Open Payments…A New Era of Transparency

USC Office of Compliance

Keck Medical Center of USC

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Today's Agenda

- USC Relationship with Industry Policy
- diSCLose
- Open Payment Rule
- In the News…Financial Interests and University Faculty

USC
Relationship with Industry (RWI) Policy Review

September 2009

What drove a need for USC to create a RWI Policy

- AAMC Task Force Report
- Continuing government enforcement
- Impact of industry disclosures and proposed Senate Bill 2029

Principles for Assessing Interactions

- The **interactions should involve knowledgeable parties** on both sides of the interactions.
- Interactions should be in **appropriate settings...** and assure evidence based exchange which is **free of bias** to the maximum extent possible.
- Interactions must **serve the academic mission** as well as legitimate missions of industry.
- **Compensation** and arrangements should be structured to **support the above principles.**

Fundamental USC Position

- USC supports meaningful interactions with Industry.
- USC recognizes that these collaborations have led to the discovery of new knowledge which has directly benefited patients/public health.
- USC seeks to maintain a culture of ethics in its business relations and to minimize conflicts of interest or even the appearance of conflicts of interest.

USC
UNIVERSITY
OF SOUTHERN
CALIFORNIA

MEMORANDUM

TO: All Faculty of the Keck School of Medicine of USC, USC School of Dentistry and USC School of Pharmacy

FROM: Carmen A. Puliafito, M.D., M.B.A.
Avishai Sadan, D.D.S
R. Pete Vanderveen, Ph.D.

DATE: November 2, 2009

SUBJECT: Relationships with Industry

The Keck School of Medicine of USC, the USC School of Pharmacy and the USC School of Dentistry support meaningful interactions and collaborations with Industry. These partnerships through the years have led to the discovery of new knowledge and the development of innovative therapies, which have directly benefited the patients we serve.

However, under no circumstances can we allow these collaborations to have or appear to have improper influence over our core missions of education, research and patient care. As such, we have supported the development of expanded university policy to guide faculty and staff in their interactions with industry. The Relationships with Industry Policy first adopted in January 2008 has now been updated and takes into consideration recommendations from the Association of American Colleges and the American Medical Student's Association. We want to thank the Academic Senate and the USC Healthcare Compliance Committee for their diligent efforts in assisting us with the updating of this policy.

We have attached a copy of the updated policy for your review. Please pay particular attention to new guidance in the following areas:

- **Disclosure of Consulting Arrangements:** Beginning January 1, 2010 these arrangements must now be disclosed, reviewed and approved prior to initiating service to ensure that they do not present a conflict of commitment or conflict of interest. In addition, they must be disclosed to students, residents and fellows when relevant.

- **Industry Sponsored Speaker's Bureaus:** These arrangements are strongly discouraged as they are defined by federal regulations as part of Industry's marketing activities. In all industry sponsored speaking arrangements, faculty must remain in control of the content presented and ensure that the information is based on the best scientific evidence available.

- **Gifts and Free Meals:** Gifts from Industry may not be accepted. Food delivered by or paid for by Industry marketing representatives is defined as a gift and may not be accepted.
- **Industry Donations of Equipment/Devices/Supplies:** These donations must be managed by the School and will require approval from the Office of Compliance.

Our faculty's academic pursuits – your academic pursuits – are the heartbeat of our university. Collaboration with faculty colleagues and with industry is vitally important to the scholarly work that you do. Just as important is your thoughtful cultivation of such relationships to ensure that all such activity is in compliance with the new university policy.

We will be sharing additional communication on this topic around campus in the weeks ahead and will be offering education on the specifics of this policy. Please relay any questions to the Office of Compliance at 213-821-5420.

Thank you for your prompt attention to the important issues surrounding our relationships with industry.

Attachment

Policy Basics

Scope

- Students, residents and fellows are included within the scope of this policy.
- Policy is applicable whether on or off campus.

Industry Sponsored Frequent Speaking Engagements for Non-CE Events

- **Strongly discouraged** as they are defined by federal regulations as part of Industry's marketing activities.
- Requires that faculty remain in control of the content presented and ensure that the presentation is based on the best scientific evidence available.

Disclosure of Consulting Arrangements

- Required disclosure and approval by the chair/or designee, of contracts for consulting and other types of service arrangements with Industry **prior** to the initiation of the consulting.
- Disclosure of consulting/service arrangements when participating in activities relating to purchasing (ex Pharmacy and Therapeutics Committee) and disclosure to students, residents and fellows when relevant.

Policy Basics

Gifts, *Food,* Free Services and Cash Payments from Industry

- Food is now defined as a gift and may not be accepted directly from Industry.

Education Grants and Trainee Scholarships

- Requires deposit of donated industry funds into USC restricted accounts.

- New procedures are in development to guide personnel on the proper mechanism by which to apply for industry sponsored educational grants.

Relationship with Industry Policy

Education Grants and Trainee Scholarships

- Education grants received from Industry must be clearly documented and signed by authorized signer for USC.
- Education events must comply with ACCME Standards for Commercial Support.
  Key Question: Budget? , Educational Objectives? , Target audience?
- Fellowship funding must not exceed the direct cost of fellowship.
- Education funding should not originate from company's sales/ marketing.
- Industry can not influence educational event / content.

Consulting Criteria for Chair Approval

- Is there a detailed Scope of Work?
- Fair Market Value review
- Is there a “quid pro quo”
- When are services provided?
- Conflict of Interest and Commitment Review
- Is the faculty member involved in research with the company requesting services?
- Paid Promotional Speaking Review

Use of diSClose for RWI Disclosures

A “one-stop” system to meet all disclosure requirements

diSClose Update

USC University of Southern California

MEMORANDUM

TO: Faculty, Keck School of Medicine of USC, Ostrow School of Dentistry of USC, USC School of Pharmacy

FROM: Carmen A. Puliafito, M.D., M.B.A, Dean, Keck School of Medicine of USC
Avishai Sadan, D.M.D., Dean, Ostrow School of Dentistry of USC
R. Pete Vanderveen, Ph.D., R.Ph., Dean, USC School of Pharmacy

DATE: April 22, 2013

SUBJECT: Use of "diSClose" to make disclosures under USC's Relationships with Industry policy

The Keck School of Medicine of USC, Ostrow School of Dentistry of USC , and USC School of Pharmacy support meaningful interactions and collaborations with pharmaceutical companies, biotechnology companies, device and medical equipment manufacturers and other healthcare suppliers ("Industry").

As you are aware, however, under no circumstances can we allow these collaborations to have or appear to have improper influence over our core missions of education, research and patient care. Since 2009, USC has required all healthcare professionals who have influence directly or indirectly over the prescribing, dispensing or purchasing of Industry products or services to disclose all consulting activity with Industry for university review and approval. It is therefore critical that all our healthcare professionals strictly adhere to USC's Relationships with Industry policy and promptly disclose all outside relationships with Industry before undertaking the activity so that the university can ensure that the relationship complies with the requirements of the policy.

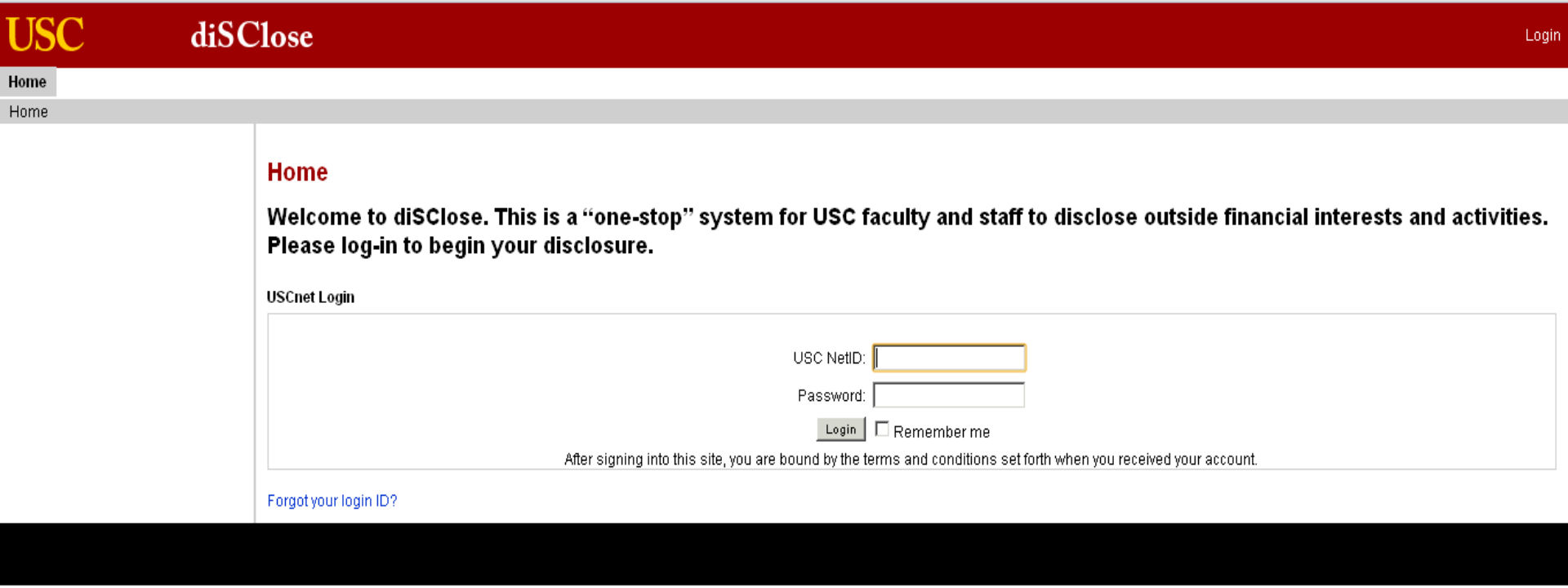
In addition, On February 1, 2013, the Centers for Medicate & Medicaid Services published a final rule commonly known as the Physician Payment Sunshine Act. The Sunshine Act requires Industry to begin gathering records of payments to healthcare professionals effective August 1, 2013. CMS will make the information gathered available to the public on September 30, 2014.

