

Patient Decision Aid Certification Process

Overview:

A key component of the Healthier Washington initiative is consumer engagement and empowering people to share in decision-making when it comes to their own health and the health of their families. By encouraging the widespread use of certified decision aids by clinicians and patients in shared-decision making (SDM), the State of Washington intends to promote patient engagement, improve health care quality, and reduce avoidable costs. Consistent with Washington law, shared decision making using state certified decision aids provides the basis for the heightened standard of proof for a prima facie case (clear and convincing evidence) under RCW 7.70.060. Use of certified patient decision aids as part of the shared decision making process may also be a requirement or preference in contracts or arrangements for state purchased health care.

Creating a “first in the nation” certification process for decision aids is a priority of Healthier Washington. The Washington State Health Care Authority (HCA) has developed patient decision aid certification criteria based on those of the International Patient Decision Aid Standards (IPDAS) Collaboration for evaluation of patient decision aids, and will begin certifying decision aids in spring 2016.

The Health Care Authority plans to request submissions up to four times a year for decision aids, emphasizing shared decision making priority areas outlined in Healthier Washington, Bree Collaborative recommendations, <http://www.breecollaborative.org>, or other priority topics important to state health purchasing or policy objectives. During these open submission periods, the Health Care Authority may also accept decision aid products that do not reflect the product type requested, but may decline or defer review based on resource limitations or review priorities.

As required by legislation, the agency is in the process of developing a fee structure for decision aid review, taking into consideration resources expended during Healthier Washington initial review cycle(s). In the future, the agency plans to charge a certification fee to the applicant to defray costs of assessments, certifications and any opportunities to resubmit or recertify under this chapter. Fees will be based on the reasonable projected or actual cost of the certification program. Except as otherwise provided, a certification fee will apply to each review of a patient decision aid. An opportunity to cure may be subject to an additional fee. HCA may, at its discretion waive or reduce otherwise applicable fees for patient decision aids in priority topic areas that will be publicly available at no cost.

Process:

Step 1: Subject Matter Selection and Initial Steps:

- a. **Call for Submissions:** HCA determines and announces the priority subject matter area(s) for the patient decision aid certification solicitation, and issues a call for submission including the timeframe during which applications will be accepted for priority review. The primary mode of notification will be via the HCA website.
- b. **Developer Response:** The developer applicant requesting review and certification must provide full written documentation using application materials and formats developed by the agency, and remit any applicable fees. Certification forms and criteria will be made available on the website.
- c. **Expert/Evidence Reviewers Determined.** An initial step in any review cycle will be convening an advisory review panel, and if determined appropriate, arranging for evidence based practice center review.

Step 2: Initial and Advisory Reviews:

- a. **Initial Application Packet Review** - The Health Care Authority's Medical Director or his or her designee will conduct an initial review of the submitted application packets to determine timeliness, completeness and clarity of all materials submitted. Untimely, unclear or incomplete applications may be declined for further action after this preliminary review, and notification will be sent to the applicant of the decision. As noted, priority will be given to applications addressing priority subject matter areas, and applicants may be notified if their decision aid will not be reviewed for certification.
- b. **Content Review:**
 1. **Evidence Based Practice Center review** -The Agency Medical director may, if deemed appropriate, refer the decision aid and associated materials for systematic review by an evidence based practice center or other appropriate expert to advise on the validity or presentation of evidence, other elements of the decision aid, or development and update policies or practices.
 2. **Advisory Panel review** - The full review packet, together with the results of the external evidence review (if any) is then forwarded as needed to the expert advisory panel for consideration, using the agency's established certification criteria. The advisory panel provides its review results to the medical director, and may submit a consensus report and/or may report any specific comments of individual reviewers.

Step 3: Medical Director Review and Decision:

The Health Care Authority Medical Director shall conduct an assessment of the decision aid and application materials together with the comments and reports resulting from the review(s) described above and will make the determination to:

- a. **Certify decision aid** - The decision aid is certified and is placed on a list of certified products posted on the Health Care Authority's website; or
- b. **Provide opportunity to cure** – The Medical Director may suspend its certification process if he or she determines that there are deficiencies in the submitted materials. The developer will be provided written notice of the deficiencies and an opportunity to provide additional information or materials. The developer will be provided 60 days to submit the materials, and the medical director shall make a final decision to certify or decline to certify the decision aid within 60 days of receipt of the materials; or
- c. **Decline certification:** Decision aid is declined for certification. The decision is final and not subject to further appeal.

Step 4: Withdrawal or Suspension:

A certified decision aid may be considered for re-review at any time at the discretion of the Medical Director. HCA may withdraw or suspend certification of the decision aid if the Medical Director determines that information has since become available that may materially change the content in the decision aid or supporting materials. Notification will be sent to the address on file for the developer. The decision aid producer may update the decision aid and supporting materials and submit them for re-review within the timelines specified in the notification. The HCA medical director may limit such review to the updated elements of the decision aid. Withdrawal, suspension and re-review decisions shall be posted on the HCA website.

Step 5: Recertification:

Certification is valid for two years from the date of the last approval.

In order to avoid expiration, the developer may request recertification by updating the decision aid and supporting materials if needed and/or documenting that they continue to meet current certification requirements without change. Recertification materials must be submitted no later than 6 months prior to expiration of certification.

Submitted materials must call out any changes or amendments to the decision aid and supporting materials, with particular attention to changes in the evidence. The recertification application must also address any new or amended sections in the application and will be considered using current certification criteria.

The application for recertification may be made either by completing all sections of the current certification application and submitting all required documentation with changes highlighted, or; by

attaching a copy of the original approved application, with an addendum that delineates any changes to the patient decision aid, supporting materials, and required responses in the application (including new or amended sections added since the original certification), together with current copies of the decision aid and any supporting materials. Any recertification request must also include an affirmation that the developer updated their evidence review, and indicate whether and where changes were made in the decision aid as a result of the review.

Visual Framework for Process to Certify Decision Aids

