

Application for Patient Decision Aid Certification

INSTRUCTIONS

Please complete the application documents in the order shown below. Supplementary information can be submitted with the completed application as needed. **All sections of the application must be fully and accurately completed. Applications containing incomplete or non-responsive sections may be returned without consideration or may lead to denial of certification.**

1. **Developer and Decision Aid Background Information** - Please provide background information for the following:
 - a. Applicant Information
 - b. Overview of Patient Decision Aid
2. **Patient Decision Aid Certification Criteria Checklist** - Please fill out the certification checklist to indicate whether the patient decision aid includes content required for certification, and where in the aid the content is located.
3. **Information about Decision Aid Development Process** - Please provide detailed information for the following:
 - a. Funding Sources, Disclosures and Attestation
 - i. Fill out Attachment A
 - ii. Fill out Attachment B
 - b. Supporting Evidence
 - i. Fill out Attachment C, or provide the required information in a similar format, to document evidence used to inform development process
 - c. Testing
 - d. Design for Readability and Comprehension (Please note that the certification criteria now include readability and comprehension requirements).
 - e. Design for Diverse Patient Populations
 - f. Evaluation Practices

Submission - Please submit the fully completed application and associated materials to the following email: shareddecisionmaking@hca.wa.gov. Please also ensure that the actual decision aids are sent along with the application, including a link to any online materials. If you would prefer to submit your application materials by mail, the address is Washington Health Care Authority P.O. Box 45502, Olympia, WA 98504-5502 in care of Laura Pennington, Practice Transformation Manager.

Please email questions, comments, or concerns to shareddecisionmaking@hca.wa.gov.



Application for Patient Decision Aid Certification:

Part 1: Developer and Decision Aid Background Information

Please supply the following information. Incomplete or unclear materials will not be accepted for review.

A. Applicant information

1. Title of Decision Aid:

2. Name and address of developer organization: (If submitting as an individual(s), please list main point of contact and address.)

3. Name of author(s) and/or development team members with editorial content to influence or control, including credentials and qualifications:

4. If applicable, please list names and addresses of corporate or institutional offices of the applicant organization, and list parent, subsidiary or affiliated entities. Indicate for all whether organized as not for profit or for profit entity:

B. Overview of Patient Decision Aid

1. Subject matter/topic addressed in the Patient Decision Aid:

2. Provide an overview of educational content included in the PDA, including the following, as relevant and appropriate:

- Information about the condition
- Treatment options presented, including:
 - Alternatives, including option to delay or decline treatment
 - Benefits and Harms described
 - Outcomes probabilities (if included)
- Values clarification

B. Overview of Patient Decision Aid (continued)

3. Describe the eligible/target audience for the PDA:

4. Describe all formats in which the PDA is available and methods of use, including:

- How the PDA can be accessed (web site openly available, secure login, etc.)
- What modalities are available (paper, smart phone, tablet, etc.)
- Intended context of use (in clinic with provider, etc.)

Submit copies of all formats or provide links, as appropriate.

B. Overview of Patient Decision Aid (continued)

5. Describe any costs or use restrictions, including:

- Intellectual property rights (copyrights, public domain, etc.)
- Availability (for use by anyone, exclusive use by specific organizations, etc.)
- Pricing structure (free, one-time-cost, price per/license)

B. Overview of Patient Decision Aid (continued)

6. List all languages in which the PDA is available:

7. Provide the production release date, and if relevant, the date of the most recent revision:



Application for Patient Decision Aid Certification:

Part 2: Patient Decision Aid Certification Criteria Checklist

The PDA *content* is reviewed against the following criteria.

Please select the most appropriate response as it applies to each specific criterion and fully describe where in the PDA the applicable information is located. Include any additional information in the “Comments” column you feel is relevant to the consideration of the criterion.

Does the PDA <i>adequately</i> ...	YES	NO	N/A	Location in PDA ¹	Comments
1. Describe the health condition or problem	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
2. Explicitly state the decision under consideration	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
3. Identify the eligible or target audience	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

¹ Location may be indicated by various methods, including a page number or timed location if in a video decision aid. This information will help reviewers rapidly locate and verify information in the PDA.

