

identification and to submit to security screening in order to inspect and photocopy comments.

Additionally, commenters may send a copy of their comments to the Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395-6974.

**FOR FURTHER INFORMATION CONTACT:** Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, [nuha.elmaghrabi@frb.gov](mailto:nuha.elmaghrabi@frb.gov), (202) 452-3884.

**SUPPLEMENTARY INFORMATION:** On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. In exercising this delegated authority, the Board is directed to take every reasonable step to solicit comment. In determining whether to approve a collection of information, the Board will consider all comments received from the public and other agencies.

During the comment period for this proposal, a copy of the proposed PRA OMB submission, including the draft reporting form and instructions, supporting statement (which contains more detail about the information collection and burden estimates than this notice), and other documentation, will be made available on the Board's public website at <https://www.federalreserve.gov/apps/reportingforms/home/review> or may be requested from the agency clearance officer, whose name appears above. Final versions of these documents will be made available at <https://www.reginfo.gov/public/do/PRAMain>, if approved.

#### **Request for Comment on Information Collection Proposal**

The Board invites public comment on the following information collection, which is being reviewed under authority delegated by the OMB under the PRA. Comments are invited on the following:

a. Whether the proposed collection of information is necessary for the proper performance of the Board's functions, including whether the information has practical utility;

b. The accuracy of the Board's estimate of the burden of the proposed

information collection, including the validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected;

d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

e. Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the Board should modify the proposal.

#### **Proposal Under OMB Delegated Authority To Extend for Three Years, With Revision, the Following Information Collection**

*Collection title:* Joint Statement for Assessing the Diversity Policies and Practices of Entities Regulated by the Agencies.

*Collection identifier:* FR 2100.

*OMB control number:* 7100-0368.

*General description of collection:* The Joint Statement for Assessing the Diversity Policies and Practices of Entities Regulated by the Agencies was published jointly in 2015 by the Board, Office of the Comptroller of the Currency, Federal Deposit Insurance Corporation, National Credit Union Administration, Consumer Financial Protection Bureau, and Securities and Exchange Commission. Standards in the statement encourage a regulated entity, in a manner reflective of its size and other characteristics, to voluntarily conduct a self-assessment of its diversity policies and practices and to report information pertaining to its self-assessment to the Office of Minority and Women Inclusion of its primary federal financial regulator, as well as to publish information pertaining to its efforts with respect to the standards. The Board has developed a voluntary reporting template entitled "Diversity Self-Assessment Template" for use by institutions regulated by the Board to facilitate the provision of self-assessment information.

*Proposed revisions:* The Board proposes to revise the FR 2100 by adding a field to the reporting template that identifies institutions and reformatting the reporting template's table identifying workforce numbers. The Board proposes to make these revisions effective August 2023.

*Frequency:* Annually.

*Respondents:* All financial institutions for which the Federal Reserve is the primary federal financial regulator.

*Total estimated number of respondents:* 156.

*Total estimated change in burden hours:* The estimated annual burden would remain unchanged.

*Total estimated annual burden hours:* 1,248.<sup>1</sup>

Board of Governors of the Federal Reserve System, March 24, 2023.

**Michele Taylor Fennell,**

*Deputy Associate Secretary of the Board.*

[FR Doc. 2023-06554 Filed 3-29-23; 8:45 am]

**BILLING CODE 6210-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Centers for Medicare & Medicaid Services**

[Document Identifiers: CMS-10275 and CMS-10062]

#### **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.

<sup>1</sup> More detailed information regarding this collection, including more detailed burden estimates, can be found in the OMB Supporting Statement posted at <https://www.federalreserve.gov/apps/reportingforms/home/review>.

**DATES:** Comments on the collection(s) of information must be received by the OMB desk officer by May 1, 2023.

**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, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

**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 collection; *Title of Information Collection:* The Home Health Care CAHPS® Survey (HHCAPHS); *Use:* The national implementation of the Home Health Care CAHPS Survey is designed to collect ongoing data from samples of home health care patients who receive skilled services from Medicare-certified home health agencies. The survey is necessary because it fulfills the goal of transparency with the public about home health patient experiences.

