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2015 QUALIFIED HEALTH PLAN APPLICATION REVIEW TOOLS USER GUIDE: NON-DISCRIMINATION FORMULARY OUTLIER TOOL

Loading the Data and Analysis

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NON-DISCRIMINATION FORMULARY OUTLIER TOOL OVERVIEW

Tool	Function
Non-Discrimination Formulary Outlier Tool	<ul style="list-style-type: none"> • Identifies and flags as outliers those plans that have unusually low numbers of unrestricted drugs in the following USP classes: <ul style="list-style-type: none"> – Antivirals/anti-HIV agents, non-nucleoside reverse transcriptase inhibitors. – Antivirals/anti-HIV agents, nucleoside and nucleotide reverse transcriptase inhibitors. – Antivirals/anti-HIV agents, protease inhibitors. – Antivirals/anti-HIV agents, other. – Blood glucose regulators/antidiabetic agents. – Blood glucose regulators/insulins. – Immunological agents/immunomodulators. – Immunological agents/immune suppressants. <p>Note: This tool requires data from all issuers in a state and will not yield meaningful results if the tool is run on templates for a single issue.</p>

Use of the tool by state regulators or issuers is optional. For the tool to run, it is imperative that users do not change the worksheet names, format, and overall structure (e.g., adding or deleting rows or columns, changing field names, copying or deleting worksheets), as this could impact the functioning of the tool macros. However, filters have been added to the table headings in many of the stand-alone tools and these may be used without disrupting tool use. These tools can be run for the following plan types: plans that are only offered on the Marketplace, plans that are only offered off the Marketplace, or for all submitted standard plans on and off the Marketplace.

Using this Guide

The following characteristics are intended to focus the user to where actions are warranted:

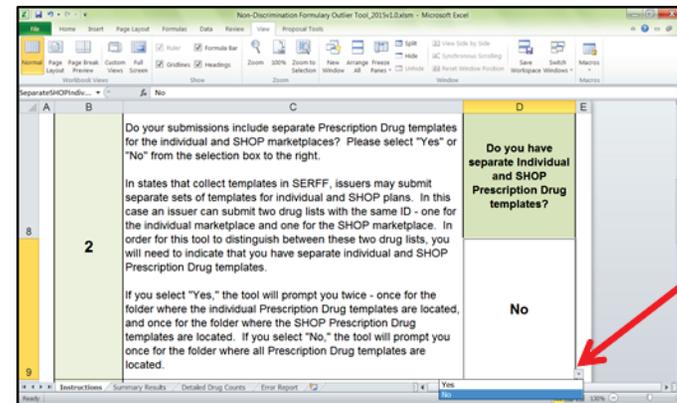
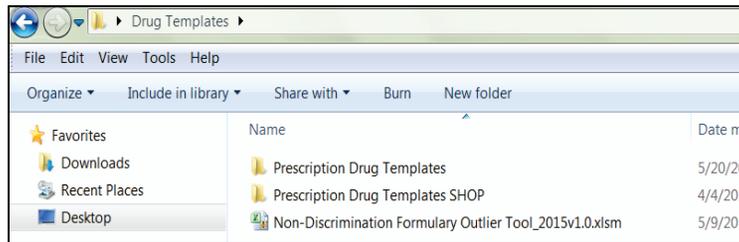
- Items that appear in *italics* are features. (e.g., See the *Instructions tab* in the Master Review Tool.)
- Items that are in **bold** type are functions. (e.g., **Click “Save.” Click “Import Data from Master Review Tool.”**)
- For space considerations, screenshots of Excel worksheets may not include the full data picture.

