

Open Payments (the Sunshine Act)

CMS Registration Overview





Medicare Learning Network®



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Agenda

- Open Payments Overview
- Operational Updates and Milestones
- Registration Overview and Instructions
- Resources
- Frequently Asked Questions

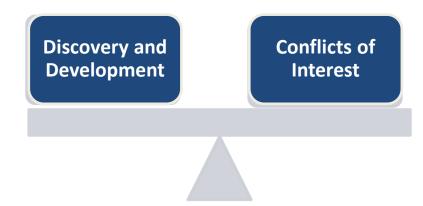


Open Payments Overview



Industry - Physician Relationships

- Collaborations between physicians and the medical industry can be beneficial by promoting discovery and development of new technologies that improve health and/or lower costs
- But, financial relationships may also influence professional judgment and conflicts of interest can potentially arise





Statute and Regulation

 Section 6002 of the Patient Protection and Affordable Care Act (Transparency Reports and Reporting of Physician Ownership or Investment Interests)

- Final Rule: Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests
 - Published February 8, 2013

Program Objectives

Open Payments is a national transparency program requiring certain manufacturers and group purchasing organizations to disclose their financial relationships with physicians and teaching hospitals

Objectives

- Make certain financial relationships transparent on a national scale
- Give consumers the information needed to ask questions and make more informed decisions about their healthcare professionals

CMS' Role

- Remain neutral and present the data on a public website
- Ensure reporting and disclosure are complete, accurate, and clear



Program Requirements

- Applicable manufacturers of covered products <u>AND</u> entities under common ownership with applicable manufacturers who also provide assistance and support are required to annually report to CMS:
 - Payments or other transfers of value made to physicians and teaching hospitals
 - Certain ownership or investment interests held by physician owners or investors or their immediate family members
- Applicable group purchasing organizations (GPOs) are required to annually report to CMS:
 - Payments or other transfers of value made to physician owners or investors
 - Certain ownership or investment interests held by physician owners or investors and their immediate family members



Program Requirements (cont.)

Who is reported on?

Covered Recipient Physicians

- Doctors of medicine or
- Doctors of dental medicine or dental surgery
- Doctors of podiatric medicine
- Doctors of optometry
- Chiropractors
- All legally authorized by the state to practice

Covered Recipient Teaching Hospitals

- The hospitals that CMS has recorded as receiving payment(s) under Medicare direct graduate medical education (GME), indirect medical education (IME) or psychiatric hospitals IME programs
- Each year, Open Payments
 publishes a list of affected
 teaching hospitals; the list is
 available on the Open
 Payments website at
 http://go.cms.gov/openpayments

Physician Owners or Investors

- Physicians who are owners or investors of an applicable manufacturer or GPO
- Immediate family members who have ownership or investment interest in an applicable manufacturer or GPO: spouse, natural or adoptive parent, child, or sibling, stepparent, stepchild, stepbrother, or stepsister, father, mother-, daughter-, son-, brother-, or sister-in-law, grandparent or grandchild, spouse of a grandparent or grandchild



Covered Recipient Physicians

Covered Recipient Physicians

- Doctors of medicine or osteopathy practicing medicine or surgery
- Doctors of dental medicine or dental surgery practicing dentistry
- Doctors of podiatric medicine
- Doctors of optometry
- Chiropractors
- All legally authorized by the state to practice

Note, for the purpose of this program:

- Fellows are included in the definition of a covered recipient
- Physicians with no other relationship with CMS (e.g., through reimbursement) are included
- Medical residents are excluded from the definition of physicians



Covered Recipient Teaching Hospital

Covered Recipient Teaching Hospitals

- The hospitals that CMS has recorded as receiving a payment(s) under Medicare direct graduate medical education (GME), indirect medical education (IME) or psychiatric hospitals IME programs
- List posted annually by CMS
- Industry has been instructed for the 2013 program year:
 - To collect and report using an institution's legal business name
 - To report data separately for each legal business name, TIN, and address combination appearing on the list
- CMS has provided industry with a supplement to the 2013 list is to ensure that applicable
 manufacturers and applicable GPOs are aware of the various institutions owned or operated
 by the legal entities, so they can collect the appropriate data; this should respond to various
 inquiries we have received
- CMS has posted the 2014 program year list for applicable manufacturers and applicable GPO use



Physician Owners/Investors and Immediate Family Members

Physician Owners or Investors

 Meet the definition of physician, and who are owners or investors of an applicable manufacturer or GPO

Physician Owners or Investors' Immediate Family Members:

- Spouse
- Natural or adoptive parent, child, or sibling
- Stepparent, stepchild, stepbrother, or stepsister
- Father-, mother-, daughter-, son-, brother-, or sister-in-law
- Grandparent or grandchild
- Spouse of a grandparent or grandchild

Data Collection

General Payments

 Payments or other transfers of value <u>not</u> made in connection with a research agreement

Research Payments

 Payments or other transfers of value made in connection with a research agreement

Ownership & Investment Interest

Ownership or investment interests



Types of Payments

- This program captures payments or other transfers of value:
 - Paid directly to physicians and teaching hospitals (known as direct payments)
 - Paid indirectly to physicians and teaching hospitals (known as indirect payments)

 It also collects information on payments designated by physicians or teaching hospitals to be paid to another party (known as third party payments)



Physician Information Reported by Industry

- Full legal name (as appears in NPPES)
- Primary and specialty
- Primary business address
- NPI (as appears in NPPES)
- State professional license number(s)
- Email address

Details Reported by Industry

- Information about the payment/transfer of value, or ownership/investment interest
- Information about the covered product payment/transfer of value is related to
- Name(s) of the related covered drug, device, biological, or medical supply, if applicable
- Amount, date, form, and nature of payment or other transfer of value, or ownership/investment interest
- Number of payments/transfers of value
- If designated to a third party, the name of individual or entity the physician indicated to receive the payment



