(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;*

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

developed by ICH and its member parties. FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) have been receiving submissions in the eCTD format since 2003, and the eCTD has been the recommended format for electronic submissions to CDER and CBER since January 1, 2008. The majority of new electronic submissions are now received in eCTD format.

FDASIA (Pub. L. 112–144, 126 Stat. 993 (2012)), signed by the President on July 9, 2012, amended the FD&C Act to add section 745A, titled ''Electronic Format for Submissions.'' Section 745A(a)(1) of the FD&C Act requires that submissions under section 505(b), (i), or (j) of the FD&C Act, and submissions under sections 351(a) or (k) of the PHS Act, be submitted to FDA in electronic format no earlier than 24 months after FDA issues the final guidance described in this section.

In accordance with section 745A(a)(1) of the FD&C Act, FDA is issuing this draft guidance, announcing its determination that submission types identified in this draft guidance must be submitted electronically (except for submissions that are exempted), in a format that FDA can process, review, and archive. Currently, the Agency can process, review, and archive electronic submissions made using the eCTD version 3.2.2 specifications. Requirements for electronic submission will be phased in according to the following schedule: (1) 24 months after publication of the final version of this draft revised guidance, the requirements will apply to new drug application (NDA), abbreviated new drug application (ANDA), and biologics license application (BLA) submissions and (2) 36 months after publication of the final guidance, the requirements will apply to investigational new drug application (IND) submissions. Section 745A(a) of the FD&C Act does not apply to master files and advertising and promotional labeling submissions. However, FDA accepts and strongly encourages the submission of master files and advertising and promotional labeling materials electronically, as described in the draft guidance.

In Section 745A(a), Congress granted explicit authorization to FDA to implement the statutory electronic submission requirements by specifying the format for such submissions in guidance. To the extent that the draft guidance provides such requirements under section 745A(a) of the FD&C Act, indicated by the use of the words *must* or *required,* it is not subject to the usual restrictions in FDA's good guidance practice (GGP) regulations, such as the requirement that guidances not establish legally enforceable responsibilities. See 21 CFR 10.115(d).

At the same time, the draft guidance also provides guidance on FDA's interpretation of the statutory electronic submission requirement and the Agency's current thinking on the best means for implementing other aspects of the electronic submission program. Therefore, to the extent that the draft guidance includes provisions that are not part of the requirements under section 745A(a), it is being issued in accordance with FDA's GGP regulation (21 CFR 10.115). Such parts of the draft guidance, when finalized, will represent the Agency's current thinking on this topic, and do not create or confer any rights for or on any person and do not operate to bind FDA or the public. You can use an alternative approach for these recommendations if such an approach would satisfy the requirements of the applicable statutes and regulations. The use of the word *should* in the draft guidance means that something is suggested or recommended, but not required. Accordingly, the final guidance will contain both binding and nonbinding provisions.

II. Paperwork Reduction Act of 1995

The draft guidance refers to collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The draft guidance pertains to sponsors and applicants making regulatory submissions to FDA in electronic format for NDAs, ANDAs, BLAs, INDs, master files, and advertising and promotional labeling. The information collection discussed in the draft guidance is contained in our IND regulations (21 CFR part 312) and approved under OMB control number 0910–0014, our NDA regulations (including ANDAs) (21 CFR part 314) and approved under OMB control number 0910–0001, and our BLA regulations (21 CFR part 601) and approved under OMB control number 0910–0338.

Sponsors and applicants have been submitting NDAs, ANDAs, BLAs, and INDs electronically since 2003, and the majority of these submissions are already received in electronic format. Under FDASIA, sponsors and applicants will be required to make all of these submissions electronically. These requirements will be phased in over 2 and 3 year periods after the issuance of the final guidance.

There may be new costs, including capital costs or operating and maintenance costs, which would result from the requirements under FDASIA and the final guidance, because some sponsors and applicants would have to convert from paper-based submissions to electronic submissions. In accordance with the PRA, prior to publication of the final guidance document, FDA intends to solicit public comment and obtain OMB approval for any costs that are new or that would represent material modifications to these previously approved collections of information found in FDA regulations.

III. Comments

Interested persons may submit either electronic comments to *http://www.regulations.gov* or written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of 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, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm253101.htm, http://www.regulations.gov,* or *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm253101.htm, http://www.regulations.gov,* or *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*

Dated: December 27, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–31577 Filed 12–31–12; 8:45 am]

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