

# Formulary Review Suite Instructions

## Contents

<b>Introduction and Background .....</b>	<b>2</b>
Use of FRS by State Regulators.....	2
Use of FRS by Issuers .....	2
Use of FRS by CMS and States .....	2
<b>Formulary Review Suite Setup .....</b>	<b>3</b>
Access to the FRS .....	3
Input Files for the FRS.....	3
Finalize FRS Setup for Reviews .....	5
<b>Run the Formulary Review Suite .....</b>	<b>8</b>
Issuer Level Summary Information .....	9
Plan Level Summary Information.....	10
Category Class Drug Count Review .....	12
Non-Discrimination Formulary Outlier Review .....	18
Non- Discrimination Clinical Appropriateness Review .....	25
Exporting FRS Results.....	31
RxCUI Submission Report .....	32
<b>Appendix A: Manipulating Groupings in Excel .....</b>	<b>35</b>
<b>Appendix B: Acronyms .....</b>	<b>36</b>

## Introduction and Background

The **Formulary Review Suite** (FRS) is a review tool used for qualified health plan (QHP) applications that contains three independent formulary reviews:

- *The Category Class Drug Count Review*
- *The Non-Discrimination Formulary Outlier Review*
- *The Non-Discrimination Clinical Appropriateness Review*

The FRS is available to the public as well as state regulators, issuers, and the Centers for Medicare & Medicaid Services (CMS). The FRS is capable of running all reviews simultaneously or individually depending on the selections you make. **This set of instructions applies to the PY2017 Formulary Review Suite Version 1.5.**

### Use of FRS by State Regulators

States may use the FRS or any parts of the FRS they believe will assist in their review process. The FRS is a method for reviewing for compliance with specific standards. Any alternative state review methods must be consistent with federal standards, but need not be identical to the approach methods via the FRS.

### Use of FRS by Issuers

Issuers are encouraged to use the FRS proactively before submitting their QHP applications and can also reference it when a state or federal regulator requests corrections after a review that relied on the FRS. Note that issuers must respond to any deficiencies identified by a state or federal regulator even if an identified issue is different than the results obtained using the FRS.

### Use of FRS by CMS and States

CMS plans to use the FRS in Federally-Facilitated Marketplaces (FFMs) for those standards that are specific to certification of QHPs. This includes certification standards for Federally-Facilitated Small Business Health Options Program (FF-SHOP). For more information on the FFM certification process and related standards, please see the “2017 Letter to Issuers in the Federally-facilitated Marketplaces” available on the CCIIO website.<sup>1</sup>

Issuers in states performing plan management functions may contact their state regulator to determine if the FRS will be part of their review processes. CMS will review and confirm the state’s QHP certification recommendations and make final QHP certification decisions. CMS will work closely with states that are performing plan management functions to coordinate this process.

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<sup>1</sup> <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2017-Letter-to-Issuers-2-29-16.pdf>

## Formulary Review Suite Setup


### Access to the FRS

Make sure that you are using the most updated version of the FRS. You can find the FRS and all other QHP review tools here: <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Step-3-Complete-Application-.html>. In addition to the FRS, you may also need to access the **Master Review Tool** (MRT). Instructions on how to use the MRT are located within the MRT itself. This FRS document details the dependencies between the MRT and the FRS.

### Input Files for the FRS

The FRS needs the **Prescription Drug** (Rx) templates and the **Plans & Benefits** (P&B) templates to function completely. The tool cannot run without Rx Templates, but the P&B templates are optional. You can find all of the QHP application templates here:

<https://www.cms.gov/ccio/programs-and-initiatives/health-insurance-marketplaces/qhp.html#Instructions, Templates and Materials>. Instructions on how to complete the QHP application templates are also located at the same website.

 **Hint:** *Gather P&B templates if you wish to see plan level results in the FRS.*

### Saving the Input Templates

You need to save the Rx and P&B templates that you want to review in folders in easily accessible locations. Figure 1 shows an example folder layout that you can use. You will want to remember these folder location because you need to find them when the tool runs.

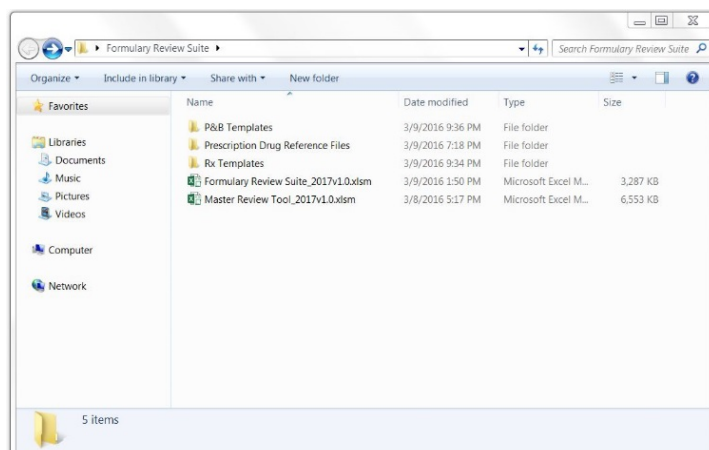
There are no FRS restrictions for the folder names or folder locations. However, save the Rx templates in one folder and the P&B templates in a separate folder to avoid producing any errors within the FRS. Keep in mind that Microsoft Excel has a limit to the number of characters that can be in the file path name.<sup>2</sup>

 **Hint:** *Save the Rx and P&B templates along with the FRS and MRT on your desktop.*

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<sup>2</sup> A file path includes the folder location plus the file name. For example, “C:\Users\jsmith\Desktop\FRS Templates\Formulary Review Suite\_TestV1.0.xlsm” is a path. Microsoft Excel might produce an error when templates have very long paths.

Figure 1 Sample Folder Layout for FRS Files



**Issuers** should save all Rx and P&B templates that they wish to perform reviews on in the designated folders. The FRS will attempt to use all information in any Rx templates stored in the folders that you select and MRTs that you select.

**States** should save all issuer Rx and P&B templates for the entire state that they wish to perform review on in the designated folders. The FRS will attempt to use all information in any Rx templates stored in the folders that you select and MRTs that you select.

#### *States that Collect Templates in SERFF*

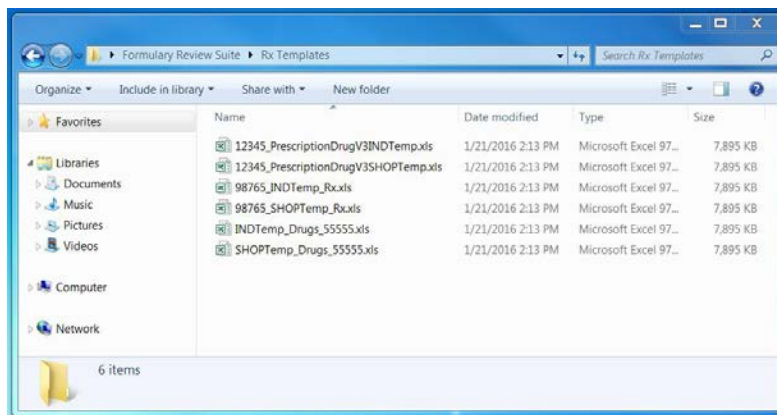
In states that collect templates in the System for Electronic Rate and Form Filing (SERFF), issuers may submit separate sets of templates for Individual and SHOP QHP application plans. In this case, an issuer can submit two drug lists with the same identification (ID) – one for the Individual marketplace and one for the SHOP marketplace. In order for the FRS to distinguish between these two drug lists, you will need to indicate that you have separate Individual and SHOP Rx templates in the FRS as depicted in Figure 2.

Figure 2 FRS SERFF Collection Indication

2.	Do you have separate Individual and SHOP Prescription Drug Templates?
	No
3.	Yes
	No

The FRS will only prompt you once for the location of Rx templates regardless of the selection in the FRS so you do not have to have separate folders for Individual and SHOP templates. **You must save all Rx with either “INDTemp” or “SHOPTemp” in the file name for the FRS to function properly.** Figure 3 shows an example of good file naming conventions.

Figure 3 Sample File Names for SERFF Users

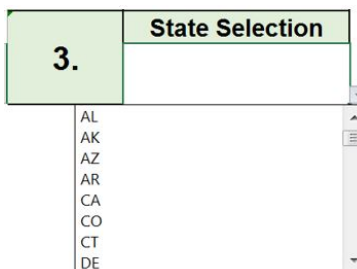


## Finalize FRS Setup for Reviews

### Choose the State for the Review

Select the state that you want to review as seen in Figure 4. The FRS will only review one state at a time. If you are reviewing a multi-state plan (MSP) use the OPM options provided in the state drop down list: for the BCBS Standard Option use OPM-1; for the BCBS Basic Option use OPM-2; and for the GEHA Standard Option use OPM-3. If the state in the FRS does not match the state selected in the Rx templates, then the FRS will not run. In addition, if your folders contain Rx templates from more than one state, then the FRS will only process those with the same state. Templates with non-matching states produce error messages in the FRS.

Figure 4 FRS State Selection



**Hint:** If applicable, save all files for different states in different folders.

### *Import P&B Data from MRT*


As an optional step, you can import P&B data from the MRT using the button in the FRS shown in Figure 5. Importing P&B data will allow you to view summary level results for each review at the plan level. Importing P&B data will also enable you to remove unused drug lists. The FRS will run without P&B data, but it will be unable to remove unused drug lists and will only be able to view summary results at the formulary level.

After selecting the import button in Figure 5, the FRS prompts you to select the MRT file that contains your P&B data. At this point, you need to have already imported P&B data into a MRT with P&B templates that correspond your Rx templates. In addition, you need to navigate to the file location to select the correct MRT.

*Figure 5 Import P&B Data Button*



The Rx templates provide information at the Formulary ID level. The P&B templates provide information at the variant plan level. P&B data will allow you to view summary level results at the plan level because the FRS can link the Formulary ID from the Rx template back to the particular standard variant plan in the P&B template.

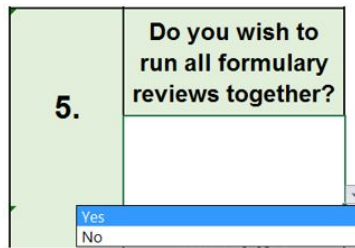
 **Hint:** *The Formulary Outlier Review state outlier threshold calculations need P&B data to run.*

In addition, some drug lists exist in the Rx template but they do not correspond to a plan in the P&B template. The FRS cannot identify unused drug lists unless it knows if the drug list is associated with a plan. The P&B data allows the FRS to associate drug lists with plans as mentioned previously. This becomes important for the Formulary Outlier Review because the state outlier calculation needs drug list data and the calculation will not be accurate if unused drug lists are included. CMS removes all unused drug lists in all of the formulary reviews. **If the FRS imports P&B data, then the FRS will automatically remove unused drug lists from all reviews.**

### *Option to Run Multiple Reviews*

The FRS provides you with the option to run multiple formulary reviews at once or run each review separately as seen in Figure 6. If you select “Yes,” then the FRS performs all three reviews. If you select “No,” then you will be able to choose the reviews you would like the FRS to perform.