NON-DISCRIMINATION FORMULARY OUTLIER TOOL: LOADING THE DATA

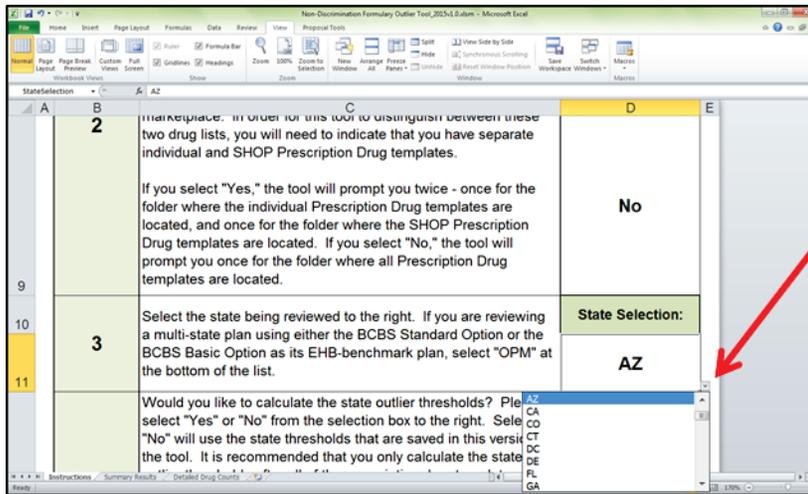
Before you can begin the Non-Discrimination Formulary Outlier Tool steps, **download** the tool from **SERVIS** (https://servis.cms.gov/resources/document_detail?doc_detail_id=c2de042d-bf0e-4e2a-46da-53691d3dc025) (states) or **CMSzONE** (<https://zone.cms.gov/document/2015-qhp-application-review-tools>) (issuers).

If you are using this stand-alone tool, we recommend that you review the validation steps in the Master Review Tool *Formulary Outlier* tab to understand the logic of the tool and where justifications may overcome the tool's automated results.

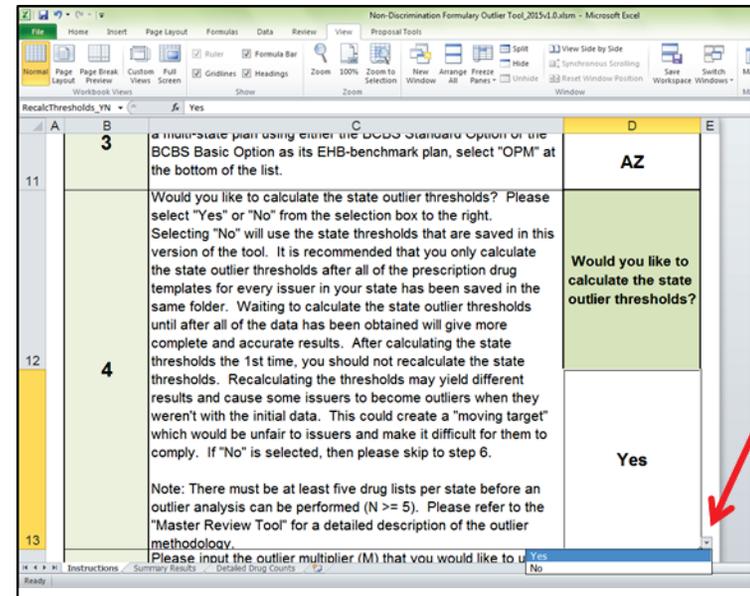
1. **Place** all the prescription drug Excel templates to be reviewed into a folder that you can easily access. Remember this folder location as you will be asked to find it when the tool is run. If you have separate individual and Small Business Health Options Program (SHOP) prescription drug templates, **place** the individual templates in one folder and the SHOP templates in a separate folder.
2. If there are separate prescription drug templates for the individual and SHOP Marketplaces, **select "Yes;"** if there are not separate submissions for individual or SHOP Marketplaces, select **"No."**



3. If you select “Yes,” the tool will prompt you twice – once for the folder where the individual prescription drug templates are located, and once for the folder where the SHOP prescription drug templates are located. If you select “No,” the tool will prompt you once for the folder where all prescription drug templates are located.
4. **Select** the state being reviewed from the drop down in row 11.

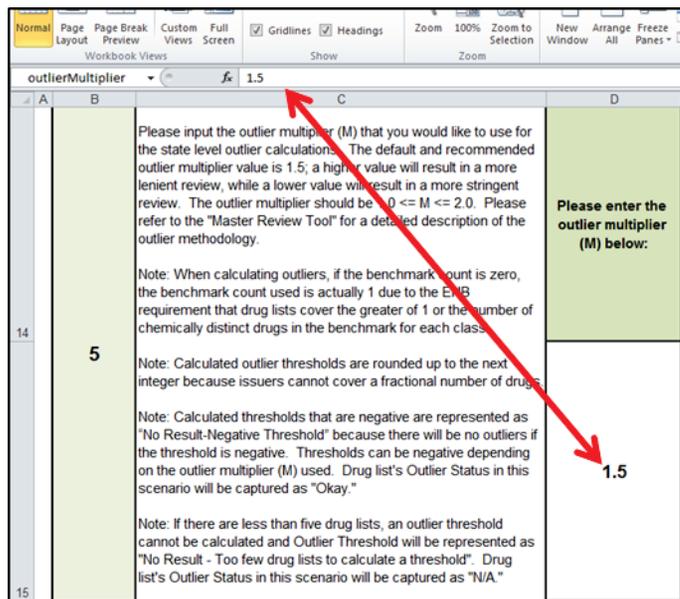


5. **Select “Yes” or “No”** from the drop down in row 13 to calculate the state outlier thresholds.
 - a. Selecting “No” will use the state thresholds; it is recommended that you only calculate the state outlier thresholds after all the prescription drug templates for every issuer in your state have been saved in the same folder.¹



