concert, to retain voting shares of Lakin Bancshares, Inc., and thereby indirectly retain voting shares of the KCB Bank, both of Lakin, Kansas.

Board of Governors of the Federal Reserve System.

Erin M. Cayce,

Assistant Secretary of the Board.

[FR Doc. 2023–28035 Filed 12–20–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–9889–N]

Charter Renewal for Advisory Committee on Ground Ambulance and Patient Billing (GAPB)—November 16, 2023

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The No Surprises Act, enacted as part of the Consolidated Appropriations Act, 2021, requires the Secretary of Health and Human Services (HHS), the Secretary of Labor, and the Secretary of the Treasury (the Secretaries) to establish and convene an advisory committee for the purpose of reviewing options to improve the disclosure of charges and fees for ground ambulance services, better inform consumers of insurance options for such services, and protect consumers from balance billing (the ''GAPB Advisory Committee'' or the ''Committee''). The Secretaries established the GAPB Advisory Committee on November 16, 2021 with a standard 2-year expiration period ending November 16, 2023. In accordance with the Federal Advisory Committee Act (FACA), HHS is hereby giving notice that the charter for the Advisory Committee on Ground Ambulance and Patient Billing (GAPB) was renewed effective November 16, 2023.

DATES: The charter for the Advisory Committee on GAPB was renewed is November 16, 2023.

ADDRESSES: Inquiries about the Committee can be mailed to Center for Consumer Information & Insurance Oversight, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop WB–22–75, Baltimore, MD 21244–8016.

FOR FURTHER INFORMATION CONTACT: Shaheen Halim, CMS, by phone (410) 786–0641 or via email at gapbadvisorycommittee@*cms.hhs.gov.*

Press inquiries may be submitted by phone at (202) 690–6145 or via email at *press@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 117(a) of the No Surprises Act, enacted as part of the Consolidated Appropriations Act, 2021, div. BB, tit. I, Public Law 116–260 (Dec. 27, 2020), requires the Secretaries of Labor, HHS, and the Treasury to establish and convene an advisory committee for the purpose of reviewing options to improve the disclosure of charges and fees for ground ambulance services, better inform consumers of insurance options for such services, and protect consumers from balance billing. The GAPB Advisory Committee is governed by the provisions of the Federal Advisory Committee Act (FACA), Public Law 92–463 (Oct. 6, 1972), as amended, 5 U.S.C. App. 2.

The GAPB Advisory Committee first convened in 2023. It will make recommendations with respect to the disclosure of charges and fees for ground ambulance services and insurance coverage, consumer protection and enforcement authorities of the Departments of Labor, Health and Human Services, and the Treasury (the Departments) and relevant States, and the prevention of balance billing to consumers. The recommendations shall address options, best practices, and identified standards to prevent instances of balance billing; steps that can be taken by State legislatures, State insurance regulators, State attorneys general, and other State officials as appropriate, consistent with current legal authorities regarding consumer protection; and legislative options for Congress to prevent balance billing. The purpose of renewing the GAPB Advisory Committee is to provide the Committee with more time to review relevant information, review options and best practices, and consider the recommendations that it has been charged with making. A copy of the charter and other information regarding the GAPB Advisory Committee's activity can be found at: *https://www.cms.gov/medicare/regulations-guidance/advisory-committees/advisory-committee-ground-ambulance-and-patient-billing-gapb.* The Administrator of CMS, Chiquita Brooks-LaSure, 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**.

Dated: December 18, 2023.

Vanessa Garcia,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2023–28128 Filed 12–20–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3455–PN]

Medicare and Medicaid Programs; Application From The Compliance Team (TCT) for Continued Approval of its Rural Health Clinics Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Notice with request for comment.

SUMMARY: This proposed notice acknowledges the receipt of an application from the Compliance Team (TCT) for continued recognition as a national accrediting organization (AO) for Rural Health Clinics (RHCs) that wish to participate in the Medicare or Medicaid programs. The statute requires that within 60 days of receipt of an organization's complete application, the Centers for Medicare & Medicaid Services (CMS) publish a notice that identifies the national accrediting body making the request, describes the nature of the request, and provides at least a 30-day public comment period.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by January 22, 2024.

ADDRESSES: In commenting, refer to file code CMS–3455–PN.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3455–PN, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for

Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3455–PN, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Joy Webb (410) 786–1667.

