



RegulatoryAnalyzer<sup>®</sup>

# User Guide

For use with application release of November, 2017

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## Regulatory Analyzer®

The CodySoft® Regulatory Analyzer® contains CMS marketing guideline rules that you can use to research regulations and to verify that template content is compliant. The Regulatory Analyzer® can also be customized to include rules of other regulatory agencies and any company-specific business rules.

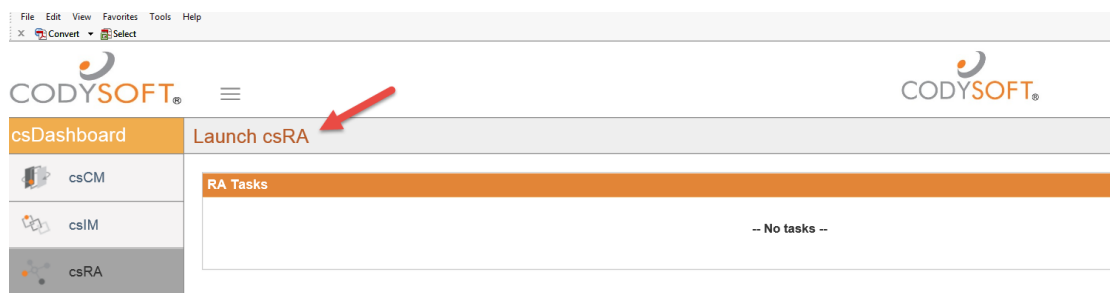
### Access to the Regulatory Analyzer

You can access the Regulatory Analyzer in two ways:

1. From this link: <https://ra.codysoft.net/#!/regulation>
2. From the CodySoft Main Dashboard
  - a. Click csRA



## b. Click Launch csRA



## REGULATIONS

From Regulations you can search the database of existing regulations, add a new regulation, or import regulations from other sources

### All

Click **All** to view all regulations, and to search and archive regulations. The Regulations/All screen displays:

The screenshot shows the 'Regulations / All' screen. On the left, there is a navigation menu with options: Regulations, All, New, Import, and Contracts. The main content area displays a table of regulations with the following columns: Id, Audience, Plan Type, Regulation Type, Version, and Status. The table contains two rows of data.

Id	Audience	Plan Type	Regulation Type	Version	Status
3041	Prospects, Members, Providers, Broker, Plan		CMS, State	V001	Active
3201	Members	MA, MAPD, PDP, COST, MMP	CMS	Issued 7-2-15	Active

You can filter on any column or combination of columns to narrow your search results

### Archive

You can archive regulations so that only active regulations are displayed. These regulations are stored in the archives and can be removed from the archives and retrieved if needed. To archive regulations from the Regulations/All screen:

1. Use the filters to define and narrow your search results to just those items you want to archive
2. Select the checkboxes for those items you want to archive
3. Click **Archive**

## Search

You can also use the Search bar to find regulations

1. Click Regulations
2. Enter a word or phrase and click **Search**. Regulatory Analyzer® returns a list of relevant responses. For example, a search of the word “appeals” returns this set of results:

Regulations / Search

Search

Did you mean? [appeal](#) [appear](#) [apply](#) [appendix](#)

