

Patient decision aid (PDA) certification process

Overview

Patient decision aids (PDAs) are tools that help patients and providers talk together about care options. PDAs help patients understand their choices about whether to have a specific treatment or screening. This includes knowing the pros and cons of each available option. PDAs also provide patients with information needed to make a decision, based on their personal values and preferences, by exploring each option and how it relates to their values.

[Washington State law](#) supports and regulates shared decision making (SDM) and the certification of PDAs. Washington is the only state in the nation to certify PDAs. The Health Care Authority (HCA) began accepting PDAs for certification in April 2016.

HCA certifies PDAs to help ensure they meet a certain standard of quality. HCA uses a list of [certification criteria](#) based on standards established by the International Patient Decision Aids Standards (IPDAS) Collaboration. [Visit HCA's website](#) for a list of currently certified PDAs.

Periodically, HCA requests submissions for PDAs, emphasizing SDM priority areas identified in the [Bree Collaborative recommendations](#) or other HCA priority topics or issues. There is an application fee of \$3,000 for review of each PDA. Fees will be waived for PDAs made available to the public at no charge.


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 PDA certification solicitation and issues a call for submission. The solicitation includes the timeframe for when applications will be accepted for priority review. This information is made available on the HCA website.
- b) **Developer response:** the applicant/developer must provide written documentation using application materials and formats developed by HCA and pay any applicable fees. Certification forms and criteria are made available on the HCA website.
- c) **Expert/evidence reviewers determined:** HCA will convene an advisory review panel and arrange for evidence-based practice center review.

Step 2: initial and advisory reviews

- a) **Initial application packet review:** HCA's medical director or their designee will conduct an initial review of the submitted application packet to determine timeliness, completeness, and clarity of materials submitted. Untimely, unclear, or incomplete applications may be declined, and notification will be sent to the applicant. Priority will be given to applications addressing priority subject matter areas, and applicants may be notified if their PDA will not be reviewed for certification.
- b) **Content review:**
 - 1) **Evidence-based practice center review:** HCA's medical director may, if deemed appropriate, refer the PDA and associated materials for review by an evidence-based practice center or other expert to advise



on the validity or presentation of evidence, other elements of the PDA, or development and update policies or practices.

- 2) **Advisory panel review:** the full review packet, along with the results of the external evidence review (if any) is forwarded to the expert advisory panel for consideration. The advisory panel provides its review results to the medical director and may submit a consensus report and/or provide any comments of individual reviewers.

Step 3: medical director review and decision:

HCA's medical director will assess the PDA and application materials, along with the comments and results from the review(s) described above. They will make the determination to:

- c) **Certify PDA:** the decision aid is certified and placed on a list of certified products that will be posted on the HCA website.
- d) **Provide opportunity to cure:** the certification process is suspended if there are deficiencies in the submitted materials. The applicant will be provided written notice of the deficiencies and an opportunity to provide additional information or materials. The applicant will be provided 60 days to submit the materials, and HCA's medical director will make a final decision to certify or decline to certify the PDA within 60 days of receipt of the materials.
- e) **Decline certification:** PDA is declined for certification. The decision is final and not subject to further appeal.

Step 4: duty to modify, withdrawal, or suspension:

The developer is obligated to notify HCA if information becomes available that may materially change the content in the PDA or supporting materials. When this occurs, the developer can submit a modified application and changes to the PDA as appropriate. If the HCA medical director identifies that information in the PDA is out of date, HCA may withdraw or suspend certification. Notification will be sent to the applicant.

The applicant may update the PDA and supporting materials and submit them for re-review within the timelines specified in the notification. Information about decision aid certification status is available on the HCA website.

Step 5: recertification:


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

To avoid expiration, a developer may request recertification by updating the PDA 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 six months prior to expiration of certification.

Submitted materials must identify any changes or amendments to the PDA and supporting materials, with attention to changes in the evidence. The recertification application must also address any new or amended sections in the application and will be reviewed using current certification criteria.

The application for recertification may be made by:

- Completing the recertification application and including current copies of the PDA 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 PDA because of the review.

Commercial use expectations:

Washington Health Care Authority is dedicated to a safer, fairer, and healthier marketplace that enables Washingtonians to make informed health care decisions.

Objective, impartial review and certification of patient decision aids enables the Health Care Authority to achieve this goal, which is why it is important that any references to Washington State's certification be used as follows:

HCA permits the following:

- Linking to HCA's [shared decision making webpage](#).
- Saying whether a PDA is certified as meeting Washington State standards pursuant to RCW 7.70.060, provided the time period for certification is also included.
- Optional: listing the following statement directly on a PDA:
This product has been certified by the Washington State Health Care Authority pursuant to RCW 7.70.060. The date of certification is (date of notification) and will expire five years from this date, or sooner pursuant to Washington State policy. A full description of Washington's certification process, including required criteria is available on the [HCA website](#).

Applicants/developers are **not** permitted to:

- Say or imply that Washington State certification means the PDA is high or of the highest quality.
- Say or imply that non-certified PDAs of the developer are higher quality because one or more of their PDAs have been certified.
- Say or imply that uncertified PDAs are inferior.
- Say or imply that state certification constitutes a promotion or endorsement of the PDA by Washington State.

If HCA learns this policy has been violated, it may revoke certification and share the decision on the HCA website. See the following page for a visual framework for the process to certify PDAs.

Figure 1: visual framework for process to certify PDAs

