Frimpong (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place both in-person and using an online meeting platform. This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. The conditions for issuance of a waiver under 21 CFR 10.19 are met.

Dated: May 3, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–10053 Filed 5–7–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Notice for Public Comments on Potential Viral Hepatitis Quality Measures in Medicaid

AGENCY: Office of Infectious Disease and HIV/AIDS Policy, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice for public comment.

SUMMARY: The Department of Health and Human Services' (HHS) Office of Infectious Disease and HIV/AIDS Policy (OIDP) in the Office of the Assistant Secretary for Health (OASH) invites public comment on potential viral hepatitis quality measures for implementation at the state and territory level. In March 2024, OIDP hosted a technical consultation meeting (*https://youtu.be/YCVC8GwFE7E*) to initiate the process of understanding the needs and developing national consensus on clinically meaningful and feasible viral hepatitis quality measures for proposal to the Medicaid Adult Core Set.

DATES: All comments must be received by 5 p.m. ET on June 7, 2024 to be considered.

ADDRESSES: All comments must be submitted electronically to *OIDPViralHepatitis@hhs.gov* to be considered.

FOR FURTHER INFORMATION CONTACT: Jessica Deerin, Ph.D., MPH, OIDP, Viral Hepatitis Policy Advisor at *Jessica.Deerin@hhs.gov* or 202–795–7625.

SUPPLEMENTARY INFORMATION: CDC released updated hepatitis C and hepatitis B screening recommendations to screen all adults aged 18 years and older at least once in a lifetime and all pregnant women during each pregnancy in April 2020 and March 2023, respectively. Screening is an important first step in the viral hepatitis continuum of care and a necessary tool to reach viral hepatitis elimination by 2030.

Additionally, hepatitis C has a life-saving treatment resulting in a cure in >95% of patients. Yet, many patients are not linked to care and complete treatment. Less than 1 in 3 people with health insurance initiated DAA treatment within a year of hepatitis C diagnosis and people with Medicaid were less likely to initiate treatment than those with private insurance. Hepatitis B treatment can reduce hepatitis B viral load, lowering the risk of liver cancer and mortality.

Quality measures are tools to monitor and improve the quality of health care. Scaling up viral hepatitis screening, linkage to care, and access to treatment will ultimately reduce transmission, incidence of new infections, prevent liver cancer and mortality, and allow the U.S. to make strides in reaching viral hepatitis elimination by 2030.

There are currently no viral hepatitis quality measures in the Medicaid Adult Core Set. The Medicaid Adult Core Set is a core set of health care quality measures related to physical and behavioral health for adult Medicaid enrollees. The Adult Core Set encourages standardized reporting by States on a uniform set of measures to drive quality improvement. Since Medicaid provides coverage for a disproportionate number of people with hepatitis B and hepatitis C, OIDP is leading an initiative to develop consensus around clinically meaningful and feasible state level viral hepatitis quality measures to propose to the Medicaid Adult Core Set.

OIDP hosted a Viral Hepatitis Quality Measures Technical Consultation Meeting on March 7, 2024. State panelists from Medicaid and public health departments shared their experience in selection, testing, and implementation of current state viral hepatitis quality measures, as well as recommendations for measures to propose to the Medicaid Adult Core Set. State panelists reached consensus to prioritize the development, use, and adoption of a hepatitis C screening and treatment initiation measure based on the following rationale:

- Clinical and public health insights are high, leading to an understanding of the cascade of care for infected people who access treatment and cure;
- The measure drives screening and linkage to care by translating recently updated CDC recommendations into routine practice in the health care delivery system;
- Data for a screening and treatment initiation measure is available to state Medicaid programs through administrative claims and encounter data, and is consistent and comparable across states; and
- The method of using administrative data sources to represent hepatitis C treatment through pharmacy claims was explained as an acceptable proxy for receipt of treatment.

HHS hereby requests public comment on the clinical significance, usability, feasibility, and likely uptake of hepatitis C screening and hepatitis C treatment initiation quality measures, as well as recommendations with adequate justifications on other feasible viral hepatitis measures to consider.

Information Needs

HHS is seeking responses with adequate justification to the questions listed below.

1. Are you in support of adopting a hepatitis C screening and treatment initiation measure within state Medicaid programs?

a. If you represent a state Medicaid program, what is the likely uptake of this measure?

2. What other measures should HHS consider for testing and proposal to the Medicaid Adult Core Set (*i.e.,* hepatitis B screening, hepatitis B linkage to care, hepatitis C sustained virological response (SVR))? Please provide support for how that measure is clinically meaningful, feasible, and actionable for state Medicaid programs. What data source or data element can be utilized to calculate the measure?

3. Would it be feasible and clinically meaningful to implement a hepatitis B screening, hepatitis C screening and hepatitis C treatment initiation quality measure within state Medicaid programs? If you represent a state Medicaid program, what is the likely uptake of this measure?

Dated: May 2, 2024.

B. Kaye Hayes,

Deputy Assistant Secretary for Infectious Disease, Department of Health and Human Services.

