DEPARTMENT OF HEALTH AND HUMAN SERVICES

Draft Five-Year Plan (2013–2017) for the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods and the Interagency Coordinating Committee on the Validation of Alternative Methods

AGENCY: Division of National Toxicology Program (DNTP), National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

ACTION: Availability of Draft Plan, Request for Comments

SUMMARY: The National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) in collaboration with the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) has developed a draft NICEATM–ICCVAM Five-Year Plan. The plan describes four core strategies to foster and promote development, validation, and regulatory acceptance of scientifically sound alternative test methods by the Federal government and by other governments and multinational organizations. This document will provide strategic direction for NICEATM and ICCVAM during 2013–2017.

NIEHS and NICEATM request public comments on the draft 2013–2017 Five-Year Plan, which is available at *http://iccvam.niehs.nih.gov/docs/5yearplan.htm.* NICEATM and ICCVAM in partnership with relevant agency program offices will consider these comments during development of the final plan.

DATES: The draft plan is available on the NICEATM–ICCVAM Web site at *http://iccvam.niehs.nih.gov/docs/5yearplan.htm.* Written comments on the draft updated NICEATM–ICCVAM Five-Year Plan should be submitted on the Web site by August 13, 2012.

FOR FURTHER INFORMATION CONTACT: Dr. William S. Stokes, Director, NICEATM, NIEHS, P.O. Box 12233, Mail Stop: K2–16, Research Triangle Park, NC, 27709, (telephone) 919–541–2384, (fax) 919–541–0947, (email) *niceatm@niehs.nih.gov.* Courier address: NICEATM, NIEHS, Room 2034, 530 Davis Drive, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION:

Background

Emerging scientific advances and technology innovations are driving transformative changes in toxicology and how safety testing is performed. The field of toxicology is evolving from a system based largely on animal testing toward one based on the integration of data from a wide range of sources, including *in vitro* methods that evaluate changes in biological pathways predictive of adverse outcomes and *in chemico* and *in silico* methods.

Congress established ICCVAM to promote the regulatory acceptance of new or revised scientifically valid toxicological test methods that protect human and animal health and the environment while reducing, refining (enhancing animal well-being and lessening or avoiding pain and distress), or replacing animal tests and ensuring human safety and product effectiveness. As directed by the ICCVAM Authorization Act (42 U.S.C. 285*l*–3), NICEATM and ICCVAM carry out activities that contribute to the validation and regulatory acceptance of new test methods and testing strategies.

In 2008, NICEATM and ICCVAM published the NICEATM–ICCVAM Five-Year Plan (2008–2012), which addressed ICCVAM's vision to play a leading role in fostering and promoting the development, validation, and regulatory acceptance of scientifically sound alternative test methods both within the Federal government and internationally (ICCVAM, 2008). NICEATM and ICCVAM have now prepared a draft plan to provide strategic direction for NICEATM and ICCVAM in accomplishing their purposes, duties, and mission for the years 2013–2017. In preparing this plan, NICEATM and ICCVAM considered information and comments submitted by member agencies and comments submitted in response to a **Federal Register** notice (76 FR 71977).

The draft plan outlines how, consistent with ICCVAM's statutory duties and purposes, NICEATM and ICCVAM will foster and promote the incorporation of scientific advances and innovative technologies into new improved test methods and strategies, and contribute to the transformation of toxicology. The draft plan describes four broad strategic opportunities for NICEATM and ICCVAM to foster and promote development, validation, and regulatory acceptance of scientifically sound alternative test methods by the Federal government and other organizations:

- *Promote the Application and Translation of Innovative Science and Technology* to develop predictive alternative test methods and efficient and predictive integrated testing and decision strategies (ITDS)
- *Advance Alternative Test Methods and Testing Strategies* through new evaluation activities for focus areas initially identified in the 2008–2012 Five-Year Plan and new focus areas for 2013–2017
- *Facilitate Regulatory Acceptance and Use of Alternative Methods* through high quality test method evaluations and effective outreach and communication
- *Develop and Strengthen Partnerships* with the broad range of ICCVAM stakeholders

The years 2013–2017 will be an essential transition period for NICEATM and ICCVAM in this transforming regulatory toxicology environment. For example, data from *in vitro* testing batteries and integrated decision strategies that consider all available information from *in chemico, in silico, in vitro, and/or in vivo* studies will be critical to regulatory decision-making in the future.

Request for Comments

NIEHS and NICEATM invite public comments from all ICCVAM stakeholders for consideration by ICCVAM and ICCVAM agencies' program offices on the draft 2013–2017 Five-Year Plan. The draft plan can be found on the NICEATM–ICCVAM Web site at *http://iccvam.niehs.nih.gov/docs/5yearplan.htm.* In addition, comments are sought on how NICEATM and ICCVAM can most effectively contribute to the evolving transformation of safety testing. Stakeholder comments will be considered in finalization of the draft plan.

