

utilized for a fresh transfer, the date of cryopreservation is not currently collected. In recent years, frozen-embryo transfers have become more prevalent as they may improve pregnancy success rates in certain groups of ART patients. For frozen-embryo transfers, the date at which fresh embryos were cryopreserved (with the date of oocyte retrieval) can be used to determine the stage of the embryo at the time of cryopreservation, which is an important predictor of ART success. Therefore, CDC proposes to add the date of fresh-embryo cryopreservation to the currently collected information as it will allow classification of embryo stage for frozen-embryo transfers and improve the reporting of factors that impact ART success rates. Addition: Date fresh embryos were cryopreserved—this date is to be reported for all frozen-embryo transfers.

Proposed Modifications to Data Validation Procedures

Pursuant to the previous FRN notice (86 FR 20496), CDC proposed to conduct targeted validation of ART clinics to better capture systematic reporting errors by assessing certain reporting characteristics that may predict erroneously inflated ART success rates. In addition, CDC proposed to remove a clinic's reported success rates from the annual ART reports if major data discrepancies were identified. Identifying major data discrepancies would require the review of a larger number of clinic records at select clinics, thereby increasing data collection burden for clinics. Given the additional burden, CDC will not pursue implementation of targeted validation of ART clinics and identification of major discrepancies during data validation. CDC will continue to calculate discrepancy rates for key variables and provide feedback to clinics to improve the reporting of data used to report success rates as described in the FRN notice (80 FR 51811). In addition, CDC will continue removing a clinic's reported success rates from annual ART reports if the clinic was selected for annual ART data validation but declined to participate as described in the FRN notice (86 FR 20496).

Tiffany Brown,

Executive Secretary, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-102 and CMS-105]

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 29, 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-102 and CMS-105—CLIA Budget Workload Reports and Supporting Regulations in 42 CFR 493.1-.2001

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:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* CLIA Budget Workload Reports and Supporting Regulations in 42 CFR 493.1-.2001; *Use:* The Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578 were enacted on October 31, 1988. Provisions of this law mandated by Congress require entities (with few exceptions) that test human specimens be subject to Federal regulation and have in effect a certificate issued by the Department of Health and Human Services. CLIA mandates that fees must be paid by each laboratory to obtain or renew a certificate and for the cost of

compliance determination if applicable. The certificate issuance fees will be set by CMS at levels sufficient to recover the full costs of administering the operational provisions of CLIA, including approval and monitoring of proficiency testing programs and accrediting bodies and implementing Federal requirements. Fees will also be collected by CMS to cover the costs of inspecting non-accredited laboratories and validating accrediting laboratories based on the lab's volume and scope of testing. Currently, CMS contracts with 50 State agencies to conduct surveys of all participating health care facilities. As part of their contract, CMS reimburses the State agencies for the reasonable cost of conducting surveys. This information collection gathers the information necessary to reimburse State agencies for a reasonable cost. *Form Number:* CMS-102 and CMS-105 (OMB control number: 0938-0599); *Frequency:* Yearly/Quarterly; *Affected Public:* State, Local or Tribal Governments; *Number of Respondents:* 50; *Total Annual Responses:* 50; *Total Annual Hours:* 34. (For policy questions regarding this collection contact Eric Powell at 312-886-0791).

Dated: November 22, 2023.

William N. Parham, III,

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

[FR Doc. 2023-26201 Filed 11-27-23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-4597]

Agency Information Collection Activities; Proposed Collection; Comment Request; Shortages Data Collections

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. 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 of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice

solicits comments on information collections associated with Shortages Data Collections and with notifications to FDA of an interruption or permanent discontinuance in manufacturing of certain medical devices as required by the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Either electronic or written comments on the collection of information must be submitted by January 29, 2024.

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 January 29, 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").

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-N-4597 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Shortages Data Collections." Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three