

Qualified Health Plan Issuer Application Instructions

2021

**Extracted section:
Section 2C: Prescription Drug**

[05/2020]

Version 1.1

Section 2C: Prescription Drug

1. Introduction

In the Prescription Drug section, issuers create cost-sharing values for each tier of drug benefits along with specific drugs included in the formulary. They also select the drugs that will be offered at each tier level. These instructions do not apply to SADP only issuers.

2. Data Requirements

To complete this section, issuers will need the following:

1. A drug list with RxNorm Concept Unique Identifiers (RXCUIs), along with their formulary tier numbers. An issuer may offer drugs that do not have associated RXCUIs, but they cannot be included on the Prescription Drug Template.²

3. Quick Reference

Key Changes for 2021

- ◆ Formulary URLs are no longer collected in the Prescription Drug section. Issuers must now submit their URLs via the Supplemental Submission Module (SSM).

Tips for the Prescription Drug Section

- ◆ RXCUIs should have one of the following Term Types (TTYs): semantic branded drug (SBD), semantic clinical drug (SCD), brand name pack (BPCK), or generic pack (GPCK).
- ◆ Set Tier Level equal to “NA” (not applicable) if the drug is not part of a given drug list.
- ◆ All formularies associated with the same drug list should have the same Number of Tiers and the same Drug Tier Type for a given tier. In other words, each drug list may have only one tier structure, as indicated by the number of tiers and drug tier types. The .XML generated from the template and submitted to HIOS includes only the Number of Tiers and Drug Tier Type fields for the first formulary associated with each drug list.

4. Detailed Section Instructions

Issuers need to complete the Drug Lists worksheet before they fill out the Formulary Tiers worksheet in the template. An example is shown in **Figure 2C-1**.

² Pursuant to 45 CFR 156.122(a)(3), for plan years beginning on or after January 1, 2018, a health plan does not provide essential health benefits (EHBs) unless it uses a pharmacy and therapeutics committee that meets certain standards.

Figure 2C-1. Drug Lists Worksheet

Drug Lists		All fields with an asterisk (*) are required. To validate the template, press the Validate button or Ctrl + Shift + V. To finalize, press Finalize button or Ctrl + Shift + F. Click the Create Formulary IDs button (or Ctrl + Shift + C) to create Formulary IDs.					
Add Drug List	After creating Formulary IDs, select the ID from the drop down in Column A and 7 tiers will automatically be populated.						
Remove Drug List	Select how many tiers a formulary uses from Number of Tiers and unused rows (tiers) will be greyed out.						
	Enter all RXCUIs on the Drug Lists sheet. To add more drug lists, click Add Drug List (Ctrl + Shift + A) and to delete the last drug list added press Delete Drug Lists (or Ctrl + Shift + D).						
	Drug List ID 1			Drug List ID 2			
RXCUI*	Tier Level*	Prior Authorization Required	Step Therapy Required	Tier Level*	Prior Authorization Required	Step Therapy Required	
Required: Enter the RXCUI	Required: Select the Tier this drug is in, or select NA if this drug is not a part of this Drug List	Required if Tier Level is not NA: Select "Yes" if Prior Authorization is Required	Required if Tier Level is not NA: Select "Yes" if Step Therapy is Required	Required: Select the Tier this drug is in, or select NA if this drug is not a part of this Drug List	Required if Tier Level is not NA: Select "Yes" if Prior Authorization is Required	Required if Tier Level is not NA: Select "Yes" if Step Therapy is Required	
405550	3	No	No		3	No	
405551	2	No	Yes	NA			
405552	1	No	No		1	No	
405553	1	No	No		1	No	
405554	2	No	No		2	No	
405555	3	No	No		3	No	
405556	3	No	No		3	No	
405557	2	No	No	NA			
405558	1	No	No	NA			
405559	1	No	No		1	No	
405560	2	No	No		2	No	
405561	3	No	No		3	No	
405562	3	No	No		3	No	
405563	2	No	No		2	No	
405564	1	No	No		1	No	
405565	1	No	No	NA			
405566	2	No	No		2	No	
405567	3	No	No		3	No	
405568	3	No	No		3	No	

Before entering details for each drug list, enter all RXCUIs included in any of the drug lists. RXCUIs are entered into Column A, beginning in Row 9. Once the issuer has entered all of the unique RXCUIs for its drug lists, it should begin entering the drug list-specific information in each row.

