

supplemental funds to expand work already underway by The National Council on Aging, the grantee who serves as the NFPRC.

DATES: May 14, 2015.

FOR FURTHER INFORMATION CONTACT: For further information or comments regarding this program expansion supplement, contact Shannon Skowronski, U.S. Department of Health and Human Services, Administration for Community Living, Office of Nutrition and Health Promotion Programs, One Massachusetts Avenue NW., Washington, DC 20001; telephone (202) 357-0149; email shannon.skowronski@acl.hhs.gov.

SUPPLEMENTARY INFORMATION:

Program Name: National Falls Prevention Resource Center.

Award Amount: \$300,000.

Project Period: The award will be issued for a project period to run concurrently with the existing grantee's budget period.

Award Type: Cooperative Agreement.

Statutory Authority: The statutory authority for this funding is contained in the Consolidated and Further Continuing Appropriations Act, 2015, Pub. L. 113-235, Div. G., Title II, § 219(a); Public Health Service Act, 42 U.S.C. 300u-2 (Community Programs) and 300u-3 (Information Programs); and the Patient Protection and Affordable Care Act, 42 U.S.C. 300u-11 (Prevention and Public Health Fund).

Catalog of Federal Domestic Assistance (CFDA) Number: 93.761.

Program Description: The Administration on Aging, within the U.S. Administration for Community Living, has been funding the National Falls Prevention Resource Center (NFPRC) since 2014. The NFPRC works to increase public education about the risks of falls and how to prevent them, and supports and stimulates the implementation and dissemination of evidence-based community programs and strategies that have been proven to reduce the incidence of falls among seniors. The purpose of the NFPRC is to help provide consumers and professionals with the resources they need to help prevent falls and decrease falls risk among older adults and adults with disabilities. The NFPRC provides a variety of resources to the field and to ACL/AoA falls prevention grantees to support the broader implementation, dissemination, and sustainability of evidence-based falls prevention programs. Examples of resources include fact sheets, issue briefs, webinars, program descriptions, best practices, and consultation of national experts on falls prevention. The NFPRC

also increases public awareness and educates consumers about falls as a preventable public health problem through consumer materials, such as the "6 Steps to Prevent a Fall" infographic and the facilitation of the annual Falls Prevention Awareness Day across the country. Professional education is provided through the NFPRC's Web site, collaboration with state falls prevention coalitions, partnerships with professional associations, presentations at professional conferences, and NFPRC-conducted meetings.

Justification: The purpose of this Supplement is to expand the National Falls Prevention Resource Center (NFPRC) activities in the following ways:

(1) Increase coordination and support for evidence-based falls prevention programs. NFPRC's current activities include providing support to the public and aging services network, including support to 14 two-year forward-funded projects that ACL awarded in FY2014 under HHS-2014-ACL-AOA-FP-0083 ("*Evidence-Based Falls Prevention Programs Financed Solely by 2014 Prevention and Public Health Funds (PPHF-2014)*"). When the NFPRC grant was initially awarded, ACL did not know if it would receive additional funding for more falls prevention grants. Subsequently, ACL received \$5 million in FY2015 funds and now anticipates awarding 10 to 14 additional grants. The NFPRC will extend its efforts to encompass activities and support involving these additional grantees, which will require the NFPRC to secure additional resources, including staffing. In addition, the NFPRC would be able to expand the scope of its planned FY2016 meeting, which will focus on developing successful strategies to implement and sustain falls prevention programs, as well as provide opportunities for networking among evidence-based program implementers.

(2) Follow-up from the National Falls Prevention Summit. The National Council on Aging hosted a National Falls Prevention Summit on April 30th, 2015. The purpose of this Summit was to update the 2005 Falls Free® National Action Plan, and to engage key stakeholders in developing steps to implement the revised Plan. The NFPRC will provide Summit follow-up to help move these efforts forward—working with national, state, and community partners to help prevent falls among older adults and adults with disabilities across the Nation.

Dated: May 6, 2015.

Kathy Greenlee,

Administrator and Assistant Secretary for Aging.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

2015 International Society for Pharmaceutical Engineering/Food and Drug Administration/Product Quality Research Institute Quality Manufacturing Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research, in cosponsorship with the International Society for Pharmaceutical Engineering (ISPE), is announcing a meeting entitled "2015 ISPE/FDA/PQRI Quality Manufacturing Conference," formerly known as the annually occurring "ISPE/FDA Current Good Manufacturing Practices Conference." The purpose of the meeting is to discuss the quality of global pharmaceutical manufacturing and the combined efforts of industry leaders and regulators to modernize manufacturing facilities and processes to ensure quality and compliance.

DATES: The meeting will be held on June 1 to 3, 2015, beginning at 7:30 a.m. on June 1 and ending at 4 p.m. on June 3.

ADDRESSES: The meeting will be held at The Mayflower Renaissance, 1127 Connecticut Ave. NW., Washington, DC 20036. The hotel's phone number is 202-347-3000.