Figure 6 Individual or Multiple Reviews



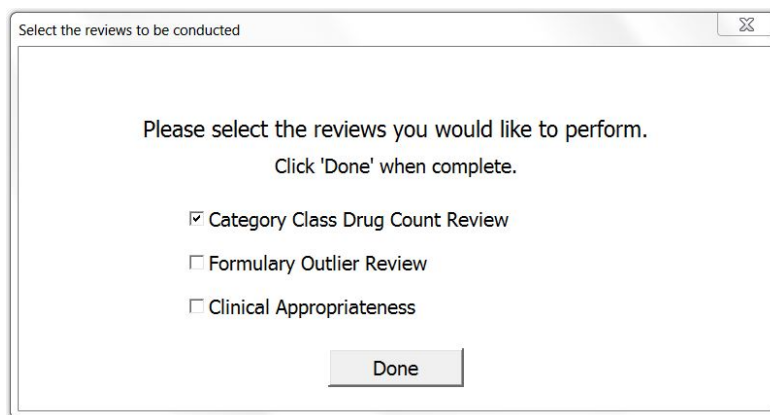
5. Do you wish to run all formulary reviews together?

Yes  
No

💡 **Hint:** You can always run the FRS for each of the three reviews individually at any time if you do not want the results for all three reviews at once. To do this, choose “No” during the step in Figure 6.

By selecting “No,” the FRS prompts you to select the reviews to run with a user form.<sup>3</sup> The first user form appears depending on the selection you choose in Figure 6. If you select “Yes,” then there will be no user form at this point. If you select “No,” then you have the option to select the review that you want to perform as seen in Figure 7.

Figure 7 Individual Review Selection



Select the reviews to be conducted

Please select the reviews you would like to perform.  
Click 'Done' when complete.

☒ Category Class Drug Count Review  
☐ Formulary Outlier Review  
☐ Clinical Appropriateness

Done

Select the reviews that you wish to run by clicking on the checkbox next to the review name. Figure 7 shows the selection of the Category Class Drug Count Review. You have the option to select any combination of reviews that you wish to run at this point. When you are finished selecting the reviews that you want to run, click “Done.” If you click “Done” before you were finished, you can gain access to the same user form by reselecting “No” in Figure 6. The next few sections of information provide background and detail for the reviews that are contained in the FRS.

<sup>3</sup> User forms for the FRS capture additional user input data. They will appear in the form of a popup box on your screen when using the FRS.

## Run the Formulary Review Suite

Finally, the FRS setup is complete at this point and you can start running the reviews that you want. After verifying that all of your user selections to this point are correct, then you can run the FRS using the button shown in Figure 8.

*Figure 8 Import P&B Data Button*



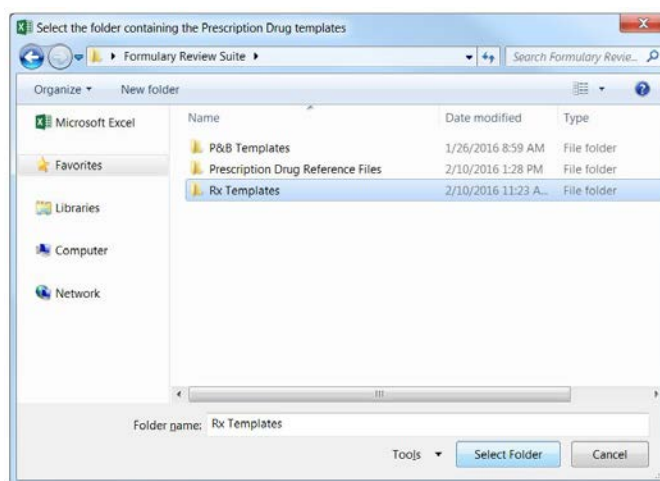
After initiating the FRS using the button in Figure 8, the FRS guides you through a series of user forms for the remaining user inputs that each individual review needs. There will be a different set of user forms for each combination of inputs up until this point.

### *Selecting the Input Templates*

The FRS prompts you to select the folders that contain your Rx and P&B templates (if applicable) after you complete all of the necessary user inputs and user forms in the FRS – you can find details for the remaining user forms for each of the FRS reviews in subsequent sections. This will be the last step to complete before the FRS processes all of the review information that you provide.

Picking up from the Input Files for the FRS section where you have saved all of your FRS review files, the FRS prompts you to select those same folders (see Figure 9). You want to select the folder that contains your Rx templates depending on the step that you are at. In addition, you want to click on the folder that you want and then click on “Select Folder.” The process is the same for each time you are prompted to select a folder.

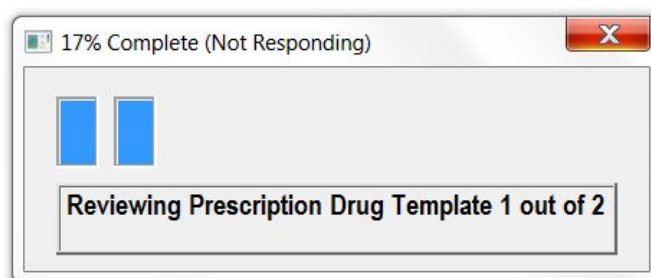
*Figure 9 Sample Folder Layout for Import*





At this point, the FRS starts processing the information in the folder that you have selected. The FRS runs until completion unless it reaches an error. During this time, the FRS displays a status bar letting you know the status of the processing. Figure 10 shows an example of the FRS status bar. The FRS prompts you when the review is complete. The FRS then directs you to the review output summary location.

Figure 10 FRS Status Bar



## Issuer Level Summary Information

The FRS produces summary information at the issuer level every time it processes information. The “**Issuer Summary**” worksheet produces the executive summary review results for each Formulary ID that the FRS processes. This worksheet identifies the Formulary IDs that do not pass the intended reviews. Figure 11 shows an example of the issuer summary output.

Figure 11 FRS Issuer Summary Sample

Executive Summary:		1 Issuer Failed		0 Issuers Failed	1 Issuer Failed
Issuer Data		Formulary Data		Category Class Drug Count Review	Formulary Outlier Review
Issuer ID	Market	Formulary ID	Drug List ID	Category Class Result	Formulary Outlier Result
12345	Individual	VAF001	1	Not Met	Met
12345	Individual	VAF002	1	Not Met	Met
					Clinical Appropriateness Result
					Clinical Appropriateness Result
					Not Met
					Not Met

Here are the definitions for the columns in this worksheet:

- **Issuer ID**: This is the five-digit issuer identification number taken from the template information.
- **Market**: This is market coverage assigned to particular Formulary ID. This is either the Individual market or SHOP market. This field helps identify differences between Formulary IDs with the same name when you use separate Individual and SHOP templates.
- **Formulary ID**: This is the six-character formulary identification code from the template information.
- **Drug List ID**: This is the drug list identification number taken from the template information.
- **Category Class Result**: This is the result of the particular drug list for the Category Class Drug Count Review.

- **Met:** A drug list is “Met” if all categories and classes pass the review.
- **Not Met:** A drug list is “Not Met” if at least one category and class fails the review.
- **Formulary Outlier Result:** This is the result of the particular drug list for the Formulary Outlier Review.
  - **Met:** A drug list is “Met” if all categories and classes pass the review.
  - **Not Met:** A drug list is “Not Met” if at least one category and class fails the review.
- **Clinical Appropriateness Result:** This is the result of the particular drug list for the Clinical Appropriate Review.
  - **Met:** A drug list is “Met” if all conditions and classes pass the review.
  - **Not Met:** A drug list is “Not Met” if at least one condition and class fails the review.

The issuer summary may produce different results depending on if you import P&B data. When you import P&B data, only those Formulary IDs in the Rx templates that correspond to a plan in the P&B templates appear in the summary. However, if you do not import P&B data, every Formulary ID in the Rx template will appear in the summary since it is not dependent to the link back to the P&B template data.

The issuer summary worksheet provides the initial insight into the formulary reviews. The subsequent review summary and detail worksheets all contain the drug list information. This feature provides the ability to easily identify issuer drug lists across multiple formulary reviews. From here you are able drill down to the details of each drug list to find the reasons for a deficiency.

### Plan Level Summary Information

The FRS produces summary information at the plan level only when you import P&B data. The “**Plan Summary**” worksheet produces the executive summary review results for each Plan ID that the FRS processes. This worksheet identifies the Plan IDs that do not pass the intended reviews. Figure 12 shows an example of the plan summary output.

Figure 12 FRS Plan Summary Sample

Issuer Data				Formulary Data		4 Plans Failed	0 Plans Failed	4 Plans Failed
Issuer ID	Market Coverage	Plan ID	Metal Level	Formulary ID	Drug List ID	Category Class Drug Count Review	Formulary Outlier Review	Clinical Appropriateness Review
						Category Class Result	Formulary Outlier Result	Clinical Appropriateness Result
12345	Individual	12345VA0011234	Gold	VAF001	1	Not Met	Met	Not Met
12345	Individual	12345VA0011236	Bronze	VAF001	1	Not Met	Met	Not Met
12345	Individual	12345VA0011237	Catastrophic	VAF001	1	Not Met	Met	Not Met
12345	Individual	12345VA0011235	Silver	VAF002	1	Not Met	Met	Not Met

Here are the definitions for the columns in this worksheet:

- **Issuer ID**: This is the five-digit issuer identification number taken from the template information.
- **Market Coverage**: This is market coverage assigned to particular Plan ID. This is either the Individual market or SHOP market.
- **Plan ID**: This is the fourteen-character plan identification code taken from the template information.
- **Metal Level**: This is general level of coverage description for each Plan ID. Values include Catastrophic, Bronze, Silver, Gold, and Platinum.
- **Formulary ID**: This is the six-character formulary identification code from the template information.
- **Drug List ID**: This is the drug list identification number taken from the template information.
- **Category Class Result**: This is the result of the particular drug list for the Category Class Drug Count Review.
  - **Met**: A drug list is “Met” if all categories and classes pass the review.
  - **Not Met**: A drug list is “Not Met” if at least one category and class fails the review.
- **Formulary Outlier Result**: This is the result of the particular drug list for the Formulary Outlier Review.
  - **Met**: A drug list is “Met” if all categories and classes pass the review.
  - **Not Met**: A drug list is “Not Met” if at least one category and class fails the review.
- **Clinical Appropriateness Result**: This is the result of the particular drug list for the Clinical Appropriate Review.
  - **Met**: A drug list is “Met” if all conditions and classes pass the review.
  - **Not Met**: A drug list is “Not Met” if at least one condition and class fails the review.

The plan summary worksheet provides additional insight into the formulary reviews. The subsequent review summary and detail worksheets all contain the drug list information. This feature provides the ability to easily identify issuer drug lists across multiple formulary reviews. From here you are able drill down to the details of each drug list to find the reasons for a deficiency.

## Category Class Drug Count Review

The Category Class Drug Count Review generates the unique count of chemically distinct drugs that are submitted on a given drug list for each category and class pairing. The FRS compares the drug counts against the state Essential Health Benefit (EHB) benchmark counts.

