

Washington, DC 20551-0001, not later than October 20, 2021.

A. Federal Reserve Bank of Dallas  
(Karen Smith, Director, Applications)  
2200 North Pearl Street, Dallas, Texas  
75201-2272:

1. Rita Hancock, individually, and as trustee of the John W. Hancock, Jr. SB Trust, both of El Campo, Texas; to acquire voting shares of Louise Bancshares, Inc., and thereby indirectly acquire voting shares of The First State Bank, both of Louise, Texas and Dilley State Bank, Dilley, Texas.

Board of Governors of the Federal Reserve System, September 30, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021-21637 Filed 10-4-21; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10417, CMS-10768 and CMS-R-43]

#### 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 *November 4, 2021*.

**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](http://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>.

**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. *Title of Information Collection:* Medicare Fee-for-Service Prepayment Review of Medical Records; *Type of Information Collection Request:* Revision; *Use:* The Medical Review program is designed to prevent improper payments in the Medicare FFS program. Whenever possible, Medicare Administrative Contractors (MACs) are encouraged to automate this process; however, it may require the evaluation of medical records and related documents to determine whether Medicare claims are billed in compliance with coverage, coding, payment, and billing policies. Addressing improper payments in the

Medicare fee-for-service (FFS) program and promoting compliance with Medicare coverage and coding rules is a top priority for the CMS. Preventing Medicare improper payments requires the active involvement of every component of CMS and effective coordination with its partners including various Medicare contractors and providers. The information required under this collection is requested by Medicare contractors to determine proper payment, or if there is a suspicion of fraud. Medicare contractors request the information from providers/suppliers submitting claims for payment when data analysis indicates aberrant billing patterns or other information which may present a vulnerability to the Medicare program. *Form Number:* CMS-10417 (OMB control number: 0938-0969); *Frequency:* Occasionally; *Affected Public:* Private Sector, State, Business, and Not-for Profits; *Number of Respondents:* 485,632; *Number of Responses:* 485,632; *Total Annual Hours:* 242,816. (For questions regarding this collection, contact Christine Grose at (410-786-1362).)

2. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* The ESRD Network Peer Mentoring Program; *Use:* The End Stage Renal Disease (ESRD) Network Peer Mentoring Program is a voluntary program designed to provide patient peer support to people with kidney disease. In part, the peer support is beneficial because patients can give each other something most practitioners do not have: Lived experience with kidney disease. The support and perspective of someone who has "been there" can help people better cope with their circumstances.

The ESRD Network Peer Mentoring Program is a partnership between dialysis facilities, ESRD Networks, and patient peer mentors and mentees that wish to engage in the program. The peer mentoring program is organized and published with educational opportunities for peer mentors and mentees, provides resources, and includes a complementary toolkit for ESRD Networks and dialysis facilities to promote and operationalize the program.

Program applicants are people with ESRD who: (1) Are adults over the age of 18; have been receiving in-center or home dialysis or have been transplanted for at least six months; actively engage in the care plan; consistently demonstrate leadership qualities at facility Quality Assurance & Performance Improvement (QAPI) meetings, Lobby Days, and other facility

activities; and wish to be a peer mentor; or (2) are over 18 years of age; are newly diagnosed patients but have been on in-center dialysis for at least six months; are looking for peer support to help them transition to their new reality; and are known as a peer mentee.

To participate in the ESRD Network Peer Mentoring Program, peer mentors and mentees will complete an online application form stored in Confluence. The application serves to validate the peer mentor or peer mentee interest in the ESRD Network Peer Mentoring Program. Information collection is important to the process of pairing peer mentors and mentees with similarly lived experience and interests with their kidney disease. In addition, the application collects information about the peers' interest in kidney disease, treatment modality, age range, preferred gender recognition, and attitudes toward their kidney disease diagnosis. It also supports aligning hobbies, and genders to support best matched peers with each other. *Form Number:* CMS-10768 (OMB control number: 0938-NEW); *Frequency:* Once; *Affected Public:* Individuals and Households; *Number of Respondents:* 75; *Total Annual Responses:* 75; *Total Annual Hours:* 19. (For policy questions regarding this collection, contact Lisa Rees at 816-426-6353.)

