

Open Payments Quick Reference Guide

Requesting or Updating a Delay in Publication

Introduction

This quick reference guide provides a high-level overview of how applicable manufacturers and applicable group purchasing organizations (GPOs), hereafter collectively referred to as “reporting entities,” can request a delay in the publication of new general and research payment records for one year or update the delay in publication status of existing general and research payment records for another year, up to a total of four years.

Prerequisites

- User is registered in the CMS Identity Management system (IDM) and obtained access to the Open Payments system.
- Reporting entity is registered in the Open Payments system.
- Reporting entity has recertified in the Open Payments system, if necessary.
- Reporting entity has submitted data to the Open Payments system.
- User holds the role of submitter.

Actions

Eligibility for Delay in Publication

Reporting entities may have the publication of a payment record delayed if the payment or other transfer of value is related to:

- Research or development of a new drug, device, biological, or medical supply;
- Research or development of a new application of an existing drug, device, biological, or medical supply; or
- Clinical investigations regarding a new drug, device, biological, or medical supply.

Note: Records are only eligible to be delayed for four years from the time of payment (i.e., the record’s program year).

Last Modified: January 2022

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Initially Requesting a Delay in Publication

When submitting a new record, you can request a delay in its publication as part of the record creation process if it is eligible for delay.

Requesting a Delay in Publication via Manual Data Entry

- During manual entry of a record, you can request a delay in publication for that record using the “Delay in Publication of Research Payment Indicator” drop-down list. Select either “R&D on New Product” or “Clinical Investigation on New Product” as appropriate.
 - For general payment records, the “Delay in Publication of Research Payment Indicator” drop-down list is found on the “General Record Information” page.
 - For research payment records, the “Delay in Publication of Research Payment Indicator” is found on the “Research Payment or Other Transfer of Value Information” page.
 - Ownership/investment records cannot be delayed.
- If you are requesting a delay for a general payment record, enter the name of the research study in the “Contextual Information” field as well as any additional information you deem helpful or appropriate regarding the payment or other transfer of value.

Requesting a Delay in Publication via Bulk File Upload

- When creating a record for bulk file upload, populate the “Delay in Publication of Research Payment Indicator” field with a ‘1’ to request a delay because the record relates to research and development on a new product or a ‘2’ to request a delay because the record relates to a clinical investigation on a new product.
- If the record is a general payment record, provide the name of the research study in the “Contextual Information” field as well as any additional information about the payment that might be helpful.
- If the record is a research payment record, populate the fields “Name of Study” and “Context of Research.” In the “Context of Research” field, provide any additional information about the payment that might be helpful.

Last Modified: January 2022

Updating a Delay in Publication

You may request that payment records have their publication delayed for up to four years after the date of payment. However, the request for a delay must be renewed each year.

If a delay in publication request is not renewed by the end of the data submission period each year, the record will be automatically flagged for publication in the next publication cycle.

Records eligible for a renewal in delay of publication are marked with one of two Delay in Publication Indicator statuses during the submission period: “Pending Renewal – R&D on New Product” or “Pending Renewal – Clinical Investigation on New Product.”

If these records do not have their delays in publication renewed by the end of the submission period, their Delay in Publication Indicator status will change to “Delay Not Renewed – R&D on New Product” or “Delay Not Renewed – Clinical Investigation on New Product”. Records with “Delay Not Renewed” status will be eligible for publication in the next publication cycle.

If a record is no longer eligible for a delay in publication because four calendar years have passed since the date of payment, the Delay in Publication Indicator status will be updated to “No Delay – R&D on New Product – Limit Reached” or “No Delay – C.I. on New Product – Limit Reached.” Delayed records that are no longer eligible for a delay but are in “Returned to Submitter” status will not be updated to a “Limit Reached” delay status. These records must be edited and the Delay in Publication Indicator changed to “No Delay Requested” as they are no longer eligible.

You may also request that records previously delayed for publication be published. Those records will have their Delay in Publication status updated to “No Delay Requested” and become eligible for publication in the next publication cycle.

After updating the delay in publication value for a record or records, the records for that program year must be attested to again for the update in delay status to be accepted. Refer to the quick reference guide “Final Submission and Attestation” for additional guidance on attestation.

Finding Records Eligible for Delay in Publication Renewal

To find which records previously delayed for publication are eligible for a delay in publication renewal, follow the steps below.

1. Log in to the Open Payments system via the CMS Enterprise Portal at <https://portal.cms.gov>. Select the “Submissions” tab on the menu bar.
2. Under the “Review Submitted Payment Records” section on the “Submissions” page, select the payment type (General or Research), the entity whose records you wish to review, and the

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program year for those records, and then select the “Review Detail” button. Note: delays in publication can only be requested for general and research payment records.

3. Search for the records eligible for renewal on the “Payment Category” page (i.e., Research Payments page or General Payments page) by using the “Delay in Publication Indicator” filter above the data table to search for records with a Delay in Publication status of either “Pending Renewal – R&D on New Product” or “Pending Renewal – C.I. on New Product.” You may also select any other search filter(s) as appropriate.

Updating a Delay In Publication Indicator via Bulk File Upload

Users can update the Delay in Publication Indicator of existing eligible record(s) by setting the “Resubmission File Indicator” field to Resubmission (“Y”) or Renew Delay in Publication (“R”) in the bulk file. If a record is not eligible, an error will be issued.

Note: Before preparing the bulk file to update delays in publication, refer to the “Resubmission File Indicator” area of the Submission Data Mapping Documents for details on required fields.

Update Delay in Publication Indicator Using Delay in Publication Resubmission File Indicator (“R”)

This process can be used to update the Delay in Publication Indicator on eligible records in “Ready for Submission”, “Ready for Attestation”, or “Attested” record status. Records renewed via this process will not be sent through the matching process nor will they be revalidated. The record will be unchanged by this process except for the update in Delay in Publication Indicator and the record’s status set to “Ready for Submission.” If a record is for a program year that is not eligible for delay, the user will receive an onscreen error message when they attempt to submit the file and the file will not be uploaded into the Open Payments system. The record must be edited to change the Delay in Publication Indicator to “No Delay Requested.”

1. Create a bulk file for the record(s) which you wish to update, with the “Resubmission File Indicator” set to “R” and the “Resubmitted Payment Record ID” field containing the Open Payments record ID that you want to update.

Refer to the “Resubmission File Indicator” area of the Submission Data Mapping Document for details on required fields.

Note: All records in the bulk file must have the same “Resubmission File Indicator” value.

- a. To Renew a Delay in Publication: Set the “Delay in Publication of Research Payment Indicator” to ‘1’ if you are requesting a delay because the record relates to research and development on a new product, or ‘2’ if you are requesting a delay because the record relates to a clinical investigation on a new product.

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- b. To Indicate a Delay is No Longer Requested: Set the value to '3,' which indicates no delay is requested.

Note: This process cannot be used to change the Delay in Publication Indicator value from "3= No Delay Requested" to "1= R&D on new Product" or "2= Clinical Investigation on New Product." Attempts to do so will be rejected and the user will receive notification of the error via email. To change the Delay in Publication Indicator value from '3' to '1' or '2', follow the process described in the *Update Delay in Publication Indicator Using Resubmit Resubmission File Indicator ("Y")* section of this document.

- 2 Log in to the Open Payments system via the CMS Enterprise Portal at <https://portal.cms.gov/> and select the "Submissions" tab on the toolbar. Select "Bulk File Upload."
- 3 On the "Upload Records" page, select the Payment Category, Reporting Entity, and Program Year for the bulk file. For the Resubmission File Indicator dropdown, select "Renew Delay in Publication." Select the appropriate file to upload, then select "Submit File to Open Payments."
- 4 You will receive email notifications regarding your file and record processing statuses. If there are records that fail file or record level validations, you will receive an email identifying the issue. Review the emails to determine the issues, correct the records, and resubmit accordingly. For more details, refer to the quick reference guides "Identifying Validation and Matching Errors" and "Correcting Validation and Matching Errors."
- 5 Once all records have been successfully loaded, they will be set to "Ready for Submission" status. To complete the submission process, proceed with final submission of these records and re-attestation of all records for that program year. Refer to the quick reference guide "Final Submission and Attestation" for instructions on how to complete re-attestation.

