device security benchmarks which are continuously validated.

### III. Questions for Consideration

FDA also requests HPH Sector stakeholders to provide perspective on the following:

1. Are stakeholders aware of the ''Framework for Improving Critical Infrastructure Cybersecurity''? If so, how might we adapt/translate the Framework to meet the medical device cybersecurity needs of the HPH Sector?

2. How can we establish partnerships within the HPH Sector to quickly identify, analyze, communicate, and mitigate cyber threats and medical device security vulnerabilities?

3. How might the stakeholder community create incentives to encourage sharing information about medical device cyber threats and vulnerabilities?

4. What lessons learned, case studies, and best practices (from within and external to the sector) might incentivize innovation in medical device cybersecurity for the HPH Sector? What are the cybersecurity gaps from each stakeholder's perspective: Knowledge, leadership, process, technology, risk management, or others? and,

5. How do HPH stakeholders strike the balance between the need to share health information and the need to restrict access to it?

The deadline for submitting answers to these questions for consideration and any other additional comments on the proposed workshop topics is October 7, 2014.

### IV. References

1. Executive Order 13636, ''Improving Critical Infrastructure Cybersecurity,'' Feb. 19, 2013, available at *http://www.gpo.gov/fdsys/pkg/FR-2013-02-19/pdf/2013-03915.pdf.*
2. Presidential Policy Directive 21, ''Critical Infrastructure Security and Resilience,'' Feb. 12, 2013, available at *http://www.whitehouse.gov/the-press-office/2013/02/12/presidential-policy-directive-critical-infrastructure-security-and-resil.*
3. National Institute of Standards and Technology (NIST), ''Framework for Improving Critical Infrastructure Cybersecurity,'' version 1, Feb. 12, 2014, available at *http://www.nist.gov/cyberframework/upload/cybersecurity-framework-021214-final.pdf.*

Dated: September 17, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014–22515 Filed 9–22–14; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2013–N–0502]**

### Report on the Standardization of Risk Evaluation and Mitigation Strategies; Availability

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

**ACTION:** Notice; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft report entitled ''Standardizing and Evaluating Risk Evaluation and Mitigation Strategies (REMS)''. This report describes the Agency's findings concerning strategies to standardize risk evaluation and mitigation strategies (REMS), where appropriate, with the goal of reducing the burden of implementing REMS on practitioners, patients, and others in various health care settings. As part of the reauthorization of the Prescription Drug User Fee Act (PDUFA), FDA has committed to standardizing REMS to better integrate them into the existing and evolving health care system. FDA is publishing this report to allow the public to provide comment on the report as it relates to PDUFA.

**DATES:** Submit either electronic or written comments by November 24, 2014.

**ADDRESSES:** Submit written requests for single copies of the draft report 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. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft report.

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. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Richard Currey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6125, Silver Spring, MD 20993–0002, 301–796–3918, FAX: 301–595–7910, email: *REMS_Standardization@fda.hhs.gov;* or Adam Kroetsch, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1192, Silver Spring, MD 20993–0002; 301–796–3842, FAX: 301–847–8443, email: *REMS_Standardization@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

### I. Background

FDA is announcing the availability of a draft report entitled ''Standardizing and Evaluating Risk Evaluation and Mitigation Strategies (REMS).'' This report describes the Agency's findings concerning strategies to standardize REMS, where appropriate, with the goal of reducing the burden on practitioners, patients, and others in various health care settings. The Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), enacted on September 27, 2007, established FDA's authority to require REMS for prescription drug and biological products when it determines that such a strategy is necessary to ensure that the benefits of a drug outweigh the risks. Since that time, REMS have become a key tool in augmenting FDA's drug safety capacities. The Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144), enacted on July 9, 2012, amended FDA's REMS authorities and strengthened the Agency's ability to safeguard and advance public health. Among other things, FDASIA reauthorized the Prescription Drug User Fee Act (known as ''PDUFA V,'' reflecting the fifth reauthorization of PDUFA). As part of its PDUFA V commitments, FDA agreed, among other things, to ''measure the effectiveness of REMS and standardize and better integrate REMS into the health care system.'' To this end, ''FDA will . . . continue to develop techniques to standardize REMS and with stakeholder input seek to integrate them into the existing and evolving (e.g., increasingly electronic) health care system.'' FDA also agreed to hold one or more public meetings to explore strategies to standardize REMS, where appropriate, with the goal of reducing the burden of implementing REMS on practitioners, patients, and others in various health care settings, and to issue a report of the Agency's findings identifying at least one priority project with a work plan for project completion in the areas of pharmacy systems, prescriber education, providing benefit-risk information to patients, and practice settings.

