

Prescription Drug Affordability Board (PDAB) Stakeholder Webinar:

Orientation to the Affordability Review Information Submission Forms and Templates

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Webinar Objectives

- ▶ Identify where to find the information submission forms and templates for stakeholders in preparation for the affordability review
- ▶ Orient stakeholders to the information submission forms, templates, and available resources
- ▶ Exchange inputs on the information and data collection process for the affordability review

Where to Find Forms

▶ [Prescription Drug Affordability Board | Washington State Health Care Authority](#)

The screenshot shows the Washington State Health Care Authority website. At the top left is the logo. To the right is a search bar and navigation links for 'In a crisis?' and 'Login'. Below the logo is a horizontal menu with links: 'Free or low-cost health care', 'Employee & retiree benefits', 'Billers, providers & partners', 'About HCA', and 'Contact'. The breadcrumb trail reads: 'Home > About HCA > Programs & initiatives > Clinical collaboration & initiatives > Boards, collaborations & work groups > Prescription Drug Affordability Board'. The main heading is 'Prescription Drug Affordability Board', followed by a sub-heading: 'Learn about the Prescription Drug Affordability Board's (PDAB) mission, members, and upcoming meetings.' A yellow callout box contains the text: 'Prescription Drug Affordability Board Advisory Group application. The Washington State Prescription Drug Affordability Board (Board) is seeking unpaid volunteer members for its Advisory Group. The Advisory Group serves at the direction of the Board. The goal of the Advisory Group is to provide guidance to the Board on the different components of drug affordability in Washington. The Advisory Group members will investigate each drug selected by the Board and will provide a written report to the Board with their findings as to the drug's affordability. Applications will be accepted on a rolling basis. [View PDAB Advisory Group Application](#).' Below this is a 'On this page' section with a list of links: 'Overview', '2025 meeting schedule', 'PDAB meetings and materials', 'PDAB Advisory Group meetings and materials', 'PDAB Board of Directors', 'Affordability reviews' (highlighted with a red box), and 'About PDAB meetings'.

Washington State Health Care Authority

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Prescription Drug Affordability Board

Learn about the Prescription Drug Affordability Board's (PDAB) mission, members, and upcoming meetings.

Prescription Drug Affordability Board Advisory Group application

The Washington State Prescription Drug Affordability Board (Board) is seeking unpaid volunteer members for its Advisory Group. The Advisory Group serves at the direction of the Board. The goal of the Advisory Group is to provide guidance to the Board on the different components of drug affordability in Washington. The Advisory Group members will investigate each drug selected by the Board and will provide a written report to the Board with their findings as to the drug's affordability. Applications will be accepted on a rolling basis. [View PDAB Advisory Group Application](#).




On this page

- [Overview](#)
- [2025 meeting schedule](#)
- [PDAB meetings and materials](#)
- [PDAB Advisory Group meetings and materials](#)
- [PDAB Board of Directors](#)
- [Affordability reviews](#)
- [About PDAB meetings](#)

Where to Find Forms

Stakeholder data request forms




Manufacturers

- [Manufacturer information submission form for affordability review](#) 
- [Manufacturer data submission guide](#) 
- [Manufacturer data submission sheet](#) 

Payers

- [Payer information submission form for affordability review](#) 
- [Payer data submission guide](#) 
- [Payer data submission sheet](#) 

Pharmacy benefit managers

- [Pharmacy benefit manager information submission form for affordability review](#) 
- [Pharmacy benefit manager data submission guide](#) 
- [Pharmacy benefit manager data submission sheet](#) 

Wholesalers

- [Wholesaler information submission form for affordability review](#) 
- [Wholesaler data submission guide](#) 
- [Wholesaler data submission sheet](#) 

Files Available For Stakeholders

▶ Letter

- ▶ Provides introductory information regarding the data submission
- ▶ Outlines the submission logistics and timeline

▶ Word Form (currently posted as a PDF for your review)

- ▶ Outlines the information requirements for each stakeholder
- ▶ Guides how the information should be submitted
- ▶ Narratives, data, estimates, assumptions, etc. can be submitted by filling in the required fields.

