

Washington State SERFF Health and Disability Binder Filing General Instructions

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Instructions

I. Binder Requirements for All Filers

- A. Plan Year 2019 Binders must be submitted in SERFF by May 24, 2018.
 - 1. Qualified Health Plans (QHPs): Carriers must file a binder containing all QHP data necessary for products offered inside, outside, or inside and outside the Health Benefit Exchange (“Exchange”). See the QHP Binder General Requirements section for more information about QHP binder filings.
 - 2. Qualified Dental Plans (QDPs): Carriers must file a binder containing all QDP data necessary for all stand-alone dental plans that provide pediatric dental benefits as one of the Essential Health Benefits (EHBs). See the QDP Binder General Requirements for more information about QDP binder filings.
- B. Only one binder per market per carrier license may be filed.
- C. Binder filings must include templates completed by the carrier as required per market and defined in Exhibit A.
- D. Carriers must add “Accrediting Entity” identifiers.
 - 1. **If an NCQA or URAQ ID is added after the Binder has been created it will not be reflected on the Binder.** See the QHP Company and Contact Tab section for more details.
- E. NAIC Uniform Transmittal Forms are not required when submitting SERFF filings.
- F. Network access reports must not be filed in SERFF.
- G. Carriers must file product forms and rates in SERFF before creating the binder.
 - 1. The “Associate Schedule Items” tab in the binder filing must be used to identify the corresponding form and rate filings.
 - a. You must use the same Electronic Funds Transfer (EFT) instance to file Product, Rate and Binder submissions. *SERFF will not support the Associate Schedule Items tab across multiple instances.*
 - b. Your binder submission is a “For-public” record. Do not associate proprietary rate information.

2. Form, rate, and binder filings must all be consistent with one another. The effective way to expedite review is comparing rates, forms and binder for consistency prior to submission. Finding and objecting to inconsistent information in corresponding filings—matching errors—is the most time-consuming part of the review process, which can be prevented by a proactive issuer. We recommend all issuers proofread and compare their filings prior to submission.
 - a. If the analyst determines that information in the binder does not match the information in the form and rate, the analyst will send an objection indicating that there is an inconsistency and requesting that the issuer amend the binder (and rate, if necessary) to match the form.
 - b. If the analyst finds that there are five or more inconsistencies between the form and the binder, the analyst will cease review of the binder. The analyst will send an objection indicating that review has ceased and request corrections.
 - c. Review of the binder will not resume until after corrections have been received.

II. QHP Binder General Requirements

A. Plans Tab

1. Binders accepted for review generally cannot be changed, other than changes required in response to objections.
 - a. A carrier may request to change a binder filing after it is accepted for review as follows:
 - i. You must send a Note to Reviewer requesting to modify or replace a template or other supporting document after it is accepted for review. The Note to Reviewer must be sent in the affected binder.
 - ii. The Reviewer will notify you in a Note to Filer whether your request is accepted or denied.
 - A. If your request is denied you may not modify or replace the template or other supporting document. You may request the binder be withdrawn.
 - B. If your request is accepted you may update your binder as directed in the Note to Filer.
 - iii. Modification made without proper notice will not be accepted and will be disapproved.
2. **Adding or removing plans – if you add or remove plans that cause a change to your HIOS Plan IDs in your binder filing, SERFF functionality may require you to submit a new binder to allow the change.**

B. Associate Schedule Items Tab

1. You must build your QHP filings using the Associate Schedule Items feature for each plan.
2. You must associate the following documents for each plan:
 - a. Exchange Products:
 - i. Application to be used for direct sale of Exchange health plans off the Exchange per consumer request;
 - ii. Policy;
 - iii. Certificate of Coverage (SHOP);
 - iv. Rate Schedule.
 - b. Outside Market Products:
 - i. Application;
 - ii. Enrollment Form;
 - iii. Policy;
 - iv. Certificate of Coverage (Small Group Market);
 - v. Rate Schedule.
3. You may not associate filing documents from different product submissions to build a plan. For example, you may not associate an application form from product filing 1, and policy form Y from product filing 2 to build a plan.
4. Do not associate supporting documents, such as, but not limited to: checklist, cover letters, certification forms, etc.
5. After adding, replacing or removing documents in the form filings, make sure that the appropriate documents are associated in the binder filing.

