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:* New collection (Request for a new OMB control number); *Title of Information Collection:* Environmental Health Hazards Checklist Medicare Coverage for Individuals Exposed to Environmental Health Hazards; *Use:* Section 1881A of the Act provides an enrollment basis for individuals who have been exposed to environmental health hazards. Currently, the only individuals eligible for Medicare under this provision are those who were present in Lincoln County, Montana, and have an asbestos-related disease (ARD) diagnosis. Eligible individuals must be diagnosed with one or more asbestos-related conditions and have been present in Lincoln County, Montana, for a total of at least 6 months (need not be consecutive) in the period ending 10 years or more before diagnosis of an asbestos-related condition. This form provides verification from a provider so that SSA can determine eligibility for Medicare enrollment.

SSA uses this information to determine whether an individual meets the requirements for Medicare enrollment on the basis of an Environmental Health Hazard. The form is faxed to the applicant's provider by SSA. The provider must complete and sign the form and submit it back to SSA via fax or mail. The information on the completed form is reviewed manually by SSA. Thus, the collection of this information does not involve the use of information technology. *Form Number:* CMS–10902 (OMB control number: 0938-New); *Frequency:* Once; *Affected Public:* Individuals and Households; *Number of Respondents:* 61; *Total Annual Responses:* 61; *Total Annual Hours:* 10. (For policy questions regarding this collection contact Tyrissa Woods at 410–786–0286 or *Tyrissa.Woods@cms.hhs.gov*).

William N. Parham III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–27359 Filed 11–21–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10796]

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 January 21, 2025.

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–10796 Dual Eligible Special Needs Plan Contract With the State Medicaid Agency

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 Collections

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Dual Eligible Special Needs Plan Contract with the State Medicaid Agency; *Use:* Special needs plans (SNPs) are Medicare Advantage (MA) plans created by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173) that are specifically designed to provide targeted care and limit enrollment to special needs individuals. Under section 1859(b)(6) of the Act, D–SNPs restrict enrollment to individuals entitled to medical assistance under a state plan

under title XIX of the Social Security Act (hereinafter referred to as the Act).

Section 1859(f)(3)(D) of the Act and 42 CFR 422.107 established the requirement for D–SNPs to have contracts with state Medicaid agencies in addition to other contracting requirements that that apply to all MA plans.

MA organizations with D–SNPs and states use the information in the contract to provide benefits, or arrange for the provision of Medicaid benefits, to which an enrollee is entitled. CMS reviews the D–SNP contract with the state Medicaid agency to ensure that it meets the minimum contract requirements at § 422.107(c) and (d). CMS uses the attestations and matrices in the appendices of this package to identify the types of D–SNPs an MA organization(s) offers and the location of the contract requirements in the document. *Form Number:* CMS–10796 (OMB control number: 0938–1410); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments, Federal Government and Private Sector; *Number of Respondents:* 886; *Total Annual Responses:* 893; *Total Annual Hours:* 17,403. (For policy questions regarding this collection contact Marla Rothouse at 410–786–8063 or *Marla.rothouse@cms.hhs.gov*).

William N. Parham III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–27358 Filed 11–21–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–0488]

Orthopedic Non-Spinal Bone Plates, Screws, and Washers—Premarket Notification (510(k)) Submissions; 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 or Agency) is announcing the availability of a final guidance entitled ''Orthopedic Non-Spinal Bone Plates, Screws, and Washers—Premarket Notification (510(k)) Submissions.'' This guidance document provides recommendations for information to include in 510(k) submissions for non-resorbable bone plate, screw, and washer devices. The scope of this guidance includes devices that are indicated for orthopedic bone fixation but does not include devices indicated for spinal, mandibular, maxillofacial, cranial, and orbital fracture fixation.

DATES: The announcement of the guidance is published in the **Federal Register** on November 22, 2024.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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–2023–D–0488 for ''Orthopedic Non-Spinal Bone Plates, Screws, and Washers—Premarket Notification (510(k)) Submissions; Guidance for Industry and Food and Drug Administration Staff.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Orthopedic Non-Spinal Bone Plates, Screws, and Washers—Premarket Notification (510(k)) Submissions; Guidance for