Total Results: 4  
1 of 1 pages, 5 records per page

Items per page: 5 ▾

MediaTypes	Final Rule #	MMCM 3. APPENDIX 3
<ul style="list-style-type: none"> <li>Script (1)</li> <li>Web Content (1)</li> </ul>	<ul style="list-style-type: none"> <li>Final Rule Title</li> </ul>	<ul style="list-style-type: none"> <li>Appendix 3 – Pharmacy Technical Help/Coverage Determinations and Appeals Call Center Requirements</li> <li>Pharmacy Technical Help Call Center Requirements 42 CFR 423.128(d)(1)</li> </ul>
<ul style="list-style-type: none"> <li>RegulatoryProjectTypes</li> <li>Post-Enrollment (2)</li> <li>Pre-Enrollment (2)</li> <li>Website (1)</li> </ul>	<ul style="list-style-type: none"> <li>Media Type</li> <li>Regulation Project Type</li> <li>Audience</li> <li>Plan</li> </ul>	<ul style="list-style-type: none"> <li>Plan</li> </ul>
<ul style="list-style-type: none"> <li>Plan Types</li> <li>Cost (3)</li> <li>Ma (3)</li> <li>Mapd (3)</li> <li>Mmp (3)</li> <li>Msa (1)</li> <li>Pdp (3)</li> <li>Pffs (1)</li> </ul>	<ul style="list-style-type: none"> <li>Media Project Type</li> <li>Major Subject</li> <li>Minor Subject</li> <li>Regulation Type</li> <li>Plan Year</li> </ul>	<ul style="list-style-type: none"> <li>PHARMACY TECHNICAL HELP/COVERAGE DETERMINATIONS AND APPEALS CALL CENTER REQUIREMENTS</li> <li>CMS</li> <li>2016</li> </ul>
<ul style="list-style-type: none"> <li>Audiences</li> <li>Members (3)</li> <li>Plan (1)</li> <li>Prospects (3)</li> </ul>	<p>Part D Sponsors must operate a toll-free pharmacy technical help call center or make available call support to respond to inquiries from pharmacies and providers regarding the beneficiary's Medicare prescription drug benefit; inquiries may pertain to operational areas such as claims processing, benefit coverage, claims submission, and claims payment. This requirement can be accommodated through the use of on-call staff pharmacists or by contracting with the organization's PBM during non-business hours as long as the individual answering the call is able to address the call at that time. The call center must operate or be available during usual business hours, which CMS interprets to mean during the entire period in which the Part D Sponsor's network pharmacies in its plans' service areas are open (e.g., Part D Sponsors whose pharmacy networks include twenty-four (24) hour pharmacies must operate their pharmacy technical help call centers twenty-four (24) hours a day as well). To be considered fully compliant with the regulatory requirement to meet standard customer service business practices, the pharmacy technical help call center operates within the following standards:</p> <ul style="list-style-type: none"> <li>• Average hold time not to exceed two (2) minutes (the average hold time is defined as the time spent on hold by the caller following the interactive voice response (IVR) system, touch-tone response system, or recorded greeting and before reaching a live person);</li> <li>• Eighty (80) percent of incoming calls answered within thirty (30) seconds; and</li> <li>• Disconnect rate of all incoming calls not to exceed five (5) percent.</li> </ul> <p>Part D Sponsor Coverage Determinations and Appeals Call Center Requirements 423.128(b)(7), 423.128(d)(1)(iv), 423.566(a) All Part D Sponsors must operate a toll-free call center with live customer service representatives available to respond to providers or enrollees for information related to coverage determinations, including exceptions, prior authorizations, and appeals. Part D Sponsors are required to provide immediate access to the coverage determination and redetermination processes via their toll-free call centers. The call centers must operate during normal business hours, which CMS interprets to mean from at least 8:00 a.m. to 8:00 p.m., Monday through Friday, in the time zones for the regions in which they operate. Part D Sponsors are expected to accept requests for coverage determinations/redeterminations outside of normal business hours, but are not required to have live customer service representatives available to accept such requests outside normal business hours. Additional details are available in Chapter 18 of the Prescription Drug Benefit Manual. Voicemail may be used outside of normal business hours and the voice mail message should:</p> <ul style="list-style-type: none"> <li>• Indicate that the mailbox is secure;</li> <li>• List the information that must be provided so the case can be worked, (e.g., provider identification, beneficiary identification, type of request (coverage determination or appeal), physician support for an exception request, and whether the enrollee is making an expedited standard request);</li> <li>• For coverage determination calls (including exceptions requests), articulate and follow a process for resolution within twenty-four (24) hours of call for expedited requests and seventy-two (72) hours for standard requests; and</li> <li>• For appeals calls, information should articulate the process information needed and provide for a resolution within seventy-two (72) hours for expedited appeal requests and seven (7) calendar days for standard appeal requests.</li> </ul>	
<ul style="list-style-type: none"> <li>MajorSubjects</li> <li>Call Center (2)</li> <li>Marketing Activities (2)</li> <li>Materials (2)</li> <li>Pharmacy Technical Help/Coverage Determinations And Appeals Call Center Requirements (1)</li> <li>Website And Social/Electronic Media (1)</li> </ul>	<ul style="list-style-type: none"> <li>MinorSubjects</li> <li>Call Center-Informational Scripts (1)</li> <li>Call Center-Requirements (2)</li> <li>Marketing Activities-Telephonic Activities (2)</li> <li>Materials-Creation (2)</li> <li>Materials-Electronic (1)</li> </ul>	<ul style="list-style-type: none"> <li>LinesOfBusiness</li> <li>Medicare (4)</li> </ul>
<ul style="list-style-type: none"> <li>RegulationTypes</li> <li>Cms (4)</li> </ul>	<ul style="list-style-type: none"> <li>MediaProjectTypes</li> <li>Creation (2)</li> <li>Website (1)</li> </ul>	<ul style="list-style-type: none"> <li>Final Rule #</li> <li>Final Rule Title</li> <li>Media Type</li> </ul>
		<ul style="list-style-type: none"> <li>MMCM 3.100.2</li> <li>100.2 – Required Content 42 CFR 422.111(b) and (h)(2), 42 CFR 423.128(b) and (d)(2)</li> <li>Web Content</li> </ul>

The search results identify categories where results are found. Click any of these links to see the specific result for that category. For example, if you clicked Script from the category Media Type above, you would see the single search result for the *Media Type/Script* category.

## New

1. Click **New** to create a new regulation.
2. Enter information about the new regulation in the required field:

Regulations / New Save Cancel

<b>Final Rule Title *</b>	<input type="text" value="Final Rule Title"/>	<b>Expiration Date</b>	<input type="text" value="Expiration Date"/>
<b>Rule</b>	<input type="text" value="Rule"/>	<b>Audience</b>	Select all / Deselect all <input type="text" value="Select Some Options"/>
<b>Regulatory Project Type *</b>	Select all / Deselect all <input type="text" value="Select Some Options"/>	<b>Dependency</b>	Select all / Deselect all <input type="text" value="Select Some Options"/>
<b>Major Subject</b>	Select all / Deselect all <input type="text" value="Select Some Options"/>	<b>Referenced Regulations</b>	Select all / Deselect all <input type="text" value="Select Some Options"/>
<b>Minor Subject</b>	Select all / Deselect all <input type="text" value="No results match"/>	<b>Other References</b>	<input type="text" value="Other References"/>
<b>Media Type</b>	Select all / Deselect all <input type="text" value="Select Some Options"/>	<b>Regulation Type *</b>	Select all / Deselect all <input type="text" value="Select Some Options"/>
<b>Media Project Type</b>	Select all / Deselect all <input type="text" value="Select Some Options"/>	<b>Plan Year *</b>	<input type="text" value="Plan Year"/>
<b>Plan Type *</b>	Select all / Deselect all <input type="text" value="Select Some Options"/>		

