

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: September 20, 2010.

**Jennifer Spaeth,**

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-23979 Filed 9-23-10; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2010-N-0481]

**Center for Veterinary Medicine eSubmitter Workshop; Public Workshop; Request for Comments**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing a public workshop entitled: "Center for Veterinary Medicine (CVM) eSubmitter Workshop." The purpose of the public workshop is to provide the regulated animal health industry that submits new animal drug applications to CVM's Office of New Animal Drug Evaluation (ONADE) access to the beta-release of the electronic submission tool (eSubmitter) developed by CVM as agreed to in the Animal Drug User Fee Amendments (ADUFA II) of 2008 (<http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/ucm044941.htm>). The ONADE will be soliciting feedback on both the eSubmitter tool and its compatibility with the industry's current IT systems, as well as the questions asked within the tool.

This workshop will fulfill one of the 10 workshops agreed to in ADUFA II. The workshop will provide insight on the eSubmitter template development and its customization for the animal health industry as well as providing break-out sessions in which specific submissions will be built as part of the demonstration. Lastly, the ONADE will be seeking up to nine participating companies to work with CVM in testing the transmission of eSubmitter developed files through FDA's electronic submission gateway (ESG) and CVM's electronic submission system (ESS). Information about the workshop and availability of the eSubmitter tool can be found on FDA's eSubmitter Web site at <http://www.fda.gov/ForIndustry/FDAeSubmitter/default.htm>.

**Dates and Time:** The public workshop will be held on October 21, 2010, from 9 a.m. to 4 p.m. (EST/EDST).

**Location:** The public workshop will be held virtually through both Adobe Connect Pro on-line and with conference call-in numbers. Both the call-in numbers and the Adobe Connect Pro web link will be emailed to all registrants.

**Contact Person:** Charles Andres, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 240-276-8229, email: [charles.andres@fda.hhs.gov](mailto:charles.andres@fda.hhs.gov).

**Registration:** Registration for the workshop can be made at: [https://collaboration.fda.gov/cvm\\_esubmitter\\_workshop\\_oct21/event/registration.html](https://collaboration.fda.gov/cvm_esubmitter_workshop_oct21/event/registration.html) on or before October 15, 2010. There is no registration fee for the public workshop. If you need special accommodations due to a disability, please contact Charles Andres (see *Contact Person*) at least 7 days in advance.

**Comments:** FDA is holding this public workshop to obtain information about the eSubmitter tool. The deadline for submitting comments regarding this public workshop is December 31, 2010.

Regardless of whether a person attended the public workshop, interested persons may submit either electronic or written comments regarding this document. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville MD 20852. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

**Transcripts:** Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page. A recording of the public workshop will be available on the Internet at <http://www.fda.gov/ForIndustry/FDAeSubmitter/default.htm>.

Dated: September 17, 2010.

**Leslie Kux,**

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-23972 Filed 9-23-10; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

[CMS-3233-N]

**Medicare Program; Town Hall Meeting on the Physician Compare Web Site, October 27, 2010**

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Notice of meeting.

**SUMMARY:** Section 10331 of the Patient Protection and Affordable Care Act of 2010, "Public Reporting of Performance Information" requires CMS to establish a Physician Compare Web site by January 1, 2011. This notice announces a Town Hall meeting to discuss the Physician Compare Web site. The purpose of this Town Hall meeting is to solicit input from stakeholders on the Physician Compare Web site. The opinions and alternatives provided during this meeting will assist us in future expansion of the Physician Compare Web site. The meeting is open to the public, but attendance is limited to space available.

**DATES: Meeting Date:** Wednesday, October 27, 2010 from 1 to 5 p.m., eastern daylight time (*e.d.t.*).

**Timeframe for Meeting Registration:** Monday, September 27, 2010 through Wednesday, October 13, 2010 at 5 p.m., *e.d.t.*

**Deadline for Special Accommodations Requests:** Wednesday, October 13, 2010 at 5 p.m., *e.d.t.*

**ADDRESSES: Meeting Location:** The Town Hall meeting will be held in the main auditorium of the Centers for Medicare and Medicaid Services single site, 7500 Security Boulevard, Baltimore, MD 21244.

**Registration and Special Accommodations:** Persons interested in attending the meeting or participating by teleconference must register by completing the online registration via the Web site at <http://www.usqualitymeasures.org/qm/>. Individuals who require special accommodations should send a request via e-mail or regular mail to the contact specified in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

*Written Comments or Statements:* Written comments or statements may be sent via e-mail to [physiciancompare@cms.hhs.gov](mailto:physiciancompare@cms.hhs.gov) or sent via regular mail to: Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244-1850, Mail Stop S3-02-01, Attn: Physician Compare Town Hall Meeting Comments. All persons planning to make a statement in person at the listening session are urged to submit statements in writing during the Town Hall meeting and should subsequently submit the information electronically by the timeframe specified in the **DATES** section of this notice.

