

Regulatory Compliance Oversight - The Medicare C & D Perspective



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Overview

- Thoughts for the Day
- CMS' Perspective
- Distribution of Regulatory Notices
- Building the Case File
- Validating Successful Implementation
- Survival Tips When Undergoing CMS Audit

Thoughts for the Day

- Law of Physics- What comes in, must go out
- If it looks simple, you probably missed something
- The devil really is in the details
- Timing is everything
- We've already had the good old days
- There's a new sheriff in town

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CMS' Expectations

Plans are to have implemented a formal process of ongoing review, analysis and improvement to ensure that both structures and processes are in place to achieve and maintain compliance with all applicable Federal and State standards, including Medicare laws, regulations, reporting requirements, CMS instructions, and Medicare Part C and D User's Manuals.

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Distribution of Regulatory Notices What Comes In – Must Go Out

- What a difference a decade makes – 2000 vs. 2010
- Broad distribution
- Topic specific distribution

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Medicare Coverage Gap Discount Program— Prospective Beneficiary Notice of Formulary Changes – CMS Notice 11/3/2010

In the May 21, 2010 Medicare Coverage Gap Discount Program (Discount Program) guidance, the Centers for Medicare & Medicaid Services (CMS) stated that Part D sponsors must provide prospective notice to affected Part D enrollees (as defined in 42 CFR 423.100) if those members were affected by failure of a manufacturer to sign a discount agreement. Although CMS collected discount agreements from manufacturers that cover all necessary applicable Part D drugs, it is still possible that a beneficiary may need to switch from their specific non-covered brand to a covered alternative. Part D sponsors will also need to remove any affected formulary drugs from their marketing materials by immediately updating formularies on their website and ensuring that future printings of formulary materials do not include these drugs. Part D sponsors should remove affected drugs from their CMS approved formulary at the time of their next formulary submission to CMS.

If a Part D sponsor determines that any beneficiaries are affected by a manufacturer's failure to sign an agreement, the sponsor should send notification to all affected enrollees as soon as possible but no later than November 30, 2010. CMS anticipates that only a limited number of these notifications will be necessary based upon our analysis of PDEs and, therefore, considers this notification to represent an ad hoc enrollee communication as defined in section 20 of chapter 3 of the Prescription Drug Benefit Manual.

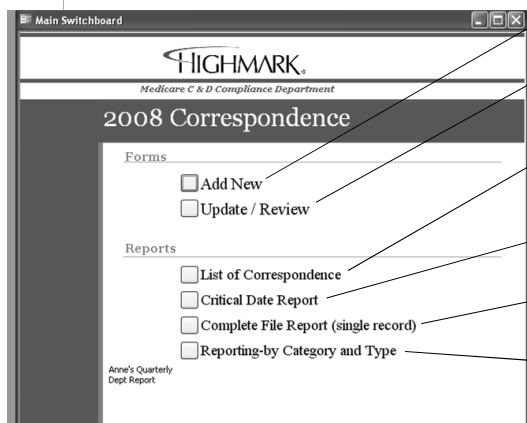
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Documentation – Building The Structure

- Determine available resources
- Evaluate approach
- Highmark's approach
 - 2000-2008: Access database
 - 2008-2010: Highmark IT designed web-based application used by MCD Compliance department
 - 2011: Expanded application for interdepartmental use

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Access Database



This form is used to enter new correspondence.

This form is used to update and view all of the data fields for a single record.

This report shows all correspondence currently in the database, organized by ID #.

This report is organized by Critical Date.

This report shows all details for a single record.

This report is organized by Category and then by Type. It is controlled by start and end date parameters.

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Access Database

Click "Add NEW" to go to the next available number.

Click to open a summary of this case

If the Author is not available on the drop down list, click **Add new Author.**

The **Search List** shows a list of #s and Subject Lines. If you click on one of them, the form will go to that record.

• AHIP email
• BCBSA email
• CMS other email
• HPMS
• OIG email
• IntegriGuard
• Medic
• Other

• Informational
• Regulatory

Various types - each begins with C, D, or C&D

Number of attachments in addition to the Memo

Check if correspondence includes model language

If applicable

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Access Database

As determined by CMS

Highmark's expected implementation date

Open Report: List of Correspondence

Open Report: Staff Report

Personal "to do" reminders

Document each activity on a different tab.

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Custom Web-based Application

The Correspondence Module of CACTUS enables storage, assignment, tracking and research applicable to Informational and Regulatory documents that are related to the Medicare Advantage (Part C) and Prescription Drug (Part D) Programs. Users have the ability to view summary listing of all or selected Correspondence cases, detailed information regarding a specific Correspondence case or on-demand reports. Correspondence cases are created or modified by manual entry. Electronic copies of documents can be attached to cases and viewed or printed.

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Custom Web-based Application

Sample Case

Corresp. ID	Assigned Reviewer/ Assigned Date	Case Status/ Closed Reason/ Status Date	Corr Type/ Medicare Part/ Subject Category	Subject Line	FBO	Memo Date/ Received Date	Critical Due/ Effective Date	Model	Docs
M1000000415	Ajibola Okerayi 11/16/2010	Closed Info Only 11/10/2010	Regulatory D Troop	FIV: Special Process for 2010 End-of-Year Non-Enrollment-Related 4Rx Changes		11/04/2010 11/04/2010	12/17/2010	1	N
M1000000414	Joan Bova 11/16/2010	Closed Now Compliant 11/16/2010	Regulatory CSD Customer Service	FIV: Call Center Operations - Thanksgiving and Christmas Day 2011		11/04/2010 11/04/2010		1	N
M1000000412	Debbie Labuda 11/16/2010	Closed Info Only 11/16/2010	Informational C Provider Issues	FIV: CMS Updates to Coverage Pages		11/04/2010 11/04/2010		0	N
M1000000410		Closed Info Only 11/16/2010	Informational CSD Other	FIV: AHP Medicare Update #10-164-CMS Announces 2011 Part A and Part B Premiums and Deductibles		11/04/2010 11/04/2010		3	N
M1000000409	Ajibola Okerayi 11/16/2010	Closed Info Only 11/19/2010	Regulatory D Coverage Gap	Clarification of Prescription Drug Event (PDE) Rules for Reporting Covered Plan Paid (CPP) Amounts		11/03/2010 11/03/2010		1	N
M1000000411	Judith Lee 11/16/2010	Closed Now Compliant 12/17/2010	Regulatory D Coverage Gap	FIV: Medicare Coverage Gap Discount Program - Prospective Beneficiary Notice of Formulary Changes		11/03/2010 11/03/2010	11/03/2010	7	N

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(Sample Case, Part 1 of 2)

Medicare C & D Compliance Case Tracking System

Angel Mzaack | Reviewer Load: 21/03/2011

Search/Summaries | Create A Case | Report Processors

Complaints Summary Report

All Correspondences | My Correspondences | Correspondence Search

Correspondence > Search/Summaries > View Detail

< Back | Re-open Record | Print Correspondence

Summary

Correspondence ID: M100000411
 Case Status: Closed
 Closed Reason: Now Compliant
 Received Date: 11/03/2010
 Memo Date: 11/03/2010
 Author: Tudor, Cynthia
 Correspondence Type: Regulatory
 Method of Receipt: HPMS
 Subject Line: FW: Medicare Coverage Gap Discount Program - Prospective Beneficiary Notice of Formulary Changes
 Subject Category: Coverage Gap
 Medicare Part: D
 Internal Distribution Date: 11/03/2010
 Assigned Reviewer 1: Judith Lee (412) 544-1553
 Assigned Date 1: 11/16/2010
 Status Date: 12/17/2010
 Co-Author:
 Assigned Reviewer 2:
 Assigned Date 2:

Milestone Dates

CMS Effective Date:
 Critical Due Date: 11/30/2010
 Highmark Planned Implementation Date:
 Model Docs?: No