Reasons Associated with a Payment, Transfer of Value, Ownership, or Investment Interest

Why did the physician or teaching hospital receive the payment, transfer of value, or ownership/investment interest? (to be reported by industry)

- Consulting fees
- Honoraria
- Gifts
- Entertainment
- Food & beverage
- Travel & lodging
- Education
- Research
- Charitable contribution
- Space rental or facility fees

- Royalty or license
- Current or prospective ownership or investment interest
- Grant
- Compensation for services other than consulting
- Direct compensation for serving as faculty or as a speaker for a medical education program (accredited and non-accredited)



Operational Updates and Milestones



2013 Program Year

Industry will:

Collect information on payments and other transfers of value, as well as ownership or investment interests held by physicians and their family members



August - December 2013

Physicians & Teaching Hospitals should:

Keep track of payments and transfers of value made to you and be mindful of ownership and investment interests held by both you and your immediate family

Industry will:

Register and submit 2013 information to CMS
Feb 18-Mar 31 (aggregate)
June 1- June 31 (detailed)

Industry will:

Correct disputed information (15 days Aug/Sept TBD)



2013 Information Posted



Q1 - Q3 - 2014



Physicians & Teaching Hospitals should:

Register with CMS in order to receive notifications and information submitted by the industry (June 1)



Physicians & Teaching Hospitals should:

Register in Open Payments system and review information for accuracy; dispute any inaccurate data with reporting entities (45 days July TBD)





Program Updates

June July August September

Phase 1: Beginning 6/1, physicians and teaching hospitals register in CMS' Enterprise Portal

Phase 1 of 2

- Physician and teaching hospital Enterprise Portal registration:
 - Begins June 1, 2014
 - No end date for this phase
 - Includes registration in CMS'
 Enterprise Portal and requesting access to the
 Open Payments system
 - Required first step of registration before Open Payments system registration

Phase 2: In July,
physicians and
teaching hospitals
register in Open
Payments system and
begin review, dispute,
and correction period

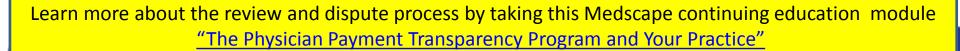
Phase 2 of 2

- Physician and teaching hospital Open Payments system registration:
 - Begins in July 2014
 - Completes registration in Open Payments system
 - Enables physicians and teaching hospitals to review and possibly dispute payments and other transfers of value submitted by industry into the Open Payments system



Review & Dispute Process (Phase 2 for Physicians and Teaching Hospitals)

- Physicians and teaching hospitals registered in the Open Payments system have the ability to review and dispute data submitted about them before public release
 - Registration is voluntary for physicians and teaching hospitals, but must be completed in both CMS' Enterprise Portal and Open Payments system
 - To participate in the review and dispute process, physicians and teaching hospitals must complete both registrations before the end of Phase 2 (TBD)
- Physicians and teaching hospitals can dispute information reported about them or their institutions
- Applicable manufacturers and applicable GPOs can see disputes and correct data before CMS makes it public
- Disputes initiated during this 45 day period that do not get resolved will be in the public data, but shown as under dispute
 - Review and dispute process projected to begin in July, 2014
- CMS will not mediate any dispute



Registration Overview & Instructions



Registration Overview

- Registration is required for physicians and teaching hospitals to review or dispute the following information reported about them by applicable manufacturers and GPOs:
 - Payments made to physicians and teaching hospitals,
 - Other transfers of value made to physicians and teaching hospitals, or
 - Ownership or investment interests held by physicians or their immediate family members
- Registration will be conducted in two phases this first reporting year

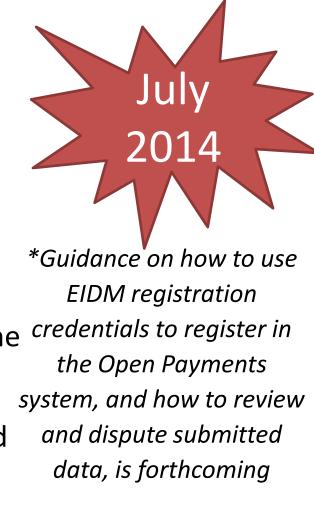
Phase 1 Registration for Physicians and Teaching Hospitals: CMS' Enterprise Portal (EIDM)

- Begins June 1, 2014
 - Physicians and teaching hospitals register in EIDM
 - Request access to the Open
 Payments system via EIDM



Phase 2 Registration for Physicians and Teaching Hospitals: Open Payments System

- In July 2014
 - Physicians and teaching hospitals use
 EIDM registration credentials to register
 in the Open Payments system
 - Once physicians and teaching hospitals
 are registered in the Open Payments
 system, they are able to participate in the
 review and dispute process
 - Note that EIDM registration is a required first step before Open Payments system registration





Let's Get Started – Phase 1 Registration

- 1. Phase 1 Registration in EIDM: Identity Verification Process
- 2. Phase 1 Registration: EIDM New User Registration
- 3. Using EIDM Registration Credentials to Request Access to the Open Payments System

EIDM Identify Verification Overview

- CMS' Enterprise Identity Management system (EIDM) is how CMS verifies user identities
- Identity verification is the process of providing information (e.g., identity history, credentials, or documents) for the purpose of proving that a person is the same person he or she claims to be
- Individuals requesting electronic access to CMS protected information or systems must first have their identities verified

EIDM Identify Verification Overview (cont.)

- All users who register for EIDM have their identities verified
- EIDM matches information entered by users to information provided by Experian
- Out of Wallet (OOW) questions are also used to verify identity
- OOW questions ask for private data and contain information pulled from your credit report such as:
 - Mortgage lender name
 - Previous employer name
 - Auto lender name
- OOW questions and answers are shared **only** between the EIDM registrant and the verification service provider, Experian; the information will **not** be stored in EIDM or in the Open Payments system.



