

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3420-FN]

Medicare and Medicaid Programs; Approval of Application by The Joint Commission (TJC) for Continued CMS-Approval of its Hospital Accreditation Program

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

ACTION: Final notice.

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

DATES: The decision announced in this final notice is effective July 15, 2022 through July 15, 2025.

FOR FURTHER INFORMATION CONTACT: Caecilia Blondiaux, (410) 786-2190.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services from a hospital, provided certain requirements are met. Section 1861(e) of the Social Security Act (the Act) establishes distinct criteria for facilities seeking designation as a 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 specify the minimum conditions that a hospital must meet to participate in the Medicare program.

Generally, to enter into an agreement, a hospital must first be certified by a state survey agency (SA) as complying with the conditions or requirements set forth in part 482 of our regulations. Thereafter, the hospital is subject to regular surveys by a SA 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 a Centers for Medicare & Medicaid Services (CMS)-approved national accrediting organization (AO) that all applicable Medicare requirements are met or exceeded, we will deem those provider entities as having met such 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 would be deemed to meet the Medicare requirements. A national AO applying for approval of its accreditation program under part 488, subpart A, must provide CMS with reasonable assurance that the AO requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare requirements. Our regulations concerning the approval of AOs are set forth at §§ 488.4, 488.5 and § 488.5(e)(2)(i). The regulations at § 488.5(e)(2)(i) require AOs to reapply for continued approval of its accreditation program every 6 years or sooner, as determined by CMS.

The Joint Commission's (TJC's) current term of approval for their hospital accreditation program expires July 15, 2022.

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 us 210 days after the date of receipt of a complete application, with any documentation necessary to make the determination, to complete our survey activities and application 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

On December 10, 2021, we published a proposed notice in the **Federal Register** (86 FR 70500), announcing TJC's request for continued approval of its Medicare hospital accreditation program. In that proposed notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and in our regulations at § 488.5 and § 488.8(h), we conducted a review of TJC's Medicare hospital accreditation application in accordance with the criteria specified by our regulations, which include, but are not limited to the following:

- An 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 hospital surveyors; (4) ability to investigate and respond appropriately to complaints against accredited hospitals; and (5) survey review and decision-making process for accreditation.

- A review of TJC's survey processes to confirm that a provider or supplier, under TJC's hospital deeming accreditation program, meets or exceeds the Medicare program requirements.
- A documentation review of TJC's survey process to do the following:

++ 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 TJC-accredited hospitals.

++ Evaluate TJC's procedures for monitoring accredited 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 SA through a validation survey, the SA monitors corrections as specified at § 488.9(c)).

++ Assess TJC's ability to report deficiencies to the surveyed hospitals and respond to the hospitals 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 December 10, 2021 proposed notice also solicited public comments regarding whether

TJC's requirements met or exceeded the Medicare conditions for participation (CoPs) for hospitals. We received one comment.

The commenter inquired about CMS activities related to AO oversight. Specifically, the commenter stated that there continues to be discrepancies between AO and CMS standards and processes. The commenter stated it would be extremely helpful if the AOs and CMS could be consistent in interpretation and surveillance.

CMS' review requires AO standards to meet or exceed those of the Medicare CoPs and for AOs to have comparable survey processes. The December 2021 proposed notice described CMS' process and oversight activities in Section III. Evaluation of Deeming Authority Request, which highlighted the evaluation CMS conducts before granting deeming authority to an AO. In Section V. of this final notice, CMS is highlighting areas which were identified to have discrepancies or lack of clarity within TJC's standards and survey processes. We note that TJC corrected these discrepancies before the renewing their deeming authority for CMS-approved hospital accreditation program.

V. Provisions of the Final Notice

A. Differences Between TJC's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements

We compared TJC's hospital accreditation requirements and survey process with the Medicare CoPs of parts 482, and the survey and certification process requirements of parts 488 and 489. Our review and evaluation of TJC's hospital application, which were conducted as described in section III. of this final notice, yielded the following areas where, as of the date of this notice, TJC has completed revising its standards and certification processes in order to—

- Meet the standard's requirements of all of the following regulations:

++ Section 482.12(c)(4)(i), to clarify that the governing body ensures that a doctor of medicine or osteopathy is responsible for the care of the patient. Specifically, that the applicability of the standard reflects both Medicare and Medicaid patients.

++ Section 482.12(d)(3), to explicitly state that the facility's overall institutional plan must provide for capital expenditures for at least a 3-year period.

++ Section 482.12(d)(4), to provide specifics as outlined within the standards, to include specifics, such as that the facility's overall institutional

plan must include and identify in detail the objective of, and the anticipated sources of financing for, each anticipated capital expenditure in excess of \$600,000 (or a lesser amount that is established, in accordance with section 1122(g)(1) of the Act, by the State in which the hospital is located).

++ Sections 482.12(d)(4)(i) through 482.12(d)(4)(iii), to provide specifics as outlined within the standard, to include acquisition of land; improvement of land, buildings, and equipment; or, the replacement, modernization, and expansion of buildings and equipment.

++ Section 482.13(d)(2), to specify that the patient has the right to receive his or her medical records based on oral or written request and comparable language that that the hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records.