C. Supporting Documentation Tab

1. You must submit the Unified Rate Review Template and Actuarial Memorandum [Part III] on the Supporting Documentation tab.
2. The SBE attestation is not currently a 2019 plan year binder requirement. If it becomes a requirement, issuers will be provided the template and asked to add it to their binders.
3. Do not submit the Uniform Product Modification Justification (UPMJ) documentation in the binder filing. **UPMJ documents should be submitted in the rate filing and the primary form filing only.**

4. You must complete and submit one snapshot document (provided by the OIC) in your binder filing. One snapshot should be completed for each binder filing and contain only information about the plans and filings corresponding to the binder filing in which it is submitted.
 - a. Medical issuers must use the snapshot document named "Snapshot-Binder- 2019 Individual and Small Group Medical Filings (Duplicate).xlsm" to prepare their snapshot.
 - b. When submitting the snapshot in the binder the issuer must provide both a PDF and Excel version:
 - i. Name the PDF file, "[Individual or Small Group] Medical Snapshot.pdf"
 - ii. Name the Excel file, "[Individual or Small Group] Medical Snapshot Duplicate.xlsx."
5. You must submit a screenshot of your Data Integrity Tool (DIT) results. You must provide justification for each error shown in your DIT results.
6. **Electronic Review Tool Results**
 - a. You must run the 2019 Category & Class Drug Count Review Tool and the Non-Discrimination Clinical Appropriateness Tool (part of the Formulary Review Suite) and report the results for each of your formularies. Within the Cost Sharing Tool, you must also run the Maximum Out-of-Pocket review and the Catastrophic Plans review (if applicable), and report the results for each of your plans. For your convenience, Submission Requirement sections have been added to the Supporting Documentation tab in SERFF for these results.
 - i. Note that each of the tools includes detailed instructions. Please refer to these instructions in running the tools.
 - ii. You must attach the entire Excel workbook showing your tool results.
 - b. **Category & Class Drug Count Review results**
 - i. When running the Category & Class Drug Count Review Tool, **you must import the Plans and Benefits Template data from the Master Review Tool.** This is necessary so that the tools show results at the plan level and will remove any unused drug lists.
 - ii. You must attach the entire Excel Workbook showing results for each Formulary in each market.
 - iii. The Excel Workbook with these results must show that each Drug List has passed the tool (or passed with justification). For each Category/Class ID that does not meet the EHB benchmark, you must submit your justification.

- A. If you make changes to your Drug List based upon the Tool results, you must run the tool again on the changed Drug List and submit the results based on the changed drug list. You may not provide the original results with a justification indicating you have added a drug to the list to meet the benchmark unless the drug added is not on the HHS EHB Rx Crosswalk.
 - iv. A “passed” result means that the number of covered drugs in each category class meets or exceeds the Benchmark Count.
 - v. Justifications must be submitted using the Washington state “Formulary - Category & Class Drug Count Review Tool Supporting Documentation and Justification” form, which is available on our website using this link. You may also paste the following URL into your browser: <https://www.insurance.wa.gov/health-coverage-filing-instructions>. **Please do not use the Justification form provided by CCIIO. Note: Justification forms must be converted to a PDF format prior to uploading in SERFF. DO NOT upload the WORD version.**
 - vi. If a Category/Class ID does not meet the EHB benchmark and your justification is not sufficient as determined by the OIC, you must add sufficient drugs to the Drug List to meet the EHB benchmark.
- c. **Non-Discrimination Clinical Appropriateness Tool Results**
- i. This is one of the two tools that comprise the Formulary Review Suite (FRS). The FRS will run both tools at once, or you can choose to run only the Non-Discrimination Clinical Appropriateness Tool. Either way is acceptable, as long as each binder filing includes the Excel Workbook showing that each formulary included in that binder has passed the Non-Discrimination Clinical Appropriateness Tool (or passed with justification). (Note that the Non-Discrimination Formulary Outlier Tool results are not required to be submitted because that tool will not produce meaningful results when run on fewer than 5 drug lists).
 - ii. Inputs for the FRS’s dialog boxes
 - A. The first dialog box for this tool asks “Do you have separate individual and SHOP Prescription Drug Templates? Leave the default answer “No”.
 - B. The third dialog box asks whether you wish to import Master Review Tool data. Leave the default answer “Yes”. When running the Category & Class Drug Count Review Tool and the Non-Discrimination Clinical Appropriateness Tool, **you must import the Plans and Benefits Template data from the Master Review Tool**. This is necessary so that the tool shows results at the plan level and will remove any unused drug lists.
 - C. The fourth dialog box asks, “Would you like to run all formulary reviews together?” You may run the suite together or separately, as desired. Only the results of the Non-Discrimination Clinical Appropriateness Tool must be attached to your binder filing.