EIDM Identify Verification Overview (cont.)

- A soft credit inquiry will be made during EIDM registration
- Soft credit inquiries are visible only to the EIDM registrant and only appear on credit reports produced by Experian (shown as an inquiry made by CMS). They are not visible to lenders. If you order a credit report from Experian, you will see an entry of inquiry by the Centers for Medicare & Medicaid Services with CMS's address and the date of request.
- Identity proofing does not affect credit score
- Contact Experian Proofing Support Services for assistance with failed identity proofing: 1-866-578-5409



EIDM New User Registration

- EIDM registration is required for access to the Open Payments system
- EIDM registration process is the same for all users
- You may already have an EIDM account if you use the Health Insurance Oversight System (HIOS), the Medicaid and CHIP Program System (MACPro), or other CMS systems

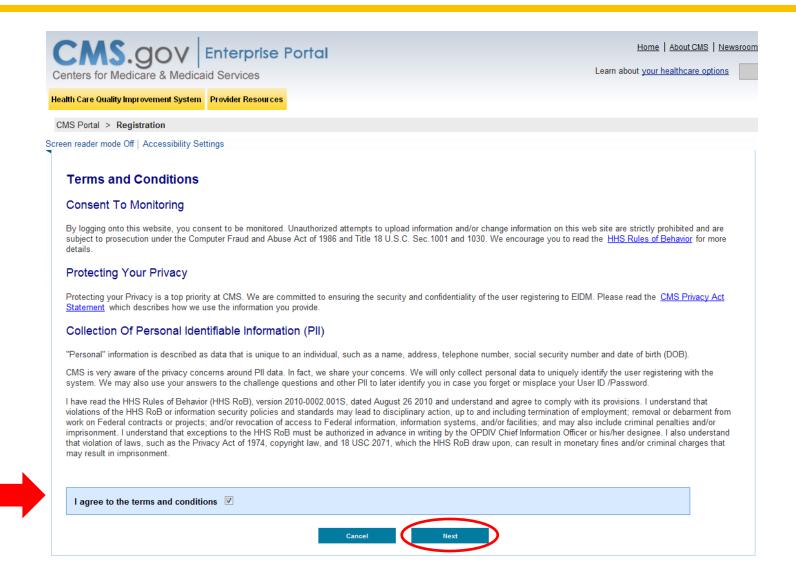
Step 1: Go to CMS Enterprise Portal and Select "New User Registration"

https://portal.cms.gov





Step 2: Accept Terms & Conditions



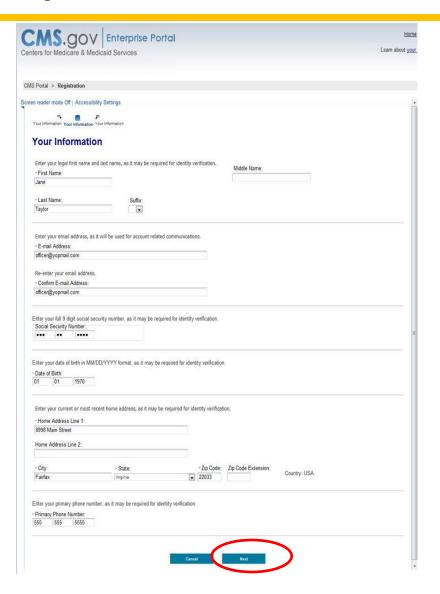


Step 2: Accept Terms & Conditions (cont.)

- Two sections are particularly important to read:
 - 1. Consent to monitoring
 - 2. Collection of Personal Identifiable Information or PII
- Consent to monitoring means that you agree to allow CMS to monitor you while you are on systems accessed through EIDM
- **PII** is information that can be used to uniquely identify, contact, or locate a single person or can be used with other sources to uniquely identify a single individual; PII is collected to aid in the identity verification process
- Identity verification is required for all users requesting access to any CMS applications
- Personal information collected will be used for the purposes of verifying your identity only
- Once you have read the terms and conditions, check the box labeled "I agree to the terms and conditions" before selecting "Next" to continue



Step 3: Enter Personal Information

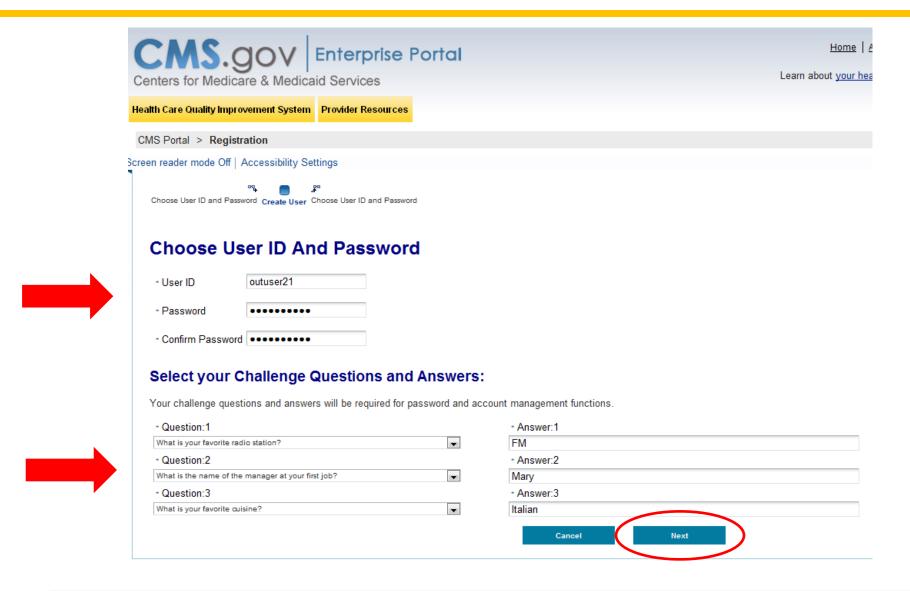


Required fields are marked with an asterisk.