The survey is used by Medicare-certified home health agencies to

improve their internal quality assurance in the care that they provide in home health. The HHCAPHS survey is also used in a Medicare payment program. Medicare-certified home health agencies (HHAs) must contract with CMS-approved survey vendors that conduct the HHCAPHS on behalf of the HHAs to meet their requirements in the Home Health Quality Reporting Program *Form Number:* CMS–10275 (OMB control number: 0938–1066); *Frequency:* Quarterly; *Affected Public:* Individuals and Households; *Number of Respondents:* 1,052,966; *Total Annual Responses:* 1,149,975; *Total Annual Hours:* 420,576. (For policy questions regarding this collection contact Lori Luria at 410–786–6684).

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Collection of Diagnostic Data in the Abbreviated RAPS Format from Medicare Advantage Organizations for Risk Adjusted Payments; *Use:* Under section 1894(d) of the Act, CMS must make prospective monthly capitated payments to PACE organizations in the same manner and from the same sources as payments to organizations under section 1853. Section 1894(e)(3)(A)(i) requires in part that PACE organizations collect data and make available to the Secretary reports necessary to monitor the cost, operation, and effectiveness of the PACE program.

CMS makes advance monthly per-enrollee payments to organizations, and is required to risk-adjust the payments based on predicted relative health care costs for each enrollee, as determined by enrollee-specific diagnoses and other factors, such as age. CMS has collected diagnosis data from organizations in two formats: (1) comprehensive data equivalent to Medicare fee-for-service claims data (often referred to as encounter data) and (2) data in an abbreviated format known as RAPS data, named for the Risk Adjustment Processing System (RAPS). The subject of this PRA package is collection of RAPS data. Encounter data collection is addressed in a separate PRA package (OMB 0938–1152).

Risk adjustment allows CMS to pay plans for the health risk of the beneficiaries they enroll, instead of paying an identical an average amount for each enrollee Medicare beneficiaries. By risk adjusting plan payments, CMS is able to make appropriate and accurate payments for enrollees with differences in expected costs. Risk adjustment is used to adjust bidding and payment based on the health status and demographic characteristics of an

enrollee. Risk scores measure individual beneficiaries’ relative risk and the risk scores are used to adjust payments for each beneficiary’s expected expenditures. By risk adjusting plan bids, CMS is able to also use standardized bids as base payments to plans. *Form Number:* CMS–10062 (OMB control number: 0938–0878); *Frequency:* Quarterly; *Affected Public:* Private Sector, Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 284; *Total Annual Responses:* 80,235,720; *Total Annual Hours:* 2,674,524. (For policy questions regarding this collection contact Amanda Johnson at 410–786–4161.

Dated: March 24, 2023.

**William N. Parham, III,**

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

[FR Doc. 2023–06564 Filed 3–29–23; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2023–D–1030]

#### Cybersecurity in Medical Devices: Refuse To Accept Policy for Cyber Devices and Related Systems Under Section 524B of the FD&C Act; Guidance for Industry and Food and Drug Administration Staff; Availability

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

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance entitled “Cybersecurity in Medical Devices: Refuse to Accept Policy for Cyber Devices and Related Systems Under section 524B of the FD&C Act of the FD&C Act.” FDA generally intends not to issue “refuse to accept” (RTA) decisions for premarket submissions submitted for cyber devices based solely on information required by the new amendments to the FD&C Act for ensuring cybersecurity of devices before October 1, 2023, but instead, work collaboratively with sponsors of such premarket submissions as part of the interactive and/or deficiency review process.

**DATES:** The announcement of the guidance is published in the **Federal Register** on March 30, 2023.

**ADDRESSES:** You may submit either electronic or written comments on