

Health Plan Management System Outlier Justification Submission Module User Manual

Version 00.01

Contract Year 2009



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1 Introduction

The Outlier Justification Submission (OJS) module provides a coordinated approach for Part D Sponsors and Formulary Consultants to submit HPMS Outlier Justifications based on requests from CMS. All Outlier Justification Submissions are evaluated by the Centers for Medicare and Medicaid Services (CMS). This module serves as a replacement for CMS' previous process of providing notification of potential formulary issues and receiving Part D sponsor justifications for these issues via email. The same justification information previously submitted to CMS using MS Excel documents will now be directly entered into HPMS. The justifications provided to CMS through the HPMS Outlier Justification Submission module should address whether the Part D Sponsors will resolve potential formulary issues via a resubmission of the formulary file or by providing a clinical justification for review by CMS.

The Outlier Justification Submission module is organized into the following two functional areas:

- Outlier Justification Submission(s) – Allows you to provide Outlier Justifications for formulary issues identified by CMS during the review of your formulary. You will be required to select a formulary (one at a time) and respond Yes/No as to whether a Resubmission will be utilized to resolve the identified issue. If a Yes is entered then you will be required to provide a Resubmission Comment. If a No is entered then a detailed Clinical Justification must be provided. Note: You will be able to export the Outlier Justification page to MS Excel.
- Reports – Allows you to access the Outlier Justification History Report to view the history for a formulary. Once a Formulary ID is selected, the Outlier History Report will open in MS Excel.

Note: There will be a Documentation link that will direct you to the OJS User Manual and will be available for download.

2 Outlier Justification Submission Module

To access the **Outlier Justification Submission module**, select the “Plan Formularies” link from the left navigation bar. From the “Plan Formularies” link, select the “Formulary Maintenance” option.

Exhibit 1 Formulary Maintenance Welcome Page

HPMS: Home Page - Microsoft Internet Explorer provided by CGI Federal

File Edit View Favorites Tools Help

HPMS Health Plan Management System Home

Plan Bids

Plan Formularies

Log Off HPMS

This is a U.S. Government computer system subject to Federal law.

Hello Mark King !

Formulary Submission

Formulary Review

Formulary Reports

Negative Formulary Change Requests

NCR Review

Formulary Maintenance

2004 and 2005 MPPF, drug card [bulletin #15](#). MA organization monitoring review guide cover [memo](#) and attachments [1](#) and [2](#).