Drug List	Steps
RXCUI	<ul style="list-style-type: none"> When selecting RXCUIs to include, use the October 7, 2019, full monthly release of RxNorm to find a list of valid RXCUIs. Download the RxNorm release at https://www.nlm.nih.gov/research/umls/rxnorm/docs/rxnormfiles.html. To download the file, the issuer will need a Unified Medical Language System (UMLS) Metathesaurus License and a UMLS Terminology Services Account. The issuer can obtain a license and account at no charge by following the instructions at http://www.nlm.nih.gov/databases/umls.html#license_request. CMS posts the EHB RX Crosswalk and a reformatted RxNorm database along with the state review tools at https://www.qhcpertification.cms.gov/s/Review%20Tools. RXCUIs should have one of the following TTYs: SBD, SCD, BPCK, or GPCK. The drug list should include all drugs on the issuer's formulary, even if they do not fall in one of the categories and classes identified in the summary of EHB benchmark information, available at https://www.qhcpertification.cms.gov/s/Prescription%20Drugs. This includes all drugs deemed by the issuer as "medical service drugs."
Tier Level	For each drug, select the RXCUI's cost-sharing tier level from the drop-down menu, or select "NA" if this drug is not part of the given drug list.
Prior Authorization Required	Indicate whether the drug requires the prescribing physician to obtain prior authorization before the plan covers the drug. Choose from the following options: <ul style="list-style-type: none"> Yes—if prior authorization is required. No—if prior authorization is <i>not</i> required. If Tier Level is "NA," leave this column blank.
Step Therapy Required	Indicate whether the plan requires the enrollee to try at least one other drug before the plan covers the given drug. Choose from the following options: <ul style="list-style-type: none"> Yes—if step therapy is required. No—if step therapy is <i>not</i> required. If Tier Level is "NA," leave this column blank.

To add another drug list, click the **Add Drug List** button (Figure 2C-2). For the new drug list, issuers need to complete the Tier Level, Prior Authorization Required, and Step Therapy Required columns as described above. Once an issuer has completed these columns, the required drug list information is complete.

Figure 2C-2. Add Drug List Button

	A	B	C	D	E	F	G	H
1	Drug Lists	All fields with an asterisk (*) are required. To validate the template, press the Validate button or Ctrl + Shift + V. To finalize, press Finalize button or Ctrl + Shift + F.						
2		Click the Create Formulary IDs button (or Ctrl + Shift + C) to create Formulary IDs.						
3		After creating Formulary IDs, select the ID from the drop down in Column A and 7 tiers will automatically be populated.						
4		Select how many tiers a formulary uses from Number of Tiers and unused rows (tiers) will be greyed out.						
5		Enter all RXCUiTs on the Drug Lists sheet. To add more drug lists, click Add Drug List (Ctrl + Shift + A) and to delete the last drug list added press Delete Drug Lists (or Ctrl + Shift + D).						
6		Drug List ID 1			Drug List ID 2			
7		RXCUi*	Tier Level*	Prior Authorization Required	Step Therapy Required	Tier Level*	Prior Authorization Required	Step Therapy Required
8		Required: Enter the RXCUi	Required: Select the Tier this drug is in, or select NA if this drug is not a part of this Drug List	Required if Tier Level is not NA: Select "Yes" if Prior Authorization is Required	Required if Tier Level is not NA: Select "Yes" if Step Therapy is Required	Required: Select the Tier this drug is in, or select NA if this drug is not a part of this Drug List	Required if Tier Level is not NA: Select "Yes" if Prior Authorization is Required	Required if Tier Level is not NA: Select "Yes" if Step Therapy is Required
9		405550	3 No	No		3 No	No	
10		405551	2 No	Yes	NA	3 No	No	
11		405552	1 No	No		1 No	No	
12		405553	1 No	No		1 No	No	

To remove a drug list, click the **Remove Drug List** button (Figure 2C-3). Drug lists are removed in the reverse order in which they were created. In other words, the last drug list created is removed first. If the issuer wants to remove a drug list that is not the last drug list created (for example, if there are four drug lists and the issuer wants to remove the second one), copy and paste the data from the last drug list into the drug list that the issuer wants to delete; then click the **Remove Drug List** button.

Delete any drug lists that are not used. A drug list that is not used links to a formulary ID that does not link to a standard component ID in the Plans & Benefits Template. When removing drug lists, make sure that all remaining formulary IDs are linked to the correct drug lists.