- **Chemically Distinct Drug**: *Two drugs are chemically distinct if they have different active ingredients. Combination drugs are chemically distinct from their component drugs.*
- **EHB Benchmark Counts**: *CMS defines EHB based on state submitted benchmark plans.<sup>4</sup> Rx benchmark counts are determined at the United State Pharmacopeia (USP) v6.0 Model Guidelines category and class level.<sup>5</sup>*

The “**Category Class Summary**” and “**Category Class Details**” worksheets within the FRS show the output for each drug list the FRS reviews. Each drug list that is reviewed is identified according to the issuer ID, issuer state, market coverage (if applicable), and drug list ID. The individual results for each issuer ID and drug list ID are on both of these worksheets if the user chooses to run this review.

### Category Class User Forms

**There are no additional user forms for the Category Class Drug Count Review.**

At this point, the FRS either prompts you to select the location of your Rx templates (see the *Selecting the Input Templates* section) or it continues to provide more user forms for any additional reviews that you selected.

### Category Class Summary Worksheet

The “**Category Class Summary**” worksheet produces the drug counts for all USP categories and classes. This worksheet produces the drug count results for all drug lists that the FRS processes. This worksheet also identifies the categories and classes that do not meet or exceed the EHB benchmark. The cell associated with a deficient drug count will be bold with red font when it does not meet the EHB benchmark count as seen in Figure 13.

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<sup>4</sup> Find out more about EHBs here: <https://www.cms.gov/CCIIO/Resources/Data-Resources/ehb.html>

<sup>5</sup> Find out more about USP here: <http://www.usp.org/usp-healthcare-professionals/usp-medicare-model-guidelines>

Figure 13 Category Class Summary Worksheet Sample

				Category Class Result:	4 Lists Not Met 63		
Category Class ID	Category	Class	Benchmark Count	Benchmark Reevaluation*	12345 Drug Lists	List 1 Count	List 1 Met? (Yes/No)
1	Analgesics	Nonsteroidal Anti-inflammatory Drugs	21	21		19	No
2	Analgesics	Opioid Analgesics, Long-acting	14	14		10	No
3	Analgesics	Opioid Analgesics, Short-acting	16	16		11	No
4	Anesthetics	Local Anesthetics	3	3		2	No
5	Anti-Addiction/ Substance Abuse Treatment Agents	Alcohol Deterrents/Anti-craving	4	4		3	No

Here are the definitions for the columns in this worksheet:

- **Category Class ID**: This is an arbitrary number assigned to the USP category and class for ease of identifying a category and class pairing.
- **Category**: The broadest classification of the USP guidelines that provides a high level formulary structure designed to include all potential therapeutic agents for conditions.<sup>6</sup>
- **Class**: A more granular classification for a USP category that provides therapeutic or pharmacologic groupings of FDA approved medications.<sup>7</sup>
- **Benchmark Count**: The state EHB benchmark chemically distinct drug count.
- **Benchmark Reevaluation**: The updated benchmark counts based on the most up-to-date EHB Rx Crosswalk. This column is only for reference purposes since issuers are still required to meet or exceed the values in “Benchmark Count” column.
- **List [#] Count**: The chemically distinct drug count for a particular drug list.
- **List [#] Met? (Yes/No)**: An indication whether the category and class has met the benchmark count.
  - **Yes**: The drug count meets the state EHB benchmark count. No further review is required.
  - **Yes – Reevaluated**: The drug count meets the reevaluated benchmark count, but it does not meet the state EHB benchmark count. No further review is required.
  - **No**: The drug count does not meet the state EHB benchmark count. A further review is required.

<sup>6</sup> See note 5 for more information.

<sup>7</sup> See note 5 for more information.

In several situations it is impossible for a particular category and class to meet the EHB benchmark count. This happens because the number of available chemically distinct drugs in the EHB Rx Crosswalk decreased for certain categories and classes. This is due to timing difference between establishing EHB benchmarks counts and the update of the EHB Rx Crosswalk. In these situations, a further review of the drug list is not required. The following categories and classes affect the states listed in Table 1.

- **EHB Rx Crosswalk**: *A CMS reference file used to ensure plans' prescription drug benefit packages are in compliance with EHB policy. CMS uses the EHB Rx Crosswalk to map RxNorm Concept Unique Identifiers (RxCUI) to categories and classes as well as to group chemically distinct drugs.*
- **RxCUI**: *An identification for a group of synonymous drug data specified by ingredient, strength, dose form, and brand name, where applicable.*

Table 1 Impossible Situations to Meet EHB Benchmark Count

Category Class ID	Category	Class	States Affected
71	Antivirals	Anti-HIV Agents, Nucleoside and Nucleotide Reverse Transcriptase Inhibitors (NRTI)	AZ; IN; MA; ME; MI; OH; OPM - 1; OPM - 2; OPM - 3; SC; VA
127	Hormonal Agents, Stimulant/ Replacement/ Modifying (Sex Hormones/ Modifiers)	Estrogens	AZ; IN; MA; ME; OH; OPM - 1; OPM - 2; OPM - 3; SC; VA
129	Hormonal Agents, Stimulant/ Replacement/ Modifying (Sex Hormones/ Modifiers)	Progestins	AZ; IN; MA; ME; OH; OPM - 1; OPM - 2; OPM - 3; SC; VA
133	Hormonal Agents, Suppressant (Adrenal)	No USP Class	AL; AK; AZ; FL; GA; IN; LA; ME; MA; MI; MN; NY; OH; RI ;SC; VA; WA; WI; WY; OPM - 1; OPM - 2; OPM - 3
144	Metabolic Bone Disease Agents	No USP Class	AZ; SC
147	Ophthalmic Agents	Ophthalmic Anti-allergy Agents	AZ; CT; DE; GA; HI; KY; MA; OPM - 1; OPM - 2; OR; PA; SC; TN; VT; WA; WV
165	Therapeutic Nutrients/ Minerals/ Electrolytes	Electrolyte/Mineral Replacement	AZ; MA; OPM - 1; OPM - 2; SC

After expanding all of the drug lists that the FRS reviewed, we can look at all of the results that the FRS produces as seen in Figure 14. The numbers in Figure 14 correspond to the list of items below.



 **Hint:** Go to Appendix A: Manipulating Groupings in Excel to learn more about expanding and contracting the groups of drug lists for any worksheet in the FRS.

Figure 14 Category Class Summary Worksheet Output

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1. Marketplace Type differentiates between market coverages **if and only if** you have separate Individual and SHOP templates. Otherwise, this row will not appear.
2. These cells will appear for every combination of issuer and market coverage (if applicable). It describes the overall performance of the issuer's drug lists in that market (if applicable). A drug list is "Not Met" if it has at least one category and class that does not meet the benchmark count.
3. These cells tally the number of categories and classes that did not meet the benchmark count. They apply to the drug list listed directly below them.
4. These cells indicate the drug list under review. Notice that we have one issuer under review with three total drug lists – two from the individual market and one from the SHOP market.

 **Hint:** The cells directly beneath the issuer, “12345 Drug Lists” for example, are meant to be blank.

## Category Class Details Worksheet

The “**Category Class Details**” worksheet provides a list of every chemically distinct drug that appears in the EHB Rx Crosswalk. Each chemically distinct drug applies to one or more category and class. This worksheet identifies if a chemically distinct drug is missing from a drug list. The cell associated with a deficient drug count will be bold with red font when it does not meet the EHB benchmark count as seen in Figure 15.


Figure 15 Category Class Details Worksheet Sample

					Marketplace Type:
Chemically Distinct Drug ID	Chemically Distinct Drug	Category Class ID	Category	Class	
1	6-Aminocaproic Acid	85	Blood Products/Modifiers/ Volume Expanders	Coagulants	
2	abacavir	71	Antivirals	Anti-HIV Agents, Nucleoside and Nucleotide Reverse Transcriptase Inhibitors (NRTI)	
3	abatacept	138	Immunological Agents	Immune Suppressants	
3	abatacept	140	Immunological Agents	Immunomodulators	
4	abiraterone	43	Antineoplastics	Antandrogens	
4	abiraterone	49	Antineoplastics	Enzyme Inhibitors	
5	acamprosate	5	Anti-Addiction/ Substance Abuse Treatment Agents	Alcohol Deterrents/Anti-craving	
6	Acarbose	80	Blood Glucose Regulators	Antidiabetic Agents	

Here are the definitions for the columns in this worksheet:

- **Chemically Distinct Drug ID**: This is an arbitrary number assigned to the chemically distinct drug for ease of identifying all instances of the chemically distinct drug.
- **Chemically Distinct Drug**: Two drugs are chemically distinct if they have different active ingredients. Combination drugs are chemically distinct from their component drugs.
- **Category Class ID**: This is an arbitrary number assigned to the USP category and class for ease of identifying a category and class pairing.
- **Category**: The broadest classification of the USP guidelines that provides a high level formulary structure designed to include all potential therapeutic agents for conditions.<sup>8</sup>
- **Class**: A more granular classification for a USP category that provides therapeutic or pharmacologic groupings of FDA approved medications.<sup>9</sup>

After expanding all of the drug lists that the FRS reviewed, we can look at all of the results that the FRS produces as seen in Figure 16. The numbers in Figure 16 correspond to the list of items below.

 **Hint**: Go to Appendix A: Manipulating Groupings in Excel to learn more about expanding and contracting the groups of drug lists for any worksheet in the FRS.

<sup>8</sup> See note 5 for more information.


<sup>9</sup> See note 5 for more information.



Figure 16 Category Class Details Worksheet Output

1															
2															
		E	F	G	H	I	J	K	L						
			Marketplace Type:	Individual			SHOP (Small Group)								
2		Category	Class	12345 Drug Lists	List 1 Missing?	List 2 Missing?	12345 Drug Lists	List 1 Missing?							
3															
4		Blood Products/Modifiers/ Volume Expanders	Coagulants		No	No		No				No			
5		Antivirals	Anti-HIV Agents, Nucleoside and Nucleotide Reverse Transcriptase Inhibitors (NRTI)		No	No		No				No			
6		Immunological Agents	Immune Suppressants		No	No		No				No			
7		Immunological Agents	Immunomodulators		No	No		No				No			
8		Antineoplastics	Antiandrogens		No	No		No				No			
9		Antineoplastics	Enzyme Inhibitors		No	No		No				No			

1. Marketplace Type differentiates between market coverages **if and only if** you have separate Individual and SHOP templates. Otherwise, this row will not appear.
2. These cells indicate the drug list under review. Notice that we have one issuer under review with three total drug lists – two from the individual market and one from the SHOP market.

 **Hint:** The cells directly beneath the issuer, “12345 Drug Lists” for example, are meant to be blank.

Both Category Class Drug Count Review worksheets provide the “Category Class ID.” This feature provides the ability to easily identify all of the chemically distinct drugs that affect that particular category and class. The “Category Class Summary” worksheet tells you if a category and class does not meet the benchmark. The “Category Class Details” worksheet tells you the chemically distinct drugs that were not included in the drug list count. From here you are able to look up the chemically distinct drug in the EHB Rx Crosswalk that you need to meet the benchmark count. This will allow you to find the RxCUIs that will satisfy the benchmark count.

## Non-Discrimination Formulary Outlier Review

The Formulary Outlier Review identifies plans that have unusually low numbers of unrestricted drugs in several USP classes. The FRS compares the unrestricted drug counts against state benchmarks, state outlier thresholds, and national outlier thresholds for each class of drugs.

