



Open Payments

Applicable Manufacturers & Applicable GPOs:

2015 Program Year Registration, Data Submission, and Attestation

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

**CREATING PUBLIC TRANSPARENCY
INTO INDUSTRY - PHYSICIAN
FINANCIAL RELATIONSHIPS**

January 2016

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 & Learning Objectives
- Reference Materials
- Program and System Overview
- Reporting Entity Registration and Re-Certification
- Data Submission & Error Correction
- Final Submission & Attestation
- Open Payments System Enhancements
- Next Steps & Available Resources

Target Audience & Learning Objectives

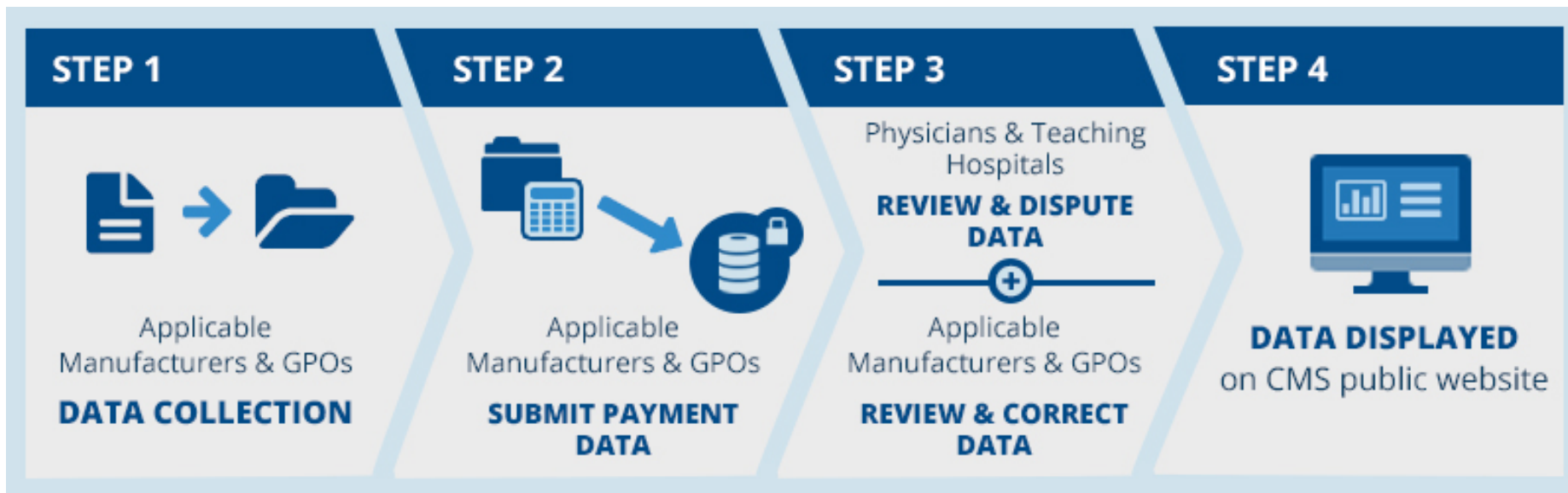
- Target audience:
 - Individuals and applicable manufacturers and applicable group purchasing organizations (reporting entities) who must submit data to the Open Payments system to comply with regulatory and reporting requirements
- Learning objective:
 - To provide high-level instructions on how to register, submit, and attest to data for the 2015 program year

Reference Materials

- Reference Materials:
 - Open Payments User Guide, Quick Reference Guides, and other resources referenced here, can be found on the Resources page of the Open Payments website
(<https://www.cms.gov/OpenPayments/About/Resources.html>)

Program and System Overview

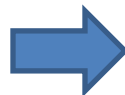
Open Payments Process Flow



Reporting entities collect payment data for a program year, which runs from January 1 to December 31



Reporting entities submit their data for the program year to the Open Payments system



Physicians and teaching hospitals review and, if necessary, dispute submitted data. Reporting entities correct the data to resolve any disputes



Data for that program year is published for public viewing in accordance with the publication guidelines

2015 Program Year Timeline



*Anticipated date

Reporting Entity Registration and Re-Certification

Two-Step Registration Process

1. Enterprise Identity Management (EIDM)

- Register self in EIDM at the CMS Enterprise Portal (only individuals register in EIDM)
- Request access to the Open Payments system



2. Open Payments System

- Register entity and/or self in Open Payments system

The CMS Enterprise Portal is at <https://portal.cms.gov>

If you registered in EIDM and requested access to Open Payments last year, it is not necessary to do so again.