Figure 2C-3. Remove Drug List Button

	A	B	C	D	E	F	G	H
1	Drug Lists	All fields with an asterisk (*) are required. To validate the template, press the Validate button or Ctrl + Shift + V. To finalize, press Finalize button or Ctrl + Shift + F.						
2		Click the Create Formulary IDs button (or Ctrl + Shift + C) to create Formulary IDs.						
3		After creating Formulary IDs, select the ID from the drop down in Column A and 7 tiers will automatically be populated.						
4		Select how many tiers a formulary uses from Number of Tiers and unused rows (tiers) will be greyed out.						
5		Enter all RXCUiTs on the Drug Lists sheet. To add more drug lists, click Add Drug List (Ctrl + Shift + A) and to delete the last drug list added press Delete Drug Lists (or Ctrl + Shift + D).						
6		Drug List ID 1			Drug List ID 2			
7		RXCUi*	Tier Level*	Prior Authorization Required	Step Therapy Required	Tier Level*	Prior Authorization Required	Step Therapy Required
8		Required: Enter the RXCUi	Required: Select the Tier this drug is in, or select NA if this drug is not a part of this Drug List	Required if Tier Level is not NA: Select "Yes" if Prior Authorization is Required	Required if Tier Level is not NA: Select "Yes" if Step Therapy is Required	Required: Select the Tier this drug is in, or select NA if this drug is not a part of this Drug List	Required if Tier Level is not NA: Select "Yes" if Prior Authorization is Required	Required if Tier Level is not NA: Select "Yes" if Step Therapy is Required
9		405550	3 No	No		3 No	No	
10		405551	2 No	Yes	NA	3 No	No	
11		405552	1 No	No		1 No	No	
12		405553	1 No	No		1 No	No	

Once the Drug Lists worksheet is completed, navigate to the Formulary Tiers worksheet.

Formulary Tiers	Steps
HIOS Issuer ID	Enter the five-digit HIOS Issuer ID.
State	Select the state for which the template applies from the drop-down menu.
Generate Formulary IDs	<p>Click the Create Formulary IDs button to create the formulary IDs.</p> <ul style="list-style-type: none"> A pop-up dialog box appears and prompts the issuer to enter the number of formularies. After entering the number of formularies, the message "Formulary IDs have been generated successfully" appears. Click OK. The IDs are automatically generated, consisting of the state abbreviation, the letter "F," and a sequenced number (such as ALF001 and ALF002). Once completed, the formulary IDs appear in a drop-down menu in the Formulary ID column.

Formulary Tiers	Steps
Formulary ID	<p>Select the formulary ID from the drop-down menu.</p> <ul style="list-style-type: none"> ◆ After a formulary ID is selected, the template populates some cells and grays out others that do not apply. When a cell is grayed out, it is locked and cannot be edited. HIOS will not process data entered into the cell before it was grayed out. ◆ Select only formulary IDs that will be linked to a standard component ID used in the Plans & Benefits Template.
Drug List ID	<p>Select the appropriate drug list ID from the drop-down menu. The menu is auto-populated with the drug list IDs that were created on the Drug Lists worksheet. If the Drug Lists worksheet has not been completed, do so now.</p>
Number of Tiers	<p>Select the number of tiers (1–7) from the drop-down menu. The number of tier levels in a given formulary should correspond to the number of tiers in the associated drug list. Cost-sharing subgroups cannot be created within a tier. All drugs within the same tier should have the same cost-sharing structure.</p>
Drug Tier ID	<p>The template populates this column according to the selection in Number of Tiers. The other cells are grayed out, indicating they do not apply. The Drug Tier ID column is controlled by the template; do not edit it.</p>
Drug Tier Type	<p>Click the drop-down menu, and select the Click here to select option to open a pop-up dialog box. Choose from the following options, and select a maximum of two drug types (one generic type and one brand type) for each tier. No additional tier type can be selected for Zero Cost Share Preventive Drugs or Medical Service Drugs.</p> <ul style="list-style-type: none"> ◆ If a tier contains both preferred and non-preferred generic drugs, select only one tier type. Choose the tier type according to the majority of drugs in the tier. For example, if the tier contains 80 percent preferred generic and 20 percent non-preferred generic, then choose the tier type of preferred generic. The same applies for a tier with preferred and non-preferred brand drugs. ◆ Multiple tiers may have the same drug tier types, but tiers should have different cost sharing. ◆ If the issuer has both preferred and non-preferred specialty drugs, create two tiers and differentiate between the two using cost sharing. One way to represent this design is to designate the first as Preferred Brand, Specialty and the second as Non-Preferred Brand, Specialty. <p><i>Zero Cost Share Preventive Drugs:</i></p> <ul style="list-style-type: none"> ◆ When Zero Cost Share Preventive Drugs is selected, it is the only tier type that can be selected for the tier. It is preferred that the issuer place the Zero Cost Share Preventive Drug tier as Tier 1 if applicable, to represent the lowest-cost tier to the consumer. ◆ The 1 Month In Network Retail Pharmacy Copayment and 1 Month In Network Retail Pharmacy Coinsurance information will automatically be set to \$0 and 0 percent, respectively, when this tier type is chosen. The remaining pharmacy benefit types can still be edited. If the remaining pharmacy benefits are offered, then the subsequent cost-sharing values should be entered as \$0 and 0 percent. ◆ If the issuer has a tier that contains preventive drugs, but those drugs can incur cost sharing for different circumstances, then complete the cost-sharing fields for the most typical or most used benefit cost-share design. Describe any cost-sharing features that do not directly fit into the Prescription Drug Template in the Explanation field of the Plans & Benefits Template, in the plan brochure, and on the formulary web page. <p><i>Medical Service Drugs:</i></p> <ul style="list-style-type: none"> ◆ Use this tier type to indicate if a formulary contains medical service drugs. CMS recognizes that there are some state benchmarks that contain medical service drugs in various categories and classes; a Medical Service Drugs tier can assist in identifying these drugs in the formulary. ◆ When Medical Service Drugs is selected, it is the only tier type that can be selected for the tier. ◆ The 1 Month In Network Retail Pharmacy Copayment and 1 Month In Network Retail Pharmacy Coinsurance will both be automatically set to Not Applicable when this tier type is chosen. The remaining pharmacy benefit types cannot be edited.
Tier Cost Sharing	<p>This section describes how to document the cost-sharing structure for each drug tier. The only columns that must be populated are 1 Month In Network Retail Pharmacy Copayment and 1 Month In Network Retail Pharmacy Coinsurance. The issuer must indicate whether each tier</p>