- **Unrestricted Drug**: *A covered drug that is not subject to prior authorization and/or step therapy requirements.*

The “**Formulary Outlier Summary**” and “**Formulary Outlier Details**” worksheets within the FRS show the output for each drug list the FRS reviews. Each drug list that is reviewed is identified according to the issuer ID, issuer state, market coverage (if applicable), and drug list ID. The individual results for each issuer ID and drug list ID will reside on both of these worksheets if the user chooses to run this review.

CMS uses state and national outlier thresholds to perform the Formulary Outlier Review. Calculations of state and national outlier thresholds happen once per year after receiving all initial QHP application data. Distribution of thresholds does not occur until after the first round of QHP application reviews. **The FRS calculates state thresholds, but not national thresholds.**

States need to collect data from all issuers in their state to yield meaningful review results before receiving the national thresholds used by CMS. States are able to use the Formulary Outlier Review portion of the FRS to calculate state benchmarks. States are also able to use the “Formulary Outlier Details” worksheet in the FRS for informational purposes until CMS releases national thresholds. Issuers are also able to use the “Formulary Outlier Details” worksheet in the FRS for informational purposes until CMS releases state and national thresholds.

### *Formulary Outlier User Forms*

The Formulary Outlier Review user forms begin if you select to run all reviews together or if you select the Formulary Outlier Review to run individually. Figure 17 shows the first user form for the Formulary Outlier Review inputs.

First, you need to finalize the inputs for state threshold calculations. Selecting “Yes” will clear any saved thresholds currently in the FRS. Selecting “No” will use the state thresholds saved in the FRS. You need to enter state thresholds if you choose to not calculate state thresholds (see Formulary Outlier Summary Worksheet section).


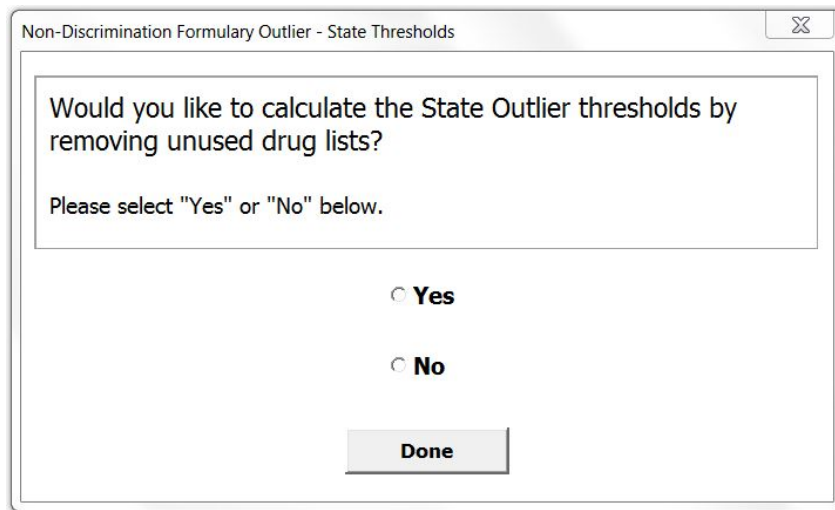
 **Hint**: *The FRS will only calculate state outlier thresholds if you imported P&B data.*

Figure 17 Formulary Outlier Review State Threshold Selections



Non-Discrimination Formulary Outlier - State Thresholds

Would you like to calculate the State Outlier thresholds by removing unused drug lists?

Please select "Yes" or "No" below.

☐ Yes

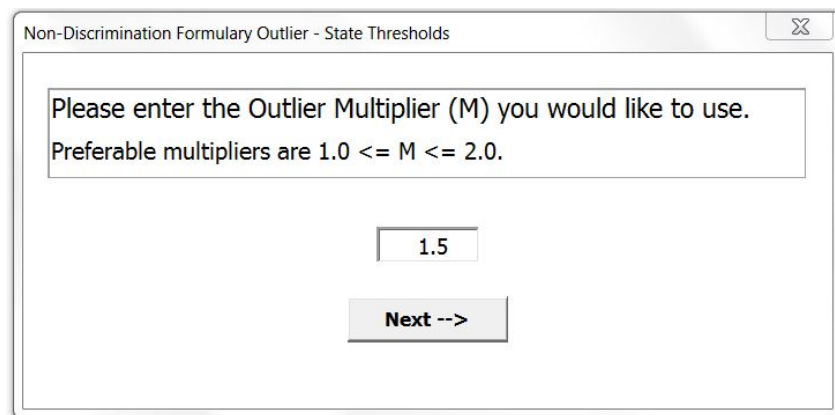
☐ No

Done

The state thresholds are blank in the FRS at first. If this is the first time that you are running the FRS and you are not planning on calculating state thresholds, then the FRS redirects you to the “Formulary Outlier Summary” worksheet after you select “No” in Figure 17. The FRS redirects you to this same worksheet after you select “No” in Figure 17 and the state thresholds are blank. The FRS hides the “Formulary Outlier Summary” worksheet at first. If the FRS redirects you to the “Formulary Outlier Summary” worksheet, then you need to manually enter state thresholds. After entering the state thresholds, then you need to start back at Step 5b as seen in Figure 8 to restart the FRS processes.

Next, you need select the outlier multiplier you want to use if calculating state thresholds as seen in Figure 18. The default and recommended outlier multiplier value is 1.5. A higher value will result in a more lenient review, while a lower value will result in a more stringent review. The outlier multiplier should be between 1.0 and 2.0. Please refer to the MRT for a detailed description of the outlier methodology.

Figure 18 Formulary Outlier Review Outlier Multiplier



Non-Discrimination Formulary Outlier - State Thresholds

Please enter the Outlier Multiplier (M) you would like to use.  
Preferable multipliers are  $1.0 \leq M \leq 2.0$ .

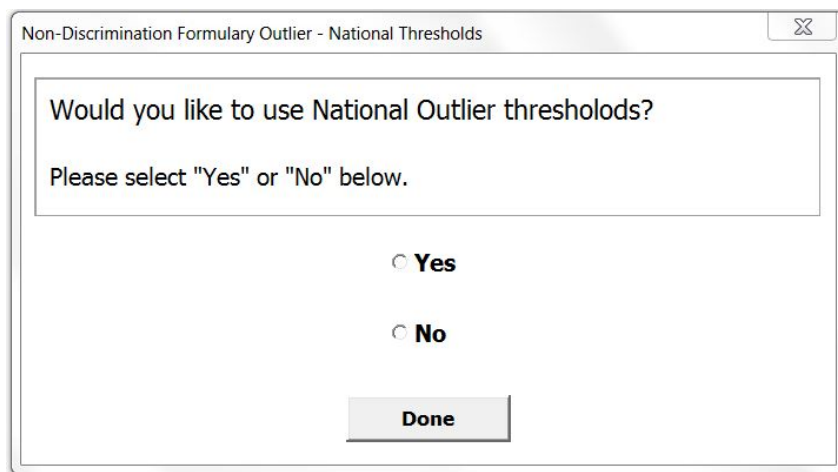
1.5

Next -->

When calculating outliers, if the benchmark count is zero, the benchmark count used is actually 1 due to the EHB requirement that drug lists cover the greater of 1 or the number of chemically distinct drugs in the benchmark for each class. Also, outlier thresholds calculations round up to the next integer because you cannot cover a fractional number of drugs. In addition, calculated thresholds can be negative depending on the outlier multiplier used. Note that an outlier calculation will not happen if there are less than five drug lists.

Figure 19 shows the next Formulary Outlier user form. Here you need to finalize the inputs for national threshold calculations. Selecting “Yes” will incorporate the national outlier thresholds that are currently stored in the FRS. Selecting “No” will ignore and remove any saved thresholds in the FRS. You need to enter national thresholds if you choose to use them in the review (see Formulary Outlier Summary Worksheet section).

*Figure 19 Formulary Outlier Review National Threshold Selections*



Non-Discrimination Formulary Outlier - National Thresholds

Would you like to use National Outlier thresholds?

Please select "Yes" or "No" below.

☐ Yes

☐ No

Done

The national thresholds are blank in the FRS at first. If this is the first time that you are running the FRS and you are planning on incorporating national thresholds, then the FRS redirects you to the “Formulary Outlier Summary” worksheet after you select “Yes” in Figure 19. The FRS redirects you to this same worksheet after you select “Yes” in Figure 19 and the national thresholds are blank. The FRS hides the “Formulary Outlier Summary” worksheet at first. If the FRS redirects you to the “Formulary Outlier Summary” worksheet, then you need to manually enter national thresholds. After entering the national thresholds, then you need to start back at Step 5b as seen in Figure 8 to restart the FRS processes.

At this point, the FRS either prompts you to select the location of your Rx templates (see the Selecting the Input Templates section) or it continues to provide more user forms for any additional reviews that you selected.

### Formulary Outlier Summary Worksheet

The “**Formulary Outlier Summary**” worksheet produces the unrestricted drug counts for all categories and classes in the Formulary Outlier Review. This worksheet produces the unrestricted drug count results for each drug list that the FRS processes. This worksheet also identifies the categories and classes that do not meet or exceed the applied threshold values. The cell associated with a formulary outlier will be bold with red font when it is lower than the applied outlier threshold as see in Figure 20.

Figure 20 Formulary Outlier Summary Worksheet Sample

							Marketplace Type:	Individual	
							Formulary Outlier Result:	2 Lists Not Met	2 Outliers
Category Class ID	Category	Class	Benchmark Count	National Outlier Thresholds	State Outlier Thresholds	Applied Thresholds	12345 Drug Lists	List 1 Unrestricted Count	List 1 Outlier Status
6	Anti-Addiction/ Substance Abuse Treatment Agents	Opioid Dependence Treatments	3	4	1	3		2	Outlier
7	Anti-Addiction/ Substance Abuse Treatment Agents	Opioid Reversal Agents	1	2	1	1		1	Okay
18	Anticonvulsants	Anticonvulsants, Other	5	2	1	2		3	Okay
19	Anticonvulsants	Calcium Channel Modifying Agents	4	2	1	2		4	Okay
20	Anticonvulsants	Gamma-aminobutyric Acid (GABA) Augmenting Agents	7	2	1	2		3	Okay

Here are the definition for the columns in this worksheet:

- **Category Class ID**: This is an arbitrary number assigned to the USP category and class for ease of identifying a category and class pairing.
- **Category**: The broadest classification of the USP guidelines that provides a high level formulary structure designed to include all potential therapeutic agents for conditions.<sup>10</sup>
- **Class**: A more granular classification for a USP category that provides therapeutic or pharmacologic groupings of FDA approved medications.<sup>11</sup>
- **Benchmark Count**: The state EHB benchmark chemically distinct drug count.
- **National Outlier Thresholds**: The calculated lower chemically distinct drug limit based on all drug lists in the nation.
- **State Outlier Thresholds**: The calculated lower chemically distinct drug limit based on all drug lists in a given state.
- **Applied Thresholds**: The combination of state benchmark, national outlier, and state outlier used as the actual lower chemically distinct drug limit for each category and class.
- **List [#] Unrestricted Count**: The chemically distinct drug unrestricted count for a particular drug list.

