Open Payments System Enhancements

Introduction

The Open Payments system has been enhanced to improve user experience and increase system functionality. This document explains the enhancements and improvements that directly affect end users.

1. Business Types updated to Applicable Manufacturer – Physician-Owned Distributorship and Group Purchasing Organization – Physician Owned Distributorship

Previous System Behavior: Applicable Manufacturers and applicable Group Purchasing Organizations (GPOs) are required to register and create a profile for their entity within the Open Payments system in order to submit payments. During registration, the entity is required to select a "Business Type" that is auto-populated in the dropdown based on their selection of Reporting Entity Type of Applicable Manufacturer or GPO.

The Entity Business Type indicates the type of Applicable Manufacturer or applicable GPO registering in Open Payments. Entities selected whether the type is any of the following:

- Applicable Manufacturer
  If applicable manufacturer is selected, an entity must select one of the following business types:
  – applicable manufacturer-drugs/biologicals
  – applicable manufacturer-devices/medical supplies
  – applicable manufacturer-drugs/biologicals and devices/medical supplies
  – applicable manufacturer-physician-owned distributor
  – applicable manufacturer-hospital-owned distributor
  – applicable manufacturer-distributor/supplier (non-hospital, non-physician-owned)

- Applicable GPO
  If GPO is selected, an entity must select one of the following business types:
  – GPO-drugs/biologicals
  – GPO-devices/medical supplies
  – GPO-drugs/biologicals and devices/medical supplies
  – GPO-physician-owned
  – GPO-hospital-owned
  – GPO-hospital and physician-owned
  – GPO-non-hospital, non-physician-owned
  – GPO-government-owned

Enhanced System Behavior: The Open Payments system is updated to enhance the text used in the "Business Type" dropdown during Entity Registration and manage entity updates. Entities may select a type from any of the following:

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- Applicable Manufacturer
  If applicable manufacturer is selected, an entity must select one of the following business types:
  − applicable manufacturer-drugs/biologicals
  − applicable manufacturer-devices/medical supplies
  − applicable manufacturer-drugs/biologicals and devices/medical supplies
  − applicable manufacturer-physician-owned distributorship
  − applicable manufacturer-hospital-owned distributor
  − applicable manufacturer-distributor/supplier (non-hospital, non-physician-owned)

- Applicable GPO
  If GPO is selected, an entity must select one of the following business types:
  − GPO-drugs/biologicals
  − GPO-devices/medical supplies
  − GPO-drugs/biologicals and devices/medical supplies
  − GPO-physician-owned distributorship
  − GPO-hospital-owned
  − GPO-hospital and physician-owned
  − GPO-non-hospital, non-physician-owned
  − GPO-government-owned

2. New required 'Reason for Deletion' field for deletion of files and attested records

Previous System Behavior: Applicable Manufacturers and GPO users could delete attested records within the Open Payments system. Attested records could be deleted by deleting files, uploading a file via Bulk File Upload, or manually deleting individual records. Applicable Manufacturers and GPO users were neither required nor able to provide a reason when deleting attested records.

Enhanced System Behavior: A new required field is added to the system when an Applicable Manufacturer or GPO user deletes files or attested records from the Open Payments system. The required field is titled "Reason for Deletion" and contains a dropdown list of reasons for deleting a file/attested record. Applicable Manufacturer/GPO users are required to select one or more reasons for deleting the files/attested record(s), depending on the method of deletion. When an Applicable manufacturer/GPO user deletes a file or delete records using bulk file upload, one or more reasons can be selected. When an Applicable Manufacturer/GPO deletes attested records manually, the user will be required to select a single reason before proceeding.

3. Review and Dispute Contact Information updated for Reporting Entities to require specific fields

Previous System Behavior: When an Applicable Manufacturer/GPO user registered or updated the information of a reporting entity, the user was required to enter contact information for the purposes of Review and Dispute. This contact information is displayed to Covered Recipient users

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for inquiries or disputes regarding submitted payments or other transfers of value.

Enhanced System Behavior: Specific review and dispute contact information fields are added to the Register Entity page. Reporting Entities are required to enter information in each field when registering or recertifying. A summary of changes is listed below:

- Specific review and dispute contact information fields replace the current free-form text box. Reporting entities are required to enter information in each field for a primary point of contact. Reporting entities also have the option to enter information for a backup point of contact. Validations are introduced to the required fields and UI error messages will be displayed if the fields fail validation.

- Review and dispute contact information on-screen text is updated for applicable manufacturer and GPO users to provide additional instructions when registering and updating an entity.

- The new review and dispute contact information fields are displayed to Covered Recipients on the review and dispute Record ID page.

4. Removed the ability to delay General Payments

Previous System Behavior: Applicable manufacturers and GPOs could request a delay to the publication of both General and Research payments. A delay in publication can be requested annually up to a period of four years from the date of the payment. Payments can be delayed either manually or via Bulk File Upload. Delayed records are included in the next publication following the non-renewal or expiration of the delay.
Records are eligible for a delay in publication only if they relate to one of the following criteria:

- 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.

- Clinical investigations regarding a new drug, device, biological, or medical supply.

Enhanced System Behavior: The functionality to delay the publication of General Payments is removed and is effective for all program years. All General Payments previously eligible for a delayed publication will not be renewed and the records will be included in the June 2024 publication . For all records going forward, regardless of the program year of the record, general payment records cannot be delayed. This means that even if a company delayed a general payment record in Program Year 2022, it will no longer be able to be delayed in Program Year 2023.

The field name that is used for storing the Delay Indictor for both General and Research payments is titled "Delay in Publication of Research Payment indicator".

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5. General Payments Nature of Payment update - ability to submit ownership records removed

Previous System Behavior: The Open Payments system requires the Nature of Payment to be specified during the submission of General Payments.