University of Southern California
1234 Trousdale Parkway, Los Angeles, California 90089-1234 • Tel: 213 740 1234 • Fax: 213 740 1234

In light of the Sunshine Act, and to assist USC providers in meeting their obligations under the Relationships with Industry policy, all new disclosures of consulting activity on behalf of Industry must be made using "diSClose" (https://disclose.usc.edu), an on-line system USC has developed to assist in the making and review of disclosures of outside activity. diSClose has been developed to make the disclosure process as efficient and simple as possible. diSClose is also the tool to be utilized if you are a researcher and have any research-related conflicts of interest. For guidance on how to use the system, please visit http://ooc.usc.edu/diSClose-training-videos to review a series of training videos.

Thank you for your cooperation in this important effort.

"…all new disclosures of consulting activity on behalf of Industry must be made using "diSClose" (https://disclose.usc.edu), an on-line system USC has developed to assist in the making and review of disclosures of outside activity."


USC
diSClose
Login
Home
Home
Home
Welcome to diSClose. This is a "one-stop" system for USC faculty and staff to disclose outside financial interests and activities. Please log-in to begin your disclosure.
USCnet Login
USC NetID:
Password:
Login
Remember me
After signing into this site, you are bound by the terms and conditions set forth when you received your account.
Forgot your login ID?

<< Back Save | | Print...

Disclosure Selection

Please check all that apply:

Research

- [ ] I am making/updating an annual financial disclosure - HHS (NIH, CDC, HRSA) researchers only
- [ ] I am making/updating a disclosure of a potential conflict of interest related to research

Relationship with Industry ("RWI")

- [x] I am a Healthcare Professional and have a relationship with a pharmaceutical or medical device company to disclose/update

Business/Personal Conflict

- [ ] I have a potential conflict of commitment to disclose/update
- [ ] I have a potential personal conflict to disclose/update
- [ ] I have a potential business conflict to disclose/update

<< Back Save | | Print...

USC diSClose Edit

<< Back | Save | Exit | Hide/Show Errors | Print... | Jump To: Disclosure Details

Financial Disclosure for Discloser Five : Entity Details

Click "Add Relationship" below to disclose a financial interest with an external company or organization. When you have disclosed all of your financial interests, click 'Continue' at the bottom of the screen.

New Disclosure

1. **Relationships Under Review:**

View/Edit	Organization	Relationship Types	Last Updated
There are no items to display			

2. **Previously Reviewed Relationships (click 'Modify' to enable editing):**

Modify	View	Organization	Disclosure Types	Last Updated
There are no items to display				

<< Back | Save | Exit | Hide/Show Errors | Print... | Jump To: Disclosure Details

Disclosure for Discloser One in Baxter International: Relationships With Industry (RWI)

Please provide details about your Consulting, Advisory Board, Management Roles and Promotional Speaking with the above Entity:

1.0 * What is the total time commitment anticipated under this consulting arrangement?

2.0 * What is the start date of the agreement?

3.0 * Is the term of the agreement limited to one year?

Yes No Clear

4.0 * Is the consulting agreement in writing?

Yes No Clear

[redacted]

4.1 Please upload a copy of the consulting agreement:

Add

Name	Description
There are no items to display	

5.0 * Is your compensation under the agreement based on an hourly rate for actual services performed?

Yes No Clear

6.0 * What is the hourly rate proposed for the services you intend to perform over the remaining term of the contract?

6.1 * To demonstrate that your rate of salary is fair market value, please check the salary scale that you used and attach documentation:

ID
☐ USC salary scale
☐ AAMC or other published salary scale
☐ Other (requires explaination)

6.1.1 Please explain other salary rate:

6.2 Please upload any supporting documents for fair market value:

Add

Name	Description
There are no items to display	

7.0 * Will you be providing these services at the same time that you are engaging in University activity?

○ Yes ○ No Clear

[redacted]

7.1 Please select all that apply:

Reasons
☐ The arrangement has the potential to enhance the health of the public
☐ The arrangement serves USC's academic mission
☐ The arrangement supports academic standards of medical professionalism
☐ Other (please explain below)

7.1.1 You selected 'Other,' please explain why this is an appropriate activity to engage in:

8.0 * Is the paid promotional speaking at an Industry-sponsored event, i.e. speaker's bureau?

○ Yes ○ No Clear

9.0 * Are you responsible for the content of the presentation?

○ Yes ○ No Clear

10.0 * Does the agreement in any way prevent with your ability to be in control of or ultimately responsible for the content of the presentation:

○ Yes ○ No Clear

11.0 * Does the speaking present unsolicited off-label uses of FDA-approved drugs or devices?

○ Yes ○ No Clear

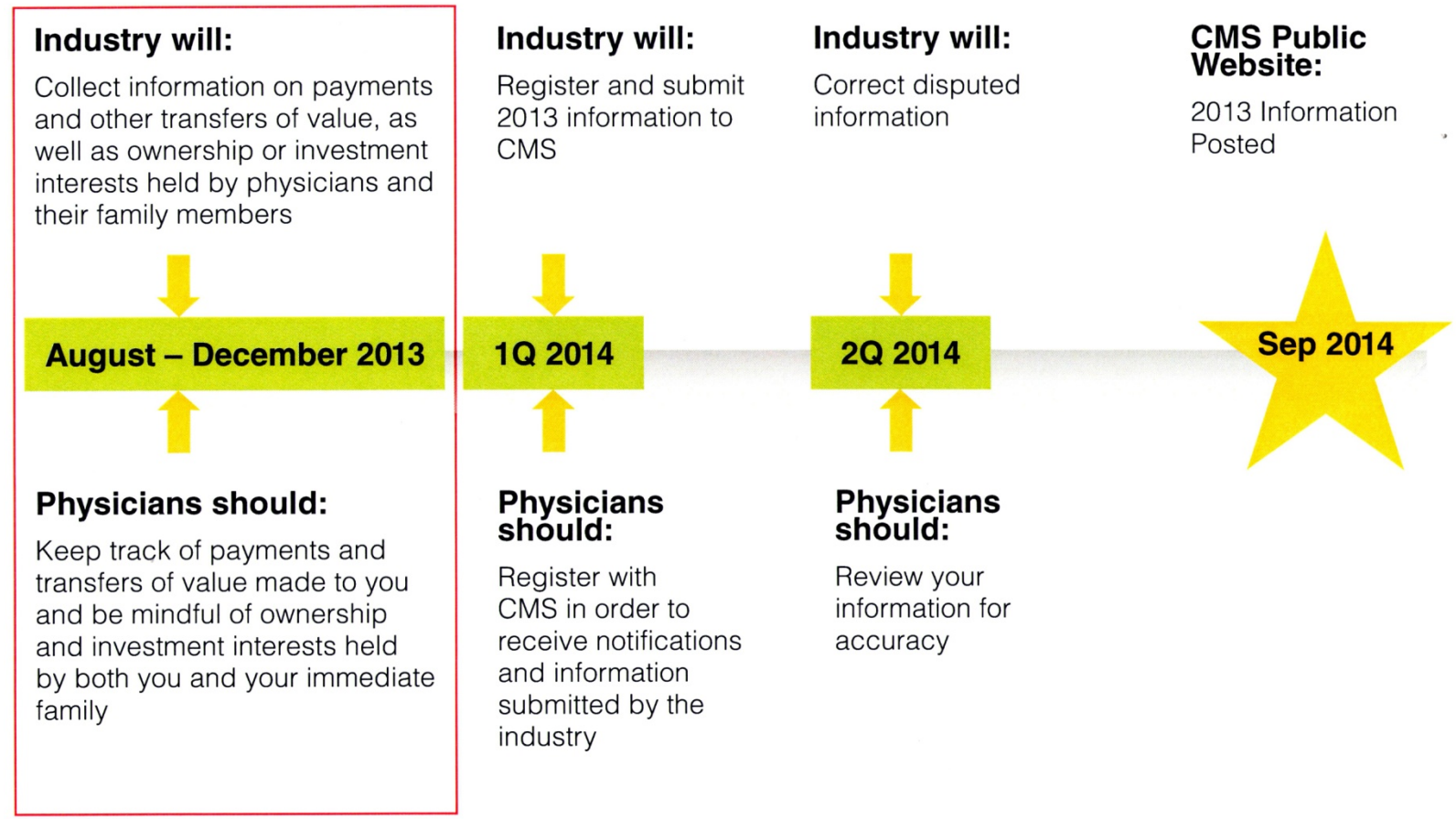
* Required

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: - Relationship With Industry (RWI)

Open Payment Rule

Formerly known as the Sunshine Act

2013 Open Payment Timeline



Reporting Requirements for Industry

- Report annually to CMS
- Report payments or other transfers of value made to physicians and teaching hospitals
- Report ownership or investment interests held by physicians or their immediate family members

Three Types Of Reporting Categories

General Payments

- *Collects and reports payments or other transfers of value not made in connection with a research agreement*

Research Payments

- *Collects and reports payments or other transfers of value made in connection with a research agreement*

Ownership & Investment Interest

- *Collects and reports ownership or investment interests*

Example: Indirect Payments

Payments or other transfer of value made by a manufacturer to a physician or teaching hospital **through an intermediary.**

Scenario	Reported
Pfizer provides $10,000 to a specialty society on October 12, 2013 requesting the award to be split between the two physicians, chosen by the specialty society physicians.	**Information about the two physicians** • Name, address, NPI, license number, specialty ($5,000 will be attributed to each physician that receives the award) **Payment information** • Form of payment, date of payment, and nature of payment
•GSK contracts with an advertisement agency to create an newsletter valued at $35, regarding cutting edge treatments. •GSK provides reprints of journal articles.	• Name, address, NPI, license number, specialty •$35 will be attributed to medical doctors receiving the newsletter **Payment information** • Form of payment, date of payment, and nature of payment