[FR Doc. 2024–10006 Filed 5–7–24; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Interagency Coordinating Committee on the Validation of Alternative Methods; Notice of Public Meeting; Request for Public Input

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) will hold a public forum to share information and facilitate direct communication of ideas and suggestions from stakeholders. Interested persons may attend in person or view the meeting remotely by webcast. Time will be set aside for questions and public statements on the topics discussed. Registration is requested for attending in person and required for viewing the webcast. Registration is also required for presenting oral statements, whether in person or online. Information about the meeting and registration are available at *https://ntp.niehs.nih.gov/go/iccvamforum-2024.*

DATES:

Meeting: May 20, 2024, 1 p.m. to approximately 5 p.m. EDT; Tuesday, May 21, 2024, 9 a.m. to approximately 4:30 p.m. EDT.

Registration for Onsite Meeting: Deadline is May 17, 2024.

Registration for Webcast: Deadline is May 21, 2024.

Registration for Oral Statements: Deadline is May 15, 2024.

Registration to attend in person is requested; registration to view the webcast and to present oral public statements (in person or online) is required.

ADDRESSES:

Meeting Location: William H. Natcher Conference Center, National Institutes of Health (NIH), Bethesda, MD 20892.

Meeting web page: Registration and other meeting materials are at *https://ntp.niehs.nih.gov/go/iccvamforum-2024.* A preliminary agenda will be posted on this page by May 3.

FOR FURTHER INFORMATION CONTACT: Dr. Nicole Kleinstreuer, Director, National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), email: *nicole.kleinstreuer@nih.gov,* telephone: 984–287–3150.

SUPPLEMENTARY INFORMATION:

Background: ICCVAM, a congressionally mandated committee, coordinates the development and validation of alternative testing strategies that protect human health and the environment while replacing, reducing, or refining animal use.

ICCVAM's goals include promotion of national and international partnerships between governmental and nongovernmental groups, including academia, industry, advocacy groups, and other key stakeholders. To foster these partnerships ICCVAM initiated annual public forums in 2014 to share information and facilitate direct communication of ideas and suggestions from stakeholders (79 FR 25136).

This year's meeting will be held on May 20 and 21, 2024. NICEATM and ICCVAM members will give presentations on current activities related to the development and validation of alternative test methods and approaches.

There will be opportunities for participants to ask clarifying or follow-up questions of the ICCVAM members about their presentations. Instructions for submitting these questions will be provided to webcast viewers prior to the event. The agenda will also include time for public oral statements relevant to the ICCVAM mission and current activities from participants who have registered to do so in advance.

Preliminary Agenda and Other Meeting Information: A preliminary agenda will be posted by May 3 at *https://ntp.niehs.nih.gov/go/iccvamforum-2024.* Interested individuals are encouraged to visit this web page to stay abreast of the most current meeting information.

Meeting and Registration: This meeting is open to the public. The public may attend the meeting at NIH, where attendance is limited only by the space available, or view remotely by webcast. Those planning to attend the meeting in person are encouraged to register at *https://ntp.niehs.nih.gov/go/iccvamforum-2024* by May 15, 2024, to facilitate planning for appropriate meeting space. Registration for the webcast is required and is open through 4:30 p.m. EDT on May 21, 2024, at *https://ntp.niehs.nih.gov/go/iccvamforum-2024.* Registrants will receive instructions on how to access and participate in the webcast in the email confirming their registration.

NIH visitor and security information is available at *http://www.nih.gov/about/visitor/index.htm.* Individuals with disabilities who need accommodation to participate in this event should contact Nicole Kleinstreuer at phone: 919–407–1609 or email: *nicole.kleinstreuer@nih.gov.* TTY users should contact the Federal TTY Relay Service at 800–877–8339. Requests should be made at least five business days in advance of the event.

Request for Oral Public Statements: In addition to time for clarifying or follow-up questions following scheduled presentations, time will be allotted during the meeting for oral public statements with associated slides on topics relevant to ICCVAM's mission. Separate registration for those wishing to provide public statements is required and is open through May 15, 2024, at *https://ntp.niehs.nih.gov/go/iccvamforum-2024.* Any meeting attendee or webcast viewer may ask clarifying questions during the appropriate times in the agenda. The additional registration is only required for those who wish to give separate public statements. The number and length of presentations may be limited based on available time. Submitters will be identified by their name and affiliation and/or sponsoring organization, if applicable. Participants registered to present oral public statements must email their statement to *ICCVAMquestions@niehs.nih.gov* by May 15, 2024, to allow time for review by NICEATM and ICCVAM and posting to the meeting page prior to the forum. Persons submitting public statements and/or associated slides should include their name, affiliation (if any), mailing address, telephone, email, and sponsoring organization (if any) with the document. Guidelines for public statements are at *http://ntp.niehs.nih.gov/ntp/about_ntp/guidelines_public_comments_508.pdf.* Persons presenting oral public statements will be contacted to arrange the logistics of their presentations. Presenters should plan for their presentation to run seven minutes or less; each public statement presentation will be followed by up to three minutes to allow for clarifying or follow-up questions. Time allotted for presentations and follow-up questions may be reduced depending on the time available.

Written statements on topics relevant to ICCVAM's mission may be submitted to support an oral public statement or as standalone documents. These should be emailed to *ICCVAMquestions@niehs.nih.gov* by May 15, 2024. Public statements received prior to the May 15