

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 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 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 21-18-053, § 182-60-040, filed 8/26/21, effective 9/26/21; WSR 17-17-039, § 182-60-040, filed 8/9/17, effective 9/9/17.]