Example: Third Party Payments

Payments or other transfer of value provided to a third party **at the request of or designated on behalf of a physician or teaching hospital.**

Scenario	Reported
GSK provides **Dr. Henry Jones** with a $500 check for serving as a speaker at a round table discussing Rx on August 5, 2013. Dr. Jones requests that GSK provide the compensation to charity.	**Dr. Henry Jones information** •Name, address, NPI, license number, specialty ($500 will be attributed Dr. Henry Jones) **Payment information** •Form of payment, date of payment, and nature of payment, indication that the payment was designated to an entity and that the entity was a charity, as well as, the name of the entity **Drug information** •The marketed name of the covered drugs

Continuing Medical Education

Compensation for speaking at a continuing education program is not required to be reported, if all of the following conditions are met:

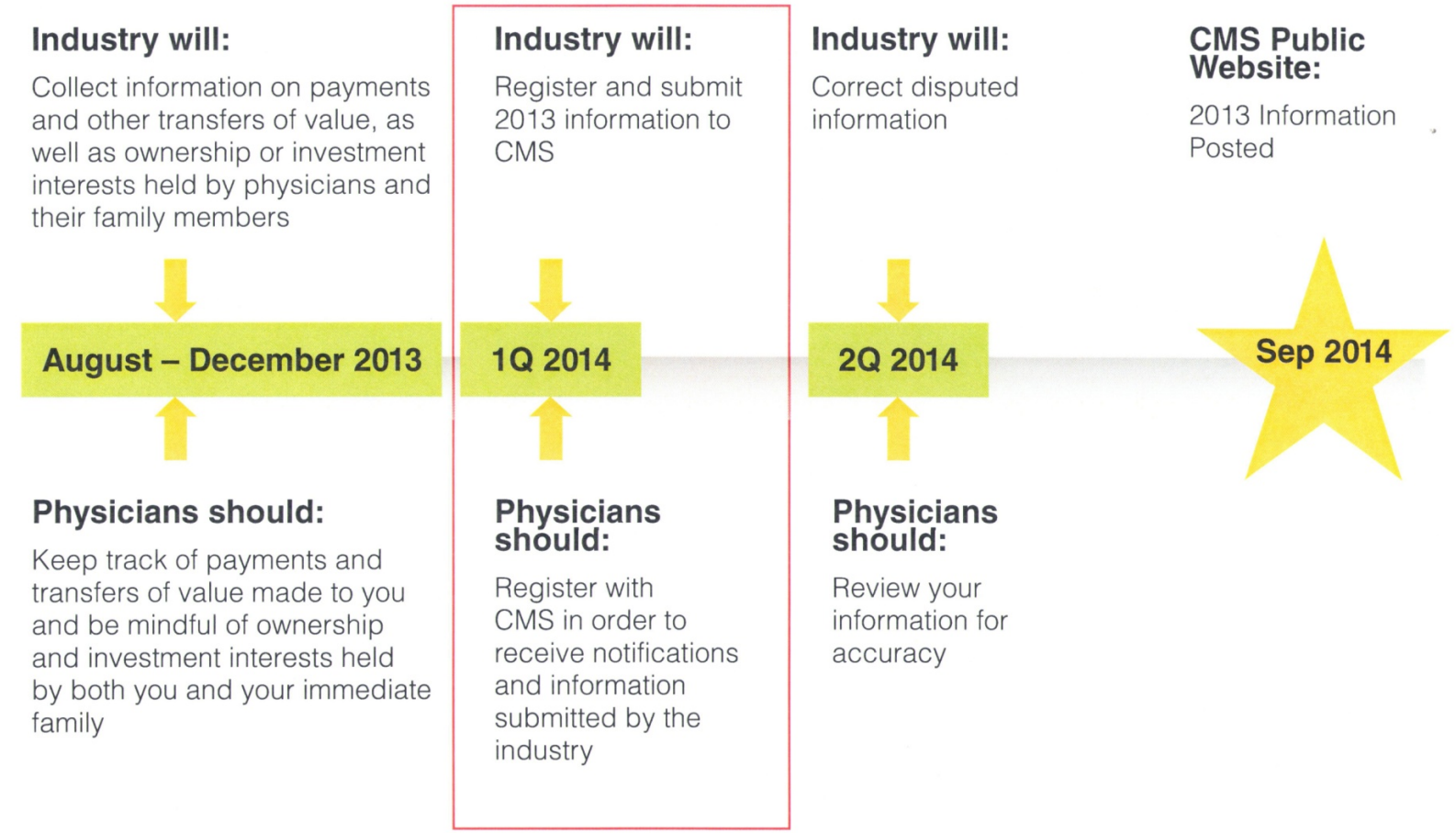
1. The program meets the accreditation or certification requirements and standards of the ACCME, AOA, AMA, AAFP or ADA CERP.
2. The manufacturer does not directly pay the physician speaker.
3. The manufacturer does not select the physician speaker nor does it provide the third party vendor with a distinct, identifiable set of individuals to be considered as speakers for the accredited or certified continuing education program.

CONTINUING MEDICAL EDUCATION
Physician-Attendees and Physician Faculty/speakers

Indirect payments associated with CME activities:	Physician-Attendees	Physician-Faculty/ Speakers	Physician-Attendees	Physician-Faculty/ Speakers
	Accredited or certified *		Non-accredited or non-certified	
Meals	✔	X	✔	✔
Travel and Lodging	✔	X	✔	✔
Tuition Fees	X	X	✔	✔
Educational Materials included in CME Tuition Fees	X	X	✔	✔
Educational Materials not included in CME Tuition Fees	✔	X	✔	✔

*Must meet all of the conditions in accordance with § 403.904(g)(1)

2013 Program Cycle: Registration



Physicians: Track and Review Your Information

- Physicians should track all interactions they have with industry involving payments or transfers of value to ensure accuracy
- Physicians should register to receive a preview of the data to be made public (discussed later)

- **Specific Physician Information Reported by Industry**
  - Full legal name (as appears in National Plan & Provider Enumeration System - NPPES)
  - Primary and specialty
  - Primary business address
  - NPI (as appears in NPPES)
  - State professional license number(s)
  - Email address
  - Information about the Covered Product
    - Name(s) of the related covered drug, device, biological, or medical supply
  - Information about the Payment
    - Amount, date, form, and nature of payment or other transfer of value
    - Number of payments
    - If designated to a third party, the name of individual or entity the physician indicated to receive the payment

Physicians: Track and Review Your Information

- 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**)

Physician/Teaching Hospital Registration

- Physicians and teaching hospitals are not required to register with the program
- However, voluntary registration will allow physicians and teaching hospitals to review their data prior to public release
- Physicians will be able to dispute any data thought to be incorrect for manufacturers and GPOs to review
- Physicians, teaching hospitals and authorized representatives will be able to review and dispute information

Industry registration ended 3/31/14. Physician registration began June 1, 2014.

Physician Registration Begins

- Phase I - Registration to the CMS Portal (6/1/14)
  - Creates account on the CMS Portal
  - Allows user to request Open Payment Application access

- Phase II
  - Will allow user to access the Open Payment Application when online in July (TBD) to review and dispute information submitted by industry regarding physician

