



Open Payments

Technology-Focused Webinar 3: Registration

O P E N P A Y M E N T S

C R E A T I N G P U B L I C T R A N S P A R E N C Y
I N T O I N D U S T R Y - P H Y S I C I A N
F I N A N C I A L R E L A T I O N S H I P S

December 2013

CMS Disclaimer: This information is a summary of the final rule implementing Open Payments (Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests [CMS-5060-F], codified at 42 CFR Parts 402 and 403) The summary is not intended to take the place of the final rule which is the official source for information on the program.

Agenda & Target Audience

- Agenda
 - Registration
 - Data Submission
 - Available Resources
 - Live Question & Answer Session
- Target Audience
 - Individuals who need to register in the Open Payments system
 - Individuals responsible for creating data submission files for manufacturers of drugs, devices, biologicals, or medical supplies, plus distributors, group purchasing organizations (GPOs), or other entities submitting data under Open Payments

Registration

Registration Overview

A 2-Step Process

Step 1

CMS Registration Enterprise Identity Management (EIDM)

- Obtain authorization and secure access to CMS business applications via EIDM
 - Registration
 - Authentication
 - Authorization
 - Identity Lifecycle Management
- **Open Payments will be available for selection in the EIDM early 2014**

Step 2

Open Payments Registration

- Obtain authorization and secure access to Open Payments
- **Available early 2014**

Note: Registration is required only if an applicable manufacturer or applicable GPO has payments or transfers of value to report to the program

Registering in Open Payments

- **What entities need to register?**
 - Applicable manufacturers and applicable GPOs, who are required to report in Open Payments
- **Who needs to register the entity?**
 - An individual significantly positioned within the entity to allow Open Payments to successfully vet the affiliation between the Authorized Official and the entity
- **Who needs to register?**
 - Individuals who need access to the Open Payments system to register and manage the entity, submit data, or attest to data including third party submitters
- **Is registration different for certain entities?**
 - Submitting a consolidated report
 - Outside of the United States

Who Accesses the Open Payments System?

Authorized Official

Possible Roles	What the Open Payments System Will Allow Them to Do
<ul style="list-style-type: none"> Any Authorized Representative Role Officer Role (default) 	<ul style="list-style-type: none"> Manage the entity in the Open Payments system, including registering the entity, nominating and approving the authorized representatives (may include external parties) submitting and attesting to the data May delegate these functions to another Officer May assume all roles within the Open Payments system User vetting is required

