

for Occupational Safety and Health, 1090 Tusculum Avenue, MS C-34, Cincinnati, Ohio 45226.

Instructions: All submissions received must include the Agency name and Docket Number. Written public comments received by April 13, 2022, will be provided to the BSC prior to the meeting. Docket number CDC-2022-0037; and NIOSH-278 will close April 13, 2022.

FOR FURTHER INFORMATION CONTACT:

Emily J.K. Novicki, M.A., M.P.H., Executive Secretary, BSC, NIOSH, CDC, 1600 Clifton Avenue, MS V24-4, Atlanta, Georgia 30329-4027, Telephone: (404) 498-2581, Email: enovicki@cdc.gov.

SUPPLEMENTARY INFORMATION:

Purpose: The Secretary, the Assistant Secretary for Health, and by delegation the Director, Centers for Disease Control and Prevention, are authorized under Sections 301 and 308 of the Public Health Service Act to conduct directly or by grants or contracts, research, experiments, and demonstrations relating to occupational safety and health and to mine health. The Board of Scientific Counselors provides guidance to the Director, National Institute for Occupational Safety and Health on research and prevention programs. Specifically, the Board provides guidance on the Institute's research activities related to developing and evaluating hypotheses, systematically documenting findings and disseminating results. The Board evaluates the degree to which the activities of the National Institute for Occupational Safety and Health: (1) Conform to appropriate scientific standards, (2) address current, relevant needs, and (3) produce intended results.

Matters to be Considered: The agenda for the meeting addresses the evolving national landscape for respiratory protection and occupational robotics research. Agenda items are subject to change as priorities dictate.

An agenda is also posted on the NIOSH website (<http://www.cdc.gov/niosh/bsc/>).

Meeting Information: It is open to the public, limited only by web conference lines (500 web conference lines are available). If you wish to attend, please register at the NIOSH website <http://www.cdc.gov/niosh/bsc/> or call (404-498-2581) no later than April 13, 2022.

Public Participation

Comments received are part of the public record and are subject to public disclosure. 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. 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. CDC will carefully consider all comments submitted into the docket. CDC does not accept comment by email.

Oral Public Comment: The public is welcome to participate during the public comment period, from 1:00 p.m. to 1:15 p.m., EDT, April 20, 2022. Please note that the public comment period ends at the time indicated above. Each commenter will be provided up to five minutes for comment. A limited number of time slots are available and will be assigned on a first come-first served basis. Members of the public who wish to address the BSC NIOSH are requested to contact the Executive Secretary for scheduling purposes (see **FOR FURTHER INFORMATION** above).

Written Public Comment: Written comments will also be accepted from those unable to attend the public session per the instructions provided in the addresses section above. Written comments received in advance of the meeting will be included in the official record of the meeting. Written comments received by April 13, 2022, will be provided to the BSC prior to the meeting.

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. 2022-05798 Filed 3-17-22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-22-1150; Docket No. CDC-2022-0035]

Proposed Data Collection Submitted for Public Comment and Recommendations

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

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Generic Clearance for Lyme and other Tickborne Diseases (TBD) Knowledge, Attitudes, and Practices (KAP) Surveys. This data collection involves the administration of a set of surveys designed to understand KAPs related to prevention of Lyme and other TBDs and to inform implementation of future TBD prevention interventions.

DATES: CDC must receive written comments on or before May 17, 2022.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2022-0035 by either of the following methods:

- *Federal eRulemaking Portal:* [Regulations.gov](https://www.regulations.gov). Follow the instructions for submitting comments.

- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21-8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to [regulations.gov](https://www.regulations.gov).

Please note: Submit all comments through the Federal eRulemaking portal ([regulations.gov](https://www.regulations.gov)) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS

H21–8, Atlanta, Georgia 30329; phone: 404–639–7570; Email: omb@cdc.gov.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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. In addition, the PRA also requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. 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;
2. Evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. 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 submissions of responses; and
5. Assess information collection costs.

Proposed Project

Generic Clearance for Lyme and other Tickborne Diseases (TBD) Knowledge, Attitudes, and Practices (KAP) Surveys (OMB Control No. 0920–1150, Exp. 9/30/2022)—Revision—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC) Division of Vector-Borne Diseases (DVBD) and other programs working on tickborne diseases (TBDs) are requesting a Revision to a previously approved generic clearance to conduct TBD prevention studies to include knowledge, attitudes, and practices (KAP) surveys TBDs among residents and businesses offering pest control services in Lyme disease endemic areas of the United States. The data collection for which approval is sought will allow DVBD to use survey results to inform implementation of future TBD prevention interventions. The Revision involves a broadening of the secondary target population from owners and employees of pest control companies to stakeholders of local entities affected by TBDs (e.g., leaders in local public health or local government; owners or employees of pest control companies, landscaping companies, or other at-risk occupations; non-governmental organizations serving at-risk populations; and/or clinicians serving at-risk populations).