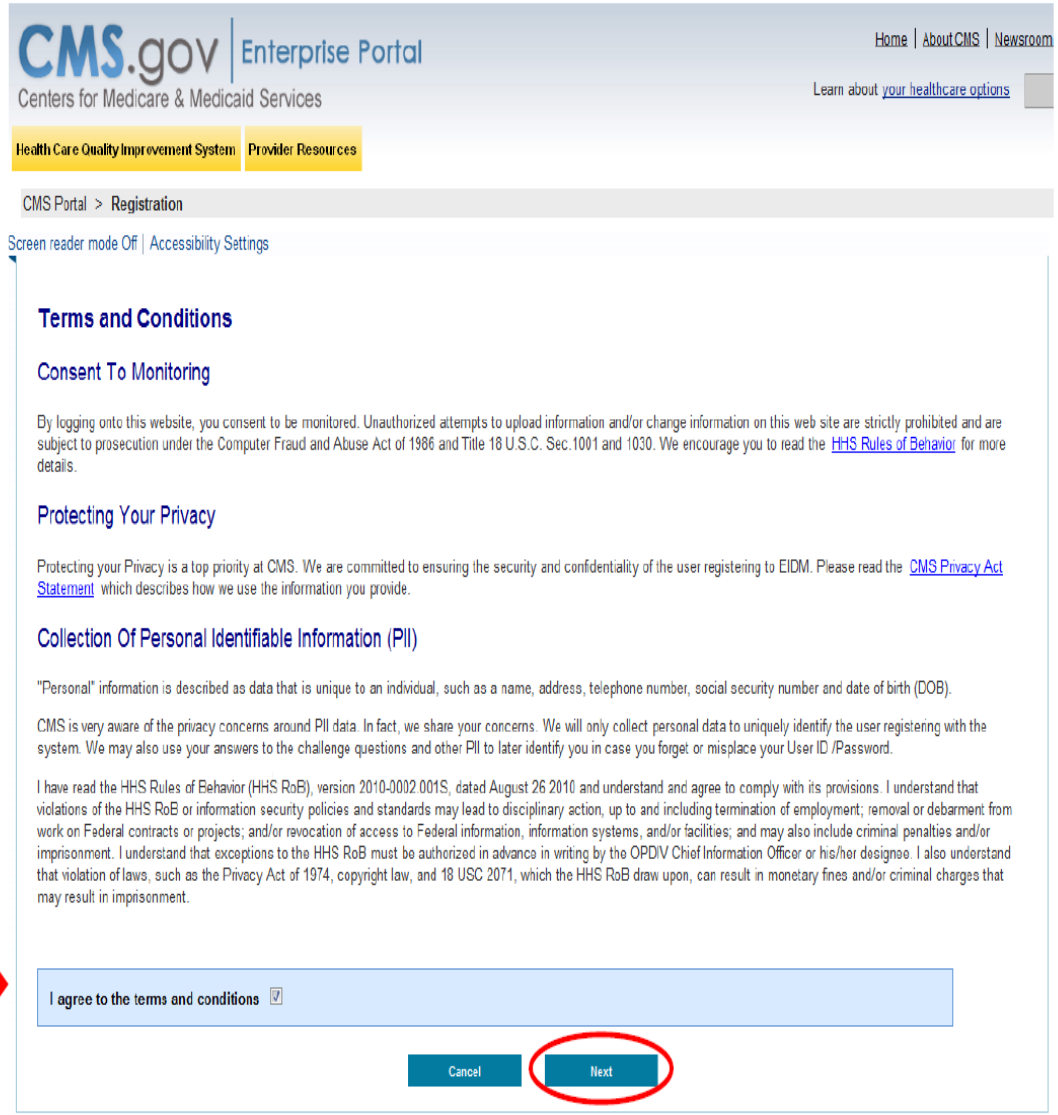
Instructions for Phase I

https://portal.cms.gov

- Go to https://portal.cms.gov

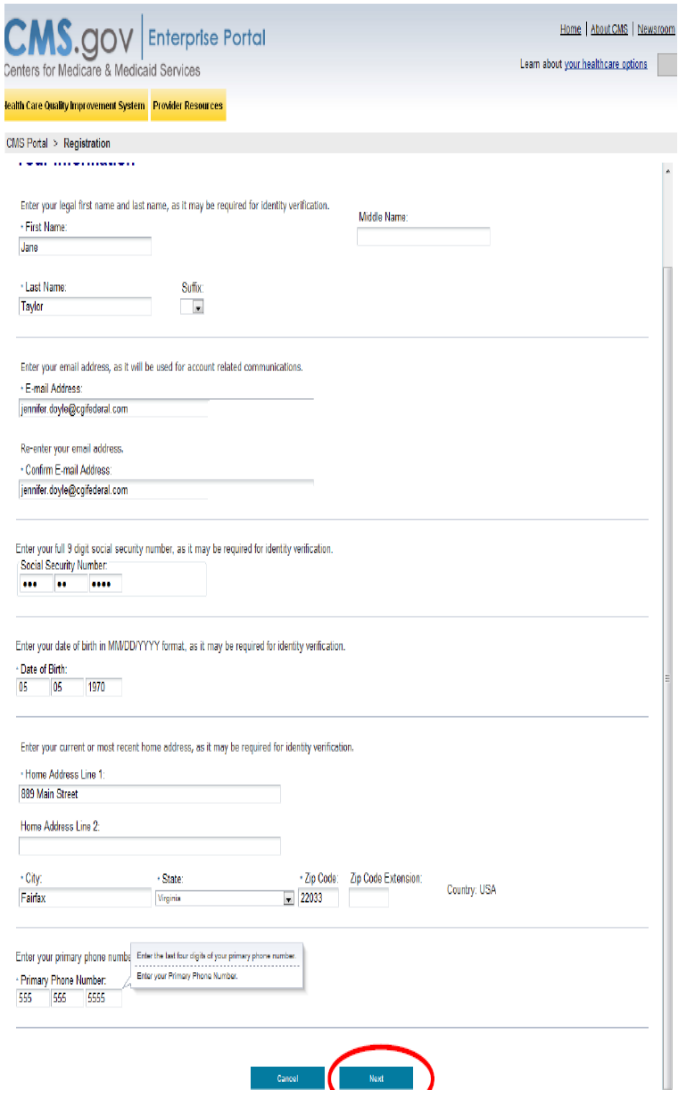
On the Right side of the screen click on "New User Registration"

Click
I accept to the Terms



Enter your personal Information

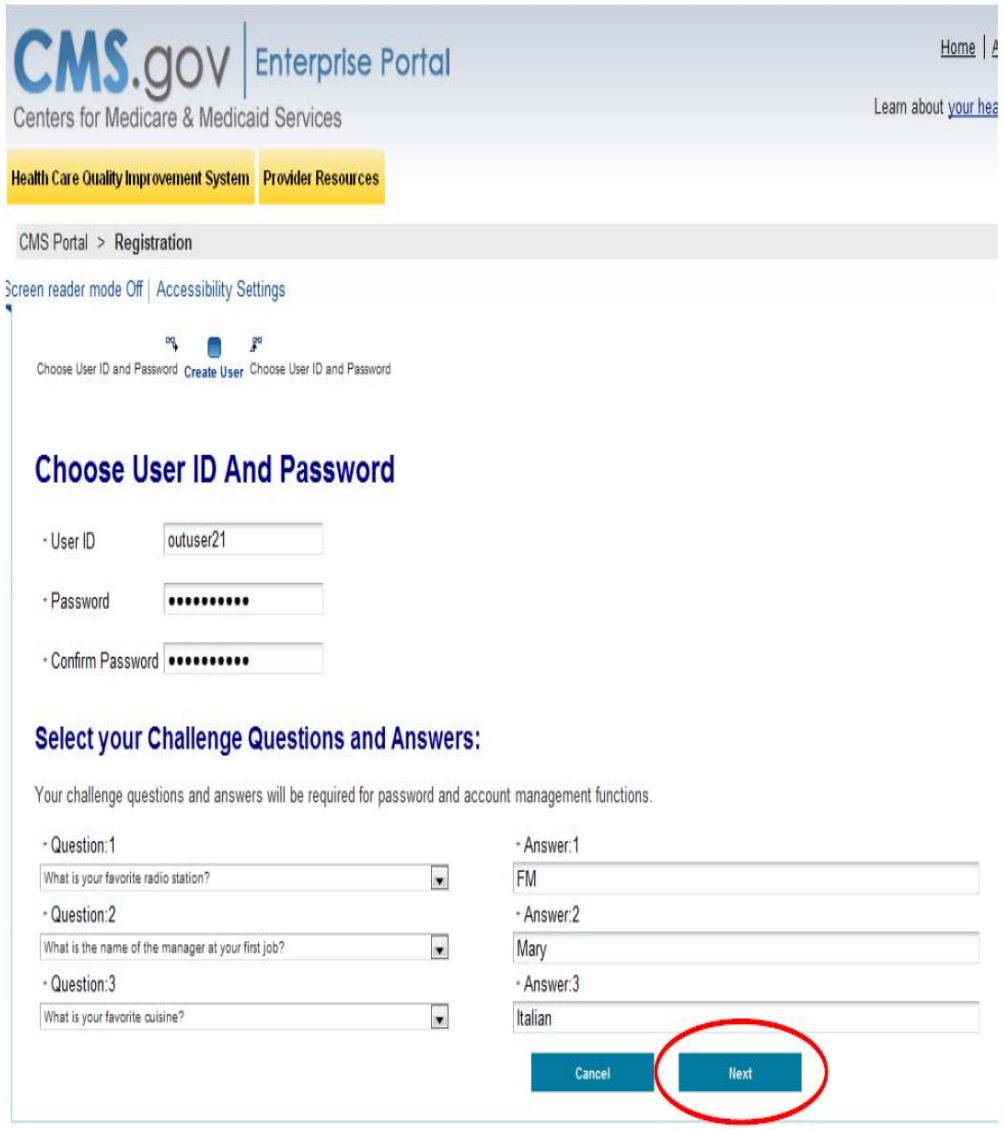
-Name
-Email
- SS
-DOB
Address
Phone #



Required fields are marked with an asterisk.

