

which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—RFA-CK-21-001, US Travelers Health Research, Surveillance, Communication, and Outreach Network; RFA-CK-21-002, Emerging Infections Network—Research for Preventing, Detecting, and Managing Travelers who Acquire Infectious Diseases Abroad; and RFA-CK-21-003, Monitoring Cause-specific School Absenteeism for Estimating Community-wide Influenza and SARS-CoV-2 Transmission.

Date: February 10–11, 2021.

Time: 10:00 a.m.–5:00 p.m., EST.

Place: Teleconference, Centers for Disease Control and Prevention, Room 1080, 8 Corporate Square Boulevard, Atlanta, GA 30329.

Agenda: To review and evaluate grant applications.

For Further Information Contact: Gregory Anderson, M.S., M.P.H., Scientific Review Officer, CDC, 1600 Clifton Road NE, Mailstop US8-1, Atlanta, Georgia 30329-4027, (404) 718-8833, GAnderson@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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Solicitation of Nominations for Appointment to the Clinical Laboratory Improvement Advisory Committee (CLIAC)

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC) is seeking nominations for membership on the CLIAC. The CLIAC consists of 20 experts including the Chair who

represents a diverse membership across laboratory specialties, professional roles (laboratory management, technical specialists, physicians, nurses) and practice settings (academic, clinical, public health), and includes a consumer representative.

DATES: Nominations for membership on the CLIAC must be received no later than March 1, 2021. Packages received after this time will not be considered for the current membership cycle.

ADDRESSES: All nominations should be mailed to Nancy Anderson, MMSc, MT(ASCP), CLIAC Secretary, Senior Advisor for Clinical Laboratories, Division of Laboratory Systems, Center for Surveillance, Epidemiology and Laboratory Services, Office of Public Health Scientific Services, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop V24-3, Atlanta, Georgia 30329-4018; telephone (404) 498-2741; or via email at CLIAC@cdc.gov.

FOR FURTHER INFORMATION CONTACT: Heather Stang, MS, Deputy Branch Chief, Quality and Safety Systems Branch, Division of Laboratory Systems, Center for Surveillance, Epidemiology and Laboratory Services, Office of Public Health Scientific Services, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Mailstop V24-3, Atlanta, Georgia 30329-4018; telephone (404) 498-2769; HStang@cdc.gov.

SUPPLEMENTARY INFORMATION: The Committee also includes three ex officio members (or designees), including the Director, CDC; the Administrator, Centers for Medicare and Medicaid Services (CMS); and the Commissioner, Food and Drug Administration (FDA). A nonvoting representative from the Advanced Medical Technology Association (AdvaMed) serves as the industry liaison. The Designated Federal Official (DFO) or their designee and the Executive Secretary are present at all meetings to ensure meetings are within applicable statutory, regulatory, and HHS General Administration manual directives.

Nominations are being sought for individuals who have the expertise and qualifications necessary to contribute to the accomplishments of the committee's objectives. Nominees will be selected based on expertise in the fields of microbiology (including bacteriology, mycobacteriology, mycology, parasitology, and virology), immunology (including histocompatibility), chemistry, hematology, pathology (including histopathology and cytology), or genetic testing (including cytogenetics); from representatives in

the fields of medical technology, bioinformatics, public health, and clinical practice; and from consumer representatives. Federal employees will not be considered for membership. Members may be invited to serve for up to four-year terms.

Selection of members is based on candidates' qualifications to contribute to the accomplishment of CLIAC objectives (<https://www.cdc.gov/cliac/>).

The U.S. Department of Health and Human Services policy stipulates that committee membership be balanced in terms of points of view represented, and the committee's function. Appointments shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, gender identity, HIV status, disability, and cultural, religious, or socioeconomic status. Nominees must be U.S. citizens, and cannot be full-time employees of the U.S. Government. Current participation on federal workgroups or prior experience serving on a federal advisory committee does not disqualify a candidate; however, HHS policy is to avoid excessive individual service on advisory committees and multiple committee memberships. Committee members are Special Government Employees (SGEs), requiring the filing of financial disclosure reports at the beginning and annually during their terms. CDC reviews potential candidates for CLIAC membership each year and provides a slate of nominees for consideration to the Secretary of HHS for final selection. HHS notifies selected candidates of their appointment near the start of the term in July, or as soon as the HHS selection process is completed. Note that the need for different expertise varies from year to year and a candidate who is not selected in one year may be reconsidered in a subsequent year. Candidates should submit the following items:

- Current curriculum vitae, including complete contact information (telephone numbers, mailing address, email address)

- At least one letter of recommendation from person(s) not employed by the U.S. Department of Health and Human Services. (Candidates may submit letter(s) from current HHS employees if they wish, but at least one letter must be submitted by a person not employed by an HHS agency (e.g., CDC, NIH, FDA, etc.).

Nominations may be submitted by the candidate, or by the person/organization recommending the candidate.

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Kalwant Smagh,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifiers: CMS-304/-304a, CMS-367a-d, and CMS-368/-R-144]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare and Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by January 29, 2021.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development Attention: Document Identifier/OMB Control Number _____, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>

2. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-304/-304a Reconciliation of State Invoice (ROSI) and Prior Quarter Adjustment Statement (PQAS)
CMS-367a-d Medicaid Drug Rebate Program Labeler Reporting Format
CMS-368/-R-144 Medicaid Drug Rebate Program State Reporting Forms

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Reconciliation of State Invoice (ROSI) and Prior Quarter Adjustment Statement (PQAS); *Use:* Form CMS-304 (ROSI) is used by manufacturers to respond to the state's rebate invoice for current quarter utilization. Form CMS-304a (PQAS) is required only in those instances where a change to the original rebate data submittal is necessary. Effective July 1, 2021, the Medicaid Drug Rebate Program (MDRP) is updating to a new Medicaid Drug Programs (MDP) system which will now accept a delimited text file format, Comma Separated Values (.CSV), in addition to the current Text (.TXT) file format. We have also increased several file format data field sizes in order to accommodate the higher priced drugs that are entering the market. These changes in conjunction with numerous edits to verbiage are applicable to Forms CMS-304 and -304a. Separately, we are also updating corresponding collection of information requests (OMB 0938-0578 and OMB 0938-0582) so that all the MDP file formats, field sizes, and verbiage will align across the MDRP. *Form Number:* CMS-304 and -304a (OMB control number: 0938-0676); *Frequency:* Quarterly; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 749; *Total Annual Responses:* 5,841; *Total Annual Hours:* 248,584. (For policy questions regarding this collection contact Andrea Wellington at 410-786-3490.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicaid Drug Rebate Program Labeler Reporting Format; *Use:* Labelers transmit drug product and pricing data to CMS within 30 days after the end of each calendar month and quarter. CMS calculates the unit rebate amount (URA) and the unit rebate offset amount (UROA) for each new drug application (NDC) and distributes to all State Medicaid agencies. States use the URA to invoice the labeler for rebates and the UROA to report onto CMS-64. The monthly data is used to calculate Federal Upper Limit (FUL) prices for applicable drugs and for states that opt to use this data to establish their pharmacy reimbursement methodology. Effective July 1, 2021, the MDRP is updating to a new Medicaid Drug Programs (MDP) system which will now accept a delimited text file format, Comma Separated Values (.CSV), in addition to the current Text