Mandatory fields are identified with a red asterisk (\*). If a field's text box is labeled "Select Some Options" you can use [CTRL = Click] to select multiple entries for that field.

- a. **Final Rule #\***  
Enter the rule # as specified by CMS
- b. **Final Rule Title\***  
Enter the rule title as specified by CMS
- c. **Rule**  
Enter a description of the rule
- d. **Regulatory Project Type\***  
Select one or more regulatory project types from the list. Use [CTRL + Click] to select multiple options
- e. **Major Subject**  
Select one or more major subjects from the list. Use [CTRL + Click] to select multiple options. Major subjects include categories such as Call Center and Marketing Materials.
- f. **Minor Subject**  
Select one or more minor subjects from the list. Use [CTRL + Click] to select multiple options. The list of minor subjects is determined by your choice of major subject(s).
- g. **Media Type**

Select one or more media types from the list. Use [CTRL + Click] to select multiple options. Media types include categories such as ANOC and Direct Mail.

h. Media Project Type

Select one or more media project types from the list. Use [CTRL + Click] to select multiple options. Media project types include categories such as ANOC and Direct Mail.

i. Plan Type

Select one or more plan types from the list. Use [CTRL + Click] to select multiple options. The list of plan types is determined by your choice of Line of Business(s).

j. Version\*

Enter the version number of the rule.

k. Expiration Date

Use the calendar widget to enter the expiration date of the rule.

l. Audience

Select one or more audiences from the list. Use [CTRL + Click] to select multiple options. Audiences include categories such as Members and Providers.

m. Dependency

Select one or more dependent rules from the list. Use [CTRL + Click] to select multiple options. Dependencies are used to tie two or more rules together. When a rule with dependent rules is displayed, all dependent rules are displayed also.

n. Cody RA Referenced Rules

Select one or more relevant rules to cross-reference to this rule.

o. Other References

Enter text to describe any other references to the rule.

p. Regulation Type\*

Select one or more regulation types from the list. Use [CTRL + Click] to select multiple options. Regulation types include categories such as CMS and State.

q. Plan Year\*

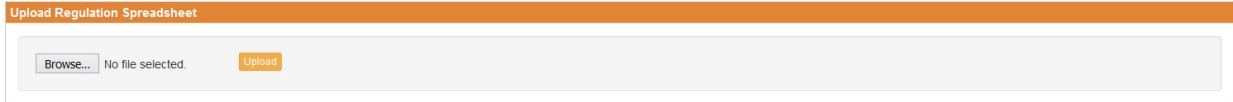
Enter the plan year to which the rule applies

3. When you have entered all information for the new regulation, click **Save**.

## Import

1. Click **Import** to import a spreadsheet of existing regulations. Use this feature when you have a set of regulations already assembled and want to upload them into the CodySoft Regulatory Analyzer.

Regulations / Import



2. Browse to select a spreadsheet that contains existing regulations
3. Click **Open**
4. Click **Upload**

The Regulatory Analyzer® database is populated with the imported regulations. Here is a sample that shows the format (headers) for creating a spreadsheet for import:

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T
	FinalRuleN umber	Version	FinalRuleTI tle	Rule	Regulation ProjectTyp	MajorSubj ect	MinorSubj ect	MediaTyp e	MediaProj ectType	PlanType	Audience	Question	Question logk	Dependen cy	Regulation Reference	OtherRefe rences	Notes	Regulation Type	PlanYear	Expiration Date
1	MMCM CH 3.10:	Issued 7-2- 15	10- Introduction	The Medicare Marketing Guidelines (MMG) implement the Centers for Medicare & Medicaid Services' (CMS) marketing requirements and related acquisitions of the Medicare	All;	Marketing Activities;		All;		MA, MAPD; PDP; COST; MMP;	All;					Title 42 of the Code of Federal Regulation;	This rule is an original	CMS;	2016;	
2	MMCM CH 3.20	Issued 7-2- 15	20- Materials Not Subject	The following types of materials are not subject to CMS marketing review, should not be submitted in HPMS, and do not require a material ID number. However, Plans/Part D Sponsors	Pre- enrollment;	Materials;	Materials- CMS review;	All;		MA, MAPD; PDP; COST; MMP;	All;				MMCM CH 3.70.8,MMCM Ch.	42 CFR 422.2260, 422.2262	KA Note 2013: Since media type	CMS;	2016;	



## CONTRACTS

You can use the Regulatory Analyzer to keep track of contracts your company has issued. From Contracts you can search the database of existing contracts, add a new contract, or import contracts from other sources

### All

Click **All** to view all contracts, and to search and archive contracts. The Contracts/All screen displays:

Contracts / All						
Contracts						
Archive						
Id	Plan Type	Contract Type	State	Section Title	Status	
<input type="checkbox"/>	193	Medicare Advantage   MAPD, Commercial   C	CT001	AR	Section #	Active
<input type="checkbox"/>	225	Medicare   Cost, Medicare   PDP, Medicare   C	CT001	CA	ST001	Active
<input type="checkbox"/>	257	Medicare   MA, Medicare   MAPD	Model Contract	FL	Definitions and Acronyms A. Definitions	Active

You can filter on any column or combination of columns to narrow your search results

### Archive

To archive contracts from the Contracts/All screen:

1. Use the filters to define and narrow your search results to just those items you want to archive
2. Select the checkboxes for those items you want to archive
3. Click **Archive**

You can also use the e Search bar to enter a word or phrase and click **Search**. Regulatory Analyzer® returns a list of relevant responses.

### New

1. Click **New** to create a new contract
2. Enter information in the fields for the new contract:

Contracts / New Save Cancel

**Contracts / New**

<b>Title *</b>	<input type="text" value="Title"/>	<b>Contract Activity Primary</b>	<input type="text" value="No results match"/>
<b>Contract Type *</b>	<input type="text" value="No results match"/>	<b>Contract Activity Supplemental</b>	<input type="text" value="No results match"/>
<b>Year From *</b>	<input type="text" value="Year From"/>	<b>Media Type</b>	<input type="text" value="Select Some Options"/>
<b>Year To *</b>	<input type="text" value="Year To"/>	<b>References</b>	<input type="text" value="No results match"/>
<b>Line Of Business *</b>	<input type="text" value="Select Some Options"/>	<b>Additional References</b>	<input type="text" value="Additional References"/>
<b>Plan Type *</b>	<input type="text" value="No results match"/>	<b>Regulation Type *</b>	<input type="text" value="Select Some Options"/>
<b>State *</b>	<input type="text" value="Select an Option"/>	<b>Notes</b>	<input type="text" value="Notes"/>
<b>Section # *</b>	<input type="text" value="Section #"/>		
<b>Section Title *</b>	<input type="text" value="Section Title"/>		
<b>Section Content *</b>	<input type="text" value="Section Content"/>		

Mandatory fields are identified with a red asterisk (\*). If a field's text box is labeled "Select Some Options" you can use [CTRL + Click] to select multiple options for that field.

- a. **Title\***  
Enter a title for the contract
- b. **Contract Type\***  
Enter the contract type, for example, a model contract or a custom contract.
- c. **Year From\***  
Enter the year from which the contract is in effect.
- d. **Year To\***  
Enter the year to which the contract remains in effect.
- e. **Line of Business\***  
Select one or more lines of business from the list. Use [CTRL + Click] to select multiple options. Lines of business include categories such as Medicare and Medicaid.
- f. **Plan Type\***  
Select one or more plan types from the list. Use [CTRL + Click] to select multiple options. The list of plan types is determined by your choice of Line of Business(s).
- g. **State\***  
Select the state in which the contract is valid from the drop-down list.
- h. **Section #\***  
Enter the relevant section number of the contract.
- i. **Section Title\***  
Enter the section title.

- j. **Section Content\***  
Enter a description of the section content.
  - k. **Contract Activity Primary**  
Enter the primary subject area to which the contract applies, for example enrollment eligibility or disenrollment.
  - l. **Contract Activity Supplemental**  
Enter the supplemental subject area to which the contract applies, for example enrollment eligibility for mandatory populations.
  - m. **Media Type**  
Select one or more media types from the list. Use [CTRL + Click] to select multiple options. Media types include categories such as ANOC and Direct Mail.
  - n. **References**  
Enter the names of any other contract's content in the Regulatory Analyzer® that reference this contract.
  - o. **Additional References**  
Enter the names of any other regulations that are referenced within the contract that should be noted but don't exist in the Regulatory Analyzer® database.
  - p. **Regulation Type\***  
Select one or more regulation types from the list. Use [CTRL + Click] to select multiple options. Regulation types include categories such as CMS and State.
  - q. **Notes**  
Add any notes relevant to the contract.
3. When you have entered all information for the new contract, click **Save**.

## Import

1. Click **Import** to import a spreadsheet of existing contracts

Contracts / Import

Upload Contract Spreadsheet

Browse... No file selected. Upload

2. Browse to select a spreadsheet that contains existing contracts
3. Click **Open**
4. Click **Upload**

The Regulatory Analyzer® database is populated with the imported contracts. Here is a sample that shows the format (headers) for creating a spreadsheet for import:

A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	
Contract Title	Contract Type	Plan Type	State	Date	Section #	Section Title	Section Content	Contract Activity Primary	Contract Activity Supplemental	Media Type	Cody RA References	Additional References	Regulation Type	Notes	Regulatory Questions	Regulatory Answer	Line of Business	
1	Florida 2012-2015 Health Plan Model Contract Attachment II - Core Contract	Model Contract	Medicaid	FL	2012-2015	Section I	Definitions and Acronyms		DEFINITION;					State;				Medicaid - Florida
2	Provisions																	
3	Florida 2012-2015 Health Plan Model Contract Attachment II - Core Contract Provisions	Model Contract	Medicaid	FL	2012-2015	Section I A.	Definitions and Acronyms A. Definitions	The following terms as used in this Contract shall be construed and/or interpreted as follows, unless the Contract otherwise expressly requires a different construction and/or interpretation. Some defined terms do not appear in all contracts.	DEFINITION;					State;				

