Services (HHS), announces the renewal of the charter of the Advisory Committee to the Director (ACD).

FOR FURTHER INFORMATION CONTACT: Melissa O'Connor, MPH, Office of the Chief of Staff, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–10, Atlanta, Georgia 30329–4027; Telephone: (404) 498–1062; Email Address: *ACDirector@cdc.gov*.

SUPPLEMENTARY INFORMATION: CDC is providing notice under 5 U.S.C. 1001–1014 of the renewal of the charter of the Advisory Committee to the Director, Centers for Disease Control and Prevention, Department of Health and Human Services. This charter has been renewed for a two-year period through April 15, 2027.

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

[FR Doc. 2025–09840 Filed 5–30–25; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3469–FN]

Medicare and Medicaid Programs; Application From The Joint Commission for Continued Approval of its Hospice 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 hospices that wish to participate in the Medicare or Medicaid programs.

DATES: The decision announced in this notice is applicable from June 18, 2025 through June 18, 2030.

FOR FURTHER INFORMATION CONTACT: Joann Fitzell, (410) 786–4280 or Lillian Williams, (410) 786–8636.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in a hospice, provided certain requirements are met by the hospice. Section 1861(dd) of the Social Security Act (the Act) establishes distinct criteria for facilities seeking designation as a hospice. 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 418 specify the conditions that a hospice must meet in order to participate in the Medicare program, the scope of covered services, and the conditions for Medicare payment for hospices.

Generally, to enter into an agreement, a hospice must first be certified as complying with the conditions set forth in part 418 and recommended to the Centers for Medicare & Medicaid (CMS) for participation by a State survey agency. Thereafter, the hospice is subject to periodic surveys by a State survey agency to determine whether it continues to meet these conditions. However, there is an alternative to certification surveys by State agencies. Accreditation by a nationally recognized Medicare accreditation program approved by CMS may substitute for both initial and ongoing State review.

Section 1865(a)(1) of the Act provides that, if the Secretary of the Department of Health and Human Services (the Secretary) finds that accreditation of a provider entity by an approved national accrediting organization (AO) meets or exceeds all applicable Medicare conditions, CMS may treat the provider entity as having met those conditions; that is, we may ''deem'' the provider entity to be in compliance. Accreditation by an AO is voluntary and is not required for Medicare participation.

If an AO is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national AO's approved program may be deemed to meet the Medicare conditions. A national AO applying for CMS approval of its accreditation program under part 488, must provide CMS with reasonable assurance that the accrediting organization requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions of participation (CoPs). Our regulations concerning the approval of AOs are set forth at § 488.5. Section 488.5(e)(2)(i) requires an AO to reapply for continued approval of its Medicare accreditation program every 6 years or sooner as determined by CMS. The Joint Commission's (TJC's) term of approval as a recognized accreditation program for hospices expires June 18, 2025.

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** of our decision to approve or deny the application.

III. Provisions of the Proposed Notice

On January 13, 2025 we published a proposed notice in the **Federal Register** (90 FR 2706), announcing TJC's request for continued approval of its Medicare hospice accreditation program. In the January 13, 2025 proposed notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and in our regulations at § 488.5, we conducted a review of TJC's Medicare hospice accreditation program application in accordance with the criteria specified by our regulations, which include, but are not limited to, the following:

- A virtual 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 hospice surveyors; (4) ability to investigate and respond appropriately to complaints against accredited hospices; and (5) survey review and decision-making process for accreditation.
- The comparison of TJC's Medicare hospice accreditation program standards to our current Medicare hospice CoPs.
- A documentation review of TJC's 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 hospices.

++ Evaluate TJC's procedures for monitoring hospices it has found to be out of compliance with TJC's program requirements. (This pertains only to monitoring procedures when TJC identifies noncompliance. 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 hospice and respond to the hospice'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 January 13, 2025 proposed notice also solicited public comments regarding whether TJC's requirements met or exceeded the Medicare CoPs for hospices. We received no comments in response to our proposed notice.

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 hospice accreditation requirements and survey process with the Medicare CoPs of part 418, and the survey and certification process requirements of parts 488 and 489. Our review and evaluation of TJC's hospice 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 standards and certification processes in order to meet the requirements at:

