SUPPLEMENTARY INFORMATION:

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data about topics related to personnel performing informatics activities, as well as data storage and retention practices related to the use of next generation sequencing (NGS) technology. In addition, CDC invites comments specifically on the following questions:

(1) What are the roles and responsibilities for all personnel performing bioinformatics or pathology/laboratory informatics activities? What training is considered essential for each of the roles? What competencies are considered essential for each of the roles? What minimum educational requirements (degrees or courses) are required for each of the roles?

(2) What are the challenges for recruitment and retention of bioinformatics or pathology/laboratory informatics personnel?

(3) What are examples of how NGS data files are used in addition to generating a clinical test result?

(4) What NGS data files should be retained for quality assurance, repeat analyses, or subsequent analyses? How long should these NGS data files be retained?

(5) What are the challenges and approaches for laboratories to maintain and utilize previous versions of sequence analysis software?

Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure.

Comments will be posted on *https://www.regulations.gov.* Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that

identifies you in the body of your comments, that information will be on public display. Do not submit public comments by email. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign.

Background and Brief Description

Clinical laboratory testing technology has advanced significantly since the CLIA regulations were first implemented approximately 30 years ago. Next generation sequencing (NGS) technologies provide the high-throughput capability to rapidly and cost-effectively sequence large regions and mixed populations of DNA and RNA, when compared to traditional sequencing methods. This technology results in a significant increase in data that requires specialized analysis to derive a clinically meaningful result. NGS has led to improvements in diagnoses and patient care in many areas of medicine that include medical genetics, pediatrics, oncology, and microbiology. In some instances, NGS has led to life-saving diagnoses and treatment pathways, not achievable using other testing modalities. One element that differentiates NGS from most laboratory methodologies is its significant reliance on informatics to achieve a meaningful and reportable result. As a consequence, clinical laboratories require personnel knowledgeable in bioinformatics or pathology/laboratory informatics to design and manage the bioinformatics analysis.

While CLIA regulations apply to clinical NGS testing, there is a lack of clarity regarding how the general CLIA quality system and personnel requirements should be specifically implemented for the NGS bioinformatics components. In April 2019, CLIAC made eight recommendations regarding CLIA's application to NGS-based technologies. This request for information is soliciting comments from the public for more information on topic areas mentioned in two of the recommendations, specifically, the qualifications of personnel performing bioinformatics activities; storage and retention of NGS data files; and maintenance of sequence analysis software. The April 2019 CLIAC summary is available in the docket under the Supporting Materials tab and at *https://www.cdc.gov/cliac/past-meetings.html.*

The qualifications and responsibilities of personnel performing the informatics component of the testing process are not addressed in the CLIA regulations. For the purpose of this request for information, the informatics component of NGS includes the analysis of NGS machine-generated data and subsequent computational processes. Therefore, CDC is asking the public to describe different responsibilities of personnel providing bioinformatics or pathology/laboratory informatics expertise such as validating and assuring that the informatics pipeline meets documented performance specifications.

CDC is also interested in learning the skills, training, and education of personnel who will fill bioinformatics or pathology/laboratory informatics positions, and how clinical and public health laboratories can recruit and retain personnel with these identified skills.

Lastly, the NGS testing process generates large amounts of data and requires multiple file types. CLIA regulations specify at 42 CFR 493.1105(a)(3) that all

analytic systems records must be kept for at least two years, but the regulations do not specify the types of data to be captured or the retention time for a given data type. The regulations do not address the capability to access and reanalyze the data after the test is performed. This capability may require retention of the version of software used in the original analysis. CDC requests comment from the public on this topic.

HHS/CDC has posted all related materials to the docket on *www.regulations.gov.*

Dated: June 30, 2020.

Sandra Cashman,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2020–14417 Filed 7–2–20; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–20–20GX]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Validated Follow-up Interview of Clinicians on Outpatient Antibiotic Stewardship Interventions to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on February 10, 2020 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Validated Follow-up Interview of Clinicians on Outpatient Antibiotic Stewardship Interventions—New—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Code of Federal Regulations under subsections C and D of section 247d–5 authorizes education of medical and health services personnel in antimicrobial resistance and appropriate use of antibiotics and the funding of eligible entities to increase capacity to detect, monitor, and combat antimicrobial resistance. Through the Centers for Disease Control and Prevention's (CDC) SHEPheRD funding mechanism, the University of Utah has been awarded a contract to perform such work as stated above within a research framework in the urgent care setting, with interventions based on the Core Elements of Outpatient Antibiotic Stewardship. Intermountain Healthcare is the subcontractor for this work, and operates the clinics participating in the intervention arm of this research study.

The proposed request for data collection will allow Intermountain Healthcare to explore knowledge, attitudes, and practices among clinicians to identify barriers and facilitators after the implementation of the antibiotic stewardship program in the urgent care setting of participating clinics. CDC requests approval for 207 estimated annualized burden hours. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Urgent Care Clinician	Interview Guide	40	1	1
Urgent Care Clinician	Survey	250	1	40/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2020–14330 Filed 7–2–20; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3018]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Healthcare Provider Perception of Boxed Warning Information Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by August 5, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comment'' or by using the search function. The title of this information collection is ''Healthcare Provider Perception of Boxed Warning Information Survey.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Healthcare Provider Perception of Boxed Warning Information Survey

OMB Control Number 0910—NEW

I. Background

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(d)(2)(C)) authorizes FDA to conduct research relating to drugs and other FDA regulated products in carrying out the provisions of the FD&C Act.

The proposed collection of information will investigate healthcare providers' (HCPs') awareness, perceptions, and beliefs about the benefits and risks of an FDA-approved product that carries a boxed warning. The prescribing information for an FDA-approved drug or biologic (sometimes