and ACHC's ability to provide continuing surveyor training.

++ Compare ACHC's processes to those of state survey agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

++ Evaluate ACHC's procedures for monitoring CAHs out of compliance with ACHC's program requirements. The monitoring procedures are used only when ACHC identifies noncompliance. If noncompliance is identified through validation reviews, the state survey agency monitors corrections as specified at § 488.7(d).

++ Assess ACHC's ability to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

++ Establish ACHC'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 staff and other resources.

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

++ Confirm ACHC's policies with respect to whether surveys are unannounced.

++ Obtain ACHC'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 July 23, 2025 proposed notice also solicited public comments regarding whether ACHC's requirements met or exceeded the Medicare CoPs for CAHs. We received one comment in favor ACHC's CAH renewal application. We thank the commenters for their input and have taken it into consideration when making our decision.

V. Provisions of the Final Notice

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

We compared ACHC's CAH requirements and survey process with the Medicare CoPs and survey process as outlined in the State Operations Manual (SOM). Our review and evaluation of ACHC's CAH application were conducted as described in section III. of this notice and has yielded the following areas where, as of the date of this notice, ACHC has completed revising its standards and certification processes in order to:

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

++ Section 485.623(c)(1)(i), revised standards to include a reference to applicable Life Safety Code (LSC) section(s) in the standards that did not include all of the applicable LSC requirements.

++ Section 485.623(d), revised standards to include a reference to applicable Health Care Facility Code (HCFC) section(s) in the standards that did not include all of the applicable HCFC requirements.

In addition to the standards review, we also reviewed ACHC'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, ACHC has completed revising its survey processes, in order to demonstrate that it uses survey processes that are comparable to state survey agency processes by:

- Revising ACHC's survey process documentation to include both the 2012 editions of Life Safety Code (LSC) and Health Care Facilities Code (HCFC), and 2013 edition of the Fire Safety Evaluation System (FSES) NFPA 101A Fire Safety for Health Care Occupancies.
- Revising ACHC's survey process eligibility requirements for organizations to also meet the 2012 HCFC (NFPA 99).
- Providing additional survey training to CAH surveyors on citing levels as it relates to the initial comprehensive assessment, for example, standard versus conditional level, to ensure compatibility with § 488.26(b).

B. Term of Approval

Based on our review and observations described in sections III. and V. of this notice, we approve ACHC as a national AO for CAHs that request participation in the Medicare program. The decision announced in this final notice is effective December 27, 2025, through December 27, 2031.

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. 2026–06499 Filed 4–2–26; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3473–FN]

Medicare and Medicaid Programs; Approval of Application by the Accreditation Commission for Health Care Inc. (ACHC) for Continued CMS-Approval of its Hospice Accreditation Program

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

ACTION: Notice.

SUMMARY: This notice acknowledges the approval of an application from the Accreditation Commission for Health Care Inc., for continued CMS approval as a national accrediting organization for hospice programs that wish to participate in the Medicare or Medicaid programs.

DATES: The decision announced in this notice is applicable from November 27, 2025, through November 27, 2031.

FOR FURTHER INFORMATION CONTACT: Lillian Williams, (410) 786–8636. Kristin Shifflett, (410) 786–4133.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services from a hospice provided certain requirements are met. Section 1861(dd) of the Social Security Act (the Act) establishes distinct definitions relating to hospices. 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 with Medicare, a hospice must first be certified as complying with the

conditions of participation (CoPs) set forth in part 418, subparts C and D, 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)(A) 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, the Secretary shall treat the provider entity as having met those conditions; that is, CMS will ''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 accrediting organization's approved program may be deemed to meet the Medicare conditions. A national AO applying for CMS approval or re-approval of their accreditation program under 42 CFR 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 conditions. Our regulations concerning the approval of AOs are set forth at § 488.5. Section 488.5(e)(2)(i) permits CMS to grant a term of approval of up to 6 years, and an accrediting organization must reapply for continued approval of its Medicare accreditation program . The Accreditation Commission for Health Care Inc. (ACHC) currently has a term of approval as a recognized accreditation program for its hospice accreditation program that expires November 27, 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 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 June 25, 2025, **Federal Register** (90 FR 27020 and 27021), we published a proposed notice with request for comment announcing ACHC's request for continued approval of its Medicare hospice accreditation program. In the June 25, 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 ACHC's Medicare hospice accreditation application in accordance with the criteria specified by our regulations, which include, but are not limited to the following:

- A virtual administrative review of ACHC'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.
- A comparison of ACHC's Medicare hospice accreditation program standards to our current Medicare hospice CoPs.
- A documentation review of ACHC's survey process to—

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

++ Compare ACHC'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 ACHC's procedures for monitoring hospices it has found to be out of compliance with ACHC's program requirements. (This pertains only to monitoring procedures when ACHC 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 ACHC's ability to report deficiencies to the surveyed hospice and respond to the hospice's plan of correction in a timely manner.

++ Establish ACHC'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 ACHC's staff and other resources.

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

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

++ Confirm ACHC'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 ACHC'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 June 25, 2025, proposed notice with request for comment, we also solicited public comments regarding whether ACHC 's requirements met or exceeded the Medicare CoPs for hospice. We received several comments. All comments were in favor of ACHC's hospice renewal application. We thank the commenters for their input and have considered it when making our decision.

V. Provisions of the Final Notice

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

We compared ACHC'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 ACHC's hospice 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, ACHC has completed revising its standards and certification processes in order to meet the requirements at:

- Section 418.52(c)(5), to address the requirement regarding confidential clinical records.
- Section 418.54(b), to include reference to § 418.24.
- Section 418.54(c), to address comfort or well-being as part of the comprehensive assessment focus.
- Section 418.54(c)(1), to address the patient's well-being and comfort as part of the comprehensive assessment and

the presence or lack of objective data and subjective complaints requirement.

- Section 418.58(c)(2), to address the requirement of tracking adverse patient events and analyzing their cause.
- Section 418.100(f)(2), to address the requirements of subparts A and C of this section.
- Section 418.104(a)(2), to include references to § 418.52 and § 418.24.
- Section 418.104(a)(4), to include reference to § 418.54(e).
- Section 418.104(a)(5), to include references to § 418.25, § 418.102(b), and § 418.102(c).
- Section 418.52(a)(6), to include reference to § 418.52(a)(2).
- Section 418.112(b), to address the requirement to make any arrangements necessary for hospice-related inpatient care.
- Section 418.112 (c), to require an agreement that specifies the provision of hospice services in the facility.
- Section 418.112(f), to address the usage of appropriate forms.
- Section 418.114(b)(3)(i)(A), to address the Master of Social Work (MSW) requirement.
- Section 418.116(a), to require a hospice to have a license in accordance with State licensure laws.

In addition to the standards review, CMS also reviewed ACHC'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, ACHC has completed revising its survey processes in order to demonstrate that it uses survey processes that are comparable to state survey agency processes by:

- Revising ACHC's survey process documentation to include both the 2012 editions of Life Safety Code (LSC) and Health Care Facilities Code (HCFC), and 2013 edition of the Fire Safety Evaluation System (FSES) NFPA 101A Fire Safety for Health Care Occupancies.
- Ensuring that all new ACHC LSC surveyors complete LSC Preceptor Evaluations in accordance with ACHC's surveyor training policy and have supporting records on file.
- Providing additional survey training to hospice surveyors on citing levels as it relates to the initial comprehensive assessment, for example standard versus conditional level to ensure compatibility with § 488.26(b).

B. Term of Approval

Based on our review and observations described in section III. and V. of this final notice, we find that ACHC has provided reasonable assurance that hospices accredited under the program will meet or exceed the applicable Medicare conditions or requirements. Therefore, we approve ACHC as a national accreditation organization for hospices that request participation in the Medicare program, effective from November 27, 2025 through November 27, 2031.

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. 2026–06500 Filed 4–2–26; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2025–E–3073; FDA–2025–E–3074]

Determination of Regulatory Review Period for Purposes of Patent Extension; EMRELIS

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for EMRELIS and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect must submit either electronic or written comments and ask for a redetermination by June 2, 2026. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by September 30, 2026. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 2, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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.''