- Section 418.52(b)(4)(iii), to include reference to the State survey agency.
- Section 418.52(c)(5), to include reference to ''45 CFR parts 160 and 164''.
- Section 418.52(c)(6), to address the right of a patient to be free of the misappropriation of the patient's property.
- Section 418.54(e), to address the hospice's quality assessment and performance improvement program.
- Section 418.58(c)(1)(ii), to address the program activity requirement to consider the incidence, prevalence, and severity of problems in those areas.
- Section 418.60(c), to address the requirement for contracted providers, patients, family members, and other caregivers.
- Section 418.66(a), to address the requirement that the hospice must provide evidence to CMS that it has made a good faith effort to hire a sufficient number of nurses to provide services.
- Section 418.76(b)(3)(xiii), to address the requirement the hospice is responsible for training hospice aids, as needed, for skills not covered in the basic checklist, as described in paragraph (b)(3)(ix) of this section.
- Section 418.100(f)(1), to address the Medicare approval requirement.
- Section 418.102(a)(1)(ii), to address the requirement that the contract must specify the physician who assumes the medical director's responsibilities and obligations.
- Section 418.104(e)(2), to address the requirement that if a patient revokes the election of hospice care or is discharged from hospice in accordance with § 418.26, the hospice must forward to the patient's attending physician a copy of the hospice discharge summary, and the patient's clinical record, if requested.
- Section 418.104(f), to address the requirement of making the clinical record available in hardcopy or electronic form.
- Section 418.110(c)(1), to address the hospice's requirement to address real or potential threats to the health and safety of patients, others, and property.
- Section 418.110(c)(2)(i) through (c)(2)(iv), to address the requirement for their associated procedures to control ''reliability and quality.''
- Section 418.110(d)(3), to address that the provisions of the adopted edition of the Life Safety Code do not apply in a State if CMS finds that a fire and safety code imposed by State law adequately protects patients in hospices.
- Section 418.110(e)(2), to address the requirement for Health Care Facilities Code waiver/equivalency requests.
- Section 418.110(n), to address the requirement that restraint or seclusion must be discontinued at the earliest possible time.
- Section 418.110(q), to include the National Fire Protection Association (NFPA 99), Standards for Health Care Facilities Code requirements.
- Section 418.113(a), to address the requirement to update the emergency preparedness plan every 2 years.
- Section 418.113(c)(7), to address the requirement that the emergency preparedness communication plan must include a means of providing information about the hospice's inpatient occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

In addition to the standards review, we also reviewed TJC's comparable survey processes, which were conducted as described in section III. of this notice, and yielded the following areas where, as of the date of this notice, TJC has completed revising its survey processes to demonstrate that it uses survey processes that are comparable to State survey agency processes by:

- Revising TJC's surveyor guide to revise the current Life Safety Code Building Assessment document to address both the Life Safety Code and Health Care Facilities Code (HCFC) in accordance with §§ 418.110(d) and (e).
- Revising TJC's surveyor guidance to be comparable with Appendix I related to inpatient hospice care.
- Ensuring that all Hospice Life Safety Code surveyors have received instructions, procedures, or resources for conducting inpatient hospice Life Safety Code/Health Care Facilities Code certification surveys consistent with SOM Chapter 4, Section 4009C—Training, Education, and Experience.

B. Term of Approval

Based on our review and observations described in section III. of this notice, we approve TJC as a national accreditation organization for hospices that request participation in the Medicare program, effective June 18, 2025 through June 18, 2030. Due to the temporary travel suspensions for non-critical or mission essential activities for the Department of Health and Human Services (HHS) in early 2025, CMS was unable to observe a hospice survey completed by TJC surveyors as part of the application review process, which is typically 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 accredited hospices will continue to meet or exceed the required standards. While TJC has taken actions based on the findings noted in section IV. of this 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 hospice survey processes and will conduct a survey observation on a modified schedule until further notice.

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), Mehmet Oz, having reviewed and approved this document, authorizes Vanessa Garcia, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Vanessa Garcia,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2025–09870 Filed 5–30–25; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–0093]

M13B Bioequivalence for Immediate-Release Solid Oral Dosage Forms: Additional Strengths Biowaiver; International Council for Harmonisation; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''M13B Bioequivalence for Immediate-Release Solid Oral Dosage Forms: Additional Strengths Biowaiver.'' The draft guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The draft guidance is the second in the ICH M13 series of guidances and describes the scientific and technical aspects of study design and data analysis to support bioequivalence (BE) assessment for additional strengths of orally administered immediate-release (IR) solid oral dosage forms (*i.e.,* tablets, capsules, and granules/powders for oral suspension), including considerations for biowaivers. The intent of this draft guidance is to provide harmonized criteria and data that support waivers for drug applications with multiple strengths when in vivo BE has been demonstrated for at least one strength using the principles outlined in the final guidance ''M13A Bioequivalence for Immediate-Release Solid Oral Dosage Forms'' published in October 2024.

DATES: Submit either electronic or written comments on the draft guidance by August 1, 2025 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time 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–2023–D–0093 for ''M13B Bioequivalence for Immediate-Release Solid Oral Dosage Forms: Additional Strengths Biowaiver.'' Received comments 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 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 to 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 this 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://*