NICEATM prefers that comments be submitted electronically via a form on the NICEATM–ICCVAM Web site at *http://iccvam.niehs.nih.gov/docs/5yearplan.htm* or via email to *niceatm@niehs.nih.gov.* Individuals submitting comments are asked to include appropriate contact information (name, affiliation, mailing address, phone number, email, and sponsoring organization, if applicable). All comments received will be posted on the NICEATM–ICCVAM Web site and identified by the individual's name, affiliation, and sponsoring organization. Comments should be received by [insert date 60 days after publication date] to ensure consideration as the NICEATM–ICCVAM 2013–2017 Five-Year Plan is finalized.

Background Information on ICCVAM and NICEATM

ICCVAM is an interagency committee composed of representatives from 15 Federal regulatory and research agencies that require, use, generate, or

disseminate toxicological and safety testing information. ICCVAM conducts technical evaluations of new, revised, and alternative safety testing methods and strategies with regulatory applicability and promotes the scientific validation and regulatory acceptance of toxicological and safety testing methods that more accurately assess the safety and hazards of chemicals and products. ICCVAM evaluations include test methods and strategies that will reduce or replace animal use, or refine animal use by enhancing animal welfare and avoiding or lessening pain and distress.

The ICCVAM Authorization Act of 2000 (42 U.S.C. 285*l*–3) established ICCVAM as a permanent interagency committee of the NIEHS under NICEATM. NICEATM administers ICCVAM, provides scientific and operational support for ICCVAM-related activities, and conducts independent validation studies to assess the usefulness and limitations of new, revised, and alternative test methods and strategies. NICEATM and ICCVAM work collaboratively to evaluate new and improved test methods and strategies applicable to the needs of U.S. Federal agencies.

NICEATM and ICCVAM welcome the public nomination of new, revised, and alternative test methods and strategies for validation studies and technical evaluations. Additional information about NICEATM and ICCVAM can be found on the NICEATM–ICCVAM Web site (*http://iccvam.niehs.nih.gov*).

References

ICCVAM. 2008. The NICEATM–ICCVAM Five-Year Plan (2008–2012). A plan to advance alternative test methods of high scientific quality to protect and advance the health of people, animals, and the environment. NIH Publication No. 08–6410. Research Triangle Park, NC: NIEHS.

Available: http://iccvam.niehs.nih.gov/docs/5yearplan.htm.

Dated: June 4, 2012.

John R. Bucher,

Associate Director, National Toxicology Program.

[FR Doc. 2012–14435 Filed 6–12–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: ''Adapting Best Practices for Medicaid Readmissions.'' In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on March 28th, 2012 and allowed 60 days for public comment. No comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by July 13, 2012.

ADDRESSES: Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395–6974 (attention: AHRQ's desk officer) or by email at *OIRA_submission@omb.eop.gov* (attention: AHRQ's desk officer).

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at *doris.lefkowitz@AHRO.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

Adapting Best Practices for Medicaid Readmissions

One particular mission of AHRQ is to improve the efficiency of health care through reducing unnecessary health care costs while maintaining or improving quality. The proposed data collection supports this goal through developing strategies to assist safety net hospitals in reducing readmissions for Medicaid patients. Previous research has shown that a focus on transitional care, including needs assessment, discharge planning, post-discharge intervention, and care coordination can reduce avoidable readmissions. Based on this evidence, there have been a number of strategies and resources developed for hospitals to reduce avoidable readmissions, including:

- The Aging & Disability Resource Centers Evidence-Based Care Transitions program by the Administration on Aging & CMS to support state efforts in implementing evidence-based care transition models for older adults and individuals with disabilities.
- The State Action on Avoidable Rehospitalizations (STAAR) initiative by the Institute for Healthcare Improvement to improve care transitions and care coordination through state-based multi-stakeholder collaborative efforts.
- The Hospital-to-Home (H2H) initiative by the American College of Cardiology to reduce readmissions for patients with cardiovascular conditions.
- Project Re-Engineered Discharge (RED), funded by AHRQ and the National Institutes of Health (NIH) National Heart, Lung, and Blood Institute, to reduce re-hospitalizations by improving hospital discharge processes.

However, the majority of these strategies and resources focuses on general patient populations or specifically targets the elderly and/or disabled, primarily Medicare populations. Recent research finds that rates of readmission among Medicaid-insured non-elderly adults equals that of the elderly, Medicare-insured population and is 60 percent higher than a privately-insured population. It is not known whether existing resources and strategies to reduce readmissions address the circumstances and characteristics of Medicaid-insured patients. Particular socio-demographic characteristics more prevalent in populations insured through Medicaid, such as low-income, racial and ethnic minority, low literacy, housing instability, mental illness, substance abuse disorders, chronic and disabling conditions, language barriers, and discontinuous insurance coverage may mean that strategies for reducing readmissions need to be tailored specifically to the unique needs of this population.

Additionally, safety net hospitals, which serve large populations of the most vulnerable in society and where Medicaid is often a major payer, face unique conditions. Not only do they serve more vulnerable populations, they are often constrained by their financing and governance structures. Safety net hospitals generally operate on lower