



RULE-MAKING ORDER PERMANENT RULE ONLY

CR-103P (August 2017) (Implements RCW 34.05.360)

CODE REVISER USE ONLY

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STATE OF WASHINGTON
FILED

DATE: August 09, 2017

TIME: 3:12 PM

WSR 17-17-039

Agency: Health Care Authority

Effective date of rule:

Permanent Rules

31 days after filing.

Other (specify) _____ (If less than 31 days after filing, a specific finding under RCW 34.05.380(3) is required and should be stated below)

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

Yes No If Yes, explain:

Purpose: The agency is revising the rules governing the certification process for patient decision aids to add more guidance and specificity.

Citation of rules affected by this order:

New: 182-60-027, 182-60-035, 182-60-040, 182-60-045, 182-60-050

Repealed:

Amended: 182-60-010, 182-60-020, 182-60-025, 182-60-030

Suspended:

Statutory authority for adoption: RCW 41.05.021, 41.05.160

Other authority:)

PERMANENT RULE (Including Expedited Rule Making)

Adopted under notice filed as WSR 17-14-057 on June 29, 2017 (date).

Describe any changes other than editing from proposed to adopted version: None

If a preliminary cost-benefit analysis was prepared under RCW 34.05.328, a final cost-benefit analysis is available by contacting:

Name:

Address:

Phone:

Fax:

TTY:

Email:

Web site:

Other:

**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Federal statute:	New	___	Amended	___	Repealed	___
Federal rules or standards:	New	___	Amended	___	Repealed	___
Recently enacted state statutes:	New	___	Amended	___	Repealed	___

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

New	___	Amended	___	Repealed	___
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The number of sections adopted in the agency's own initiative:

New	___	Amended	___	Repealed	___
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The number of sections adopted in order to clarify, streamline, or reform agency procedures:

New	<u>5</u>	Amended	<u>4</u>	Repealed	___
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The number of sections adopted using:

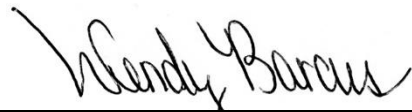
Negotiated rule making:	New	___	Amended	___	Repealed	___
Pilot rule making:	New	___	Amended	___	Repealed	___
Other alternative rule making:	New	<u>5</u>	Amended	<u>4</u>	Repealed	___

Date adopted: August 9, 2017

Name: Wendy Barcus

Title: HCA Rules Coordinator

Signature:



AMENDATORY SECTION (Amending WSR 12-24-052, filed 11/30/12, effective 1/1/13)

WAC 182-60-010 Definitions. When used in this chapter:

(1) **"Agency"** means the Washington state health care authority (HCA), created pursuant to chapter 41.05 RCW.

(2) **"Certification fee"** means a fee assessed by the agency to an individual or organization applicant requesting (~~(an independent review)~~) certification or recertification of a patient decision aid not already certified by an organization located in the United States or Canada and recognized by the agency's medical director.

(3) **"Certified patient decision aid"** means a patient decision aid, as defined in this section, for any medical condition or procedure, including abortion as defined in RCW 9.02.170, that:

(a) Is certified by one or more national certifying organizations recognized by the agency's medical director; or

(b) Has been evaluated based on the International Patient Decision Aid Standards (IPDAS) by an organization located in the United States or Canada and has current scores satisfactory to the agency's medical director in each of the following categories: Content criteria, development process criteria, and effectiveness criteria; or

(c) Is independently assessed and certified by the agency's medical director based on the International Patient Decision Aid Standards developed by the IPDAS Collaboration if a current evaluation is not available from an organization located in the United States or Canada.

(4) **"National certifying organization"** means a group, entity, or organization in the United States or Canada that is recognized by the agency's medical director to certify patient decision aids under this chapter.

(5) **"Patient decision aid"** means a written, audio-visual, or on-line tool that provides a balanced presentation of the condition and test or treatment options, benefits, and harms including, if appropriate, a discussion of the limits of scientific knowledge about outcomes (~~((and a means to acknowledge that the tool has been fully reviewed and understood))~~), for any medical condition or procedure.