Completing all fields, even those that are not required, will speed-up identity verification.



Step 4: Select User ID, Password, and Challenge Questions





User ID and Password Criteria

User ID

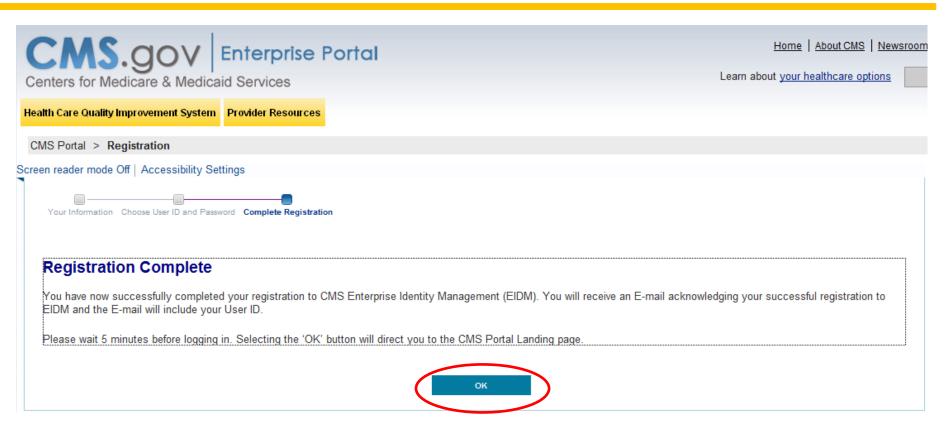
- Must be a minimum of 6 and a maximum of 74 characters
- Special characters permitted: dashes (-), underscores (_), apostrophes ('), periods (.), and at signs (@)

Password

- Must be a minimum of 8 and a maximum of 20 characters
- Must contain at least 1 number, 1 uppercase letter, and 1 lowercase letter
- Cannot contain your user ID and must differ from your previous 6 passwords
- Must be changed every 60 days
- EIDM will prompt for password change when the 60 day deadline approaches



Step 5: Registration Complete

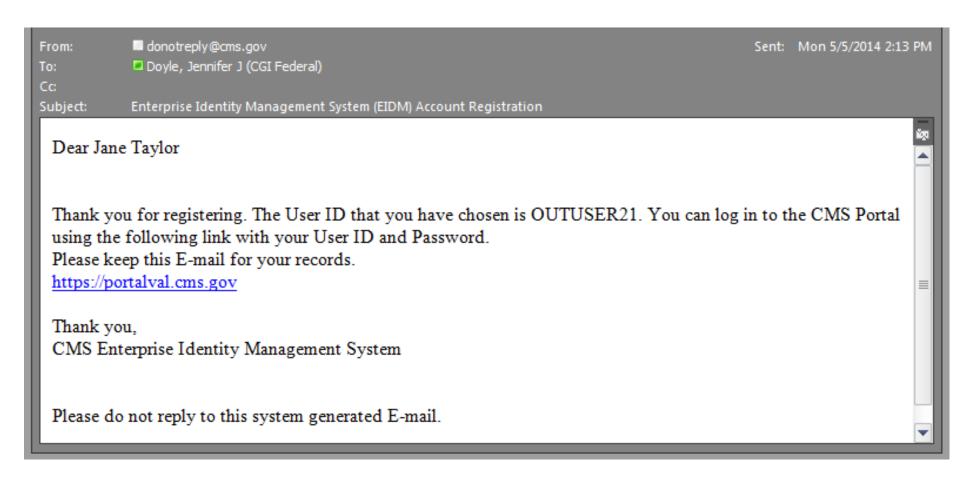


Click on "OK" to exit and return to the CMS Enterprise Portal home page.

After clicking on OK, you will receive a confirmation email message that contains your user ID and a link to the CMS Enterprise Portal.



Confirmation Email





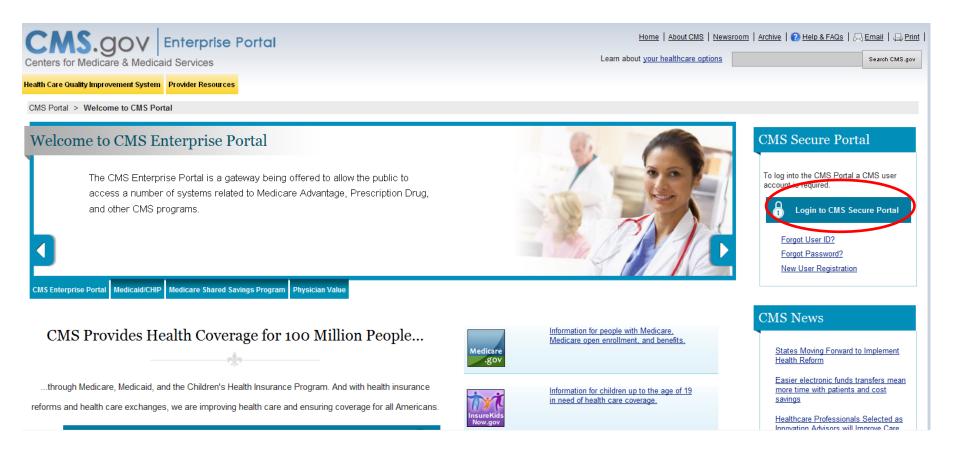
Unsuccessful EIDM Registration

- Individuals with addresses outside of the United States may not register successfully in EIDM
- They should contact the Open Payments Help Desk for assistance with EIDM registration
- Any additional EIDM issues should be directed to the Open Payments Help Desk at <u>openpayments@cms.hhs.gov</u> or 1-855-326-8366, Monday through Friday, from 7:30 a.m. to 6:30 p.m. (CT), excluding Federal holidays