Update Delay in Publication Indicator Using Resubmit Resubmission File Indicator ("Y")

The resubmission process described below can be used to update most data elements in the record, including the Delay in Publication Indicator.

Eligible records updated via this process will go through the entire matching and validation process upon resubmission, and are not restricted to records in certain record statuses.

Ineligible records that are submitted with the Resubmission File Indicator set to "Y" (Resubmission) and a request for a delay in publication will fail validation checks. The submitters will receive an email notification of the records' failure and an error log file will be created for the file. The failed records

must be edited to change the Delay in Publication Indicator to “No Delay Requested” and resubmitted again.

1. When preparing the file, set the “Resubmission File Indicator” to "Y" and enter the Open Payments record ID created for the record after its initial submission in the "Resubmitted Payment Record ID" field.
2. In the bulk data file, set the value for the “Delay in Publication of Research Payment Indicator” field:
 - a. To Renew a Delay in Publication: Set the value to ‘1’ if you are requesting a delay because the record relates to research and development on a new product, or ‘2’ if you are requesting a delay because the record relates to a clinical investigation on a new product.
 - b. To Indicate a Delay is No Longer Requested: Set the value to ‘3,’ which indicates no delay is requested.
3. For a general payment record, if you are selecting a value of ‘1’ or ‘2’, ensure that the name of the research study is displayed in the “Contextual Information” field, as well as any additional information you deem helpful regarding the payment or other transfer of value.

Note: “Contextual Information” is not required if you select a value of ‘3.’

4. Log in to the Open Payments system via the CMS Enterprise Portal at <https://portal.cms.gov/> and select the “Submissions” tab on the toolbar. Select “Bulk File Upload.”
5. On the “Upload Records” page, select the Payment Category, Reporting Entity, and Program Year for the bulk file. For the Resubmission File Indicator dropdown, select “Resubmission”. Select the appropriate file to upload. Select “Submit File to Open Payments.”

You will receive email notifications regarding your file and record processing statuses. If the file fails file-level validations or records in the file fail record-level validations, including a validation that records are eligible to be delayed, you will receive an email identifying the issue. Review the email to determine the issues, correct the records, and resubmit accordingly. For more details, refer to the quick reference guides “Identifying Validation and Matching Errors” and “Correcting Validation and Matching Errors.”

6. If the file uploads successfully, you can complete the submission process by putting the file through final submission and re-attesting to the records for that program year. Refer to the

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quick reference guide “Final Submission and Attestation” for instructions on how to complete re-attestation.

Updating the Delay in Publication Indicator via Manual Data Entry – Using Edit Functionality

To manually update the delay in publication status for eligible records using the record edit functionality, follow the steps below. Users will receive an on-screen error message if they select to delay the publication of a record that is not eligible for a delay. The record’s Delay in Publication Indicator must be changed to “No Delay Requested.”

Records updated via this process will go through the entire matching and validation process.

1. Log in to the Open Payments system via the CMS Enterprise Portal at <https://portal.cms.gov/> and select the “Submissions” tab on the toolbar. On the “Review Submitted Payment Records” menu, select payment type (General or Research), the reporting entity whose record you wish to view, and the program year for that record, and then select “Review Detail.”
2. Locate the record you wish to update in the data table, using the filtering tools if necessary. Select “Edit” from the “Actions” column for that record.
3. If it is a general payment record, navigate to the record’s “General Record Information” page by selecting “Continue.” If it is a research payment record, navigate to the “Research Payment or Other Transfer of Value Information” page by selecting “Continue.”
 - a. To Renew a Delay in Publication: From the “Delay in Publication of Research Payment Indicator” drop-down, select either “R&D on New Product” or “Clinical Investigation on New Product.” For a general payment record, ensure that the name of the research study is displayed in the “Contextual Information” field, as well as any additional information you deem helpful or appropriate regarding the payment or other transfer of value.
 - b. To Indicate No Delay is requested: Select “No Delay Requested” from the “Delay in Publication of Research Payment Indicator” drop-down. The record will then be eligible for publication in the next publication cycle.
4. Select “Continue to Review,” then “Save Record” to save the changes. Edited records will go through the validation and matching process.

