October 2010, notice is hereby given that the Federal Accounting Standards Advisory Board (FASAB) has released for public comment an exposure draft of a proposed Interpretation, *Guidance on Recognizing Liabilities Involving Multiple Component Reporting Entities: An Interpretation of SFFAS 5.*

The proposed Interpretation is available on the FASAB website at *http://www.fasab.gov/documents-for-comment/.* Copies can be obtained by contacting FASAB at (202) 512–7350.

Respondents are encouraged to comment on any part of the exposure draft and to provide the reasons for their positions. Written comments are requested by January 17, 2019, and should be sent to *fasab@fasab.gov* or Wendy M. Payne, Executive Director, Federal Accounting Standards Advisory Board, 441 G Street NW, Suite 1155, Washington, DC 20548.

FOR FURTHER INFORMATION CONTACT: Ms. Wendy M. Payne, Executive Director, 441 G Street NW, Suite 1155, Washington, DC 20548, or call (202) 512–7350.

Authority: Federal Advisory Committee Act, Pub. L. 92–463.

Dated: October 17, 2018.

Wendy M. Payne,

Executive Director.

[FR Doc. 2018–23110 Filed 10–22–18; 8:45 am]

BILLING CODE 1610–02–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank 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 applications will also 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 BHC Act (12 U.S.C. 1842(c)). 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 4 of the BHC Act (12 U.S.C. 1843). 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 20, 2018.

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

1. *Foote Financial Shares, LLC, Manhattan, Kansas;* to become a bank holding company by acquiring 100 percent of the voting shares of Peoples State Bank, Manhattan, Kansas.

Board of Governors of the Federal Reserve System, October 18, 2018.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2018–23099 Filed 10–22–18; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–224–14, CMS–10684, CMS–10524, CMS–10572, CMS–10433 and CMS–10657]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid 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 (the 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 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates 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 must be received by December 24, 2018.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

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. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

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

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–1326.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–224–14 Federal Qualified Health Center Cost Report

CMS–10684 21st Century Cures Act Section 12002 IMD Study

CMS–10524 Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetic, Orthotics, and Supplies (DMEPOS)

CMS–10572 Transparency in Coverage Reporting by Qualified Health Plan Issuers
CMS–10433 Data Collection to Support QHP Certification and other Financial Management and Exchange Operations
CMS–10657 The State Flexibility to Stabilize the Market Grant Program

Under the 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 requires federal agencies to publish a 60-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.

Information Collection

1. *Title of Information Collection:* Federal Qualified Health Center Cost Report; *Type of Information Collection Request:* Extension of a currently approved collection; *Use:* Under the authority of sections 1815(a) and 1833(e) of the Act, CMS requires that providers of services participating in the Medicare program submit information to determine costs for health care services rendered to Medicare beneficiaries. Furthermore, these sections of the Act provide that no Medicare payments will be made to a provider unless it furnishes the information. CMS requires that providers follow reasonable cost principles under 1861(v)(1)(A) of the Act when completing the Medicare cost report. Under the regulations at 42 CFR 413.20 and 413.24, CMS defines adequate cost data and requires cost reports from providers on an annual basis. The Form CMS–224–14 cost report is needed to determine a provider's reasonable cost incurred in furnishing medical services to Medicare beneficiaries and to calculate the FQHC settlement amount. These providers, paid under the FQHC prospective payment system (PPS), may receive reimbursement outside of the PPS for Medicare reimbursable bad debts and pneumococcal and influenza vaccines. The FQHC cost report is also used for rate setting and payment refinement activities, including developing a FQHC market basket. Additionally, the Medicare Payment Advisory Commission (MedPAC) uses the FQHC Medicare cost report data to calculate Medicare margins, to formulate recommendations to Congress regarding the FQHC PPS, and to conduct additional analysis of the FQHC PPS. *Form Number:* CMS–224–14 (OMB control number: 0938–1298); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 2,240; *Number of Responses:* 2,240; *Total Annual Hours:* 129,920. (For questions regarding this collection contact Julie Stankivic at (410) 786–5725.)