<sup>10</sup> See note 5 for more information.

<sup>11</sup> See note 5 for more information.

- **List [#] Outlier Status:** An indication whether the category and class has met the applied threshold.
  - **Okay:** The drug count meets the applied threshold. No further review is required.
  - **Outlier:** The drug count does not meet the applied threshold. A further review is required.
  - **NA:** The drug count cannot be reviewed since there are not enough drug lists in a state to calculate a threshold.

After expanding all of the drug lists that the FRS reviewed, we can look at all of the results that the FRS produces as seen in Figure 21. The numbers in Figure 21 correspond to the list of items below.



 **Hint:** Go to Appendix A: Manipulating Groupings in Excel to learn more about expanding and contracting the groups of drug lists for any worksheet in the FRS.

Figure 21 Formulary Outlier Summary Worksheet Output

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81	82	83	84	85	86	87	88	89	90	91	92	93	94	95	96	97	98	99	100	101	102	103	104	105	106	107	108	109	110	111	112	113	114	115	116	117	118	119	120	121	122	123	124	125	126	127	128	129	130	131	132	133	134	135	136	137	138	139	140	141	142	143	144	145	146	147	148	149	150	151	152	153	154	155	156	157	158	159	160	161	162	163	164	165	166	167	168	169	170	171	172	173	174	175	176	177	178	179	180	181	182	183	184	185	186	187	188	189	190	191	192	193	194	195	196	197	198	199	200	201	202	203	204	205	206	207	208	209	210	211	212	213	214	215	216	217	218	219	220	221	222	223	224	225	226	227	228	229	230	231	232	233	234	235	236	237	238	239	240	241	242	243	244	245	246	247	248	249	250	251	252	253	254	255	256	257	258	259	260	261	262	263	264	265	266	267	268	269	270	271	272	273	274	275	276	277	278	279	280	281	282	283	284	285	286	287	288	289	290	291	292	293	294	295	296	297	298	299	300	301	302	303	304	305	306	307	308	309	310	311	312	313	314	315	316	317	318	319	320	321	322	323	324	325	326	327	328	329	330	331	332	333	334	335	336	337	338	339	340	341	342	343	344	345	346	347	348	349	350	351	352	353	354	355	356	357	358	359	360	361	362	363	364	365	366	367	368	369	370	371	372	373	374	375	376	377	378	379	380	381	382	383	384	385	386	387	388	389	390	391	392	393	394	395	396	397	398	399	400	401	402	403	404	405	406	407	408	409	410	411	412	413	414	415	416	417	418	419	420	421	422	423	424	425	426	427	428	429	430	431	432	433	434	435	436	437	438	439	440	441	442	443	444	445	446	447	448	449	450	451	452	453	454	455	456	457	458	459	460	461	462	463	464	465	466	467	468	469	470	471	472	473	474	475	476	477	478	479	480	481	482	483	484	485	486	487	488	489	490	491	492	493	494	495	496	497	498	499	500	501	502	503	504	505	506	507	508	509	510	511	512	513	514	515	516	517	518	519	520	521	522	523	524	525	526	527	528	529	530	531	532	533	534	535	536	537	538	539	540	541	542	543	544	545	546	547	548	549	550	551	552	553	554	555	556	557	558	559	560	561	562	563	564	565	566	567	568	569	570	571	572	573	574	575	576	577	578	579	580	581	582	583	584	585	586	587	588	589	590	591	592	593	594	595	596	597	598	599	600	601	602	603	604	605	606	607	608	609	610	611	612	613	614	615	616	617	618	619	620	621	622	623	624	625	626	627	628	629	630	631	632	633	634	635	636	637	638	639	640	641	642	643	644	645	646	647	648	649	650	651	652	653	654	655	656	657	658	659	660	661	662	663	664	665	666	667	668	669	670	671	672	673	674	675	676	677	678	679	680	681	682	683	684	685	686	687	688	689	690	691	692	693	694	695	696	697	698	699	700	701	702	703	704	705	706	707	708	709	710	711	712	713	714	715	716	717	718	719	720	721	722	723	724	725	726	727	728	729	730	731	732	733	734	735	736	737	738	739	740	741	742	743	744	745	746	747	748	749	750	751	752	753	754	755	756	757	758	759	760	761	762	763	764	765	766	767	768	769	770	771	772	773	774	775	776	777	778	779	780	781	782	783	784	785	786	787	788	789	790	791	792	793	794	795	796	797	798	799	800	801	802	803	804	805	806	807	808	809	810	811	812	813	814	815	816	817	818	819	820	821	822	823	824	825	826	827	828	829	830	831	832	833	834	835	836	837	838	839	840	841	842	843	844	845	846	847	848	849	850	851	852	853	854	855	856	857	858	859	860	861	862	863	864	865	866	867	868	869	870	871	872	873	874	875	876	877	878	879	880	881	882	883	884	885	886	887	888	889	890	891	892	893	894	895	896	897	898	899	900	901	902	903	904	905	906	907	908	909	910	911	912	913	914	915	916	917	918	919	920	921	922	923	924	925	926	927	928	929	930	931	932	933	934	935	936	937	938	939	940	941	942	943	944	945	946	947	948	949	950	951	952	953	954	955	956	957	958	959	960	961	962	963	964	965	966	967	968	969	970	971	972	973	974	975	976	977	978	979	980	981	982	983	984	985	986	987	988	989	990	991	992	993	994	995	996	997	998	999	1000

1. Marketplace Type differentiates between market coverages **if and only if** you have separate Individual and SHOP templates. Otherwise, this row will not appear.
2. These cells will appear for every combination of issuer and market coverage (if applicable). It describes the overall performance of the issuer's drug lists in that market (if applicable). A drug list is an "Outlier" if it has at least one category and class that does not meet the applied threshold.
3. These cells tally the number of categories and classes that did not meet the applied threshold. They apply to the drug list listed directly below them.
4. These cells indicate the drug list under review. Notice that we have one issuer under review with two total drug lists – two from the individual market and one from the SHOP market.

 **Hint:** The cells directly beneath the issuer, "12345 Drug Lists" for example, are meant to be blank.

### Formulary Outlier Details Worksheet

The “**Formulary Outlier Details**” worksheet provides the results of the review for each chemically distinct drug in the categories and classes being reviewed. This worksheet provides the count of covered drugs and unrestricted drugs to give the issuer or reviewer an indication of where a drug list is deficient. This worksheet also identifies how a chemically distinct drug is covered on a particular drug list. The cell associated with a deficient drug count will be bold with red font when it not covered without restrictions as seen in Figure 22.

Figure 22 Formulary Outlier Details Worksheet Sample

	Marketplace Type:	Individual			SHOP (Small Group)	
Category; Class	Chemically Distinct Drug	12345 Drug Lists	Drug List 1	Drug List 2	12345 Drug Lists	Drug List 1
Anti-Addiction/ Substance Abuse Treatment Agents; Opioid Dependence Treatments	Buprenorphine		PA	PA		PA
	Buprenorphine; Naloxone		PA	PA		PA
	Methadone		Unrestricted	Unrestricted		Unrestricted
	Naltrexone		Unrestricted	Unrestricted		Unrestricted
	Covered Count		4	4		4
	Unrestricted Count		2	2		2

Here are the definition for the columns in this worksheet:

- **Category; Class:** The category is the broadest classification of the USP guidelines that provides a high level formulary structure designed to include all potential therapeutic agents for conditions. The class is a more granular classification for a USP category that provides therapeutic or pharmacologic groupings of FDA approved medications.
- **Chemically Distinct Drug:** Two drugs are chemically distinct if they have different active ingredients. Combination drugs are chemically distinct from their component drugs.

For each drug list, each chemically distinct drug is either:

- Uncovered:** The drug list does not contain any RxCUIs associated with the chemically distinct drug.
- Unrestricted:** The drug list contains at least one RxCUI associated with the chemically distinct drug without prior authorization or step therapy.
- Restricted with Prior Authorization (PA):** All of the RxCUIs on the drug list associated with the chemically distinct drug have only a prior authorization requirement.
- Restricted with Step Therapy (ST):** All of the RxCUIs on the drug list associated with the chemically drug have only a step therapy requirement.
- Restricted with both Prior Authorization and Step Therapy (PA, ST):** All of the RxCUIs on the drug list associated with the chemically distinct drug have either prior authorization or step therapy requirements. Some RxCUIs may have both requirements.



After expanding all of the drug lists that the FRS reviewed, we can look at all of the results that the FRS produces as seen in Figure 23. The numbers in Figure 23 correspond to the list of items below.


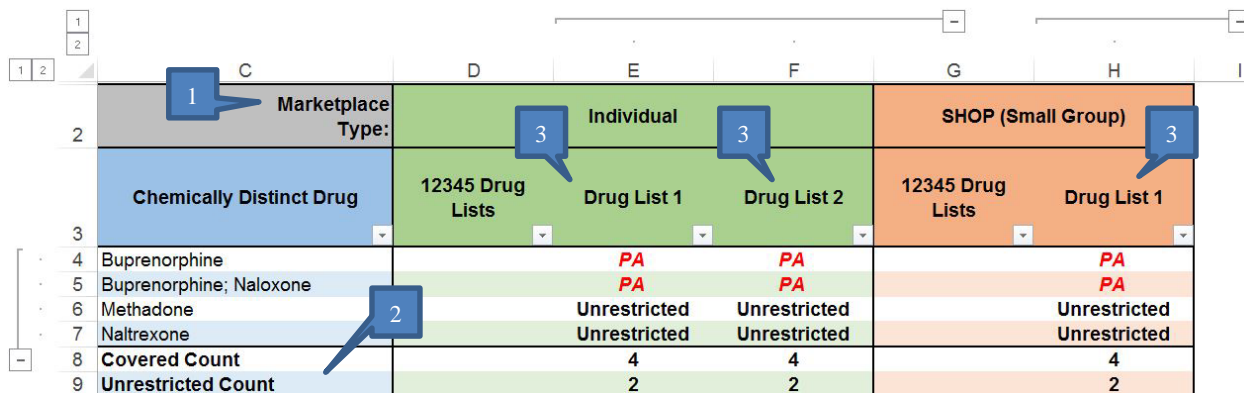

 **Hint:** Go to Appendix A: Manipulating Groupings in Excel to learn more about expanding and contracting the groups of drug lists for any worksheet in the FRS.

Figure 23 Formulary Outlier Details Worksheet Output



	C	D	E	F	G	H	I
2	Marketplace Type:	Individual		SHOP (Small Group)			
	Chemically Distinct Drug	12345 Drug Lists	Drug List 1	Drug List 2	12345 Drug Lists	Drug List 1	
4	Buprenorphine		PA	PA		PA	
5	Buprenorphine; Naloxone		PA	PA		PA	
6	Methadone		Unrestricted	Unrestricted		Unrestricted	
7	Naltrexone		Unrestricted	Unrestricted		Unrestricted	
8	Covered Count		4	4		4	
9	Unrestricted Count		2	2		2	

1. Marketplace Type differentiates between market coverages **if and only if** you have separate Individual and SHOP templates. Otherwise, this row will not appear.
2. The covered count and unrestricted count are listed for each category and class. This is the sum of chemically distinct drugs within a category and class that are either covered or unrestricted as defined previously.
3. These cells indicate the drug list under review. Notice that we have one issuer under review with three total drug lists – two from the individual market and one from the SHOP market.