¹ Waiting to calculate the state outlier thresholds until after all of the data has been obtained will give more complete and accurate results. After calculating the state thresholds the first time, you should not recalculate the state thresholds. Recalculating the thresholds may yield different results and cause some issuers to become outliers when they were not with the initial data. This could create a "moving target," which would be unfair to issuers and make it difficult for them to comply.

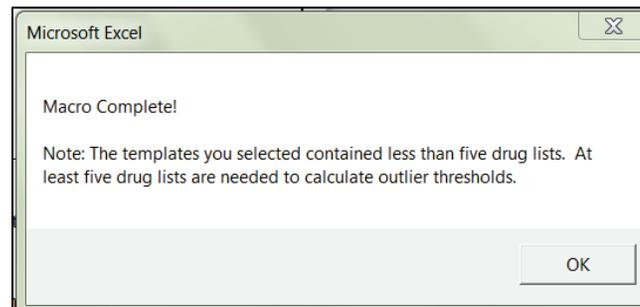
6. **Type** in the outlier multiplier (M) in row 15. The default and recommended outlier multiplier value is 1.5; a higher value will result in a more lenient review, while a lower value will result in a more stringent review.²



7. **Save** the workbook.
8. **Click “Run Review Tool”** in row 18 to run the tool.



9. A pop-up window will open confirming review completion. The pop-up confirmation will not always have a “Note:” with an explanation of data run results.



10. **Save** the workbook again.

Note: If there is an error tab displayed, this tab lists any errors that were found while running the review. This tab will not be displayed if no data errors were detected.

Warning! Depending on the number of templates and drug lists that are run, this process could take several minutes. After selecting the folder containing your prescription drug templates, do not do anything with Excel until the process has finished. If you interrupt the process, the process will have to be started all over again.

² The outlier multiplier should be $1.0 \leq M \leq 2.0$. See appendix for a detailed description of the outlier methodology (Tukey’s Outlier Test).

NON-DISCRIMINATION FORMULARY OUTLIER TOOL: ANALYSIS

1. **Run** the Non-Discrimination Formulary Outlier Tool according to the instructions provided in the *Instructions tab*.
2. Once you have run the tool, **open** the *Summary Results tab*.

This worksheet provides a high-level overview of the tool results. The results for each category and class being reviewed are listed by issuer and their associated drug lists. It shows the outliers, the benchmark counts, the unrestricted count of chemically distinct drugs, and the individual formulary outlier review results for each category and class. Finally, it shows the overall formulary outlier review result for each drug list reviewed.

		Anti-HIV Agents, Non-nucleoside Reverse Transcriptase Inhibitors		Anti-HIV Agents, Nucleoside and Nucleotide Reverse Transcriptase Inhibitors		Anti-HIV Agents, Protease Inhibitors		Anti-HIV Agents, Other		Blood Gluc Antidia	
		No Result - Too few drug lists to calculate a threshold		No Result - Too few drug lists to calculate a threshold		No Result - Too few drug lists to calculate a threshold		No Result - Too few drug lists to calculate a threshold		No Result lists to calc	
		5		11		3		9			
Issuer ID	Drug List ID	UM Non-Discrimination Standard Met?	Unrestricted Count	Outlier Status	Unrestricted Count	Outlier Status	Unrestricted Count	Outlier Status	Unrestricted Count	Outlier Status	Unrestricted Count
12345	1	Met	5	N/A	11	N/A	9	N/A	3	N/A	19
12345	2	Met	5	N/A	11	N/A	9	N/A	3	N/A	19
12345	1	Met	5	N/A	11	N/A	9	N/A	3	N/A	19
12345	2	Met	5	N/A	11	N/A	9	N/A	3	N/A	19

3. The *Detailed Drug Counts tab* displays the results of the review for each chemically distinct drug in the categories and classes being reviewed. This review identifies plans with an unusually low number of unrestricted drugs in one of eight categories and classes:

- Antivirals/anti-HIV agents, non-nucleoside reverse transcriptase inhibitors.
- Antivirals/anti-HIV agents, nucleoside and nucleotide reverse transcriptase inhibitors.
- Antivirals/anti-HIV agents, protease inhibitors.
- Antivirals/anti-HIV agents, other.
- Blood glucose regulators/antidiabetic agents.