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

Select User ID, Password and Challenge Questions

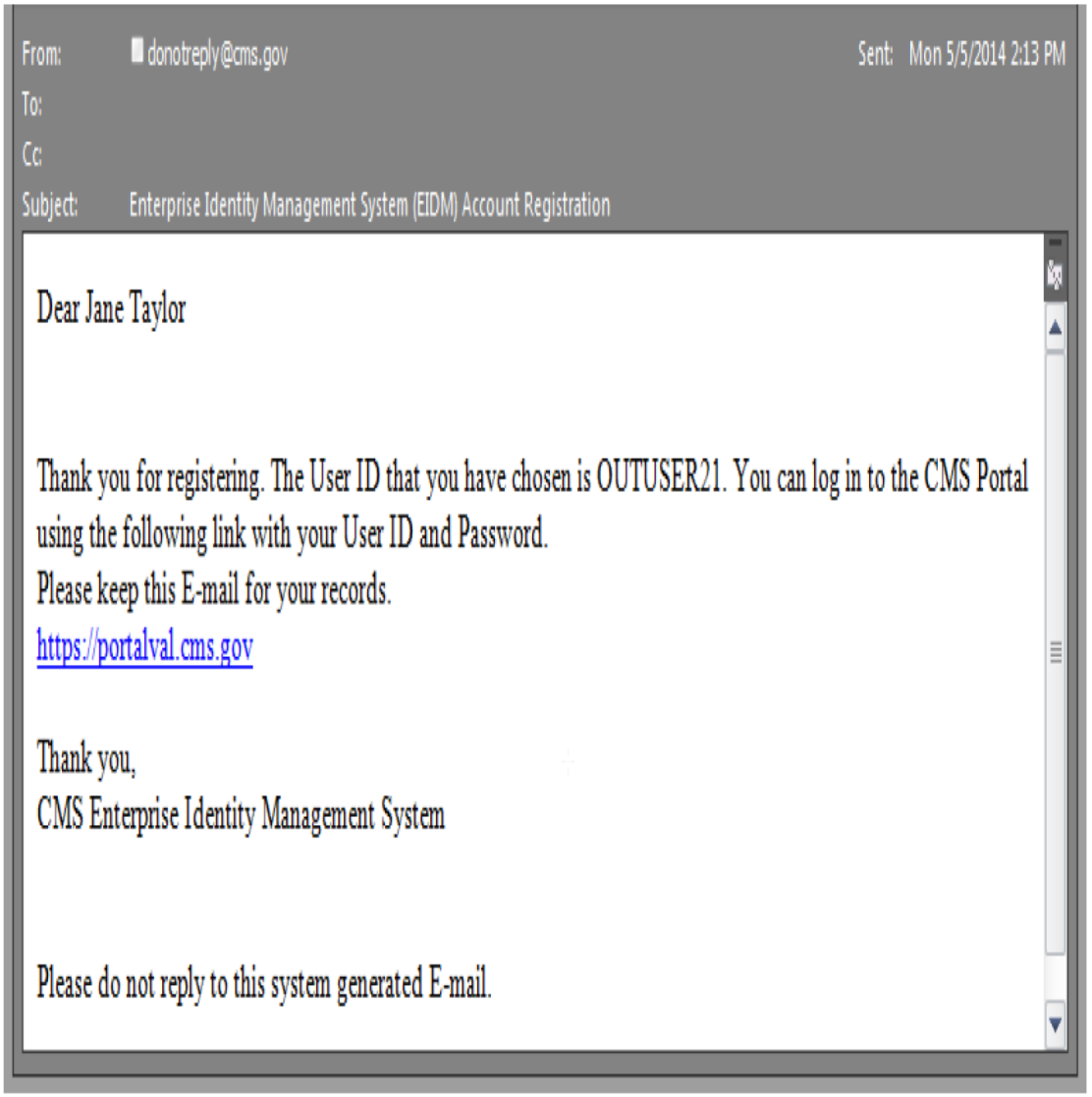


Click "OK" to complete Part 1 of Registration

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.

Look for an email providing User ID to continue registration



From: donotreply@cms.gov Sent: Mon 5/5/2014 2:13 PM
To:
Cc:
Subject: Enterprise Identity Management System (EIDM) Account Registration

Dear Jane Taylor

Thank you for registering. The User ID that you have chosen is OUTUSER21. You can log in to the CMS Portal using the following link with your User ID and Password.
Please keep this E-mail for your records.
https://portalval.cms.gov

Thank you,
CMS Enterprise Identity Management System

Please do not reply to this system generated E-mail.

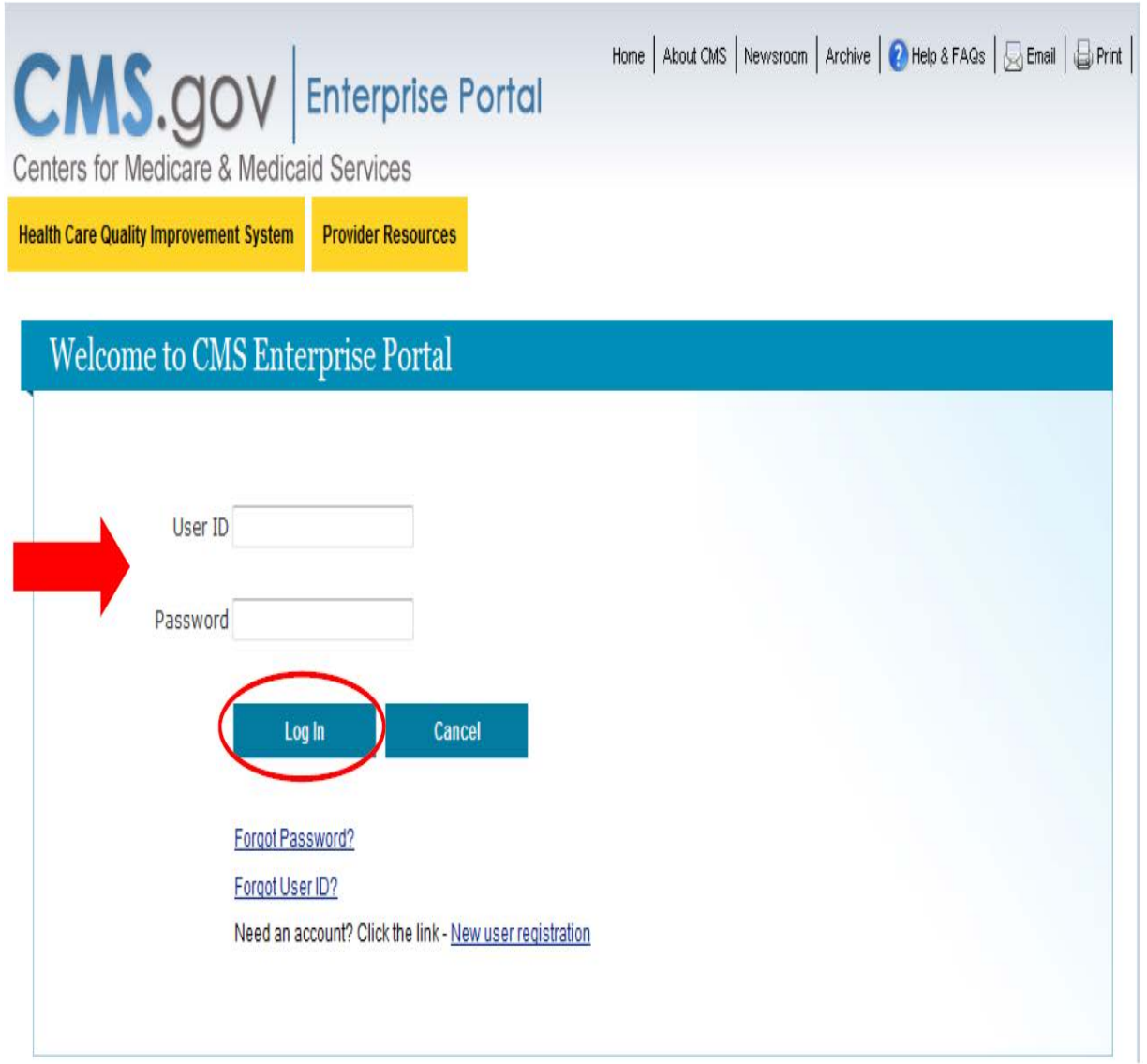
Go back to
https:/portal.cms.gov

On the right side of the screen click on “Login to the CMS Secure Portal”

