related to finances, environmental responsibilities, and decision-making for legal matters.

*Proposed Effective Date:* 10/16/2020.

*Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/2077.*

Dated: September 8, 2020.

**Rachel Dickon,**

*Secretary.*

[FR Doc. 2020–20066 Filed 9–10–20; 8:45 am]

**BILLING CODE 6730–02–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 public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments regarding each of these applications must be received at the Reserve Bank(s) indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington DC 20551–0001, not later than October 13, 2020.

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

1. *The Reisher Family Foundation, Lakewood, Colorado;* to become a bank holding company by acquiring 16.95 percent of the voting shares of FirstBank Holding Company, and thereby indirectly acquire FirstBank, both of Lakewood, Colorado.

Board of Governors of the Federal Reserve System, September 4, 2020.

**Yao-Chin Chao,**

*Assistant Secretary of the Board.*

[FR Doc. 2020–20015 Filed 9–10–20; 8:45 am]

**BILLING CODE P**

## FEDERAL RESERVE SYSTEM

### Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than September 28, 2020.

*A. Federal Reserve Bank of San Francisco* (Sebastian Astrada, Director, Applications) 101 Market Street, San Francisco, California 94105–1579:

*1. Richard B. Fowler II, Carmichael, California, and Karl K. Klessig, Sante Fe, New Mexico;* as a group acting in concert, to acquire additional voting shares of Golden Pacific Bancorp, Inc., and thereby indirectly acquire voting shares of Golden Pacific Bank, National Association, both of Sacramento, California.

Board of Governors of the Federal Reserve System, September 8, 2020.

**Yao-Chin Chao,**

*Assistant Secretary of the Board.*

[FR Doc. 2020–20086 Filed 9–10–20; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[Document Identifier: CMS–359/CMS–360, CMS–10706, CMS–10725 and CMS 10728]**

### 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 13, 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:* Extension of a currently approved information collection; *Title of Information Collection:* Comprehensive Outpatient Rehabilitation Facility (CORF) Certification and Survey Forms; *Use:* The form CMS–359 is an application for health care providers that seek to participate in the Medicare program as a Comprehensive Outpatient Rehabilitation Facility (CORF). The form initiates the process for facilities to become certified as a CORF and it provides the CMS Location and State Survey Agency (SA) staff identifying information regarding the applicant that is stored in the Automated Survey Processing Environment (ASPEN) system.

The form CMS–360 is a survey tool used by the SAs to record information in order to determine a provider's compliance with the CORF Conditions of Participation (COPs) and to report this information to the Federal government. The form includes basic information on the COP requirements, check boxes to indicate the level of compliance, and a section for recording notes. CMS has the responsibility and authority for certification decisions which are based on provider compliance with the COPs and this form supports this process. *Form Number:* CMS–359/360 (OMB control number: 0938–0267); *Frequency:* Occasionally; *Affected Public:* Private Sector (Business or other for-profits); *Number of Respondents:* 49 *Number of Responses:* 8; *Total Annual Hours:* 74. (For questions regarding this collection contact Caroline Gallaher (410)786–8705.)

2. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Generic Clearance for the Center for Clinical Standards and Quality IT Product and Support Teams; *Use:* The Health Information Technology for Economic and Clinical Health (HITECH) Act is part of the American Reinvestment and Recovery Act (ARRA) of 2009. As noted in the HITECH Act, CMS is responsible for defining ''meaningful use'' of certified electronic health record (EHR) technology and developing incentive payment programs for Medicare and Medicaid providers. CMS is continually implementing and updating information systems as legislation and requirements change. To support this initiative, CCSQ IT Product and Support Teams (CIPST) must have the capacity for engagement with users in an ongoing variety of research, discovery, and validation activities to create and refine systems that do not place an undue burden on users and instead are efficient, usable, and desirable.

The Center for Clinical Standards and Quality (CCSQ) is responsible for administering appropriate information systems so that the public can submit healthcare-related information. While beneficiaries ultimately benefit, the primary users of (CIPST) are healthcare facility employees and contractors. They are responsible for the collection and submission of appropriate beneficiary data to CMS to receive merit-based compensation.

The generic clearance will allow a rapid response to inform CMS initiatives using a mixture of qualitative and quantitative consumer research strategies (including formative research studies and methodological tests) to improve information systems that serve CMS audiences. CMS implements human-centered methods and activities for the improvement of policies, services, and products. As information systems and technologies are developed or improved upon, they can be tested and evaluated for end-user feedback regarding utility, usability, and desirability. The overall goal is to apply a human-centered engagement model to maximize the extent to which CMS CIPST product teams can gather ongoing feedback from consumers. Feedback helps engineers and designers arrive at better solutions, therefore minimizing the burden on consumers and meeting their needs and goals.

