

a.m., with the call to order by the Council Chair and approval of previous Council summary notes. The meeting will begin with an update on AHRQ's recent accomplishments in Research, Practice Improvements and Data and Analytics. The agenda will also include an update on AHRQ and COVID-19 and a presentation on Improving Health Services Research Across the Federal Enterprise. The meeting will adjourn at 1:15 p.m. The meeting is open to the public. For information regarding how to access the meeting as well as other meeting details, including information on how to make a public comment, please go to <https://www.ahrq.gov/news/events/nac/>.

The final agenda will be available on the AHRQ website no later than Tuesday, July 7, 2020.

Dated: June 29, 2020.

Virginia L. Mackay-Smith,
Associate Director.

[FR Doc. 2020-14336 Filed 7-2-20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Center for Injury Prevention and Control, (BSC, NCIPC); Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Board of Scientific Counselors, National Center for Injury Prevention and Control, (BSC, NCIPC); July 22, 2020, from 10:00 a.m. to 01:00 p.m., EDT (OPEN) and July 22, 2020, from 01:45 p.m. to 04:15 p.m., EDT (CLOSED), Teleconference 1-800-369-3110; Participant Code 7563795, which was published in the **Federal Register** on May 20, 2020, Volume 85, Number 98, pages 30709-30710.

The meeting is being amended to extend the oral public comment period during the open session, change the time of the closed session, and request written comments by email submission; and should read as follows:

SUMMARY: In accordance with the Federal Advisory Committee Act, the CDC announces the following meeting for the Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC, NCIPC). This meeting is partially open and partially closed to the public. The open session is limited only by the ports available. There will be 2,000 telephone ports available. There will also be 55 minutes allotted for oral public comments at the end of

the open session from 12:20 p.m. to 1:15 p.m., EDT on July 22, 2020. In addition, written comments may also be submitted for the meeting record. Written comments should be emailed to NCIPCBSC@cdc.gov and will be accepted until July 28, 2020, 5:00 p.m., EDT.

The public is encouraged to register to participate by telephone and/or provide oral public comment using the registration form available at the link provided: <https://www.surveymonkey.com/r/NVV9XM2>.

Individuals registered to provide oral public comment will be called upon to speak based on the order of registration. After persons who have registered have spoken, any remaining time in the oral public comment period will be used for members of the public who have not registered to speak but wish to offer comment. Individuals making oral public comment during the meeting will have a 2-minute speaking limit to allow for as many comments as possible.

DATES: The meeting will be held on July 22, 2020, 10:00 a.m. to 1:15 p.m., EDT (OPEN) and July 22, 2020, 2:00 p.m. to 4:30 p.m., EDT (CLOSED).

FOR FURTHER INFORMATION CONTACT:

Gwendolyn H. Cattledge, Ph.D., M.S.E.H., Deputy Associate Director for Science, NCIPC, CDC, 4770 Buford Highway, NE, Mailstop S106-9, Atlanta, GA 30341, Telephone (770) 488-3953, Email address: NCIPCBSC@cdc.gov.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2020-14447 Filed 7-2-20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC-2020-0051]

Request for Information Concerning Personnel and the Retention of Next Generation Sequencing Data in Clinical and Public Health Laboratories; Extension of Comment Period

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: On May 15, 2020, the Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS) published a notice in the **Federal Register** requesting public comment on the Request for Information Concerning Personnel and the Retention of Next Generation Sequencing Data in Clinical and Public Health Laboratories (85 FR 29456). Written and electronic comments were to be received on or before July 14, 2020. HHS/CDC has received a request asking for a 60-day extension of the comment period. In consideration of this request, HHS/CDC is extending the comment period to September 14, 2020.

DATES: Written comments must be received on or before September 14, 2020.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2020-0051 by any of the following methods only. CDC does not accept comment by email.

Internet: Access the Federal eRulemaking portal at <http://www.regulations.gov>. Follow the instructions for submitting comments.

Mail: Heather Stang, MS, MT, Division of Laboratory Systems, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop V24-3, Atlanta, GA 30329. Docket No. CDC-2020-0051.

All relevant comments received will be posted publicly without change, including any personal or proprietary information provided. To download an electronic version of the plan, please access <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Heather Stang, MS, MT, Center for Surveillance, Epidemiology and Laboratory Services, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop V24-3, Atlanta, GA 30329, telephone (800) 232-4636; email: dlsinquiries@cdc.gov.

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]

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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: