

The evaluation and reporting process is necessary to ensure that CDC receives standardized, accurate, thorough evaluation data from both health department and CBO grantees. For these reasons, CDC developed standardized NHM&E variables through extensive consultation with representatives from health departments, CBOs, and national partners (e.g., The National Alliance of State and Territorial AIDS Directors, Urban Coalition of HIV/AIDS Prevention Services, and National Minority AIDS Council).

CDC requires CBOs and health departments who receive federal funds

for HIV prevention to report non-identifying, client-level and aggregate-level, standardized evaluation data to: (1) Accurately determine the extent to which HIV prevention efforts are carried out, what types of agencies are providing services, what resources are allocated to those services, to whom services are being provided, and how these efforts have contributed to a reduction in HIV transmission; (2) improve ease of reporting to better meet these data needs; and (3) be accountable to stakeholders by informing them of HIV prevention activities and use of funds in HIV prevention nationwide.

CDC HIV prevention program grantees will collect, enter or upload, and report agency-identifying information, budget data, intervention information, and client demographics and behavioral risk characteristics with an estimate of 200,846 burden hours. Data collection will include searching existing data sources, gathering and maintaining data, document compilation, review of data, and data entry or upload into the web-based system.

There are no additional costs to respondents other than their time. The total estimated annual burden hours are 206,226.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Health jurisdictions .....	Agency Data .....	69	2	1377
	HE/RR Data .....	69	2	67
	HIV Testing Data .....	69	2	1,229
	NEM&E Data Training .....	69	2	52
Community-based Organizations .....	Agency Data .....	200	2	30/60
	HE/RR Data .....	200	2	20
	NHM&E Data Training .....	200	2	20

Dated: December 27, 2012.

**Ron A. Otten,**

Director, Office of Scientific Integrity (OSI), Office of the Associate Director for Science (OADS), Office of the Director, Centers for Disease Control and Prevention.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

[CMS-3278-NC]

**Medicare Program; Request for Information on Hospital and Vendor Readiness for Electronic Health Records Hospital Inpatient Quality Data Reporting**

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

**ACTION:** Request for information.

**SUMMARY:** This document is a request for information from hospitals, electronic health record (EHR) vendors, and other interested parties regarding hospital readiness beginning calendar year 2014 discharges to electronically report certain patient-level data under the Hospital Inpatient Quality Reporting (IQR) Program using the Quality

Reporting Document Architecture (QRDA) Category I.

**DATES:** The information solicited in this document must be received at the address provided below, no later than 5 p.m. eastern standard time (e.s.t.) on January 22, 2013.

**ADDRESSES:** In commenting, refer to file code CMS-3278-NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-3278-NC, P.O. Box 8013, Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-3278-NC, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

**FOR FURTHER INFORMATION CONTACT:** Maria Harr, (410) 786-6710.

**SUPPLEMENTARY INFORMATION:**

*Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

**I. Background**

We are interested in increasing efficiency and reducing the burden associated with hospital collection and submission of patient-level data on clinical quality measures (CQMs) and are exploring ways that hospitals might be able to report data on a subset of Hospital Inpatient Quality Reporting (IQR) Program measures specified under section 1886(b)(3)(B)(viii) of the Social Security Act (the Act) using the same certified electronic health record technology (CEHRT) that is used for reporting under the Electronic Health Record (EHR) Incentive Program as authorized by section 4102 of the American Recovery and Reinvestment Act of 2009 (ARRA). The goals of aligning quality measurement and reporting among our quality reporting programs are all of the following:

- Streamline our quality reporting programs through automatic collection and reporting of data on CQMs using CEHRT.
- Reduce burden to hospitals by allowing them to use EHRs to submit data on CQMs that are adopted for both the Hospital IQR Program and the EHR Incentive Program.
- Develop a single set of electronic specifications for CQMs adopted under multiple quality reporting programs.
- Support quality care improvement.

- Adopt data standards to facilitate hospitals' capturing, transmitting, and formatting data elements consistently and clearly.

The Health Information Technology for Economic and Clinical Health (HITECH) Act, part of the American Recovery and Reinvestment Act of 2009 (ARRA, Pub. L. 111-5), authorized Medicare and Medicaid incentive payments to eligible professionals and eligible hospitals when they adopt and meaningfully use CEHRT, as well as payment adjustments under Medicare beginning in 2015 for failure to demonstrate meaningful use. We have promulgated regulations establishing the criteria for Stage 1 and Stage 2 of meaningful use. More than 120,000 eligible health care professionals and more than 3,300 hospitals have qualified to participate in the program and receive an incentive payment since it began in January 2011.

The EHR Incentive Program Stage 2 final rule (77 FR 53968) outlines our commitment to aligning quality measurement and reporting programs, including the Hospital IQR program, the Physician Quality Reporting System (PQRS), the Children's Health Insurance Program (CHIP), and the Pioneer Accountable Care Organization (ACO) Model. The automatic collection and reporting of data elements for many measures through CEHRT is expected to greatly simplify reporting for various quality reporting programs. We envisage that hospitals will be able to switch primarily to EHR-based reporting of clinical quality data for many measures that are currently manually chart-abstracted and submitted to CMS for the Hospital IQR Program.

The Hospital IQR Program (<http://www.qualitynet.org/dcs/ContentServer?cid=1138115987129&pagename=QnetPublic%2FPage%2FQnetTier2&c=Page>), which is authorized by section 1886(b)(3)(B)(viii) of the Act, is intended to equip patients with hospital quality of care information to make informed decisions about healthcare options and is also intended to encourage hospitals and clinicians to improve the quality of inpatient care provided to all patients. Hospital IQR Program data is available to consumers on the Hospital Compare Web site (<http://www.hospitalcompare.hhs.gov/>).