Does the PDA <i>adequately</i> ...	YES	NO	N/A	Location in PDA ¹	Comments
4. Describe the options available for the decision, including non-treatment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
5. Describe the positive features of each option (benefits)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
6. Describe the negative features of each option (harms, side effects, disadvantages)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

¹Location may be indicated by various methods, including a page number or timed location if in a video decision aid. This information will help reviewers rapidly locate and verify information in the PDA.

Does the PDA <i>adequately</i> ...	YES	NO	N/A	Location in PDA ¹	Comments
<p>7. Help patients clarify their values for outcomes of options by a) asking patients to consider or rate which positive and negative features matter most to them, AND/OR b) describing each option to help patients imagine the physical, social (e.g. impact on personal, family or work life), and/or psychological effects</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<p>8. Make it possible to compare features of available options</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<p>9. Show positive and negative features of options with balanced detail</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

¹Location may be indicated by various methods, including a page number or timed location if in a video decision aid. This information will help reviewers rapidly locate and verify information in the PDA.

Does the PDA <i>adequately</i> ...	YES	NO	N/A	Location in PDA ¹	Comments
10. If outcome probabilities are included, allow comparison across options using the same denominator	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
11. Provide information about the funding sources for development	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
12. Report whether authors or their affiliates stand to gain or lose by choices patients make using the PDA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

¹Location may be indicated by various methods, including a page number or timed location if in a video decision aid. This information will help reviewers rapidly locate and verify information in the PDA.

Does the PDA <i>adequately</i> ...	YES	NO	N/A	Location in PDA ¹	Comments
13. Include authors/developers' credentials or qualifications	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
14. Provide date of most recent revision (or production)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
15. Follow plain language guidelines to ensure understanding of people with low literacy and/or low health literacy skills*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

¹ Location may be indicated by various methods, including a page number or timed location if in a video decision aid. This information will help reviewers rapidly locate and verify information in the PDA.

*New criteria added for certification in 2017

Does the PDA <i>adequately</i> ...	YES	NO	N/A	Location in PDA ¹	Comments
16. Describe what the test is designed to measure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
17. Describe next steps taken if test detects a condition/problem	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
18. Describe the next steps if no condition/problem detected	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

¹Location may be indicated by various methods, including a page number or timed location if in a video decision aid. This information will help reviewers rapidly locate and verify information in the PDA.

Does the PDA <i>adequately</i> ...	YES	NO	N/A	Location in PDA ¹	Comments
19. Describe consequences of detection that would not have caused problems if the screen was not done	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
20. Include information about chances of true positive result	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
21. Include information about chances of false positive result	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

¹Location may be indicated by various methods, including a page number or timed location if in a video decision aid. This information will help reviewers rapidly locate and verify information in the PDA.

Does the PDA <i>adequately</i> ...	YES	NO	N/A	Location in PDA ¹	Comments
22. Include information about chances of true negative result	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
23. Include information about chances of false negative result	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
¹ Location may be indicated by various methods, including a page number or timed location if in a video decision aid. This information will help reviewers rapidly locate and verify information in the PDA.					

Application for Patient Decision Aid Certification:

Part 3: Information About Decision Aid Development Process

Please supply the following information.

A. Funding Sources, Disclosures and Attestation

Conformance with certification requirements will be based on the information provided below.

The applicable criteria are:

- Do the Patient Decision Aid and/or the accompanying external documentation adequately disclose and describe actual or potential financial or professional conflicts of interest?
- Are the efforts used to eliminate bias fully described and adequately reflected in the decision aid content?
- Are listed developer entities and personnel free from listed disqualifications in Attachment A?