 **Hint:** The cells directly beneath the issuer, “12345 Drug Lists” for example, are meant to be blank.

Both Formulary Outlier Review worksheets provide the category and class. This feature provides the ability to identify all of the chemically distinct drugs that affect that particular category and class. The “Formulary Outlier Summary” worksheet tells you if a category and class is an outlier. The “Formulary Outlier Details” worksheet tells you how the chemically distinct drugs were covered. Only unrestricted drugs count for the Formulary Outlier Review. From here you are able to look up the chemically distinct drug that you need in RxNorm. Adding the appropriate RxCUI to your formulary will allow you to meet the threshold count and satisfy the review.



### Non-Discrimination Clinical Appropriateness Review

The Clinical Appropriateness Review identifies plans that do not meet the recommended clinical guidelines for several medical conditions. The FRS compares either the drug count or the unrestricted drug count against the recommended clinically appropriate threshold.

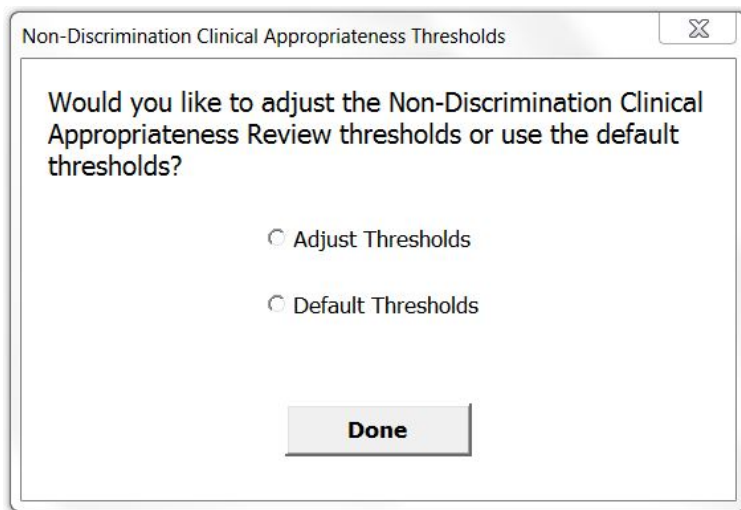
The “**Clinical Summary**” and the “**Clinical Details**” worksheets within the FRS show the output for each drug list the FRS reviews. Each drug list that is reviewed is identified according to the issuer ID, issuer state, market coverage (if applicable), and drug list ID. The individual results for each issuer ID and drug list ID will reside on both of these worksheets if the user chooses to run this review.

CMS uses clinically appropriate thresholds to perform the Clinical Appropriateness Review. The thresholds are static, meaning do not change over the course of the review, and they are not calculated. The FRS contains prepopulated, recommended thresholds to start. However, the FRS lets you adjust threshold values. Any different threshold value that you choose affects the final outcome of the review. A higher value will result in a more stringent review, while a lower value will result in a more lenient review. Note that the threshold values are limited to values between zero and the highest number possible for a particular test, also called the maximum threshold.

### Clinical Appropriateness User Forms

The Clinical Appropriateness Review user forms begin if you select to run all reviews together or if you select the Clinical Appropriateness Review to run individually. Figure 24 shows the first user form for the Clinical Appropriateness Review inputs.

Figure 24 Clinical Appropriateness Review Thresholds



Non-Discrimination Clinical Appropriateness Thresholds

Would you like to adjust the Non-Discrimination Clinical Appropriateness Review thresholds or use the default thresholds?

☐ Adjust Thresholds

☐ Default Thresholds

**Done**

First, you need to choose to adjust the thresholds or use the default thresholds. The default thresholds are the recommended thresholds that CMS deemed clinically appropriate. If you choose to use the default thresholds, then the FRS prompts you to select the location of your Rx templates (see the Selecting the Input Templates section). Otherwise, by choosing to adjust thresholds, the FRS displays the review conditions where you enter in new thresholds as shown in Figure 25.


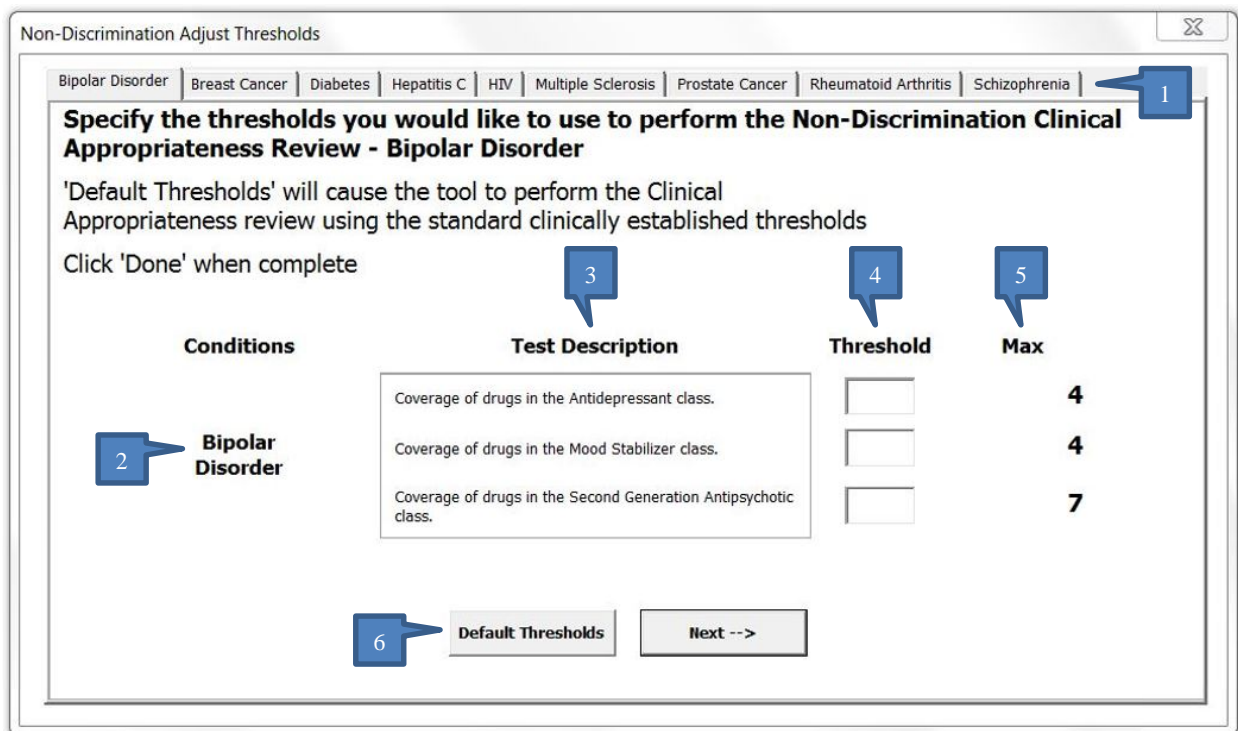
 **Hint:** You are able to choose the default thresholds even if you continue with the adjust thresholds path.

Figure 25 Clinical Appropriateness Review Conditions



Non-Discrimination Adjust Thresholds

Bipolar Disorder | Breast Cancer | Diabetes | Hepatitis C | HIV | Multiple Sclerosis | Prostate Cancer | Rheumatoid Arthritis | Schizophrenia

**Specify the thresholds you would like to use to perform the Non-Discrimination Clinical Appropriateness Review - Bipolar Disorder**

'Default Thresholds' will cause the tool to perform the Clinical Appropriateness review using the standard clinically established thresholds

Click 'Done' when complete


Conditions	Test Description	Threshold	Max
Bipolar Disorder	Coverage of drugs in the Antidepressant class.	<input type="text"/>	4
	Coverage of drugs in the Mood Stabilizer class.	<input type="text"/>	4
	Coverage of drugs in the Second Generation Antipsychotic class.	<input type="text"/>	7

Default Thresholds Next -->

The initial condition thresholds that you see are those for the Bipolar Disorder review. The numbers in Figure 25 correspond to the list of items below.

1. These are the different conditions reviewed for clinical appropriateness. You either click on each condition tab to set the thresholds or click on the “Next” button to move to additional conditions.
2. This is the name of the condition you are currently setting thresholds.
3. The test description provides a brief explanation for each review that the FRS performs for the particular condition. All tests are at the class level. The coverage can be unrestricted or regular coverage.

- This is when you provide the threshold that you want to use other than the default threshold. If you want to use the default thresholds, see number 6 below. You can enter a number into the boxes next to the test descriptions. Each test will need a threshold. The threshold can be between 0 and the maximum possible value.
- This is the maximum possible threshold that the test can be. This represents the total number of clinically distinct drugs that make up the particular test description.
- The default thresholds button populates the default thresholds into the boxes next to the test descriptions. Clicking this button will overwrite any existing threshold you may have entered.

 **Hint:** You may want to click the “Default Thresholds” button first to identify the recommended thresholds before changing them.

Once you enter all of the thresholds for the review conditions, the FRS prompts you to select the location of your Rx templates (see the Selecting the Input Templates section). The Clinical Appropriateness Review is the last review that the FRS runs, so there are no more user forms at this point.

### *Clinical Summary Worksheet*

The “**Clinical Summary**” worksheet displays the overall results of the Clinical Appropriateness Review. This worksheet produces the review drug count results for each drug that the FRS processes. This worksheet also identifies the review tests that do not meet or exceed the applied threshold values. The cell associated with a review test that is not clinically appropriate will be bold with red font when it the drug count value is lower than the applied thresholds as seen in Figure 26.

Figure 26 Clinical Appropriateness Summary Worksheet Sample

		Clinical Appropriateness Result:	2 Lists Not Met		4 Tests Not Met		4 Tests Not Met		1 List Not Met		4 Tests Not Met	
Condition	Test Description	Threshold Selected	12345 Drug Lists	List 1 Test Count	List 1 Result	List 2 Test Count	List 2 Result		12345 Drug Lists	List 1 Test Count	List 1 Result	
Bipolar Disorder	Coverage of drugs in the Antidepressants class.	4		4	Met	4	Met			4	Met	
	Coverage of drugs in the Mood Stabilizers class.	4		4	Met	4	Met			4	Met	
	Coverage of drugs in the Second Generation Antipsychotics class.	7		7	Met	7	Met			7	Met	

Here are the definition for the columns in this worksheet:

- Condition**: The medical condition under review.
- Test Description**: The specific test under review for the given condition. Generally, the test lists the drug class under review. Certain tests require multiple tests for a single drug class.
- Threshold Selected**: The threshold selected by the user through the user forms. These are either the default thresholds or the user selected thresholds.

- **List [#] Test Count:** The number of clinically distinct drugs that satisfy the test description.
- **List [#] Result:** An indication whether the test description has met the selected threshold.
  - **Met:** The drug count meets the selected threshold. No further review is required.
  - **Not Met:** The drug count does not meet the selected threshold. A further review is required.