The activities under this clearance involve voluntary engagement with target CIPST users to receive design and research feedback. Voluntary end-users from samples of self-selected customers, as well as convenience samples, with respondents selected either to cover a broad range of customers or to include specific characteristics related to certain products or services. All collection of information under this clearance is for use in both quantitative and qualitative groups collecting data related to human-computer interactions with information system development. We will use the findings to create the highest possible public benefit. *Form Number:* CMS–10706 (OMB control number: 0938–NEW); *Frequency:* Occasionally; *Affected Public:* Individuals and Private Sector (Business or other for-profit and Not-for-profit institutions); *Number of Respondents:* 11,476; *Total Annual Responses:* 11,476; *Total Annual Hours:* 4,957. (For policy questions regarding this collection contact Stephanie Ray at 410–786–0971).

3. *Type of Information Collection Request:* New information collection; *Title of Information Collection:* Pharmacy Benefit Manager Transparency; *Use:* The Patient Protection and Affordable Care Act (Pub. L. 111–148) and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (collectively, the Patient Protection and Affordable Care Act (PPACA)) were signed into law in 2010. The PPACA established competitive private health insurance markets, called Marketplaces or Exchanges, which give millions of Americans and small businesses access to qualified health plans (QHPs), including stand-alone dental plans

(SADPs)—private health and dental insurance plans that are certified as meeting certain standards. The PPACA added section 1150A of the Social Security Act, which requires pharmacy benefit managers (PBMs) to report prescription benefit information to the Department of Health and Human Services (HHS). PBMs are third-party administrators of prescription programs for a variety of types of health plans, including QHPs. The Centers for Medicare and Medicaid Services (CMS) files this information collection request (ICR) in connection with the prescription benefit information that PBMs must provide to HHS under section 1150A. The burden estimate for this ICR reflects the time and effort for PBMs to submit the information regarding PBMs and prescription drugs. *Form Number:* CMS–10725 (OMB control number: 0938–NEW); *Frequency:* Annually; *Affected Public:* Private Sector (business or other for-profits), *Number of Respondents:* 40; *Number of Responses:* 275. *Total Annual Hours:* 1,400. For questions regarding this collection contact Ken Buerger at 410–786–1190.

4. *Type of Information Collection Request:* New Collection; *Title of Information Collection:* Value in Opioid Use Disorder Treatment Demonstration; *Use:* Value in Opioid Use Disorder Treatment (Value in Treatment) is a 4-year demonstration program authorized under section 1866F of the Social Security Act (Act), which was added by section 6042 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act). The purpose of Value in Treatment, as stated in the statute, is to ''increase access of applicable beneficiaries to opioid use disorder treatment services, improve physical and mental health outcomes for such beneficiaries, and to the extent possible, reduce Medicare program expenditures.'' As required by statute, Value in Treatment will be implemented no later than January 1, 2021.

Section 1866F(c)(1)(A)(ii) specifies that individuals and entities must apply for and be selected to participate in the Value in Treatment demonstration pursuant to an application and selection process established by the Secretary. Section 1866F(c)(2)(B)(iii) specifies that in order to receive CMF and performance-based incentive payments under the Value in Treatment program, each participant shall report data necessary to: Monitor and evaluate the Value in Treatment program; determine if criteria are met; and determine the performance-based incentive payment. *Form Number:* CMS–10728 (OMB control number: 0938-New); *Frequency:* Yearly; *Affected Public:* Individuals and Households; *Number of Respondents:* 12,096; *Total Annual Responses:* 12,096; *Total Annual Hours:* 1,285. (For policy questions regarding this collection contact Rebecca VanAmburg at 410–786–0524.)

Dated: September 8, 2020.

**William N. Parham, III,**

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

[FR Doc. 2020–20089 Filed 9–10–20; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2019–E–3015]**

### Determination of Regulatory Review Period for Purposes of Patent Extension; EVERSENSE CONTINUOUS GLUCOSE MONITORING SYSTEM

**AGENCY:** Food and Drug Administration, Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for EVERSENSE CONTINUOUS GLUCOSE MONITORING SYSTEM (EVERSENSE CGM SYSTEM) and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that medical device.

**DATES:** Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by November 10, 2020. 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 March 10, 2021. 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. Electronic comments must be submitted on or before November 10, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 10, 2020. 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–2019–E–3015 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; EVERSENSE CGM SYSTEM.'' 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*