Click

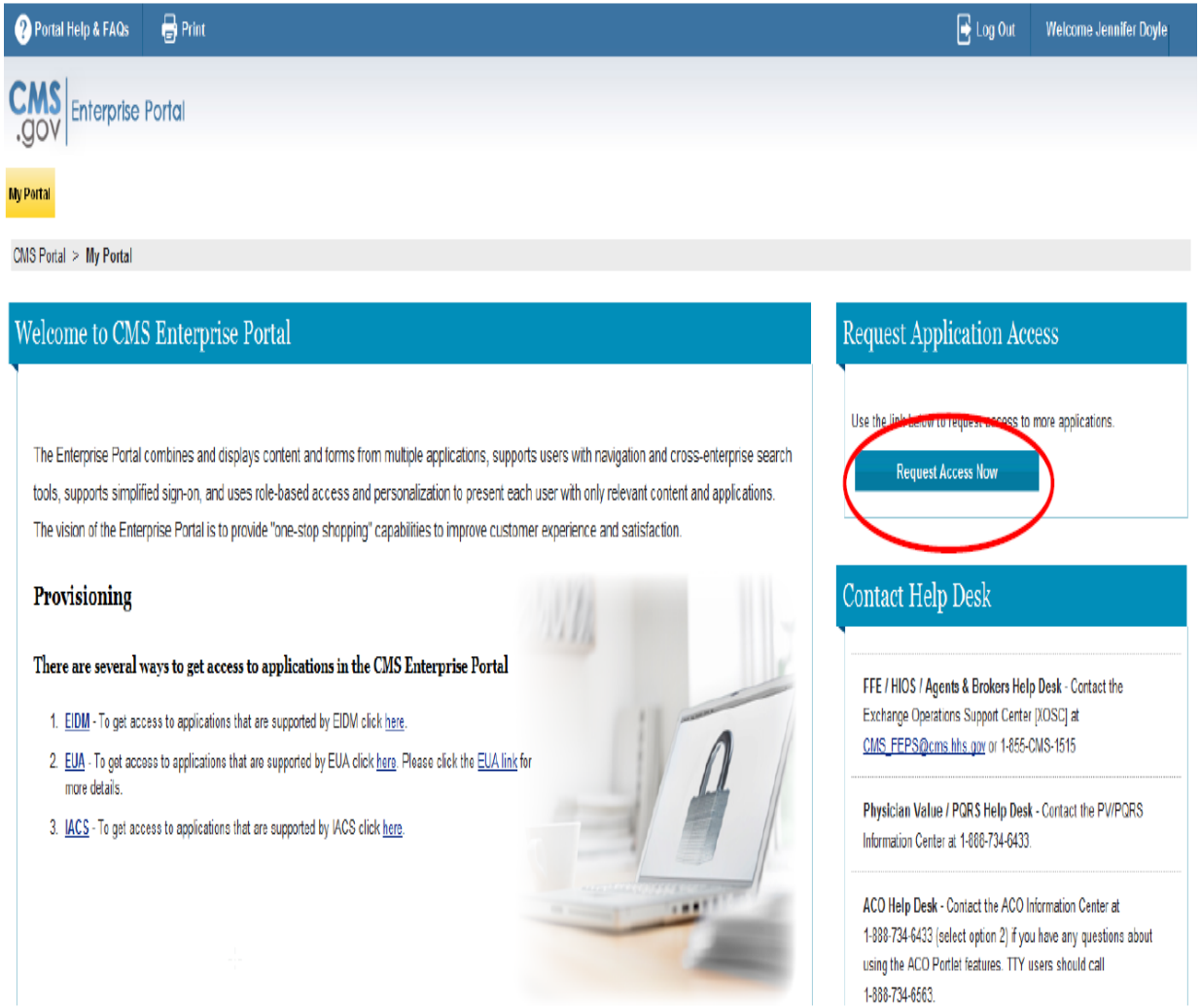
I Accept

Enter User ID and Password



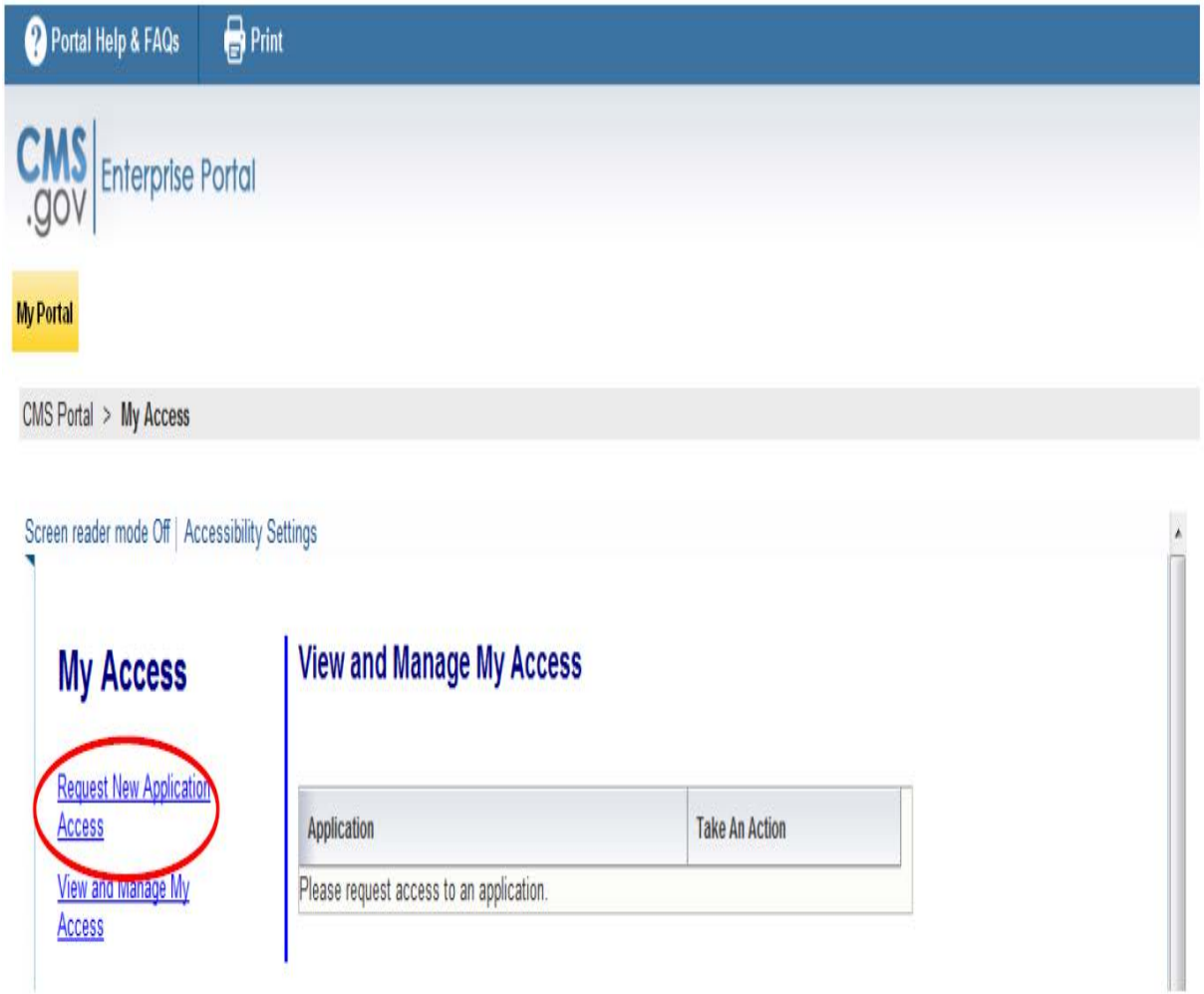
Click

"Request Access Now"



Click

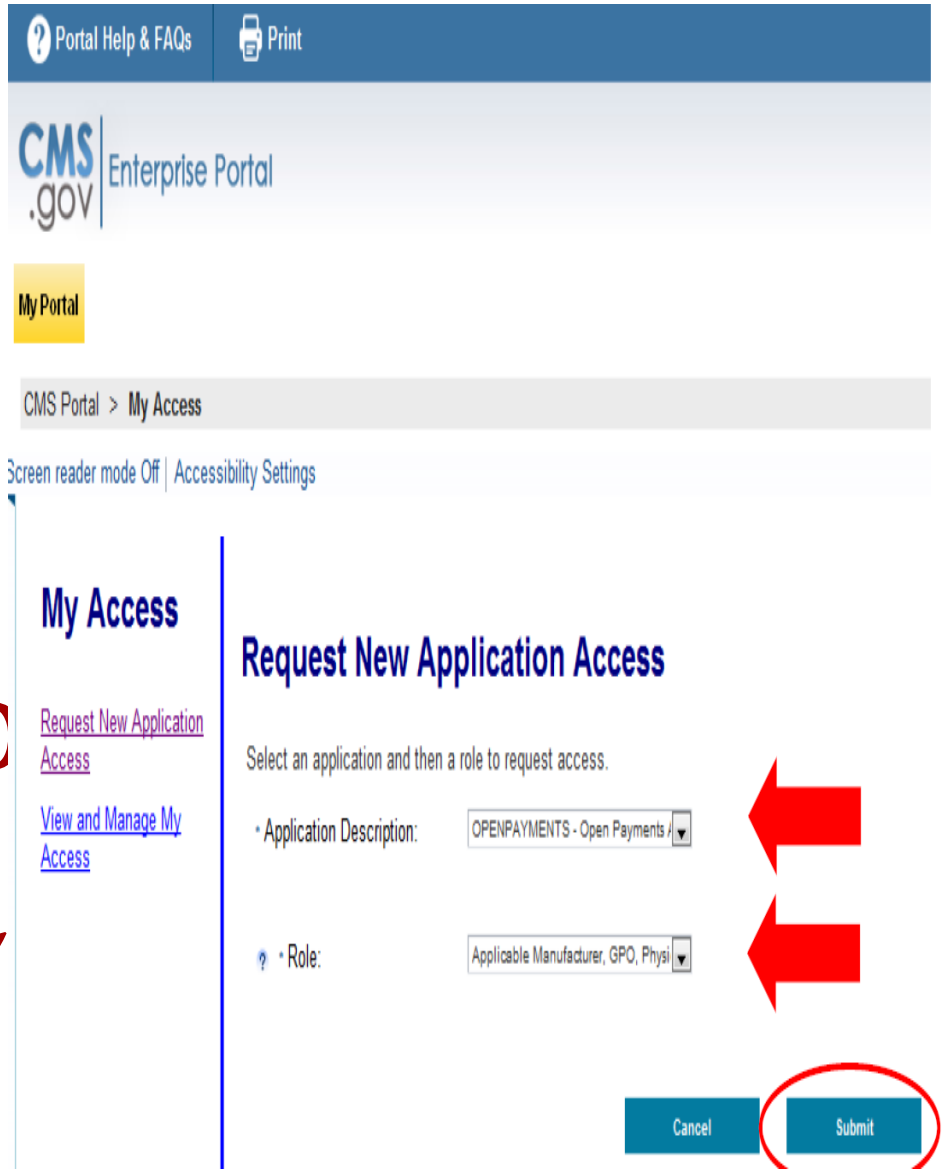
"Request New Application Access"



Select

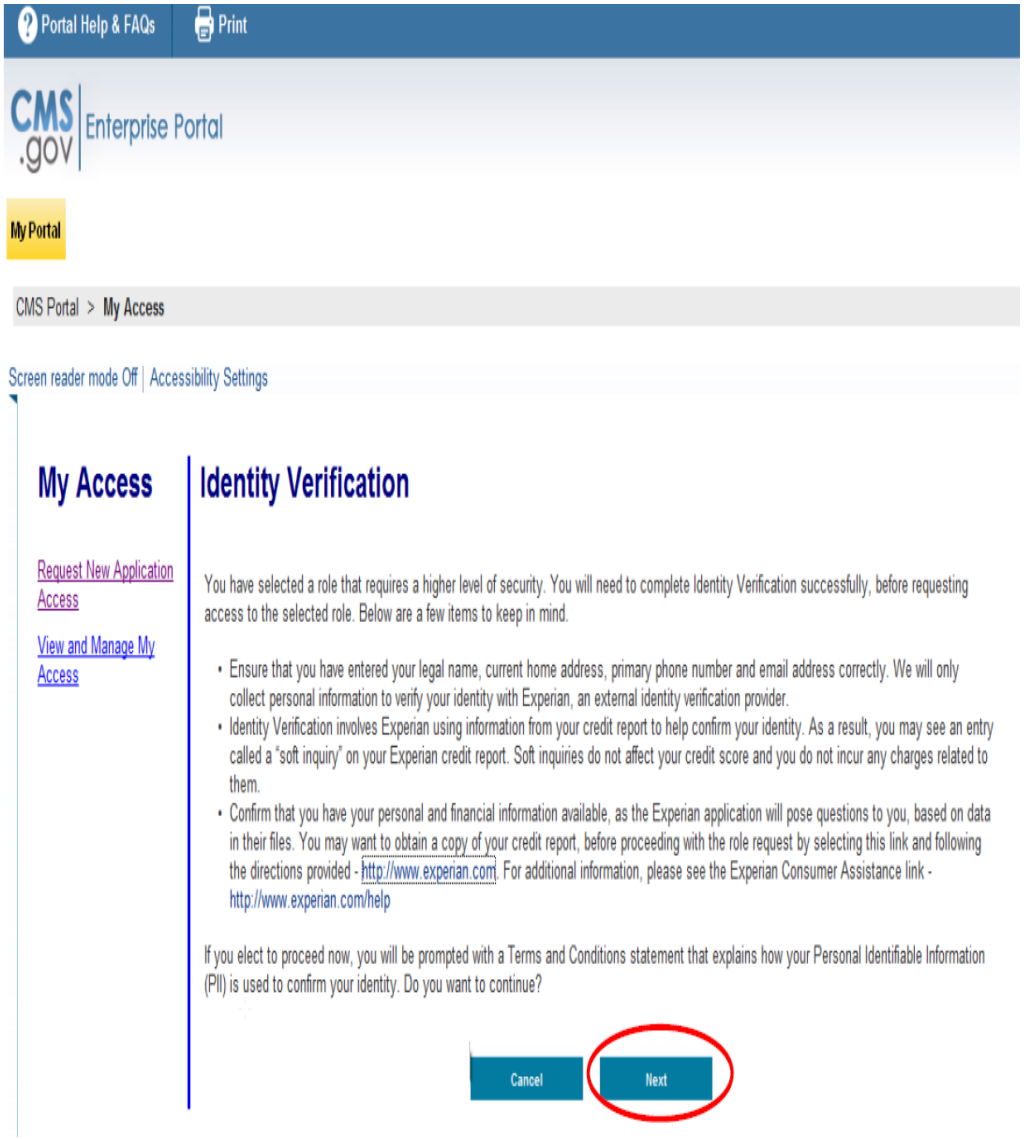
"Open Payments"