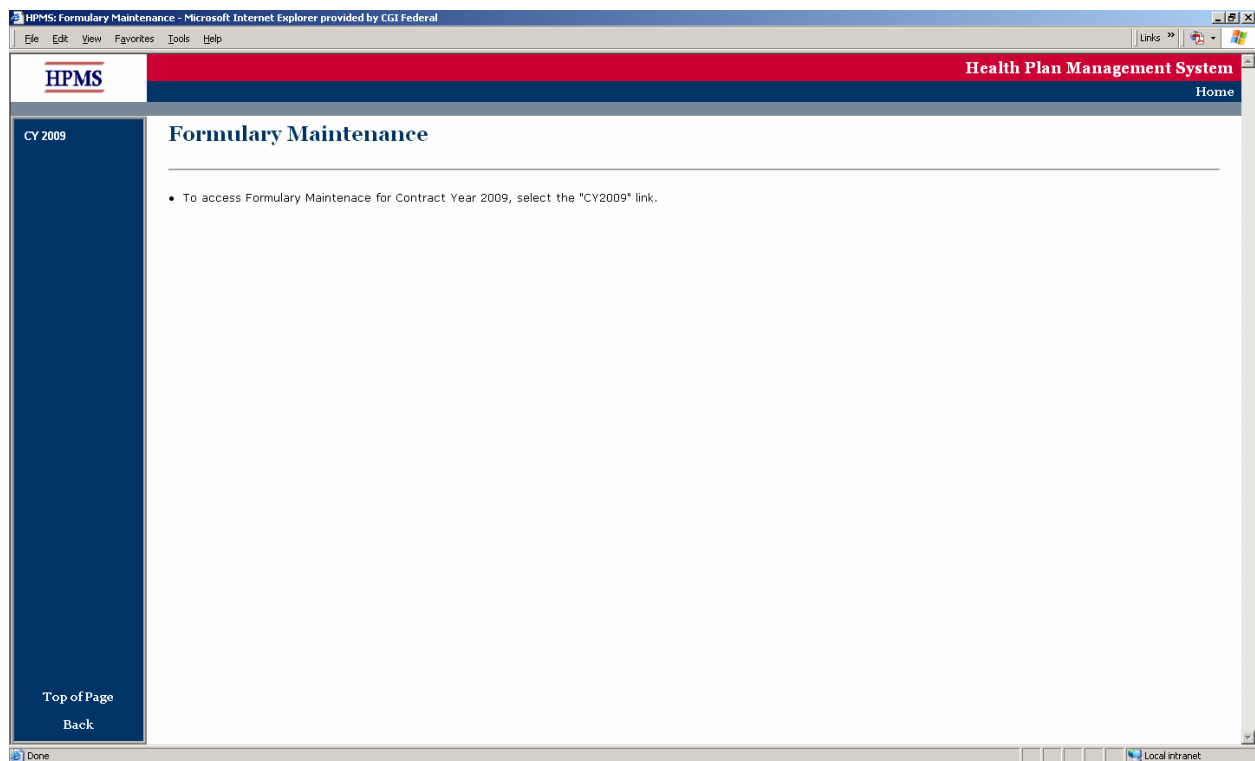
- 10/05/2004 Release of [letter](#) re: 2005 Model Evidences of Coverage.
- 10/04/2004 - 10/05/2004 Second MCO preview of 10/19 MPPF update.
- 9/29/2004 Release of updated [drug card reporting requirements](#).
- 9/27/2004 Release of [Medicare Health Outcomes Survey](#) (HOS) Cohort 4 Performance Measurement Reports and Cohort 6 Baseline Reports in HPMS.
- 9/20/2004 - 9/22/2004 MCO preview of CY 2005 handbook data and 10/19 MPPF update.
- 9/20/2004 Release of drug card [bulletin #14](#) (Attachments [1](#) and [2](#)).
- 9/20/2004 [Update](#) to Chapter 13 of the Medicare Managed Care Manual.
- 9/17/2004 3rd Quarter Medicare Managed Care Manual [Training Call](#).
- 9/13/2004 Release of Version 3.0 of [HPMS Monitoring Worksheet Tool](#).
- 9/13/2004 Deadline for CY 2005 ACRP uploads.
- 9/10/2004 Release of [memo](#) re: the 2005 Medicare Part B premium and rates and the PBR/SB.
- 9/8/2004 Release of [memo](#) re: the Part B premium and the ACR.
- 9/8/2004 Release of [cover memo](#) and attachments [1](#), [2](#), [3](#), [4](#), and [5](#) re: pancreatic islet cell transplants.
- 9/7/2004 - 9/10/2004 Annual Managed Care Enrollment and Payment Conference in Baltimore, Maryland.
- 9/7/2004 [Update](#) to Chapter 17 of the Medicare Managed Care Manual.
- 9/7/2004 Release of drug card [bulletin #11](#) (attachment [1](#)).
- 9/7/2004 Release of drug card [bulletin #12](#).
- 9/7/2004 Release of drug card [bulletin #13](#) (Attachments [1](#), [2](#), [3](#), [4](#)).

Click here for the [archived in the News](#) items.