## HPMS MEMO

From HPMS Memo you can search the database of existing HPMS memos, add a new memo, or import memos from other sources

### All

Click **All** to view all HPMS memos, and to search and archive memos. The HPMS Memo/All screen displays:

HPMS Memo						
Archive						
Id	Title	Plan Type	Owner	Urgency	Status	
<input type="checkbox"/>	673	HPMS for 050416	Cost Medicare, PDP Medicare, MA Medicare,			Active
<input type="checkbox"/>	705	Memo0504001	Cost Medicare, PDP Medicare, MA Medicare,			Active

You can filter on any column or combination of columns to narrow your search results

### Archive

To archive HPMS Memos from the HPMS Memo/All screen:

1. Use the filters to define and narrow your search results to just those items you want to archive
2. Select the checkboxes for those items you want to archive
3. Click **Archive**

You can also use Search bar to enter a word or phrase and click **Search**. Regulatory Analyzer® returns a list of relevant responses.

## New

1. Click **New** to create a new HPMS Memo
2. Enter information in the fields for the new HPMS Memo:

HPMS Memo / New Save Cancel

**Memo Details**

<b>Title *</b>	<input type="text" value="Title"/>	<b>References</b>	Select all / Deselect all <input type="text" value="Select Some Options"/>
<b>Description *</b>	<input type="text" value="Description"/>	<b>Website</b>	<input type="text" value="Website"/>
<b>Release Date *</b>	<input type="text" value="Release Date"/>	<b>Action Required</b>	<input type="text" value="Action Required"/>
<b>CMS Director *</b>	<input type="text" value="CMS Director"/>	<b>Action Due Date</b>	<input type="text" value="Action Due Date"/>
<b>Type *</b>	Select all / Deselect all <input type="text" value="Select Some Options"/>	<b>Attachment Type *</b>	Select all / Deselect all <input type="text" value="Select Some Options"/>
<b>Plan Type *</b>	Select all / Deselect all <input type="text" value="Select Some Options"/>	<b>To *</b>	<input type="text"/>
<b>Media Type</b>	Select all / Deselect all <input type="text" value="Select Some Options"/>	<b>Owner</b>	<input type="text"/>
<b>Regulation Type *</b>	Select all / Deselect all <input type="text" value="Select Some Options"/>	<b>CPE Element</b>	<input type="text"/>
<b>Urgency</b>	<input type="text" value="No results match"/>	<b>Department</b>	Select all / Deselect all <input type="text" value="Select Some Options"/>
<b>Include in Compliance Committee Agenda</b>	<input checked="" type="radio"/> Yes <input type="radio"/> No	<b>Contract Number</b>	Select all / Deselect all <input type="text" value="Select Some Options"/>
		<b>User Notes *</b>	<input type="text" value="User Notes"/>

Mandatory fields are identified with a red asterisk (\*). If a field's text box is labeled "Select Some Options" you can use [CTRL = Click] to select multiple entries for that field.

- a. **Title\***  
Enter the title of the HPMS Memo as specified by CMS
- b. **Release Date\***  
Enter the release of the HPMS Memo as specified by CMS
- c. **CMS Director\***  
Enter the name of the CMS Director that issued the memo.
- d. **Type\***  
Select the type of the HPMS Memo, either Informational or Actionable.
- e. **Plan Type\***  
Select one or more plan types from the list. Use [CTRL + Click] to select multiple options.
- f. **Media Type**  
Select one or more media types from the list. Use [CTRL + Click] to select multiple options. Media types include categories such as ANOC and Direct Mail.
- g. **Regulation Type**

For HPMS Memos the regulations type is set to CMS

h. Urgency

Enter the Urgency level of the HPMS Memo. Common urgency levels are Low, Medium, and High.

i. Include in Compliance Committee Agenda

Select Yes to have the memo included in the next Compliance Committee Agenda.

j. References

Select any regulations that are relevant to this this memo. Use [CTRL + Click] to select multiple options.

k. Website

If the HPMS Memo references a website, enter the URL here.

l. Action Required

Enter any action requires by the memo.

m. Action Due Date

Enter a due date by which the action must be completed.

n. Attachment Type\*

Specify whether the memo was an email only, an email with a pdf attachment or an email with some other type of attachment.

o. To\*

Specify whether the memo was addressed to all MA plans, or only a certain subset of the plans.

p. Owner

Indicate who is the owner of the memo within the organization.

q. CPE Element

Specify which element of the CMS Compliance Program Effectiveness (CPE) protocol (if any) is being discussed in the memo.

r. Department

Select which department or departments the memo is to be assigned to within the organization

s. Contract Number

If a memo has to do with a particular contract, enter the contract number.

t. User Notes\*

Enter any notes relevant to the HPMS memo.

3. When you have entered all information for the new HPMS Memo, click **Save**.

## Import

1. Click **Import** to import a spreadsheet of existing HPMS Memos

HPMS Memo / Import

Upload HPMS Spreadsheet » Upload PDF Comments » Complete

Browse... No file selected.