FDA held a 2-day public meeting on REMS Standardization and Assessment on July 25–26, 2013, on approaches to standardizing REMS and better

integrating them into the health care delivery system. A transcript of the public meeting and a background document, as well as FDA presentations made at the meeting, are available on FDA's Web site at *http://www.fda.gov/forindustry/userfees/prescriptiondruguserfee/ucm351029.htm.*

This report summarizes stakeholder engagement achieved in fiscal year (FY) 2013, including suggestions and recommendations received from meetings, an expert panel workshop, and comments received electronically (posted to a Federal docket) and via teleconferences. Stakeholder feedback guided the Agency in selecting four priority projects within the areas specified by PDUFA V: (1) Providing benefit/risk information to patients, (2) prescriber education, (3) pharmacy systems, and (4) practice settings. This report briefly reviews the background and context for REMS as well as FDA initiatives for REMS administration and program improvement, summarizes key feedback from stakeholders and experts, and presents the design and the proposed workplans of projects in the four designated priority areas.

## II. Draft Report Describing Findings Concerning REMS Standardization and Plans for Projects To Standardize REMS

### *A. Stakeholder Recommendations*

Stakeholder input and recommendations received by FDA in 2013 emphasize the need for better communication by FDA about REMS, improved leveraging of information technology, and flexibility to tailor REMS programs to specific health care settings. The four priority projects that are discussed in detail at the end of the report flow, in part, from these recommendations, and represent the Agency's next steps toward an improved and integrated REMS strategy.

FDA found that stakeholders in various settings have successfully implemented REMS requirements, in some cases developing systems to manage REMS requirements specific to their institutions and integrate the REMS into their practices. However, FDA also heard that REMS programs affect specific stakeholder responsibilities and organizational structures differently, presenting a central challenge to standardizing REMS while meeting the needs of multiple stakeholders across an array of health care environments. Stakeholders indicated that they want flexibility to implement a REMS program based upon the nature of the health care setting.

Stakeholders emphasized that communication by FDA about REMS should be improved. They stated that FDA communications about REMS are often inadequate, inconsistent, unclear, or too difficult to access, navigate, and digest.

Stakeholders recommended that FDA create more comprehensive, evidence-based, and organized communications that can function within existing health care systems; deliver clear, actionable information to clinicians; and help to ensure that patients receive the drugs they require with excellent safety monitoring and oversight. They frequently suggested that FDA invest in and improve leveraging of existing information technology systems to better integrate REMS into standard medical practice and ongoing health care delivery.

Several stakeholders noted that current REMS documentation is not standardized and generally cannot be easily searched, queried, or managed. They recommended Structured Product Labeling (SPL) as a possible designated standard that may allow for a centralized, standardized REMS information repository.

Several stakeholders expressed interest in human factors evaluation methods like Failure Modes and Effect Analysis (FMEA) or a ''Health Care FMEA'' that might be deployed to help to develop criteria for levels of risk (e.g., illness, injury, death) that could prompt regulatory action.

Stakeholders suggested that REMS assessments might benefit from leveraging of data sources (e.g., electronic health records, claims data) to conduct assessments. A related recommendation was that FDA assess programs earlier and more frequently throughout a product's life cycle, and apply information gleaned from assessments to modify REMS if needed.

### *B. Priority Projects*

Guided by stakeholder feedback and recommendations, FDA has identified four priority projects, one for each topic area described previously. Each project responds to input the Agency has received regarding significant areas of opportunity for REMS standardization and evaluation efforts.

- Project 1: Providing Benefit-Risk Information to Patients

This project aims to improve the tools used for prescriber-to-patient counseling about REMS drugs. To that end, FDA proposes to conduct research into existing REMS patient counseling tools, other patient counseling initiatives, and counseling literature to identify current tactics and strategies for patient counseling about medication benefits and risk. The Agency intends to seek feedback from a range of stakeholders to identify opportunities to improve the content, format, processes, techniques, and delivery of effective counseling within REMS programs. In addition, FDA intends to develop a public report of findings and counseling processes and tools that could serve as the basis for designing new tools and validating them in demonstration projects.

- Project 2: Prescriber Education

Numerous stakeholders asked FDA to facilitate the provision of health care provider continuing education (CE) for the education and training that is provided in a REMS program. This project will assess whether it is feasible to provide CE certified by the Accreditation Council of Continuing Medical Education, Accreditation Commission for Education in Nursing, and Accreditation Council for Pharmacy Education associated with a specific REMS. FDA will seek to determine at what stage in the drug approval process CE development would best fit (e.g., before or after product approval) and which CE model(s) would be best suited for this type of activity; and provide an analysis of the time and resource burden associated with developing such CE programs.