- iii. Reporting Non-Discrimination Clinical Appropriateness Tool results
- A. You must include the entire Excel Workbook showing results of the Non-Discrimination Clinical Appropriateness Tool for each formulary in the binder. If the results show that all formularies have passed the tool, that is all you must submit.
 - B. The “Clinically Appropriateness Details” worksheet shows results for each condition and drug class being reviewed, and identifies areas where drug coverage does not meet or exceed the applied threshold. Each cell associated with a result of “not met” will be in bold with red font.
 - C. For any Condition and Class that does not meet the State threshold, you must submit a justification using the Washington state “Formulary - Non-Discrimination Clinical Appropriateness Tool Supporting Documentation and Justification” form, which is available on our website using this link. You may also paste the following URL into your browser:
<https://www.insurance.wa.gov/health-coverage-filing-instructions>. **Please do not use the Justification form provided by CCIO. Note: Justification forms must be converted to a PDF format prior to uploading in SERFF. DO NOT upload the WORD version.**
 - D. For each Condition and Class that was not met, you must use these documents to justify why your benefit design is not discriminatory even though it does not meet the State threshold for clinically appropriate drug coverage in that Condition and Class.
 - 1. If a Condition and Class does not meet the State threshold and your benefit design is found to be discriminatory (in other words, if your justification(s) is(are) not sufficient as determined by OIC), you must add unrestricted drugs or remove drug restrictions sufficient enough to meet the State threshold for that Condition and Class.
 - 2. If you make changes to your Drug List based upon the Tool results, you must run the tool again on the changed Drug List. You may not provide the original results with a justification indicating you have added a drug to the list to meet the benchmark unless the drug added is not on the HHS EHB Rx Crosswalk.

d. **Cost Sharing Tool Results**

- i. You must run the Maximum Out of Pocket (MOOP) Review on each of the plans in your binder. If your binder includes any Catastrophic plans, you must run the Catastrophic Plan Review tool on those plans. The Cost Sharing Tool requires input from the Master Review Tool. The Cost Sharing Tool will run 5 different checks on your entire portfolio at once. You may perform all 5 checks, or you may perform only the Maximum Out of Pocket Review and, if applicable, the Catastrophic Plan Review.
- ii. You must run the review tools using the default values.
- iii. You must submit the entire Excel Workbook showing that each plan in your binder has passed the MOOP Review and, if applicable, the Catastrophic Plan Review.

e. **Non-Discrimination Benefit Review Tool**

- i. Issuers should not run the Non-Discrimination Benefit Review Tool or submit results.
 - ii. Because this is a market-wide tool, OIC will run this tool when all Washington plans for Plan Year 2019 have been filed. The tool can only be run once in order to avoid creating a moving target. We will be using the default values in the tool.
 - iii. If any of your plans show outliers, you may be asked to correct or justify your benefit design.
7. You may submit the following 2019 "QHP Application Justification Documents":
- a. "Unique Plan Design - Supporting Documentation and Justification"
 - b. Washington state "Formulary - Category & Class Drug Count Review Tool Supporting Documentation and Justification form"
 - c. Washington State "Formulary - Non-Discrimination Clinical Appropriateness Tool Supporting Documentation and Justification" form.
8. If your Plans and Benefits Template (PBT) contains plans that have unique plan designs as indicated on the Cost-Share Variances tab of the PBT, you must complete and submit a Unique Plan Design Benefit Crosswalk for each plan that qualifies
- a. Issuer's should use the "Checklist-Binder-2019 Individual and Small Group-Unique Plan Design Benefit Crosswalk" document. Submit a PDF version of the Unique Plan Design Benefit Crosswalk in the binder filing only.

D. Templates Tab

You must complete the templates according to the 2019 "QHP Application Instructions" guide unless given other specific guidance by the OIC.

