1. *Community First Bancshares, MHC, Covington, Georgia;* to convert from mutual to stock form. As part of the conversion, Community First Bancshares, MHC, and Community First Bancshares, Inc., Covington, Georgia, an existing mid-tier savings and loan holding company, will cease to exist and Newton Federal Bank, Covington, Georgia, will become a wholly-owned subsidiary of Affinity Bancshares Inc., Covington, Georgia, a newly-formed Maryland corporation, which has applied to become a savings and loan holding company by acquiring Newton Federal Bank.

B. 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. *The Seneca Falls Savings Bank, MHC, Seneca Falls, New York;* to convert from mutual to stock form. As part of the conversion, The Seneca Falls Savings Bank, MHC and Seneca-Cayuga Bancorp, Inc., Seneca Falls, New York, an existing mid-tier savings and loan holding company, will cease to exist and Generations Bank, Seneca Falls, New York, will become a wholly-owned subsidiary of Generations Bancorp NY, Inc., Seneca Falls, New York, a newly formed Maryland corporation, which has applied to become a savings and loan holding company by acquiring Generations Bank.

Board of Governors of the Federal Reserve System, September 15, 2020.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2020–20662 Filed 9–17–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers CMS–10443, CMS–10265, CMS–10171, and CMS–10291]

Agency Information Collection Activities: Proposed Collection; 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 (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 November 17, 2020.

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

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

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–10443 Transcatheter Valve Therapy (TVT) Registry

CMS–10265 Mandatory Insurer Reporting Requirements of Section 111 of the Medicare, Medicaid and SCHIP Act of 2007

CMS–10171 Part D Coordination of Benefits Data

CMS–10291 State Collection and Reporting of Dental Provider and Benefit Package Information on the Insure Kids Now! Website and Hotline

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. *Type of Information Collection Request:* Extension of a previously approved collection: *Title of Information Collection:* Transcatheter Valve Therapy (TVT) Registry; *Use:* The data collection is required by the Centers for Medicare and Medicaid Services (CMS) National Coverage Determination (NCD) entitled, ''Transcatheter Aortic Valve Replacement (TAVR)''. The TAVR device is only covered when specific conditions are met including that the heart team and hospital are submitting data in a prospective, national, audited registry. The data includes patient, practitioner and facility level variables that predict outcomes such as all cause mortality and quality of life. CMS finds that the Society of Thoracic Surgery/American College of Cardiology Transcatheter Valve Therapy (STS/ACC TVT) Registry, one registry overseen by the National Cardiovascular Data Registry, meets the requirements specified in the NCD on TAVR. The TVT Registry will support a national

surveillance system to monitor the safety and efficacy of the TAVR technologies for the treatment of aortic stenosis.

The data will also include the variables on the eight item Kansas City Cardiomyopathy Questionnaire (KCCQ–10) to assess heath status, functioning and quality of life. In the KCCQ, an overall summary score can be derived from the physical function, symptoms (frequency and severity), social function and quality of life domains. For each domain, the validity, reproducibility, responsiveness and interpretability have been independently established. Scores are transformed to a range of 0–100, in which higher scores reflect better health status.

The conduct of the STS/ACC TVT Registry and the KCCQ–10 is in accordance with Section 1142 of the Social Security Act (the Act) that describes the authority of the Agency for Healthcare Research and Quality (AHRQ). Under section 1142, research may be conducted and supported on the outcomes, effectiveness, and appropriateness of health care services and procedures to identify the manner in which disease, disorders, and other health conditions can be prevented, diagnosed, treated, and managed clinically. Section 1862(a)(1)(E) of the Act allows Medicare to cover under coverage with evidence development (CED) certain items or services for which the evidence is not adequate to support coverage under section 1862(a)(1)(A) and where additional data gathered in the context of a clinical setting would further clarify the impact of these items and services on the health of beneficiaries.