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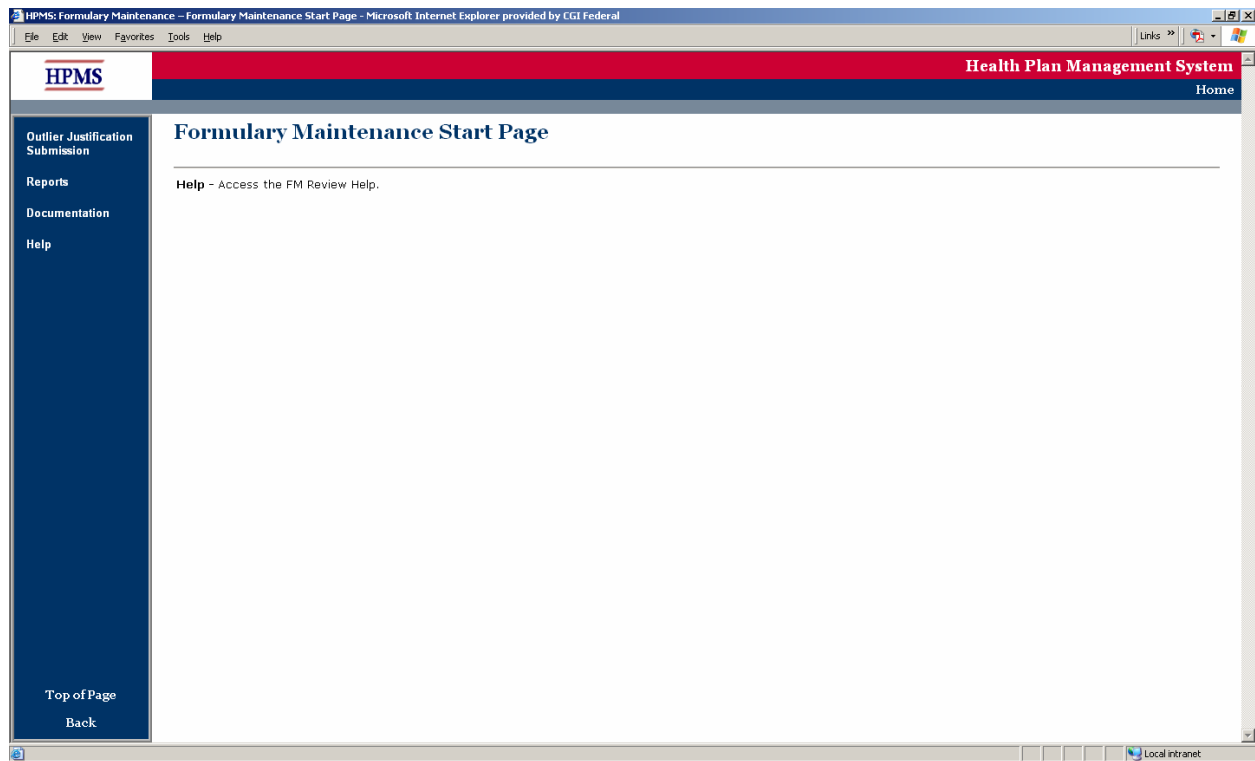
Back

Exhibit 2 *Formulary Maintenance Module Selection Page*



You must click on the “CY 2009” link from the left navigation bar. Once the **Contract Year** is selected, you will be able to access the **Formulary Maintenance Start Page**.

Exhibit 3 *Formulary Maintenance Start Page*



The following links will be available from the left navigation bar:

- Outlier Justification Submission -- Allows you to complete Outlier Justification Submissions for one Formulary ID at a time.
- Reports -- Allows you to access the Outlier Justification Submission History Report.
- Documentation -- Allows you to access the Outlier Justification Submission User Manual.
- Help -- Allows you to access the Outlier Justification Submission on-line Help files.

3 Submit Outlier Justifications

When you click on the “Outlier Justification Submission” link from the left navigation bar, the **Outlier Justification Formulary Selection** page will display. This page allows you to select a formulary for submission of Outlier Justifications.

Exhibit 4 **Outlier Justification Formulary Selection Page**

HPMS: Formulary Maintenance - Outlier Justification Formulary Selection - Microsoft Internet Explorer provided by CGI Federal

File Edit View Favorites Tools Help

HPMS **Health Plan Management System** Home

Outlier Justification Submission

Outlier Justification Formulary Selection

Select a Formulary

1. Select one Formulary ID.
2. Click Next.

Formulary ID: (-Select a Formulary ID-)
(-Select a Formulary ID-)
00090022
00090061

Top of Page
Back

The following fields will be displayed on the Outlier Justification Formulary Selection page.

Field	Definition
Formulary ID	Drop Down. Displays formularies for which you can submit Outlier Justifications. Only one Formulary ID may be selected.

Please complete the following steps to view search results:

Step 1. Select a “Formulary ID” from the drop down. Only one Formulary ID can be selected from this

page.

Step 2. Click the “Next” button to view the Outliers requiring Justification for the selected formulary. The

Outlier Justification Details Page will display.

3.1 Outlier Justification Details

The Outlier Justification Details page allows you to provide details as to how you will address potential formulary issues identified by CMS. For each potential issue, you must select “Yes” or “No” from the “Resubmission? (Yes/No)” drop down and enter a Resubmission Comment or Justification. Selecting a “Yes” indicates that you will modify your formulary resubmission to appropriately address the listed potential issue. You must also enter a brief Resubmission Comment that describes how you modified your formulary file to address the potential issue. Selecting “No” indicates that you do not intend to modify your formulary submission and thus you must provide a detailed clinical justification that supports the submitted formulary structure and content.

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Note: You must address all potential issues that are available for justification submission by the listed deadline.