1. Essential Community Provider/Network Adequacy Template
 - a. The Essential Community Provider/Network Adequacy template and Network ID template are interdependent. You must import the Network IDs template into the ECP/Network Adequacy Template.
 - b. You must complete the essential community provider (ECP) section of the template following Instructions for the Essential Community Providers/Network Adequacy Application Section (1E) and Instructions for Network Identification Application.
 - c. **Do Not** complete the Network Adequacy section of the template. Washington State will not be using this template section for review. Per CMS guidance, the ECP section of the template can be completed and validated without completion of the NA template section. Templates received with this section completed will be disapproved.
2. Business Rule Template
 - a. This template must be the same for all binders of the same insurance type (medical or dental).
3. Rate Data Template
 - a. If rates in the corresponding rate filing change, you must also update the rates in the Rate Data Template. If an objection letter is active in the binder filing, update the Rate Data Template when responding to the objection letter. If an objection letter is not active, request to update the Rate Data Template via Note to Reviewer; after receiving a response to the Note to Review, proceed as instructed in the response.
4. Unified Rate Review Template and Actuarial Memorandum
 - a. Part I – Unified Rate Review Template (URRT)
 - i. In the Supporting Documentation tab, you must attach an identical copy of the Part I Unified Rate Review Data Template Duplicate.xls document that was submitted with your initial rate filing. The Part I Unified Rate Review Template is required by all issuers in the individual and small group market.
 - b. Part III – Actuarial Memorandum
 - i. In the Supporting Documentation tab, you must attach an identical copy of the Part III Rate Filing Documentation and Actuarial Memorandum.pdf document that was submitted with your initial rate filing. A Part III Actuarial Memorandum, including corresponding actuarial certifications, must be submitted with each Part I Unified Rate Review Template by all issuers in the individual and small group market.

- c. Both, Part I and Part III
 - i. Please note that the primary review of Part I and Part III is done through the review of rate filing. When we finish the review of the rate filing, we will specifically request that you load the final version of Part I and Part III in the binder. Regardless of the number of versions of Part I and Part III you have filed in the rate filing, you will have only two versions, initial and final versions, loaded in your binder. Please note that per 45 CFR 154.215, there are separate requirements to submit each version of Part I (URRT), Part II, and Part III (Actuarial Memorandum) to CMS through HIOS.
- 5. Plan Benefit Template, Service Area Template, Prescription Drug Template and Network Template
 - a. The Plan Benefit Template, Service Area Template, Prescription Drug Template, and Network template are interdependent. You must complete the Service Area Template, Prescription Drug Template and Network Template **before** creating the Plan Benefits Template. You must import the IDs created in the Service Area Template, Prescription Drug Template and Network Template into the Plan Benefits Template.
 - i. You must complete the Prescription Drug Template, listing every covered drug including Medical Service Drugs.
 - A. In order to demonstrate compliance with the prescription drug Essential Health Benefit, every covered drug must be included in the applicable drug list for each plan. If a drug is not listed on the drug list for a formulary, this means the drug is not covered under plans using that formulary. This includes all covered Medical Service Drugs.
 - 1. "Medical Service Drugs" are drugs which are only administered in a clinical setting, such as Monoclonal Antibodies, Hemophilia clotting factors, and certain cancer chemotherapy drugs.
 - B. For each formulary, all covered Medical Service Drugs must be included in the drug list for that formulary on the Drug List tab of the Prescription Drug Template.
 - 1. The Drug Tier Type column (Column F) on the Formulary Tiers tab of the Prescription Drug Template allows you to create a tier for Medical Service Drugs. If a drug is available only as a Medical Service Drug you may use this drug tier type to reflect that.

2. You are not required to create a separate Medical Service Drug Tier. If you choose not to, or are unable to, list Medical Service Drugs as a separate tier (for example, if your formulary already includes the maximum 7 tiers), you need only ensure that the coverage conditions for these drugs are reflected accurately. If you are unsure how to accomplish that within the functionality of the Prescription Drug Template, please contact your Forms Analyst to determine how to accurately reflect each plan's coverage of Medical Service Drugs.
- ii. You must complete the Plans and Benefits Template.
- iii. A visit limit is considered a "benefit" in the definition of "product" and NOT a "cost-sharing structure" in the definition of "plan."
- iv. Child Only Plans. You must use a separate line for each child only plan. Indicate on the Child Only Offering field that the plan is child only. Enter the child only plan's Standard Component ID in the Child Only Plan ID for the corresponding adult only offering.
- v. Benefit Specific Instructions. After applying the WA Add-In file, the Essential Health Benefits (EHB) data is automatically entered into the sheet using the "Refresh EHB button." The Plan Benefits Add-In file for plan year 2019 requires manual modifications to meet individual state standards. The OIC has reviewed the Washington-specific content on the CMS Plan Benefits Revised Benchmark instructions and identified a few additional requirement modifications.

Apply the changes as identified in the market-specific benefits benchmark files:

- Exhibit B: Washington EHBs on the 2019 Plans & Benefits Template
- Exhibit C: Visual Maps of PBT with Washington EHBs

Note: The files listed above are separate documents that can be found on SERFF: Plan Management tab, Plan Management General Instruction's section for Washington.