2. *Title of Information Collection:* 21st Century Cures Act Section 12002 IMD Study; *Type of Information Collection Request:* New collection (request for a new OMB control number); *Use:* The Act requires that HHS conduct a study of the effects of the 2016 Medicaid Managed Care final rule's provisions that clarified policy on coverage of IMD services in lieu of other covered services. The survey is needed to help answer the 5 mandated study questions. The collected data will be used by CMS develop a Report to Congress as required by the Act. *Form Number:* CMS–10684 (OMB Control Number: 0938–TBD); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 43; *Number of Responses:* 43; *Total Annual Hours:* 86. (For questions regarding this collection contact Laura Snyder at (410) 786–3198.)

3. *Title of Information Collection:* Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetic, Orthotics, and Supplies (DMEPOS); *Type of Information Collection Request:* Revision of a currently approved collection; Use: The CMS has had longstanding concerns about the improper payments related to DMEPOS items. The Department of Health and Human Services' Office of the Inspector General and the U.S. Government Accountability Office have published multiple reports indicating questionable billing practices by suppliers, inappropriate Medicare payments, and questionable utilization of DMEPOS items. The fiscal year (FY) 2017 Medicare FFS program improper payment rate for the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) was 44.6%, accounting for over $3.7 billion in projected improper payments. The CMS has implemented several initiatives in recent years to address these issues, such as the DMEPOS Competitive Bidding Program, as well as heightened screening of suppliers, as authorized by the Affordable Care Act.

In addition to those actions, CMS is continuing the use of prior authorization in fee for service Medicare. Prior authorization is a process through which a request for provisional affirmation of coverage is submitted for review before an item is rendered to a Medicare patient and before a claim is submitted for payment. Prior authorization helps make sure that applicable Medicare coverage, payment, and coding rules are met before item(s) are rendered. Prior to furnishing the item to the beneficiary and prior to submitting the claim for processing, a requester must submit a prior authorization request that includes evidence that the item complies with all applicable Medicare coverage, coding, and payment rules. Consistent with § 414.234(d), such evidence must include the order, relevant information from the beneficiary's medical record, and relevant supplier-produced documentation. After receipt of all applicable required Medicare documentation, CMS or one of its review contractors will conduct a medical review and communicate a decision that provisionally affirms or non-affirms the request. A provisional affirmative decision is a preliminary finding that a future claim submitted to Medicare for the DMEPOS item likely meets Medicare's coverage, coding, and payment requirements. Suppliers who receive a non-affirmative decision have unlimited resubmission opportunities. *Form Number:* CMS–10524 (OMB control number: 0938–1293); *Frequency:* Occasionally; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents:* 321,551; *Total Annual Responses:* 321,551; *Total Annual Hours:* 160,775.68 (For policy questions regarding this collection contact Yuliya Cook at (410) 786–0157.)

4. *Title of Information Collection:* Information Collection for Transparency in Coverage Reporting by Qualified Health Plan Issuers; *Type of Information Collection Request:* Extension of a currently approved information collection request; *Use:* Section 1311(e)(3) of the Affordable Care Act requires issuers of Qualified Health Plans (QHPs), to make available and submit transparency in coverage data. This data collection would collect certain information from QHP issuers in Federally-facilitated Exchanges and State-based Exchanges that rely on the

federal IT platform (*i.e.,* HealthCare.gov). HHS anticipates that consumers may use this information to inform plan selection.

As stated in the final rule Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers (77 FR 18310; March 27, 2012), broader implementation will continue to be addressed in separate rulemaking issued by HHS, and the Departments of Labor and the Treasury (the Departments).

Consistent with Public Health Service Act (PHS Act) [1] section 2715A, which largely extends the transparency reporting provisions set forth in section 1311(e)(3) to non-grandfathered group health plans (including large group and self-insured health plans) and health insurance issuers offering group and individual health insurance coverage (non-QHP issuers), the Departments intend to propose other transparency reporting requirements at a later time, through a separate rulemaking conducted by the Departments, for non-QHP issuers and non-grandfathered group health plans. Those proposed reporting requirements may differ from those prescribed in the HHS proposal under section 1311(e)(3), and will take into account differences in markets, reporting requirements already in existence for non-QHPs (including group health plans), and other relevant factors. The Departments also intend to streamline reporting under multiple reporting provisions and reduce unnecessary duplication. The Departments intend to implement any transparency reporting requirements applicable to non-QHP issuers and non-grandfathered group health plans only after notice and comment, and after giving those issuers and plans sufficient time, following the publication of final rules, to come into compliance with those requirements. *Form Number:* CMS–10572 (OMB control number: 0938–1310); *Frequency:* Annually; *Affected Public:* Private Sector (Business or other for-profits); *Number of Respondents:* 160; *Number of Responses:* 160; *Total Annual Hours:* 10,880. (For questions regarding this collection contact Valisha Jackson at (301) 492–5145.)

5. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Data Collection to Support QHP Certification and other Financial Management and Exchange Operations; *Use:* As directed by the rule Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers (77 FR 18310) (Exchange rule), each Exchange is responsible for the certification and offering of Qualified Health Plans (QHPs). To offer insurance through an Exchange, a health insurance issuer must have its health plans certified as QHPs by the Exchange. A QHP must meet certain minimum certification standards, such as network adequacy, inclusion of Essential Community Providers (ECPs), and non-discrimination. The Exchange is responsible for ensuring that QHPs meet these minimum certification standards as described in the Exchange rule under 45 CFR 155 and 156, based on the Patient Protection and Affordable Care Act (PPACA), as well as other standards determined by the Exchange. Issuers can offer individual and small group market plans outside of the Exchanges that are not QHPs.

The instruments in this information collection will be used for the 2020 certification process and beyond. Providing these instruments now will give issuers and other stakeholders more opportunity to familiarize themselves with the instruments before releasing the 2020 application. *Form Number:* CMS–10433 (OMB control number: 0938–1187); *Frequency:* Annually; *Affected Public:* State, Local, or Tribal Governments, Private Sector (Business or other for-profits); *Number of Respondents:* 2,892 *Number of Responses:* 2,892; *Total Annual Hours:* 68,666. (For questions regarding this collection contact Joshua Annas at (301) 492–4407).

6. *Type of Information Collection Request:* Request for a new OMB control number; *Title of Information Collection:* The State Flexibility to Stabilize the Market Grant Program Reporting; *Use:* Section 1003 of the Affordable Care Act (ACA) adds a new section 2794 to the PHS Act entitled, ''Ensuring That Consumers Get Value for Their Dollars.'' Specifically, section 2794(a) requires the Secretary of the Department of Health and Human Services (the Secretary) (HHS), in conjunction with the States, to establish a process for the annual review of health insurance premiums to protect consumers from unreasonable rate increases. Section 2794(c) directs the Secretary to carry out a program to award grants to States. Section 2794(c)(2)(B) specifies that any appropriated Rate Review Grant funds that are not fully obligated by the end of FY 2014 shall remain available to the Secretary for grants to States for planning and implementing the insurance market reforms and consumer protections under Part A of title XXVII of the Public Health Service Act (PHS Act). States that are awarded funds under this funding opportunity are required to provide CMS with four quarterly reports and one annual report (except for the last year of the grant) until the end of the grant period detailing the state's progression towards planning and/or implementing the pre-selected market reforms under Part A of Title XXVII of the PHS Act. A final report is due at the end of the grant period. *Form Number:* CMS–10657 (OMB control number: 0938–NEW); *Frequency:* Annually and Quarterly; *Affected Public:* State, Local or Tribal Governments; *Number of Respondents:* 31; *Total Annual Responses:* 5; *Total Annual Hours:* 2,108. (For policy questions regarding this collection contact Jim Taing at (301) 492–4182.)

Dated: October 17, 2018.

William N. Parham, III,

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

[FR Doc. 2018–23027 Filed 10–22–18; 8:45 am]

BILLING CODE 4120–01–P

[1] PHS Act section 2715A also is incorporated into section 715(a)(1) of the Employee Retirement Income Security Act and section 9815(a)(1) of the Internal Revenue Code.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2017–E–5940, FDA–2017–E–5941, FDA–2017–E–5943, and FDA–2017–E–5944]

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

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 SILIQ 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 the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by December 24, 2018. Furthermore, any interested person may petition FDA for a determination