Requesting Access to the Open Payments System

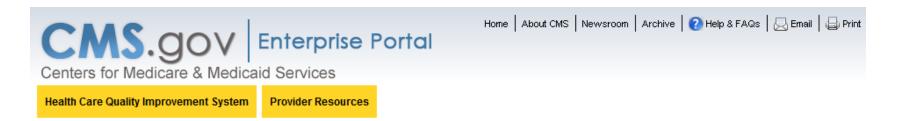
- Request for this access can occur only after EIDM registration is successful
- Request for this access is made through the CMS Enterprise Portal (EIDM)
- In Phase 2 registration, this request in EIDM will allow the individual access to the Open Payments system

Step 1: On CMS Enterprise Portal, select "Login to CMS Secure Portal"





Step 2: Accept Terms & Conditions



Terms and Conditions

You are accessing a U.S. Government information system, which includes (1) this computer, (2) this computer network, (3) all computers connected to this network, and (4) all devices and storage media attached to this network or to a computer on this network. This information system is provided for U.S. Government-authorized use only.

Unauthorized or improper use of this system may result in disciplinary action, as well as civil and criminal penalties.

By using this information system, you understand and consent to the following:

You have no reasonable expectation of privacy regarding any communication or data transiting or stored on this information system.

At any time, and for any lawful Government purpose, the government may monitor, intercept, and search and seize any communication or data transiting or stored on this information system.

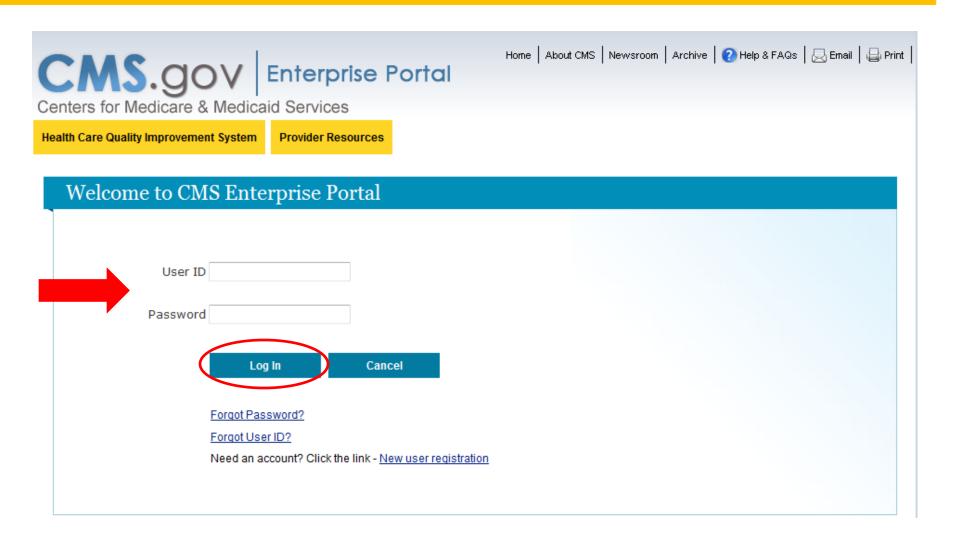
Any communication or data transiting or stored on this information system may be disclosed or used for any lawful Government purpose.

To continue, you must accept the terms and conditions. If you decline, your login will automatically be cancelled.





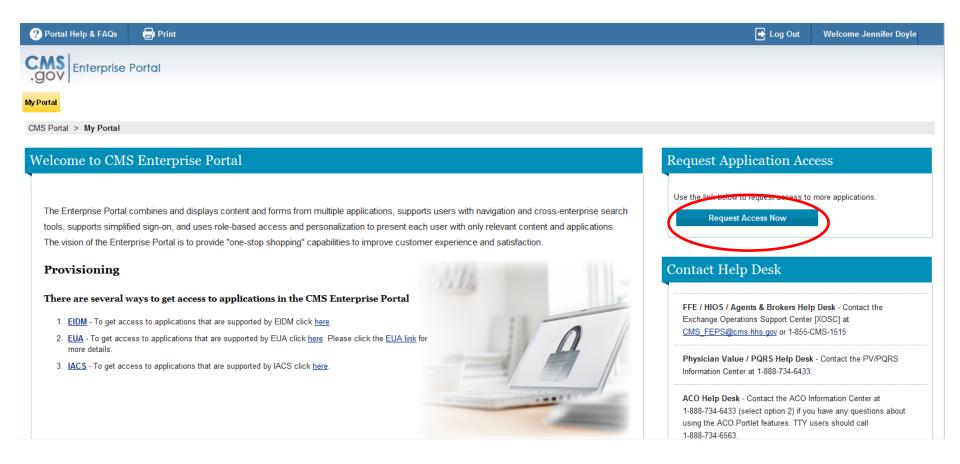
Step 3: Enter EIDM User ID and Password





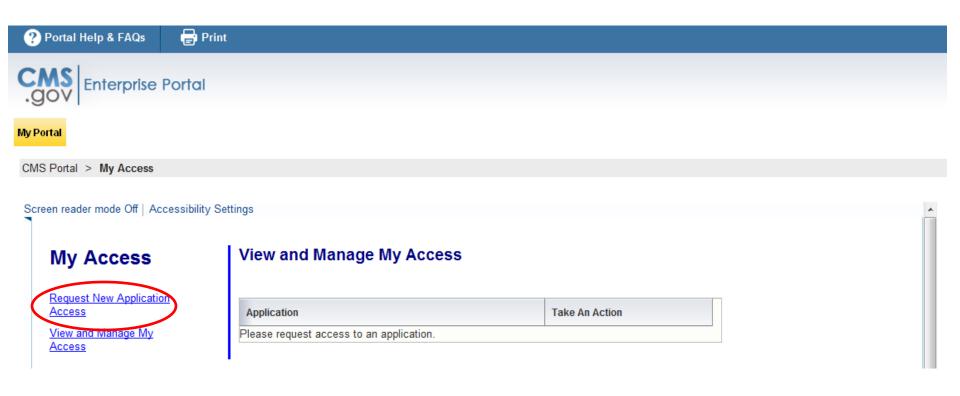
Step 4: Select "Request Access Now" under "Request Application Access"

After a successful CMS Enterprise Portal login, you will be taken to the CMS Portal home page (shown below).