- b. Plans and Benefits Template: For **non-preferred brand drugs**, please refer to the QHP Application Instructions (see Section 2D, Subsection 5.8 and Appendix 1, Subsection 6.11.5).

E. Company and Contact Tab

1. Carriers must add "Accrediting Entity" identifiers in Company Information and Accreditation Information sections of the Company and Contact Tab. Enter either the NCQA Org ID (the number assigned by NCQA when an issuer applies for accreditation) and/or a URAC App Number (the identifier assigned by URAC when an issuer applies for accreditation). The Accreditation IDs are entered on the Company maintenance screen. **If an NCQA or URAQ ID is added after the Binder has been created it will not be reflected on the Binder.**

III. QDP Binder General Requirements

A. Plans Tab

1. Binders accepted for review generally cannot be changed, other than changes required to be made in response to objections.
 - a. A carrier may request to change a binder filing after it is accepted for review as follows:
 - i. You must send a Note to Reviewer requesting to modify or replace a template or other supporting document after it has been accepted for review. The Note to Reviewer must be sent in the affected binder.
 - ii. The Reviewer will notify you in a Note to Filer whether your request is accepted or denied.
 - A. If your request is denied you may not modify the template or other supporting document. You may request the binder be withdrawn.
 - B. If your request is accepted you may update your binder as directed in the Note to Filer.
 - iii. Modification made without proper notice will not be accepted and will be disapproved.

Note: The Plan name and Availability indicator are automatically imported into the Plan tab after successfully validating the Plans and Benefits template. **You can only change this information by revision and resubmission of the template.**

B. Associate Schedule Items Tab

1. You must build your QDP filings using the Associate Schedule Items feature for each plan you intend to sell in the marketplace.
2. You must associate the following documents for each plan:
 - a. Exchange Products:
 - i. Application to be used for direct sale of Exchange plans off the Exchange per consumer request;
 - ii. Policy;
 - iii. Schedule of Benefits;
 - iv. Rate Schedule.
 - b. Outside Market Products:
 - i. Application;
 - ii. Enrollment Form (Small Group Market);
 - iii. Policy;
 - iv. Certificate of Coverage (Small Group Market);

v. Rate Schedule.

3. You may not associate filing documents from different product submissions to build a plan. For example, you may not associate an application form from product filing 1, and policy form Y from product filing 2 to build a plan.
4. Do not associate supporting documents, such as, but not limited to: checklist, cover letters, certification forms, etc.

C. Supporting Documentation Tab

1. The SBE attestation is not currently a 2019 plan year binder requirement. If it becomes a requirement, issuers will be provided the template and asked to add it to their binder.
2. You must submit requested documents or attachments as Supporting Documentation.
3. You may submit the following 2019 "QHP Application Justification Documents":
 - a. "Stand-Alone Dental Plan Actuarial Value Supporting Documentation and Justification"
 - b. "Stand-Alone Dental Plan – Description of EHB Allocation"
4. You must complete and submit in your binder filing one snapshot document provided by the OIC. One snapshot should be completed for each binder filing and contain only information about the plans and filings corresponding to the binder filing in which it is submitted.
 - a. Dental issuers must use the snapshot document named "Snapshot-Binder-2019 Individual and Small Group Dental Filings (Duplicate).xism" document to prepare
 - b. When submitting the snapshot in the binder the issuer must provide both a PDF and Excel version:
 - i. Name the PDF file, "[Individual or Small Group] Stand-Alone Dental Snapshot.pdf"
 - ii. Name the Excel file, "[Individual or Small Group] Stand-Alone Dental Snapshot Duplicate.xlsx"
5. You must submit a screenshot of your Data Integrity Tool (DIT) results. You must provide justification for each error shown in your DIT results.

D. Templates Tab

You must complete the following templates using the 2019 "QHP Application Instructions".

1. Essential Community Provider/Network Adequacy Template

- a. The Essential Community Providers/Network Adequacy template and Network ID template are interdependent. You must import the Network IDs template into the ECP/Network Adequacy Template.
- b. You must complete the essential community provider (ECP) section of the template following Instructions for the Essential Community Providers/Network Adequacy Application Section (1E) and Instructions for Network Identification Application.
- c. **Do Not** complete the Network Adequacy section of the template. Washington State will not be using this template section for review. Per CMS guidance, the ECP section of the template can be completed and validated without completion of the NA template section. Templates received with this section completed will be disapproved.

