

Chapter 12: Instructions for the Prescription Drug Application Section

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1. Overview

Issuers applying for certification to sell on the Marketplace must complete the Prescription Drug Template as part of their Qualified Health Plan (QHP) Application. The Centers for Medicare & Medicaid Services (CMS) uses data collected in the Prescription Drug Template to review compliance for two standards: Essential Health Benefits (EHBs) and non-discrimination of benefit designs.

Regulations in 45 *Code of Federal Regulations* (CFR) 156.122 require a health plan providing EHBs to cover at least the greater of (1) one drug in every United States Pharmacopeial (USP) convention category and class or (2) the same number of prescription drugs in each category and class as the EHB state benchmark plan.

Under 45 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, 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 in QHPs. CMS uses data collected in the Prescription Drug Template as part of the review for compliance with the non-discrimination standard.

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.

2. Purpose

This chapter guides issuers through completing the Prescription Drug section of the QHP Application.

3. Prescription Drug Data Requirements

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

1. Formulary URLs
2. A drug list with RxNorm Concept Unique Identifiers (RxCUIs), along with their formulary tier numbers. You must submit your complete drug list in order for CMS to monitor for compliance with the EHB and non-discrimination standards. You may offer drugs that do not have associated RxCUIs, but they cannot be included on the Prescription Drug Template and are not used in the evaluation of EHB benchmark and non-discrimination compliance.

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 12-1 shows key items in these instructions for completing the Prescription Drug section.

Figure 12-1. Prescription Drug Section Highlights

- Download the latest version of the Prescription Drug Template from <http://cciiio.cms.gov/programs/exchanges/qhp.html>.
- Using the correct template version is critical. The current and correct version of template includes 2015 in the banner.
- Complete the Drug Lists worksheet before the Formulary Tiers worksheet.
- Use the November 4, 2013, full monthly release of RxNorm to find a list of valid RxCUIs.
- RxCUIs should have one of the following term types (TTYs): 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 a part of a given drug list.
- The *Formulary ID* drop-down menu includes the formulary 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.
- If you have no cost sharing for the tier, select “Copayment” as the cost-sharing type, and set the copayment equal to “\$0,” or select “Coinsurance” as the cost-sharing type, and set the coinsurance equal to “0 percent.”

4.1 Template Instructions

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

Before using this template, you must enable macros in Microsoft 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 these data and you have to reenter them. 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.

You need to complete the Drug List worksheet before you fill out the Formulary Tiers worksheet in the template. You can paste data into any cells below row 8 (Figure 12-2). Figure 12-2 shows a partially completed Drug Lists worksheet; when you open the template, it does not appear this way.

Figure 12-2. Drug Lists Worksheet

	A	B	C	D	E	F	G
1	Drug Lists						
2							
3	Add Drug List						
4							
5	Remove Drug List						
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			
11	405552	1 No	No		2 No	No	
12	405553	2 No	No		1 No	No	
13	405554	3 No	No	NA			
14	405555	2 No	No	NA			
15	405556	1 No	No		2 No	No	
16	405557	3 No	No	NA			
17	405558	3 No	No		1 No	No	
18	405559	3 No	No		3 No	No	
19	405560	2 No	No		3 No	No	
20	405561	1 No	No		3 No	No	
21	405562	2 No	No		2 No	No	
22	405563	1 No	No		2 No	No	
23	405564	3 No	No		1 No	No	
24	405565	3 No	No		2 No	No	
25	405566	1 No	No	NA			
26	405567	2 No	No		5 Yes	No	

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). Enter the RxCUIs included in any of the drug lists:
 - i. When selecting RxCUIs to include, use the November 4, 2013, 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_11042013.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.

CMS anticipates posting the Rx Crosswalk and a reformatted RxNorm database in the following locations:

- CMS Zone (issuer access) (<https://zone.cms.gov/>)
- SERVIS (state regulator access only) (<https://www.servis.cms.gov/resources/>)
- National Association of Insurance Commissioners (NAIC) SERFF website (state regulator access only).

- ii. RxCUIs should have one of the following term types (TTYs): semantic branded drug (SBD), semantic clinical drug (SCD), branded pack (BPCK), or generic pack (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>.
 - 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 non-discrimination 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 a part of the given drug list. (Details of the cost share applied to each Tier Level are entered later in the process using the Formulary Tiers worksheet.)
 - 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 the *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 the *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 for instructions on completing the Formulary Tiers worksheet.