EIDM Overview

- If you registered in EIDM and requested access to Open Payments last year, it is not necessary to do so again
- Individuals who request electronic access to CMS-protected information or systems (such as EIDM) must first have their identities verified
- Identity verification is the process of providing information (e.g., identity history, credentials, or documents) to prove that a person is the same person he or she claims to be
- For returning EIDM users who need help with User ID or password, visit <https://portal.cms.gov> or contact the Open Payments Help Desk
- EIDM will lock a user account after 60+ days of inactivity; EIDM will deactivate a user account after 180+ days of inactivity
- For step-by-step instructions on how to register in EIDM, refer to the quick reference guide “Enterprise Identity Management (EIDM) Registration,” available on the Resources page on the Open Payments website

Open Payments System Registration

- Reporting entities must register in the Open Payments system to submit, attest, correct, and view records of payments, other transfers of value, and ownership/investment interests
- Open Payments system registration can only be completed after EIDM registration
- Reporting entities must be registered and individuals who wish to use the system on behalf of a reporting entity must also register themselves
- The individual who registers the reporting entity will simultaneously register him/herself for the role of officer with the reporting entity in the Open Payments system
- Prepare information before beginning registration; registration must be completed in one session, as users cannot save partially completed entries for completion at a later time and sessions are timed out after 30 minutes of inactivity
- Quick reference guide “Applicable Manufacturer and Applicable GPO Registration and Recertification” and the Open Payments User Guide provide additional guidance on system registration

Entity Re-Certification

- **Before performing any system-related functions in the Open Payments system in 2016, reporting entities that registered in the previous year must re-certify in the Open Payments system**
- If your reporting entity is due for re-certification, entity re-certification must be completed in order to perform any system-related functions for that reporting entity
- Re-certification can only be completed by an individual in an officer role for the reporting entity in the Open Payments system
- Re-certification confirms reporting entity details in the Open Payments system are accurate
- During re-certification, officers can update outdated or inaccurate reporting entity information

Entity Re-Certification (cont.)

- Entity information can be updated at any time, not only during re-certification.
- Re-vetting of the reporting entity will occur if any of the following fields in the entity's profile change:
 - Entity Legal Name
 - Tax Identifier Number (TIN)/Employee Identification Number (EIN)
 - Dun and Bradstreet DUNS Number (D&B)
- Quick reference guide “Applicable Manufacturer and Applicable GPO Registration and Recertification” and the Open Payments User Guide provide additional guidance on the re-certification process

Vetting

- After the reporting entity registration has been submitted in the Open Payments system or a previously registered entity's name, TIN/EIN, or DUNS number is changed in the entity's profile, the system will vet the reporting entity
- Vetting verifies that the applicable manufacturer or applicable GPO is a valid reporting entity
- The officer will receive an email confirming vetting success or failure. If vetting was successful, the officer may begin performing actions in the system for the reporting entity
- To ensure successful vetting, provide as much information as possible during registration
- If vetting fails, the officer may update the profile information and re-submit for vetting
- If vetting fails after three re-submissions, the officer must contact the Open Payments Help Desk (openpayments@cms.hhs.gov or 1-855-326-8366) for assistance
- **No system actions are permitted on behalf of a reporting entity until it has been successfully vetted**
- Refer to the Open Payments User Guide for more information on vetting

Registration & Re-Certification Enhancements

- Special characters are now allowed in all fields throughout the Open Payments system
 - All special characters listed on the United States keyboard layout (ANSI) are permitted
 - Excludes fields where specific formatting is required
 - A complete list of these special characters is in Appendix A of the Open Payments User Guide

Registration & Re-Certification Enhancements (cont.)

- Reporting entity's Registration ID is now displayed under the entity's Profile information on the following pages in the Open Payments system:
 - Manage Entity
 - Entity Details
 - Entity Lookup
 - Confirm Entity
 - Review & Submit Profile

The screenshot displays the 'Open Payments (Sunshine Act)' website. At the top, there is a navigation bar with buttons for 'Home', 'Submissions', 'Review and Dispute', 'Manage Entities', and 'My Profile'. Below this is a 'Manage Entities' section with a 'Register New Entity' button. The main content area shows a table of 'Your Entities' with columns for Name, Registration ID, Status, and Date Verified. The 'Registration ID' for 'ABCDEF Medical' is highlighted with a red box. To the right of the main content, there are three utility links: 'Access the Open Payments User Guide', 'Need help with the website? Contact Us by email', and 'Review the Open Payments Privacy Policy [PDF, 102 KB]'. At the bottom right, there is a photograph of a man and a woman in professional attire.