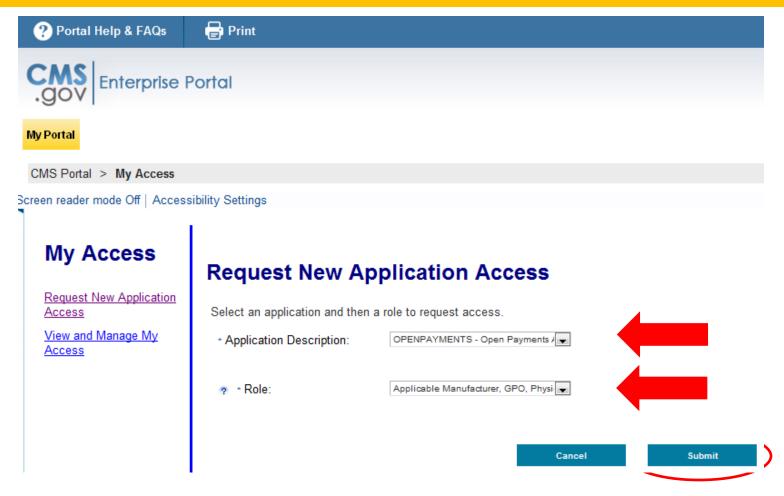


Step 5: Select "Request New Application Access"



If you have access to other CMS applications, you will see those applications listed in the "View and Manage My Access" table.

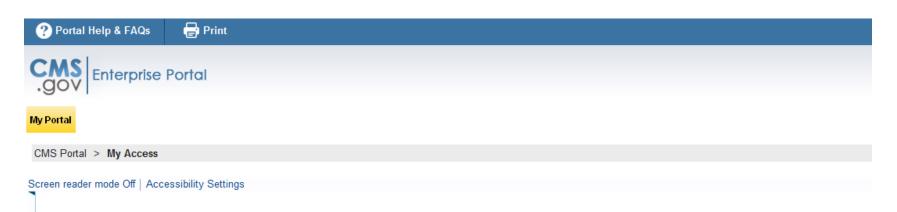
Step 6: Select Application and Role



- Application Description: "Open Payments"
- Role: "Applicable Manufacturer, GPO, Physician, or Teaching Hospital"



Step 7: Review Identity Verification Information



My Access

Request New Application Access

View and Manage My Access

Identity Verification

You have selected a role that requires a higher level of security. You will need to complete Identity Verification successfully, before requesting access to the selected role. Below are a few items to keep in mind.

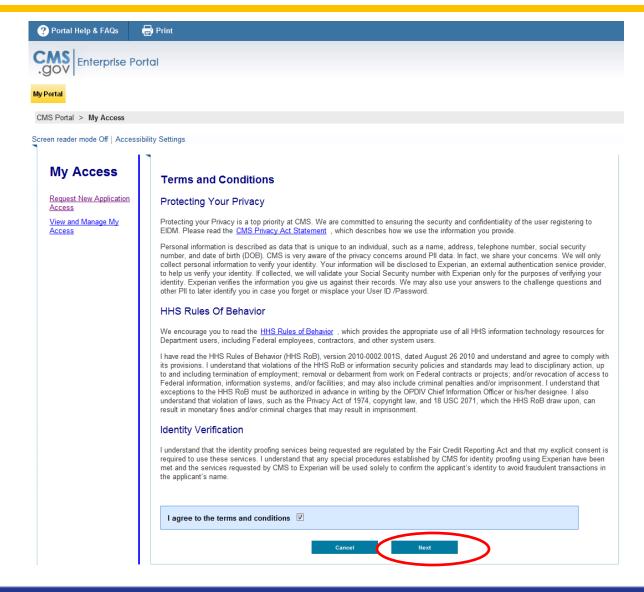
- Ensure that you have entered your legal name, current home address, primary phone number and email address correctly. We will only
 collect personal information to verify your identity with Experian, an external identity verification provider.
- Identity Verification involves Experian using information from your credit report to help confirm your identity. As a result, you may see an entry
 called a "soft inquiry" on your Experian credit report. Soft inquiries do not affect your credit score and you do not incur any charges related to
 them
- Confirm that you have your personal and financial information available, as the Experian application will pose questions to you, based on data
 in their files. You may want to obtain a copy of your credit report, before proceeding with the role request by selecting this link and following
 the directions provided http://www.experian.com. For additional information, please see the Experian Consumer Assistance link http://www.experian.com/help

If you elect to proceed now, you will be prompted with a Terms and Conditions statement that explains how your Personal Identifiable Information (PII) is used to confirm your identity. Do you want to continue?



