

WSR 21-18-053

PERMANENT RULES

HEALTH CARE AUTHORITY

[Filed August 26, 2021, 7:50 a.m., effective September 26, 2021]

Effective Date of Rule: Thirty-one days after filing.

Purpose: The health care authority (HCA) is amending WAC 182-60-027 to add patient representative to the list of panel members. Patient representatives add value to HCA's patient decision aid (PDA) review advisory panels. After conducting several rounds of certification and recertification, HCA has determined that two years is too short of a time frame between the initial certification of a patient decision aid and its recertification. Therefore, HCA is amending WAC 182-60-040 to change the length of time for certification of PDAs from two years to five years.

Citation of Rules Affected by this Order: Amending WAC 182-60-027 and 182-60-040.

Statutory Authority for Adoption: RCW 41.05.021, 41.05.160.

Adopted under notice filed as WSR 21-15-099 on July 20, 2021.

Number of Sections Adopted in Order to Comply with Federal Statute: New 0, Amended 0, Repealed 0; Federal Rules or Standards: New 0, Amended 0, Repealed 0; or Recently Enacted State Statutes: New 0, Amended 0, Repealed 0.

Number of Sections Adopted at the Request of a Nongovernmental Entity: New 0, Amended 0, Repealed 0.

Number of Sections Adopted on the Agency's own Initiative: New 0, Amended 0, Repealed 0.

Number of Sections Adopted in Order to Clarify, Streamline, or Reform Agency Procedures: New 0, Amended 2, Repealed 0.

Number of Sections Adopted using Negotiated Rule Making: New 0, Amended 0, Repealed 0; Pilot Rule Making: New 0, Amended 0, Repealed 0; or Other Alternative Rule Making: New 0, Amended 2, Repealed 0.

Date Adopted: August 26, 2021.

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Rules Coordinator

OTS-3088.2

AMENDATORY SECTION (Amending WSR 17-17-039, filed 8/9/17, effective 9/9/17)

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; and

(e) Patient representatives.

(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.

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 17-17-039, § 182-60-027, filed 8/9/17, effective 9/9/17.]

AMENDATORY SECTION (Amending WSR 17-17-039, filed 8/9/17, effective 9/9/17)

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 website.

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

(2) Certification period. For patient decision aids certified on January 1, 2021, and after, a certification under this chapter is valid for ((two)) five 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) For patient decision aids certified on January 1, 2021, and after, recertification is effective for ((two)) five 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 website.

(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.

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 17-17-039, § 182-60-040, filed 8/9/17, effective 9/9/17.]