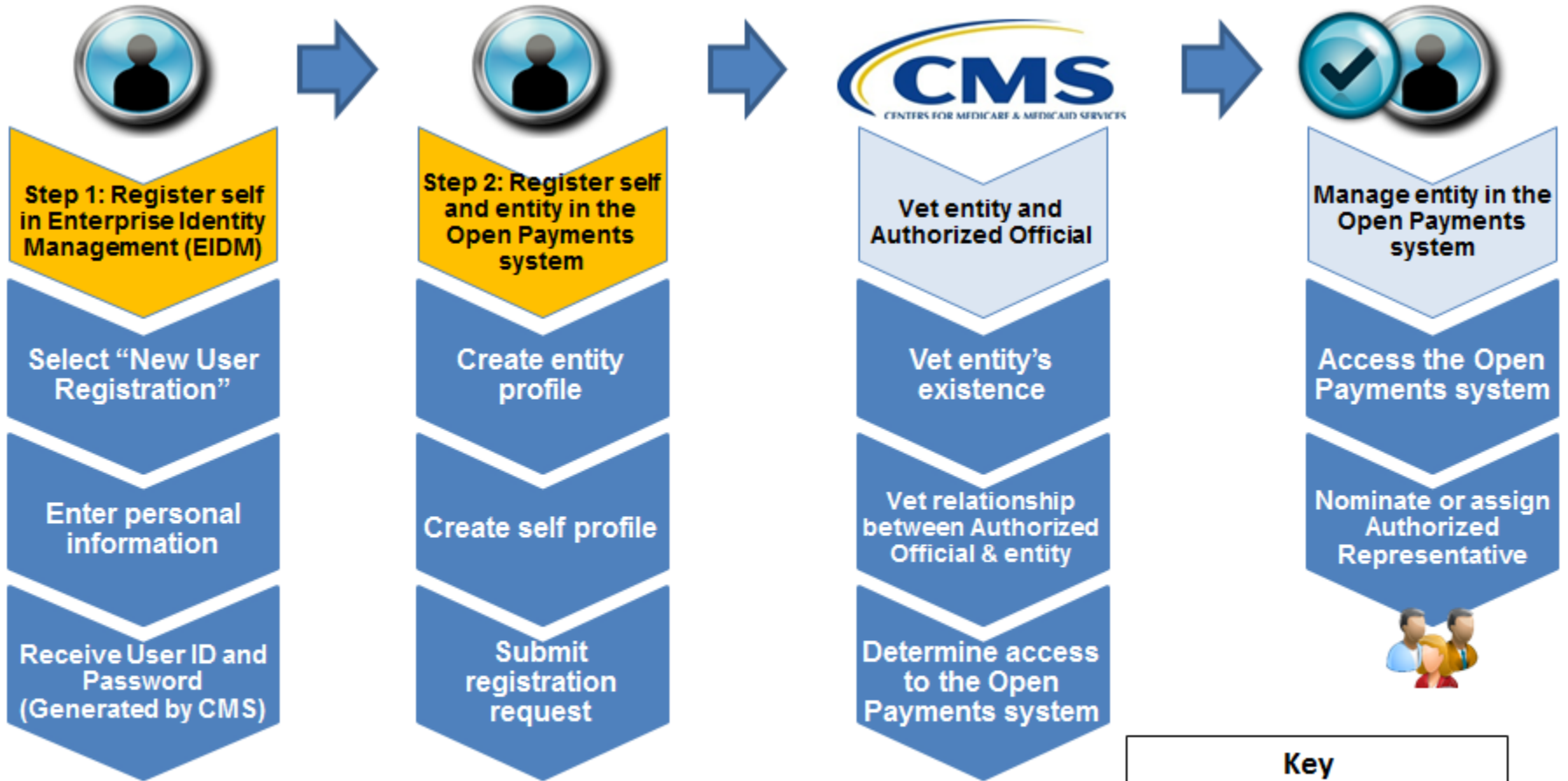
Authorized Representative(s)

Possible Roles	What the Open Payments System Allow Them to Do
Officer Role	<ul style="list-style-type: none"> Must be an Officer of the applicable manufacturer or applicable group purchasing organization (GPO) May be the Authorized Official May manage other Authorized Representatives and their user roles (includes nominate others, delete users) Must accept nomination (approval) by Authorized Official/Officer Role Manage the entity in the Open Payments system Will not be vetted by CMS unless they are the Authorized Official
Submitter Role	<ul style="list-style-type: none"> Not required to be an officer of the applicable manufacturer or applicable GPO Must accept nomination (approval) by Authorized Official/Officer Role May be the Authorized Official Submits data in Open Payments on behalf of the applicable manufacturer or applicable GPO Will not be vetted by CMS unless they are the Authorized Official
Attester Role	<ul style="list-style-type: none"> Must be an officer of the applicable manufacturer or applicable GPO May be the Authorized Official or Officer Role Must accept nomination (approval) by Authorized Official/Officer Role Attests to data in Open Payments system on behalf of the applicable manufacturer or applicable GPO

NOTE: Ten (10) users per entity, including the Authorized Official

Registration Process

For Authorized Official & Entity



- Only the Authorized Official and the entity will be vetted
- Vetting is based on the information provided during the Open Payments registration
- Vetting timing varies and may take up to an estimated 14 days
- Registration will be validated and renewed on an annual basis