Exhibit 5 Outlier Justification Details Page

HPMS: Formulary Maintenance - Outlier Justification Details - Microsoft Internet Explorer provided by CGI Federal

File Edit View Favorites Tools Help

HPMS **Health Plan Management System** Home

Outlier Justification Details

1. Select a Resubmission Yes/No Option.
2. Enter a Resubmission Comment/Justification.
3. Click Submit.

Formulary ID - Version 00090061 - v1

Issue	Deadline Date	Detail 1	Detail 2	Detail 3	Resubmission? (Yes/No)	Resubmission Comment/Justification
Discrimination Review	04/03/2008	Antibacterials	Tetracyclines		<input type="text"/>	<input type="text"/>
Six Classes Review	04/03/2008	SAQUINAVIR MESYLATE			<input type="text"/>	<input type="text"/>
Two Drugs Requirement	04/03/2008	ANTINEOPLASTICS	RETINOIDS		<input type="text"/>	<input type="text"/>

Submit Reset Export to Excel Select Another Formulary

Go To: [HPMS Home](#) | [Formulary Maintenance Home](#) | [Outlier Justification Submission](#) | [Reports](#) | [Documentation](#)

The following fields will be displayed on the Outlier Justification Detail Page.

Field	Definition
Formulary ID – Version	Display Only. Displays the Formulary ID and Version selected.
Issue	Display Only. Displays the Issue which generated with the Outlier.
Deadline Date	Display Only. Displays the date by which the Outlier Justification must be submitted.
Detail 1	Display Only. The first Detail Level associated with the Issue.
Detail 2	Display Only. The second Detail Level associated with the Issue.
Detail 3	Display Only. The third Detail Level associated with the Issue.
Resubmission? (Yes/No)	Drop Down. Yes or No selection must be made to indicate whether a new version of the formulary will be submitted to address the Outlier.
Resubmission	Text Field. Allows you to enter a Resubmission Comment or Clinical

Comment/Justification	Justification. Field completion is mandatory and the maximum character length is 2000. You may copy and paste text into the text field.
Submit Button	Finalizes the submission. Allows Outlier Justifications to be submitted for CMS evaluation.
Reset Button	Removes any Resubmission? (Yes/No) selection(s) and removes any Comment/Justification entries prior to submission.
Select Another Formulary Button	Returns the user to the Outlier Justification Formulary Selection Page. Note: If this option is selected prior to submitting active Outlier Justifications, the active Outlier Justifications will not be saved.

Exhibit 6 Outlier Justification Details Page

HPMS: Formulary Maintenance - Outlier Justification Details - Microsoft Internet Explorer provided by CGI Federal

File Edit View Favorites Tools Help

HPMS **Health Plan Management System** Home

Outlier Justification Details

1. Select a Resubmission Yes/No Option.
2. Enter a Resubmission Comment/Justification.
3. Click Submit.

Formulary ID - Version 00090061 - v1

Issue	Deadline Date	Detail 1	Detail 2	Detail 3	Resubmission? (Yes/No)	Resubmission Comment/Justification
Discrimination Review	04/03/2008	Antibacterials	Tetracyclines		Yes	You may use this field to enter your Resubmission or Justification Comment.
Six Classes Review	04/03/2008	SAQUINAVIR MESYLATE			No	You may use this field to enter your Resubmission or Justification Comment.
Two Drugs Requirement	04/03/2008	ANTINEOPLASTICS	RETINOIDS		Yes	You may use this field to enter your Resubmission or Justification Comment.

Submit Reset Export to Excel Select Another Formulary

Go To: [HPMS Home](#) | [Formulary Maintenance Home](#) | [Outlier Justification Submission](#) | [Reports](#) | [Documentation](#)

4 Reports

Via the **Outlier Justification Submission module**, you will be able to access a history report for all CMS identified formulary issues that have ever been available for justification. You will be able to access the History Report by selecting the “Reports” link from the left navigation bar. The History Report will allow you to select one or multiple formularies and the report will open in Microsoft Excel.