AMENDATORY SECTION (Amending WSR 12-24-052, filed 11/30/12, effective 1/1/13)

WAC 182-60-020 National certifying organizations. The agency's medical director (~~((will))~~):

(1) Maintains a list of recognized national certifying organizations so that individuals or organizations seeking certification may identify organizations recognized by the agency's medical director.

(2) Considers organizations recommended by applicants for inclusion in the list.

(3) Updates the list as needed.

AMENDATORY SECTION (Amending WSR 12-24-052, filed 11/30/12, effective 1/1/13)

WAC 182-60-025 Agency review process and certification. (1) When independently reviewing decision aids under RCW 7.70.060 (4)(a)(ii), the agency's medical director ((considers the most current)) uses agency certification criteria, which are based on criteria developed by the International Patient Decision Aid Standards (IPDAS) ((developed by the IPDAS)) Collaboration, for evaluation of a patient decision aid.

(2) The agency's medical director may certify a patient decision aid ((may be certified)) if it is reviewed by a national certifying organization and has current scores satisfactory to the agency's medical director in each of the following categories: Content criteria, development process criteria, and effectiveness criteria.

(3) ((The)) An applicant requesting review and certification must provide written documentation of the basis for certification as provided in subsection (1) of this section, using the application materials developed by the agency.

(4) The agency's medical director may contract for an assessment of the patient decision aid.

(a) The contract will:

(i) Be with an evidence-based organization or other appropriate entity; and

(ii) ((Provide)) Require an assessment to evaluate the patient decision aid based on the ((most current International Patient Decision Aid Standards developed by the IPDAS Collaboration)) agency's IP-DAS-based certification criteria using information provided by the applicant and the agency's medical director.

(b) The agency's medical director may use the results of the assessment in whole or part as the basis for a certification determination.

(5) The agency's medical director may establish minimum scores in each of the following ((eriteria)) areas: Content criteria, development process criteria, and effectiveness criteria ((, based on IPDAS Collaboration criteria, necessary to qualify as a certified patient decision aid)).

NEW SECTION

WAC 182-60-027 Patient decision aid review advisory panel. (1) The agency's medical director has the authority to establish one or more expert advisory panels to review patient decision aids using established criteria under WAC 182-60-025.

(2) The panel may include the following as necessary:

(a) Practicing physicians or other relevant licensed health professionals;

(b) Health literacy and numeracy experts;

(c) Experts in shared decision making; and

(d) Legal experts.

(3) The agency's medical director may contract with an evidence-based practice center or other appropriate expert to review and advise

on the validity or presentation of evidence, other elements of the decision aid, or on developing and updating policies or practices.

(4) Advisory review panel members must meet conflict of interest and disclosure requirements. Each advisory panel member must:

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

(b) Abide by confidentiality requirements and keep all proprietary information confidential; and

(c) Not use information gained as a result of advisory panel membership outside of advisory panel responsibilities, unless the information is publicly available.

(5) The agency's medical director makes the final determination on certification.

AMENDATORY SECTION (Amending WSR 12-24-052, filed 11/30/12, effective 1/1/13)

WAC 182-60-030 Certification fees. ~~((+1))~~ The agency ~~((will charge a certification fee))~~ charges one or more fees to ((the)) an applicant to defray the costs of ((the assessment and certification under)) assessments, certifications, recertifications, and any opportunities to remedy deficiencies in the application, according to this chapter.

~~((a))~~ (1) Fees ((will be)) are based on the reasonable projected or actual cost of ((obtaining an assessment)) the certification program.

~~((b) One))~~ (2) Except as otherwise provided in this chapter, a certification fee ((will apply)) applies to each review of a patient decision aid. An opportunity to remedy deficiencies as described in WAC 182-60-045 may require an additional fee.