Open Payments (Sunshine Act)

Manufacturer or Group Purchasing Organization Switch User Type

Home Submissions Submit, Review, Attest Review and Dispute View, Respond, Resolve Manage Entities Register, Edit, Nominate Roles My Profile Account, Roles, Nominations Help

Manage Entities

Register New Entity

The entities you are authorized to view are listed below. Select an entity from the list below to view the entity details and manage user roles affiliated with the entity.

If an entity is pending recertification, you must complete recertification before performing any system action for that entity. Entity recertification requires that an active officer within the Open Payments system reviews, updates (as necessary), and confirms all of the entity details submitted during the previous program year.

Your Entities	Registration ID:	Status:	Date Verified:
Name: ABCDEF Medical	100000345011	Vetted	12/14/2015 11:45:08

Access the Open Payments User Guide

Need help with the website? Contact Us by email

Review the Open Payments Privacy Policy [PDF, 102 KB]

Registration & Re-Certification Enhancements (cont.)

- New Requirement: Reporting entities must now provide at least one review and dispute point of contact during entity registration or re-certification
- When providing new contact information to be used during the review and dispute period, please note when entering this information:
 - Do not use the “Enter/Return” key (you may not be able to save your entry).
 - Copying and pasting your entry from another source such as Word or PDF may not allow you to save your entry. The information should be typed into the field or pasted from a “plain text” source.

Contact Information for Review and Dispute

In the "Contact Information" box below, provide contact information for individual(s) from your entity who are assisting with the dispute resolution process. You may also include additional instructions for physicians and teaching hospitals.

Note that the contents of the "Contact Information" box will be shared with all covered recipients you have reported payments or transfers of values for. The contents will be displayed exactly as entered in the box.

***Contact Information:**
500 characters maximum

Susan Jones
Phone: 555-555-5555
Email: Officer@yopmail.com

Cancel Back Continue

Registration & Re-Certification Enhancements (cont.)

- The review and dispute contact information is made available to covered recipients to assist with the dispute resolution process,
- The contact information is displayed on the “Record ID” page of individual payment records

Open Payments (Sunshine Act)

Physician Switch User Type

Home **Review and Dispute** My Profile Help
[Review](#) [Affirm](#) [Dispute](#) Account, Roles, Nominations

Record ID: 664745

[Back](#)

Reporting Entity Contact Information

If you have any questions about this record, you may use the contact information provided below to directly contact the reporting entity.

Please contact either Jeff or Paula at 888-888-9999. Or email at mailbox@fjrtestest.com
Enter special characters &&&&\$\$\$##@

Record Details


Program Year: 2015
Reporting Entity: Fjr Enterprises
Payment Category: General Payments
Consolidated Reporting: No
Last Modified Date: 2015-12-15
Submission Date: 2015-11-19
Record Status: Attested

Active Disputes

[Access the Open Payments User Guide](#)

[Need help with the website? Contact Us by email](#)

[Review the Open Payments Privacy Policy \[PDF, 102 KB\]](#)



Data Submission & Error Correction

Data Submission Process

- **During the 2016 data submission period, reporting entities are required to submit data regarding payments and other transfers of value made to covered recipients, and ownership or investment interests, for the 2015 program year**
- Data can be submitted to the Open Payments system in two ways:
 - Bulk file upload using either CSV files or a ZIP file containing CSV files
 - Manual data entry of each data record through the Open Payment system's Graphic User Interface
- CMS encourages reporting entities with smaller volume of records to use manual data entry, as preparing CSV files will require data handling expertise and may require additional software tools in order to prepare the files; reporting entities who do not have such expertise on hand and have a small volume of records to report should use the manual data entry option
- Reporting entities may choose to use either or both of these submission methods to report transactions

Data Submission Process (cont.)

