

2,304,450; *Number of Responses*: 2,304,450; *Total Annual Hours*: 282,366. (For policy questions regarding this collection, contact William G. Lehrman at 410-786-1037.)

Dated: August 18, 2023.

William N. Parham, III,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10809]

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 *September 22, 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. 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:* New collection (Request for a new OMB control number); *Title of Information Collection:* Ambulatory Surgical Center Covered Procedures List (ASC CPL); *Use:* The ASC CPL (Ambulatory Surgical Center Covered Procedures List) was authorized in accordance with section 1833(i)(1) of the Social Security Act, which requires the Secretary to specify surgical procedures which are appropriately performed on an inpatient basis in a hospital but which also can be performed safely on an ambulatory basis in an ASC, critical access hospital, or hospital outpatient department. The statute also requires the Secretary to regularly review and update the ASC CPL.

During rulemaking, CMS receives surgical procedure code nominations from a variety of external interested parties and evaluates them for inclusion to the CPL in the OPPTS/ASC proposed rule. After reviewing the nominations

and evaluating them against the criteria, CMS proposes the list of procedures that they will add to the CPL for the following calendar year. The public has 60 days to comment on the proposals, CMS takes these perspectives into account, and the final list of procedure nominations are finalized in the OPPTS/ASC final rule.

The information collected in this request will be used by CMS annually to determine what covered surgical procedures should be added to the ASC CPL. Specifically, the policy analysts and medical officers in the Division of Outpatient Care will individually review each procedure nomination, as well as any supporting evidence (clinical studies, literature, data or letters of support) submitted. The agency will use this information to propose a list of covered surgical procedures for the OPPTS/ASC Proposed Rule starting with the CY 2025 Proposed Rule. *Form Number:* CMS-10809 (OMB control number: 0938-New); *Frequency:* Yearly; *Affected Public:* Private Sector, Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 15; *Total Annual Responses:* 100; *Total Annual Hours:* 50. (For policy questions regarding this collection contact Nate Vercauteren at Nathan.Vercauteren@cms.hhs.gov.)

Dated: August 18, 2023.

William N. Parham, III,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-2462]

Workshop To Enhance Clinical Study Diversity; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a public workshop entitled "Workshop To Enhance Clinical Study Diversity." This public workshop will satisfy a mandate of the Food and Drug Omnibus Reform Act of 2022 (FDORA) for FDA to convene one