Chapter 12: Instructions for the Prescription Drug Application Section

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1. Purpose
The purpose of the Prescription Drug section of the Qualified Health Plan (QHP) Application is to allow the issuer to provide the formulary information associated with each plan. This chapter guides issuers through completing the Prescription Drug section of the QHP Application.

2. Overview
Issuers applying for certification to sell on the Marketplace must complete the Prescription Drug Template as part of their QHP Application. The Centers for Medicare & Medicaid Services (CMS) uses data collected in the Prescription Drug Template to review compliance for nondiscrimination standards. CMS may use the data collected to review for the drug count standard.

According to 45 Code of Federal Regulations (CFR) 156.125, issuers cannot use or implement benefit designs that have the effect of discriminating against individuals on the basis of age, expected length of life, present or predicted disability, quality of life, or other health conditions. In addition, 45 CFR 156.225(b) states that a QHP issuer must not employ marketing practices or benefit designs that have the effect of discouraging the enrollment of individuals with significant health needs. CMS uses data collected in the Prescription Drug Template as part of the review for compliance with the nondiscrimination standard.
45 CFR 156.122 requires a health plan providing Essential Health Benefits (EHBs) to cover at least the greater of (1) one drug in every United States Pharmacopeial convention category and class or (2) the same number of prescription drugs in each category and class as the EHB state benchmark plan.

The Prescription Drug section of the QHP Application consists of a template with two worksheets: Formulary Tiers and Drug Lists. A formulary consists of the cost sharing for each tier of drug benefits, along with an associated drug list defining the specific drugs included in the formulary. The Formulary Tiers worksheet allows you to define the cost sharing for each formulary and associate each formulary with a drug list. The Drug Lists worksheet allows you to enter the specific drugs, along with their tier placements, included in your formularies. A drug list can be linked to more than one formulary, but a formulary can be linked to only one drug list. The Prescription Drug Template links back to the Plans & Benefits Template through the Formulary ID. Each plan in the Plans & Benefits Template must list the Formulary ID with which it is associated.

Instructions for this chapter apply to QHP issuers in the Individual and SHOP Markets. SADP issuers are not required to complete a Prescription Drug Template.

2.1 Key Template Updates

Figure 12-1 identifies the key changes made to the structure and content of the 2017 version of the Prescription Drug Template.

![Figure 12-1. 2017 Prescription Drug Template Updates](image)

### Key Changes to the Prescription Drug Template

- The 2017 template banner has been updated with the 2017 plan year identifier and version number.
- 2017 templates must be used for 2017 QHP Certification submission.

3. Prescription Drug Data Requirements

To complete this section of the QHP Application, you need the following:

1. Formulary URLs. Enter the website location for formulary information. URLs must start with “http://” or “https://” to work properly for the consumer.

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

¹ Pursuant to 45 CFR 156.122(a)(3), for plans’ years beginning on or after January 1, 2017, a health plan does not provide EHBs unless it uses a pharmacy and therapeutics (P&T) committee that meets the certain standards.
4. Application Instructions
The Prescription Drug section of the QHP Application uses an Excel template, called the Prescription Drug Template, to collect prescription drug information. Figure 12-2 includes highlights from these instructions for completing the Prescription Drug section.

Figure 12-2. Prescription Drug Section Highlights

- Instructions for this chapter apply to QHP issuers in the individual and Small Business Health Options Program markets. Stand-alone dental plan issuers are not required to complete a Prescription Drug Template.
- Complete the Drug Lists worksheet before the Formulary Tiers worksheet.
- Use the November 2, 2015, full monthly release of RxNorm to find a list of valid RxCUIs.
- RxCUIs should have one of the following Term Types (TTY): semantic branded drug (SBD), semantic clinical drug (SCD), branded 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.
- The Formulary ID drop-down menu includes the formulary identifications (IDs) generated after clicking the Create Formulary IDs button.
- 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.
- Using the correct template version is critical to completing the Prescription Drug section of the QHP Application. The current and correct version of the template includes 2017 in the banner. The latest version of the Prescription Drug Template is available from http://cciio.cms.gov/programs/exchanges/qhp.html.
- To allow data input in the template, enable template macros using the Options button on the Security Warning toolbar, and select Enable this content. Please see Appendix C for information regarding enabling macros.
- All header fields in the template marked with an asterisk (*) are required.

4.1 HIOS User Interface Instructions
There are no Health Insurance Oversight System (HIOS) user interface instructions for this chapter.

4.2 Template Instructions
To begin, you must download and save a copy of the 2017 Prescription Drug Template onto your computer.