- Once all records have been successfully uploaded, the system will check each record for validation and matching errors
- **All errors must be corrected before final submission and attestation can occur**
- Submitters will receive notification emails at various stages of the upload and submission process. These emails will notify the submitter of the success or failure of their submissions, note the existence of any matching or validation errors, and include high-level instructions on next steps
- Reporting entities may choose to have their data prepared and submitted by a third party organization
- Third-party organizations may format, prepare, and submit data on behalf of a reporting entity
- The role of submitter is the only role third party companies can fulfill within the Open Payments system on behalf of a reporting entity; attestation must be completed by the reporting entity
- Refer to the submissions-related quick reference guides and the Open Payments User Guide for more information on data submission

Data Submission Process Flow

STEP 1

Log into
Open
Payments
System

Submitter
Logs into
Open
Payments
System

STEP 2

Upload Data

Two Options
Available:

1. Bulk Data Upload (CSV Files)
2. Manual Entry (Graphic User Interface)

Bulk File Upload:

- Accepted file formats include CSV or ZIP files containing CSV files
- Files may not exceed 250MB in size
- Correct sample files must be used for each payment type

Manual Data Entry using
Graphic User Interface
(GUI)

STEP 3

Data
Submission
Validation
& Matching

System performs
data validation &
matching:

- For bulk file upload, system notifies failure or success via email
- For manual data entry validation checks are real time

STEP 4

Final
Submission

Once data has
been successfully
uploaded and is
free of validation
and matching
errors, the
submitter will
perform final data
submission

STEP 5

Attestation

- Attester receives an email notification once records are in "Ready for Attestation" status
- Attester attests to the accuracy, completeness, and timeliness of the data
- Attestation is conducted for all records for that program year, across all three payment types

Bulk File Upload

- Reporting entities with large volumes of data to report will likely want to upload bulk data files
- The two acceptable file formats for bulk data upload are:
 - CSV (Character-Separated Values) that use pipes (|) as field delimiters
 - Sample files, also referred to as templates, are available on the Resources page of the Open Payments website. Each of the payment types – general, research, ownership/investment – has its own sample file/template
 - ZIP (must contain only pipe-delimited CSV files)
- Maximum file size accepted, for both CSV and ZIP files, is 250 MB. There is no limit to how many files may be uploaded into the system
- Each file can contain only one payment type: general payments, research payments, or ownership and investment interests
- Quick reference guide “Bulk File Upload” and the Open Payments User Guide provide additional guidance on how to perform bulk file upload

Manual Data Entry

- CMS encourages reporting entities with smaller volumes of data to use manual data entry
- Manual entry of data into the Open Payments system is made via the Graphic User Interface
- Manual entry can be used in conjunction with bulk data file uploads
- Quick reference guide “Manual Data Entry” and the Open Payments User Guide provide additional guidance on completing manual data submission

Validation and Matching Errors

- After records are uploaded, the Open Payments system will begin validating and matching the data
- This may uncover errors that must be corrected for the records to be submitted successfully
- There are three basic types of errors for data submitted to the Open Payments system:
 1. File format errors
 2. File content errors
 3. Data matching errors

Validation and Matching Errors (cont.)

- 1. File Format Errors:** Applies only to records submitted via bulk file upload. The system will fail a file's upload if any of the following formatting errors are detected:
 - Submitted file size is larger than 250 MB
 - File is not in CSV or ZIP format
 - File is missing a header row and/or columns, or has incorrect number of columns
 - Payment category of the sample file used to create the submitted file and payment category selected when uploading the file do not match

Validation and Matching Errors (cont.)

2. File Content Errors: Information in a record does not match the formatting accepted by the system. Acceptable system formatting is explained in detail in the “Submission Data Mapping Document”

Manually entered records undergo formatting checks during data entry. Records submitted via bulk file upload undergo checks as part of the file submission process.

Common content errors include:

- Invalid characters in the data element
- Required data element left blank
- Too many or too few characters in the data element
- Invalid value in the data element

Validation and Matching Errors (cont.)

3. Data Matching Errors: When the covered recipient information in a record cannot be matched to a valid covered recipient using existing CMS resources and information. A record must be successfully matched to a valid covered recipient to be accepted by the Open Payments system.