TBDs are a substantial and growing public health problem in the United States. From 2004–2016, over 490,000 cases of TBDs were reported to CDC, including cases of anaplasmosis, babesiosis, ehrlichiosis, Lyme disease, Rocky Mountain spotted fever, and tularemia. Lyme disease accounted for 82% of all TBDs, with over 400,000 cases reported during this time period. Recent studies estimate nearly 500,000 cases of Lyme disease are diagnosed annually in the United States. In addition, several novel tickborne pathogens have recently been found to cause human disease in the United States. Factors driving the emergence of TBDs are not well defined and current prevention methods have been insufficient to curb the increase in cases. Data is lacking on how often certain prevention measures are used by individuals at risk as well as what the barriers to using certain prevention measure are.

The primary target population for these data collections are individuals and their household members who are

at risk for TBDs associated with *I. scapularis* ticks and who may be exposed to these ticks residentially, recreationally, and/or occupationally. The secondary target population includes stakeholders of local entities affected by TBDs (e.g., leaders in local public health or local government; owners or employees of pest control companies, landscaping companies, or other at-risk occupations; non-governmental organizations serving at-risk populations; and/or clinicians serving at-risk populations) in areas where *I. scapularis* ticks transmit diseases to humans. Specifically, these target populations include those residing or working in the 15 highest incidence states for Lyme disease (CT, DE, ME, MD, MA, MN, NH, NJ, NY, PA, RI, VT, VA, WI and WV). We anticipate conducting one to two surveys per year, for a maximum of six surveys conducted over a three-year period. Depending on the survey, we aim to enroll 500–10,000 participants per study. It is expected that we will need to target recruitment to about twice as many people as we intend to enroll. Surveys may be conducted daily, weekly, monthly, or bi-monthly per participant for a defined period (whether by phone or web survey), depending on the survey or study. The surveys will range in duration from approximately 5–30 minutes. Each participant may be surveyed 1–64 times in one year; this variance is due to differences in the type of information collected for a given survey. Specific burden estimates for each study and each information collection instrument will be provided with each individual project submission for OMB review.

Insights gained from KAP surveys will aid in prioritizing which prevention methods should be evaluated in future randomized, controlled trials and ultimately help target promotion of proven prevention methods that could yield substantial reductions in TBD incidence. CDC requests OMB approval for an estimated 98,830 annual burden hours. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondent | Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden hours |
|--|----------------------------|-----------------------|------------------------------------|--|--------------------|
| General public, individuals or households. | Screening instrument | 20,000 | 1 | 15/60 | 5,000 |
| | Consent form | 10,000 | 1 | 20/60 | 3,330 |
| | Introductory Surveys | 10,000 | 1 | 30/60 | 5,000 |

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

| Type of respondent | Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden hours |
|--|--------------------------|-----------------------|------------------------------------|--|--------------------|
| Stakeholders of local entities affected by TBDS. | Monthly surveys | 10,000 | 12 | 15/60 | 30,000 |
| | Final surveys | 10,000 | 1 | 30/60 | 5,000 |
| | Daily surveys | 10,000 | 60 | 10/60 | 50,000 |
| | Stakeholder Survey | 1,000 | 1 | 30/60 | 500 |
| Total | | | | | 98,830 |

Jeffrey M. Zirger,

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

[FR Doc. 2022-05753 Filed 3-17-22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-0297]

Draft Pharmaceutical Quality/Chemistry Manufacturing and Controls Data Exchange; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is requesting comment on the draft Pharmaceutical Quality/Chemistry Manufacturing and Controls (PQ/CMC) Data Exchange for the electronic submission of PQ/CMC data. This document provides draft design of Health Level 7 (HL7) Fast Health Interoperability Resources (FHIR) profiles that contain the data elements and terminologies associated with PQ/CMC subject areas and scoped to some of what is currently submitted in Module 3 of the electronic Common Technical Document (eCTD) submission. It is not intended to be comprehensive in covering all eCTD product quality information, only those concepts that were considered amenable to structuring and would bring value to the quality review process. The Agency is seeking comment on the mapping of the PQ/CMC data elements to the various FHIR Resources. This document should not be viewed as guidance, technical specification, or an implementation guide, as it is meant solely for comment. The FHIR mapping presented in this document is bound to the HL7 FHIR R5 draft release. As such,

it is likely that some parts of the mapping presented in this document may change based on comments during the HL7 balloting and reconciliation process. However, since HL7 balloting has variable and extensive timelines, the Agency determined that it would be prudent to provide an early opportunity for comment that will inform final development of the exchange standard.

DATES: Submit either electronic or written comments by May 17, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 17, 2022. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 17, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you

do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2022-N-0297 for "Draft Pharmaceutical Quality/Chemistry Manufacturing and Controls (PQ/CMC) Data Exchange for the electronic submission of PQ/CMC data; Request for Comments." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available