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, 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 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–10387—Minimum Data Set 3.0 Nursing Home and Swing Bed Prospective Payment System (PPS) For the collection of data related to the Patient Driven Payment Model and the Skilled Nursing Facility Quality Reporting Program (QRP)

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:* Revision of a currently approved collection; *Title of Information Collection:* Minimum Data Set 3.0 Nursing Home and Swing Bed Prospective Payment System (PPS) For the collection of data related to the Patient Driven Payment Model and the Skilled Nursing Facility Quality Reporting Program (QRP); *Use:* We are requesting to implement the MDS 3.0 v1.19.1 beginning October 1, 2024 in order to meet the requirements of policies finalized in the Federal Fiscal Year (FY) 2024 Skilled Nursing Facility (SNF) Prospective Payment System (PPS) final rule (CMS–1779–F, RIN 0938–AV02). Specifically, CMS adopted two new measures and removed three measures from the SNF QRP. As a result of these changes, the total annual hour burden across facilities has decreased, and the annual cost burden across facilities has decreased. *Form Number:* CMS–10387 (OMB control number: 0938–1140); *Frequency:* Yearly; *Affected Public:* Private Sector: Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 15,471; *Total Annual Responses:* 3,469,183; *Total Annual Hours:* 2,861,351. (For policy questions regarding this collection contact Heidi Magladry at 410–786–6034).

Dated: December 4, 2023.

William N. Parham, III,

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

[FR Doc. 2023–26927 Filed 12–7–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10219 and CMS–10593]

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 (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 February 6, 2024.

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, 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 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–10219 HEDIS Data Collection for Medicare Advantage

CMS–10593 Establishment of an Exchange by a State and Qualified Health Plans

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:* Revision of a currently approved collection; *Title of Information Collection:* HEDIS Data Collection for Medicare Advantage; *Use:* Sections 422.152 and 422.516 of Volume 42 of the Code of Federal Regulations (CFR) specify that MAOs must submit quality performance measures as specified by the Secretary of the Department of Health and Human Services and by CMS. These quality performance measures include HEDIS®. HEDIS® data are used in the Medicare Part C Star Ratings which are used to determine Quality Bonus Payments to Medicare Advantage contracts.

CMS requires MAOs, § 1876 cost contracts, and Medicare Medicaid Plans (MMPs or demonstrations) to submit HEDIS® data on an annual basis to (1) assess care that is provided to Medicare beneficiaries and (2) to provide information to Medicare beneficiaries to make more informed decisions when choosing a health plan.

The HEDIS® data collection supports the CMS strategic goals of advancing health equity and improving health outcomes for Medicare beneficiaries. The HEDIS® measures are part of the Medicare Part C Star Ratings as described at §§ 422.160, 422.162, 422.164, and 422.166. CMS publishes the Medicare Part C Star Ratings each year to: (1) incentivize quality improvement in Medicare Advantage (MA); and (2) assist beneficiaries in finding the best plan for them. The Star Ratings are used to determine MA Quality Bonus Payments. *Form Number:* CMS–10219 (OMB control number: 0938–1028); *Frequency:* Yearly; *Affected Public:* Private Sector, Business or other for-profits and Not-for-profits institutions ; *Number of Respondents:* 808; *Total Annual Responses:* 808; *Total Annual Hours:* 258,560. (For policy questions regarding this collection contact Lori Luria at *Lori.Luria@cms.hhs.gov*).

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Establishment of an Exchange by a State and Qualified Health Plans; *Use:* Section 1311(d) of the Affordable Care Act requires an Exchange to be a governmental agency or nonprofit entity established by a State; requires an Exchange make Qualified Health Plans (QHPs) available to eligible individuals and employers; and identifies the minimum functions an Exchange must perform. CMS and other federal partners will use the data collected from states operating SBEs to determine Exchange compliance with federal standards for operating the Exchange. The data that health insurance issuers, Exchanges, and other entities that Exchanges contract within performing Exchange functions collect will help to inform CMS, Exchanges, and health insurance issuers on the participation of individuals, employers, and employees in the individual Exchange and SHOP. *Form Number:* CMS–10593 (OMB control number: 0938–1312); *Frequency:* Annually; *Affected Public:* Private Sector, Business or other for-profits and Not-for-profits institutions; *Number of Respondents:* 20; *Total Annual Responses:* 20; *Total Annual Hours:* 55,026. (For policy questions regarding this collection contact Tiffany Y. Animashaun at *Tiffany.Animashaun@cms.hhs.gov*).

Dated: December 5, 2023.

William N. Parham, III,

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

[FR Doc. 2023–27035 Filed 12–7–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2022–E–2194, FDA–2022–E–2195, and FDA–2022–E–2196]

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

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 Tivdak 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 patents which claim that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect must submit either electronic or written comments and ask for a redetermination by February 6, 2024. 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 June 5, 2024. 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. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 6, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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'').