shares of Security State Bank Holding Company, Fargo, North Dakota, and thereby indirectly acquire additional voting shares of Bank Forward, Hannaford, North Dakota.

B. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *Bern Bancshares, Inc., Bern, Kansas*; to acquire up to 7 percent of the voting shares of UBT Bancshares, Inc., and thereby indirectly acquire voting shares of United Bank & Trust, both of Marysville, Kansas.

Board of Governors of the Federal Reserve System, September 22, 2020.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2020–21213 Filed 9–24–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–R–153]

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 October 26, 2020.

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.*

2. Call the Reports Clearance Office at (410) 786–1326.

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:* Revision of a currently approved collection; *Title of Information Collection:* Medicaid Drug Use Review (DUR) Program; *Use:* States must provide for a review of drug therapy before each prescription is filled or delivered to a Medicaid patient. This review includes screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse. Pharmacists must make a reasonable effort to obtain, record, and maintain Medicaid patient profiles. These profiles must reflect at least the patient's name, address, telephone number, date of birth/age, gender, history, *e.g.,* allergies, drug reactions, list of medications, and pharmacist's comments relevant to the individual's drug therapy.

The States must conduct RetroDUR which provides for the ongoing periodic examination of claims data and other records in order to identify patterns of fraud, abuse, inappropriate or medically unnecessary care. Patterns or trends of drug therapy problems are identified and reviewed to determine the need for intervention activity with pharmacists and/or physicians. States may conduct interventions via telephone, correspondence, or face-to-face contact.

Annual reports are submitted to CMS for the purposes of monitoring compliance and evaluating the progress of States' DUR programs. The information submitted by States is reviewed and results are compiled by CMS in a format intended to provide information, comparisons, and trends related to States' experiences with DUR. States benefit from the information and may enhance their programs each year based on State reported innovative practices that are compiled by CMS from the DUR annual reports. *Form Number:* CMS–R–153 (OMB control number: 0938–0659); *Frequency:* Yearly, quarterly, and occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 51; *Total Annual Responses:* 663; *Total Annual Hours:* 41,004. (For policy questions regarding this collection contact Mike Forman at 410–786–2666.)

Dated: September 22, 2020.

William N. Parham, III,

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

[FR Doc. 2020–21181 Filed 9–24–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3393–FN]

Medicare Program; Approval of Application by the Community Health Accreditation Partner for Initial CMS-Approval of Its Home Infusion Therapy Accreditation Program

AGENCY: Centers for Medicare and Medicaid Services, HHS.

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve the Community Health Accreditation Partner (CHAP) for initial recognition as a national accrediting organization for home infusion therapy suppliers that wish to participate in the Medicare program. A home infusion therapy supplier that participates must meet the Medicare conditions for coverage.

DATES: The approval announced in this final notice is effective September 25, 2020 through September 25, 2024.

FOR FURTHER INFORMATION CONTACT:

Christina Mister-Ward, (410) 786–2441.

Shannon Freeland, (410) 786–4348.

Lillian Williams, (410) 786–8636.

SUPPLEMENTARY INFORMATION:

I. Background

Home Infusion therapy (HIT) is a treatment option for Medicare beneficiaries with a wide range of acute and chronic conditions. Section 5012 of the 21st Century Cures Act (Pub. L. 114–255, enacted on December 13, 2016) added sections 1861(iii) and 1834(u) to the Social Security Act (the Act), establishing a new Medicare benefit for HIT services. Section 1861(iii)(1) of the Act defines HIT as professional services, including nursing services; training and education not otherwise covered under the Durable Medical Equipment (DME) benefit; remote monitoring; and other monitoring services. Home infusion therapy must be furnished by a qualified HIT supplier and furnished in the individual's home. The individual must:

- Be under the care of an applicable provider (that is, physician, nurse practitioner, or physician assistant); and
- Have a plan of care established and periodically reviewed by a physician in coordination with the furnishing of home infusion drugs under Part B, that prescribes the type, amount, and duration of infusion therapy services that are to be furnished.

Section 1861(iii)(3)(D)(i)(III) of the Act requires that a qualified HIT supplier be accredited by an accrediting organization (AO) designated by the Secretary in accordance with section 1834(u)(5) of the Act. Section 1834(u)(5)(A) of the Act identifies factors for designating AOs and in reviewing and modifying the list of designated AOs. These statutory factors are as follows:

- The ability of the organization to conduct timely reviews of accreditation applications.
- The ability of the organization take into account the capacities of suppliers located in a rural area (as defined in section 1886(d)(2)(D) of the Act).
- Whether the organization has established reasonable fees to be charged to suppliers applying for accreditation.
- Such other factors as the Secretary determines appropriate.

