Formulary Review Suite Instructions

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# **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 1.0.**

## 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.[[1]](#footnote-1)

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.

# **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/qhp.html#2016 QHP Application Tools](https://www.cms.gov/cciio/programs-and-initiatives/health-insurance-marketplaces/qhp.html%232016%20QHP%20Application%20Tools). 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/cciio/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.*

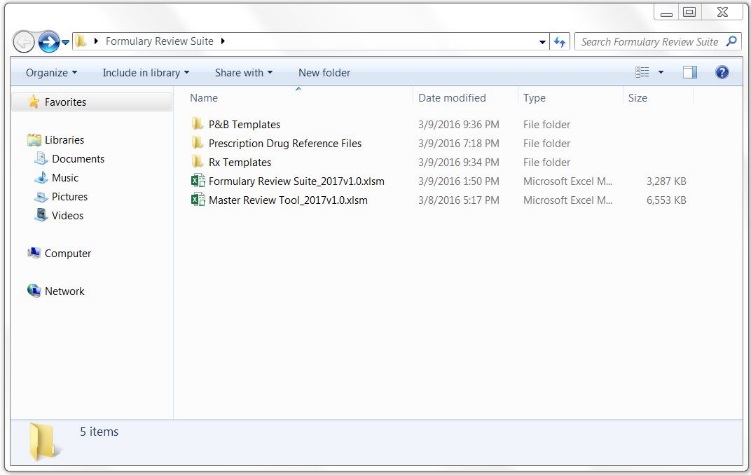
#### Saving the Input Templates

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.[[2]](#footnote-2)

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

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

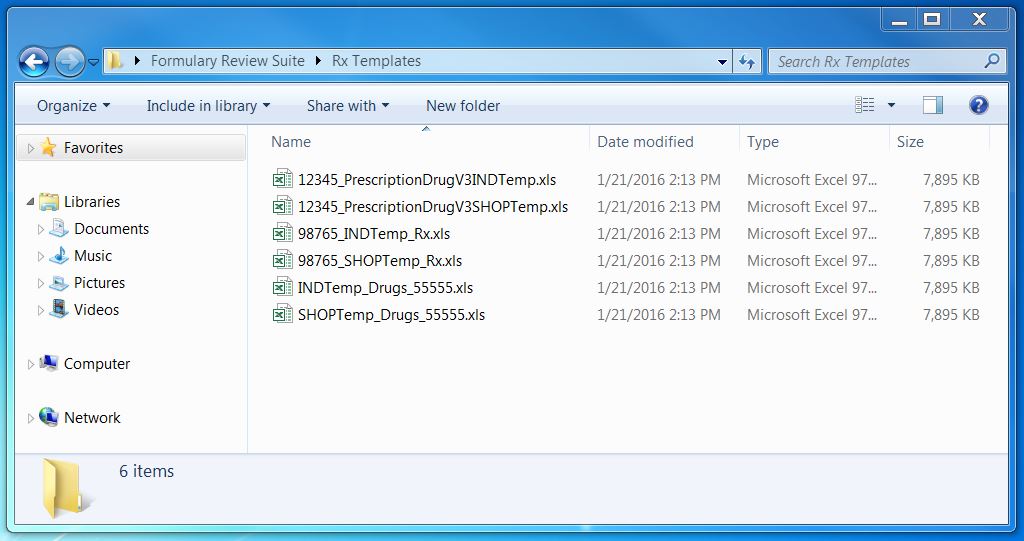
In states that collect templates in the System for Electronic Rate and Form Filing (SERFF), issuers may submit separate sets of templates for Individual and SHOP QHP application plans. In this case, an issuer can submit two drug lists with the same identification (ID) – one for the Individual marketplace 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



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

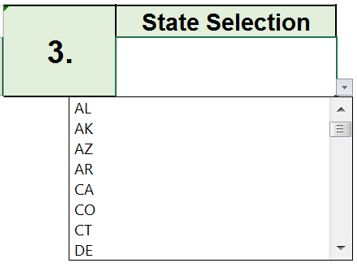


## Finalize FRS Setup for Reviews

#### 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.

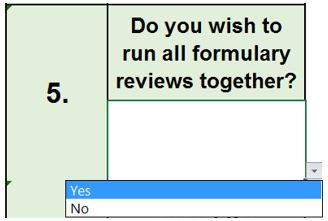
 **Hint**: T*he Formulary Outlier Review state outlier threshold calculations need P&B data to run.*

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

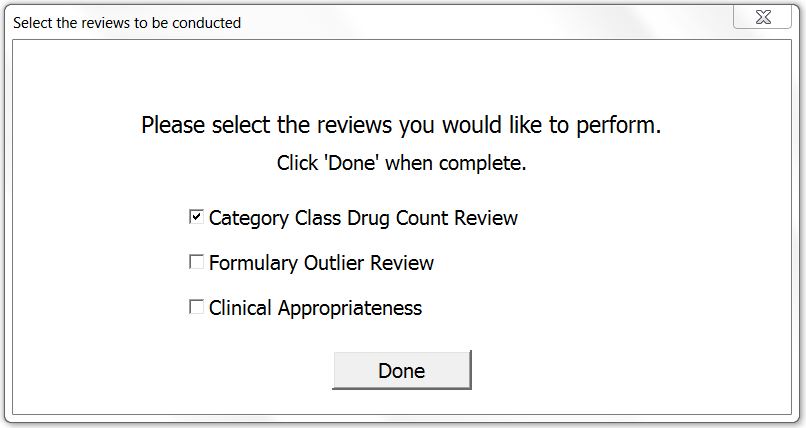


**Hint**: *You can always run the FRS for each of the three reviews individually at any time if you do not want the results for all three reviews at once. To do this, choose “No” during the step in Figure 6.*



By selecting “No,” the FRS prompts you to select the reviews to run with a user form.[[3]](#footnote-3) 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 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.