- To add another drug list, click the **Add Drug List** button (Figure 12-3). For the new drug list, you need to complete the *Tier Level*, *Prior Authorization Required*, and *Step Therapy Required* columns as described above.

Figure 12-3. Add Drug List Button

	A	B	C	D	E	F	G
1	Drug Lists						
2							
3							
4	Add Drug List						
5	Remove Drug List						
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
10	405551	2	No	Yes	NA		
11	405552	1	No	No		2	No
12	405553	2	No	No		1	No

- If you need to remove a drug list, click the **Remove Drug List** button (Figure 12-4). 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 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.

Figure 12-4. Remove Drug List Button

	A	B	C	D	E	F	G
1	Drug Lists						
2							
3							
4	Add Drug List						
5	Remove Drug List						
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
10	405551	2	No	Yes	NA		
11	405552	1	No	No		2	No
12	405553	2	No	No		1	No

Once the Drug List worksheet is completed, go to the Formulary Tiers worksheet (Figure 12-5).

Figure 12-5. Formulary Tiers Worksheet

Formulary ID*	Formulary URL*	Drug List ID*	Number of Tiers*	Drug Tier ID*	Drug Tier Type*
ALF001	www.google.com	1	4	1	All Generics
				2	All Preferred Generics
				3	All Brands
				4	All Non-Preferred Brands

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 drop-down menu.
2. Click the **Create Formulary IDs** button (Figure 12-6). To create your Formulary IDs, you must have entered your state information in row 7 before clicking this button.
 - a. A pop-up dialog box appears and prompts you to enter the number of formularies you have (Figure 12-7).
 - 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.

Figure 12-6. Create Formulary IDs Button

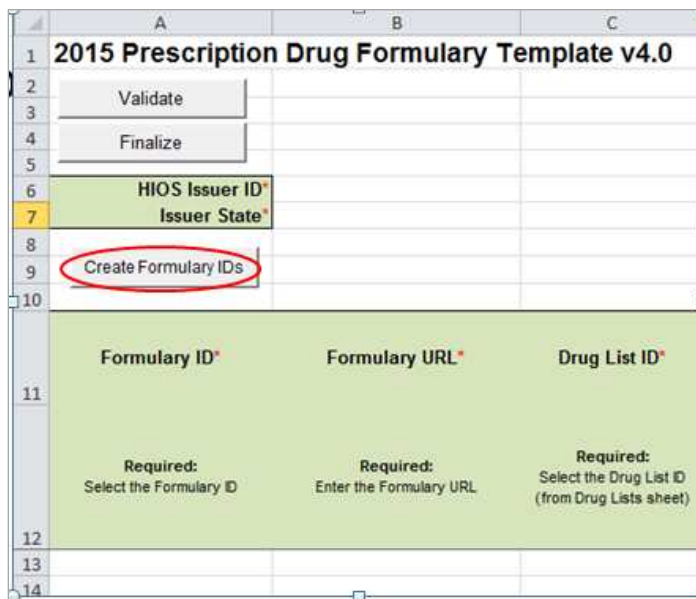
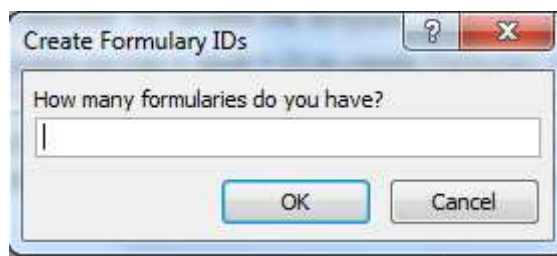


