology assessment. (1) Upon providing notice on the centralized, internet-based communication tool required by RCW 70.14.100 (1)(b) that the health technology has been selected for review, the 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. The information must be submitted to the director or designee within thirty calendar days from the date of the notice.

(2) Upon notice of the health technology selected for review, the director or designee shall request participating agencies to provide information relevant to the health technology, including data on safety, health outcome, and cost. The relevant information must be submitted to the director or designee within thirty calendar days from the date of the notice.

(3) Upon notice of the health technology selected for review, the director or designee shall identify relevant decisions made under the federal medicare program and expert treatment guidelines, including those from specialty physician and patient advocacy organizations, and any referenced information used as the basis for such determinations or guidelines.

(4) The director shall provide all information gathered under 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 the centralized, internet-based communication tool.

(5) Upon completion of the health technology assessment by the evidence-based technology assessment center, the director shall publish a copy of the health technology assessment on the centralized, internet-based communication tool and provide the committee with:

(a) A copy of the health technology assessment;

(b) A copy of decisions made under the federal medicare program related to the health technology being reviewed and accompanying information describing the basis for the decision;

(c) Information as to whether expert treatment guidelines exist, including those from specialty physician organizations and patient advocacy organizations, and describing the basis for the guidelines.

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 16-18-023, § 182-55-055, filed 8/26/16, effective 9/26/16. Statutory Authority: RCW 41.05.013, 41.05.160, and 70.14.090. WSR 06-23-083 (Order 06-10), § 182-55-055, filed 11/13/06, effective 12/14/06.]