The data collected and analyzed in the TVT Registry will be used by CMS to determine if the TAVR is reasonable and necessary (*e.g.,* improves health outcomes) for Medicare beneficiaries under Section 1862(a)(1)(A) of the Act. Furthermore, data from the Registry will assist the medical device industry and the Food and Drug Administration (FDA) in surveillance of the quality, safety and efficacy of new medical devices to treat aortic stenosis. For purposes of the TAVR NCD, The TVT Registry has contracted with the Data Analytic Centers to conduct the analyses. In addition, data will be made available for research purposes under the terms of a data use agreement that only provides de-identified datasets. *Form Number:* CMS–10443 (OMB control number: 0938–1202); *Frequency:* Annual; *Affected Public:* Individuals, Households and Private Sector; *Number of Respondents:* 37,221; *Total Annual Responses:* 148,884; *Total Annual Hours:* 47,765. (For policy questions regarding this collection contact Sarah Fulton at 410–786–2749.)

2. *Type of Information Collection Request:* Revision with change of a currently approved collection; *Title of Information Collection:* Mandatory Insurer Reporting Requirements of Section 111 of the Medicare, Medicaid and SCHIP Act of 2007; *Use:* The Centers for Medicare & Medicaid Services (CMS) collects various data elements from the applicable reporting entities (see supporting documents) for purposes of carrying out the mandatory MSP reporting requirements of Section 111of the Medicare, Medicaid and SCHIP Extension Act. This information is used to ensure that Medicare makes payment in the proper order and/or takes necessary recovery actions. 42 U.S.C. 1395y(b)(7)(A)(i)(II) was updated by the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act. Section 4002 of the SUPPORT Act also applies to Section 111 that requires Group Health Plan (GHP) reporting of primary prescription drug coverage.

MSP is generally divided into ''pre-payment'' and ''post-payment'' activities. Pre-payment activities are generally designed to stop mistaken primary payments in situations where Medicare should be secondary. Medicare post-payment activities are designed to recover mistaken payments or conditional payments made by Medicare where there is a contested liability insurance (including self-insurance), no-fault insurance, or workers' compensation which has resulted in a settlement, judgment, award, or other payment. CMS specialty contractors perform most of the MSP activity.

Pre-payment

The information is collected from applicable reporting entities for the purpose of coordination of benefits and the recovery of mistaken and conditional payments. Section 111 mandates the reporting of information in the form and manner specified by the Secretary, DHHS. Data the Secretary collects is necessary for both pre-payment and post-payment coordination of benefit purposes, including necessary recovery actions.

Both GHP and NGHP entities have had and continue to have the responsibility for determining when they are primary to Medicare and to pay appropriately, even without the mandatory Section 111 process, Insurers should always collect the NGHP, GHP and GHP prescription drug information that CMS requires in connection with Section 111 of the MMSEA. *Form Number:* CMS–10265 (OMB control number: 0938–1074); *Frequency:* Yearly; *Affected Public:* Private Sector, Business or other for-profits; *Number of Respondents:* 21,141; *Total Annual Responses:* 8,079,697; *Total Annual Hours:* 618,060. (For policy questions regarding this collection contact Richard Mazur at 410–786–1418.)

3. *Type of Information Collection Request:* Revision with change of a currently approved collection; *Title of Information Collection:* Part D Coordination of Benefits Data; *Use:* Sections 1860D–23 and 1860D–24 of the Act require the Secretary to establish requirements for prescription drug plans to promote effective coordination between Part D plans and SPAPs and other payers. These Part D Coordination of Benefits (COB) requirements have been codified into the Code of Federal Regulations at 42 CFR 423.464. In particular, CMS' requirements relate to the following elements: (1) Enrollment file sharing; (2) claims processing and payment; (3) claims reconciliation reports; (4) application of the protections against high out-of-pocket expenditures by tracking TrOOP expenditures; and (5) other processes that the Secretary determines.

This information collection assists CMS, pharmacists, Part D plans, and other payers coordinate prescription drug benefits at the point-of-sale and track beneficiary True out-of-pocket (TrOOP) expenditures using the Part D Transaction Facilitator (PDTF).

The collected information will be used by Part D plans, other health insurers or payers, pharmacies and CMS to coordinate prescription drug benefits provided to the Medicare beneficiary. Part D plans share data with each other and with CMS. The types of data collected for sharing include enrollment data, other health insurance information, TrOOP and Gross drug spending and supplemental payer data. *Form Number:* CMS–10171 (OMB control number: 0938–0978); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 63,910; *Total Annual Responses:* 770,855,926; *Total Annual Hours:* 938,065. (For policy questions regarding this collection contact Chad Buskirk at 410–786–1630.)

4. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* State Collection and Reporting of Dental Provider and Benefit Package Information on the Insure Kids Now! Website and Hotline; *Use:* On the Insure Kids Now (IKN)

website, the Secretary is required to post a current and accurate list of dentists and providers that provide dental services to children enrolled in the state plan (or waiver) under Medicaid or the state child health plan (or waiver) under CHIP. States collect the information pertaining to their Medicaid and CHIP dental benefits. *Form Number:* CMS–10291 (OMB control number: 0938–1065); *Frequency:* Yearly and quarterly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 51; *Total Annual Responses:* 255; *Total Annual Hours:* 11,781. (For policy questions regarding this collection contact Andrew Snyder at 410–786–1274.)

Dated: September 14, 2020.

William N. Parham, III,

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

[FR Doc. 2020–20561 Filed 9–17–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–4763]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Assessment of Terms and Phrases Commonly Used in Prescription Drug Promotion

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by October 19, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The title of this information collection is ''Assessment of Terms and Phrases Commonly Used in Prescription Drug Promotion.'' Also, include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

For copies of the questionnaire, contact: Office of Prescription Drug Promotion (OPDP) Research Team, *DTCresearch@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Assessment of Terms and Phrases Commonly Used in Prescription Drug Promotion

OMB Control Number 0910-New

I. Background

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(d)(2)(C)) authorizes FDA to conduct research relating to drugs and other FDA regulated products in carrying out the provisions of the FD&C Act.

The Office of Prescription Drug Promotion's (OPDP) mission is to protect the public health, in part, by helping to ensure that prescription drug promotional material is truthful, balanced, and accurately communicated, so that patients and health care providers can make informed decisions about treatment options. OPDP's research program provides scientific evidence to help ensure that our policies related to prescription drug promotion will have the greatest benefit to public health. Toward that end, we have consistently conducted research to evaluate the aspects of prescription drug promotion that are most central to our mission. Our research focuses in particular on three main topic areas: Advertising features, including content and format; target populations; and research quality. Through the evaluation of advertising features, we assess how elements such as graphics, format, and disease and product characteristics impact the communication and understanding of prescription drug risks and benefits. Focusing on target populations allows us to evaluate how understanding of prescription drug risks and benefits may vary as a function of audience, and our focus on research quality aims at maximizing the quality of our research data through analytical methodology development and investigation of sampling and response issues. This study will inform all three topic areas.

Because we recognize that the strength of data and the confidence in the robust nature of the findings is improved by utilizing the results of multiple converging studies, we continue to develop evidence to inform our thinking. We evaluate the results from our studies within the broader context of research and findings from other sources, and this larger body of knowledge collectively informs our policies as well as our research program. Our research is documented on our homepage, which can be found at: *https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm090276.htm.* The website includes links to the latest **Federal Register** notices and peer-reviewed publications produced by our office. The website maintains information on studies we have conducted, dating back to a survey on direct-to-consumer advertisements conducted in 1999.

The present research involves assessment of how consumers and primary care physicians (PCPs) interpret terms and phrases commonly used in prescription drug promotion, as well as those used to describe prescription drugs and prescription drug promotion more generally. This includes both what these terms and phrases mean to each population (*e.g.,* definitions) and what these terms and phrases imply (*e.g.,* about efficacy and safety). Some examples of interest include: ''natural'' or ''naturally-occurring,'' and ''targeted'' or ''targeted therapy.'' The full list for assessment will include approximately 30 terms and phrases for each population. To accommodate such a large number, presented terms and phrases will be accompanied by only limited context (terms within sentences and phrases within paragraphs, as opposed to full promotional materials). Understanding the most prevalent interpretations of these terms and phrases can help OPDP determine the impact of specific language in prescription drug promotion. For example, certain terms and phrases, when used without additional contextual information, might overstate the efficacy or minimize the risk of a product. Additionally, from a health literacy perspective, it is helpful to ascertain general understanding of such terms and phrases as this may aid in the development of best practices around communicating these concepts.