Upload

2. Browse to select a spreadsheet that contains existing HPMS Memos
3. Click **Open**
4. Click **Upload**

The Regulatory Analyzer® database is populated with the imported HPMS Memos. Here is a sample that shows the format (headers) for creating a spreadsheet for import:

A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	U	
Release Date	Email Memo, Other Attach	From: CMS Director	To:	Title	Description	Plan Contract #	Plan Name/Type	Dept / Functional Area	Urgency	Type	Action Required	Action Due Date	Codified/Referenced Rules / HPMS Memos	Media Type	Website/URL	Regulation Type	Attachment	Audit Element	Included in Compliance		
1/15/16	Email Memo, Other Attach	Gerard Khulak, Director, Medicare Part C and D Oversight and Enforcement Group	All Medicare Advantage Organizations and Prescription Drug Plan Sponsors	Addendum to the 2015/2016 Program Audit Protocols	On October 19, 2016, CMS issued a memorandum announcing the release of the 2015/2016 Program Audit Protocols. Since the release of the protocols, we have received questions from industry requesting clarification on certain items in the protocols, largely in the various record inputs. Record inputs detail all of the data CMS requests in advance of a program audit, and it is from this data that we pull our samples to perform the audit. CMS created an addendum to the protocols (attached to this memo) that offers clarification on the fields causing confusion, and should be used in conjunction with the OCT 2016 audit protocols. It does not change any of the data we are requesting, it simply provides clarification on certain items that continue to cause confusion.		MA, MAPD, PDP				Actionable	Use of updated audit protocols		HPMS MEMO 16-19-16			CMS				
1/15/16	Email Memo, Other Attach	HPMS	ALL	Medicare Prescription Drug Benefit Manual - Chapter 6	CMS releases a revised chapter 6 Part D Drugs and Formulary Requirements of the Medicare Prescription Drug Benefit Manual. We released a draft version for stakeholder review on January 20, 2015. We received over 60 timely submissions of comments, which were carefully considered when finalizing this version. The updated chapter reflects updates from pertinent final regulations, Call Letters, and memoranda. Changes were also made in consideration of feedback relating to operationalizing the Part D benefit.		MA, MAPD, PDP, COST, PAACE				Actionable	Use of updated regulatory requirements				CMS	PDBMCH6				



## P&Ps

From P&Ps you can search the database of existing P&Ps, add a new P&P, or import P&Ps from other sources

## All

Click **All** to view all P&Ps, and to search and archive P&Ps. The P&Ps/All screen displays:

Id	Title	Plan Type	Owner	Urgency	Status
<input type="checkbox"/> 673	HPMS for 050416	Cost Medicare, PDP Medicare, MA Medicare,			Active
<input type="checkbox"/> 705	Memo0504001	Cost Medicare, PDP Medicare, MA Medicare,			Active

You can filter on any column or combination of columns to narrow your search results

### Archive

To archive P&Ps from the P&Ps/All screen:

1. Use the filters to define and narrow your search results to just those items you want to archive
2. Select the checkboxes for those items you want to archive
3. Click **Archive**

You can also use Search bar to enter a word or phrase and click **Search**. Regulatory Analyzer® returns a list of relevant responses.

In the Search bar, enter a word or phrase and click **Search**. Regulatory Analyzer® returns a list of relevant responses.

## New

1. Click **New** to create a new P&P

## 2. Enter information in the fields for the new P&amp;P:

P & Ps / New Save Cancel

<b>Issue Department *</b>	Select an Option	<b>Definitions *</b>	Definitions
<b>Version Number *</b>	Version Number	<b>Policy *</b>	Policy
<b>Author *</b>	Author	<b>Procedure *</b>	Procedure
<b>Effective Date *</b>	Effective Date	<b>Source Documents References</b>	Source Documents References
<b>Review Date *</b>	Review Date	<b>Related Policies</b>	Select all / Deselect all No results match
<b>Expiration Date</b>	Expiration Date		
<b>Archive Date</b>	Archive Date		
<b>Department Scope *</b>	Select all / Deselect all Select Some Options		
<b>Line Of Business *</b>	Select all / Deselect all Select Some Options		
<b>Plan Type *</b>	Select all / Deselect all No results match		
<b>Media Type *</b>	Select all / Deselect all Select Some Options		

Mandatory fields are identified with a red asterisk (\*). If a field's text box is labeled "Select Some Options" you can use [CTRL = Click] to select multiple entries for that field.

- a. **Title\***  
Enter the P&P title.
- b. **Policy Number\***  
Enter the policy number.
- c. **Issue Department\***  
Select an issuing department from the dropdown list.
- d. **Version Number\***  
Enter the policy's version number
- e. **Author\***  
Enter the name of the author of the policy
- f. **Effective Date\***  
Use the calendar widget to enter the effective date of the policy.
- g. **Review Date\***  
Use the calendar widget to enter the review date of the policy.
- h. **Expiration Date**  
Use the calendar widget to enter the date on which the policy will expire
- i. **Archive Date**  
Use the calendar widget to enter the date on which the policy should be archived.