# **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



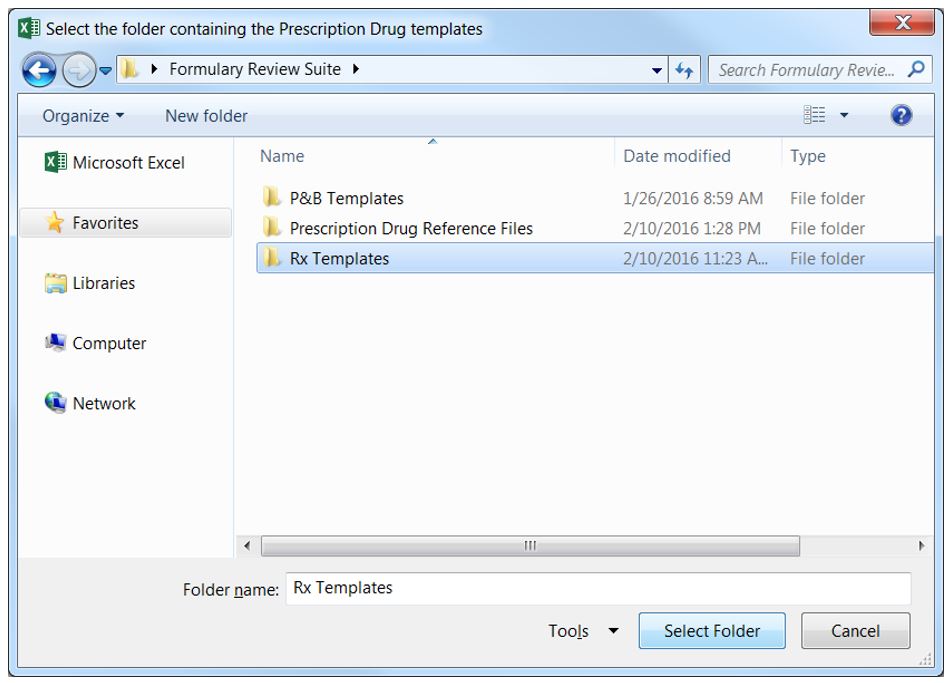
After initiating the FRS using the button in Figure 8, the FRS guides you through a series of user forms for the remaining user inputs that each individual review needs. There will be a different set of user forms for each combination of inputs up until this point.

#### 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.

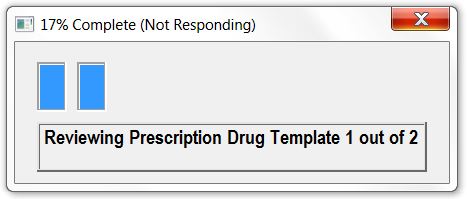
Picking up from the Input Files for the FRS section where you have saved all of you FRS review files, the FRS prompts you to select those same folders (see Figure 9). You want to select the folder that contains your Rx templates depending on the step that you are at. In addition, you want to click on 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.

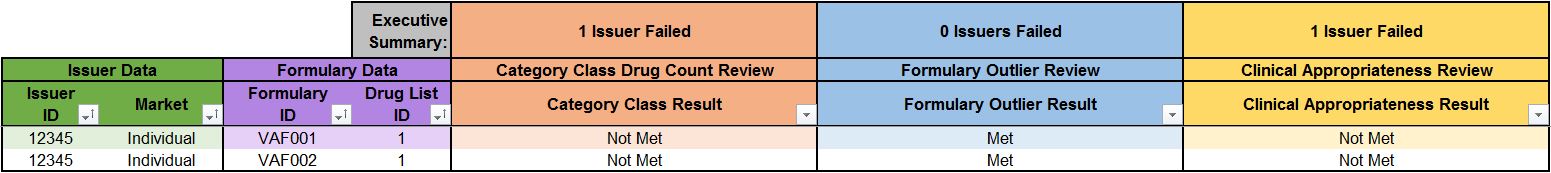
Figure 10 FRS Status Bar



## 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



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.

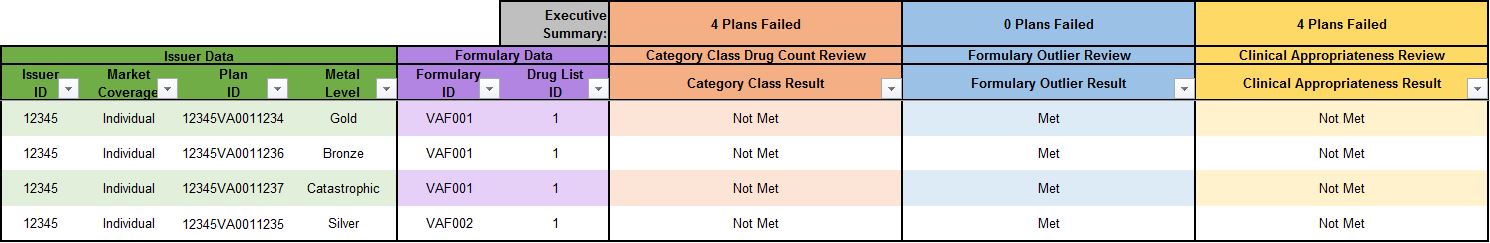
The issuer summary may produce different results depending on if you import P&B data. When you import P&B data, only those Formulary IDs in the Rx templates that correspond to a plan in the P&B templates appear in the summary. However, if you do not import P&B data, every Formulary ID in the Rx template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