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5. Re-attest to the data for the program year. Refer to the quick reference guide “Final Submission and Attestation” for instructions on how to complete re-attestation.

Updating the Delay in Publication Indicator via Manual Data Entry – Using Delay in Publication Update Functionality

You can update the delay of publication of multiple eligible General and Research Payment record(s) from the “Payment Category” page. The records must be in the “Ready for Submission”, “Ready for Attestation”, or “Attested” status. This functionality will not be available for records that are not eligible for a delay in publication. To manually update the delay in publication status of records in other statuses, you must use the process described in the section *Updating the Delay in Publication Indicator via Manual Data Entry – Using Edit Functionality*, above.

Records updated through this process do not undergo re-validation and re-matching.

Note: This process cannot be used to change the Delay in Publication Indicator value from “3= No Delay Requested” to “1= R&D on new Product” or “2= Clinical Investigation on New Product.”

1. Log in to the Open Payments system via the CMS Enterprise Portal at <https://portal.cms.gov/> and select the “Submissions” tab on the toolbar. On the “Review Submitted Payment Records” menu, select payment type (General or Research), the reporting entity whose record you wish to view, and the program year for that record, and then select “Review Detail.”
2. Locate and select the records you wish to update in the data table, using the filtering tools if necessary.
3. Select the “Update Delay Indicator” button.
4. The “Update Delay in Publication Indicator” page will be displayed. From the drop-down menu “Delay in Publication Indicator”, select one of three options:
 - R&D on New Product;
 - Clinical Investigation on New Product; or
 - No Delay Requested.
5. The status of the records will be updated to “Ready for Submission”.

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6. Re-attest to the data for the program year. Refer to the quick reference guide “Final Submission and Attestation” for instructions on how to complete re-attestation.

Delay in Publication – Publication Impact

The publication impact of the Delay in Publication statuses is as follows:

- Records with a Delay in Publication status of “Delay Requested” will not be published in the next publication cycle.
- Records with a Delay in Publication status of “No Delay Requested,” “No Delay – R&D on New Product – Limit Reached,” or “No Delay – C.I. on New Product – Limit Reached” will be published in the next publication cycle.
- If no action is taken on records with a Delay in Publication status of “Pending Renewal” by the end of the submission period, the records will be eligible for publication. These records will be published in the next publication cycle.

Next Steps

- Review and update records eligible for a delay in publication.

Additional Resources

All data submission resources are available on the Resources page of the Open Payments website at <https://www.cms.gov/OpenPayments/About/Resources.html>.

The “Data Submission and Attestation” section of the Open Payments User Guide for Reporting Entities covers the entire data delay in publication process in detail and provides step-by-step instructions for various scenarios.

Quick reference guides relevant to delay in publication include:

- Payment Category Page
- Bulk File Upload
- Manual Data Entry
- Identifying Validation and Matching Errors
- Correcting Validation and Matching Errors

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- Record Deletion
- Final Submission and Attestation

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Disclosure

- **Disclaimer:** The contents of this document do not have the force and effect of law and are not meant to bind the public in any way unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law.
- **Activities/persons addressed by this document:** Guidance of how applicable manufacturers and applicable group purchasing organizations, can request a one-year delay in publication for eligible payment records and instructions on how to request a renewal of the delay after a previous one expires.
- **Date of Issuance:** January 2022
- **Replacement / Revision Status:** Revision to previous versions
- **Agency Identifier:** CPI DASG/CPI DTP/DASG/CPI 1586
- **Summary of Document:** Overview of how applicable manufacturers and applicable group purchasing organizations, can request a one-year delay in publication for eligible payment records and instructions on how to request a renewal of the delay after a previous one expires.
- **Citation to statutory provision/regulation applicable to this document:**
 - **Statute citation:** Social Security Act SEC. 1128G. [42 U.S.C. 1320a-7h]
 - **Rule citation:** 42 C.F.R. §403.900-14

Last Modified: January 2022