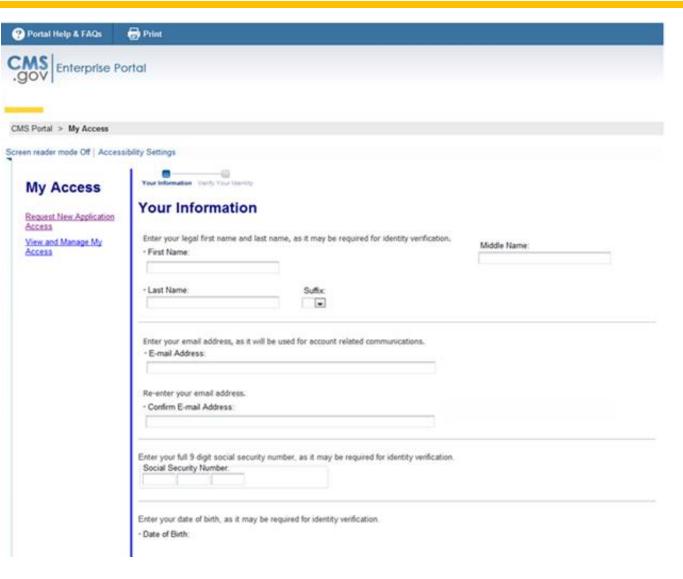


Step 8: Accept Terms & Conditions





Step 9: Confirm Your Information



Some fields will be pre-populated with information from your EIDM profile.

Confirm its accuracy; edit fields to correct errors.

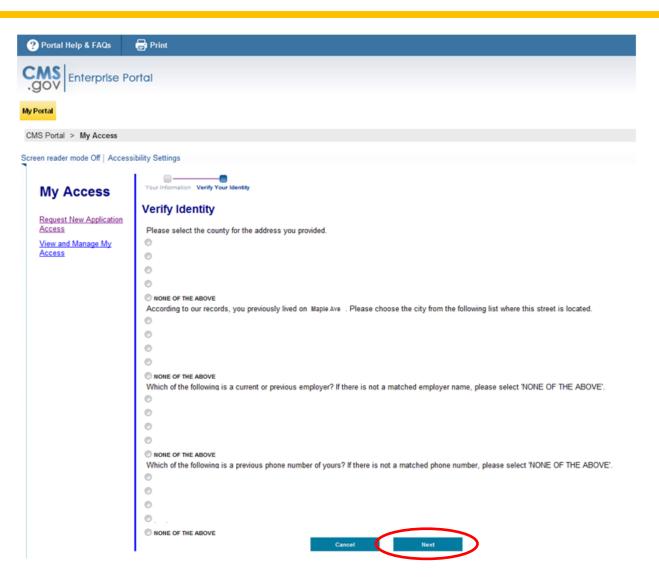


Step 9: Confirm Your Information (cont.)

- Home Address Line 1: Home Address Line 2:				
- City:	- State:	- Zip Code:	Zip Code Extension:	Country: USA
iter your primary phone r	number, as it may be required for idea	ntity verification.	The state of the s	
Primary Phone Number		•		



Step 10: Verify Identity

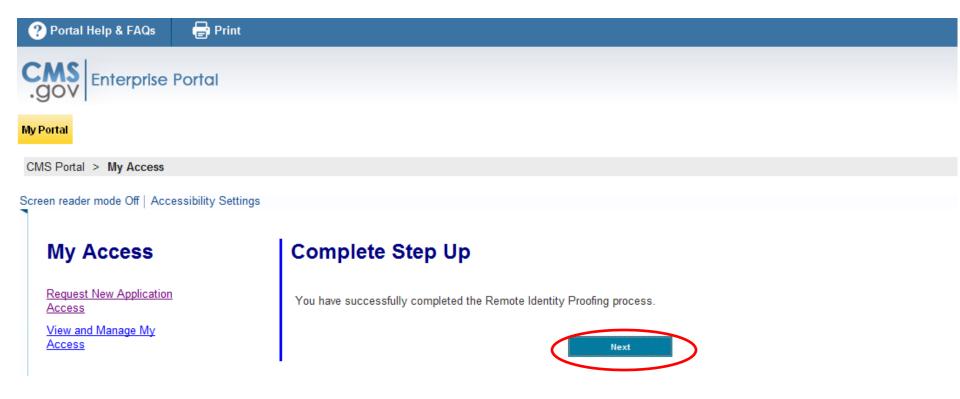


As previously explained, identity proofing questions are pulled from the "soft-credit" inquiry done during EIDM registration.

"Out-of-Wallet"
(OOW) questions are based upon information in your credit report.

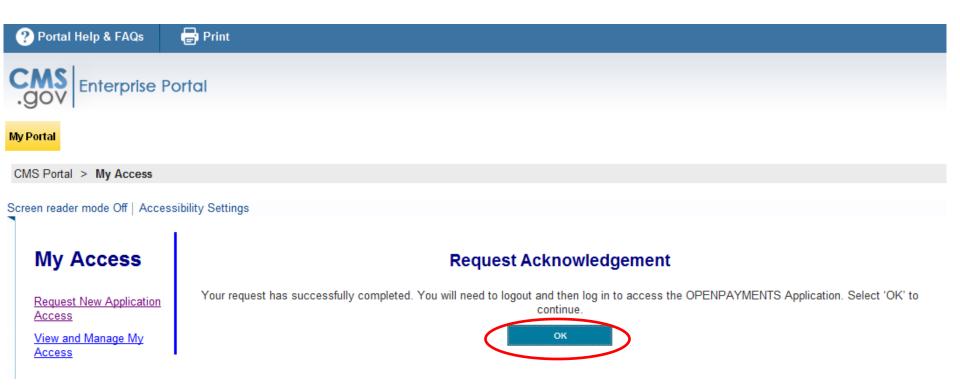


Step 11: Verifying Identity Successful





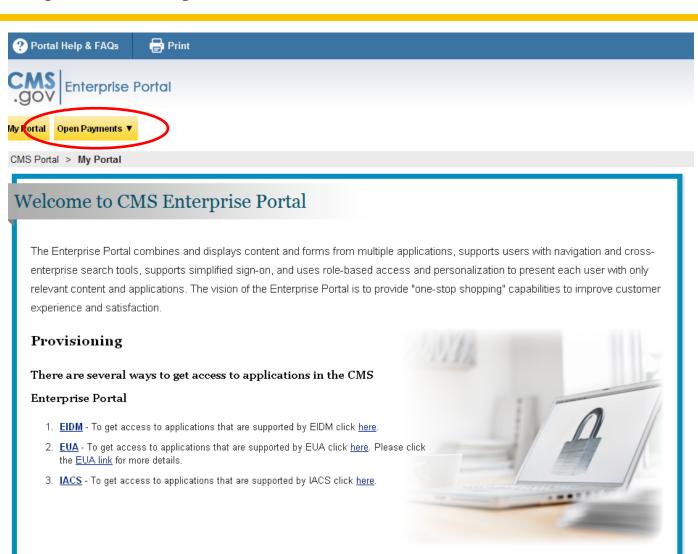
Step 12: Requesting Application Access Successful