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.[[4]](#footnote-4) Rx benchmark counts are determined at the United State Pharmacopeia (USP) v6.0 Model Guidelines category and class level.**[[5]](#footnote-5)*

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

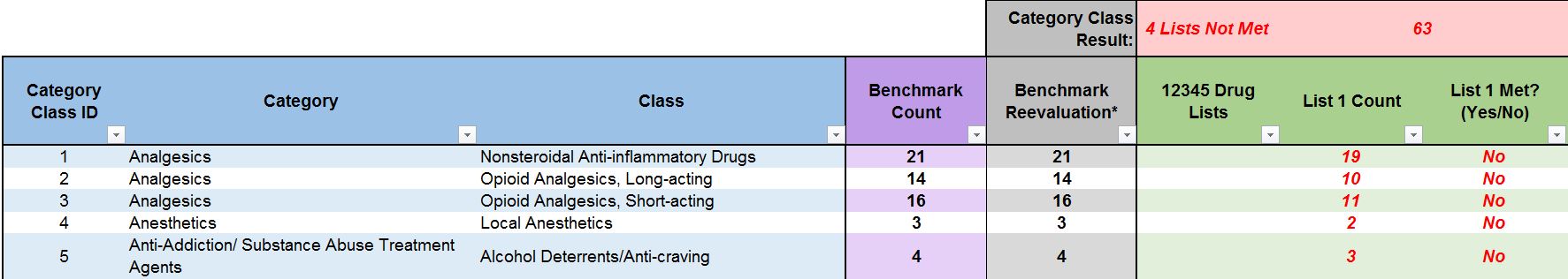
**There are no additional user forms for the Category Class Drug Count Review.**

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.

Figure 13 Category Class Summary Worksheet Sample



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.[[6]](#footnote-6)
* **Class**: A more granular classification for a USP category that provides therapeutic or pharmacologic groupings of FDA approved medications.[[7]](#footnote-7)
* **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. The decision is left to the state to require a further review
  + **No**: The drug count does not meet the state EHB benchmark count. A further review is required.

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.*

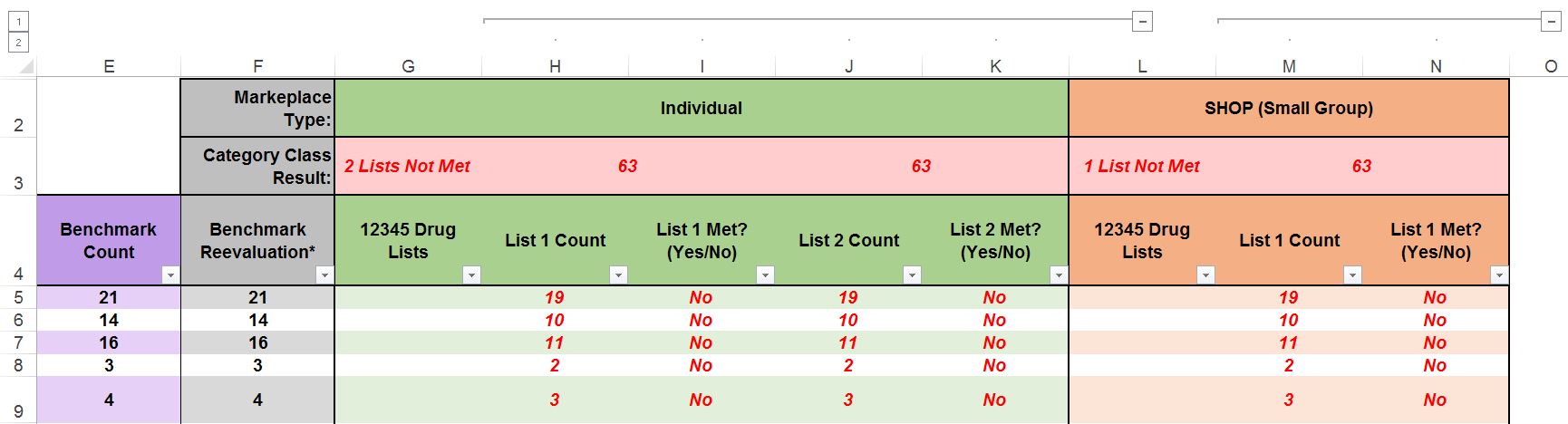
Table 1 Impossible Situations to Meet EHB Benchmark Count

|  |  |  |  |
| --- | --- | --- | --- |
| **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 |
| 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