Exhibit 7 Report Selection Page

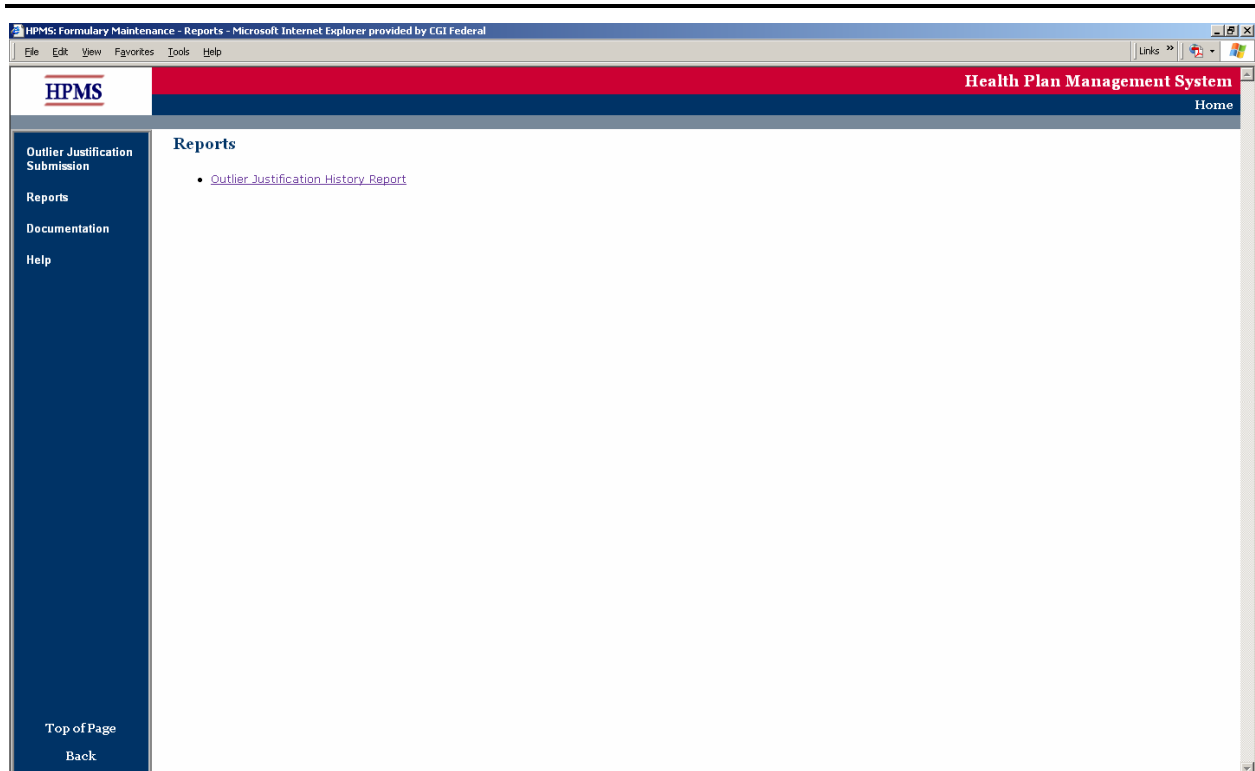


Exhibit 8 Outlier Justification History Report - Selection Page

HPMS: Formulary Maintenance - Outlier Justification History Report - Selection Page - Microsoft Internet Explorer provided by C

File Edit View Favorites Tools Help

HPMS Health Plan Management System Home

Outlier Justification Submission

Reports

Documentation

Help

Outlier Justification History Report - Selection Page

Select Formulary

1. Select Formulary ID.
2. Click Next.

Formulary ID:

Select one or more Formulary IDs

00090013
00090014
00090022
00090060
00090061

Next

Top of Page
Back

The following fields are available on the **Outlier Justification History Report** Selection Page.

Field	Definition
Formulary ID	A list box with Formulary IDs. You may select one or many. If none are selected, the system will display all.

Please complete the following steps to view search results:

1. Select one or many Formulary IDs. Use the CTRL key to select multiple formularies.
2. Click the “Next” button to view search results in Microsoft Excel.

Note: If no formularies are selected and you click the “Next” button, all Formulary IDs in the list will be displayed in the Excel file.

The following fields are displayed in the **Outlier Justification History Report** (Excel):

Field	Definition
Formulary ID – Version	Displays the Formulary ID and Version for the Outlier Justification(s).
Issue	Displays the Issue which generated the Outlier.
Submission Date	Displays the date the Outlier Justification was submitted for CMS evaluation.
Detail 1	Displays the first Detail Level associated with the Issue.
Detail 2	Displays the second Detail Level associated with the Issue.
Detail 3	Displays the third Detail Level associated with the Issue.
Resubmission (Y/N)	Displays the Resubmission Yes or No selection for the Outlier.
Resubmission Comment/Justification	Displays the Resubmission Comment or Justification Comment for the Outlier.
Gate Open Date	Displays the date the “Gate” for Outlier Justification was opened.
Gate Close Date	Displays the date the “Gate” for Outlier Justification was closed.

5 Documentation

Via the OJS module, you will be able to access an on-line **Outlier Justification Submission User Manual**. This document is in Portable Document Format (PDF) format. In order to read this document you will need Adobe Reader. This program is available for download from the following link <http://www.adobe.com/products/acrobat/readstep2.html>.

Exhibit 9 Documentation