Formulary Tiers	Steps
	<p>offers these types of pharmacy benefits, but should only complete the information for the other three pharmacy types if they apply to the given drug tier. The pharmacy benefits are as follows:</p> <ul style="list-style-type: none"> ◆ 1 Month In Network Retail Pharmacy (Copayment & Coinsurance) ◆ 1 Month Out of Network Retail Pharmacy Benefit Offered? ◆ 1 Month Out of Network Retail Pharmacy (Copayment & Coinsurance) ◆ 3 Month In Network Mail Order Pharmacy Benefit Offered? ◆ 3 Month In Network Mail Order³ Pharmacy (Copayment & Coinsurance) ◆ 3 Month Out of Network Mail Order Pharmacy Benefit Offered? ◆ 3 Month Out of Network Mail Order Pharmacy (Copayment & Coinsurance).
Benefit Offered	Select Yes if the pharmacy benefit is offered for the corresponding tier. Otherwise, select No .
Copayment	<p>Enter the copayment amount for the given pharmacy type. Round any copayments to the hundredths decimal place. Choose from the following options:</p> <ul style="list-style-type: none"> ◆ No Charge—no cost sharing is charged (this indicates that this benefit is <i>not</i> subject to the deductible). <i>Note:</i> Use Not Applicable, <i>not</i> No Charge, if only a coinsurance is charged. ◆ No Charge after deductible—the consumer first pays the deductible, and after the deductible is met, no copayment is charged (this indicates that this benefit is subject to the deductible). ◆ \$X—the consumer always pays just the copay and the issuer pays the remainder of allowed charges (this indicates that this benefit is <i>not</i> subject to the deductible). ◆ \$X Copay after deductible—the consumer first pays the deductible, and after the deductible is met, the consumer is responsible only for the copay (this indicates that this benefit is subject to the deductible). ◆ \$X Copay with deductible—the consumer first pays the copay, and any net remaining allowed charges accrue to the deductible (this indicates that this benefit is subject to the deductible). ◆ Not Applicable—the consumer pays only a coinsurance. <i>Note:</i> When using Not Applicable for copay, Not Applicable cannot also be used for coinsurance (unless the drug tier type is Medical Service Drugs).
Coinsurance	<p>Enter the coinsurance amount for the given pharmacy type. Round any coinsurance to the hundredths decimal place. Choose from the following options:</p> <ul style="list-style-type: none"> ◆ No Charge—no cost sharing is charged (this indicates that this benefit is <i>not</i> subject to the deductible). <i>Note:</i> Use Not Applicable, <i>not</i> No Charge, if only a copay is charged. ◆ No Charge after deductible—the consumer first pays the deductible, and after the deductible is met, no coinsurance is charged (this indicates that this benefit is subject to the deductible). ◆ X%—the consumer always pays just the coinsurance and the issuer pays the remainder of allowed charges (this indicates that this benefit is <i>not</i> subject to the deductible). ◆ X% Coinsurance after deductible—the consumer first pays the deductible, and after the deductible is met, the consumer pays the coinsurance portion of allowed charges (this indicates that this benefit is subject to the deductible). ◆ Not Applicable—the consumer pays only a copay. <i>Note:</i> When using Not Applicable for coinsurance, Not Applicable cannot also be used for copay (unless the drug tier type is Medical Service Drugs).