- Blood glucose regulators/insulins.
- Immunological agents/immune suppressants.
- Immunological agents/immunomodulators.

		C	D	E	F	
	Issuer ID	12345	12346	12347	12358	
	Drug List ID	1	2	1	2	
	Category, Class					
	Chemically Distinct Drug					
5	Antiviral, Anti-HIV Agents, Non-nucleoside Reverse Transcriptase Inhibitors	Delavirdine	Unrestricted	Unrestricted	Unrestricted	Unrestricted
6		efavirenz	Unrestricted	Unrestricted	Unrestricted	Unrestricted
7		etravirine	Unrestricted	Unrestricted	Unrestricted	Unrestricted
8		Nevirapine	Unrestricted	Unrestricted	Unrestricted	Unrestricted
9		Rilpivirine	Unrestricted	Unrestricted	Unrestricted	Unrestricted
10		Covered Count	5	5	5	5
11	Unrestricted Count	5	5	5	5	
12	Antiviral, Anti-HIV Agents, Nucleoside and Nucleotide Reverse Transcriptase Inhibitors	abacavir	Unrestricted	Unrestricted	Unrestricted	Unrestricted
13		abacavir; Lamivudine	Unrestricted	Unrestricted	Unrestricted	Unrestricted
14		Didanosine	Unrestricted	Unrestricted	Unrestricted	Unrestricted
15		emtricitabine	Unrestricted	Unrestricted	Unrestricted	Unrestricted
16		emtricitabine; tenofovir disoproxil	Unrestricted	Unrestricted	Unrestricted	Unrestricted
17		Lamivudine	Unrestricted	Unrestricted	Unrestricted	Unrestricted
18		Stavudine	Unrestricted	Unrestricted	Unrestricted	Unrestricted
19		tenofovir disoproxil	Unrestricted	Unrestricted	Unrestricted	Unrestricted
20		Zidovudine	Unrestricted	Unrestricted	Unrestricted	Unrestricted
21		Zidovudine; abacavir; Lamivudine	Unrestricted	Unrestricted	Unrestricted	Unrestricted
22		Zidovudine; Lamivudine	Unrestricted	Unrestricted	Unrestricted	Unrestricted
23	Covered Count	11	11	11	11	
24	Unrestricted Count	11	11	11	11	
25		Atazanavir	Unrestricted	Unrestricted	Unrestricted	Unrestricted
26		darunavir	Unrestricted	Unrestricted	Unrestricted	Unrestricted
27		fosamprenavir	Unrestricted	Unrestricted	Unrestricted	Unrestricted

4. Using the data in the Non-Discrimination Formulary Outlier Tool tabs, go to the Master Review Tool *Formulary Outlier* tab and **populate** “Met” or “Not Met” from the drop-down menus at the top of each column in the SELECT REVIEW RESULT row for each issuer.

Users may select if the overall standard is “Met” or “Not Met” at the top of the worksheet which will auto-populate the summary review. This is the only information auto-populated to the review summary from this tab.

Review	Review step	Review description and procedure	Step description	Source	67899, ZZFO05	67899, ZZFO06	67899, ZZFO07
1		For each drug list, create a list of <i>RxCUIs</i> on the EHB Rx Crosswalk included in the drug class being reviewed for utilization management non-discrimination.			Not Met	Met	Not Met
	a		For each <i>RxCUI</i> , if the <i>RxCUI</i> has a <i>Tier Level</i> not equal to “NA” in the drug list under review, add the <i>RxCUI</i> to the list of <i>RxCUIs</i> for potential review.	<i>RxCUI, Tier Level</i>	Not Met	Check validation	
	b		Map each <i>RxCUI</i> in the list for potential review to one or more drug classes by using the EHB Rx Crosswalk.		Not Met	Met	
			If the <i>RxCUI</i> maps to the drug class being reviewed, keep the <i>RxCUI</i> in the list of <i>RxCUIs</i> for review.	<i>RxCUI, EHB Rx Crosswalk</i>	Not Met	Met	
			If the <i>RxCUI</i> does not map to the drug class being reviewed, remove the <i>RxCUI</i> from the list of <i>RxCUIs</i> for review.		TBD	Met	Not Met
2		For each drug list, count the number of chemically distinct drugs in the drug class being reviewed without a prior authorization or step therapy requirement.			Not Met	Met	Not Met

Each standard provides space for user-determined evaluation of whether the standards are “Met” or “Not Met.” Additional information on standards review may be included in the space adjacent to the standard review steps.