**3. Type of Information Collection Request:** Revision of a previously approved collection; *Title of Information Collection:* Conditions of Coverage for Portable X-ray Suppliers and Supporting Regulations; *Use:* The requirements contained in this information collection request are classified as conditions of participation or conditions for coverage. Portable X-rays are basic radiology studies (predominately chest and extremity X-rays) performed on patients in skilled nursing facilities, residents of long-term care facilities and homebound patients. The CoPs are based on criteria described in the law, and are designed to ensure that each portable X-ray supplier has properly trained staff and provides the appropriate type and level of care for patients. The information collection requirements described below are necessary to certify portable X-ray suppliers wishing to participate in the Medicare program. There are currently 506 portable X-ray suppliers participating in the Medicare program.

On September 30, 2019 (84 FR 51732), CMS updated the personnel requirements for portable X-ray technicians at 42 CFR 486.104(a), to focus on the qualifications of the individual performing services removing school accreditation

requirements and simplifying the structure of the requirements. Additionally, CMS also revised the requirements for referral of service at 42 CFR 486.106(a) for portable X-ray requirements for orders. This change removed the requirement that physician or non-physician practitioner's orders for portable X-ray services must be written and signed and replacing the specific requirements related to the content of each portable X-ray order with a cross-reference to the requirements at 42 CFR 410.32, which also apply to portable X-ray services. *Form Number:* CMS-R-43 (OMB Control number: 0938-0338); *Frequency:* Yearly; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 506; *Total Annual Responses:* 1,012; *Total Annual Hours:* 324. (For policy questions regarding this collection contact James Cowher at 410-786-1948.)

Dated: September 29, 2021.

**William N. Parham, III,**  
*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2021-21580 Filed 10-4-21; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2021-N-0031]

#### Best Practices for Development and Application of Disease Progression Models; Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

**SUMMARY:** The Food and Drug Administration (FDA) Center for Drug Evaluation and Research, and Center for Biologics Evaluation and Research, are announcing a public workshop entitled "Best Practices for Development and Application of Disease Progression Models." The purpose of this public workshop is to discuss the best practices for developing disease progression models and their application to support drug development decisions, share experiences and case studies that highlight the opportunities and limitations in the development and application of disease progression models including models for natural history of disease and clinical trial simulations, and discuss the knowledge gaps and research needed to advance

the development and use of disease progression models.

**DATES:** The public workshop will be held on November 19, 2021, from 9:30 a.m. to 2:30 p.m., Eastern Time. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

**ADDRESSES:** This workshop will be virtual only.

**FOR FURTHER INFORMATION CONTACT:** Maryanne Dingman, Office of Clinical Pharmacology, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-8777; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 240-402-7911.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Under the FDA Reauthorization Act of 2017 (Pub. L. 115-52), FDA agreed, in accordance with section I of the Prescription Drug User Fee Act (PDUFA) VI Performance Goals, "Ensuring the Effectiveness of the Human Drug Review, part J, Enhancing Regulatory Decision Tools to Support Drug Development and Review," to hold several workshops to identify best practices for model-informed drug development. This workshop, "Best Practices for Development and Application of Disease Progression Models," fulfills FDA's performance commitment under PDUFA VI.

##### II. Topics for Discussion at the Public Workshop

The following topics will be discussed at the public workshop:

- Role of disease models in drug development and regulatory review;
- Lessons learned from past experiences of applying disease models in drug development;
- Best practice considerations for disease modeling to support drug development and regulatory decisions; and
- Best practice considerations for clinical trial simulations based on disease progression/natural history models to support drug development and regulatory decisions.

##### III. Participating in the Public Workshop

*Registration:* Persons interested in attending this public workshop must register by November 9, 2021, at <https://go.usa.gov/xMxPZ>.

If you need special accommodations due to a disability, please contact