2. Business Rule Template

- a. This template must be the same for all binders of the same insurance type (medical or dental).

3. Rate Data Template

- a. If rates in the corresponding rate filing change, you must also update the rates in the Rate Data Template. If an objection letter is active in the binder filing, update the Rate Data Template when responding to the objection letter. If an objection letter is not active, request to update the Rate Data Template via Note to Reviewer; after receiving a response to the Note to Reviewer, proceed as instructed in the response.

4. Plan Benefit Template, Service Area Template and Network Template

- a. The Plan Benefit Template, Service Area Template, and Network template are interdependent. You must complete the Service Area Template and Network Template **before** creating the Plan Benefits Template. You must import the IDs created in the Service Area Template and Network Template into the Plan Benefits Template.
- b. You must complete the Plans Benefits Template.
 - i. A visit limit is considered a "benefit" in the definition of "product" and NOT a "cost-sharing structure" in the definition of "plan."

- ii. Child Only Plans. You must use a separate line for each child only plan. Indicate on the Child Only Offering field that the plan is child only. Enter the child only plan's Standard Component ID in the Child Only Plan ID for the corresponding adult only offering.

Benefit Specific Instructions. After applying the WA Add-In file, the Essential Health Benefits (EHB) data is automatically entered into the sheet using the "Refresh EHB button". The Plan Benefits Add-In file for plan year 2019 requires manual modifications to meet individual state standards. The OIC has reviewed the Washington-specific content on the CMS Plan Benefits Revised Benchmark instructions and identified a few additional requirement modifications. Apply the changes as identified in the benefits benchmark files:

- Exhibit B: Washington EHBs on the 2019 Plans & Benefits Template
- Exhibit C: Visual Maps of PBT with Washington EHBs

Note: The files listed above are separate documents that can be found on SERFF: Plan Management tab, Plan Management General Instructions section for Washington.

IV. Beginning 2019: Quarterly Formulary Filings [WAC 284-43-5642(6)(e)(i)]

- A. Carriers who file non-grandfathered individual and small group plans must file their formularies quarterly. **Note: This section does not apply to Student Health Plans under TOI H22 (Please refer to the *Washington State SERFF Health and Disability Form Filing General Instructions, Section VII, for instructions regarding filing formularies for Student Health Plans*).**
- B. When to file:
 1. For non-grandfathered individual and small group health plans the 1st quarter formularies are filed as part of the annual binder filing.
 2. For all non-grandfathered individual and small group health plans the 2nd, 3rd, and 4th quarter formularies must be filed in .xls format prior to the beginning of the quarter during which they will be in effect. Therefore, the 2nd quarter filings are due prior to April 1, the 3rd quarter filings are due prior to July 1, and the 4th quarter filings are due prior to October 1. For your convenience, Submission Requirement sections have been added to the Supporting Documentation tab in SERFF for these quarterly results.

- C. You must file each quarterly formulary using the current Prescription Drug Template published by CCIIO, in your Binder filing for that Plan Year.
1. Issuers of non-grandfathered individual and small group health plans must file each quarterly formulary using the Prescription Drug Template published by CCIIO for that plan year. For example, formularies for the 1st quarter of the 2019 Plan Year will be filed as part of the Binder using the Prescription Drug Template for Plan Year 2019. The 2nd, 3rd, and 4th quarter 2019 formularies for those plans will be filed using the same version of the Prescription Drug Template.
 2. You can obtain the Template and the instructions for completing it using this link, or by pasting the following URL into your browser: <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/qhp.html#Instructions, Templates and Materials>
- D. **Electronic Review Tool Results**
1. For each non-grandfathered individual and small group formulary filing you must run the current Category & Class Drug Count Review Tool and the Non-Discrimination Clinical Appropriateness Tool (part of the Formulary Review Suite). You must report the results for each of your quarterly formularies.
 - a. Note that each of the tools includes detailed instructions. Please refer to these instructions in running the tools. (The Formulary Review Suite detailed instructions are a PDF document included in the folder called "Prescription Drug Reference Filed.")
 - b. The entire Excel workbook of tool results must be submitted by attaching the Workbook on the Supporting Documentation tab.
 2. **Category & Class Drug Count Review results**
 - a. When running the Category & Class Drug Count Review tool, **you must import the Plans and Benefits Template data from the Master Review Tool**. This is necessary so that the tools show results at the plan level and will remove any unused drug lists.
 - b. Submit the entire Excel Workbook showing results for each Formulary in each market by attaching it on the Supporting Documentation tab under the applicable Submission Requirement section.
 - c. Your formulary filing must include documentation showing that each Drug List has passed the tool (or passed with justification). For each Category/Class ID that does not meet the EHB benchmark, you must submit your justification.
 - i. If you make changes to your Drug List based upon the Tool results, you must run the tool again on the changed Drug List and submit the results based on the changed drug list. You may not provide the original results with a justification indicating you have added a drug to the list to meet the benchmark unless the drug added is not on the HHS EHB Rx Crosswalk.
 - ii. A "passed" result means that the number of covered drugs in each category class meets or exceeds the Benchmark Count.