Issuers should complete cost-sharing fields in the Prescription Drug Template for the most typical or most used benefit cost-share design. Issuers can describe any cost-sharing features that do not directly fit into the Prescription Drug Template in the **Explanation** field of the Plans & Benefits Template, in the plan brochure, and on the Formulary web page.

CMS will review tier placement to ensure that the formulary does not substantially discourage the enrollment of certain beneficiaries. When developing their formulary tier structure, issuers should use standard industry

³ Pursuant to 45 CFR 156.122, for plan years beginning on or after January 1, 2017, a health plan providing EHBs must have access to prescription drug benefits at in-network retail pharmacies, unless the drug meets an exception under 45 CFR 156.122(1)(i) and (ii).

practices. Tier 1 should be considered the lowest cost-sharing tier available, which means a Zero Cost Share Preventive tier should be listed first. Any and all subsequent tiers in the formulary structure will be higher cost-sharing tiers in ascending order. Place the Medical Service Drug tier as the last tier for all formulary designs.

Preventive services under the Patient Protection and Affordable Care Act (PPACA) must be covered without requiring the consumer to pay a copayment or coinsurance or meet a deductible. For more information on the coverage of preventive services, see <https://www.healthcare.gov/coverage/preventive-care-benefits/>.

CMS recommends that issuers place preventive drugs in a separate Zero Cost Share Preventive tier in the Prescription Drug Template. If an issuer has a tier that contains preventive drugs, but those drugs can incur cost sharing for different circumstances, complete the cost-sharing fields for the most typical or most used benefit cost-share design. Describe any cost-sharing features that do not directly fit into the Prescription Drug Template in the **Explanation** field of the Plans & Benefits Template, in the plan brochure, and on the Formulary web page.

If an issuer has already used all seven available tiers, include zero cost preventive drugs in the lowest-cost tier and clearly identify that these drugs are available at zero cost sharing in the plan brochures and on the Formulary web page; all drugs within the same tier should have the same cost sharing.

Alternatively, if an issuer has already used all seven available tiers and one of the tiers is a medical service drug tier, include the zero cost preventive drugs as a tier and remove the medical service drug tier.

If an issuer has a tier with cost sharing of zero and it is not a preventive tier, then the issuer may either select **No Charge** for copayment and **Not Applicable** for coinsurance or **Not Applicable** for copayment and **No Charge** for coinsurance in the Formulary Tiers worksheet. Note that an issuer cannot use **Not Applicable** for both copayment and coinsurance at the same time.

The Prescription Drug Template does not capture minimum or maximum copay or coinsurance. CMS recommends that issuers describe in detail any cost-sharing designs that are not captured in the Prescription Drug Template in the **Explanation** field of the Plans & Benefits Template, in a plan brochure, and on the Formulary web page.

Once the Prescription Drug Template is completed, issuers must validate, finalize, and upload it into HIOS.

Template Validation	Steps
Validate Template	Click the Validate button in the top left of the template. The validation process identifies any data issues that need to be resolved. If no errors are identified, finalize the template.
Validation Report	If the template has any errors, a Validation Report will appear in a pop-up box showing the data element and cell location of each error. Correct any identified errors and click Validate again. Continue this process until all errors are resolved.
Finalize Template	Click the Finalize button in the template. The Finalize function creates the .XML file of the template that will need to be uploaded in the Prescription Drug section of the Benefits and Service Area Module in HIOS.
Save Template	Save the XML Template. CMS recommends saving the validated template as a standard Excel .XLSM file in the same folder as the finalized .XML file.
Upload Template	Upload the saved .XML file in the Prescription Drug section of the Benefits and Service Area Module in HIOS. Refer to the Benefits and Service Area Module User Guide for details on how to upload this file.