Shonte Carter (410) 786–3532.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments. We will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. We continue to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services from a Medicare-participating Rural Health Clinic (RHC), provided certain requirements are met. Sections 1861(aa)(1) and (2) and 1905(l)(1) of the Social Security Act (the Act) establish distinct criteria for an entity seeking designation as an RHC. Regulations concerning provider agreements are at 42 CFR part 489, and those pertaining to activities relating to the survey and certification of facilities and other entities are at 42 CFR part 488. The regulations at 42 CFR part 491 specify the conditions that a RHC must meet to participate in the Medicare program.

Generally, to enter into an agreement, a RHC must first be certified by a State survey agency as complying with the conditions or requirements set forth in part 491 of our regulations. Thereafter, the RHC is subject to regular surveys by a State survey agency to determine whether it continues to meet these requirements.

However, there is an alternative to surveys by State agencies. Section 1865(a)(1) of the Act provides that if a provider entity demonstrates through accreditation by a Center for Medicare & Medicaid Services (CMS) approved national accrediting organization (AO) that all applicable Medicare conditions are met or exceeded, we will deem those provider entities 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 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 conditions. A national AO applying for approval of its 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 AO are set forth at § 488.4 and 488.5. The regulations at § 488.5(e)(2)(i) require AOs to reapply for continued approval of their accreditation program every 6 years or sooner as determined by CMS.

The Compliance Team's (TCT's) term of approval for their RHC accreditation program expires July 17, 2024.

II. Approval of Deeming Organization

Section 1865(a)(2) of the Act and our regulations at § 488.5 require that our findings concerning review and approval of a national AO's requirements consider, among other factors, the applying AO's requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and ability to provide us with the necessary data for validation.

Section 1865(a)(3)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. We have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

The purpose of this proposed notice is to inform the public of TCT's request for continued approval for its RHC accreditation program. This notice also solicits public comment on whether TCT's requirements meet or exceed the Medicare conditions for certification (CfCs) for RHCs.

III. Evaluation of Deeming Authority Request

TCT submitted all the necessary materials to enable us to make a determination concerning its request for continued approval of its RHC accreditation program. This application was determined to be complete on October 25, 2023. Under section 1865(a)(2) of the Act and our regulations at § 488.5 (Application and re-application procedures for national accrediting organizations), our review and evaluation of TCT will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of TCT's standards for RHCs as compared with CMS' RHC CfCs.
- TCT's survey process to determine the following:

++ The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.

++ The comparability of TCT's processes to those of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited RHCs.

++ TCT's processes and procedures for monitoring RHCs found out of compliance with TCT's program requirements. These monitoring procedures are used only when TCT identifies noncompliance. If noncompliance is identified through validation reviews or complaint surveys, the State survey agency monitors corrections as specified at § 488.9(c).

++ TCT's capacity to report deficiencies to the surveyed RHCs and respond to the RHC's plan of correction in a timely manner.

++ TCT's capacity to provide us with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

++ The adequacy of TCT's staff and other resources, and its financial viability.

++ TCT's capacity to adequately fund required surveys.

++ TCT's policies with respect to whether surveys are announced or unannounced, to assure that surveys are unannounced.

++ TCT'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.

++ TCT's agreement to provide us 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. 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.*).

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the ''DATES'' section of this preamble, and when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

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

Trenesha Fultz-Mimms,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2023–28111 Filed 12–20–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–2565]

510(k) Third Party Review Program and Third Party Emergency Use Authorization (EUA) Review; Draft Guidance for Industry, Food and Drug Administration Staff, and Third Party Review Organizations; 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 the draft guidance entitled ''510(k) Third Party Review Program and Third Party Emergency Use Authorization (EUA) Review.'' This draft guidance provides FDA's current thinking regarding the 510(k) Third Party (3P510k) Review Program and review of Emergency Use Authorizations (EUA) requests by a third party review organizations (3PEUA review). The 3P510k Review Program and 3PEUA review create an alternative process for manufacturers to seek review of 510(k) submissions and EUA requests to assist FDA in reviewing in a timely manner. This draft guidance is not final nor is it for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by February 20, 2024 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–2016–D–2565 for ''510(k) Third Party Review Program and Third Party Emergency Use Authorization (EUA) Review.'' 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://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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the