4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-2372]

Promoting Semantic Interoperability of Laboratory Data; 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), the Centers for Disease Control and Prevention (CDC), and the National Library of Medicine (NLM) of the National Institutes of Health are announcing the following public workshop entitled "FDA/CDC/NLM Workshop on Promoting Semantic Interoperability of Laboratory Data." The purpose of this workshop is to receive and discuss input from stakeholders regarding proposed approaches to promoting the semantic interoperability of laboratory data between in vitro diagnostic devices and database systems, including laboratory information systems and electronic health records.

Date and Time: The public workshop will be held on September 28, 2015, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security

information, please refer to http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

Contact Person: Steven Gitterman, Food and Drug Administration, Center for Devices and Radiological Health, Bldg. 66, rm. 5518, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-6694, FAX: 301-847-2512, email: steven.gitterman@fda.hhs.gov.

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 4 p.m. September 18, 2015. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the public workshop will be provided beginning at 7 a.m. (EDT).

If you need special accommodations due to a disability, please contact Susan Monahan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5231, Silver Spring, MD 20993-0002, 301-796-5661, email: susan.monahan@fda.hhs.gov no later than 4 p.m. on September 14, 2015.

To register for the public workshop, please visit FDA's Medical Devices News & Events--Workshops & Conferences calendar at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm. (Select this public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title and affiliation, address, email, and telephone number. Those without Internet access should contact Susan Monahan to register. Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. Persons interested in viewing the Webcast must register online by September 18, 2015, 4 p.m. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after September 23, 2015. If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit http://www.adobe.com/go/connectpro_overview. (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

Requests for Oral Presentations: This public workshop includes a public comment session. During online registration you may indicate if you wish to present during a public comment session, and which topics you wish to address. FDA has included general topics in this document which will be addressed in greater detail in a subsequent discussion paper (see SUPPLEMENTARY INFORMATION). FDA will do its best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. All requests to make oral presentations must be received by September 2, 2015. FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by September 7, 2015. If selected for presentation, any presentation materials must be emailed to Michael Waters at michael.waters@fda.hhs.gov no later than

September 18, 2015, 5 p.m. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Comments: FDA, CDC, and NLM are holding this public workshop to receive input from stakeholders and discuss proposed approaches to promoting the semantic interoperability of laboratory data between in vitro diagnostic devices and database systems, including electronic health records. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. The deadline for submitting comments related to this public workshop is 4 p.m. on October 26, 2015.

Regardless of attendance at the public workshop, interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or 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. 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.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at http://www.regulations.gov. It may be viewed at the Division of Dockets Management (see Comments). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcripts will also be

available approximately 45 days after the public workshop on the Internet at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm. (Select this public workshop from the posted events list).

SUPPLEMENTARY INFORMATION:

I. Background

There is broad acknowledgement that interoperability between information providers and information consumers is essential for progress in health care. Semantic interoperability is the building block for permitting meaningful use of medical information across disparate systems; it is essential for supporting patient care, medical research, epidemiology, and numerous other patient health public health goals.

Laboratory tests are a critical aspect of patient care that may influence between 70 to 80 percent of clinical decisions and represent an important target for achieving interoperability. Much of laboratory information is directly generated by medical devices and as such should be readily amenable to standardization that would enable semantic interoperability; however, significant challenges exist both in the adoption of standards by device manufacturers and implementation by clinical and public health laboratories. FDA, CDC, and NLM are in unique positions to encourage and promote the adoption of standards for laboratory data that can enable semantic interoperability through the public health mandate of the Department of Human and Health Services (HHS), the role of FDA in device regulation, the leadership role of CDC in laboratory science and support, and the pivotal role of NLM in the development, enhancement, and adoption of clinical vocabulary standards.

The primary purpose of this workshop is to discuss and receive input from stakeholders regarding standards for the reporting of laboratory data and means to facilitate adoption by

industry and laboratories. Specific models for semantic interoperability of laboratory data will be discussed, including the use of Logical Observation Identifiers Names and Codes (LOINC) for identifying laboratory tests, uniform Systematized Nomenclature of Medicine-Clinical Terms (SNOMED-CT) coding sets for describing results of qualitative test results and Unified Code for Units of Measure (UCUM) reporting of quantitative results. The use of other standards within interoperable laboratory result messages such as Unique Device Identifier (UDI) codes will also be addressed, as well as mechanisms for distributing device coding information such as Structured Product Labeling (SPL) or Electronically Exchanging Directory of Services (eDOS). Specifically, NLM, CDC, and FDA seek input from laboratorians, industry, government, academia, health care practitioners, and other stakeholders on these topics. This discussion is viewed as essential in expediting the adoption of standards to facilitate semantic interoperability of laboratory results.

II. Topics for Discussion at the Public Workshop

This public workshop will consist of brief presentations providing information to frame the goals of the workshop, and an interactive discussion via several panel sessions. The presentations will focus on proposed interoperability standards and mechanisms to promote adoption and implementation. Following the presentations there will be a moderated discussion where the participants and additional panelists will be asked to provide their individual perspectives.

In advance of the meeting, FDA, CDC, and NLM will place a summary of the issues they believe need to be addressed for promoting semantic interoperability on file in the public docket (docket number found in brackets in the heading of this document) and will post it at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm. The

deadline for submitting comments to this document for presentation at the public workshop is September 18, 2015, although comments related to this document can be made until September 28, 2015.

The Agencies will use the input from this workshop and public comments to determine appropriate next steps to advance sematic interoperability of laboratory data.

Dated: July 28, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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