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Custom Web-based Application

(Sample Case, Part 2 of 2)

Synopsis

Summary: On 11/3/2010, CMS issued a memo related to the Med. Cov. Gap Discount program. If a Part D sponsor determines that any benes are affected by a mfg. failure to sign an agreement, the sponsor should send notification to all affected benes no later than 11/30/2010. CMS anticipates only a limited number of notifications will be necessary and considers this an ad hoc notification. Plans must submit this ad hoc communication to CMS in accordance with section 90.2.2 of the Mkt. Manual and must include the language as provided by CMS. The other part of this memo indicates that Part D sponsors will also need to remove any affected formulary drugs from their marketing materials by immediately updating formularies on their website and ensure that future printings of formulary materials do not include these drugs. Part D sponsors should remove affected drugs from their CMS approved formulary at the time of their next formulary submission to CMS.

MCD Case Notes: This CMS memo originally forwarded to the Highmark Pharmacy Affairs department on November 4, 2010. On November 8, Pharmacy began the process of having the template reviewed according to Marketing Guidelines. On November 17, Pharmacy confirmed that the targeted mail date is November 24. A follow-up e-mail was forwarded to Pharmacy on November 22 to determine if they are still on track to mail on November 24 as the letters must be mailed before November 30. In all, 129 members are impacted. On November 22 an e-mail was forwarded to Pharmacy (from P. Suffern), regarding the formulary/marketing materials/website portion of this memo. This e-mail asked for information as to how these items would be addressed. On November 30, T. Lessa confirmed that letters were mailed to 129 members. A list of members was included in the e-mail and forwarded to Member Service. On 12/07/2010, received an e-mail from D. Stackhouse that states as follows: The 2011 formulary web site has been updated. The drugs excluded due to manufacturers not signing the discount program agreement have been removed. The printed abridge formulary will include an insert, which has been submitted to MCDMarketing for CMS review. This insert is attached. Pharmacy has also confirmed that upon depletion of the abridged formularies, new supplies can be provided that exclude the drugs listed on the formulary insert. Confirmation is attached. All actions in this memo have been completed and plan is compliant.

FBO Case Notes:

Transfer History

Owner Name	Department	FBO Assigned Date	FBO Returned Date	Action Taken

Attachments (7)

File Description	Date	Filename	Attached By
MemoCGDPBeneficiaryNotice_11.03.10	11/16/2010	MemoCGDPBeneficiaryNotice_11.03.10.pdf	Robert Stanley Mooney
Notification to Pharmacy Part 1	12/01/2010	Pharmacy E-mails_Member Letter_Part 1.pdf	Judith K Lee
Member Notification Confirmation	12/01/2010	Member Mailing Confirmation e-mails_Part 2.doc	Judith K Lee
Member Mailing List	12/01/2010	HMK_NonParticipating_Mfgrs_Members_Addresses.xls	Judith K Lee
Removal from Website Confirmation	12/07/2010	Pharmacy E-mails_Removal From Formulary_website.doc	Judith K Lee
Future Printing of Abridged Formulary	12/17/2010	e-mails_Abridged Formulary.doc	Judith K Lee
Formulary Insert to MCDMarketing	12/17/2010	Medicare Coverage Gap Discount Program_2011.pdf	Judith K Lee

< Back | Re-open Record | Print Correspondence

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Validating Implementation

- ❑ Meeting with impacted business units
- ❑ Tracking actions outlined in project plan
- ❑ Supporting documentation
- ❑ Business owner attestation

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Monitoring & Auditing

- ❑ Regulatory Notification Policy/Procedure
- ❑ Regulatory Notification Log for audit period
- ❑ Evaluate selected correspondence case file

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Survival Tips for CMS Audit

- ❑ Ensure notification policy reflects current practice
- ❑ Timely update of distribution log
- ❑ Ensure high risk business units familiar with notification process and their role
- ❑ Test ability to produce reports outlined in policy/procedure

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Question and Answer Session



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