

Chapter 182-55 WAC

HEALTH TECHNOLOGY ASSESSMENT PROGRAM

WAC

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

- (1) Selects health technologies for assessment;
- (2) Contracts with an evidence-based technology assessment center to produce health technology assessments;
- (3) Establishes an independent health technology committee; and
- (4) Maintains a centralized, internet based communication tool.

[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) "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" means a group established under RCW 70.14.110 (2)(c).
- (3) "Committee" means the health technology clinical committee established under RCW 70.14.090.
- (4) "Coverage determination" 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) "Health technology" 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) "Participating agency" 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

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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.

[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 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.

[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 administrator, in consultation with the participating state agencies, shall make appointments to vacant committee positions, including the appointment of a chair, from a pool of interested applicants. Interested persons will be provided an opportunity to submit applications to the administrator for consideration.

(2) When appointing committee members, the administrator will consider, in addition to the membership requirements imposed by RCW 70.14.090 and any other relevant information, 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; health technology assessment review experience.

[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 terms. (1) As a continuing condition of appointment, committee members:

- (a) Shall 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;

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

(d) Shall not utilize information gained as a result of committee membership outside of committee responsibilities, unless such information is publicly available. The administrator, in his/her sole discretion, may disqualify committee members if he/she 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 members may be appointed initially for less than three years. If an initial appointment is for less than twenty-four months, that period of time shall 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.

[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 182-55-030 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, 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).

[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. 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, or not cost-effective.

(2) Identify whether the determination is consistent with the identified medicare decisions and expert guidelines.

(3) For decisions that are inconsistent with either the identified medicare decisions or expert 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.

[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 Publication of committee determinations. (1) The administrator shall publish final committee determinations by posting on a centralized, internet-based communication tool within ten days.

(2) Upon publication, participating agencies will implement the committee 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.

[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 182-55-045 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: An ad hoc temporary advisory group shall 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 include at least one enrollee, client, or patient; and two or more experts or specialists within the field relevant to the health technology, preferably with demonstrated experience in the use, evalua-

tion, or research of the health technology. If substantial controversy over the health technology is present, at least one expert that is a proponent or advocate of the health technology and at least one expert that is 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) Must complete an advisory group member agreement, including a conflict of interest disclosure form, and keep disclosure statements current;

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

(c) Shall 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 41.05.013, 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)

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 administrator may also consider petitions 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) A health technology selected by the committee shall be referred to the administrator for the next available contract for health technology assessment review.

[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 notice of the selection of the health technology for review, the administrator 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 information shall be required to be submitted to the administrator, or designee, no earlier than thirty days from the date of the notice.

(2) Upon notice of the selection of the health technology for review, the administrator shall request participating agen-

cies to provide information relevant to the health technology, including data on safety, health outcome, and cost. Such information shall be required to be submitted to the administrator, or designee, no earlier than thirty days from the date of the notice.

(3) Upon notice of the selection of the health technology for review, the administrator 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 shall provide all information relevant to the selected health technology to the evidence-based technology assessment center; and shall post such information, along with the key questions for review, on a centralized, internet based communication tool.

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

(a) Final 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 national coverage decisions and accompanying information describing the basis for the decision;

(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 describing the basis for the guidelines.

[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.]