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.

[FR Doc. 2023–03961 Filed 2–24–23; 8:45 am]

BILLING CODE 4163–18–P

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

comment period. At the end of the 210-day period, we must publish a notice in the **Federal Register** approving or denying the application.

III. Provisions of the Proposed Notice

In the September 30, 2022 **Federal Register** (87 FR 59435), we published a proposed notice announcing The Joint Commission (TJC) request for continued approval of its Medicare psychiatric hospital accreditation program. In the September 30, 2022 notice, we detailed our evaluation criteria. Under the authority of Section 1865(a)(2) of the Act and our regulations at § 488.5, we conducted a review of TJC's Medicare psychiatric hospital accreditation renewal application in accordance with the criteria specified by our regulations, which include, but are not limited to, the following:

- An onsite administrative review of TJC's: (1) Corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its psychiatric hospital surveyors; (4) ability to investigate and respond appropriately to complaints against accredited psychiatric hospitals; and (5) survey review and decision-making process for accreditation.
- The comparison of TJC's Medicare psychiatric hospital accreditation program standards to our current Medicare hospitals Conditions of Participation (CoPs) and psychiatric hospital special conditions.
- A documentation review of TJC's psychiatric hospital survey process to:

++ Determine the composition of the survey team, surveyor qualifications, and TJC's ability to provide continuing surveyor training.

++ Compare TJC's processes to those we require of state survey agencies, including periodic resurvey and the ability to investigate and respond appropriately to complaints against accredited psychiatric hospitals.

++ Evaluate TJC's procedures for monitoring psychiatric hospitals it has found to be out of compliance with TJC's program requirements. (This pertains only to monitoring procedures when TJC identifies non-compliance. If noncompliance is identified by a state survey agency through a validation survey, the state survey agency monitors corrections as specified at § 488.9(c)).

++ Assess TJC's ability to report deficiencies to the surveyed hospital and respond to the psychiatric hospital's plan of correction in a timely manner.

++ Establish TJC's ability to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

++ Determine the adequacy of TJC's staff and other resources.

++ Confirm TJC's ability to provide adequate funding for performing required surveys.

++ Confirm TJC's policies with respect to surveys being unannounced.

++ Confirm TJC's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions.

++ Obtain TJC's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as we may require, including corrective action plans.

IV. Analysis of and Responses to Public Comments on the Proposed Notice

In accordance with section 1865(a)(3)(A) of the Act, the September 30, 2022 proposed notice also solicited public comments regarding whether TJC's requirements met or exceeded the Medicare CoPs for psychiatric hospitals. We received one comment in response to the proposed notice.

Comment: A commenter expressed concern about TJC's ability to protect disabled patients in facilities that engage in misconduct and that do not follow best practices.

Response: We appreciate this comment and the commenter's concern for patient safety. We continue to prioritize patient safety and our responsibility for oversight of AOs. As described in Section III of this notice, CMS takes various steps when considering to approve or not approve a national AO. Each national AO wishing to be recognized by Medicare as a national AO must go through a rigorous process to obtain CMS approval. We remain steadfast in our commitment to keeping the public informed of our evaluation process for national AO seeking CMS approval.

V. Provisions of the Notice

A. Differences Between TJC's Standards and Requirements for Accreditation and Medicare Conditions of Participation (CoPs) and Survey Process Requirements

We compared TJC's psychiatric hospital accreditation program requirements and survey process with the Medicare CoPs at Part 482 subpart E, and the survey and certification process requirements of Parts 488 and 489. Our review and evaluation of TJC's psychiatric hospital application, which were conducted as described in section III of this notice, yielded the following areas where, as of the date of this notice, TJC has completed revising its survey processes in order to demonstrate that it uses survey processes that are comparable to state survey agency processes by:

- Providing additional training to ensure that TJC psychiatric hospital surveyors document findings of noncompliance consistent with the regulatory requirement in Section § 488.5 (a)(4)(iv).
- Providing additional training to surveyors to ensure any actions taken by the facility to address the deficiencies include specific information in the corrective measures, as provided by § 488.5 (a)(4)(vii), and are consistent with the plan of correction requirements as described in the State Operations Manual (SOM), Chapter 2, Section 2728B.
- Revising TJC's intake/triage process for all complaint requirements to ensure comparability with CMS requirements, § 488.5(a)(12), and consistent with the SOM, Chapter 5, Section 5075.2.
- Revising TJC's complaint policy regarding offsite investigations and maximum timeframes to investigate complaints as described in SOM, Chapter 5, Sections 5075.5 and 5075.9.

B. Term of Approval

Based on our review and observations described in section III. and V. of this notice, we approve TJC as a national AO for psychiatric hospitals that request participation in the Medicare program. The decision announced in this notice is effective February 25, 2023 through February 25, 2029. In accordance with § 488.5(e)(2)(i), the term of the approval will not exceed 6 years.

VI. Collection of Information Requirements

This document does not impose information collection requirements; that is, reporting, recordkeeping. or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: February 21, 2023.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2023–03925 Filed 2–24–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2782]

Antimicrobial Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Antimicrobial Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held virtually on March 16, 2023, from 9 a.m. to 5 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of the COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2022–N–2782. Please note that late, untimely filed comments will not be considered. The docket will close on March 15, 2023. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 15, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Comments received on or before March 9, 2023, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments as follows:

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–2782 for ''Antimicrobial Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; 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.'' FDA 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 for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify the information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Joyce Frimpong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–7973, email: *AMDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and