including two deaths, have been reported among AS fabrication workers in the United States. The anticipated impacts of this project are increased understanding of industry scale, practices, and medical monitoring, and increased collaboration and communication to inform the AS Countertop industry of industry hazards, methods to mitigate exposure, and improve medical surveillance. Understanding how or if current RCS recommendations and regulations are used by various AS Countertop fabrication facilities will identify approaches for improved intervention.

The purpose of the proposed collection is to conduct a survey with AS Countertop fabrication facilities to better understand: (1) work practices and controls related to respirable crystalline silica; (2) barriers or facilitators to implementation of medical and exposure monitoring requirements; (3) identify areas for potential intervention; and (4) identify countertop fabrication facilities willing to participate in future NIOSH exposure and health research.

The estimate of burden hours is based on an internal pilot test of the survey instrument. The average time for reviewing instructions, gathering mock information, and completing the survey was between 10–30 minutes. For the purposes of estimating burden hours, the median time to complete the survey is used. An estimated 8,600 respondents are anticipated to participate in the survey. for 2,150 annual burden hours. There are no costs to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Facility Managers/Owners	Workplace Survey	8,600	1	15/60

Jeffrey M. Zirger,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–23–22HY]

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, ''Centralized Institutional Review for the CDC Expanded Access Investigational New Device (EA–IND) for Use of Tecovirimat (TPOXX®) for Treatment of Human Non-Variola Orthopoxvirus Infections in Adults and Children (IND 116039/CDC #6402),'' 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 August 22, 2022, to obtain comments from the public and affected agencies. CDC received two 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

Centralized Institutional Review for the CDC Expanded Access Investigational New Device (EA–IND) for ''Use of Tecovirimat (TPOXX®) for Treatment of Human Non-Variola Orthopoxvirus Infections in Adults and Children'' (IND 116039/CDC #6402)—New—Office of Science (OS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Monkeypox is a zoonosis, caused by the Orthopoxvirus (OPXV) Monkeypox virus (MPXV), and is endemic to forested areas of West and Central Africa. In humans, infection with MPXV can lead to a smallpox-like illness with fatal outcomes in up to 11% of patients without prior smallpox vaccination.

Since May 2022, clusters of monkeypox cases, have been reported in 19 countries that do not normally have monkeypox, and the number of confirmed cases in the U.S. is rapidly increasing.

Tecovirimat (TPOXX) is FDA-approved for the treatment of human smallpox disease caused by Variola virus in adults and children. However, its use for other orthopoxvirus infections, including monkeypox, is not approved by the FDA. CDC currently holds a non-research expanded access Investigational New Drug (EA–IND) protocol that allows for the use of tecovirimat for primary or early empiric treatment of non-variola orthopoxvirus

infections, including monkeypox, in adults and children of all ages.

FDA regulations require that an Institutional Review Board (IRB) review, approve and maintain oversight of the activities under the EA–IND as set forth in 21 CFR parts 50, 56, and 312. The CDC IRB is positioned to serve as the central IRB for review and approval of the EA–IND consistent 21 CFR 56.114. This arrangement allows facilities to use or rely on the CDC IRB for centralized review and approval for this protocol in place of review by the site-specific IRB to help reduce duplication of effort, delays, and increased expenses. Any facility that receives tecovirimat for treatment of orthopoxvirus infection under the EA–IND may elect to rely on the CDC IRB to meet FDA's regulatory requirements.

The IRB review is required by FDA under the CDC's approved EA–IND. Therefore, CDC must maintain records of which facilities have elected to rely on the CDC IRB for centralized review and which facilities elect to obtain IRB review on their own. CDC will use collected data to track and document the institutions relying on the CDC IRB so they can provide TPOXX treatment to their patients with monkeypox under the EA–IND.

This collection was initially approved as an Emergency ICR in August 2022 (OMB Control No. 0920–1366), and is being submitted here to create a standard version of the collection. CDC requests OMB approval for an estimated 1,333 annual burden hours. There is no cost to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number responses per respondent	Avg. burden per response (in hours)
Hospital/IRB Administrators	CDC IRB Authorization Agreement (for review).	500	1	1
Hospital/IRB Administrators	CDC IRB Authorization Agreement (for completion and submission to CDC).	500	10	10/60

Jeffrey M. Zirger,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3430–FN]

Application From the Joint Commission (TJC) for Continued Approval of its Psychiatric Hospital Accreditation Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces our decision to approve the Joint Commission for continued recognition as a national accrediting organization for psychiatric hospitals that wish to participate in the Medicare or Medicaid programs.

DATES: This notice is effective February 25, 2023 through February 25, 2029.

FOR FURTHER INFORMATION CONTACT: Danielle Adams (410) 786–8818, Donald Howard (410) 786–6764 or Lillian Williams (410) 786–8636.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services from a psychiatric hospital provided certain requirements are met. Section 1861(f) of the Social Security Act (the Act) establishes distinct criteria for facilities seeking designation as a psychiatric hospital. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488. The regulations at 42 CFR part 482, subpart E, specify the minimum conditions that a psychiatric hospital must meet to participate in the Medicare program, the scope of covered services, and the conditions for Medicare payment for psychiatric hospitals.

Generally, to enter into a provider agreement, a psychiatric hospital must first be certified by a State Survey Agency as complying with the conditions or requirements set forth in part 482 subpart E of our regulations. Thereafter, the psychiatric hospital is subject to regular surveys by a State Survey Agency to determine whether it continues to meet these requirements.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national accrediting organization (AO) that all applicable Medicare conditions are met or exceeded, we may treat the provider entity as having met those conditions; that is, we may ''deem'' the provider entity as having met the requirements. Accreditation by an AO is voluntary and is not required for Medicare participation.

If an AO is recognized by the Secretary of the Department of Health and Human Services (the Secretary) as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program may be deemed to meet the Medicare conditions. A national AO applying for approval of its accreditation program under part 488, subpart A, must provide Centers for Medicare & Medicaid Services (CMS) with reasonable assurance that the AO requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of AO are set forth at § 488.5. The regulations at § 488.5(e)(2)(i) require AO to reapply for continued approval of its accreditation program every 6 years or sooner as determined by CMS.

The Joint Commission's current term of approval for their psychiatric hospital accreditation program expires February 25, 2023.

II. Application Approval Process

Section 1865(a)(3)(A) of the Act provides a statutory timetable to ensure that our review of applications for CMS approval of an accreditation program is conducted in a timely manner. The Act provides no more than 210 days after the date of receipt of a complete application, including any documentation necessary to make the determination, for CMS to complete its application review process. Within 60 days after receiving a complete application, we must publish a notice in the **Federal Register** that identifies the national accrediting body making the request, describes the request, and provides no less than a 30-day public