1. Provide full, detailed disclosure about the funding source(s) used for development:

2. Describe the editorial control, if any, the funder(s) had over final content:

A. Funding Sources, Disclosures and Attestation (continued)

3. Report whether funding to develop or distribute the PDA has been received from individuals or entities, whether for profit or non-profit, that sell devices, treatment, or services described in the PDA. If yes, please describe the relationship and what efforts were used to eliminate bias:

4. Describe whether and how the developer, including all team members or their organizational affiliates, stand to gain or lose by choices patients make using the patient decision aid.

5. Complete Attachment A: Applicant Debarment, Suspension and Exclusion Checklist

Complete Attachment A: attestation for organization, parent, subsidiary or affiliated entities, project leads, and team members — no basic disqualifications (e.g., criminal, Medicare/Medicaid sanctions, medical disciplinary sanctions.)

6. Complete Attachment B: Team Member Conflict of Interest Disclosure Form

This must be completed by the author(s) and/or development team members with editorial content influence or control.

B. Supporting Evidence

Conformance with certification requirements will be based on the information provided below.

The applicable criteria is: (PDA or external information)

- Has the Patient Decision Aid been developed and updated (if applicable) using current, high quality evidence in a systematic and unbiased fashion?

1. Describe steps to find, appraise, summarize evidence:

B. Supporting Evidence (continued)

2. Describe the quality of research evidence used:

3. Provide citations to the research evidence used, using the Evidence Table format provided in Appendix C, or a similar format.

B. Supporting Evidence (continued)

4. Does the PDA use evidence from studies of patients similar to those of the target audience, If no, why?

C. Testing

Conformance with certification requirements will be based on the information provided below.

The applicable criteria is:

- Did the developer test its decision aids with patients and incorporate those learnings into its tools?

1. Describe whether and how the developer elicited feedback from patients, including results:

C. Testing (continued)

2. Describe whether and how the developer uses testing with providers, including results: (Responses will be used for informational purposes only.)

C. Testing (continued)

3. Describe whether and how the developer uses testing with interpreters who work in healthcare settings, including results: (Responses will be used for informational purposes only.)

D. Design for Readability and Comprehension

Conformance with certification requirements will be based on the information provided below.

The applicable criteria are:

- Does the Patient Decision Aid or accompanying external documentation report readability levels?
- Does the Patient Decision Aid follow plain language guidelines to ensure understanding of people with low literacy and/or low health literacy and/or numeracy skills?

1. Describe design steps to ensure understanding by those with limited reading, health literacy and/or numeracy skills:

D. Design for Readability and Comprehension (continued)

2. Report readability levels and how measured:

D. Design for Readability and Comprehension (continued)

3. Describe whether PDA provides ways to help patients understand information other than by reading (audio, video, in person discussion):

D. Design for Readability and Comprehension (continued)

4. Describe how, if applicable, the PDA provides information about level of uncertainty around benefits and harm:

D. Design for Readability and Comprehension (continued)

5. Describe how, if applicable, the PDA includes use of probabilities, and why used/not used:

E: Design for Diverse Patient Populations

Responses to the following are required, but will be used for informational purposes only.

- 1. Describe whether and how you have considered a wide range of perspectives among diverse patient populations in the development of this PDA:**

E: Design for Diverse Patient Populations (continued)

2. Describe whether the PDA is available in multiple languages, and design steps, if any, taken to ensure the PDA will be understood by those with no/limited English proficiency, including but not limited to the following:

- Qualifications of the translators (including certification in health care translation)
- Cultural adaptation (either of the translated content or of the source English content to be more inclusive of diverse populations)
- Quality assurance process, including review by target language-speaking medical experts.

F: Evaluation Practices

Responses to the following are required, but will be used for informational purposes only.

1. Did you evaluate whether this or similar PDAs improve the match between patient values and the chosen options?
How?

F: Evaluation Practices (continued)

2. Did you evaluate whether this or similar PDAs help patients improve knowledge about options' features? How?

F: Evaluation Practices (continued)

3. Did you evaluate whether this or similar PDAs help patients recognize that a decision needs to be made? How?

F: Evaluation Practices (continued)

4. Did you evaluate whether this or similar PDAs help patients clarify option features that matter most to them? How?

F: Evaluation Practices (continued)

5. Did you evaluate whether this or similar PDAs help patients discuss values with their provider? How?

Attachment A

Application for Patient Decision Aid Certification: Applicant Debarment, Suspension and Exclusion Checklist

Complete this section by checking yes or no for each question. A response is required.
If you answered "yes" to any of the questions in Section A, complete Section B.