- j. **Department Scope\***  
Select one or more Departments from the list. Use [CTRL + Click] to select multiple options. Departments include categories such as Compliance and Marketing.
  - k. **Line of Business\***  
Select one or more lines of business from the list. Use [CTRL + Click] to select multiple options. Lines of business include categories such as Medicare and Medicaid.
  - l. **Plan Type\***  
Select one or more plan types from the list. Use [CTRL + Click] to select multiple options.
  - m. **Media Type\***  
Select one or more media types from the list. Use [CTRL + Click] to select multiple options. Media types include categories such as ANOC and Direct Mail.
  - n. **Policy Statement\***  
Enter a policy statement that provides the purpose of the policy.
  - o. **Definitions\***  
Enter the meaning, clarification and explanation of terms, words or concepts unique to the policy
  - p. **Policy\***  
Enter the guiding principle of the policy that provides a rule, strategy, plan, program, plan or procedure
  - q. **Procedure\***  
Enter the particular course or manner of action or for an action or process described within the policy.
  - r. **Source Documents References**  
Enter any sections of the policy that capture primary source documents or references to laws, rules, or other policies that affect the policy
  - s. **Related Policies**  
Select the names and numbers of any policies that are related to this policy.
3. When you have entered all information for the new P&P, click **Save**.

## Import

1. Click **Import** to import a spreadsheet of existing P&Ps

P & Ps / Import

Upload Policy Spreadsheet » Upload Attachments » Complete

Browse... No file selected.

Upload

2. Browse to select a spreadsheet that contains existing P&Ps
3. Click **Open**
4. Click **Upload**

- On the P&Ps/Import screen, save workflow and document attachments related to the policies you are importing via the spreadsheet:

Workflow attachments include workflow diagrams. Document attachments are the actual policies.

- Click **Save Documents** to save the documents for each policy (each row in the spreadsheet you are importing)
- Click **Save All Documents** when you have uploaded all attachments.

The Regulatory Analyzer® database is populated with the imported P&Ps.

Here is a sample that shows the format (headers) for creating a spreadsheet for import:

Column Header	POLICY TITLE	POLICY NUMBER	ISSUING DEPT	Version Number	Author	Effective Date	Review Date	Expiration Date	Archive Date	LINE OF BUSINESS	DEPT SCOPE	PLAN TYPE	MEDIA TYPE	Policy Statement	Definitions	Policy	Procedure	Workflow Attached? Y/N	Documents Attached	Source Documents References	Related Policies Policy Name	Related Policies Policy Number
---------------	--------------	---------------	--------------	----------------	--------	----------------	-------------	-----------------	--------------	------------------	------------	-----------	------------	------------------	-------------	--------	-----------	------------------------	--------------------	-----------------------------	------------------------------	--------------------------------

## ANALYZE

You can perform an analysis that returns a list of relevant documents in the Regulatory Analyzer® database, including CMS guidelines, rules of other regulatory agencies, and company-issued documents, based on criteria you specify.

- Enter information in the Select Options dialog box:

Mandatory fields are identified with a red asterisk (\*).

- Line of Business\***  
Select one or more lines of business from the list. Use [CTRL + Click] to select multiple options. Lines of business include categories such as Medicare and Medicaid.
- Media Type\***

Select one or more media types from the list. Use [CTRL + Click] to select multiple options. Media types include categories such as ANOC and Direct Mail.

c. Plan Year\*

Enter the plan year for which you want to search for documents

d. Project Name\*

Enter the name of the project for which you are searching for documents

e. Audience\*

Select one or more audiences from the list. Use [CTRL + Click] to select multiple options. Audiences include categories such as Members and Providers.

f. Plan Type\*

Select one or more plan types from the list. Use [CTRL + Click] to select multiple options.

g. Regulatory Project Type\*

Select one or more regulatory project types from the list. Use [CTRL + Click] to select multiple options

2. Click **Start**. The Questions Wizard opens

3. Answer the questions in the wizard

a. *Does this piece include co-branding?* Click **Yes** or **No**

b. *Does this piece include co-branding with providers or downstream entities?* Click **Yes** or **No**

c. Respond to any additional questions (list of questions may vary by the criteria you enter in the Select Options dialog box)

d. Click **Generate Report**

The Regulatory Analyzer® generates a report with a listing of all rules that meet the criteria you specify, with their major subjects and other references listed also.

project: Test

Media Type: ANOC

Project Type: Post-Enrollment

Plan Type: MADD

Rule: MMCM CH 3.1E

Major Subject: Marketing Activities, Materials

The Medicare Marketing Guidelines (MMG) implement the Centers for Medicare & Medicaid Services' (CMS) marketing requirements and related provisions of the Medicare Advantage (MA, MA-PD) (also referred to as Plan), Medicare Prescription Drug Plan (PDP) (also referred to as Part D Sponsor), and except where otherwise specified 1876 cost plans (also referred to as Plan) rules, (i.e., Title 42 of the Code of Federal Regulations, Parts 422, 423, and 417). These requirements also apply to Medicare-Medicaid Plans (MMPs), except as modified or clarified in state-specific marketing guidance for each state's demonstration. State-specific guidance is considered an addendum to the MMG. State-specific marketing guidance for MMPs will be posted to <http://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/InformationandGuidanceforPlans.html> as it is finalized. These requirements do not apply to Program of All-Inclusive Care for the Elderly (PACE) plans or section 1833 Health Care Pre-payment Plans unless otherwise noted in the MMG. The term "marketing" is referenced at Section 1851(h) and 1860 D-4 of the Social Security Act (the Act), as well as in CMS regulations. The scope of the definition of "marketing materials" extends beyond the public's general concept of advertising materials. Pursuant to 42 CFR section 417.428, section 422.2260, and section 423.2260, the following materials, while not an exhaustive list, may fall under CMS' purview per the definition of marketing materials:

- General audience materials, such as general circulation brochures, direct mail, newspapers, magazines, television, radio, billboards, yellow pages, or the Internet
- Marketing representative materials, such as scripts or outlines for telemarketing or other presentations
- Presentation materials, such as slides and charts
- Promotional materials, such as brochures or leaflets, including materials circulated by physicians, other providers, or third-party entities
- Membership communications and communication materials including membership rules, subscriber agreements, enrollee handbooks and wallet card instructions to enrollees (e.g., Annual Notice of change (ANOC), Evidence of Coverage (EOC), Provider/Pharmacy Directory)
- Communications to enrollees about contractual changes, and changes in providers, premiums, benefits, plan procedures
- Membership activities (e.g., materials on rules involving non-payment of premiums, confirmation of enrollment or disenrollment, or non-claim specific notification information)
- The activities of a Plan's/Part D Sponsor's employees, independent agents or brokers, Third Party Marketing Organizations (TMO) (downstream contractors), or other similar type organizations that contribute to the steering of a potential enrollee toward a specific plan or limited number of plans, or may receive compensation directly or indirectly from a Plan/Part D Sponsor for marketing activities
- In addition, 42 CFR section 417.428, section 422.2268, and section 423.2268 define the standards for marketing. CMS' authority for marketing oversight, and the MMG, encompasses not only marketing materials but also marketing/sales activities. As Plans/Part D Sponsors implement their programs, they should consider the following guiding principles:
- Plans/Part D Sponsors are responsible for ensuring compliance with CMS' current marketing regulations and guidance, including monitoring and overseeing the activities of their subcontractors, downstream entities, and/or delegated entities. If CMS finds that the Plan/Part D Sponsor failed to comply with applicable rules and guidance, CMS may take compliance action, including intermediate sanctions and civil money penalties.
- Plans/Part D Sponsors are responsible for full disclosure when providing information about plan benefits, policies, and procedures
- Plans/Part D Sponsors are responsible for documenting compliance with all applicable marketing requirements described in the MMG

It is important to note that the marketing guidance set forth in this document is subject to change as policy, communication technology, and industry marketing practices continue to evolve. Any new rulemaking or interpretive guidance (e.g., annual Call Letter or HPMS guidance memoranda) may supersede the marketing guidance provided in this document. Specific questions regarding a marketing material or marketing practice should be directed to the Plan's/Part D Sponsor's Account Manager or designated Marketing Reviewer.

Other References:

Title 42 of the Code of Federal Regulations, Parts 422, 423, and 417; <http://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/InformationandGuidanceforPlans.html>; Section 1851(h) and 1860 D-4 of the Social Security Act (the Act); 42 CFR section 417.428, section 422.2260, and section 423.2260; 42 CFR section 417.428, section 422.2268, and section 423.2268

**NOTE:** Click the links for Primary Regulation or Dependent Regulation to display the regulation within the report.



## ADMIN

Use Admin to set up categories for the Regulatory Analyzer®

Admin

Project Types   Contract Types   Contract Activity   Media Project Types   Major Subjects   Urgencies

**Project Types** Add Item

#	Title
1	Pre-enrollment
2	Post-enrollment
3	Enrollment
4	Website
5	Mobile Application

### *Project Types*

Use this tab to create and update the different project types for use in the Regulatory Analyzer®.

1. Select **Add Item**
2. Give the new project type a **Name**
3. Click **OK**

### *Contract Types*

Use this tab to create and update the different contract types for use in the Regulatory Analyzer®.

1. Select **Add Item**
2. Give the new contract type a **Name**
3. Click **OK**

### *Contract Activity*

Use this tab to create and update the different contract activities for use in the Regulatory Analyzer®.

1. Select **Add Item**
2. Give the new contract activity a **Name**
3. Add a **contract supplemental activity**
4. Click **Add Sub**
5. Add additional **contract supplemental activities**
6. Click **Add Sub** after adding each new contract supplemental activity
7. Click **OK**

### *Media Project Types*

Use this tab to create and update the different media project types for use in the Regulatory Analyzer®.

1. Select **Add Item**
2. Give the new media project type a **Name**
3. Click **OK**

### *Major Subjects*

Use this tab to create and update the different major subjects for use in the Regulatory Analyzer®.

1. Select **Add Item**
2. Give the new contract activity a **Name**
3. Add a **minor subject**
4. Click **Add Sub**
5. Add additional **minor subjects**
6. Click **Add Sub** after adding each new minor subject
7. Click **OK**

### *Urgencies*

Use this tab to create and update the urgency levels for use in the Regulatory Analyzer®. Common urgency levels are Low, Medium, and High.

1. Select **Add Item**
2. Give the new urgency a **Name**
3. Click **OK**