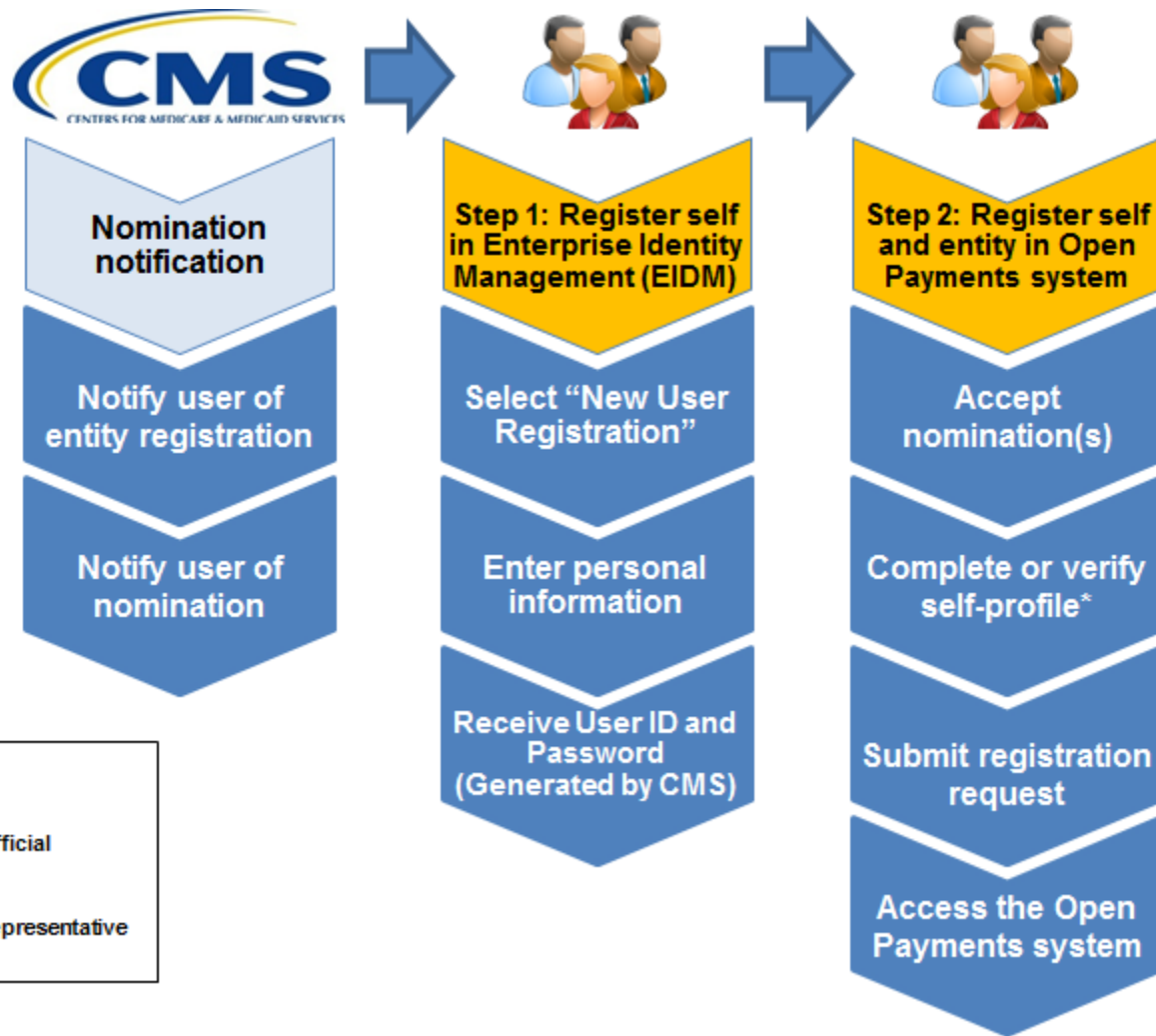


What is Vetting?

- Vetting is the process of verifying:
 - Applicable manufacturer or applicable GPO as an entity
 - Authorized Official is linked to the vetted entity
 - Authorized Official is significantly positioned to act on entity's behalf
- Successful vetting is required for successful registration
- Register early to allow time for vetting

Registration Process

For Nominated Authorized Representatives



NOTE: The Authorized Official creates the Authorized Representative's profile during nomination

What Information You Will Need When Registering?

If you are an:	Authorized Official, Authorized Representatives (Officer, Submitter, & Attester)	Entity (Applicable Manufacturer or Applicable GPO)
You will need:	<ul style="list-style-type: none"> • First name • Middle name • Last name • Name suffix • Job title • Business address • Business phone • Email address 	<ul style="list-style-type: none"> • Registering entity legal name • Doing business as (DBA) name • Registering entity business address • Registering entity business telephone number • Taxpayer Identification Number (TIN)/Employer Identification Number (EIN) • D&B D-U-N-S® Number • Food and Drug Administrator (FDA) Establishment Identifier (FEI) • Uniform Resource Locator (URL) of Parent Company • Consolidated Report Indicator (Y/N) (default to N)

NOTE for Applicable manufacturer and applicable GPO:

- When registering with the Open Payments system, reporting entities are required to provide both, their legal business name and doing business as (DBA) name.
- Organizational components without their own TIN and DUNS number should report under their parent legal entity's TIN and DUNS.