Before using this template, you must enable macros in Excel. Enable template macros using the Options button on the Security Warning toolbar, and select Enable this content. If you do not enable macros before entering data, the template does not recognize the data and you have to reenter them. Please refer to Appendix C for instructions on enabling macros. After you have enabled the template, click the Save button before you begin entering data. As you fill out the template, remember that all fields with a header marked with an asterisk (*) are required.
4.2.1 Entering Data
You need to complete the Drug Lists worksheet before you fill out the Formulary Tiers worksheet in the template.

4.2.1.1 Drug List
You can paste data into any cells below row 8 (Figure 12-3). Figure 12-3 shows a partially completed Drug Lists worksheet; when you open the template, it does not appear this way.

**Figure 12-3. Drug Lists Worksheet**

1. Before entering details for each drug list, enter all of the RxCUIs included in any of your drug lists. RxCUIs are entered into column A, beginning in row 9:

   a. **RxCUI** (required).

      i. When selecting RxCUIs to include, use the November 2, 2015, full monthly release of RxNorm to find a list of valid RxCUIs. Download the RxNorm release at [http://download.nlm.nih.gov/umls/kss/rxnorm/RxNorm_full_11022015.zip](http://download.nlm.nih.gov/umls/kss/rxnorm/RxNorm_full_11022015.zip). To download the file, you need a Unified Medical Language System (UMLS) Metathesaurus License and a UMLS Terminology Services Account. You can obtain a license and account at no charge by following the instructions at [http://www.nlm.nih.gov/databases/umls.html#license_request](http://www.nlm.nih.gov/databases/umls.html#license_request).

      CMS anticipates posting the EHB Rx Crosswalk and a reformatted RxNorm database along with the state review tools at [https://www.cms.gov/cciio/programs-and-initiatives/health-insurance-marketplaces/qhp.html#2016 QHP Application Tools](https://www.cms.gov/cciio/programs-and-initiatives/health-insurance-marketplaces/qhp.html#2016 QHP Application Tools).

      ii. RxCUIs should have one of the following TTY: SBD, SCD, BPCK, or GPCK.
iii. The drug list should include all drugs on your formulary, even if they do not fall in one of the categories and classes identified in the summary of EHB benchmark information, available at http://cciio.cms.gov/resources/data/ehb.html. This includes all drugs deemed by the user as “medical service drugs.”

iv. Issuers may offer drugs that do not have associated RxCUIs, but they are not considered when evaluating a drug list for EHB benchmark and nondiscrimination compliance.

2. Once you have entered all of the unique RxCUIs for your drug lists, begin entering the drug-list-specific information in each row.

   a. **Tier Level** (required). 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.

   b. **Prior Authorization Required** (required if **Tier Level** is not **NA**). Indicate whether the drug requires the prescribing physician to obtain prior authorization before the plan covers the drug. Choose from the following:

      i. **Yes**—if prior authorization is required.

      ii. **No**—if prior authorization is not required.

      If **Tier Level** is **NA**, leave this column blank.

   c. **Step Therapy Required** (required if **Tier Level** is not “NA”). 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:

      i. **Yes**—if step therapy is required.

      ii. **No**—if step therapy is not required.

      If **Tier Level** is **NA**, leave this column blank.

   d. Drugs can have both a step therapy and prior authorization requirement. Once you have completed the **Tier Level**, **Prior Authorization Required**, and **Step Therapy Required** columns, you have completed the required information for your drug list. If you have more than one drug list, go to the next step to add drug lists. If you do not have drug lists to add, go to the next section (4.2.1.2) for instructions on completing the Formulary Tiers worksheet.

3. To add another drug list, click the **Add Drug List** button (Figure 12-4). For the new drug list, you need to complete the **Tier Level**, **Prior Authorization Required**, and **Step Therapy Required** columns as described above.
4. If you need to remove a drug list, click the **Remove Drug List** button (Figure 12-5). 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 you want to remove a drug list that is not the last drug list created (for example, if there are four drug lists and you want to remove the second one), copy and paste the data from the last drug list into the drug list that you want to delete; then click the **Remove Drug List** button.

Delete any drug lists that are not used. Keep only those drug lists that have an applicable **Formulary ID** in the Plans & Benefits Template. When removing drug lists, make sure that Formulary IDs are still linked to the correct drug lists.

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**Figure 12-5. Remove Drug List Button**

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Once the Drug Lists worksheet is completed, go to the Formulary Tiers worksheet (Figure 12-6).
4.2.1.2 Formulary Tiers

**Figure 12-6. Formulary Tiers Worksheet**

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1. Enter the following general information in rows 6 and 7:
   a. **HIOS Issuer ID** (required). Enter the five-digit number that identifies the issuer.
   b. **Issuer State** (required). Select the state to which the template applies from the dropdown menu.