Examples of data matching errors include:

- Teaching Hospital Name in a record does not match the value for the corresponding Hospital Name in the CMS Teaching Hospital List
- The Teaching Hospital Address in a record does not match the value for the corresponding Teaching Hospital NPPES Business Address in the CMS Teaching Hospital List
- Physician First Name in a record does not match the information in validation sources used by Open Payments

Error Notifications

- **File Format Errors** will be communicated to submitters via email
- **File Content Errors** will be communicated based upon the data submission method:
 - Bulk file upload: Errors will be communicated through a notification email that notes the existence of a detailed error report for the bulk file
 - Manual data entry: Errors will be communicated during data entry in real time
- **File Matching Errors** will be communicated through emails
- Error reports contain error codes that explain errors. Error codes are explained in the “Error Code Key,” available on the Resources page of the Open Payments website
- Submission errors must be corrected and the records re-submitted for records to be successfully submitted
- Quick reference guide “Identifying and Correcting Validation and Matching Errors” and the Open Payments User Guide provide additional guidance

Final Submission & Attestation

Final Data Submission

- All records uploaded to the Open Payments system, either via bulk file upload or manual entry, must go through a final data submission
- Final data submission can begin when all records for a payment category (i.e., general, research, ownership) are free of errors and are in “Ready for Submission” status
- Records submitted through bulk file upload and manual entry will go through final submission **simultaneously**

Attestation

- Attestation legally affirms and certifies that information submitted on behalf of a reporting entity is accurate and complete – only users holding the role of attester may attest
- Attestation occurs after all errors are corrected, matching is successful, records have undergone final submission, and all records for the program year are in “Ready for Attestation” status
- Attesters will receive email notification for initial attestations, when there are records in “Ready for Attestation” status
- Re-attestation is required when any previously attested data is changed, including any data fields, delay in publication indicator, or deletion of records
- When re-attestation is required, use the “**Notify Attester**” button to send an email notification. Note: The “Notify Attester” button will only be enabled if there are records in “Attested” or “Ready for Attestation” status

Attestation (cont.)

- Attestation must be done for **all** records submitted for a program year; **not** individual records, file submissions, or payment types
- Attestation must be completed by the reporting deadline for the program year
- Data submissions that are not attested to by the reporting deadline will be considered late and may be subject to civil monetary penalties
- **Attestation is conducted for all records for that program year, across all three payment types**

Assumptions

- Attester has the option of submitting an assumptions statement during the attestation process
- Assumptions explain the reasonable assumptions made and methodologies used when reporting payments, other transfers of value, or ownership or investment interests
- Assumptions are documented in a free-form text field during the attestation process
- Assumptions cannot be longer than 4,000 characters (including spaces) and can be edited later
- Quick reference guide “Final Submission and Attestation” provides additional guidance on attestation process
- Refer to Open Payments User Guide for a complete list of attestation statements

Delay in Publication

- Reporting entities can request a one-year delay in publication for eligible payment records, as well as request a renewal of the delay after a previous one expires
- Eligible payment records may be delayed for publication 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
- The request for a delay must be renewed each year. If this request is not renewed each year by the end of the data submission period, the record will be eligible for publication in the next publication cycle
- After renewing delay in publication flag, all records for that program year must be re-attested to for the request for delay to be confirmed
- Quick reference guide “Requesting or Renewing Delay in Publication” provides additional guidance on the delay in publication process

Submission & Attestation Enhancements

- Deleting previously attested-to records requires re-attestation
 - Previously attested records deleted by submitters will be placed in “Marked for Deletion” status
 - Records remain in the system after being marked for deletion until re-attestation is complete; after attestation, those records are removed from the Open Payments system
 - Records that remain in “Marked for Deletion” status and are not re-attested to are visible to covered recipients and eligible for publication
- Records in “System Processing” status can now be deleted
- Covered recipient information and recipient type cannot be changed after final submission occurs
 - Once a record has undergone final submission in the Open Payments system, the covered recipient identifying information cannot be changed
 - To change covered recipient identifying information in a record, the submitter must delete the record and resubmit a new record with the updated covered recipient information

Submission & Attestation Enhancements (cont.)

- When reporting an NDC code, it is now required to report the name of the covered drug or biological in the corresponding name field
- NDCs must be reported in one of the following formats:
 - 9999-9999-99
 - 99999-999-99
 - 99999-9999-9

Open Payments (Sunshine Act)
Manufacturer or Group Purchasing Organization Switch User Type

Home | Submissions (Submit, Review, Attest) | Review and Dispute (View, Respond, Resolve) | Manage Entities (Register, Edit, Nominate Roles) | My Profile (Account, Roles, Nominations) | Help

Enter Payments Manually

- ✓ Recipient Demographic Information
- ② **Associated Drug, Device, Biological, or Medical Supply Information**
- ③ Transfer of Value (Payment) Information
- ④ General Record Information
- ⑤ Review and Submit

Access the Open Payments User Guide | Need help with the website? Contact Us by email | Review the Open Payments Privacy Policy [PDF, 102 KB]

Associated Drug, Device, Biological, or Medical Supply Information

A field with an asterisk (*) is required.

