must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than November 27, 2018.

A. Federal Reserve Bank of New York (Ivan Hurwitz, Vice President) 33 Liberty Street, New York, New York 10045–0001. Comments can also be sent electronically to *Comments.applications@ny.frb.org:*

1. *The Adirondack Trust Company Employee Stock Ownership Trust, Saratoga Springs, New York;* to acquire fifty additional shares of 473 Broadway Holding Corporation and two thousand additional shares of The Adirondack Trust Company, both of Saratoga Springs, New York.

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

1. *Foote Financial Services, LLC, Hoxie, Kansas;* to become a bank holding company by acquiring voting shares of Peoples State Bank, Manhattan, Kansas.

Board of Governors of the Federal Reserve System, October 25, 2018.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2018–23682 Filed 10–29–18; 8:45 am]

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FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Savings and Loan Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Home Owners' Loan Act (12 U.S.C. 1461 *et seq.*) (HOLA), Regulation LL (12 CFR part 238), and Regulation MM (12 CFR part 239), and all other applicable statutes and regulations to become a savings and loan holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a savings association and nonbanking companies owned by the savings and loan holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the HOLA (12 U.S.C. 1467a(e)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 10(c)(4)(B) of the HOLA (12 U.S.C. 1467a(c)(4)(B)). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than November 27, 2018.

A. Federal Reserve Bank of Philadelphia (William Spaniel, Senior Vice President) 100 North 6th Street, Philadelphia, Pennsylvania 19105–1521. Comments can also be sent electronically to *Comments.applications@phil.frb.org:*

1. *WSFS Financial Corporation, Wilmington, Delaware;* to merge with Beneficial Bancorp, Inc., Philadelphia, Pennsylvania, and therefore indirectly acquire shares of Beneficial Bank, Philadelphia, Pennsylvania. WSFS Financial Corporation has applied to become a savings and loan holding company with respect to Beneficial Bank's conversion to a stock federal savings association.

Board of Governors of the Federal Reserve System, October 25, 2018.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2018–23683 Filed 10–29–18; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Performance Review Board Membership

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice of Performance Review Board Membership.

FOR FURTHER INFORMATION CONTACT: Kathy Vaughn, 410–786–1050 or *katherine.vaughn@cms.hhs.gov.*

SUMMARY: 5 U.S.C. 4314(c)(1) through (5) requires each agency to establish, in accordance with regulations prescribed by the Office of Personnel Management, one or more Senior Executive Service (SES) Performance Review Boards.

The PRB shall review and evaluate the initial summary rating of a senior executive's performance, the executive's response, and the higher-level official's comments on the initial summary rating. In addition, the PRB will review and recommend executive performance bonuses and pay increases.

5 U.S.C. 4314(c)(4) requires the appointment of board members to be published in the **Federal Register**. The following persons comprise a standing roster to serve as members of the SES PRB for the Centers for Medicare & Medicaid Services:

Elisabeth Handley, Director, Office of Human Capital (serves as the Chair)
Demetrious Kouzoukas, Principal Deputy Administrator for Medicare
Karen Jackson, Deputy Chief Operating Officer
Jeffrey Wu, Deputy Director for Operations, Center for Consumer Information and Insurance Oversight
Jean Moody-Williams, Deputy Center Director, Center for Clinical Standards and Quality
Nancy O'Connor, Philadelphia Regional Administrator

Dated: October 16, 2018.

Elisabeth Handley,

Director, Office of Human Capital.

[FR Doc. 2018–23814 Filed 10–29–18; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3369–PN]

Medicare and Medicaid Programs: Application From the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF) for Continued CMS-Approval of Its Outpatient Physical Therapy and Speech Language Pathology Services Accreditation Program

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

ACTION: Notice with request for comment.

SUMMARY: This proposed notice acknowledges the receipt of an application from the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF) for continued recognition as a national accrediting organization (AO) for clinics, rehabilitation agencies, or public health agencies that furnish outpatient physical therapy and speech language pathology services that wish to participate in the Medicare or Medicaid programs.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on November 29, 2018.

ADDRESSES: In commenting, please refer to file code CMS–3369–PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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–3369–PN, P.O. Box 8010, Baltimore, MD 21244–8010.

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–3369–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: Erin McCoy, (410) 786–2337, Monda Shaver, (410) 786–3410, or Renee Henry, (410) 786–7828.

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.

I. Background

Under section 1861(p) of the Medicare statute, eligible beneficiaries may receive outpatient physical therapy and speech language pathology (OPT) services from a provider of services, a clinic, rehabilitation agency, a public health agency, or others, provided certain requirements are met. Section 1832(a)(2)(C) of the Social Security Act (the Act) permits payment for OPT services. 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 485 subpart H specify the conditions that a clinic, rehabilitation agency or public health agency (''OPT providers'') must meet in order to participate in the Medicare program, the scope of covered services, and the conditions for Medicare payment for OPT providers.

Generally, to enter into an agreement, an OPT provider must first be certified by a State survey agency as complying with the conditions of participation set forth in part 485, subpart H of our Medicare regulations. Thereafter, the OPT provider is subject to regular surveys by a State survey agency 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 conditions are met or exceeded, we may 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 the Department of Health and Human Services as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program may be deemed to meet the Medicare conditions. An 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 conditions. Our regulations concerning the approval of AOs are set forth at § 488.5.

AAAASF's current term of approval for its OPT provider accreditation program expires April 4, 2019.

II. Approval of Deeming Organizations

Section 1865(a)(2) of the Act and our regulations at § 488.5 require that our findings concerning review and approval of an 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 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 AAAASF's request for continued CMS approval of its OPT provider accreditation program. This proposed notice also solicits public comment on whether AAAASF's requirements meet or exceed the Medicare conditions of participation (CoPs) for OPT providers.

III. Evaluation of an AO's Accreditation Program

AAAASF submitted all the necessary materials to enable us to make a determination concerning its request for continued CMS-approval of its OPT provider accreditation program. This application was determined to be complete on September 6, 2018. Under Section 1865(a)(2) of the Act and our regulations at § 488.5, our review and evaluation of AAAASF will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of AAAASF's standards for OPT providers as compared with Medicare's CoPs for OPT providers.
- AAAASF'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 AAAASF's processes to those of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

++ AAAASF's processes and procedures for monitoring an OPT provider found out of compliance with AAAASF's program requirements. These monitoring procedures are used only when AAAASF identifies noncompliance. If noncompliance is identified through validation reviews or complaint surveys, the State survey agency monitors corrections as specified at § 488.9(c)(1).

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

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

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

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

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

++ AAAASF's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as CMS 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 Public 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.

Upon completion of our evaluation, including evaluation of comments received as a result of this proposed notice, we will publish a final notice in the **Federal Register** announcing the result of our evaluation.

Dated: October 19, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2018–23611 Filed 10–29–18; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3689]

21st Century Cures: Announcing the Establishment of a Surrogate Endpoint Table; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the establishment of a public docket to receive suggestions and comments from interested parties (including academic institutions, regulated industry, and patient groups) on the Agency's publication of the surrogate endpoint table (SE table). FDA has developed a web page, available at *https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm613636.htm* that displays the SE table, describes the purpose of the table, and provides additional background information. Comments received on the SE table will help FDA determine its utility and may assist FDA in developing future iterations of the SE table and identifying best methods for conveying information about SEs on the FDA's website.

DATES: Submit either electronic or written comments on this notice by December 31, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 31, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 31, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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.''

Instructions: All submissions received must include the Docket No. FDA–2018–N–3689 for ''21st Century Cures: Announcing the Establishment of a Surrogate Endpoint Table.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

- 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