2. Click the **Create Formulary IDs** button (Figure 12-7). To create your Formulary IDs, you must have entered your state information in row 7 before clicking this button.
   a. A pop-up dialogue box appears and prompts you to enter the number of formularies you have (Figure 12-8).
   b. After you enter 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 plus an “F” and then a sequenced number (such as ALF001 and ALF002).
   c. Once you have completed this step, your Formulary IDs appear in a drop-down menu in the **Formulary ID** column.
3. Once you have generated the Formulary IDs, complete the following information for each formulary:

   a. *Formulary ID* (required).

      i. Beginning in row 13, select the Formulary ID from the drop-down menu. The menu options include the Formulary IDs generated after clicking the **Create Formulary IDs** button.

      ii. 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. The QHP Application System will not process data entered into the cell before it was grayed out.

   b. *Formulary URL* (required). Enter the URL (web address) for your formulary document or website. CMS expects the URL link to direct consumers to an up-to-date formulary where they can view the covered drugs, including tiering, specific to a given QHP. The URL provided to the Marketplace as part of the QHP Application should link directly to the formulary, such that consumers do not have to log on, enter a policy number, or otherwise navigate the issuer’s website before locating it. If an issuer has multiple formularies, it should be clear to consumers which formulary
applies to which QHPs. CMS makes issuer-provided formulary links available to consumers on HealthCare.gov.

c. **Drug List ID** (required). Select the appropriate Drug List ID from the drop-down menu. The menu is auto-populated with the Drug List IDs you created on the Drug Lists worksheet. If you have not completed the Drug Lists worksheet, do so now.

d. **Number of Tiers** (required). 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. You cannot create cost sharing subgroups within a tier. All drugs within the same tier should have the same cost sharing.

e. **Drug Tier ID** (required). The template populates this column according to your 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.

f. **Drug Tier Type** (required). Click the drop-down menu and select the **Click here to select** option to open a pop-up dialogue box (Figure 12-9). 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. No additional tier type can be selected for Medical Service Drugs.

![Figure 12-9. Drug Types Box](image)

If a tier contains both preferred and non-preferred generic drugs, you should select only one tier type. Choose the tier type based on 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, as seen in Figure 12-10.
i. **Generic**—if the tier contains the formulary’s generic drugs.

ii. **Preferred Generic**—if the tier contains the formulary’s preferred generic drugs.

iii. **Non-Preferred Generic**—if the tier contains the formulary’s non-preferred generic drugs.

iv. **Brand**—if the tier contains the formulary’s brand drugs.

v. **Preferred Brand**—if the tier contains the formulary’s preferred brand drugs.

vi. **Non-Preferred Brand**—if the tier contains the formulary’s non-preferred brand drugs.

vii. **Specialty Drugs**—if the tier contains the formulary’s specialty drugs.

If you have both preferred and non-preferred specialty drugs, you can 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** as shown in Figure 12-11.
viii. **Zero Cost Share Preventive Drugs**—if the tier contains the formulary’s zero cost share preventive drugs.

1) 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.

2) **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 fields should be entered as $0 and 0 percent.

3) If you have 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 and in a plan brochure and **Formulary URL**.

ix. **Medical Service Drugs**—if the tier contains the formulary’s medical service drugs.

1) 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; therefore, a Medical Service Drugs tier can assist in identifying these drugs in your formulary.

2) When Medical Service Drugs is selected, it is the only tier type that can be selected for the tier.
3) 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.

g. 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 the QHP Application System includes only the Number of Tiers and Drug Tier Type fields for the first formulary associated with each drug list.

h. Tier Cost Sharing. 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. Complete the information for the other three pharmacy types only if they apply to the given drug tier, but you must indicate whether each tier offers these types of pharmacy benefits. The four types of pharmacy benefits are as follows:

i. 1 Month In Network Retail Pharmacy

ii. 1 Month Out of Network Retail Pharmacy

iii. 3 Month In Network Mail Order Pharmacy

iv. 3 Month Out of Network Mail Order Pharmacy.

Complete Copayment and Coinsurance for 1 Month In Network Retail Pharmacy. Copayment and Coinsurance apply to a given pharmacy type only if you indicate that it’s offered in Benefit Offered. Otherwise, leave Copayment and Coinsurance blank.