▶ Data Submission Guide (DSG)

- ▶ Provides additional clarification and examples to fill in the Excel data templates

▶ Excel Data Template

- ▶ Provides data fields for specific information requested

Word Form Example (currently posted as PDF)



Manufacturer Information Submission Form for Affordability Review: [Drug Name]

Washington State Health Care Authority
Prescription Drug Affordability Board (PDAB)
Cherry Street Plaza
626 8th Avenue SE
Olympia, WA 98501
Phone: 360-725-0944
Email: hca_wa_pdab@hca.wa.gov
hca.wa.gov

[Month Day Year]

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PDAB Affordability Review: [Drug Name]
[Month Day Year]

Word Form Example

Background Information

Generic Name

[generic name]

Brand Name

[brand name (this "Brand Name" subsection can be omitted if the selected drug is a generic)]

Drug Class

- If the drug belongs to multiple therapeutic classes, list them all.
- Classification based on FDB HIC3 in the context of a Clinical Formulation ID (GCN_SEQNO)
 - [Class 1]
 - [Class 2]

National Drug Code(s) (NDC)

- List of applicable NDCs for the PDAB Affordability Review
- If there are multiple NDCs, a description of each is requested, including information on dosage, formulation, and package size, and the approximate share of revenue that each NDC represents relative to total revenue from sales of the drug in the United States over the most recent 12-month period.
 - [NDC 1]: [dosage, formulation, package size, approximate share of revenue]
 - [NDC 2]: [dosage, formulation, package size, approximate share of revenue]

Indications and Approval Date by the Food and Drug Administration (FDA)

- List FDA-approved indications of the drug and FDA approval date
- Also, list indication(s) for which the manufacturer is currently seeking approval
 - [Indication 1]: [approval date, MM/DD/YYYY]
 - [Indication 2] (Write "under review" if the manufacturer is currently seeking approval.)

Orphan Drug Approval Status

- List of indications with orphan drug approval status if any
 - [Orphan Indication 1]: [orphan status approval date, MM/DD/YYYY]
 - [Orphan Indication 2] (Write "under review" if the manufacturer is currently seeking approval.)

Drug Shortage Status

- Based on the list published by the United States food and drug administration, as well as information available from the manufacturer

| NDC | Formulation | Strength | Estimated Shortage Duration | Related Information | Shortage Reason |
|-----|-------------|----------|-----------------------------|---------------------|-----------------|
| | | | | | |
| | | | | | |

Manufacturer Contact Information

- Provide the name and contact information of an individual who will be able to answer questions regarding the information submitted to the Health Care Authority.

| Contact Information | |
|----------------------------------------------------------------------|--|
| Name of Manufacturer | |
| Contact Name | |
| Contact Title | |
| Email Address | |
| Telephone Number | |
| Street Address | |
| City | |
| State | |
| Zip | |
| Washington (WA) Drug Price Transparency (DPT) Number (if applicable) | |

DSG Example

WAC template

| Data Field | Description | Type | Max. Length | Rules | Example |
|-----------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|-------------|--------------------------------------------------|------------|
| NDC | Codes maintained by the Federal Food and Drug Administration that includes a labeler code, a product code, and a package code for a drug product. 11 digits with a leading zero. Must contain a value for a drug that is being evaluated. Data requested for the previous five years or the five most current price changes, whichever is longer. Do not include any special characters (e.g. - or space). | Integer | 11 | Must retain a leading zero. | 0000000001 |
| Number of Unit | Number of the medication unit for the NDC. | Integer | 14 | Must contain a value equal to or greater than 1. | 10 |
| Unit Description | Description of Unit. Describe how the unit is defined such as one tablet, one 5-mL volume of liquid etc. | Text | 15 | | One tablet |
| Strength (number and unit) | Strength of the medication for the NDC. Standard abbreviations for strength should be included, such as mcg, mg, g, IU, mg/dL, %. | Text | 15 | | 1 mg |
| Strength (number) | Strength of the medication for the NDC. Number only. | Decimal | 12 | Must contain a value greater than 0 | 1 |