Figure 12-7. Create Formulary IDs Dialog Box

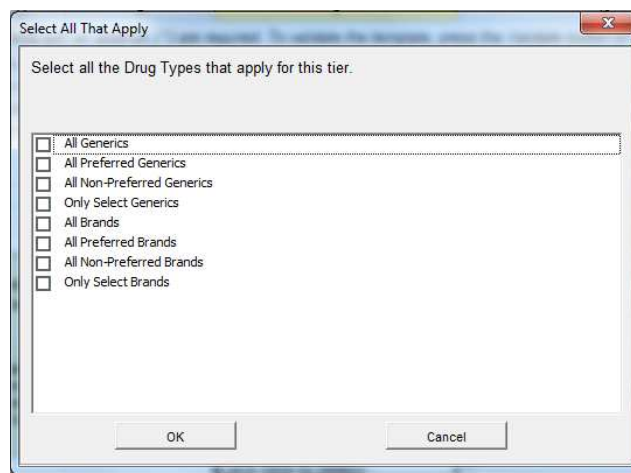


3. Once you have generated the Formulary IDs, complete the following information for each formulary:
 - a. *Formulary ID* (required). Enter the formulary ID.
 - i. Beginning on row 13, select the formulary ID from the drop-down menu. The menu options include the formulary IDs generated after clicking 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. 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 List 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 dialog box (Figure 12-8). Choose from the following options (a maximum of two drug types, one generic type and one brand type, should be selected for each tier).

Figure 12-8. Drug Types Box



If a tier contains both preferred and non-preferred generics, you may use the **Only Select Generics** option, likewise for preferred and non-preferred brands):

- i. **All Generics**—if the tier contains all of the formulary’s generic drugs
- ii. **All Preferred Generics**—if the tier contains all of the formulary’s preferred generic drugs

- iii. **All Non-Preferred Generics**—if the tier contains all of the formulary’s non-preferred generic drugs
- iv. **Only Select Generics**—if the tier contains only some of the formulary’s preferred generic or non-preferred generic drugs, or contains both preferred and non-preferred generic drugs
- v. **All Brands**—if the tier contains all of the formulary’s brand drugs
- vi. **All Preferred Brands**—if the tier contains all of the formulary’s preferred brand drugs
- vii. **All Non-Preferred Brands**—if the tier contains all of the formulary’s non-preferred brand drugs
- viii. **Only Select Brands**—if the tier contains only some of the formulary’s preferred brand or non-preferred brand drugs. Also, use this tier type to indicate specialty drugs. If you have both preferred and non-preferred specialty drugs, you create two **Only Select Brands** tiers and differentiate between them using cost sharing (Figure 12-9).

Figure 12-9. Creating Multiple Only Select Brands Tiers

Drug Tier ID*	Drug Tier Type*	1 Month In Network Retail Pharmacy Cost Sharing Type*	Copayment*	Coinsurance*
Required: The template will populate a Drug Tier ID 1-7	Required: Select all the Drug Types included in this tier	Required: Select the Cost Sharing Type	Required: Enter the Copayment for 1 Month In Network Retail Pharmacy	Required: Enter the Coinsurance for 1 Month In Network Retail Pharmacy
1	Only Select Brands	Coinsurance		20%
2	Only Select Brands	Copayment	\$20	
3				

- 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 *Cost Sharing Type*, *Copayment*, and *Coinsurance* for 1 Month In Network Retail Pharmacy. 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 pharmacies 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 fields 1 through 3 for 1 Month In Network Retail Pharmacy. These fields are optional for the other three pharmacy types. Fields 1–3 apply only if you indicate that you offer the given pharmacy type.

- 1) *Cost Sharing Type* (required). Select the cost-sharing type for the given pharmacy type (such as “1 Month In Network Retail Pharmacy”). All cost sharing is assumed to be after the deductible has been met. Choose from the following:
 - a) **Copayment**—if enrollees pay only a copay for drugs in the tier when they use the given pharmacy type.
 - b) **Coinsurance**—if enrollees pay only a coinsurance for drugs in the tier when they use the given pharmacy type.
 - c) **Lesser of Copayment or Coinsurance**—if enrollees pay the minimum of the copayment and coinsurance cost for drugs in the tier when they use the given pharmacy type (in other words, there is a Maximum Out of Pocket (MOOP), equal to the copayment, for each prescription).
 - d) **Greater of Copayment or Coinsurance**—if enrollees pay the maximum of the copayment and coinsurance cost for drugs in the tier when they use the given pharmacy type (in other words, there is a floor, equal to the copayment, for each prescription). For example, if a consumer has a \$5 copay or a 10 percent coinsurance for a drug that costs \$20 and the *Cost Sharing Type* is “Greater of Copayment of Coinsurance,” the consumer’s cost sharing would be the copayment of \$5 instead of the coinsurance of \$2.