1) Benefit Offered (required). Select Yes if the pharmacy benefit (such as 3 Month In Network Mail Order Pharmacy) is offered for the corresponding tier. Otherwise, select No. The 3 Month In Network Mail Order type will display on Plan Compare.

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2 Pursuant to 45 CFR 156.122, for plan years beginning on or after January 1, 2017, a health plan providing EHB at in-network retail pharmacies, unless the drug meets an exception under 45 CFR 156.122(1)(i) and (ii).
2) **Copayment** (required if the pharmacy benefit is offered). Enter the copayment amount for the given pharmacy type. The copayment field allows values to the hundredths decimal. Round any copayments to the hundredths decimal. Choose from the following:

a) **No Charge**—no cost sharing is charged (this indicates that this benefit is not subject to the deductible). Note that **Not Applicable**, not **No Charge**, should be used if only a coinsurance is charged.

b) **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).

c) **$X**—the consumer always pays just the copay and the issuer pays the remainder of allowed charges (this indicates that this benefit is not subject to the deductible).

d) **$X Copay after deductible**—the consumer first pays the deductible and after the deductible is met, the consumer is only responsible for the copay (this indicates that this benefit is subject to the deductible).

e) **$X Copay before 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).

f) **Not Applicable**—the consumer only pays a coinsurance. Note that when using **Not Applicable** for copay, **Not Applicable** cannot be used for coinsurance (unless the drug tier type is **Medical Service Drugs**).

3) **Coinsurance** (required if the pharmacy benefit is offered). Enter the coinsurance amount for the given pharmacy type. The coinsurance field allows values to the hundredths decimal. Round any coinsurance to the hundredths decimal. Choose from the following:

a) **No Charge**—no cost sharing is charged (this indicates that this benefit is not subject to the deductible). Note that **Not Applicable**, not **No Charge**, should be used if only a copay is charged.

b) **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).

c) **X%**—the consumer always pays just the coinsurance and the issuer pays the remainder of allowed charges (this indicates that this benefit is not subject to the deductible).

d) **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).

e) **Not Applicable**—the consumer only pays a copay. Note that when using **Not Applicable** for coinsurance, **Not Applicable** cannot 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 and in a plan brochure and *Formulary URL*.

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 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 with 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.

### 4.2.2 Preventive Drugs

Preventive services under the Affordable Care Act must be covered without the consumer having to pay a copayment or coinsurance or meet a deductible. For more information on the coverage of preventive services, see [http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/#Prevention](http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/#Prevention) and [http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs18.html](http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs18.html).

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, 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 and in a plan brochure and *Formulary URL*.

If an issuer has already used all seven available tiers, include zero cost preventive drugs in the lowest cost tier and clearly identify in the plan brochures and *Formulary URL* that these drugs are available at zero cost sharing because 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 cost share 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 and in a plan brochure and Formulary URL.

4.2.3 Finalizing Template

Once you have completed the Prescription Drug Template, follow these steps to finalize the template.

1. Click the **Validate** button in the top left of the template (Figure 12-12). The validation process identifies any data issues that need to be resolved. If no errors are identified, proceed directly to the third step.

![Figure 12-12. Validate and Finalize Buttons](image)

2. If the template has any errors, a Validation Report will appear in a pop-up box (Figure 12-13) 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. Once the template is valid, proceed to the next step.

![Figure 12-13. Validation Report](image)
3. Click the **Finalize** button in the template. The **Finalize** function creates the XML file of the template that you need to upload in the applicable QHP Application System.

4. **Save** the XML template. We recommend saving the validated template on your computer as an XML file. Upload the saved file in the Benefits and Service Area Module. Before closing the template, save an XLSM version of the Excel file onto your computer for future reference.

### 4.3 Supporting Documentation and Justification

Supporting documentation and justification documents are located along with the QHP Application Instructions at [http://cciio.cms.gov/programs/exchanges/qhp.html](http://cciio.cms.gov/programs/exchanges/qhp.html). Please refer to the following for specific supporting documentation and justification requirements for this chapter:

- **Formulary—Inadequate Category/Class Count Supporting Documentation and Justification**
- **Discrimination—Formulary Outlier Review Supporting Documentation and Justification**
- **Discrimination—Formulary Clinical Appropriateness Supporting Documentation and Justification**
- **Discrimination—Treatment Protocol Supporting Documentation and Justification**

For additional information regarding supporting documents, see Chapter 16.

### 5. Integration with the Plans & Benefits Template

For instructions on how to link plans to formularies, see Chapter 10, Section 5.8, which also includes guidance on how to map the cost sharing entered on the Prescription Drug Template into the drug benefit categories in the Plans & Benefits Template.