Excel Data Template Example

| | A | B | C | D | E | F | G |
|----|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------|--------------------|
| 1 | NDC | Number of Unit | Unit Description | Strength (number and unit) | Strength (number) | Strength (unit) | Formulation |
| 2 | Required | Required | Required | Required | Required | Required | Required |
| | Numeric response (integer). 11 digits. Must contain a value for a drug that is being evaluated. NDC may be included 1 to X times in file. Data requested for the previous five years or the five most current price changes, whichever is longer. Do not include any special characters (e.g. - or space). Include the leading 0. | Numeric response (integer). Must contain a value greater than or equal to 1. | Text response. E.g. one tablet, one 5-mL volume of liquid. | Text response. Standard abbreviations for strength should be included, such as mcg, mg, g, IU, mg/dL, %. | Numeric response. Must contain a value greater than or zero (e.g. for the 1-mg strength, enter "1"). | Text response. Standard abbreviations for strength, such as mcg, mg, g, IU, mg/dL, % (e.g. for the 1-mg strength, enter "mg"). | Text response. |
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| 25 | | | | | | | |

11-digit NDC. Do NOT include any - or space.

WAC | NADAC | AMP | WAC for Therapy Duration | Discounts | Rebates | Other Price Concessions | Manufacturer Net Price | Manufac ... +

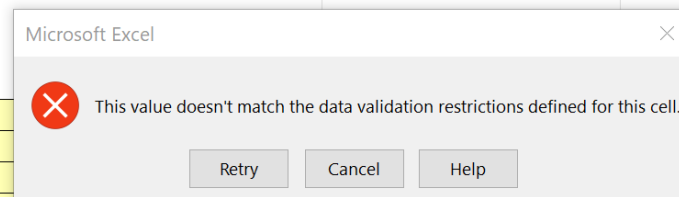
← 2. The first three rows are locked to guide you on what information to be entered, whether it is required or not, and what data format should be used.

← 3. Data specification info might appear when you hover over certain columns.

1. Various templates can be found by clicking tabs on the bottom.

Excel Data Template Example

| NDC | Number of Unit | Unit Description | Strength (number and unit) | Strength (number and unit) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------|
| Required | Required | Required | Required | Required |
| Numeric response (integer). 11 digits. Must contain a value for a drug that is being evaluated. NDC may be included 1 to X times in file. Data requested for the previous five years or the five most current price changes, whichever is longer. Do not include any special characters (e.g. - or space). Include the leading 0. | Numeric response (integer). Must contain a value greater than or equal to 1. | Text response. E.g. one tablet, one 5-mL volume of liquid. | Text response. Standard abbreviations for strength should be included, such as mcg, mg, g, IU, mg/dL, %. | Numeric response. Must contain a value greater than or equal to 1. |
| | -1 | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |



| | B | C |
|------|---------------------------------------------------------------------------------|------------------------------------------------------------|
| | Number of Unit | Unit Description |
| | Required | Required |
| r). | Numeric response (integer). Must contain a value greater than or equal to 1. | Text response. E.g. one tablet, one 5-mL volume of liquid. |
| drug | | |
| | | |
| | | |
| | | |

▶ If you receive an error message, or if the cells turn "red," there is an issue with the data format.

- ▶ Please correct the formatting.
- ▶ DSG will be your resource.

| | | |
|---|------------------------------------------------------------------------------------|----|
| | Do not include any special characters (e.g. - or space). Include the leading 0. | |
| 3 | | |
| 4 | | -1 |
| 5 | | |
| 6 | | |