Tips for Completing Registration

- Information should be readily available to you when registering self and your entity (refer to prior slide)
- Ensure that all contact information provided at registration is accurate
- If your entity has a D&B D-U-N-S[®] Number, confirm that the Authorized Official is also listed in your entity's D&B profile
- If your entity does not have a D&B D-U-N-S[®] Number, CMS strongly encourages you to obtain one

Data Submission

Available Submission Resources

Document Name	Description
Submission Data Mapping Document	<ul style="list-style-type: none">• Mapping of data elements listed in the Submission File Specifications to the specific data fields in the XML and CSV sample files
Bulk Data Upload Instructions	<ul style="list-style-type: none">• Detailed instructions on how to use the XML schema, and XML and CSV sample files to bulk upload data
XML Schema and XML Samples Files	<ul style="list-style-type: none">• The XSD (XML Schema Definition) document used to create and validate XML submission files for the three payment types• A sample of the exact format (in XML files) that will be used by reporting entities to upload data into the Open Payments system
CSV Sample Files	<ul style="list-style-type: none">• A sample of the exact format (in CSV files) that will be used by reporting entities to upload data into the Open Payments system
Open Payments User Guide	<ul style="list-style-type: none">• Detailed document that includes a summary of program requirements and technical updates; chapters related to registration and submission will be added
Technology-focused Webinar Material	<ul style="list-style-type: none">• Recording of past webinars and material used during the webinar

All documents will be available on our webpage

<http://go.cms.gov/openpayments>

Data Entry

- Data can be entered (submitted) into the system in multiple sessions by:
 - Manual entry
 - Bulk file upload
 - A combination of manual entry and bulk uploads.

For example, data can be entered through bulk file upload(s) for one payment type and through manual entry for another or part of the records can be entered through bulk upload(s) and the rest can be entered manually.

- All payment records can be edited via Graphic User Interface (GUI) regardless of the method of initial submission
- Data entry though both manual and bulk uploads will be available year round for both submissions of new data and corrections to the existing data

Bulk Data Uploads

Maximum File Size

- In the first release of the Open Payments system, the maximum file size for bulk uploads is 250MBs for both CSV and XML files
- Files larger than 250MBs need to be separated into multiple files
- There is no limit on the number of files that can be uploaded

CMS is analyzing other options such as File Transfer Protocol (FTP) to increase the maximum upload size in future system releases.

Bulk Data Uploads

Filing Name Conventions

- There are no naming conventions for the uploaded files
- However, the file name:
 - Cannot exceed 50 characters
 - Cannot contain special characters prohibited and/or reserved for use in a UNIX system

Bulk Data Uploads

Recommended File Format

- Data in XML format tends to result in larger file size than its CSV equivalent
- For reporting entities with large amount of data who would like to minimize the number of files for upload, CSV would be recommended
- For smaller uploads, XML is recommended, as it provides for better data validations upfront

Bulk Data Uploads

Using CSV Files

- CSV files accepted by Open Payments are pipe (|) delimited
- The sample files and submission instructions provide detailed information related to using the pipe delimiter and the headers
- No control totals are required
- All columns specified in the sample files are required. The data within optional columns can be left blank.
- General Submission File Information should be repeated for each record in CSV files

Bulk Data Uploads

Using Microsoft Excel Files

- Excel format is not accepted, only pipe (|) delimited text file or XML files are accepted
- Excel can be used to create CSV files
 - Bulk Data Upload Instructions detail how to use the pipe (|) character as the delimiter instead of comma
 - If the delimiter is not changed to | character, Excel's default is comma, which is not accepted by the Open Payments system
- Since a specific XML Schema Definition (XSD) is used for the XML submission, in general Microsoft Excel cannot generate XML compliant with the Open Payments XSD

Bulk Data Uploads

New Submission vs. Resubmission

- The order in which files are uploaded is not important
- All files where the records do not have a pre-populated Open Payments ID and the Resubmission Flag is not set to “Y” will be treated as new submissions

Viewing and Reconciling Data

- Each payment record, whether uploaded or manually entered, is assigned an Open Payments Payment ID
 - Open Payments Payment IDs will be sent in an email notification
 - Open Payments Payment IDs can be viewed online and downloaded
- Open Payments View Submission functionality will enable viewing, searching and filtering of all payment records uploaded or manually entered through GUI
- The data can be printed using a web browser's print functionality
- No extract functionality is currently planned

Testing Submissions

- Submission of test files is not required
- Applicable manufacturers and applicable GPOs will be able to test bulk uploads in the Open Payments system after the system goes live
- Test submission:
 - Will help reporting entities determine whether the format of the files and records within the files are compliant with the Open Payments system requirements
 - Will not validate submitted data for accuracy, only the format (the fact that all required fields are included and are of specified length, data types, etc.)