A. Has the applicant organization, project lead(s) or any team member:	Yes	No
1. Had exclusion under Medicare, Medicaid or any other federal health care program taken against them?	<input type="checkbox"/>	<input type="checkbox"/>
2. Had civil money penalties or assessment imposed under Section 1128A of the Social Security Act?	<input type="checkbox"/>	<input type="checkbox"/>
3. Had a restriction or sanction imposed on their professional license accreditation or certification?	<input type="checkbox"/>	<input type="checkbox"/>
4. Had a program exclusion taken against them? More info: http://exclusions.oig.hhs.gov and https://www.sam.gov	<input type="checkbox"/>	<input type="checkbox"/>
5. Been convicted of any health-related crimes as defined by the Washington State Department of Health? RCW 18.130.180; and WAC 246-16.	<input type="checkbox"/>	<input type="checkbox"/>
6. Been convicted of a criminal offense as described in Section 1128A of the Social Security Act?	<input type="checkbox"/>	<input type="checkbox"/>

If you answered "yes" to any of the questions listed under Section A:
Report final adverse legal action history, including each final legal adverse action, when it occurred, the federal or state agency or the court/administrative body that imposed the action, and the resolution, if any. Attach a copy of the relevant final legal adverse action documents.

Final Adverse Legal Action	Date	Taken by	Resolution

Attachment B

Application for Patient Decision Aid Certification: Conflict of Interest Disclosure

All team members must disclose any potential sources of conflict of interest. Any interest, financial or otherwise, that might be perceived as influencing a team member's objectivity is considered a potential source of conflict of interest. This must be disclosed when directly relevant or indirectly related to the content of the decision aid under review. Potential sources of conflict of interest include but are not limited to patent or stock ownership, membership of an organizational board of directors, membership of an advisory board or committee for an organization or group, and consultancy for or receipt of speaker's fees from an organization or group. The existence of a conflict of interest does not preclude consideration of a decision aid for certification, but it must be disclosed. Failure to disclose may result in loss of certification.

If the team members have no conflict of interest to declare, they must also state this using this form. It is responsibility of the decision aid developer lead to review this policy with all team members, and to assure all members fully and accurately complete this form. This requirement may be met by having all team members submit one form, or by submitting multiple forms.

Do you or any of your team members have a conflict of interest to declare?

YES

NO

If yes, please have the relevant team member(s) provide their name and details below:

I certify that the information given above is complete and accurate.

Developer Lead

Name: _____ Signature: _____ Date: _____

Team Member

Name: _____ Signature: _____ Date: _____

Attachment C

Application for Patient Decision Aid Certification: Evidence Table "Sample" Format

Each study submitted as part of the evidence package should be summarized in accordance with the evidence table format below. See steps 1–4 under **Part 3: Supporting Evidence**.

STUDY 1
Citation and publication dates:
Study design:
Description of the treatments or interventions evaluated:
Inclusion/exclusion criteria:
Sample size:
Results:
Statistical assessment: (P-Value)

STUDY 2

Citation and publication dates:

Study design:

Description of the treatments or interventions evaluated:

Inclusion/exclusion criteria:

Sample size:

Results:

Statistical assessment: (P-Value)

STUDY 3

Citation and publication dates:

Study design:

Description of the treatments or interventions evaluated:

Inclusion/exclusion criteria:

Sample size:

Results:

Statistical assessment: (P-Value)

STUDY 4

Citation and publication dates:

Study design:

Description of the treatments or interventions evaluated:

Inclusion/exclusion criteria:

Sample size:

Results:

Statistical assessment: (P-Value)