1

2

2

4

4

4

3

3

3

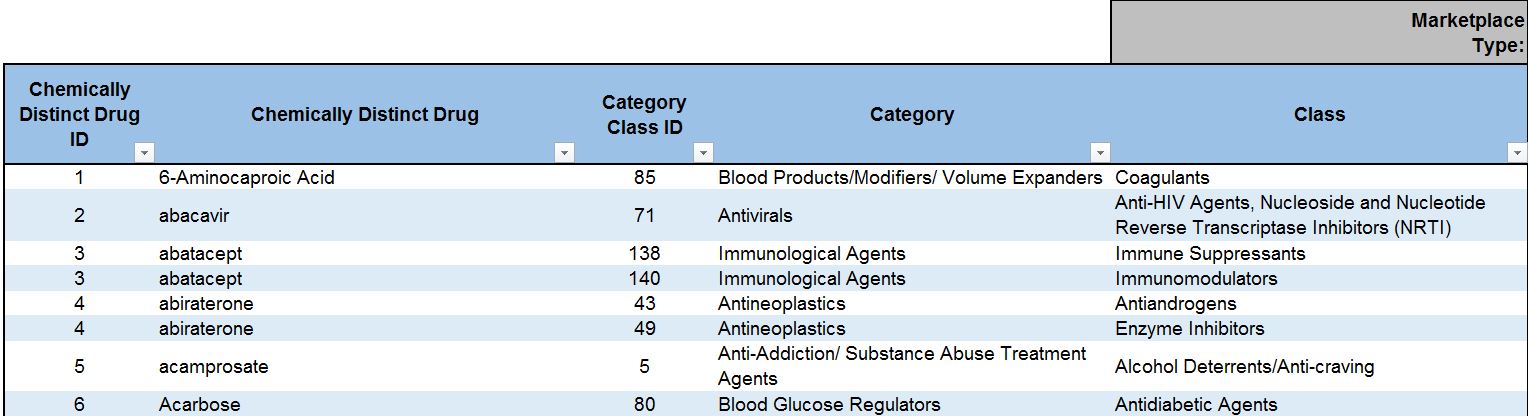
1. Marketplace Type differentiates between market coverages **if and only if** you have separate Individual and SHOP templates. Otherwise, this row will not appear.
2. These cells will appear for every combination of issuer and market coverage (if applicable). It describes the overall performance of 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



Here are the definitions for the columns in this worksheet:

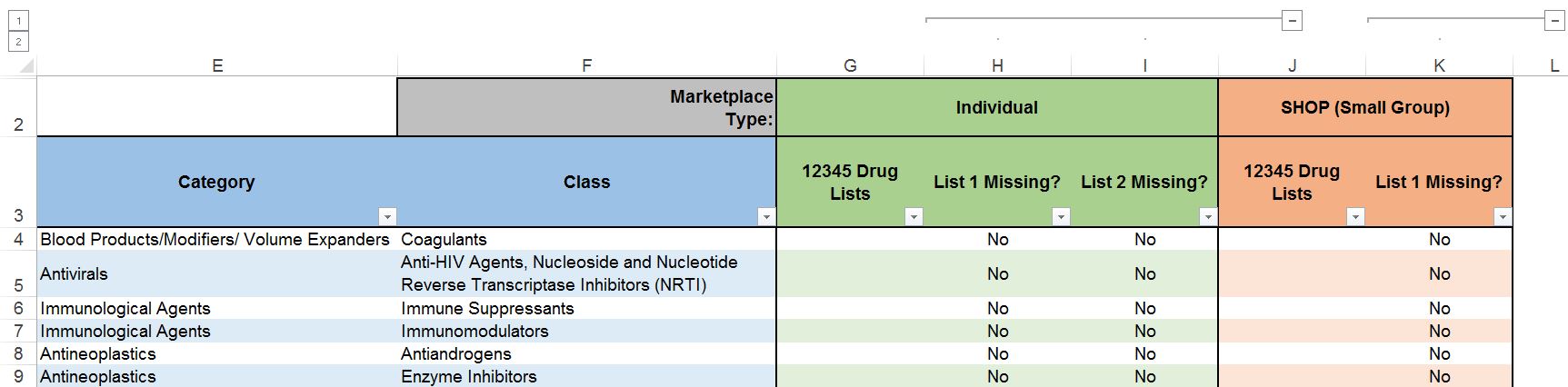
* **Chemically Distinct Drug ID**: This is an arbitrary number assigned to the chemically distinct drug for ease of identifying all instances of the chemically distinct drug.
* **Chemically Distinct Drug**: Two drugs are chemically distinct if they have different active ingredients. Combination drugs 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.[[8]](#footnote-8)
* **Class**: A more granular classification for a USP category that provides therapeutic or pharmacologic groupings of FDA approved medications.[[9]](#footnote-9)

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.*



Figure 16 Category Class Details Worksheet Output



1

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. 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.

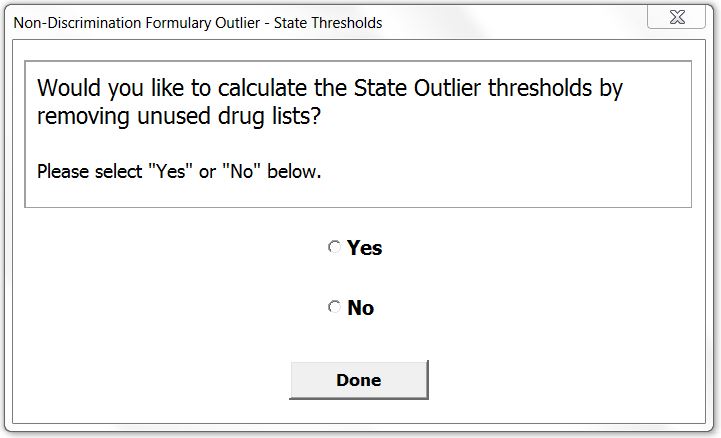
#### Formulary Outlier User Forms

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.*

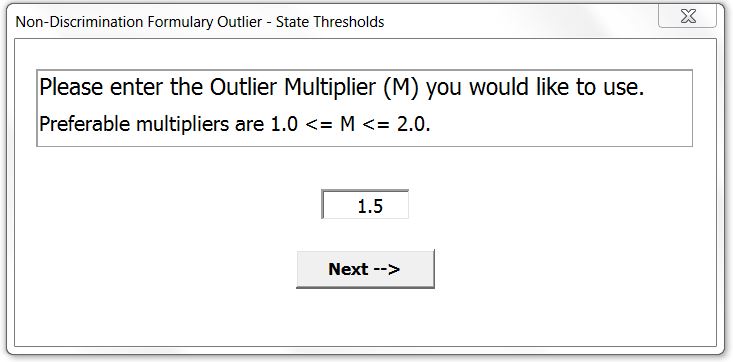
Figure 17 Formulary Outlier Review State Threshold Selections



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.

