principles in the International Conference on Harmonisation (ICH) Q9, and knowledge management as defined in ICH Q10) by the regulated industry. This will also provide the FDA pathways to better regulate postapproval changes by utilizing more flexibility and risk-based principles, as envisioned by the pharmaceutical product quality initiatives laid out in FDA's ''Pharmaceutical Current Good Manufacturing Practices (cGMPs) for the 21st Century—A Risk Based Approach'' (see *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/QuestionsandAnswersonCurrentGoodManufacturingPracticescGMPforDrugs/UCM071836*).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Established Conditions: Reportable CMC Changes for Approved Drug and Biologic Products.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. 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.*

III. Paperwork Reduction Act

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 211, 314, and 601 have been approved under OMB control numbers 0910–0139, 0910–0001, and 0910–0338, respectively.

IV. Electronic Access

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

Dated: May 26, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–13104 Filed 5–29–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received no later than July 31, 2015.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 594–4306.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Rural Outreach Benefits Counseling Program Measures OMB No. 0915–XXXX—New.

Abstract: The Rural Outreach Benefits Counseling Program (Benefits Counseling Program) is authorized by section 330A(e) of the Public Health Service (PHS) Act (42 U.S.C. 254c(e)), as amended, to ''promote rural health care services outreach by expanding the delivery of health care services to include new and enhanced services in rural areas.'' The purpose of the 3-year Benefits Counseling Program is to expand outreach, education, and enrollment efforts to eligible uninsured and newly insured individuals and families in rural communities.

The overarching goals of this grant funding are to coordinate and conduct innovative outreach activities through a strong consortium in order to: (1) Identify and enroll uninsured individuals and families who are eligible for public health insurance, such as Medicare, Medicaid, and the Children's Health Insurance Program, and qualified health plans offered through Health Insurance Marketplaces and/or private health insurance plans in rural communities and (2) educate the newly insured individuals and families in rural communities about their health insurance benefits, help connect them to primary care and preventive services to which they now have access, and help them retain their health insurance coverage.

Need and Proposed Use of the Information: For this program, performance measures were drafted to provide data to the program and to enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Act (GPRA) of 1993. These measures cover the principal topic areas of interest to the Federal Office of Rural Health Policy (FORHP), including: (a) Access to care; (b) population demographics; (c) staffing; (d) consortium/network; (e) sustainability; and (f) benefits counseling process and outcomes. Several measures will be used for the Benefits Counseling Program. All measures will speak to FORHP's progress toward meeting the goals set.

Likely Respondents: The respondents will be recipients of the Rural Outreach Benefits Counseling Program grant funding.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review

the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

Total Estimated Annualized burden hours:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average urden per response in hours)	Total burden hours
Rural Outreach Benefits Counseling Grant Program Measures	10	1	10	1.5	15
Total	10	1	10	1.5	15

HRSA specifically requests comments on: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2015–13088 Filed 5–29–15; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Ryan Asherin, Oregon Health Authority: Based on the report of an investigation conducted by the Oregon Health Authority (OHA) and analysis conducted by ORI in its oversight review, ORI found that Ryan Asherin, former Surveillance Officer and Principal Investigator, OHA, Public Health Division engaged in research misconduct in research supported by the Centers for Disease Control and Prevention (CDC) Emerging Infections Program Grant 5U01CI00306–05.

ORI found that the Respondent engaged in research misconduct by falsifying and/or fabricating data that were included in the CDC research record, a manuscript submitted to *JAMA Intern Med* in January 2013, a published CDC report (*CDC Morbidity and Mortality Weekly Report* 61(09):157–162, March 2012), and presentations in 2012 to CDC and at the 11th Biennial Congress of the Anaerobe Society.

ORI found that the Respondent falsified and/or fabricated fifty-six (56) case report forms (CRFs) while acquiring data on the incidence of *Clostridium difficile* infections in Klamath County, Oregon. Specifically, the Respondent (1) fabricated responses to multiple questions on the CRFs for patient demographic data, patient health information, and *Clostridium difficile* infection data, including the diagnoses of toxic megacolon and ileus and the performance of a colectomy, with no evidence in patient medical records to support the responses; and (2) falsified the CRFs by omitting data on the CRFs that clearly were included in patient medical records.

Mr. Asherin has entered into a Voluntary Settlement Agreement (Agreement) and has voluntarily agreed for a period of two (2) years, beginning on May 12, 2015:

(1) To have his research supervised; Respondent agrees that prior to submission of an application for U.S. Public Health Service (PHS) support for a research project on which the Respondent's participation is proposed and prior to Respondent's participation in any capacity on PHS-supported research, Respondent shall ensure that a plan for supervision of Respondent's duties is submitted to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of Respondent's research contribution; Respondent agrees that he will not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI; Respondent agrees to maintain responsibility for compliance with the agreed upon supervision plan;

(2) that any institution employing him must submit, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract; and

(3) to exclude himself voluntarily from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

FOR FURTHER INFORMATION CONTACT: Acting Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453–8200.

Donald Wright,

Acting Director, Office of Research Integrity.

[FR Doc. 2015–13054 Filed 5–29–15; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the 2015 Hurricane Sandy Conference: Translating Research Into Practice

AGENCY: Department of Health and Human Services, Office of the Secretary.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR) is hereby giving notice that ASPR will convene a Hurricane Sandy Conference: Translating Research into Practice public meeting on August 10–11, 2015. The purpose of the meeting is to broadly share, with interested stakeholders, outcomes of Hurricane Sandy recovery science research and training projects awarded under ASPR FOAs EP–HIT–13–001 and EP–HIT–14–001, Centers for Disease Control and Prevention (CDC) FOAs TP13–001 and OH13–002, and National Institute of Environmental Health Sciences (NIEHS) FOAs RFA–ES–13–008 and NOT–ES–13–003. Meeting participants will discuss opportunities to build a community of practice around Hurricane Sandy recovery research and the path forward for translating Hurricane Sandy recovery science research results into practice; highlight Hurricane Sandy recovery science grants as a model for disaster research science preparedness; and demonstrate the benefit of