- Project 3: Pharmacy Systems

FDA proposes to identify an approach for incorporating REMS information into SPL. The project's purpose is to develop a method to share clear and consistent information about the content of REMS, including REMS documents, requirements, and materials. Doing so will, among other things, facilitate integrating REMS into pharmacy systems and health information technology, including systems for electronic prescribing. SPL will also enable FDA to make structured REMS information available to health care providers and patients, and provide a single conduit of comprehensive information about REMS programs.

- Project 4: Practice Settings

The purpose of this project is to provide a centralized, standardized, reliable, and user-friendly repository of information about REMS, including stakeholders' specific activities and requirements under each REMS program. FDA intends to develop its REMS Web page as a central source of REMS information, which will provide stakeholders in a range of practice settings with a reliable and accessible resource to help them quickly learn

about REMS programs, understand and comply with REMS requirements, and compare requirements across REMS to minimize confusion associated with complying with multiple REMS programs.

*C. Scope of the Report*

This report describes the Agency's findings concerning strategies to standardize REMS where appropriate, with the goal of reducing the burden of implementing REMS on practitioners, patients, and others in various health care settings. This report contains project plans to: (1) Increase access to REMS-related information through the use of SPL, (2) enhance the Agency's REMS Web page to better meet the needs of stakeholders, (3) assess the feasibility of using accredited CE courses for prescriber training, and (4) enhance existing tools for prescribers to communicate with patients regarding risks of drugs with REMS, and how those risks should be weighed against the potential benefits of the drug.

**III. Electronic Access**

Persons with access to the Internet may obtain the document on FDA's Web site at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm350852.htm* or *http://www.regulations.gov.*

**IV. Comments**

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments 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.* After consideration of comments, FDA will finalize the report and project plans. The Agency intends to post updates to the project plans on FDA's Web site.

Dated: September 17, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014–22513 Filed 9–22–14; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Submission for OMB Review; 30-Day Comment Request: State and Community Tobacco Control Research Initiative Evaluation (NCI)

**SUMMARY:** Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on June 6, 2014 (79 FR 32742) and allowed 60 days for public comment. One public comment was received. The purpose of this notice is to allow an additional 30 days for public comment. The National Cancer Institute (NCI), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

*Direct Comments to OMB:* Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

*Comment Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

**FOR FURTHER INFORMATION CONTACT:** To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Elizabeth M. Ginexi, Ph.D., Tobacco Control Research Branch, Behavioral Research Program, Division of Cancer Control and Population Sciences, National Cancer Institute, 9609 Medical Center Drive, Room 3E564 MSC 9761, Bethesda, Maryland 20892–9761 or call non-toll-free number 240–276–6765 or email your request, including your address to: *LGinexi@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

*Proposed Collection:* State and Community Tobacco Control Research Initiative Evaluation (SCTC), 0925–NEW, National Cancer Institute (NCI), National Institutes of Health (NIH).

*Need and Use of Information Collection:* The National Cancer Institute State and Community Tobacco Control Research Initiative is a program within the Tobacco Control Research Branch in the Behavioral Research Program of the Division of Cancer Control and Population Sciences. The program targets 4 high-priority tobacco control research areas at the state and community level in the United States: (1) Secondhand smoke policies, (2) Tobacco tax and pricing policies, (3) Mass media countermeasures and community and social norms, and (4) Tobacco industry practices. The initiative supports innovative research to yield rapid and actionable findings for state and community tobacco control programs. The purpose of the evaluation is to assess the dissemination, implementation, and community collaboration processes of the grantees and their respective state and community partners and stakeholders. The evaluation will utilize archival grant project data and archival data collected from the scientists in the first two years of the initiative. The evaluation also will collect new data to: (1) Determine relationships, interactions, and connectedness among different network partnerships over time and with policy makers; (2) assess the utility of research tools, interventions, products, and findings from the perspective of key tobacco control stakeholders; and (3) determine key indicators for broad adoption of research products. Results will address research-to-practice gaps by providing a critical window into the process of disseminating evidence-based research tools, products, and science findings in community public health settings. Intended audiences include staff at NIH Institutes and Centers interested in supporting translation/dissemination and implementation science.

OMB approval is requested for one year. There are no costs to respondents other than their time. The total estimated annualized burden hours are 112.