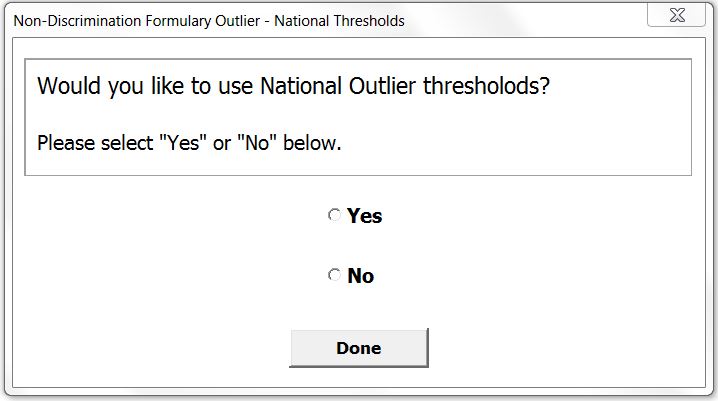
Figure 18 Formulary Outlier Review Outlier Multiplier



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



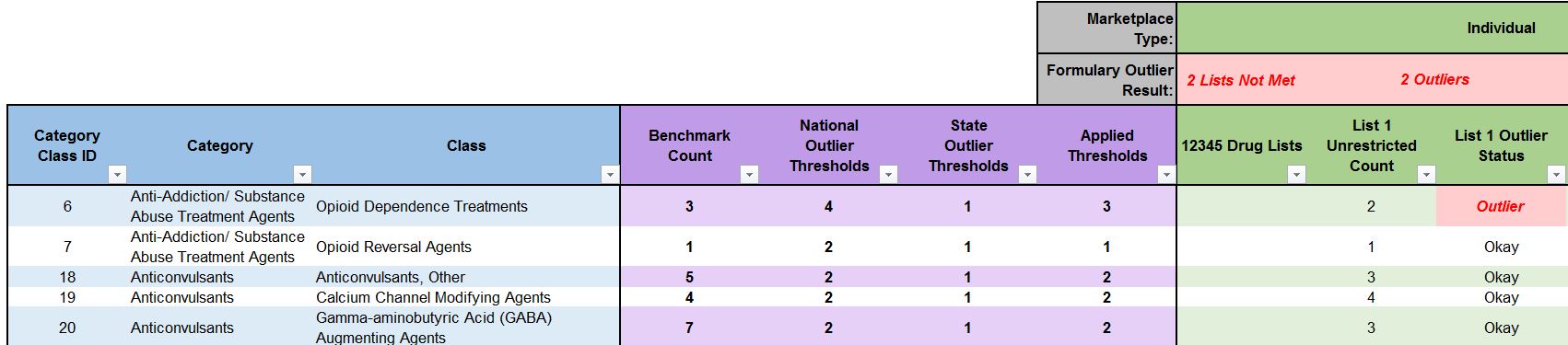
The national thresholds are blank in the FRS at first. If this is the first time that you are running the FRS and you are planning on incorporating national thresholds, then the FRS redirects you to the “Formulary Outlier Summary” worksheet after you select “Yes” in Figure 19. The FRS redirects you to 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



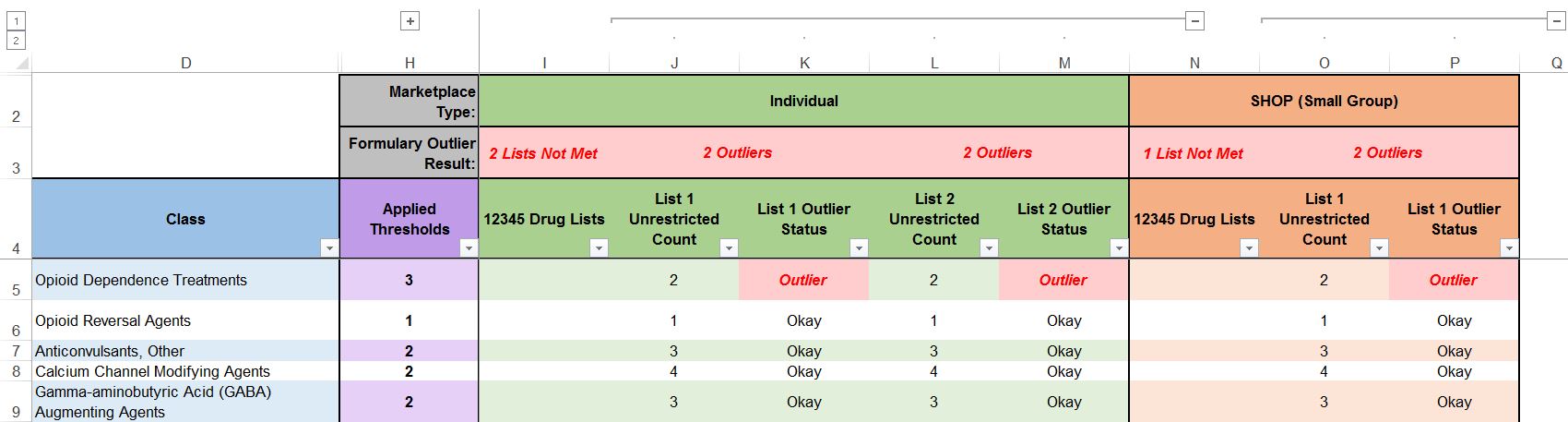
Here are the definition for the columns in this worksheet:

* **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.[[10]](#footnote-10)
* **Class**: A more granular classification for a USP category that provides therapeutic or pharmacologic groupings of FDA approved medications.[[11]](#footnote-11)
* **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 al 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.
* **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



4

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4

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2

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1

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.