- d. Justifications must be submitted using the Washington state "Formulary - Category & Class Drug Count Review Tool Supporting Documentation and Justification" form, which is available on our website using this link. You may also paste the following URL into your browser: <https://www.insurance.wa.gov/health-coverage-filing-instructions>. **Please do not use the Justification form provided by CCIIO. Note: Justification forms must be converted to a PDF format prior to uploading in SERFF. DO NOT upload the WORD version.**
 - e. If a Category/Class ID does not meet the EHB benchmark and your justification is not sufficient as determined by the OIC, you must add sufficient drugs to the Drug List to meet the EHB benchmark.
3. **Non-Discrimination Clinical Appropriateness Tool Results**
- a. This is one of the two tools that comprise the Formulary Review Suite (FRS). The FRS will run both tools at once, or you can choose to run only the Non-Discrimination Clinical Appropriateness Tool. Either way is acceptable (note that the Non-Discrimination Formulary Outlier Tool results are not required to be submitted because that tool will not produce meaningful results when run on fewer than 5 drug lists).
 - b. Submit the entire Excel Workbook showing results for each formulary in each market by attaching it on the Supporting Documentation tab under the applicable Submission Requirement section.
 - c. Your formulary filing must include documentation showing that each formulary has passed the tool (or passed with justification). For any Condition and Class that does not meet the State Threshold, you must submit your justification.
 - i. If you make changes to your Drug List based upon the Tool results, you must run the tool again on the changed Drug List and submit the results based on the changed drug list. You may not provide the original results with a justification indicating you have added a drug to the list or removed a restriction to meet the benchmark unless the drug in question is not on the HHS EHB Rx Crosswalk.
 - d. Justifications must be submitted using the Washington state "Formulary - Non-Discrimination Clinical Appropriateness Tool Supporting Documentation and Justification" form, which is available on our website using this link. You may also paste the following URL into your browser: <https://www.insurance.wa.gov/health-coverage-filing-instructions>. **Please do not use the Justification form provided by CCIIO. Note: Justification forms must be converted to a PDF format prior to uploading in SERFF. DO NOT upload the WORD version.**
 - e. Inputs for the FRS's dialog boxes.
 - i. The first dialog box for this tool asks, "Do you have separate individual and SHOP Prescription Drug Templates?" Leave the default answer "No."
 - ii. The third dialog box asks whether you wish to import Master Review Tool data. Leave the default answer "Yes." When running the Non-Discrimination Clinical Appropriateness Tool, **you must import the Plans and Benefits Template data from the Master Review Tool**. This is necessary so that the tool shows results at the plan level and will remove any unused drug lists.