"Applicable Manufacturer, GPO, Physician or Teaching Hospital"



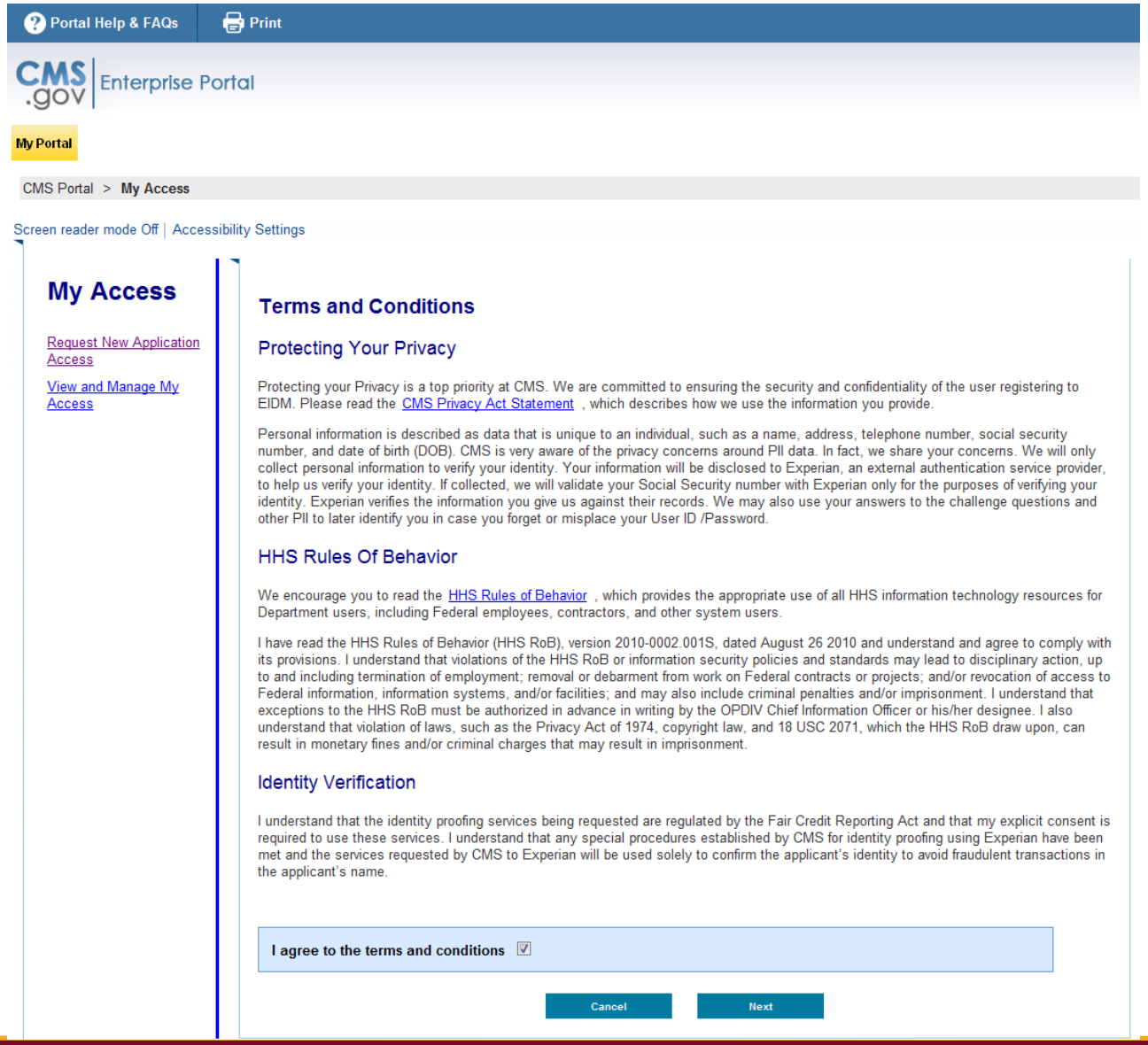
Review Identity Verification Terms

Click Next

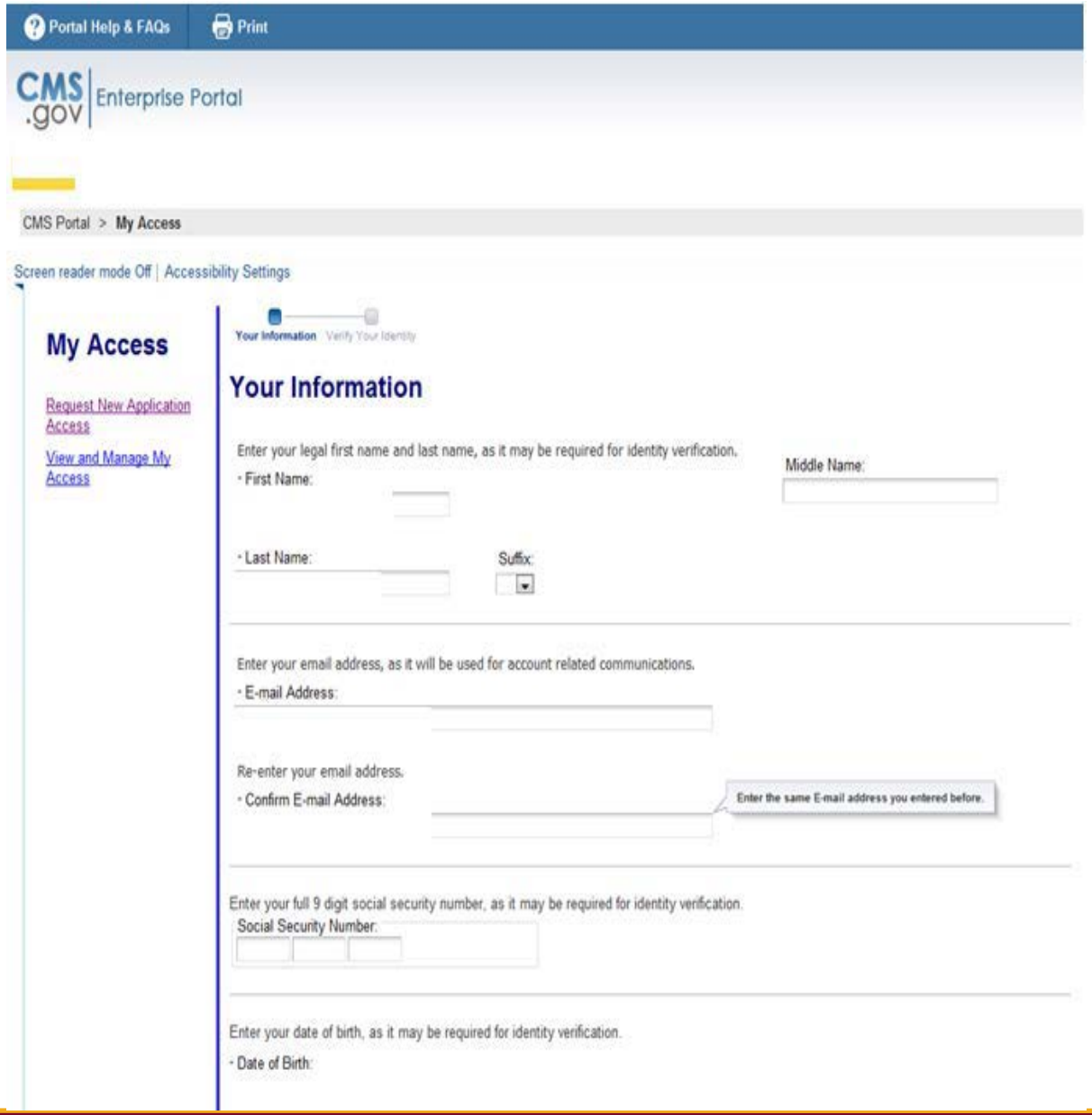


Click
I agree to the terms

Click
Next

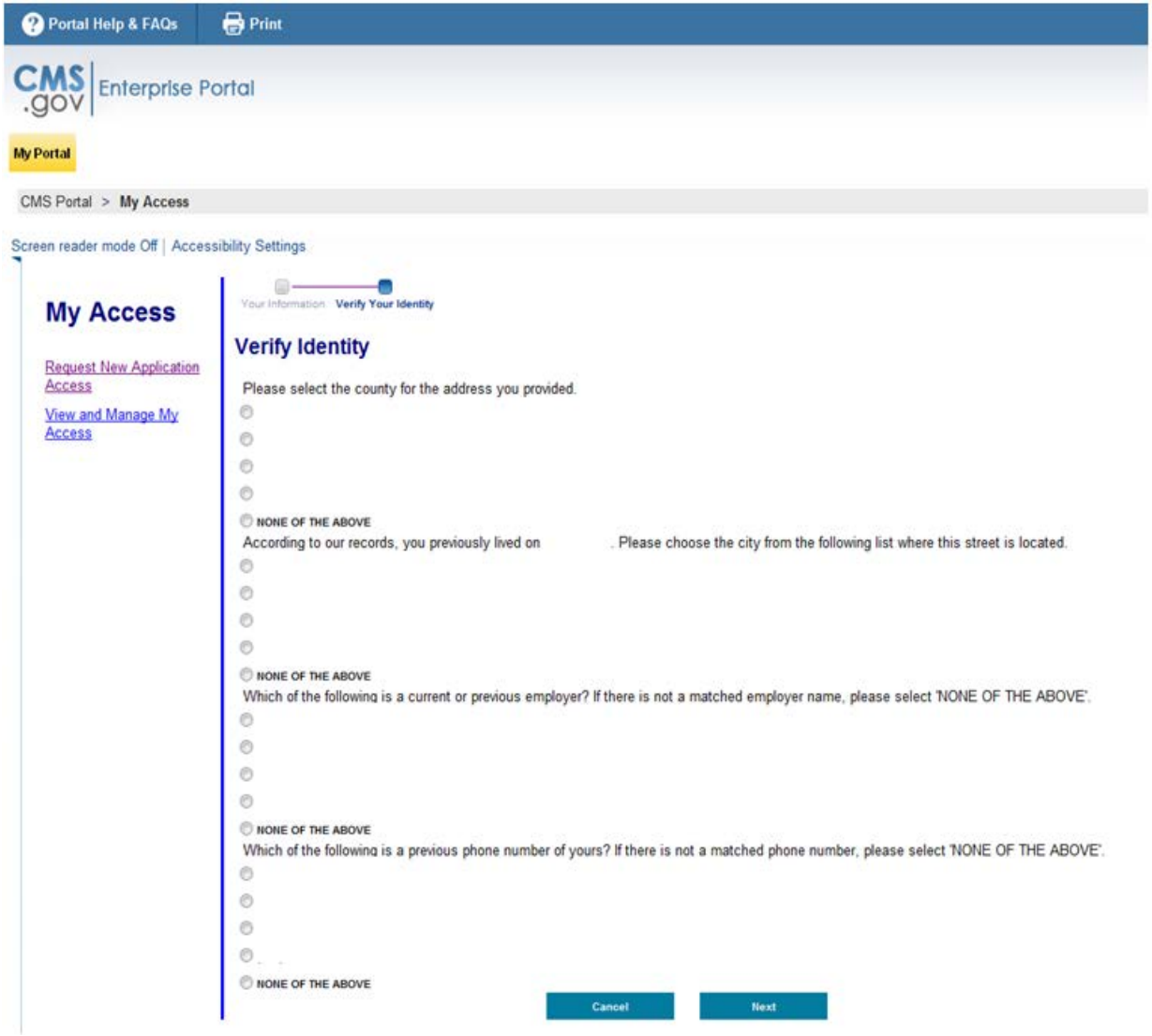


Confirm Your Information and Edit (if necessary)



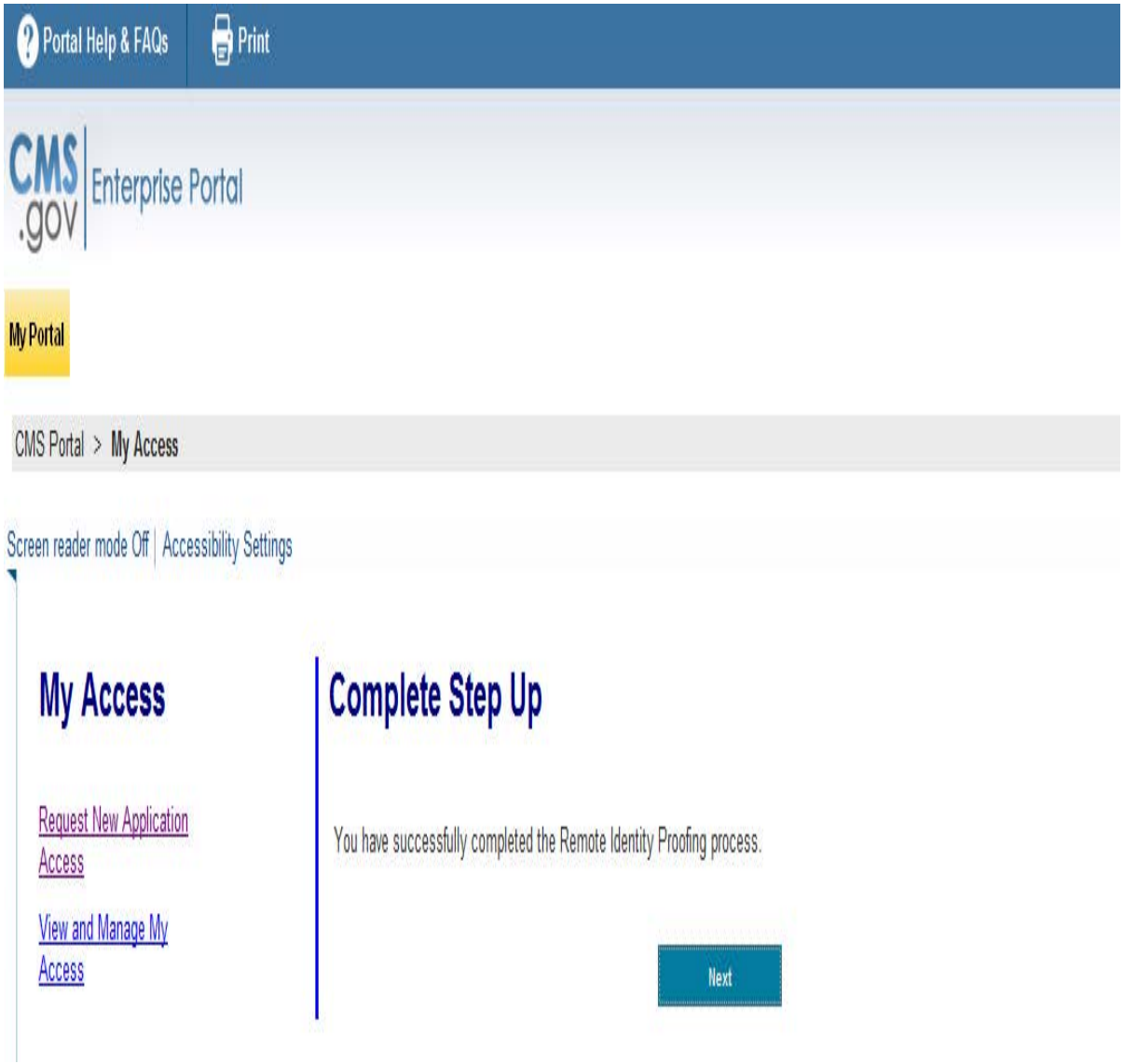
Verify Identity

Questions are based on "Out of Wallet" questions taken from your credit report



Verifying Identity Successful

Click Next



Select OK to continue

Next Step

July 2014

Phase 2 roll out for Physicians and Teaching Hospitals. At that time you will be able to:

- Review,
- Dispute
- Request Corrections

Dispute and Resolution

- Physicians may initiate data disputes to correct inaccurate information anytime before the end of the calendar year in which the information was publically available.
- If the manufacturer is unable to resolve the dispute with the physician or teaching hospital and correct the data in the initial 45-day or subsequent 15-day period, the manufacturer and physician or teaching hospital should continue to seek a resolution.
- Corrections from disputes initiated after 45 days may not be reflected in the initial public data.
- Data from unresolved disputes will still be posted publically but will be marked as "disputed."
- CMS will monitor the dispute and resolution process and will update the public data at least once annually.

Physician Tools & Resources

Information

- ✓ Webpage dedicated to physicians (http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Physicians.html)
- ✓ Fact Sheets specific to physicians
- ✓ Continuing Medical Education modules (2)
- ✓ Brochure summarizing Open Payments for physicians (http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Downloads/Physician-Publication.pdf)
- ✓ Brochure summarizing Open Payments for patients
- ✓ See Summary Sheet provided as a quick reference