After expanding all of the drug lists that the FRS reviewed, we can look at all of the results that the FRS produces as seen in Figure 27. The numbers in Figure 27 correspond to the list of items below.


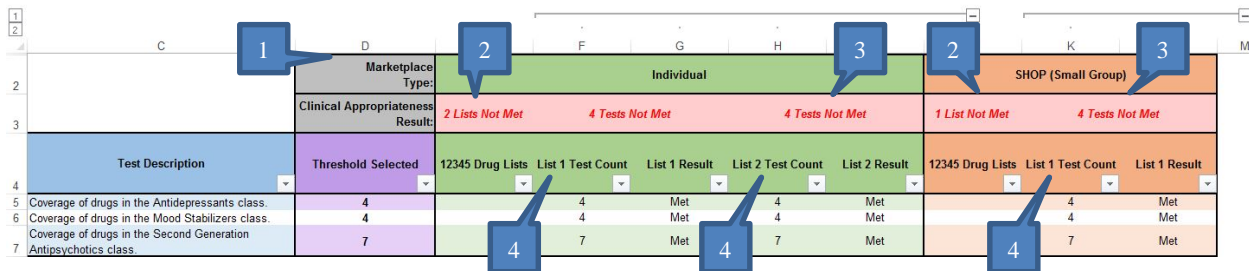

 **Hint:** Go to Appendix A: Manipulating Groupings in Excel to learn more about expanding and contracting the groups of drug lists for any worksheet in the FRS.

Figure 27 Clinical Appropriateness Summary Worksheet Output



	C	D	F	G	H	K	M
1		Marketplace Type:	Individual			SHOP (Small Group)	
2		Clinical Appropriateness Result:	2 Lists Not Met			4 Tests Not Met	
3		Test Description	Threshold Selected	12345 Drug Lists	List 1 Test Count	List 1 Result	List 2 Test Count
4							
5		Coverage of drugs in the Antidepressants class.	4	4	Met	4	Met
6		Coverage of drugs in the Mood Stabilizers class.	4	4	Met	4	Met
7		Coverage of drugs in the Second Generation Antipsychotics class.	7	7	Met	7	Met

1. Marketplace Type differentiates between market coverages **if and only if** you have separate Individual and SHOP templates. Otherwise, this row will not appear.
2. These cells will appear for every combination of issuer and market coverage (if applicable). It describes the overall performance of the issuer's drug lists in that market (if applicable). A drug list is "Not Met" if it has at least test that does not meet the selected threshold.
3. These cells tally the number of tests that did not meet the selected threshold. They apply to the drug list listed directly below them.
4. These cells indicate the drug list under review. Notice that we have one issuer under review with two total drug lists – two from the individual market and one from the SHOP market.

 **Hint:** The cells directly beneath the issuer, "12345 Drug Lists" for example, are meant to be blank.

### Clinical Details Worksheet

The “**Clinical Details**” worksheet displays the results of the review for each drug in the conditions and classes under review. This worksheet provides the count of covered drugs and unrestricted drugs to give the issuer or reviewer an indication of where a drug list is deficient. This worksheet also identifies how a clinically distinct drug is covered on a particular drug list. The cell associated with a deficient drug count will be bold with red font when it not covered without restrictions as seen in Figure 28.

Figure 28 Clinically Appropriate Details Worksheet Sample

		Marketplace Type:	Individual			SHOP (Small Group)	
Condition	Class	Drug Name	12345 Drug Lists	List 1	List 2	12345 Drug Lists	List 1
Bipolar Disorder	Antidepressants	Bupropion	Unrestricted	Unrestricted		Unrestricted	
		Fluoxetine	Unrestricted	Unrestricted		Unrestricted	
		Paroxetine	Unrestricted	Unrestricted		Unrestricted	
		Tranylcypromine	Unrestricted	Unrestricted		Unrestricted	
		Covered Count	4	4		4	
	Mood Stabilizers	Carbamazepine	Unrestricted	Unrestricted		Unrestricted	
		Lamotrigine	Unrestricted	Unrestricted		Unrestricted	
		Lithium	Unrestricted	Unrestricted		Unrestricted	
		Valproate	Unrestricted	Unrestricted		Unrestricted	
		Covered Count	4	4		4	
		Unrestricted Count	4	4		4	

Here are the definition for the columns in this worksheet:

- **Condition:** The medical condition under review.
- **Class:** The class of drugs under review that relates to the given medical condition.
- **Drug Name:** The individual drugs that create each class for the given medical condition.

For each drug list, each drug is either:

- Uncovered:** The drug list does not contain any RxCUIs associated with the specified drug.
- Unrestricted:** The drug list contains at least one RxCUI associated with the specified drug without prior authorization or step therapy.
- Restricted with Prior Authorization (PA):** All of the RxCUIs on the drug list associated with the specified drug have only a prior authorization requirement.
- Restricted with Step Therapy (ST):** All of the RxCUIs on the drug list associated with the drug have only a step therapy requirement.
- Restricted with both Prior Authorization and Step Therapy (PA, ST):** All of the RxCUIs on the drug list associated with the drug have either prior authorization or step therapy requirements. Some RxCUIs may have both requirements.

After expanding all of the drug lists that the FRS reviewed, we can look at all of the results that the FRS produces as seen in Figure 29. The numbers in Figure 29 correspond to the list of items below.


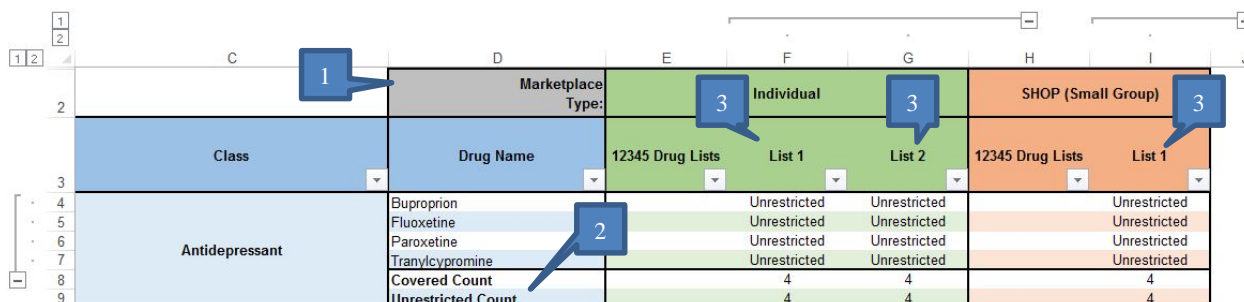

 **Hint:** Go to Appendix A: Manipulating Groupings in Excel to learn more about expanding and contracting the groups of drug lists for any worksheet in the FRS.

Figure 29 Formulary Outlier Summary Worksheet Output



	Class	Drug Name	Marketplace Type:	Individual	SHOP (Small Group)
			12345 Drug Lists	List 1	List 2
			12345 Drug Lists	List 1	
	Antidepressant	Bupropion	Unrestricted	Unrestricted	Unrestricted
		Fluoxetine	Unrestricted	Unrestricted	Unrestricted
		Paroxetine	Unrestricted	Unrestricted	Unrestricted
		Tranylcypromine	Unrestricted	Unrestricted	Unrestricted
		Covered Count	4	4	4
		Unrestricted Count	4	4	4

1. Marketplace Type differentiates between market coverages **if and only if** you have separate Individual and SHOP templates. Otherwise, this row will not appear.
2. The covered count and unrestricted count are listed for each condition and class. This is the sum of clinically distinct drugs within a condition and class that are either covered or unrestricted as defined previously.
3. These cells indicate the drug list under review. Notice that we have one issuer under review with three total drug lists – two from the individual market and one from the SHOP market.

 **Hint:** The cells directly beneath the issuer, “12345 Drug Lists” for example, are meant to be blank.

Both Clinical Appropriateness Review worksheets provide the condition and class. This feature provides the ability to identify all of the clinically distinct drugs that affect that particular condition and class. The “Clinical Summary” worksheet tells you if a test for a condition is deficient. The “Clinical Details” worksheet tells you how the clinically distinct drugs were covered. From here you are able to look up the clinically distinct drug that you need in RxNorm. Adding the appropriate RxCUI to your formulary will allow you to meet the threshold count and satisfy the review.



## Exporting FRS Results

The FRS contains a feature that allows you to export any review results to a separate Excel file. This step is optional, and the purpose is so that you can save all individual review results for your records. This step is only useful after you have run the FRS and produced meaningful results. In order for the FRS to export the results in the workbook, you will need to indicate that you would like to export the results as depicted in Figure 30.

Figure 30 Export Results Indication

6.	Would you like to export the Formulary Review Suite Results?
	No
	Yes
	No

By selecting “Yes,” the FRS displays the option to export the results. Use the Export Formulary Review Results button to export the results of the FRS as seen in Figure 31. The FRS tells you when the export finishes and provides a link to the exported file.

Figure 31 Export Results Location

6.	<b>New for 2017:</b> Using the selection menu in cell H25, the user will have the option to export the results of the Formulary Review Suite. The results will be exported to a separate Excel file, which the user can then save for his or her records.	Would you like to export the Formulary Review Suite Results?
	<b>Note:</b> If the user selects Yes, a button will appear below to perform the export process.	Yes
	<b>New for 2017:</b> Use <b>Export Formulary Review Results</b> button below to export the results of the Formulary Review Suite. Once the export process has been completed, a message will appear informing the user that the export has completed. A link to the exported file will also be located in cell H27.	Export File:
	<b>Export Formulary Review Results</b>	<a href="#">Formulary Review Tool Output</a>

The link location of the exported file relates to the location of the templates used to run the reviews. The FRS creates a new folder located within the same path as the location of the templates called “Formulary Review Tool Output.” The FRS saves the exported results in this newly created folder. Clicking on the blue highlighted “Formulary Review Tool Output” link will open a new Excel file containing the same results as the FRS.

## RxCUI Submission Report

The FRS contains a feature that allows you to produce a detailed report of all RxCUIs submitted for review into a separate Excel file. This step is optional, and the purpose is so that you can review the specific drug list details submitted for the reviews. You do not have to run the FRS in order to produce this report. However, you must indicate if you have separate market templates and you must indicate your state. In order for the FRS to produce the RxCUI detailed results, you will need to indicate that you would like to produce the results as depicted in Figure 32.

Figure 32 RxCUIs Report Indication

7.	Would you like to review all RxCUIs Submitted?
	No
	Yes No

By selecting “Yes,” the FRS displays the option to produce the RxCUI detailed results. Use the RxCUI Submission Report button to produce the RxCUI detailed results as seen in Figure 33. The FRS tells you when the export finishes and provides a link to the exported file.