Under the Hospital IQR Program, subsection (d) hospitals report data on selected quality measures to CMS. In selecting measures for the program, we strive to be consistent with the priorities identified in the National Quality Strategy. Subsection (d) hospitals report quality measures of process, structure,

outcomes, patient perspectives on care, and efficiency that relate to services furnished in an inpatient acute care hospital setting in order to receive the full annual payment update (APU). Sections 1886(b)(3)(B)(viii)(I) of the Act states that the applicable percentage increase, for FY 2007 and each subsequent fiscal year, shall be reduced by 2.0 percentage points (or, beginning with FY 2015, by one-quarter of such applicable percentage increase (determined without regard to sections 1886(b)(3)(B)(ix), (xi), or (xii) of the Act)) for any subsection (d) hospital that does not submit quality data in a form and manner, and at a time, specified by the Secretary.

**II. Solicitation for Information**

We are soliciting information from hospitals, EHR vendors, and other interested parties on a variety of subject matters.

The following questions are intended for all hospitals, EHR vendors, and other interested parties:

- How do hospitals and vendors perceive the alignment of EHR-based reporting and hospital quality reporting programs? What are the foreseen benefits and challenges?
- Do hospitals and vendors envision being able to meet the criteria for reporting clinical quality measures electronically for the EHR Incentive Program as set forth in the EHR Incentive Program—Stage 2 final rule (77 FR 53968) and any related guidance issued? If not, what are the issues in meeting the requirements and what additional information is needed?

We are specifically soliciting comments from hospitals and other interested parties on the following topics:

- Is the hospital planning to adopt EHR technology that has been certified to the 2014 Edition EHR certification criteria during or before calendar year (CY) 2014?
- Is the hospital aware of the payment adjustments authorized under the HITECH Act beginning in FY 2015 for failing to demonstrate meaningful use under the Medicare EHR Incentive Program?
- Is the hospital planning to *electronically* report CQM data—specifically venous thromboembolism (VTE) and stroke (STK) and emergency department (ED) measures—under the Medicare EHR Incentive Program in FY 2014?
- Is the hospital already participating in or planning to participate in the 2013 Medicare EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and Critical Access Hospitals

(CAHs) (“Pilot”)? The pilot provides eligible hospitals and CAHs with an opportunity to meet the CQM reporting requirements of the Medicare EHR Incentive Program through electronic submission of CQM data. The pilot is a voluntary electronic reporting method used to satisfy the CQM reporting requirements for the Medicare EHR Incentive Program. If not, what barriers prevent the hospital from participating?

- Does the hospital plan to report data leveraging any state health information exchange (HIE) initiative?
- Does the hospital plan to report data leveraging the Nationwide Health Information Network (NwHIN) Exchange, which is now the eHealth Exchange?

- Will the hospital use a third party to report quality data required under the EHR Incentive Program?

- Are there operational challenges to electronically reporting quality data? If so, does the hospital have mitigation plans to overcome these challenges?

- Has the hospital chief information officer (CIO) and/or chief operating officer (COO) prioritized electronically reporting quality data over the next 3 years (2013 through 2015)?

- Are there any evaluation or data validation methodologies that have been used by the hospital to assess the accuracy and reliability of clinical process of care quality data using QRDA category I standards?

- What barriers and opportunities would be created by including sampling criteria for electronically reported measures under the EHR Incentive Program?

We are specifically soliciting comments from EHR vendors and other interested parties in the following areas:

- Is the EHR vendor’s technology currently certified under the Office of the National Coordinator for Health Information Technology (ONC) Health Information Technology (HIT) Certification Program to the 2001 Edition EHR Certification Criteria? Does the vendor intend to have its EHR technology certified to the 2014 Edition EHR Certification Criteria? If so, when?

- What are the top three operational challenges facing EHR vendors over the next 3 years (2013 through 2015)? Of those identified, does the EHR vendor have mitigation plans to overcome these challenges?

- Are there any evaluation or data validation methodologies that have been used to assess the accuracy and reliability of clinical process of care quality data using QRDA category I standards?

- Have vendors included random sampling functionalities in currently

certified systems? If yes, what guidance for random sampling has been employed, if any? If no, what barriers are presented by adding this functionality to your currently certified systems?

### III. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this request for information, and, when we proceed with a subsequent document, we will respond to the comments in that document.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: *December 21, 2012.*

**Marilyn Tavenner,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 2012–31582 Filed 12–28–12; 11:15 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2012–D–1256]

#### Draft Revision of Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the Electronic Common Technical Document Specifications; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of draft guidance for industry entitled “Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications.” The draft guidance announced in this notice is being issued in accordance with the Food and Drug Administration Safety and Innovation Act (FDASIA) which amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to require that certain submissions under the FD&C Act and Public Health Service Act (PHS Act) be submitted in electronic format, beginning no earlier than 2 years after publication of the final version of

the draft guidance. The draft guidance describes how FDA plans to implement the requirements for the electronic submission of applications for certain human pharmaceutical products and is being issued for public comment. In its final form, this document will also supersede the guidance titled “Guidance for Industry Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications” that was issued in October 2005 and revised in April 2006 and June 2008.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by March 4, 2013.

**ADDRESSES:** Submit written requests for single copies of the documents to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002 or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the documents.

Submit electronic comments on the draft guidance 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.

**FOR FURTHER INFORMATION CONTACT:**

Virginia Hussong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 1161, Silver Spring, MD 20993, email: [virginia.hussong@fda.hhs.gov](mailto:virginia.hussong@fda.hhs.gov);

or

Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852, 301–827–6210.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

The electronic Common Technical Document (eCTD) is an International Conference on Harmonisation (ICH) standard based on specifications