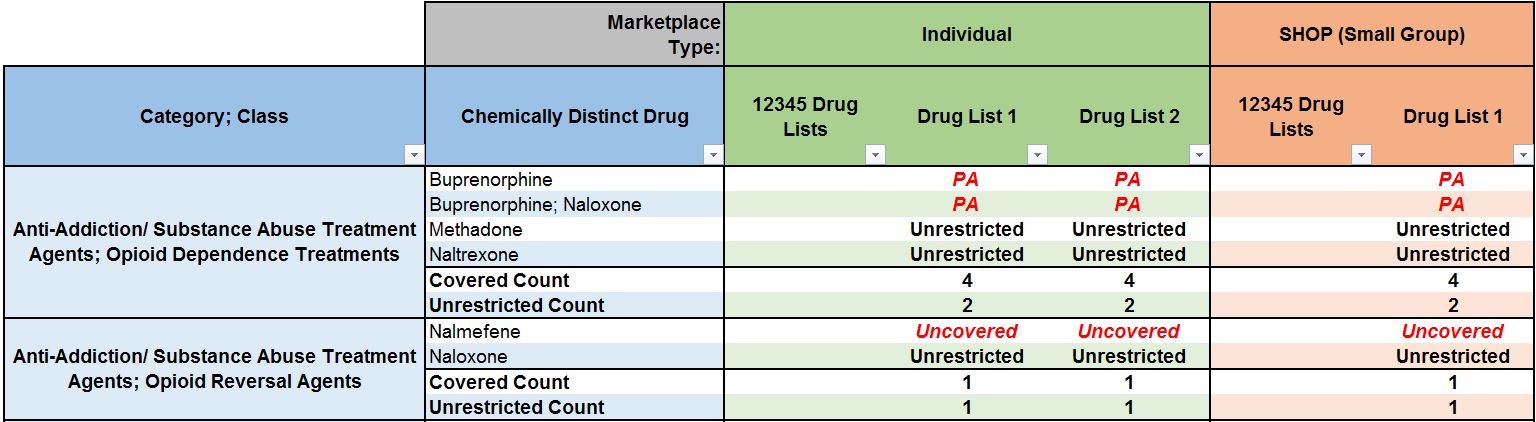
**Hint**: *The cells directly beneath the issuer, “12345 Drug Lists” for example, are meant to be blank.*



#### 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



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.

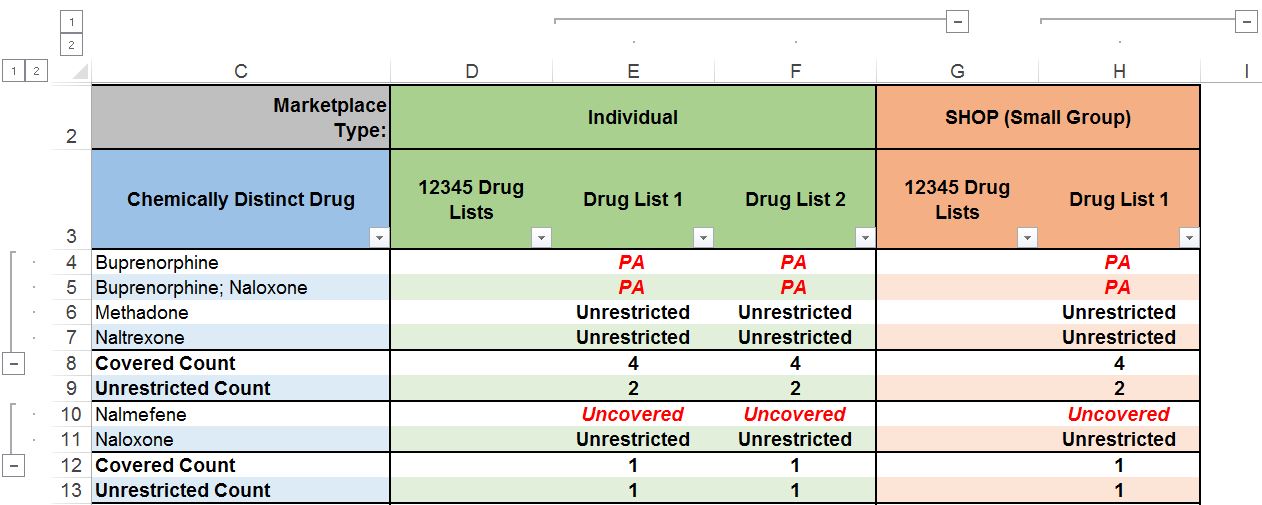
For each drug list, each chemically distinct drug is either:

1. **Uncovered**: The drug list does not contain any RxCUIs associated with the chemically distinct drug.
2. **Unrestricted**: The drug list contains at least one RxCUI associated with the chemically distinct drug without prior authorization or step therapy.
3. **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.
4. **Restricted with Step Therapy (ST)**: All of the RxCUIs on the drug list associated with the chemically drug have only a step therapy requirement.
5. **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



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3

1

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 (Placeholder)

#### Clinical Appropriateness User Forms

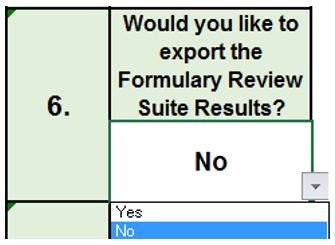
#### Clinical Summary Worksheet

#### Clinical Details Worksheet

## Exporting FRS Results

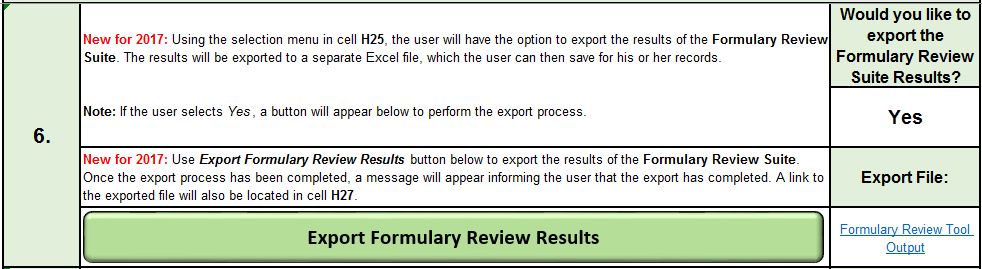
The FRS contains a feature that allows you to export any review results to a separate Excel file. This step is optional, and the purpose is so that you can save all individual review results for your records. This step is only useful after you have run the FRS and produced meaningful results. In order 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 24.

Figure 24 Export Results Indication



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 25. The FRS tells you when the export finishes and provides a link to the exported file.

Figure 25 Export Results Location

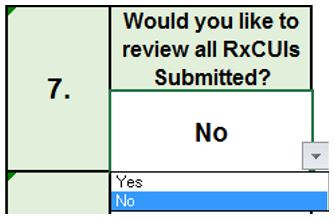


The link location of the exported file relates to the location of the templates used to run the reviews. The FRS creates a new folder located within the same path as the location of the templates called “Formulary Review Tool Output.” The FRS saves the exported results in this newly created folder. Clicking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

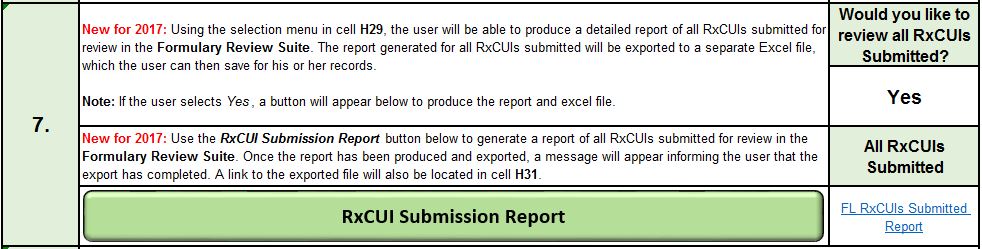
The FRS contains a feature that allows you to produce a detailed report of all RxCUIs submitted for review into a separate Excel file. This step is optional, and the purpose is so that you can review the specific drug list details submitted for the reviews. You do not have to run the FRS in order to 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 26.

Figure 26 RxCUIs Report Indication



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 27. The FRS tells you when the export finishes and provides a link to the exported file.

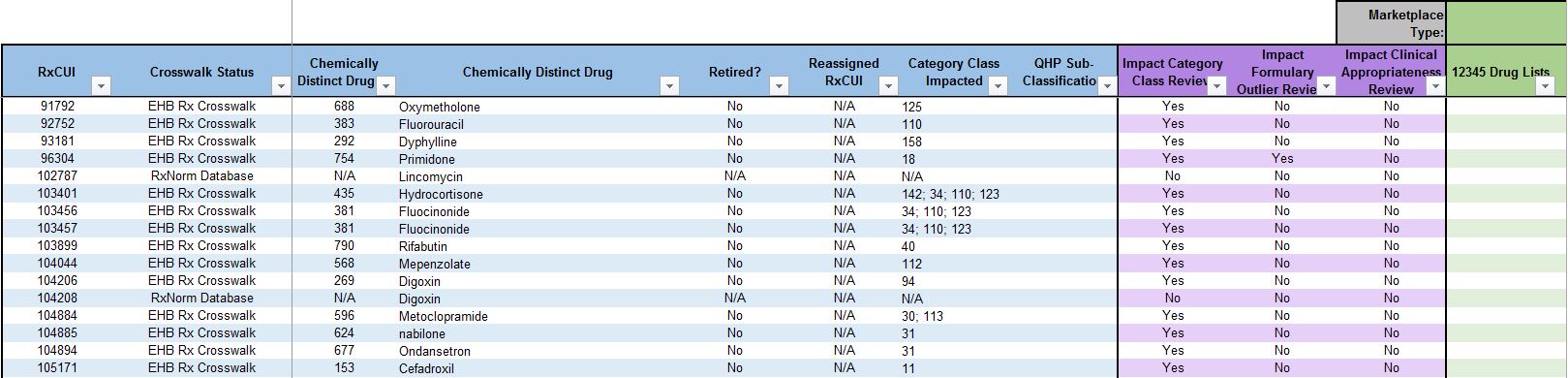
Figure 27 RxCUIs Report Location



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 28 shows an example of the RxCUI details.