Data Deletions

- Submitted records can be deleted at any time before or after the reporting deadline for as long as they are retained in the system
 - Currently, the Open Payments system plans on retaining all records for 10 years from the date of data publication on the public website
- Users will be able to delete individual payment records and entire files submitted via the View Payments page in the Open Payments system
- The user with the Submitter role can search by the File ID, Open Payments Payment ID, and/or Home System Payment ID, and then delete selected records
 - The Open Payments system will send the File ID in an email notification after processing the submission file

Changes and Re-submissions

- Changes to the data can be made through either bulk file uploads or GUI regardless of the original data entry method used
- Once submitted, data can be viewed and edited via the View Payments functionality within the Open Payments system
 - The records can then be edited as individual payment records by clicking on Edit function, which is available for the Submitters of the entity and allows users to edit individual records via the GUI

Changes and Re-submissions

(Continued)

- Users may also resubmit/edit the previously submitted data through bulk upload making sure that:
 1. The Resubmission File Indicator data element is set to “Y.” This identifies that all the information in the file will be resubmitted to the Open Payments system for processing.
 2. The Resubmitted Payment Record ID noted in the error report or being revised must be populated with the Open Payments Payment ID(s) of the record(s) being resubmitted.
 - Without the Open Payments Payment ID, the system will not be able to link the changes to the record to which they pertain.
 - If the file contains some records with Open Payments Payment ID and some without, the records without Open Payments Payment ID will be rejected. The system will notify users of the failure via email and system messages.

Changes and Re-submissions

(Continued)

- All individual payment records that are updated via resubmission process need to be identified by the original Open Payments Payment ID.
 - If there are multiple resubmissions for the same payment record, the same original Open Payments Payment ID needs to be referenced.
- New payment records can be submitted at any time in a separate file with The Resubmission File Indicator set to “N” and Resubmitted Payment Record IDs left blank.

Data Validation

- The business rules that will be used in validation are defined in the Data Mapping Document
- The Open Payments system will reject the entire file if:
 - The file is in an invalid format (not CSV or XML)
 - The structure of the file does not align with the schema (for example, does not include all the data elements collected)
- The Open Payments system will process the file and reject individual records if the file is in a supported format and schema compliant but has errors on the record level (for example, if required fields are not populated or if text characters are used in numeric fields).

Data Validation

(Continued)

- Records entered manually online are validated in real time
- For bulk uploads
 - Simple file format validations are performed right after the upload (for example, whether the file is in XML or CSV format)
 - More in-depth validations are performed offline
- All records in the submitted file will be processed (not just up to the first encountered error).
- File processing time will depend upon the volume of all of the submission data the system receives during the time period

Data Validation

(Continued)

- After the file is processed, users will receive an email notification stating the:
 - Acceptance of the submission, or
 - Validation errors that prevented its acceptance. The notification email will give an error code to explain rejections.
- The error listing:
 - Will include the Home System Payment Identifier and the Open Payments Payment Identifier to enable the reporting entity to reconcile with their internal systems
 - Will be downloadable in a text format to local machines
- The list of error codes and error descriptions will be available on the CMS Open Payments webpage in the future.
- All validation errors need to be rectified before data submission can be completed.

Matching

- After submission is complete and validation errors are rectified, submitted data enters the matching process to ensure that payments are consistently attributed to the correct physicians and teaching hospitals
- The Open Payments system will attribute reported data to recipient profiles by matching recipient identifiers submitted by reporting entities on the information contained in CMS systems and proprietary physician database provided by Truven Health.
 - Recipient identifiers include:
 - For physicians: Name, NPI and state license number
 - For teaching hospitals: Name, TIN and address for teaching hospitals
 - CMS systems include:
 - NPPES
 - PECOS
 - Open Payments Teaching Hospital List

Matching

(Continued)

- After the matching process is complete and if there are any records that could not be attributed with a sufficient degree of confidence, reporting entities will receive a follow-up email with information about unsuccessful matches.
 - Reporting entities will have the opportunity to make corrections to the data or proceed with submission as entered.
 - Inability to reliably match a submitted record to a physician or teaching hospital in the reference sources will not result in record rejection and will not prevent submission or attestation.