Section 1834(u)(5)(B) of the Act requires the Secretary to designate AOs to accredit HIT suppliers furnishing HIT not later than January 1, 2021. Section 1861(iii)(3)(D) of the Act defines ''qualified home infusion therapy suppliers'' as being accredited by a CMS-approved AO.

In the March 1, 2019 **Federal Register**, we published a solicitation notice entitled, ''Medicare Program; Solicitation of Independent Accrediting Organizations To Participate in the Home Infusion Therapy Supplier Accreditation Program'' (84 FR 7057). This notice informed national AOs that accredit HIT suppliers of an opportunity to submit applications to participate in the HIT supplier accreditation program. Complete applications will be considered for the January 1, 2021 designation deadline if received by February 1, 2020.

Regulations for the approval and oversight of AOs for HIT organizations are located at 42 CFR part 488, subpart L. The requirements for HIT suppliers are located at 42 CFR part 486, subpart I.

II. Approval of Accreditation Organizations

Section 1834(u)(5) of the Act and the regulations at § 488.1010 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 CMS with the necessary data.

Section 488.1020(a) requires that we publish, after 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. In accordance with § 488.1010(d), we have 210 days from the receipt of a complete application to approve or deny the application.

III. Provisions of the Proposed Notice

In the April 27, 2020 **Federal Register** (85 FR 23364), we published a proposed notice announcing the Community Health Accreditation Partner's (CHAP's) request for initial approval of its Medicare HIT accreditation program. In that proposed notice, we detailed our evaluation criteria. Under section 1834(u)(5) the Act and in our regulations at § 488.1010, we conducted a review of CHAP's Medicare HIT accreditation application in accordance with the criteria specified by our regulations, which included, but are not limited to the following:

- An administrative review of CHAP's: (1) Corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its home infusion therapy surveyors; (4) ability to investigate and respond appropriately to complaints against accredited home infusion therapies; and (5) survey review and decision-making process for accreditation.
- The ability for CHAP to conduct timely review of accreditation applications.
- The ability of CHAP to take into account the capacities of suppliers located in a rural area.
- The comparison of CHAP's Medicare HIT accreditation program standards to our current Medicare home infusion therapy conditions for coverage (CfCs).
- CHAP's survey process to determine the following:

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

++ CHAP's processes, including periodic resurvey and the ability to investigate and respond appropriately to complaints against accredited home infusion therapies.

++ Evaluate CHAP's procedures for monitoring home infusion therapies it has found to be out of compliance with CHAP's program requirements.

++ Assess CHAP's ability to report deficiencies to the surveyed home infusion therapy and respond to the home infusion therapy's plan of correction in a timely manner.

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

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

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

++ Review CHAP'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 CHAP'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.

The April 27, 2020 proposed notice also solicited public comments regarding whether CHAP's requirements met or exceeded the Medicare CfCs for home infusion therapy. No comments were received in response to our proposed notice.

IV. Provisions of the Final Notice

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

We compared CHAP's HIT accreditation requirements and survey process with the Medicare CfCs of part 486, subpart I and the survey and certification process requirements of part 488, subpart L. Our review and evaluation of CHAP's HIT application, which was conducted as described in section III. of this final notice, yielded the following areas where, as of the date of this notice, CHAP has completed revising its standards and certification processes in order to meet the condition at:

- Section 486.520(b), to address the requirement of the plan of care must be established by a physician prescribing the type, amount and duration for home infusion therapy.
- Section 486.525(a), to include the required language ''plan of care''.
- Section 488.1010(a)(6)(iv), to revise CHAP's procedures for survey reviews.

B. Term of Approval

As authorized under § 488.1040(a), we reserve the right to conduct onsite observations of accrediting organization operations at any time as part of the ongoing review and continuing oversight of an accrediting organization's performance. Based on the review and observations described in section III. of this final notice, we have determined that CHAP's requirements for HIT meet or exceed our requirements. Therefore, we approve CHAP as a national accreditation organization for HITs that request participation in the Medicare program, effective September 25, 2020 through September 25, 2024.

V. Collection of Information Requirements

This document does not impose information collection and 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. Chapter 35).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Seema Verma, 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: September 21, 2020.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid.

[FR Doc. 2020–21147 Filed 9–24–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–3805]

The Accreditation Scheme for Conformity Assessment Pilot Program; Guidances for Industry, Accreditation Bodies, Testing Laboratories, and Food and Drug Administration Staff; 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 three final guidance documents for the Accreditation Scheme for Conformity Assessment Pilot Program—specifically, ''The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program; Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff''; ''Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment—Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program: Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff''; and ''Biocompatibility Testing of Medical Devices—Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program: Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff.'' These guidances describe the goals, scope, procedures, and framework for the voluntary ASCA Pilot program, and provide information about two groups of consensus standards within the scope of the pilot program.

DATES: The announcement of these guidances is published in the **Federal Register** on September 25, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2019–D–3805 for ''The Accreditation Scheme for Conformity Assessment