- iii. The fourth dialog box asks, "Would you like to run all formulary reviews together?" You may run the suite together or separately, as desired. Only the results of the Non-Discrimination Clinical Appropriateness Tool must be attached to your formulary filing.
 - f. If a formulary's unrestricted drug coverage does not meet the threshold for a Category/Class for any condition, and the justification is not sufficient as determined by the OIC, you must add unrestricted drugs or remove drug restrictions sufficient to meet the State threshold for that Condition and Category/Class.
4. **How to File Quarterly Formularies for the 2nd, 3rd, and 4th Quarters.**
- a. Due to SERFF functionality, quarterly formularies must be filed by adding them to your Binder filing for that market for that Plan Year.
 - i. When you are prepared to file your quarterly formularies, you must request permission to amend or re-open your Binder filing for that market and Plan Year via a Note to Reviewer in SERFF.
 - A. For example, you would request to re-open your Individual Market Binder for Plan Year 2019 in order to file the 2nd quarter 2019 formulary for your Individual plans.
 - ii. OIC will notify you that the Binder filing has been re-opened and you may amend the filing via a Note to Filer in SERFF.
 - iii. Under the Supporting Documentation tab, locate the appropriate Submission Requirement for that quarter (i.e. "2nd Quarter (2019) Formulary Tool Results, Washington Justification Attestations, and Objection Letter Responses") and attach the updated Prescription Drug Template for that quarter, the Excel Workbooks showing the results for each of the required Electronic Review tools, and any required justifications.
5. **Requirements to Include Covered Medical Service Drugs in Formulary Filings.**
- a. In order to demonstrate compliance with the prescription drug Essential Health Benefit, every covered drug must be included in the applicable drug list for each plan. If a drug is not listed on the drug list for a formulary, that means the drug is not covered under plans using that formulary. This includes all covered Medical Service drugs.
 - i. "Medical Service Drugs" are drugs which are only administered in a clinical setting, such as Monoclonal Antibodies, Hemophilia clotting factors, and certain cancer chemotherapy drugs.
 - b. For each formulary, all covered Medical Service Drugs must be included in the drug list for that formulary on the Drug List tab of the Prescription Drug Template.
 - i. The Drug Tier Type column (Column F) on the Formulary Tiers tab of the Prescription Drug Template allows you to create a tier for Medical Service Drugs. If a drug is available only as a Medical Service Drug you may use this drug tier type to reflect that.

- ii. You are not required to create a separate Medical Service Drug Tier. If you choose not to, or are unable to, list Medical Service Drugs as a separate tier (for example, if your formulary already includes the maximum 7 tiers), you need only ensure that the coverage conditions for these drugs are reflected accurately. If you are unsure how to accomplish that within the functionality of the Prescription Drug Template, please contact your Forms Analyst to determine how to accurately reflect each plan's coverage of Medical Service Drugs.

V. Your Binder Filing is Incomplete and will be rejected if:

- A. Your filing does not comply with chapters 284-44A, 284-46A, or 284-58 WAC.
- B. We cannot download your filing into our back office system.
 1. There are a number of reasons why we cannot download filings into our back office system. The most common reasons include: an incorrect CoCode number is entered in the Filing Company Information, under the Companies and Contact Tab. This CoCode number is the same number as your company's 5-digit NAIC number.
- C. The Associate Schedule Items tab is bypassed or improperly completed.
- D. The form or rate schedule items are associated across multiple EFT instances.
- E. The binder is submitted for multiple market types.
- F. The binder is submitted for multiple carrier licenses.
- G. All required templates are not loaded.
- H. All required templates are not loaded on the appropriate tab.
- I. All required supporting documentation files are not attached on the Supporting Documentation tab.
- J. For QHP's the Accrediting Entity identifier has not been added to the Company Profile.
- K. Rejected Filings will not be Re-Opened
 1. If the OIC Technical Support Unit rejects your filing, you must submit a new filing following the procedures in our Rejection Notice and General Instructions.

VI. SERFF Objection Letter Response Requirements for Binder Filings

- A. You may not submit a partial response to an objection letter.
 1. You must provide a complete Response Letter that addresses all objections listed in the objection letter. It is highly recommended that carriers use a single point of contact to respond to all issues presented in an objection letter. A partial response letter will cause your filing to be delayed and may require it to be closed without additional review.

- B. When you are requested to make corrections to your binder, you must make the correction on every tab in the binder where the error appears.
1. Example 1: You are requested to change the entry in Column K on the Benefits Package tab to correctly reflect an EHB. You must ensure that you have correctly made the change on every Benefits Package tab in the binder.
 2. Example 2: Your analyst has informed you that review of your primary review product is complete. The analyst requests that you make all changes to the tabs for the other products according to the changes made in the primary review product. You must ensure that you correctly make all the changes on every tab in the binder.
 3. If your analyst finds that you have not made corrections in every tab of the binder, the analyst will cease review of the binder. The analyst will send an objection indicating that review has ceased and requesting a corrected binder.

VII. After a Final Disposition by OIC Analyst

After final disposition by an OIC Analyst you may not change or correct the filing. You must make a new filing in SERFF.

Contact Information

For questions related to Template filing completion, validation and other procedures contact:

Exchange Operations Support Center (XSOC)

855-CMS-1515

CMS_FEPS@cms.hhs.gov

For questions related to SERFF System, Submission Requirement, or General Workflow Issues contact:

SERFF Help Desk

816-783-8990

serffhelp@naic.org

For question related to Washington filing procedures, contact:

Rates & Forms Help Desk

(360) 725-7111

rfhelpdesk@oic.wa.gov