If you have no cost sharing for the tier, you may either select “Copayment” as the cost-sharing type, and set the copayment equal to “\$0,” or select “Coinsurance” as the cost-sharing type, and set the coinsurance equal to “0 percent.”

- 2) *Copayment* (required if you selected “Copayment,” “Lesser of Copayment or Coinsurance,” or “Greater of Copayment or Coinsurance” as the cost-sharing type for the given pharmacy type). Enter copayment for the given pharmacy type. The copayment field accepts only whole dollar values. Round any copayment amounts to the nearest dollar.

- 3) *Coinsurance* (required if you selected “Coinsurance,” “Lesser of Copayment or Coinsurance,” or “Greater of Copayment or Coinsurance” as the cost-sharing type for the given pharmacy type). Enter coinsurance for the given pharmacy type. The coinsurance field accepts only whole numbers. Round any coinsurance value off to the nearest whole number.

Issuers should complete cost-sharing fields in the Prescription Drug Template for the most typical or most utilized 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 or in a plan brochure and *Formulary URL*.

Preventive services under the Affordable Care Act (ACA) must be covered without the consumer having to pay a copayment, coinsurance, or meet a deductible. Please go to <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 for more information on coverage of preventive services.

CMS recommends that issuers place these drugs in a separate \$0 cost-sharing tier in the Prescription Drug Template. To indicate that a tier has no cost sharing, select “Copayment” as the cost-sharing type and set the copayment equal to “\$0” or “Coinsurance” equal to “0 percent” in the Formulary Tiers worksheet. 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 the *Formulary URL* that these drugs are available at zero cost sharing because all drugs within the same tier should have the same cost sharing.

4.2 Validate and Finalize

Once you have completed the Formulary Tiers worksheet, click the **Validate** button on the worksheet (Figure 12-10). If validation errors occur, a Validation Report (Figure 12-11) appears showing the data element and cell location of each error. You must correct these errors in order for your Prescription Drug Template to be accepted.

Once the validation is successful, click the **Finalize** button to save the template as an XML file. Upload the saved file in the Benefits and Service Area Module of the QHP Application system.

Before closing the template, it is also recommended to save a version of the Excel file to your hard drive as an XLSM for future reference.

Figure 12-10. Validate and Finalize Buttons

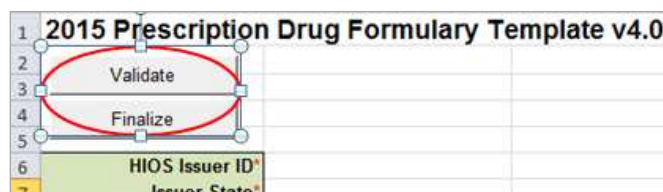
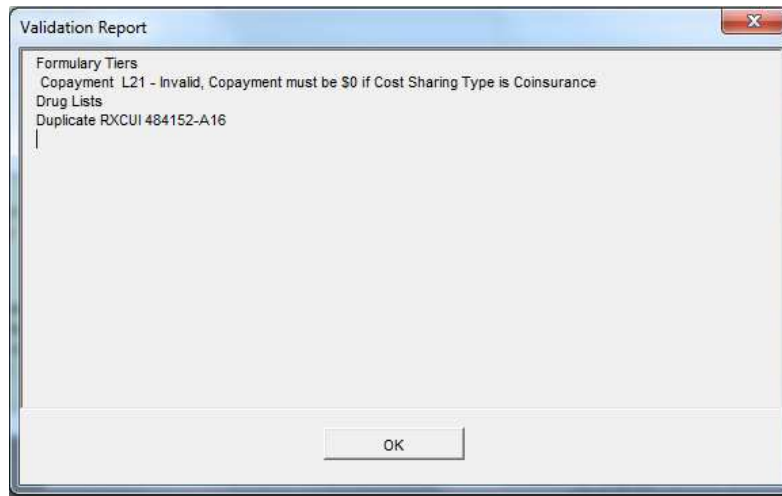


Figure 12-11. Validation Report



4.3 Integration with the Plans & Benefits Template

For instructions on how to link plans to formularies, see Chapter 10, 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.