For PY2013 – PY2020, entities may select whether the type is any of the following from the Nature of Payment Categories:
- "1" = Consulting Fee;
- "2" = Compensation for services other than consulting, including serving as faculty or as a speaker at a venue other than a continuing education program;
- "3" = Honoraria;
- "4" = Gift;
- "5" = Entertainment;
- "6" = Food and Beverage;
- "7" = Travel and Lodging;
- "8" = Education;
- "9" = Charitable Contribution;
- "10" = Royalty or License;
- "11" = Current or prospective ownership or investment interest
- "12" = Compensation for serving as faculty or as a speaker for an unaccredited and non-certified continuing education program.
- "13" = Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program.
- "14" = Grant;
- "15" = Space rental or facility fees (teaching hospital only);

For PY2021 and Onwards, entities may select whether the type is any of the following from the Nature of Payment Categories:
- "1" = Consulting Fee;
- "2" = Compensation for services other than consulting, including serving as faculty or as a speaker at a venue other than a continuing education program;
- "3" = Honoraria;
- "4" = Gift;
- "5" = Entertainment;
- "6" = Food and Beverage;
- "7" = Travel and Lodging;
- "8" = Education;
- "9" = Charitable Contribution;
- "10" = Royalty or License;
- "11" = Current or prospective ownership or investment interest
- "14" = Grant;
- "15" = Space rental or facility fees (teaching hospital only);
- "16" = Compensation for serving as faculty or as a speaker for a medical education program

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- "17" = Debt forgiveness
- "18" = Long term medical supply or device loan
- "19" = Acquisition

The Nature of Payment is a required field for general payment submission. One of the above listed Nature of Payment categories needs to be selected in both manual and bulk submission. If there is no option selected, then the user will get an error message.

Enhanced System Behavior: Open Payments updated the Nature of Payment categories to remove "11" = Current or prospective ownership or investment categories for Program Year 2023-onwards. *This payment category is still available and editable for Program Years 2018 – 2022.*

- Beginning with Program Year 2023, "Current or prospective ownership or investment" is not available as a Nature of Payment option for General Payment records.

- The Nature of Payment category, "Current or prospective ownership or investment" reportable and editable for Program Years 2018 – 2022.

6. Context Field added for Teaching Hospital Payment

Previous System Behavior: Previously, there was not a teaching hospital payment context field, nor was there a requirement for applicable manufacturers to provide a description of the payment or transfer of value.

Enhanced System Behavior: A "Context of Teaching Hospital Payment" text box field is added and required for Reporting Entities to use when submitting a payment or transfer of value to a Teaching Hospital for Program Year 2023 and onwards. Reporting Entities are required to enter information in the field when submitting any General or Research Payment associated with a Teaching Hospital. If the Teaching Hospital Context Field is not completed, the user will receive an error message and will not be able to proceed with submitting the record until this field is completed .

7. Ability to track deleted records and link them to new records submitted

Previous System Behavior: There was not a way within the Open Payments system to track the previously deleted records and link them with newly submitted records.

Enhanced System Behavior: The Open Payments system is enhanced with a feature to track deleted records and link them to new records.
The following enhancements are made to the Open Payments system.

- Two new fields are introduced as input fields to be received from the users in both UI/Bulk submission template
  - The first new field is a Yes/No indicator to tell if the record was previously attested and then deleted, and then later newly submitted

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- If the value of the indicator is selected as "Yes", then, a new text field is displayed for the reporting entity to provide the Record ID of previously deleted record

8. Allow Reporting Entities to indicate they have no records to report for a Program Year

Previous System Behavior: Applicable manufacturers and GPOs could recertify within the Open Payments system however, they did not have the option to indicate or attest that they do not have any reportable payments or transfers of value or ownership and investment interest to report for the current or previous program year(s).

Enhanced System Behavior: The Open Payments system is enhanced to allow active applicable manufacturers and GPO officers and attesters to indicate that their entity does not have any payments or transfers of value or ownership and investment interest to report starting with Program Year 2023 for all Program Years.

9. Application User Roles expanded to support updates with Remote Identity Proofing (RIDP)

Previous System Behavior: Previously, users selected one role to gain access to the Open Payments application, and the users were required to pass RIDP.

- Role: Applicable Manufacturer, GPO, Physician, Non-Physician Practitioner, or Teaching Hospital.

Enhanced System Behavior: Now there are three user roles to gain access to the Open Payments system with one role limited to RIDP verification. The roles and descriptions are as follows:

Reporting Entity Officer or Teaching Hospital Authorized Official Role: Only US users that will be registering a NEW reporting entity profile (applicable manufacturer or applicable group purchasing organization not already registered in the Open Payments system) or a NEW teaching hospital profile, should choose this role.

Physician, Non-Physician Practitioner, Teaching Hospital Authorized Representative, or Reporting Entity Submitter/Attester/Compliance Role: Only US and foreign (those users that do not have a US-based address and/or a US Social Security number) physicians, non-physician practitioners, and users nominated for a role by a covered recipient/registered entity should choose this role including reporting entity officers and teaching hospital authorized officials who were nominated (or are self-nominating). Users who will be registering a NEW reporting entity profile (applicable manufacturer or applicable group purchasing organization) or users registering a NEW teaching hospital profile should NOT choose this role.

Open Payments Foreign User Role: Only foreign users (those users that do not have a US-

based address and/or a US Social Security number) who will be registering a NEW reporting entity profile (applicable manufacturer or applicable group purchasing organization) not already registered in the Open Payments system) or a NEW teaching hospital profile, should choose this role. Note: After selecting this role, users should wait for an email from the Open Payments Help Desk that will provide additional information.

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 for applicable manufacturers and applicable group purchasing organizations on overview of the Open Payments system and enhancements.

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