Attestation

- Reporting is **not considered** complete until formal electronic attestation is received
- Attestation:
 - Does not have to occur at the point of submission
 - Must occur before the reporting deadline
- Attester **should attest only** when all submissions are completed and finalized for the collection year

Attestation

(Continued)

- Standardized attestation statements to which the Attester will be required to agree will be displayed on the system screen
 - Users will not be able to upload any additional attestation documents
- At the time of attestation, users will be able to enter assumptions for reporting data
 - Assumptions can be entered as plain text in a text box, no document upload functionality will be provided
- Data can be modified at any time before or after the attestation
 - If data are modified after attestation, only the modified records will have to be re-attested

Consolidated Reporting

- If the Authorized Official indicates at registration that their entity will be a part of a consolidated report, it **does not** limit or restrict the entity to being a part of a consolidated report
 - This field will be used by CMS for informational purposes only
 - CMS will not use this information to notify entities that other entities indicated that they plan to be in their consolidated report
- Entities should submit an individual report or a consolidated report submission per collection year – not both
 - CMS should only receive one attested report per entity per collection year; this does not apply to any correction reports

Consolidated Reporting

(Continued)

- Each entity included in consolidated report must be registered in the Open Payments system and the consolidated report must reference the registration IDs for all entities included in the report
- Individuals submitting and/or attesting to consolidated report on behalf of multiple entities have to be approved in Submitter and/or Attester roles for all entities included in the consolidated report and the entity submitting consolidated report

Third Parties

- The Submitter role in the Open Payments system can be filled by a third party user who is not affiliated with the applicable manufacturer or applicable GPO but is submitting data on its behalf
 - The third party submitter must be approved by an Officer in the same fashion as applicable manufacturer or GPO internal Submitters
- Third parties submitting data on behalf of applicable manufacturers or applicable GPOs:
 - Will be associated with the reporting entity through their nomination and approval in the Submitter role
 - Will be able to use test submission functionality only if registered in the system and approved in the Submitter role for a particular reporting entity
- Third party software vendors who are not associated with a vetted organization will not have access to the Open Payments system and will not be able to test submission files

Review and Dispute

- Review and dispute functionality is still being designed
- More detail will be provided in a future webinar
- However, CMS envisions that individual line items under dispute would be resubmitted and re-attested, not entire submissions

Clarifications on Reporting Requirements

- If a reporting entity has multiple transactions for a covered recipient, each transaction should be reported separately rather than aggregated into a single entry
- At least one state license number is required for a physician covered recipient even if NPI is provided
- If a physician covered recipient does not have an NPI, the NPI field may be left blank
 - If a physician covered recipient **does have an NPI**, the applicable manufacturer or applicable GPO is responsible for making the best effort to obtain the NPI from the physician for the purposes of reporting
- The NPI listed in NPDES is the official record that the Open Payments system uses for matching (as noted on slide 30)

Clarifications on Reporting Requirements

(Continued)

- Reporting entities do not need to submit a blank file if they don't have any transactions of a particular payment type to report.

For example, an applicable manufacturer may have reportable general payments but not research payments. In that case, only the general payments file needs to be submitted to the Open Payments system.

Available Resources

General Resources Available

- **Open Payments webpage**
 - <http://go.cms.gov/openpayments>
- **Open Payments technology-focused webinar**
 - Current and upcoming webinar listed, along with past recordings and materials
 - Available on the Events page of the Open Payments website:
<http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Events.html>
- **Supplemental materials, instruction documents, FAQs & other resources**
 - Available on the Data Submission and Attestation page of the Open Payments website: <https://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Data-Submission-and-Attestation.html>
- **Help Desk**
 - Email questions to openpayments@cms.hhs.gov

Coming Soon

- **Technical Frequently Asked Questions**
- **Phone line dedicated to answering technical questions**

Register to receive email updates on new Open Payments tools and resources, plus announcements of future webinars, calls, and meetings.

Next Webinar

- Next Webinar:
 - January 2014
 - More information to follow

Questions & Answers