Select the product indicator from the drop-down menu and then enter the applicable information for the associated covered drugs, devices, biologicals, or medical supplies. If you select "Covered" or "Combination" from the drop-down menu, you must enter the name of an associated covered drug or biological, or the name of the associated covered device or medical supply. If you are entering multiple drugs, biologicals, devices, or medical supplies, do not skip fields between each entry, including the first field (e.g., if you have two items, they must be entered in the first and second fields). If the National Drug Code (NDC) of the associated covered drug or biological is available, you are required to enter it. Note that if you enter an NDC, you are also required to enter the corresponding Name of Associated Covered Drug or Biological field. When done, select the "Continue" button.

*Product Indicator: Covered

*Required: Enter the name of the associated covered drug or biological, or name of the associated covered device or medical supply.

Name of Associated Covered Drug or Biological:	National Drug Code (NDC) of Associated Covered Drug or Biological: 9999-9999-99 OR 99999-999-99 OR 99999-9999-9
1. <input type="text"/>	1. <input type="text"/>
2. <input type="text"/>	2. <input type="text"/>
3. <input type="text"/>	3. <input type="text"/>
4. <input type="text"/>	4. <input type="text"/>
5. <input type="text"/>	5. <input type="text"/>

Name of Associated Covered Device or Medical Supply:

1. <input type="text"/>
2. <input type="text"/>
3. <input type="text"/>
4. <input type="text"/>
5. <input type="text"/>

Cancel Back Continue

Submission & Attestation Enhancements (cont.)

- Reporting entities can now download up to 400k records from the “Payment Category” page into a CSV file
- Users will now receive an email notification when submitted records fail the matching process
- For General and Research payments, Open Payments system will not accept records where the payment value is \$0.00
- For Ownership/Investment records, only one of the following fields can be \$0.00:
 - Dollar Amount Invested or
 - Value of Interest

Submission & Attestation Enhancements (cont.)

- Physician and principal investigator license number character limit has been increased to 25 characters
 - Applies to both manual entry and bulk file upload submissions
 - Bulk File Upload: License format remains the same; field size increased to 28 to allow for 25-character license number, state code, and hyphen
 - E.g. MD-99999999999999999999999999999999
 - Manual Data Entry: Select a state from the drop-down menu, then enter up to 25 characters in “Physician License Number” or “Covered Recipient Physician License Number” field

Reporting Enhancements

- Reporting entities can now export disputed records into a CSV file
- One CSV report will be generated containing all 3 payment categories. Note: Data will only be populated across columns that are applicable to the specific payment category on a select record
- CSV file may contain up to approximately 400K records
- For a detailed list of all enhancements, refer to the “Program Year 2015 Open Payments System Enhancements” document on the Resources page of the Open Payments website

Next Steps & Available Resources

Next Steps

For New Reporting Entities:

- Register in EIDM and request access to the Open Payments system
- Register self and reporting entity (if applicable) in the Open Payments system
- Assign user roles
- Continue collecting 2015 payment data, and prepare to report it in early 2016

For Returning Reporting Entities:

- Re-certify reporting entity information
- Confirm user roles
- Continue collecting 2015 payment data and prepare to report it in early 2016

Available Resources

- Review available resources on the CMS Open Payments website Resources page at <http://www.cms.gov/openpayments>:
 - Open Payments User Guide
 - Tutorials
 - Quick Reference Guides
- Register for the CMS e-mail updates, on the Open Payments website, to receive updates about Open Payments
- For additional questions, you can also contact the Open Payments Help Desk at:
 - openpayments@cms.hhs.gov
 - 1-855-326-8366

Data Submission and Attestation Resources

- Resources to help reporting entities ensure accurate data submission include:
 - Validated Physician List
 - Teaching Hospital Lists
 - 2016 Teaching Hospital List is now available
 - Teaching Hospital Lists for previous program years are still available for records that need to be created or edited
 - Program year 2013 submissions should be made using the hospital's legal name
 - **Submissions for all other program years should be made using the hospital's "doing business as" name instead of legal name**
 - All Teaching Hospital Lists are available on the Resources page of the Open Payments website