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
- Applications are available for Apple (iOS) and Android

- Benefits include:
  - Provides a tool to track payments and transfers of value in real-time.
  - Serves as a reference tool during review or information disputes

Accessing the App

Visit the iOS or Google Play Store online or on your phone and follow the steps listed below.

Available on the iPhone App Store

ANDROID APP ON Google play

1. Select "Search."
2. Search for Open Payments – both apps will appear for download.
3. Select "Install" for the app you want and the app will download to your device.

In the News…

"More scrutiny for UCLA's School of Medicine"

LA Times Article 4/25/14 (http://www.latimes.com/business/la-fi-ucla-outside-money-20140426,0,1223431.story#axzz2zx8MEt4q)

- UCLA $10-million settlement between the UC system and the former head of orthopedic surgery at UCLA to address failure to act on complaints about widespread conflicts of interest among medical school faculty and retaliation.
- Article brings more attention around university faculty financial ties to industry and the repercussions on patient care and references the Journal of American Medical Association (JAMA) recent study that raised concerns over university officials having financial interests in industry.
- The study named Eugene Washington who serves as the UCLA Medical School dean and on the board of Johnson & Johnson and Dean Pete Vanderveen of USC School of Pharmacy who serves on the board of Mylan Inc.
- The JAMA Study found that 41 board members at large companies held leadership posts at academic medical centers.

Instances such as these are drawing more and more attention from the government and patient advocates. The article references the Open Payment Rule and that the public disclosure of financial relationships between medical companies and doctors will go into effect in Fall 2014.

We are here to help…

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