Figure 28 All RxCUIs Submitted Worksheet Sample



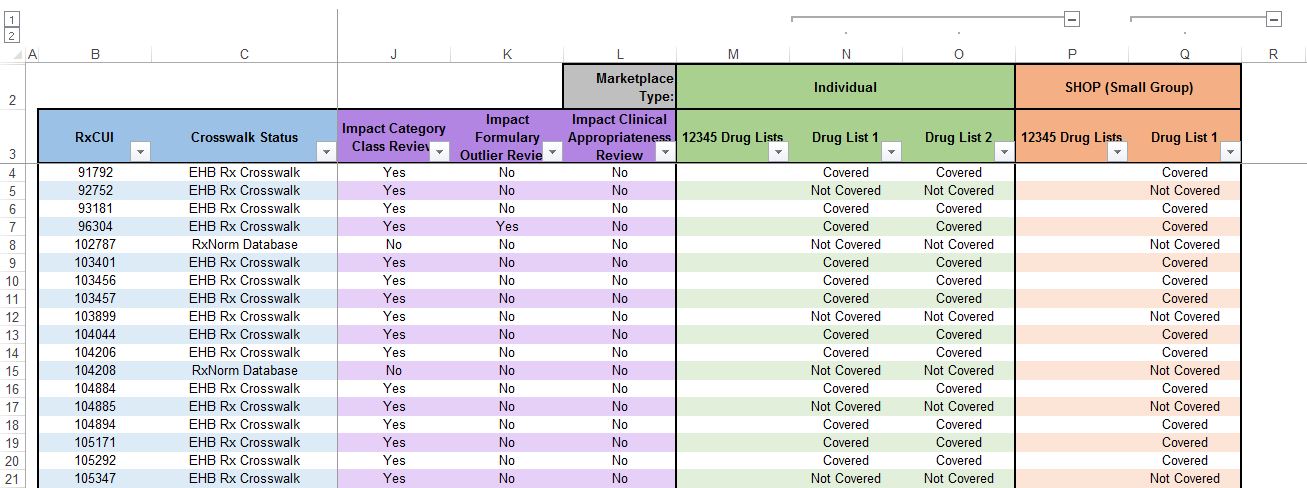
Here are the definitions for the columns in this worksheet:

* **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 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 All RxCUIs Submitted Worksheet Output



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**

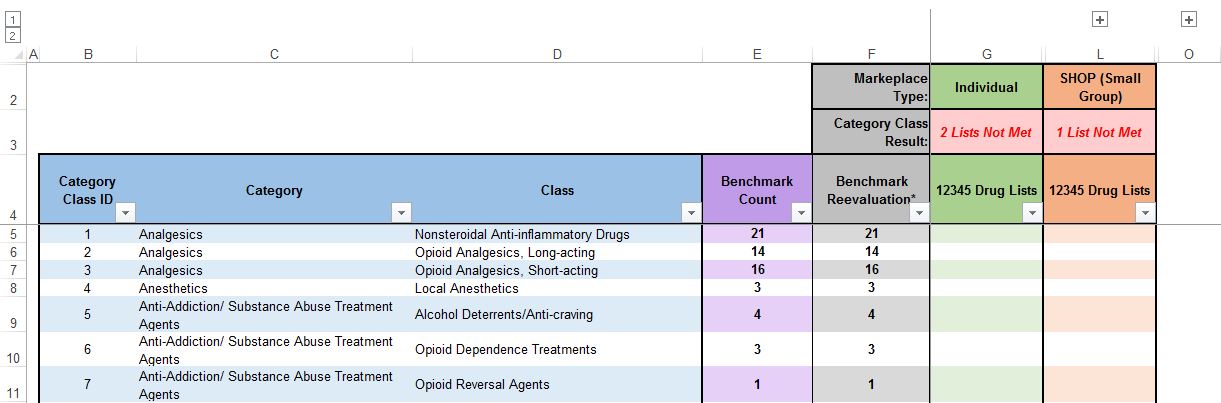
The FRS presents the output results in a way that is unique to all of the other QHP Application Review Tools. The two methods below describe the possible ways to view the results for the majority of the output worksheets.

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 30 shows an example of an output worksheet taken directly after the FRS completes its processing.

1

2

Figure 30 Initial Output Worksheet Example



**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 30 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 30.

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.[[12]](#footnote-12)

# **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 |

1. <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2017-Letter-to-Issuers-2-29-16.pdf> [↑](#footnote-ref-1)
2. 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. [↑](#footnote-ref-2)
3. 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. [↑](#footnote-ref-3)
4. Find out more about EHBs here: <https://www.cms.gov/CCIIO/Resources/Data-Resources/ehb.html> [↑](#footnote-ref-4)
5. Find out more about USP here: <http://www.usp.org/usp-healthcare-professionals/usp-medicare-model-guidelines> [↑](#footnote-ref-5)
6. See note 4 for more information. [↑](#footnote-ref-6)
7. See note 4 for more information. [↑](#footnote-ref-7)
8. See note 4 for more information. [↑](#footnote-ref-8)
9. See note 4 for more information. [↑](#footnote-ref-9)
10. See note 4 for more information. [↑](#footnote-ref-10)
11. See note 4 for more information. [↑](#footnote-ref-11)
12. https://support.office.com/en-us/article/Outline-group-data-in-a-worksheet-08ce98c4-0063-4d42-8ac7-8278c49e9aff [↑](#footnote-ref-12)