**FOR FURTHER INFORMATION CONTACT:** Regina Chell, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, Mailstop S3-02-01, Attn: Physician Compare Town Hall Meeting, 7500 Security Boulevard, Baltimore, MD 21244 or contact Ms. Chell by phone at 410-786-6551, or via e-mail at [Regina.Chell@cms.hhs.gov](mailto:Regina.Chell@cms.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Section 10331 of the Patient Protection and Affordable Care Act of 2010 (the Affordable Care Act) requires CMS to establish a Web site, which will be known as Physician Compare, containing information on physicians enrolled in the Medicare program and other eligible professionals who participate in the Physician Quality Reporting Initiative (PQRI) by January 1, 2011. Section 10331 of the Affordable Care Act also requires CMS to implement a plan to make information on physician performance publicly available through the Physician Compare Web site no later than January 1, 2013 (and for reporting periods beginning no earlier than January 1, 2012).

In implementing section 10331 of the Affordable Care Act, the law requires establishing processes, to the extent practicable, to ensure the following:

- The data made public are statistically valid and reliable, and provide an accurate and robust portrayal of performance.
- Appropriate attribution of care.
- Timely statistical performance feedback.
- The data reflects the care provided to all patients including Medicare and other payers where such data would more accurately portray performance.
- Physicians and other eligible professionals have a reasonable opportunity to review their individual data prior to publication.

The Affordable Care Act also requires the assurance of patient privacy, input

from multi-stakeholder groups, and taking into consideration the plan to transition to value-based purchasing. Section 10331 of the Affordable Care Act also requires CMS to submit a Report to Congress on the Physician Compare Web site by January 15, 2015, and authorizes CMS to establish a demonstration program by January 1, 2019, to provide financial incentives to Medicare beneficiaries who are furnished services by high quality physicians. The Affordable Care Act requires that the measures include, to the extent practicable, the following:

- Measures collected under the PQRI;
- An assessment of patient health outcomes and the functional status of patients;
- An assessment of the continuity and coordination of care and care transitions, including episodes of care and risk-adjusted resource use;
- An assessment of efficiency;
- An assessment of patient experience and patient, caregiver, and family engagement;
- An assessment of the safety, effectiveness, and timeliness of care; and
- Other information as determined appropriate by the Secretary.

**II. Town Hall Format**

The Town Hall meeting will begin with an overview of the objectives for the session. The remainder of the meeting will be devoted to presenting and receiving input on possible key Web site design issues.

Following each presentation, the meeting agenda will provide opportunities for brief 2-minute comments on each of the key issues from on-site session attendees. As time allows, telephone participants will also have the opportunity to provide brief 2-minute comments on each of the key issues. Written submissions will also be accepted through the timeframe specified in the **DATES** section of this notice.

**III. Registration Instructions**

There is no registration fee. For security reasons, any persons wishing to attend this meeting must register by the date listed in the **DATES** section of this notice. Persons interested in attending the meeting or participating by teleconference must register by completing the online registration via the Web site at <http://www.usqualitymeasures.org/qm/>. The online registration system will generate a confirmation page to indicate the completion of your registration. Please print this page as your registration receipt. If seating capacity has been

reached, you will be notified that the meeting has reached capacity.

Individuals may also participate in the Town Hall meeting by teleconference. Registration is required as the number of call-in lines will be limited. The call-in number will be provided upon confirmation of registration.

We anticipate posting an audio download and/or transcript of the Town Hall meeting on the CMS Web site after completion of the listening session at <http://www.usqualitymeasures.org/qm/>.

**IV. Security, Building, and Parking Guidelines**

Because this meeting will be located on Federal property, for security reasons, any persons wishing to attend this meeting must register by the deadline specified in the **DATES** section of this notice at the address specified in the **ADDRESSES** section of this notice. Individuals who have not registered in advance will not be allowed to enter the building to attend the meeting. Seating capacity is limited to the first 250 registrants.

The on-site check-in for visitors will begin 45 minutes prior to the start of the meeting. Please allow sufficient time to go through the security checkpoints. It is suggested that you arrive no later than 30 minutes before the start of the meeting so that you will be able to arrive at the meeting on time. All items brought to the building, whether personal or for the purpose of demonstration or to support a presentation, are subject to inspection.

Security measures will include inspection of vehicles, inside and out, at the entrance to the grounds. In addition, all persons entering the building must pass through a metal detector. All items brought to CMS, including personal items such as laptops, cell phones, and P.D.A.'s, are subject to physical inspection.

**Authority:** Section 10331 of the Affordable Care Act.

(Catalog of Federal Domestic Assistance Program No. 93-773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Insurance Program)

Dated: September 16, 2010.

**Donald M. Berwick,**

*Administrator, Centers for Medicare and Medicaid Services.*

[FR Doc. 2010-23792 Filed 9-23-10; 8:45 am]

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