Figure 33 RxCUIs Report Location

7.	<b>New for 2017:</b> Using the selection menu in cell H29, the user will be able to produce a detailed report of all RxCUIs submitted for review in the <b>Formulary Review Suite</b> . The report generated for all RxCUIs submitted will be exported to a separate Excel file, which the user can then save for his or her records.	Would you like to review all RxCUIs Submitted?
	<b>Note:</b> If the user selects Yes, a button will appear below to produce the report and excel file.	Yes
	<b>New for 2017:</b> Use the <b>RxCUI Submission Report</b> button below to generate a report of all RxCUIs submitted for review in the <b>Formulary Review Suite</b> . Once the report has been produced and exported, a message will appear informing the user that the export has completed. A link to the exported file will also be located in cell H31.	All RxCUIs Submitted
	<b>RxCUI Submission Report</b>	<a href="#">FL RxCUIs Submitted Report</a>

The link location of the exported file relates to the location of the templates used to run the reviews. The FRS creates a new folder located within the same path as the location of the templates called “Formulary Review Tool Output.” The FRS saves the exported results in this newly created folder. Clicking on the blue highlighted “RxCUIs Submitted Report” link will open a new Excel file containing the same results as the FRS.

The “**All RxCUIs Submitted**” worksheet produces a list of every RxCUI submitted in all of the Rx templates reviewed. This worksheet provides detailed information for all RxCUIs that the FRS processes. This worksheet also identifies whether the RxCUI is used in any of the FRS reviews. Figure 34 shows an example of the RxCUI details.



Figure 34 All RxCUIs Submitted Worksheet Sample

											Marketplace Type:	
RxCUI	Crosswalk Status	Chemically Distinct Drug	Chemically Distinct Drug	Retired?	Reassigned RxCUI	Category Class Impacted	QHP Sub-Classification	Impact Category Class Review	Impact Formulary Outlier Review	Impact Clinical Appropriateness Review	12345 Drug Lists	
91792	EHB Rx Crosswalk	688	Oxymetholone	No	N/A	125		Yes	No	No		
92752	EHB Rx Crosswalk	383	Fluorouracil	No	N/A	110		Yes	No	No		
93181	EHB Rx Crosswalk	292	Dyphylline	No	N/A	158		Yes	No	No		
96304	EHB Rx Crosswalk	754	Primidone	No	N/A	18		Yes	Yes	No		
102787	RxNorm Database	N/A	Lincomycin	N/A	N/A	N/A		No	No	No		
103401	EHB Rx Crosswalk	435	Hydrocortisone	No	N/A	142, 34, 110, 123		Yes	No	No		
103456	EHB Rx Crosswalk	381	Fluocinonide	No	N/A	34, 110, 123		Yes	No	No		
103457	EHB Rx Crosswalk	381	Fluocinonide	No	N/A	34, 110, 123		Yes	No	No		
103999	EHB Rx Crosswalk	790	Ritabutin	No	N/A	40		Yes	No	No		
104044	EHB Rx Crosswalk	568	Mepenzolate	No	N/A	112		Yes	No	No		
104206	EHB Rx Crosswalk	269	Digoxin	No	N/A	94		Yes	No	No		
104208	RxNorm Database	N/A	Digoxin	N/A	N/A	N/A		No	No	No		
104894	EHB Rx Crosswalk	596	Metoclopramide	No	N/A	30, 113		Yes	No	No		
104895	EHB Rx Crosswalk	624	nabixin	No	N/A	31		Yes	No	No		
104894	EHB Rx Crosswalk	677	Ondansetron	No	N/A	31		Yes	No	No		
105171	EHB Rx Crosswalk	153	Cefadroxil	No	N/A	11		Yes	No	No		

Here are the definitions for the columns in this worksheet:

- **RxCUI**: An identification for a group of synonymous drug data specified by ingredient, strength, dose form, and brand name, where applicable.
- **Crosswalk Status**: An identification for the RxCUI source.
  - **EHB Rx Crosswalk**: The RxCUI can be found on the EHB Rx Crosswalk. This means the RxCUI is also in the RxNorm Database.
  - **RxNorm Database**: The RxCUI can be found in the November release of the RxNorm. This means that the RxCUI cannot be found in the EHB Rx Crosswalk.
  - **N/A**: The RxCUI does not exist in neither the EHB Rx Crosswalk nor the November release of the RxNorm.
- **Chemically Distinct Drug ID**: This is an arbitrary number assigned to the chemically distinct drug for ease of identifying all instances of the chemically distinct drug.
- **Chemically Distinct Drug**: Two drugs are chemically distinct if they have different active ingredients. Combination drugs are chemically distinct from their component drugs.
- **Retired?**: An indication whether the RxCUI is considered retired or not in the RxNorm database.
- **Reassigned RxCUI**: The parent RxCUI for the retired RxCUI. The FRS gives issuers credit for retired RxCUIs by mapping the retired RxCUIs to their reassigned values.
- **Category Class Impacted**: The category class ID that the RxCUI belongs to in the EHB Rx Crosswalk.
- **QHP Sub-Classification**: Additional sub-level classification of certain USP classes.
- **Impact Category Class Review**: An indication that the RxCUI counts for the Category Class Count Review.
- **Impact Formulary Outlier Review**: An indication that the RxCUI counts for the Formulary Outlier Review.
- **Impact Clinical Appropriateness Review**: An indication that the RxCUI counts for the Clinical Appropriateness Review.

After expanding all of the drug lists that the FRS reviewed, we can look at all of the results that the FRS produces as seen in Figure 35. The numbers in Figure 35 correspond to the list of items below.



 **Hint:** Go to Appendix A: Manipulating Groupings in Excel to learn more about expanding and contracting the groups of drug lists for any worksheet in the FRS.

Figure 35 All RxCUIs Submitted Worksheet Output

1													
2	A	B	C	J	K	L	M	N	O	P	Q	R	
2						Marketplace Type:	Individual			SHOP (Small Group)			
3		RxCUI	Crosswalk Status	Impact Category Class Review	Impact Formulary Outlier Review	Impact Clinical Appropriateness Review	12345 Drug Lists	Drug List 1	Drug List 2	12345 Drug Lists	Drug List 1		
4		91792	EHB Rx Crosswalk	Yes	No	No		Covered	Covered		Covered		
5		92752	EHB Rx Crosswalk	Yes	No	No		Not Covered	Not Covered		Not Covered		
6		93181	EHB Rx Crosswalk	Yes	No	No		Covered	Covered		Covered		
7		96304	EHB Rx Crosswalk	Yes	Yes	No		Covered	Covered		Covered		
8		102787	RxNorm Database	No	No	No		Not Covered	Not Covered		Not Covered		
9		103401	EHB Rx Crosswalk	Yes	No	No		Covered	Covered		Covered		
10		103456	EHB Rx Crosswalk	Yes	No	No		Covered	Covered		Covered		
11		103457	EHB Rx Crosswalk	Yes	No	No		Covered	Covered		Covered		
12		103899	EHB Rx Crosswalk	Yes	No	No		Not Covered	Not Covered		Not Covered		
13		104044	EHB Rx Crosswalk	Yes	No	No		Covered	Covered		Covered		
14		104206	EHB Rx Crosswalk	Yes	No	No		Covered	Covered		Covered		
15		104208	RxNorm Database	No	No	No		Not Covered	Not Covered		Not Covered		
16		104884	EHB Rx Crosswalk	Yes	No	No		Covered	Covered		Covered		
17		104885	EHB Rx Crosswalk	Yes	No	No		Not Covered	Not Covered		Not Covered		
18		104894	EHB Rx Crosswalk	Yes	No	No		Covered	Covered		Covered		
19		105171	EHB Rx Crosswalk	Yes	No	No		Covered	Covered		Covered		
20		105292	EHB Rx Crosswalk	Yes	No	No		Covered	Covered		Covered		
21		105347	EHB Rx Crosswalk	Yes	No	No		Not Covered	Not Covered		Not Covered		

1. Marketplace Type differentiates between market coverages **if and only if** you have separate Individual and SHOP templates. Otherwise, this row will not appear.
2. These cells indicate the drug list under review. Notice that we have one issuer under review with three total drug lists – two from the individual market and one from the SHOP market.
3. Each RxCUI can take on a value of Covered, Not Covered, or Not in Drug List. Covered means that the RxCUI is located on a tier in the issuer’s formulary for that drug list. Not Covered means that the RxCUI is located on the Rx template but is not on an issuer’s formulary for that drug list. Not in Drug List means the RxCUI is not in the issuer’s Rx template, which will appear only if multiple issuers are reviewed at the same time.

 **Hint:** The cells directly beneath the issuer, “12345 Drug Lists” for example, are meant to be blank.

## Appendix A: Manipulating Groupings in Excel

The FRS presents the output results in a way that is unique to all of the other QHP Application Review Tools. The two methods below describe the possible ways to view the results for the majority of the output worksheets.

Every output worksheet in the FRS collapses the actual results and makes the worksheet look blank or empty. The FRS does this on purpose to decrease the amount of material viewed at one time. The results are part of “groupings” where the actual information can be hidden or unhidden based on your preference. Each drug list reviewed by the FRS is part of a grouping. Figure 36 shows an example of an output worksheet taken directly after the FRS completes its processing.

*Figure 36 Initial Output Worksheet Example*

Category Class ID	Category	Class	Benchmark Count	Benchmark Reevaluation*	12345 Drug Lists	12345 Drug Lists
1	Analgesics	Nonsteroidal Anti-inflammatory Drugs	21	21		
2	Analgesics	Opioid Analgesics, Long-acting	14	14		
3	Analgesics	Opioid Analgesics, Short-acting	16	16		
4	Anesthetics	Local Anesthetics	3	3		
5	Anti-Addiction/ Substance Abuse Treatment Agents	Alcohol Deterrents/Anti-craving	4	4		
6	Anti-Addiction/ Substance Abuse Treatment Agents	Opioid Dependence Treatments	3	3		
7	Anti-Addiction/ Substance Abuse Treatment Agents	Opioid Reversal Agents	1	1		

**Method 1:** In the left-hand corner of the output worksheets, there are two squares with numbers inside. The top square has a value of “1” and the bottom square has a value of “2.” Clicking these numbers manipulate the groupings in different ways. Clicking on the “2” will expand all groupings. This means that Column G and Column L in Figure 36 will unhide the columns that are part of their groupings. Clicking on the “1” does the opposite and collapses all groupings.

**Method 2:** At the top of the output worksheets, there are squares with pluses (“+”) inside. Clicking on a single “+” will expand the individual grouping. Notice that the “+” becomes a minus (“-”) after the group is expanded. Clicking on a single “-” will collapse the individual grouping. After clicking the “-” the box becomes a “+” once again. Also, notice that the “+” and “-” are offset from the grouping that they control dictated by the arrows in Figure 36.

Using either of the methods described allows you to view the drug list results produced by the FRS. You can find more information about these features through Microsoft support websites.<sup>12</sup>

<sup>12</sup> <https://support.office.com/en-us/article/Outline-group-data-in-a-worksheet-08ce98c4-0063-4d42-8ac7-8278c49e9aff>

## Appendix B: Acronyms

Acronym	Phrase
CMS	Centers for Medicare & Medicaid Services
EHB	Essential Health Benefit
FFM	Federally-Facilitated Marketplaces
FF-SHOP	Federally-Facilitated Small Business Health Options Program
FRS	Formulary Review Suite
HIV	Human Immunodeficiency Virus
ID	Identification
MOOP	Maximum Out-Of-Pocket
MRT	Master Review Tool
MSP	Multi-State Plan
P&B	Plans & Benefits
QHP	Qualified Health Plan
Rx	Prescription Drug
RxCUI	RxNorm Concept Unique Identifiers
USP	United States Pharmacopeia