Files to be Submitted by Stakeholders

▶ From the Manufacturers

| Expected File | File Type | How to Name the File |
|-----------------------------------|--------------------------------------------------|------------------------------------------------------------------------|
| Filled-in Word template form | .doc | [DrugA]_[ManufacturerName]_Word_YYYYMMDD_v1 |
| Filled-in Excel data form | .xlsx | [DrugA]_[ManufacturerName]_Excel_YYYYMMDD_v1 |
| Cost-effectiveness analysis model | .xlsx or print out from the ICER platform (.pdf) | [DrugA]_[ManufacturerName]_CEA_YYYYMMDD_v1 |
| Budget impact analysis model | .xlsx or print out from the ICER platform (.pdf) | [DrugA]_[ManufacturerName]_BIA_YYYYMMDD_v1 |
| References (full-text) | .pdf | [DrugA]_Ref_[PublicationYear]_[FirstAuthorLastName]_[AbbreviatedTitle] |
| Supplemental materials | Various | [DrugA]_[ManufacturerName]_SUPP[##]_YYYYMMDD_v1 |

- YYYYMMDD is the submission date to keep track of versions in case of multiple submissions from the stakeholders.
- If multiple submissions in one day, name the file as v1, v2, v3 etc. at the end of the file name.
- Name the supplemental materials as SUPP01, SUPP02, SUPP03 etc. for the “SUPP[##].”

Files to be Submitted by Stakeholders

▶ From the Payers, PBMs, and Wholesalers

| Expected File | File Type | How to Name the File |
|-------------------------------------|-----------|------------------------------------------------|
| Filled-in Word template form | .doc | [DrugA]_[StakeholderName]_Word_YYYYMMDD_v1 |
| Filled-in Excel data form | .xlsx | [DrugA]_[StakeholderName]_Excel_YYYYMMDD_v1 |
| Supplemental materials | Various | [DrugA]_[StakeholderName]_SUPP[##]_YYYYMMDD_v1 |

- YYYYMMDD is the submission date to keep track of versions in case of multiple submissions from the stakeholders.
- If multiple submissions in one day, name the file as v1, v2, v3 etc. at the end of the file name.
- Name the supplemental materials as SUPP01, SUPP02, SUPP03 etc. for the “SUPP[##].”

Important Notes for Stakeholders

- ▶ Use the form and template from the HCA to submit your information and data.
 - ▶ The agency cannot accept and process information unless the templates are used.
 - ▶ If you use your own documentation or data sheet, this will be rejected and will not be considered as a submission.
- ▶ Do NOT modify the forms and templates.
 - ▶ Some exceptions may apply for blue tables within the Word Form, if additional rows are needed, for example.
 - ▶ Excel data templates should not be modified at all, other than entering requested data, so that they get correctly ingested into agency's system in a confidential and consistent manner.

Insights from the Agency for the Stakeholders to Prepare for the Information Submission

- ▶ Use the Word form and Excel data template as your resource to navigate what information needs to be submitted and how.
 - ▶ If you have information you'd like to submit, but if there are no fields on the Word nor the Excel forms, let us know by submitting this input to us (HCA_WA_PDAB@hca.wa.gov).
- ▶ If you do not have the information/data requested, please make the best estimates based on any related information you might have or from any external references.
 - ▶ The agency will consider your estimates/assumptions as long as you disclose that the information is an estimate and not an actual data with some justification/methodology written on the Word form.
 - ▶ If you need any extra time or extension to the submission deadlines to draw estimates or assumptions, contact the agency.

Insights from the Agency for the Stakeholders to Prepare for the Information Submission

- ▶ If you are writing a narrative, descriptions, etc. on the form, please consider your primary audience is the Board members.
 - ▶ Someone with training in the medical field
 - ▶ But not necessarily an expert in the therapeutic area where the reviewed drug is utilized

Call for Stakeholder Inputs and Feedback

- ▶ How to submit your inputs and feedback
 - ▶ Verbal feedback today
 - ▶ Written feedback is appreciated via PDAB contact email.
 - ▶ **Specific and detailed feedback** will be very helpful to figure out exact changes needed to the forms.
- ▶ Inputs and feedback are welcome as an ongoing basis.
 - ▶ We'll likely renew the forms and templates as we move forward with you in the affordability review.
 - ▶ For the initial forms and templates to be posted for the first round of the affordability review, please submit your inputs and feedback by:
 - ▶ **March 14th, 2025**
 - ▶ Email: HCA_WA_PDAB@hca.wa.gov