FOR FURTHER INFORMATION CONTACT: John Bournas, President, International Society for Pharmaceutical Engineering, 600 North Westshore Blvd., Suite 900, Tampa, FL 33609, telephone: 1-813-960-2105, FAX: 1-813-264-2816, email: ASK@ispe.org.

SUPPLEMENTARY INFORMATION:

I. Background

The International Society for Pharmaceutical Engineering is a not-for-profit international association of more than 20,000 engineers, scientists, manufacturing, quality and company executives, their suppliers, and regulatory agencies involved in the development, manufacture, quality control, and regulation of

pharmaceuticals and related products. The goal of the conference is to ensure widespread opportunities for attendees to learn about important and critical issues that intersect with pharmaceutical manufacturing quality and regulatory topics that impact manufacturers, suppliers, and regulatory health authorities.

II. Registration

There is a registration fee to attend this meeting. The registration fee is charged to help defray the costs of conference sessions and presentations, facilities, materials, and food. Seats are limited, and registration will be on a first-come, first-served basis.

To register, please complete registration online at <http://www.ispe.org/2015-quality-manufacturing-conference/fees-and-registration>. (FDA has verified the Web address, but FDA is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.) The costs of registration for the different categories of attendees are as follows:

Category	Cost
ISPE Members	\$2,095
Nonmembers	2,475
Government	700

III. Accommodations

Attendees are responsible for their own hotel accommodations. Attendees making reservations at The Mayflower Renaissance, Washington DC, may check for the availability of a reduced rate by mentioning ISPE when making their reservation.

Dated: May 8, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-1349]

Electronic Study Data Submission; Data Standards; Support for the Logical Observation Identifiers Names and Codes

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is encouraging sponsors and applicants to provide

Logical Observation Identifiers Names and Codes (LOINC) codes (available at <http://loinc.org/>) for clinical laboratory test results in investigational study data provided in regulatory submissions submitted to the Center for Drug Evaluation and Research and to the Center for Biologics Evaluation and Research. LOINC code is defined as electronic messages for laboratory test results and clinical observations. The decision to adopt LOINC for lab test results is part of a larger FDA effort to align the use of data standards for clinical research with ongoing nationwide health information technology initiatives. FDA invites public comment on appropriate steps the Agency could take to promote the use and utility of LOINC-coded clinical data submitted to the Agency. The LOINC common terminology will be listed in the FDA Data Standards Catalog that is posted to FDA's Study Data Standards Resources Web page at <http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm>.

DATES: Although you can comment on this notice at any time, to ensure that the Agency considers your comments submit either electronic or written comments by June 29, 2015.

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, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests.

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.

FOR FURTHER INFORMATION CONTACT: Ron Fitzmartin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1192, Silver Spring, MD 20993-0002, 301-796-5333, ronald.fitzmartin@fda.hhs.gov, or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

LOINC is a clinical terminology housed by the Regenstrief Institute, a nonprofit medical research organization associated with Indiana University (available at <http://www.regenstrief.org/>). LOINC was initiated in 1994 as a response to the demand for electronic movement of clinical data from laboratories that produce the data to consumers of clinical data. LOINC codes are universal identifiers for laboratory and other clinical observations that enable semantically interoperable clinical data exchange. The purpose of LOINC is to facilitate the exchange and pooling of clinical data for clinical care, outcomes management, and research.

The laboratory portion of the LOINC database contains the categories of chemistry, hematology, serology, microbiology (including parasitology and virology), toxicology, and more. The clinical portion of the LOINC database includes entries for vital signs, hemodynamics, intake/output, EKG, obstetric ultrasound, cardiac echo, urologic imaging, gastroendoscopic procedures, and selected survey instruments.

FDA is now encouraging sponsors and applicants to provide LOINC codes for laboratory test data in investigational studies provided in regulatory submissions (*e.g.*, investigational new drug applications (INDs), new drug applications (NDAs), abbreviated new drug applications (ANDAs), biologics license applications (BLAs)) when those LOINC codes are available (*e.g.*, from the clinical laboratory that performed the test). FDA supports LOINC-coded laboratory test results because: (1) LOINC is widely used among clinical laboratories, (2) LOINC-coded lab data make the information easier to understand and analyze, and (3) the currently supported exchange standard for laboratory test results in clinical trials, the Study Data Tabulation Model (available at <http://www.cdisc.org/sdtm>) already supports the exchange of LOINC codes. FDA's decision to adopt LOINC for lab test results is part of a larger FDA effort to align the use of data standards for clinical research with ongoing nationwide health information technology initiatives.

FDA recognizes that there are additional steps the Agency could take to promote the use and utility of LOINC-coded clinical data submitted to the Agency. FDA invites public comment on what those additional steps should be, along with a suggested sequence and timing of those steps. For example, the Agency recognizes that the high level of granularity inherent in LOINC has