~~((2) Applicants requesting review and certification of a patient decision aid must pay a fee established by the agency to defray the cost of review by a contracted review organization or group.)~~ (3) The agency may, at its discretion, waive or otherwise reduce applicable fees for patient decision aids publicly available at no cost.

NEW SECTION

WAC 182-60-035 Patient decision aid topic selection. (1) The agency may, at the medical director's discretion, give preference to certification of patient decision aids identified as priority topics for shared decision making by the Healthier Washington Initiative, the Robert Bree collaborative, or other topics that are important to state health care purchasing or policy objectives.

(2) Periodically throughout the year, the agency may issue a request for submission of specific patient decision aid topics that address state priorities.

(3) The agency may review additional decision aids that do not reflect the topics requested in its solicitation but may decline or defer review based on resource limitations or priorities for review.

NEW SECTION

WAC 182-60-040 Agency medical director certification. (1) Decisions.

(a) The agency's medical director, with input as determined necessary by an advisory review team, or contracted experts, or both, makes a written determination to:

(i) Certify the decision aid;

(ii) Notify the developer of areas of deficiency and provide an opportunity to remedy deficiencies as described in WAC 182-60-045; or

(iii) Decline to certify the decision aid.

(b) Upon certification, the agency adds the decision aid to a list of certified products posted on the agency web site.

(c) Certification determinations are final and not subject to appeal.

(2) Certification period. A certification under this chapter is valid for two years from the date of the written certification determination, except in the case of withdrawal or suspension under subsection (4) of this section.

(3) Recertification.

(a) The developer may request recertification by taking the following steps six months before the current certification expires:

(i) Request recertification;

(ii) Submit any needed updates or modifications using HCA 82-328 form; and

(iii) Pay the required certification fee.

(b) The agency's medical director may limit review to the updated elements of the application and the decision aid, together with associated evidence and may make the determinations described in subsection (1) of this section.

(c) Recertification is effective for two years from the date of the written recertification determination.

(4) Withdrawal or suspension of certification.

(a) Developers must notify the agency's medical director when they become aware of information that may materially change the content of an approved decision aid or supporting application materials on file.

(b) The agency's medical director may withdraw or suspend a certification:

(i) On the medical director's own initiative, if information becomes available that may materially change the decision aid's content or supporting application materials; or

(ii) In response to developer notification under (a) of this subsection.

(c) Within ten business days of the agency's withdrawal or suspension of a certification, the agency sends notification to the developer's address on file.

(d) The developer must submit its updated application materials to the agency's medical director within the time frame specified in the agency's notice. The agency charges the developer reasonable costs associated with the recertification.

(e) The agency's medical director may limit review to the updated elements of the decision aid and may make the determinations described in subsection (1) of this section.

(f) If a developer fails to submit updated application materials within the time frame in (d) of this subsection, the agency withdraws the certification.

(g) The agency posts withdrawal, suspension, and recertification decisions on the agency's web site.

(5) Effect of certification determination.

(a) Certification under this chapter provides the basis for heightened legal protections under RCW 7.70.065; and

(b) A certified patient decision aid used as part of a shared decision-making process may also be a requirement or preference in contract or arrangements for state-purchased health care.

NEW SECTION

WAC 182-60-045 Opportunity to remedy deficiencies. (1) The agency's medical director may suspend the certification or recertification process if the medical director determines there are deficiencies in an application, including the decision aid and supporting materials.

(2) The agency provides the developer with a written notice of deficiencies and gives an opportunity to provide additional information or materials. The developer must pay any additional fees related to the review of additional information.

(3) The developer must submit any additional materials within sixty calendar days of the date on the written notice.

(4) The medical director makes a final decision to certify or to decline to certify the decision aid within sixty calendar days of receipt of the developer's materials.

NEW SECTION

WAC 182-60-050 Public notices. The agency posts the following information on its web site:

(1) Priority certification topics and the timeline for application and consideration of submitted decision aids;

(2) Certification forms and criteria;

(3) A complete listing of certified decision aids and certification effective dates; and

(4) All notifications of certification expirations, withdrawals, and suspensions.