++ Section 482.23(c)(6)(i)(A), to remove terminology of "independent" practitioners consistent with the regulation.

++ Section 482.41(b)(5), to include language that requires the hospital fire control plan to contain provisions for cooperating with firefighting authorities.

++ Section 482.41(d)(2), to include specifically, the requirement for supplies to be maintained to ensure and acceptable level of safety and quality.

++ Section 482.41(d)(3), to provide clarifications that the physical environment must be based on the complexity of the facility and services offered.

++ Section 482.41(e), to provide comparable standards which incorporate by reference the National Fire Protection Association (NFPA) standards.

In addition to the standards review, CMS reviewed TJC's comparable survey processes, which were conducted as described in section III. of this final notice, and 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:

++ Removing language suggesting a timeframe for completion of certain survey activities. In particular, revising the survey process to avoid imposing a time restriction, which could potentially suggest that a full assessment of all life safety and environment of care standards may not be conducted if timeframe exceeds.

++ Revising TJC's survey processes to include surveyor review to determine that a path of egress is well lit,

including outside the building as required by NFPA 101–2012, 7.8.1.1.

++ Developing survey procedures to incorporate that on any Medicare hospital survey, contracted patient care activities or patient services (such as dietary services, treatment services, and diagnostic services) located on hospital campuses or hospital provider-based locations should be surveyed as part of the hospital for compliance with the CoPs.

++ Emphasizing in TJC's policy and procedures that only CMS may approve temporary closures of deemed facilities. Specifically, TJC closely aligned their organizational policies with CMS' guidance provided in Administrative Memorandum 22–02–ALL,¹ which provided guidance related to temporary closures and cessation of business situations.

++ Providing additional training to surveyors related the appropriate level of citations for Governing Body and Nursing Services when deficiencies are found in a hospital.

++ Clarifying the complaint processes during the public health emergency and ensuring that all survey activities continue to be unannounced.

B. Term of Approval

Based on our review and observations described in section III. and section V. of this final notice, we approve TJC as a national accreditation organization for hospitals that request participation in the Medicare program. The decision announced in this final notice is effective July 15, 2022 through July 15, 2025 (3 years). In accordance with § 488.5(e)(2)(i) the term of the approval will not exceed 6 years. Due to travel restrictions and the reprioritization of survey activities brought on by the 2019 Novel Coronavirus Disease (COVID–19) Public Health Emergency (PHE), CMS was unable to observe a hospital survey completed by TJC surveyors as part of the application review process, which is one component of the comparability evaluation. Therefore, we are providing TJC with a shorter period of approval. Based on our discussions with TJC and the information provided in its application, we are confident that TJC will continue to ensure that its deemed hospitals will continue to meet or exceed Medicare standards. While TJC has taken actions based on the findings annotated in section V.A., of this final

¹ Administrative Memorandum 22–02–ALL (December 23, 2021). Transitioning Certification Functions for Changes of Ownership, Administrative Changes, and Initial Enrollment Performed by the CMS Survey and Operations Group <https://www.cms.gov/files/document/admin-info-22-02-all.pdf>.

notice, (Differences Between TJC's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements) as authorized under § 488.8, we will continue ongoing review of TJC's hospital survey. In keeping with CMS's initiative to increase AO oversight broadly, and ensure that our requested revisions by TJC are completed, CMS expects more frequent review of TJC's activities in the future.

VI. Collection of Information

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: April 27, 2022.

Lynette Wilson,

Federal Register Liaison, Center for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-3427]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & 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 (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 a second opportunity for public

comment on the notice. Interested persons are invited to send comments regarding the burden estimate 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 on the collection(s) of information must be received by the OMB desk officer by June 1, 2022.

ADDRESSES: Written 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.

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>.

FOR FURTHER INFORMATION CONTACT:

William Parham at (410) 786-4669.

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. 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 (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-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 that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* End Stage Renal Disease Application and Survey and Certification Report; *Use:* The Form CMS-3427 is required for each new ESRD facility seeking initial certification and for each existing facility seeking recertification, relocation, expansion/change of service(s), or change of ownership. The form is also used for information collection purposes related to a complaint survey of an ESRD facility. The Form CMS-3427 information is currently collected on paper as a manual option or may be completed in an online fillable format based on facility preference. This online form is a step in the direction towards electronic submission. *Form Number:* CMS-3427 (OMB control number: 0938-0360); *Frequency:* Every three years; *Affected Public:* Private sector (Business or other for-profit and Not-for profit institutions); *Number of Respondents:* 7,883; *Total Annual Responses:* 2,601; *Total Annual Hours:* 866. (For policy questions regarding this collection contact Jennifer Milby at 410-786-8828).

Dated: April 27, 2022.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-0354]

Acrotech Biopharma LLC; Withdrawal of Approval of New Drug Application for MARQIBO (VinCRISTine Sulfate LIPOSOME Injection), 5 milligrams/5 milliliters

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of new drug application (NDA) for MARQIBO (vinCRISTine sulfate LIPOSOME injection), 5 milligrams (mg)/5 milliliters (mL), held by Acrotech Biopharma LLC (Acrotech), 29 Princeton Hightstown Rd., East Windsor, NJ 08520. Acrotech has voluntarily requested that FDA withdraw approval of this application