5. Save the Master Review Tool after you have completed the non-discrimination review.

After you have populated “Met” or “Not Met” for each issuer’s plan in the Master Review Tool *Non-Discrimination tab*, open the Master Review Tool *Review Summary tab* to see the auto-populated results in row 16.

Section/Standard	Function of Review	L	M	N	O	P	Q
ECP	Ensure issuers have ECPs, where available, that meet the policy standards.	Not Met	Not Met	Not Met		Not Met	
Category Class Drug Count	Ensure compliance with EHBs and check for discrimination by counting drugs in each USP category and class.	Met	Met	Met	Not Met	Not Met	Not Met
Non-Discrimination Formulary Outlier	Identifies plans with an unusually large number of drugs that require step therapy or prior authorization in one or five	Not Met	Met	Met	Not Met	Not Met	Not Met
Non-Discrimination Clinical Appropriateness	Ensures that enrollees have access to the drugs recommended in clinical guidelines for four diseases:	Met	Not Met	Not Met	Met	Met	Met
Benefit Cost Sharing	Check in-network out-of-pocket maximum costs for individual and family EHB coverage against the annual dollar limit and ensure the cost sharing variations and catastrophic plans meet all requirements.	Met	Met	Met	Met	Met	Met
Meaningful Difference	Identify if an issuer submits one or more QHPs of the same plan type and metal level in a county and review further for network, deductible, and out-of-pocket maximum differences.	Met	Met	Met		Met	
Non-Discrimination Benefit	Perform an outlier analysis on selected benefits cost-sharing.	Met	Met	Met	Met	Met	Met
Service Area	Confirm that issuers include full counties or have a justifiable reason for partial counties.	Not Met	Not Met	Not Met		Met	
OVERALL PLAN VALIDATION		Not Met					

6. Save the Master Review Tool after you have completed the non-discrimination formulary outlier review

APPENDIX: TUKEY OUTLIER

Non-Discrimination Review Outlier Methodology

The outlier test used for the Non-Discrimination Cost-Sharing Outlier and Non-Discrimination Formulary Outlier reviews is a modified version of Tukey's Outlier Test 1. Tukey's Outlier Test (also known as Tukey's Outlier Filter or Tukey's Method) uses quartiles to determine the outliers in a given data set. It is a commonly utilized outlier test due to its ease of use and applicability to a variety of analyses. Tukey's Outlier Test can be used regardless of data distribution, while most other outlier tests require advance knowledge or assumptions about the data distribution.

To find outliers, the test first finds the interquartile range (IQR) of the data set: the middle 50 percent of the data set, or the 75th percentile (Q3) minus the 25th percentile (Q1). The IQR is then multiplied by a multiplier (M), subtracted from Q1, and added to Q3. The two most commonly used multiplier values are 1.5 and 2.0 (1.5 is the default value used in the tools). The two resulting values then set the bounds for what is considered an outlier. (Anything outside of the bounds is an outlier, and anything inside the bounds is not an outlier.) Expressed mathematically, the two bounds are calculated as follows:

$$\text{IQR} = Q3 - Q1.$$

$$\text{Lower Bound (LB)} = Q1 - (M \times \text{IQR}).$$

$$\text{Upper Bound (UB)} = Q3 + (M \times \text{IQR}).$$

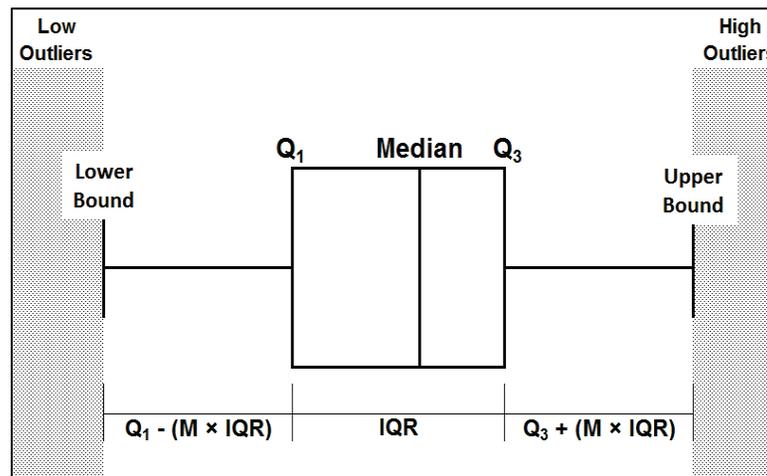
One flaw of using the IQR is the potential for a zero IQR if too many data points have the same value. A zero IQR makes it impossible to identify outliers using the method described above. Although the chances of this occurring are low, it does present a potential issue. The test used for the reviews modifies Tukey's Outlier Test so that if an IQR is initially equal to zero, Q1 will be multiplied by 0.75, and

Q3 will be multiplied by 1.25. This will create a spread between Q1 and Q3 and make a non-zero IQR. The rest of the test will then be performed as described above.

Another flaw of Tukey's Outlier Test is that there needs to be at least five data points in a data grouping to calculate outlier bounds. If there are four data points or less in a data grouping, none of the data points in that grouping can be evaluated.

Any value below the LB is considered a "low outlier," while any value above the UB is considered a "high outlier." For the Non-Discrimination Cost-Sharing Outlier review, Tukey's Outlier Test is used to identify high outliers in the cost sharing fields. For the Non-Discrimination Formulary Outlier review, Tukey's Outlier Test is used to identify low outliers in the number of un-restricted drugs for various USP classes. The test is often displayed as a "box-and-whiskers plot," as shown below.

[1] David Hoaglin, Frederick Mosteller, and John Tukey, eds., *Understanding Robust and Exploratory Data Analysis* (New York: John Wiley & Sons, 1983), p. 39, 54, 62, 223.



APPENDIX: ACRONYMS AND TERMS

Acronym	Definition
AAAHC	Accreditation Association for Ambulatory Health Care
AV	actuarial value
AVC	actuarial value calculator
APTC	advance premium tax credits
ACA	Affordable Care Act
API	Application Programming Interface
BCBS	Blue Cross Blue Shield
BPCK	branded pack
CCIO	Center for Consumer Information and Insurance Oversight
CMS	Centers for Medicare & Medicaid Services
COA	certificate of authority
CALT	Collaborative Application Lifecycle Tool
CAHPS	Consumer Assessment of Healthcare Providers and Systems
CSR	cost-sharing reduction
DOB	date of birth
DIT	data integrity tool
DMARDs	disease-modifying antirheumatic drugs

Acronym	Definition
DOI	Department of Insurance
DPP	diabetes prevention program
DSH	disproportionate share hospital
EIDM	Electronic imaging and document management
EIN	employer identification number
ECP	essential community provider
EHB	essential health benefit
EPO	exclusive provider organization
FEIN	Federal employer identification number
FPL	Federal poverty level
FQHC	Federally qualified health center
FFM	Federally-facilitated Marketplace
GSA	General Services Administration
GPCK	generic pack
HHS	U.S. Department of Health and Human Services
HIOS	Health Insurance Oversight System
HIPAA	Health Insurance Portability and Accountability Act
HMO	health maintenance organization

Acronym	Definition
HPSA	health professional shortage area
HRA	health reimbursement arrangement
HSA	health savings account
ISS	interactive survey system
MCO	managed care organization
MOOP	maximum out-of-pocket
M	multiplier
NAIC	National Association of Insurance Commissioners
NCQA	National Committee for Quality Assurance
NPI	national provider identifier
OIG	Office of the Inspector General
OOPM	out-of-pocket maximum
POS	point of service
PPO	preferred provider organization
PA	prior authorization
QHP	qualified health plan
RXCUI	RxNorm Concept Unique Identifier
SBC	summary of benefits and coverage
SBD	semantic branded drug

Acronym	Definition
SCD	semantic clinical drug
SHOP	Small Business Health Options Program
SEP	special enrollment period
SBM	State-based Marketplace
SPM	State Partnership Marketplace
SSN	Social Security number
SGLT2	sodium glucose co-transporter 2 inhibitors
ST	step therapy
TIN	taxpayer identification number
TNF	tumor necrosis factors
TTY	term types
UMLS	Unified Medical Language System
UCAA	Uniform Certificate of Authority Application
USP	United States Pharmacopeia
.xlms	Excel macro-enabled workbook