- Access may take a few minutes to process
- Log out of EIDM and log back in to view if it was successful



Open Payments Access Successful



Log back into the CMS Enterprise Portal to see the Open Payments tab in the menu bar at the top of the screen.

It may take a few minutes for the Open Payments tab to appear.

Resources



What You Can Do Now

- Complete Phase 1 by:
 - Registering for your EIDM user ID and password
 - Requesting access to the Open Payments system via EIDM
- Continue to organize or gather records on any payments or transfers of value received from applicable manufacturers and applicable GPOs between August 1, 2013 and December 31, 2013 – this material will be referenced during the review and dispute process.
- Work with applicable manufacturers and applicable GPOs to ensure that information submitted about you is accurate
- Register on CMS listserv to receive e-mail updates about the Open Payments program – go to http://go.cms.gov/openpayments and enter email address on the main page, in the "Email Updates" box
- Review resources on the CMS Open Payments website: <u>http://go.cms.gov/openpayments</u>



Resources Available

- CMS is planning a series of tutorial materials to explain the following topics – all will be available on the Open Payments website:
 - AVAILABLE NOW: How to complete registration in CMS'
 Enterprise Portal, explained through step-by-step screenshots
 - COMING SOON: How to complete registration in the Open
 Payments system, explained through step-by-step screenshots
 - COMING SOON: How to complete the review and dispute process, explained through step-by-step screenshots

http://go.cms.gov/openpayments

Mobile Applications

- Two FREE mobile applications to aid physicians and industry in tracking data collected for Open Payments
 - Open Payments Mobile for Physicians
 - Open Payments Mobile for Industry
- The applications are available on mobile platforms Apple (iOS) and Android
- They can be used as a personal information collection and storage tool only







Benefits of Using the App

- Provides a tool to track payments and other transfers of value in real-time
- Serves as a reference tool during data review or information disputes
- Allows physician to provide accurate profile information to industry
- Minimizes the risk of data mismatches later when submitted by industry
- Allows physicians to share event and payment or transfer of value, plus profile information, with industry







Exchanging Information is Easy

Physician App Industry App Send Profile Information Send Profile Information Send TOV Information OPEN PAYMENTS OPEN PAYMENTS



 QUESTION: I have successfully registered in CMS' Enterprise Portal (via EIDM) but I can't register in the Open Payments system. Why is that?

• ANSWER: Remember, you will not be able to access the Open Payments system before Phase 2 begins in July—so if you attempt to access Open Payments through the Enterprise Portal, the radio buttons and functions that you will see on the "Welcome to Open Payments" main screen will not be operational until the system opens for Phase 2 in July.



- QUESTION: Can physicians delegate system access to other users?
- ANSWER: Yes, after physicians have registered themselves through the CMS Enterprise Portal and in the Open Payments system, they can delegate an authorized representative who can review and dispute data on their behalf. The representative will also have to go through the CMS Enterprise Portal (EIDM) and Open Payments registration process, and they would need to also accept their nomination as an authorized representative.



- QUESTION: Will physicians be able to limit the access of their authorized representative?
- ANSWER: Yes. Physicians will have the ability to select one of three access levels for their authorized representative:
 - 1) View only, which will enable the authorized representative to only view the data that was submitted about the physician;
 - Review and dispute, which will enable the authorized representative to dispute records that were reported relating to that physician, and
 - 3) Modify profile, which enables the authorized representative to modify information in a physician's profile, such as update their business address or phone number



 QUESTION: Will the authorized representative of the physician and teaching hospital have access to the physician's private personal data that is used for identification?

• ANSWER: Authorized representatives will be able to view a physician's first and last name, business address, business telephone and email, NPI, and state license numbers. Authorized representatives will not have access to physician user IDs or passwords and will not be able to modify or reset them.



 QUESTION: How many users from a teaching hospital can register to review the pre-published data?

 ANSWER: A teaching hospital may have up to 10 users registered; however, one of the 10 users, but no more than 5, must be an authorized representative. The teaching hospital may also delete one authorized representative and replace him/her with another individual.

 QUESTION: How many users may a physician delegate to review the pre-published data?

 ANSWER: A physician may have 1 authorized representative at a time. The physician may also delete one authorized representative and replace him/her with another individual.

 QUESTION: Does the Open Payments system allow the user to register multiple physicians at the same time.
 For example, physicians in the same group practice?

 ANSWER: No, each physician must register separately and individually.

Questions

 For more information contact the Help Desk at <u>openpayments@cms.hhs.gov</u> or visit us at <u>http://go.cms.gov/openpayments</u>

Thank you!

Question & Answer Session

Evaluate Your Experience

 Please help us continue to improve the MLN Connects™ National Provider Call Program by providing your feedback about today's call.

To complete the evaluation, visit
 http://npc.blhtech.com/ and select the title for today's call.

Thank You

For more information about the MLN Connects™
National Provider Call Program, please visit
http://cms.gov/Outreach-and-Education/Outreach/NPC/index.html

 For more information about the Medicare Learning Network® (MLN), please visit
 http://cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNGenInfo/index.html

